CHRISTUS Spohn Health System Laboratories

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CHRISTUS Spohn Health System Laboratories

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CHRISTUS SPOHN HEALTH SYSTEM
GUIDELINE AND POLICY MANUAL

TITLE: Point of Care Testing Programs

Date Issued: 10/04
Date(s) Revised: 8/07, 05/10, 05/14
Date(s) Reviewed: 05/10,05/14

Section: Patient Care
Number: H-150
Originator: Laboratory

Approved By : Pamela S. Robertson — President, CEO

Dr. James Cato — Chief Nurse Executive
(Original with signatures archived in Document Control)

PURPOSE:

To standardize the implementation of Point of Care testing and assure compliance with regulatory authorities

POLICY:

Point of Care testing shall not be performed unless specific policies and procedures have been approved by the person named on the CLIA certificate, training has been provided to testing associates, and documentation of competency is available for review.

GUIDELINES:

1. Requests for new Point of Care tests will be routed directly to the person named on the CLIA certificate. The person named on the CLIA certificate will direct an inquiry to determine the efficacy of the requested test. The person named on the CLIA certificate is the final authority in the decision to approve or reject a request for a new test.

2. Associates performing waived testing must complete competency training before commencing testing, and at least annually thereafter. Associates performing tests of moderate complexity must complete competency training before commencing testing, at six months, one year, and annually thereafter.

3. Competency training must be presented and documented by the person named on the CLIA certificate, Point of Care Testing Coordinator (designee), Education Department associates, or Unit Trainers.

4. Documentation of competencies must be maintained under the supervision of the person named on the CLIA certificate or Point of Care Testing Coordinator (designee). Initial training will include a written test and a return demonstration of test procedures. Recurring competency will be assessed using at least two of the following methods on each associate for each test.

    a. Performing a test on a blind specimen (unknown)
    b. Observation of routine work in progress by the Point of Care Testing Coordinator or Unit Trainer
    c. Monitoring of each user's quality control results by the Point of Care Testing Coordinator or Unit Trainer
    d. Written testing specific to the method assessed

5. Complaints and/or findings indicating Competency or Policy non-compliance shall be investigated by the person named on the CLIA certificate or the Point of Care Testing Coordinator (designee). Associates or Departments found to be substantially out of compliance may have their testing privileges suspended, at the discretion of the person named on the CLIA certificate. Reinstatement of testing privileges is at the discretion of the person named on the CLIA certificate.

6. The person named on the CLIA certificate is the final authority and responsible party for all aspects of any test performed under their CLIA certificate, including testing, quality control, maintenance, and regulatory compliance.

7. The Point of Care Testing Coordinator is authorized as designee to perform the duties of the person named on the CLIA certificate.

8. Education Department associates are authorized to provide instruction to operators, certify operators as proficient, and document compliance under the direction of Point of Care Testing Coordinator.

9. Testing Associates (operators) are responsible for compliance with all procedures and policies pertaining to any Point of Care tests they perform.

11. The person named on the CLIA certificate or the Point of CareTesting Coordinator (designee) will review testing policies and procedures at minimum once every three years or whenever an edit is made to confirm compliance with the Code of Federal Regulations 42 CFR 493, the CAMH sections PC.16, applicable sections of the CAMLAB, and to assure inclusion of the following elements—

    a. Definition of the context and scope of the test
    b. Identification of testing associates by job title
    c. Specimen type, collection, identification, preservation, and required labeling.
    d. Instrument maintenance and function checks, including equipment performance evaluations
    e. Storage conditions for test components
    f. Quality control including remedial action and audits
    g. Test performance
    h. Result Reporting
    i. Record Retention

Resources:

Centers for Medicare and Medicaid Services (CMS)
www.cms.hhs.gov/clia

Centers for Disease Control and Prevention (CDC)
www.phppo.cdc.gov/clia

Food and Drug Administration (FDA)
www.fda.gov/cdrh/clia

The Joint Commission's Frequently Asked Questions (FAQs)
www.jointcommission.org

Reviews:
05/10, 05/14

CHRISTUS SPOHN HEALTH SYSTEM
POLICY and PROCEDURE MANUAL

TITLE: Specimen Rejection

Date Issued:
Date(s) Revised: 11/04, 08/11, 03/13
Date(s) Reviewed: 08/11, 03/13, 04/15

Section: Laboratory
Number: LAB-103
Originator: Laboratory

Approved By: *See last page for Laboratory Medical Director/Administrator approvals
(Original with signatures archived in Document Control)

PURPOSE:

To define the standards of acceptability for specimens received by CHRISTUS Spohn Health System Laboratories.

POLICY:

It is the policy of the Laboratories of CHRISTUS Spohn Health System to provide analytic and/or procedural results that are accurate and not compromised by specimen integrity of any kind. The Laboratory Specimen Rejection Policy and procedure outlined therein shall to be strictly adhered to by all Laboratory Associates. This policy specifically defines, section by section, what constitutes an unacceptable specimen. Specimen unacceptability can be discovered during any stage of specimen processing – pre-analytic, analytic, post-analytic - and thus rejected at any of these stages. The protocol and procedures for specimen rejection during the pre-analytic stage is outlined below.

PROCEDURES:

The basic pre-analytic specimen rejection criteria are defined in the following sections. If the specimen in question is a special means collection specimen (e.g., CSF, tissue, non-indwelling catheter, other body fluid), refer to section II Special Means Collection for proper protocol. NOTE: rejections from outside clients will be communicated to the Laboratory Manager for appropriate follow-up with the client.

I. Rejection Criteria for **Non-special Means Collection** Specimens (blood, urine, stool, etc.):
   a. A specimen is completely unlabeled with no accompanying requisition or identification of any kind.
      i. Laboratory Action: Reject and discard the specimen. Document date, time, and specimen type received in the Central Processing Log Book for future reference..
   b. Misidentified specimens:
      i. A specimen is received with two different patient labels, one patient has resulted tests.
         1. Laboratory Action: Reject and discard the specimen. Look up both patients in LIS and determine if either patient has received specimens or resulted tests. If so, notify the appropriate personnel and request a recollection on the appropriate patient. Complete a Risk Management Variance Report and document in the LIS and/or Central Processing Log Book.
      ii. A specimen is received with two patient labels, neither of which have resulted tests.
         1. Laboratory action: Reject and discard the specimen. Notify the appropriate personnel and request a recollection of both patients. Complete a Risk Management Variance Report and document in the LIS and/or Central Processing Log Book.
   c. Unlabeled/mislabeled specimens:
      i. A specimen is received with a test requisition (label) in the biohazard bag, but no identification of any kind is on the actual specimen itself.
         1. Laboratory Action: Reject and discard the specimen. Notify the appropriate personnel and request a recollection. File a Risk Management Variance Report and document in the LIS and/or Central Processing Specimen Log Book.

ii. A mislabeled or unlabeled specimen is walked to the laboratory and handed directly to a Laboratory Associate.
    1. Laboratory Action: Hand the specimen back to the person who brought the specimen and explain that the specimen is unacceptable as submitted. He or she can decide whether to take corrective action or recollect and resubmit the specimen.

d. The blood specimen has been collected in the wrong tube or a nurse collected specimen has been submitted in an inappropriate container:
    i. Laboratory Action: Reject and discard the specimen. Notify the appropriate personnel and request a recollection. Document in LIS and/or Central Processing Specimen Log.

e. Blood specimen is unacceptable for testing:
    i. A blood specimen submitted is of obvious insufficient quantity, is hemolyzed, clotted, possibly contaminated with IV fluid, too lipemic or other condition unacceptable for testing purposes.
        1. Laboratory Action: Reject and discard the specimen. Notify the appropriate personnel and request a recollection. Document in LIS and/or Central Processing Specimen Log.
    ii. A blood specimen submitted is of obvious insufficient quantity, is hemolyzed, clotted, possibly contaminated with IV fluid, too lipemic or other condition unacceptable for testing purposes; however the requesting physician insists that the testing be performed on it.
        1. Laboratory Action: Inform the requesting physician that he/she may speak to a Pathologist when available, but that the specimen shall be rejected and discarded per department policy. Request recollection. Document in LIS and/or Central Processing Log Book.

NOTE: When multiple recollection attempts fail to produce a non-hemolyzed specimen, a Pathologist and/or the patient's physician will be consulted for appropriate action.

f. Leaking specimens:
    i. A leaking specimen is submitted to the Laboratory.
        1. Laboratory Action: Accept the specimen if the quantity is sufficient for testing and the leaking is minimal. Follow safety protocol for cleaning any surfaces that may have come in contact with the leaking specimen.
    ii. A leaking specimen is received with the container lid off.
        1. Laboratory Action: Reject and discard the specimen. Follow safety protocol for decontamination should cleaning the area be necessary. Notify the appropriate personnel and request a recollection. Document in LIS and/or Central Processing Log Book.
    iii. A leaking specimen is received for testing requiring a sterile specimen, e.g. a urine culture. Specimens that have leaked out of their primary container into the specimen bag have also compromised the sterile integrity of the specimen itself rendering results suboptimal.
        1. Laboratory Action: Reject and discard the specimen. Follow safety protocol for decontamination should cleaning the receiving area be necessary. Notify the appropriate personnel and request a recollection. Document in LIS and/or Central Processing Log Book.

g. Blood bank specimens:
    i. A blood bank specimen received is labeled, but does not have the blood bank ID bracelet label on it.
        1. Laboratory Action: Reject and discard the specimen. Notify the appropriate personnel and request a recollection. Document in LIS and/or Central Processing Log Book.
    ii. A blood bank specimen is received that is labeled and has the blood bank ID bracelet label on it, but the information on the bracelet is partially missing or partially inaccurate (medical record number instead of hospital account number or letter missing from part of name).

1. Laboratory Action: Notify the nursing unit or phlebotomist that required information is missing or inaccurate and request that the Associate who collected the specimen personally provide and/or correct the label and initial the changes. After this has been corrected, accept the specimen. Document in LIS and/or the Central Processing Specimen Log Book.

iii. A blood bank specimen is received that is labeled and has the blood bank ID bracelet label on it, but the information on the bracelet is partially missing or partially inaccurate (medical record number instead of hospital account number or letter missing from part of name) and that Associate who collected the specimen is unavailable to make corrections.

1. Laboratory Action: Notify the nursing unit that required information is missing or inaccurate and that because the Associate who collected the specimen cannot personally make the necessary corrections, the specimen has been rejected and discarded. Request a recollection if testing is still desired. Document in LIS and/or Central Processing Log Book.

h. A specimen has been submitted that poses potential health and safety hazards to laboratory personnel. This includes specimen submitted in broken blood culture bottles or in any externally contaminated container that cannot be safely handled with gloves:

i. Laboratory Action: Reject and discard the specimen. Notify the appropriate personnel and request a recollection. Complete a Risk Management Variance Report for inadequate packaging and potential Associate exposure. Document in the Central Processing Log Book.

II. **Special Means Collection Specimens** (CSF, other body fluids, tissue, biopsy, FNA or other histology specimen, non-in-dwelling catheter urine, etc.)

a. A special means collection specimen is received into the laboratory with any of the aforementioned labeling or identification problems.

i. Laboratory Action: Notify the nurse or collector of the situation and request that he/she assume responsibility of resolving/correcting the error. Complete a Risk Management Variance Report for the documented cause of rejection. Document in LIS and/or Central Processing Log Book.

III. **Analytic and post-analytic specimens** that are found to contain any of the aforementioned issues:

a. Laboratory Action: Reject specimen according to the protocol listed above.

Reviews:
08/11, 03/13, 04/15

Approved: **CSHCC – Memorial**

Dr. Joe Lewis 04/24/15
Laboratory Medical Director Date

Sylvia Buentello 04/22/15
Laboratory Administrator Date

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Aamer Qidwai 04/07/15
Laboratory Administrator Date

CHRISTUS SPOHN HEALTH SYSTEM

POLICY and PROCEDURE MANUAL

TITLE: Laboratory Proficiency Testing

Date Issued: Section: Laboratory

Date(s) Revised: 08/11, 03/13, 03/14, 03/15 Number : LAB- 104

Date(s) Reviewed: 08/11, 03/13, 03/14, 03/15 Originator: Laboratory

Approved By: *See last page for Laboratory Medical Director / Administrator approval

(Original with signature archived in Document Control)

PURPOSE:

To provide the laboratory with an external audit system to ensure the accuracy and reliability of all regulated and non-regulated analytes.

To provide the laboratory with an alternate performance assessment system to ensure the accuracy and reliability of analytic results for which no external audit system is offered.

To provide a procedure for assessing performance on external proficiency testing challenges that were not graded due to lack of consensus, failure to submit results by the deadline for receipt or at all, or submission of an inappropriate method code. In both the external audit system and alternate performance assessment system, any problems identified are corrected and documented. Any results that show a clinically significant are investigated, followed and documented. Proficiency testing results and any necessary corrective action are discussed and reviewed as determined at each facility.

POLICY:

The Laboratories of CHRISTUS Spohn Health System subscribe to the CAP proficiency testing program or a CAP/TJC approved alternative, as an external audit quality control system. Each discipline within the Laboratory is encompassed within this program to provide a full and accurate account of inter-laboratory comparison. The Laboratory handles all proficiency testing materials as it would any other patient sample by integrating the external survey samples within the routine laboratory workload for all shifts where applicable. Inter-laboratory communication regarding proficiency testing materials prior to the submission of data and receipt of results from the CAP is strictly prohibited as is sending out any proficiency testing materials to a reference laboratory. All records of proficiency testing, to include worksheets, instrument printouts where applicable, report forms, evaluation reports and summaries as well as any corrective action taken as indicated are retained for a minimum of two years. The procedures for handling proficiency testing samples, data submission and results are defined in the following sections.

The Laboratory has established an alternate performance assessment system to determine the accuracy and reliability of analytic testing for which no external proficiency testing program is offered. The Laboratory has two sections, chemistry, and hematology, where patient test results are issued for which no external proficiency is performed. The analytes are listed below by section along with the testing procedures as approved by the Laboratory Medical Director to fulfill the requirement for determining the accuracy and reliability of analytic results. All testing records and materials are contained within the section-specific proficiency testing programs, along with alternate assessment test results, evaluations and corrective action as indicated.

PROCEDURE:

Commercial Proficiency Testing Procedures:

1. Receipt, handling and submission of data
    a. Date of receipt is documented and the proficiency testing kit is stored as indicated until testing is to take place.
    b. Testing samples are incorporated into the routine workload and rotated or assigned amongst testing personnel. Testing samples are treated as patient samples.

c. The section Lead Technologist will ensure completion of the survey response form and the summary response documentation form.
d. The proficiency testing attestation statement must be signed by the laboratory director or designee and the individual(s) performing the testing. NOTE: Physical signatures must appear on the original paper attestation form.
e. The section Lead Technologist is responsible for ensuring that the survey response form is submitted by the cut-off date for receipt. The form may be submitted on line, faxed or mailed.
f. The section Lead Technologist is responsible for storage of the completed survey response form, instrument printouts, result worksheets, etc. where applicable.

2. Review of results and corrective action, as indicated:
   a. Upon receipt of results, the section Lead Technologist will review and complete the results review documentation sheet as follows:
      i. If no unacceptable results or discrepancies are noted, this will be documented on the survey results review sheet and signed by the section Lead Technologist, Medical Director or section Pathologist designee and Laboratory Administrator. Should a clinically significant bias or trend be identified, investigation will be initiated, followed up on and documented.
      ii. If an unacceptable result(s) is noted, the section Lead Technologist will investigate and take corrective action, which is documented on the survey results form review sheet and signed by the section Lead Technologist. Once completed, the results data and survey results review sheet will be forwarded to the Medical Director or section Pathologist designee and Laboratory Administrator for review and signatures.
      iii. Ungraded challenges due to lack of consensus will be reviewed via the Participant Summary as to acceptability against expected response with investigation and follow-up documentation as appropriate.
      iv. Educational ungraded challenges will be reviewed via the Participant Summary as to acceptability against expected response with investigation and follow-up documentation as appropriate.
   b.. Failure to submit results prior to the cut-off date/ failure to submit results:
      i. The section Lead Technologist will document the reason for the failure to submit results on the Proficiency Testing Exception Summary (PTES). Review of internal test results against expected responses is required with follow-up corrective action documentation as appropriate. Once completed, the PTES response form and any accompanying documentation will be reviewed and signed by section Lead Technologist, the Medical Director or section Pathologist designee and Laboratory Administrator.
   c. Failure to submit the appropriate method code:
      i. This results in a Proficiency Testing Exception Summary and is usually the result of a transcription error. The section Lead Technologist will determine the reason and document on the PTES response form. Once completed, the PTES response form and accompanying documentation will be reviewed and signed by the section Lead Technologist, the Medical Director or section Pathologist designee and Laboratory Administrator.

A detailed description of each survey program, which includes number of specimens submitted, mailing dates, expected response time, and performance evaluation criteria are available at each facility.

1. List of Un-surveyed Analytes:
   a. Kleberg/Beeville Hematology: Bleeding Time
   b. Alice: Stool reducing substance, stool pH
   c. Memorial Chemistry: Body fluid electrolytes (split survey with South), Body fluid

lipase (split survey with Shoreline)

d. Shoreline Chemistry: Body fluid lipase (split survey with Memorial), Urine Protein Electrophoresis (split samples between techs), Blood pH (split samples between techs)
e. South Chemistry: Body fluid electrolytes (split survey with Memorial)

2. Proficiency testing procedure for performance of un-surveyed samples:
   a. Un-surveyed assays are performed by split-sample methods at least twice per year or are performed upon receipt of materials.
   b. Assays are ordered/entered in the LIS or instrument and run with routine patient samples.
   c. Testing for these assays is performed according to specimen handling for each procedure.

3. Proficiency testing procedure for resulting and evaluating un-surveyed samples:
   a. All worksheets/instrument printouts are submitted to the section Lead Technologist.
   b. All results must be compatible. Any discrepancies must be addressed immediately.
   c. All results must be reviewed by the Medical Director or section Pathologist designee, Laboratory Administrator, and section Lead Technologist.
   d. All un-surveyed results and evaluations are kept on file for a minimum of two years.

Reviews:
08/11, 03/13, 03/14, 03/15

Approved: **CSHCC – Memorial**

Dr. Joe Lewis 04/24/15
Laboratory Medical Director Date

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Dr. Randall Simonsen 04/12/15
Laboratory Medical Director Date

Aamer Qidwai 04/07/15
Laboratory Administrator Date

CHRISTUS SPOHN HEALTH SYSTEM
POLICY and PROCEDURE MANUAL

TITLE: Laboratory Quality Control Program

Date Issued:
Date(s) Revised: 06/04, 05/05, 01/07, 05/09, 04/11, 08/11, 03/13
Date(s) Reviewed: 08/11, 03/13, 03/15

Section: Laboratory
Number: LAB-105
Originator: Laboratory

Approved By: *See last page for Laboratory Medical Director/Administrator approvals
(Original with signatures archived in Document Control)

PURPOSE:

To assure the accuracy and reliability of test results, to utilize a preventative approach to circumvent potential problems and to ensure the timely reporting of all results.

POLICY:

The Laboratories of CHRISTUS Spohn Health System have defined a quality control program essential to guarantee the accuracy and reliability of analytic and procedural results. All factors that affect the accuracy, precision, and reproducibility of result data are consistently monitored. The following is a description of the general quality control guideline that applies to all sections of the Laboratory. The guidelines are reviewed biannually by the Laboratory Medical Director and/or Laboratory Administrators, revised as indicated and submitted to each laboratory Section Lead Technologist for implementation.

PROCEDURE:

1. Equipment and Instruments:
   Each Section Lead Technologist is responsible for setting up and performing/monitoring the performance of routine equipment maintenance and function checks on all equipment in that section. Routine and non-scheduled maintenance and function checks are recorded in the appropriate equipment maintenance log, including date, type of maintenance, and initials of the person performing the maintenance.

2. Temperature Checks:
   Equipment temperatures: Personnel within each section are responsible for keeping a daily record of water baths, refrigerators, freezers, incubators, heating blocks, temperature-controlled flow cells, ovens, and room temperature as applicable within their section. These records are to include limits on temperature variation in accordance with the CAP/TJC and are reviewed monthly by the Section Lead Technologist or designee.

3. Glassware:
   Checking glassware for cleanliness and for traces of soap is the responsibility of
   Kleberg/Beeville/Alice – No glassware is in use.
   Memorial - Microbiology Dept.
   Shoreline - Chemistry Dept.
   South - Lead Technologist or Designee.

4. Water Quality:
   Monitoring water quality is the responsibility of:
   Kleberg – Lead Technologist or designee
   Alice – Lead Technologist or designee
   Memorial campus - Microbiology Lead Technologist or designee
   Shoreline campus - Chemistry Lead Technologist or designee
   South campus - Lead Technologist or designee

The Lead Technologist or Laboratory Administrator sets the standards and specifies procedures for monitoring levels of impurities. Microbiology will culture for possible contamination as scheduled or upon request from the Lead Technologist or Designee. Records are maintained by the Lead Technologist.

5. Reagents and Chemicals:
    a. Reagents and solutions should be properly labeled, as applicable , with the following elements:
        i. Content and quantity, concentration or titer
        ii. Storage requirements
        iii. Date prepared or reconstituted by Laboratory
        iv. Expiration date – Note a new expiration date must be recorded when opening the container changes the expiration date
    b. New reagent lots are checked against old reagent lots when applicable.
    c. Laboratory-prepared reagents, standards or controls: reagents prepared in the Laboratory should be labeled as to content, concentration, date prepared, and expiration date. If a reagent is toxic, caustic or corrosive, it must be labeled as such. Each reagent, control or standard should be checked before being placed into use, as applicable, by running it in parallel with reagents already in use, when applicable.
    d. Agreement of results with those from previous reagent lots, when applicable, and use of control values within accepted limits of variation will permit the new reagent, control or standard to be put into general use.

6. Quality Control:
    The Lead Technologist or Laboratory Administrator of each section is responsible for defining the quality control program in their respective sections. This includes the following:
    a. Description of the quality control program, including control materials used
    b. Design of quality control governing rules and criteria for allowing rule exceptions
    c. Procedure for recording and reviewing quality control data and documenting corrective action.
    d. Designing a mechanism for comparing instruments and methodologies that produce results which are reported interchangeably. These comparisons are performed at least twice per year.
    e. For test procedures for which neither calibration nor control materials are available, the Laboratory must establish procedures to verify the reliability of patient test results.
    f. Provision to retain records for at minimum 2 years.

Reviews:
08/11, 03/13, 03/15

Approved: **CSHCC – Memorial**

Dr. Joe Lewis 04/23/15
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Dr. Randall Simonsen 04/13/15
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Aamer Qidwai 04/07/15
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CHRISTUS SPOHN HEALTH SYSTEM
POLICY and PROCEDURE MANUAL

TITLE: Blood / Blood Product Utilization Criteria

Date Issued: 05/95
Date(s) Revised: 06/96, 03/00, 06/01, 01/04, 02/12,03/15
Date(s) Reviewed: 02/12, 03/15

Section: Laboratory
Number: LAB-110
Originator: Laboratory

Approved By: Pamela S. Robertson — President, CEO

Dr. Charles Volk — Chief Medical Officer

Estela Chapa — Chief Clinical Officer

(Original with signatures archived in Document Control)
*See last page for Laboratory Medical Director / Administrator approvals

PURPOSE:

To provide guidelines for blood/blood product utilization. These guidelines should be used in conjunction with patient symptomotology, clinical status trajectory, and/or other laboratory perameters. These guidelines generally pertain to hemodynamically stable patients and are not intended to supplant physician critical thinking or judgement. These guidelines may not pertain to some trauma, pediatric/neonatal, oncology, or patients requiring massive transfusion. The physician orders to transfuse should include thorough documentation on the clinical indications to transfuse.

The minimum effective dose of all blood components should be used; **SINGLE UNIT** transfusions of red cells are often effective.

RED BLOOD CELLS

Autologous transfusions and auto transfusions are monitored as red blood cells.

1. **Indications - Adults**
   Red cells are transfused to improve oxygen-carrying capacity. One unit should increase the hemoglobin level by 1g/dL in a 70 kg recipient. Pre-transfusion and post-transfusion hemoglobin and/or hematocrit measurements should be obtained.

   a. Appropriate criteria for transfusion of red blood cells include the following:
      i. Hemoglobin ≤7 g/dL as a general transfusion threshold in most patients.
      ii. Acute blood loss with evidence of inadequate oxygen delivery documented by one of the following:
         1. 10% fall in BP or systolic pressure less than 100 mmHg
         2. Pulse rate greater than 100 bpm
         3. Pulmonary wedge pressure of less than 5mm Mercury
         4. Central venous pressure of less than 4cm of water
         5. Blood loss of greater than 750mL within 2 hours
      iii. Acute loss of greater than or equal to 15% of estimated blood volume
      iv. Symptomatic anemia in a normovolemic patient, regardless of hemoglobin level. Symptoms may include the following:
         1. Syncope
         2. Cerebral vascular disease manifestations
         3. Tachycardia
         4. Tachypnea
         5. Angina pectoris/Coronary artery disease
         6. Fatigue to minimal exertion
      v. Pre-operative hemoglobin less than or equal to 8g/dL and operative procedure associated with major blood loss.
      vi. Hemoglobin less than or equal to 9g/dL in a patient on a chronic transfusion regimen.

vii. Hemoglobin less than or equal to 10g/dL in a patient undergoing radiation therapy.

b. Hemoglobin ≤8 g/dL in patients with:
   i. coronary artery disease and unstable angina/myocardial infarction/cardiogenic shock.
   ii. CHF
   iii. ESRD on dialysis
   iv. Sickle cell disease
   v. Within 72 hours post-op
   vi. Patients with concerning cardiovascular symptoms such as:
      1. Tachycardia not responsive to fluids
      2. orthostatic hypotension
      3. dyspnea on exertion
      4. chest pain

c. The patient has been determined to be normovolemic and there is evidence to support the need for increased oxygen carrying capacity as witnessed by:
   i. Severe hypoxemia (PO2 < 55-60 despite FiO of 1.00)
   ii. ScVO2 < 70 in patients with shock despite adequate filling pressure (CVP > 8, if not on mechanical ventilation and >12 if on mechanical ventilation) and mean arterial pressure (MAP) > 65.

2. **Indications – Pediatric Patients less than 4 months of age**
   a. Hemoglobin (Hgb) less than 13g/dL in a newborn:
      i. Requiring assisted ventilation and supplemental oxygen
      ii. With severe pulmonary disease, cyanotic heart disease, or heart failure
      iii. Extracorporeal membrane oxygenation (ECMO)
   b. Hgb less than 10g/dL
      i. Significant apnea
      ii. Poor weight gain
   c. Hgb less than 8 g/dL in stable newborn with clinical manifestations of anemia
   d. Acute blood loss greater than 10% of total blood volume

3. **Indications – Pediatric Patients ≥ 4 months of age**
   a. Hgb less than 8g/dL
      i. Symptomatic medical and surgical patients
      ii. While on chemotherapy/radiotherapy
      iii. Chronic/congenital anemia
   b. Acute blood loss greater than 10-15% of total blood volume
   c. Hgb < 13g/dL with:
      i. Severe pulmonary disease
      ii. ECMO
      iii. Complications of sickle cell disease

4. Clinical Outcome Measures
   a. Pre transfusion Hgb documented
   b. Post transfusion Hgb within 24 hours of transfusion.
   c. QRM chart review of transfusions initiated above Hgb thresholds, described above.

PLATELET CONCENTRATE

1. **Indications – Adults**
   Platelets are cells required for primary hemostasis and circulate normally at counts of 150,000 to 400,000/uL. Platelet transfusion is appropriate to prevent or control bleeding associated with deficiencies in platelet number or function. One single donor apheresis platelet unit should increase the platelet count by 30,000/uL in a 70 kg recipient. One single donor apheresis unit is usually adequate. A platelet count should be obtained before platelet transfusion. Daily platelet

counts are ordinarily adequate in the thrombocytopenic patient, but when response to transfusion is poor, the platelet count should be measured 10 minutes to one hour after transfusion.

At platelet counts below 5000/uL a high likelihood of spontaneous hemorrhage exists and is extremely likely with trauma, invasive procedure and ulceration. At counts between 5,000 to 10,000/uL there is an increased likelihood of spontaneous hemorrhage and a high likelihood of bleeding with trauma, invasive procedure or ulceration. At counts between 10,000 to 50,000/uL there is a variable increased risk of bleeding with trauma, invasive procedure or ulceration. At counts greater than 50,000/uL bleeding due to platelet deficiency is exceeding unlikely.

a. Appropriate criteria for transfusion of platelets include the following:
    i. Platelet count less than or equal to 10,000/uL in a non-bleeding patient with failure of platelet production.
    ii. Platelet count ≤20,000/μL and signs of hemorrhagic diathesis (petechiae, mucosal bleeding).
    iii. Platelet count ≤ 50,000/uL in a patient with
        a. Active hemorrhage OR
        b. Impending major surgery OR
        c. Invasive procedure (recent, in-progress, planned)
    ii. Anticipating an invasive procedure and 1.) patient on anti-platelet therapy or 2.) with documented platelet dysfunction as evidenced by some form of platelet analysis such as but not limited to:
        a. TEG
        b. Platelet function assay (PFA)
        c. Platelet Works
    iv. Diffuse microvascular bleeding in a patient with documented disseminated intravascular coagulation or transfusion of ≥ one blood volume and platelet count ≤ 50,000/uL or laboratory values not yet available.
    v. Diffuse microvascular bleeding following cardiopulmonary bypass or with intra-aortic balloon pump and platelet count not yet available or ≤ 100,000/uL.
    vi. Diffuse microvascular bleeding in patients undergoing other major surgery and platelet count not yet available or ≤ 50,000/mm.
    vii. Bleeding in a patient with a qualitative platelet defect, regardless of platelet count.

2. **Indications – Pediatric Patients less 4 months of age:**
    a. Infants ≤ 37 weeks gestation:
        i. Less than 50,000/uL in stable infant
        ii. Less than 100,000/uL in sick infant:
            1. ECMO
            2. Active bleeding
            3. Invasive procedure

    b. **Infants greater than 37 weeks:**
        i. Less than 100,000/uL with active bleeding
        ii. Less than 50,000/uL with need for invasive procedure
        iii. Less than 20,000/uL in non-bleeding patient with failure of platelet production and risk factors such as coagulopathy, sepsis, fever etc.
        iv. Less than 20,000 in non-bleeding patient with failure of platelet production
        v. Bleeding with qualitative platelet defect regardless of platelet count
        vi. Diffuse microvascular bleeding following cardiac bypass, regardless of platelet count

3. **Indications – Pediatric Patients greater than 4 months of age**
    a. Less than 5,000-10,000/uL in non-bleeding patient with failure of platelet production
    b. Less than 20,000/uL in non-bleeding patient with failure of platelet production and risk factors such as coagulopathy, sepsis, fever etc.

c. Less than 50,000/uL with impending surgery or invasive procedure
d. Platelet count less than 100,000 and :
e. Trauma/massive transfusion
f. CNS or ocular surgery
g. Major surgery with bleeding
h. Treatment with certain antithrombotic/anticoagulant agents (e.g. Plavix)
i. Diffuse microvascular bleeding and no platelet count available
j. Bleeding in patient with quantitative platelet function defect

4. **Clinical Outcome Measures**
   a. Pre-transfusion platelet count documented
   b. Post-transfusion platelet count within less than 24 hours of transfusion
   c. Platelet transfusions are relatively contraindicated in patients with thrombotic thrombocytopenic purpura (TTP) and heparin-induced thrombocytopenia (HIT). Review any platelet transfusions to TTP or HIT patients.
   d. QRM chart review of transfusions not meeting the above described criteria

FRESH FROZEN PLASMA

1. **Indications - Adult**

   Fresh Frozen Plasma is separated from the red blood cells and platelets of whole blood donations. It contains all of the blood coagulation factors as well as naturally occurring inhibitors. Fresh Frozen Plasma is administered to correct bleeding due to single or multiple coagulation factor abnormalities when specific therapy in unavailable. One unit contains approximately 200 to 250 ml plasma and the usual initial dose is 15ml/kg. A prothrombin time and partial thromboplastin time should be performed before and after transfusion.

2. Appropriate criteria for transfusion of Fresh Frozen Plasma may include the following:
   a. History or clinical course suggestive of coagulopathy due to a congential or acquired deficiency of coagulation factors, prior to an operative or other invasive procedure. This will be documented by one or more of the following:
      i. Prothrombin time (PT) greater than 1.3 times the International Normalized Ratio (INR).
      ii. Activated partial thromboplastic time (APTT) greater than 1.3 times the upper limits of the normal range.
      iii. Coagulation factor assay of less than 25% activity.
   b. Massive blood transfusion: Replacement of more than 1 blood volume (approximately 5000 ml in a 70 kg adult) within several hours with evidence of a coagulation deficiency and with continued bleeding.
   c. Reversal of Warfarin effect, if immediate hemostasis is required to stop active bleeding or prior to emergency surgery or invasive procedure.
   d. Massive bleeding or intraoperative hemorrhage in a patient at risk for clotting factor deficiency when clotting studies are pending.
   e. Documented congenital or acquired coagulation factor deficiency and active continuous bleeding.
   f. Deficiency of antithrombin III (when a concentrate is not available), heparin co-factor II, protein C, or protein S.
   g. Plasma exchange for thrombotic thrombocytopenic purpura.

3. **Indications – Pediatric Patients**
   a. PT INR greater than 1.5, aPTT greater than 60 seconds, or factor assay less than 25% and active bleeding, or anticipated major surgery/invasive procedure within 24 hours
   b. Diffuse microvascular bleeding and PT/PTT not available
   c. Plasma exchange in TTP/HUS or cryo-poor FP
   d. Emergency reversal of bleeding associated with Coumadin, TPA, Streptokinase, Urokinase, etc.

e. Protein C, protein S, or ATIII deficiency if purified concentrate not available
f. Initial stabilization on ECMO circuit

4. **Clinical Outcome Measures**
   a. Pre transfusion PT and/or PTT.
   b. PT and/or PTT less than 24 hours of transfusion.
   c. QRM chart review of transfusions not meeting the above described criteria.

CRYOPRECIPITATE ANTIHEMOPHILIC FACTOR

1. **Indications - Adults**
   Cryoprecipitate or cryoprecipitate antihemophilic factor is the cold precipitable protein fraction derived from Fresh Frozen Plasma. Cryoprecipitate is administered for prevention or treatment of bleeding due to dysfibrinogenemia and hypofibrinogenemia, von Willebrand's disease and in some circumstances for Hemophilia A, as a source of Factor VIII. When bleeding with acute blood loss is treated pre-transfusion fibrinogen levels should be determined. The usual dose in this circumstance is one concentrate per 7-10 kg body weight.

2. Appropriate criteria for administration of cryoprecipitate may include the following:
   a. Fibrinogen level of less than or equal to 100 mg/dL associated with one of the following:
      i. Clinical bleeding
      ii. Trauma
      iii. Imminent invasive procedure
   b. Von Willebrand's disease unresponsive to a Factor VIII concentrate preparation with high molecular weight vWF multimers (Humate-P) or unresponsive to 1 Desamino-8-D-arginine vasopressin (Desapressin, DDAVP).
   c. Hemophilia A as a source of Factor VIII when noninfectious Factor VIII concentrates are not available.

3. **Indications – Pediatric Patients**
   a. Hypofibrinogenemia (fibrinogen less than 100 mg/dL) and:
      i. Active bleeding
      ii. Anticipated surgery or major invasive procedure
   b. Factor XIII deficiency
   c. Uremia with bleeding unresponsive to non-transfusion therapy
   d. Fibrin glue
   e. Active bleeding and Hemophilia A or vWD when purified factor concentrates not available

4. **Clinical Outcome Measures**
   a. Pre and Post Fibrinogen levels, when used for fibrinogen replacement.
   b. Chart documentation of diagnosis, blood loss, clinical management and appropriate lab coagulation testing.
   c. QRM chart review of transfusions not meeting the above described criteria.

Reviews: 09/11, 02/12, 03/15

Approved: **CSHCC – Memorial**

Joe A. Lewis, M.D. 04/24/15
Laboratory Medical Director Date

Sylvia Buentello 04/22/15
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Aamer Qidwai 04/07/15
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CHRISTUS SPOHN HEALTH SYSTEM
POLICY and PROCEDURE MANUAL

TITLE: Laboratory Local, State, Federal Compliance

Date Issued: 03/13
Date(s) Revised:
Date(s) Reviewed: 03/15

Section: Laboratory
Number: LAB-112
Originator: Laboratory

Approved By: *See last page for Laboratory Medical Director / Administrator approvals
(Original with signatures archived in Document Control)

Purpose:

To ensure the laboratory operates in compliance with federal, state and local regulations.

Policy:

Each hospital laboratory has procedures and processes to ensure compliance with all applicable local, state and federal laws and regulations. These include but are not limited to the handling of radioactive materials, shipping infectious or diagnostic materials, personnel qualifications, retention of specimens and records, hazardous waste disposal, fire codes, medical examiner or coroner jurisdiction, legal testing, acceptance of specimens only from authorized personnel, handling controlled substances, patient consent for testing, confidentiality of test results, and donation of blood

Legal and regulatory compliance will be addressed in corporate, regional and/or laboratory specific policies or procedures that can be found in the laboratory or on the CHRISTUS Spohn Health System CHRISTUS Connect site.

Associates are accountable for understanding and complying with the policies and procedures associated with regulatory compliance, and are instructed to bring compliance issues to the attention of the supervisor or manager. Each hospital has a compliance officer to handle any concerns related to regulatory compliance, and the CHRISTUS Integrity Hotline is available by calling 1-888-728-8383 to report violations.

Reviews: 03/15

Approved: **CSHCC – Memorial**

Dr. Joe Lewis 04/24/15
Laboratory Medical Director Date

Sylvia Buentello 04/22/15
Laboratory Administrator Date

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CHRISTUS SPOHN HEALTH SYSTEM
POLICY and PROCEDURE MANUAL

TITLE: Laboratory Document Control

Date Issued: 03/13
Date(s) Revised: 12/14
Date(s) Reviewed: 12/14,04/15

Section: Laboratory
Number: LAB-113
Originator: Laboratory

Approved By: *See last page for Laboratory Medical Director / Administrator approvals
(Original with signatures archived in Document Control)

Purpose:

To ensure that Laboratory policies and procedures are current and readily available, that associates have read the policies/procedures relevant to their job duties, and that all policies and procedures have been approved by the laboratory Medical Director or designee prior to implementation.

To ensure that Laboratory policies and procedures are reviewed at least every two years by the laboratory director or designee and that discontinued policies/procedures are retained for a minimum of two years.

Policy:

The following document control requirements apply to all policies, procedures, and forms (including quality management documents) for all processes and activities that are subject to CAP accreditation.

1. All copies of policies and procedures are current
2. Policies and procedures are reviewed by the staff as applicable to their job duties upon initial staff training, upon implementation of new policies or procedures, with major changes to existing policies or procedures and at least biennially
3. All policies/procedures have been authorized by the laboratory director, before implementation
4. Policies and procedures are reviewed at least biennially by the laboratory director or designee
5. Discontinued policies/procedures are quarantined in a separate file for a minimum of 2 years after the date of discontinuation (5 years for transfusion medicine)

Electronic (computerized) manuals are fully acceptable. There is no requirement for paper copies to be available for the routine operation of the laboratory, so long as the electronic versions are readily available to all personnel. However, procedures must be available to laboratory personnel when the electronic versions are inaccessible (e.g. during laboratory information system or network downtime); thus, the laboratory must maintain either paper copies or electronic copies on CD or other media that can be accessed via designated computers. All procedures, in either electronic or paper form, must be readily available for review by the inspector at the time of the CAP inspection.
Electronic versions of procedures must be subjected to proper document control. Documentation of review of electronic procedures may be accomplished by including statements such as “reviewed by [name of reviewer] on [date of review]” in the electronic record. Alternatively, paper review sheets may be used to document review of electronic procedures. Documentation of review by a secure electronic signature is NOT required.

Reviews: 12/14 **,**04/15

Approved: **CSHCC – Memorial**

Dr. Joe Lewis 04/23/15
Laboratory Medical Director Date

Sylvia Buentello 04/22/15
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CHRISTUS SPOHN HEALTH SYSTEM
POLICY and PROCEDURE MANUAL

TITLE: Laboratory Retention Times

Date Issued: 03/13
Date(s) Revised:
Date(s) Reviewed: 03/15

Section: Laboratory
Number: LAB-114
Originator: Laboratory

Approved By: *See last page for Laboratory Medical Director / Administrator approvals
(Original with signatures archived in Document Control)

Purpose:

To ensure that all records, slides, blocks, and tissues are retained and available for appropriate times should the laboratory cease operation.

Policy:

The Laboratory will retain all records, slides, blocks and tissues and other materials for the minimum standard amount of time recommended by the College of American Pathologists, unless otherwise mandated by states or federal requirements.

The current laboratory retention times are as follows:

Material/Record	**Period of Retention**
General Laboratory	
Accession log and patient results not otherwise specified	2 years
Maintenance/instrument maintenance records	2 years
Quality management and proficiency testing records	2 years
Non-interfaced logs, worksheets, & printouts	2 years
Surgical Pathology (including bone marrows)	
Wet tissue	2 weeks after final report
Paraffin blocks	10 years
Slides	10 years
Reports	10 years
Cytology	
Slides (negative-unsatisfactory)	5 years
Slides (suspicious-positive)	5 years
Fine needle aspiration slides	10 years
Reports	10 years
Non-Forensic Autopsy	
Wet tissue	3 months after final
Paraffin blocks	10 years
Slides	10 years
Reports	10 years

Forensic Autopsy	
Wet stock tissue	1 year
Paraffin blocks	Indefinitely
Reports	Indefinitely
Slides	Indefinitely
Gross photographs/negatives	Indefinitely
Accession log	Indefinitely
Body fluids and tissues for toxicology	1 year
Representative tissue suitable for DNA Analysis	Indefinitely
Clinical Pathology	
Patient test records	2 years
Serum/heparinized or EDTA plasma/CSF/Body fluids (except urine)	48 hours
Urine	24 hours*
**Exceptions may be made at the discretion of the laboratory director*	
Peripheral blood smears/body fluid smears	7 days
Permanently stained slides – microbiology (gram, trichrome, etc)	7 days
Cytogenetics	
Permanently stained slides	3 years
Fluorchrome stained slides	At the discretion of the laboratory director
Wet specimen/tissue	Until adequate metaphase cells are obtained
Fixed cell pellet	2 weeks after final report
Final reports	20 years
Diagnostic images (digitized, prints or negatives)	20 years
Flow Cytometry	
Gated dot plots and histograms	10 years
Blood Bank	
Donor and recipient records	10 years
Patient records	10 years
Records of employee signatures, initials, and identification codes	10 years
Quality control records	5 years
Records of indefinitely deferred donors, permanently deferred donors, or donors placed under surveillance for the recipient's protection (e.g., those donors that are hepatitis B core positive once, donors implicated in a hepatitis positive recipient)	Indefinitely
Specimens from blood donors units and recipients	7 days post-transfusion

Reviews: 03/15

Approved: **CSHCC – Memorial**

Dr. Joe Lewis 04/24/15
Laboratory Medical Director Date

Sylvia Buentello 04/22/15
Laboratory Administrator Date

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Laboratory Medical Director Date

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Laboratory Administrator Date

CHRISTUS SPOHN HEALTH SYSTEM
POLICY and PROCEDURE MANUAL

TITLE: Laboratory Compliance with CAP terms of Accreditation

Date Issued: 03/13
Date(s) Revised:
Date(s) Reviewed: 03/15

Section: Laboratory
Number: LAB-115
Originator: Laboratory

Approved By: *See last page for Laboratory Medical Director / Administrator approvals
(Original with signatures archived in Document Control)

Purpose:

To ensure compliance with the laboratory notification requirements defined in the College of American Pathologists terms of accreditation.

Policy:

The laboratory must notify the CAP of any of the following:

1. Investigation of the Laboratory by a government entity or adverse media attention related to laboratory performance. Notification must occur no later than two working days after the laboratory learns of an investigation or adverse media attention. This notification must include any complaint investigations conducted or warning letters issued by any oversight agency (i.e. CMS, State Department of Health, The Joint Commission, FDA, OSHA).

2. The facility must notify the CAP as soon as it finds itself to be the subject of a validation inspection.

3. Discovery of actions by laboratory personnel that violate national, state, or local regulations.

4. Change in the laboratory test menu (notification must occur prior to starting new patient testing).

5. Change in location, ownership, or directorship of the laboratory; notification must occur no later than 30 days prior to the changes; or in the case of unexpected changes, no later than 2 working days afterwards.

In addition, the laboratory must adhere to the following:

1. Provision of an inspection team comparable in size and scope if requested by CAP.

2. Cooperation with CAP when the laboratory is subject to a CAP investigation or inspection.

3. Adherence to the Terms of Use for the CAP Certification Mark of Accreditation.

Reviews: 03/15

Approved: **CSHCC – Memorial**

Dr. Joe Lewis 04/24/15
Laboratory Medical Director Date

Sylvia Buentello 04/22/15
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CHRISTUS SPOHN HEALTH SYSTEM
POLICY and PROCEDURE MANUAL

TITLE: Laboratory Reference Laboratory Selection

Date Issued: 03/13
Date(s) Revised:
Date(s) Reviewed: 03/15

Section: Laboratory
Number: LAB-117
Originator: Laboratory

Approved By: *See last page for Laboratory Medical Director / Administrator approvals
(Original with signatures archived in Document Control)

Purpose:

To provide the laboratory with an effective means for the evaluation and selection of reference laboratories

To ensure that all reference laboratories selected are CLIA-88 certified for high complexity testing in the appropriate specialty/subspecialty, where applicable and that turnaround times meet clinical needs

Policy:

1. All reference laboratories utilized by CHRISTUS Spohn Hospital Laboratories are CLIA-88 and/or CAP certified and approved for use by the Laboratory Medical Director in consultation with the institutional medical staff and/or physician clients.

2. The reference laboratories are chosen based primarily on the quality of performance and service they provide as determined by the above.

3. Reports released by CHRISTUS Spohn Hospital Laboratories will contain all essential elements of referred test results as received from the reference laboratory.
    a. This includes but is not limited to transcription, where necessary, of direct test data and any interpretive commentary.
    b. Test results issued by the reference laboratories are also periodically monitored for quality.

4. Procedure for reference lab selection:
    a. The clinical reference laboratories have first been evaluated by laboratory administrative management based on the CHRISTUS Health System Resource Group criteria of quality, service and price.
    b. The anatomic reference laboratories are selected based on pathologist's professional discretion and must meet the same criteria established for the clinical laboratories.
    c. The findings of these evaluations are then presented to the laboratory Medical Director for final approval.

Reviews: 03/15

Approved: **CSHCC – Memorial**

Dr. Joe Lewis 04/24/15
Laboratory Medical Director Date

Sylvia Buentello 04/22/15
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CHRISTUS SPOHN HEALTH SYSTEM
POLICY and PROCEDURE MANUAL

TITLE: Laboratory Continuing Education Program

Date Issued: 03/13
Date(s) Revised:
Date(s) Reviewed: 03/15

Section: Laboratory
Number: LAB-119
Originator: Laboratory

Approved By: *See last page for Laboratory Medical Director / Administrator approvals
(Original with signatures archived in Document Control)

PURPOSE:

To provide the laboratory associates of CHRISTUS Spohn Hospital with a functional ongoing continuing education program designed to develop and maintain high quality standards of technical and/or job-specific performance that meets the needs of all laboratory personnel.

POLICY:

It is the policy of the CHRISTUS Spohn Hospital Laboratory Department to provide continuing education (CE) for all laboratory associates. *Continuing education is defined as any educational activity that enhances an associate's job-specific performance and/or clinical laboratory science knowledge above what is required by an associate's job duties.* The responsibility for developing and maintaining high-quality technical and/or job-specific competency and service lies first and foremost with each associate. Resources for the provision of such development (equipment, materials, supplies, finances, etc.) shall be allocated in accordance with System policy.

Continuing Education Material Provision
As part of our commitment to providing continuing education opportunities, CHRISTUS Spohn Hospital Laboratory is enrolled in the Medical Training Solutions Training and Competency Program provided by the University of Washington Dept. of Lab Medicine. Additional opportunities for continuing education, i.e., workshops, webinars, audio conferences, etc., are made available as opportunities arise. In addition, self instruction material can be sought out and must be approved by the Associate's section/shift Lead Technologist or immediate supervisor and must pertain to the laboratory and/or the Associate's job duties.

Approved Continuing Education Activities/Materials include but are not limited to:
1. MTS Training and Competency Assessments approved for CE credit
2. Online Educational Material and Courses
3. Attending In-services & Workshops
4. Article & Publication Review
5. Audio conferences, Video Conferences, Webinars
6. Instrument Training Videos
7. Performance of In-services
8. Performance of Laboratory Inspections
9. College of American Pathologist Proficiency Program Final Critique CE

Requests for Attendance to Outside Continuing Education Events:
All requests for attendance to outside educational activities must go through the Associate's Lead Technologist or immediate supervisor for approval. The Associate must attach a copy of the program brochure or program description to the continuing education request form. Approval is contingent upon the following considerations:
1. Usefulness/applicable knowledge of the event
2. Current budget and cost of event
3. Adequate staffing

Once approved by the Lead Technologist or immediate supervisor, the Associate must submit a **Travel Request Form** to his/her Lead Technologist who will forward the request to the Laboratory Director. All arrangements (travel, registration, etc.) are the responsibility of the associate. At completion of the CE the associate is responsible for:

1. Submitting an **Expense Report** to obtain reimbursement.
2. Provision of a seminar summary to the Lead Tech. An in-service to the laboratory staff may be requested.
3. Ensuring CE credit is documented.

Continuing Education Credit Accrual
Continuing Education credit awarded is based on the actual time spent performing the CE unless the course defines otherwise.

Documentation of Continuing Education Credit:
Associates are responsible for recording and ensuring documentation of continuing education credit earned. Documentation is kept within online competency and training programs including Healthstream Learning Center and Medical Training Solutions (MTS).

Healthstream Learning Center (HLC):

1. Documenting CE credit:
    a. Logon to Healthstream
    b. Go to **My Transcript** & click on **Add a Learning Event**
    c. Enter the Course Name, Completion Date, and Estimated Completion Time
    d. In the Comments section, add details about the event such as the source of the CE material, objectives, etc
    e. Click on **Save**

2. Retrieval of CE records - Records are available online. If paper records are needed such as for Certification Maintenance Program they can be obtained in the following manner:
    a. Log into Healthstream
    b. Go to **My Transcript** & click on **Customize and Print Transcript**
    c. Select desired criteria for printing
    d. Click **Continue** and then click **Print**

Medical Training Solutions (MTS):

1. Documenting CE credit:
    a. Login to MTS
    b. Click on the **CE Tab** to view courses eligible for CE credit.
    c. To receive CE credit, click **Apply for CE** and complete the Course Evaluation Form.
    d. You must apply for a minimum of two competency assessment tests per period to receive P.A.C.E. credit.
    e. Completed courses with a minimum test score of 80% are eligible for CE credit.

2. Retrieval of CE records - Records are available online. If paper records are needed such as for the Certification Maintenance Program they can be obtained in the following manner:
    a. Log into MTS
    b. Click on the **CE Tab**
    c. Click on the course link to print the certificate.
    d. Alternatively, MTS Program Administrators (Lead Techs) can print a Continuing Education Report which is inclusive of all CE performed for a given time period upon request.

Reviews: 03/15

Approved: **CSHCC – Memorial**

Dr. Joe Lewis 04/24/15
Laboratory Medical Director Date

Sylvia Buentello 04/23/15
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Dr. Randall Simonsen 04/13/15
Laboratory Medical Director Date

Aamer Qidwai 04/07/15
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Dr. Randall Simonsen 04/13/15
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Aamer Qidwai 04/07/15
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CHRISTUS SPOHN HEALTH SYSTEM
POLICY and PROCEDURE MANUAL

TITLE: Laboratory – Intra-Laboratory Communication

Date Issued: 03/13
Date(s) Revised:
Date(s) Reviewed: 03/15

Section: Laboratory
Number: LAB-120
Originator: Laboratory

Approved By: *See last page for Laboratory Medical Director / Administrator approvals
(Original with signatures archived in Document Control)

PURPOSE:

To define a policy for effective communication between laboratory Associates. To provide a means of communicating information about pending specimens, tests and patient care issues when responsibility is "handed off" from one person to another.

POLICY:

It is the policy of the laboratory to provide mechanisms for effective communication and feedback between Associates that ensures a safe transition of responsibility. At least one method of communication must be used in each department that establishes two-way communication across shifts.

The following means of communication are approved for use in the lab:

1. **Magnetic Boards** may be used to provide incoming personnel with updated information on the location of laboratory Associates or pathologists

2. **Communication Logs/Notebooks** may be used to document anything that impacts daily operations, such as absences, testing delays, supply needs, specimen rejections, etc.

3. **Communication Boards/White Boards** may be used for quick read announcement and alerts that need to be conveyed across shifts.

4. **CHRISTUS Outlook Web Access (OWA)** email is provided to all laboratory Associates. This email account is the primary communication tool of the laboratory, and it is the responsibility of all laboratory Associates monitor their email for important notifications. Associates may use this method or their OWA calendar to arrange meeting times with their supervisor of manager.

5. **Department meetings or huddles** offer Associates an opportunity to discuss and receive feedback regarding team performance with laboratory leadership and their peers.

6. **Individual Feedback** may be provided through:
    a. Associate rounding by managers or lead techs
    b. Coaching for success opportunities pertaining to performance concerns or expectations

7. The **Problem and Concern Resolution** process can be used to bring compliance and safety concerns to the attention of management or CHRISTUS Spohn Leadership. The process that includes steps for escalation through the chain of command can be found on the homepage of the CHRISTUS Compliance department, or in the laboratory Associate Communication of Concerns policy.

8. **Verbal Handoff Communication** should occur in the form of face- to-face communication anytime delays, difficult draws, or other challenges present themselves during a change in responsibility, especially shift changes or temporary relief for breaks. The receiving Associate

must have the opportunity to ask questions and get responses that will assist them in taking over pending responsibilities.

9. **Mobile Devices** such as mobile phones or pagers provided by the CHRISTUS Spohn or approved by management may be used for business related communication only.

Reviews: 03/15

Approved: **CSHCC – Memorial**

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CHRISTUS SPOHN HEALTH SYSTEM
POLICY and PROCEDURE MANUAL

TITLE: Laboratory – Technical Procedure Review

Date Issued: 03/13
Date(s) Revised:
Date(s) Reviewed: 03/15

Section: Laboratory
Number: LAB-121
Originator: Laboratory

Approved By: *See last page for Laboratory Medical Director / Administrator approvals
(Original with signatures archived in Document Control)

PURPOSE:

The purpose of Technical Procedure Review is to review, for approval and implementation, proposed technical changes for accuracy, reliability, precision, cost-effectiveness, safety, and feasibility in order to ensure high quality of diagnostic and health-monitoring test results from the clinical laboratory. All supporting data, as well as the final presentation material with final approvals, is maintained by the Technical Lead Technologist whose respective section is involved.

POLICY:

Any changes that involve the major revision of an existing technical procedure, the introduction of a new test or procedure and/or test methodology is presented for Technical Procedure Review for evaluation, review, and approval prior to implementation. All materials subject to review, as well as the signatures of approval, are documented for record and retained for the life of the new test, methodology, or other aforementioned change and for at least two years thereafter.

PROCEDURE:

1. An initial proposal for introduction of a new, revised, or updated methodology is most often from the Technical Lead. The review process should include Lab Management and the Laboratory Medical Director. Proposals should include, unless otherwise indicated, pertinent references (i.e., literature, other valid resource information) which effectively describe the clinical application and usefulness of the test or modified methodology. In addition, the proposal should have a description of current methodology along with reasons for and against the proposed change. Cost analysis should include instrumentation needs, physical modifications, reagents, training and LIS requirements as well as any additional factors affecting supply and labor budgets.

   The data to be reviewed should include as applicable:
   a. Correlation between old and new procedures/methodologies or reference laboratory results, if possible
   b. Recovery data comparison, linearity, precision and reportable limits
   c. Sensitivity and specificity
   d. Stability of kits, reagents, and analytes
   e. Quality control materials and applicable procedures
   f. Safety requirements, MSDS data as available, and disposal requirements
   g. Space utilization and physical renovations, if necessary
   h. Equipment needed, training and computer additions or enhancements
   i. Reporting issues, such as state and/or local health agency notification
   j. Cost comparison, including reference laboratory cost and potential revenue generation where indicated, as well as labor productivity impact

   Other issues to be considered include:
   a. Effect on patient diagnosis, treatment, and length of stay
   a. Projected test volume for new tests
   b. Computer interfaces where applicable
   c. Charting of results
   d. Workload, productivity

e. Testing personnel training and competency verification
f. Turnaround time for result reporting
g. Confirmatory test requirements
h. Proficiency testing materials and enrollment

2. Upon acceptance and approval and after method performance validations the Laboratory Medical Director signs a summary statement documenting review of the validation study and approval of each test for clinical use.

3. If analytic methodology changes so that test results or their interpretations may be SIGNIFICANTLY different, the change is explained to clients. This can be accomplished in any of several different ways including directed mailings, laboratory newsletters or as part of the test report itself.

4. The laboratory must retain records of method performance specifications while the method is in use and for at least two years after discontinuation.

Reviews: 03/15

Approved: **CSHCC – Memorial**

Dr. Joe Lewis 04/24/15
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CHRISTUS SPOHN HEALTH SYSTEM
POLICY and PROCEDURE MANUAL

TITLE: Reflex, Confirmatory, and Composite Testing

Date Issued: 05/09
Date(s) Revised: 06/10, 05/12, 10/12, 12/13, 05/14, 01/16, 01/17
Date(s) Reviewed: 02/14, 05/14, 01/16, 01/17

Section: Laboratory
Number: LAB- 124
Originator: Laboratory

Approved By: *See last page for Laboratory Medical Director / Administrator approval
(Original with signature archived in Document Control)

PURPOSE:

To establish guidelines regarding Laboratory reflex, confirmatory, and composite testing.

POLICY:

To state the definitions of and consequent ordering and performance processes appropriate for reflex, confirmatory, and composite testing in the Clinical Pathology Laboratory.

PROCEDURE:

The types of testing with their respective tables of component tests/procedures and request protocol are listed in table below along with corresponding CPT-4 codes.

DEFINITIONS:

1. **Reflex Testing:** A **reflex test** is an additional test generally performed in order *to augment initial test results for the potential furtherance of patient treatment,* and thus afford the clinician further significant diagnostic information required for appropriate patient care.

Initial Test Performed	CPT-4	Criteria for Reflex	Test Ordered by Reflex	CPT
BLOOD BANK				
Antibody Screen	86850	Positive	Antibody ID	86870
Antibody ID	86870	Positive Auto	Direct Antiglobulin (IGG)	86880
Crossmatch	86920/86922	Significant Antibody	Antigen Typing	86905/86903
Direct Antiglobulin	86880	Positive	Eluate	86860
Fetal Hemoglobin (Kleihauer-Betke)	85460	Positive	Fetal Hemoglobin Quantitation	86356
Newborn ABO/Rh Blood Type	86900/86901	Rh Positive	ABO/Rh on mother; if mother is Rh negative- Antibody Screen and Fetal Screen	86901,86900,86850, 85461
Type & Screen	Antibody Screen - 86850	Positive	Compatibility Test Antiglobulin	86922
CHEMISTRY/IMMUNOLOGY				
Cryptococcus Antigen Screen	86403	Positive	Cryptococcus Ag Titer, Culture Fungus	87327 87102
Rapid Plasma Reagin	86592	Positive	Rapid Plasma Reagin Titer	86780
VDRL CSF	86592	Positive	VDRL CSF Titer	86593
B pertussis Ab IgA w/Reflex	86615	=>1.2	B pertussis Ab IgA Immunoblot	86615

B pertussis Ab IgG w/Reflex	86615	=>2.5	B pertussis Ab IgG Immunoblot	86615
B pertussis Ab IgM w/Reflex	86615	=>1.2	B pertussis Ab IgM Immunoblot	86615
Celiac Disease IGA Reflex Panel	82784	<7.0	Tissue Transglutaminase Ab,IgG Gliadin Peptide Ab - IgG	83516 83516
Celiac Disease IGA Reflex Panel	82784	=>7.0	Tissue Transglutaminase Ab,IgA Gliadin Peptide Ab - IgA	83516 83516
ANA Screen IFA with reflex titer	86038	Positive	Titer and pattern	86039
Hemoglobin Electrophoresis	83020	Presence of HbS	Sickle Cell Screen	85660
Urine Protein Electrophoresis	84166	Ordered upon pathologist discretion	Immunofixation including Kappa:Lambda	86335,83883
Lactic Acid	83605	>2.0	Lactic Acid Repeat	No change to CPT code
Lactic Acid Whole Blood	83605	>2.0	Lactic Acid Whole Blood Repeat	No change to CPT code
HEMATOLOGY				
CBC with automated differential	85025	Internal laboratory criteria	CBC with manual differential	No change to CPT code
Lupus Anticoagulant Screen	85612	Positive Result (ratio > 1.3)	Lupus Anticoagulant (Hexagonal)	85613
Urinalysis	81003	Any of the following Protein:1+ or more Blood: 1+ or more Leukocyte esterase or Nitrite: Positive	Urinalysis with Microscopic	81001 (81003 cancelled)
Urinalysis (Emergency Dept)	81003	> 5-10 Wbcs/hpf AND > 5-10 or > 1+ bacteria/hpf AND < few or < 2+ epithelial cells /lpf	Urine culture	87086
Urinalysis with Reflex Culture (non-ER patients, written order must specify to perform culture if indicated)	81003	> 5-10 Wbcs/hpf AND > 5-10 or > 1+ bacteria/hpf AND < few or < 2+ epithelial cells /lpf	Urine culture	87086

MICROBIOLOGY				
Microbiology Culture	** varies by culture type (Aerobic, Anaerobic AFB, Fungus, etc.)	Significant Organism	Identification Susceptibility	**varies by culture type / methodology used
Herpes Simplex Viral Culture with Reflex Typing	87252 87253	Positive	HSV Typing (1 & 2)	87140 x 2

2. **Confirmatory testing:** A **confirmatory test** is an additional test or procedure performed to *validate the accuracy of the initial test result*, as a means to determine or define the medical necessity of subsequent patient treatment(s).

Initial Test	CPT	Result	Confirmatory Test	CPT
BLOOD BANK				
Fetal Screen	85461	Positive	Fetal Hemoglobin (Kleihauer-Betke)	85460
CHEMISTRY				
Hepatitis B Surface Ag	87340	Positive	HBSAg Neutralization	87341
Rapid Plasma Reagin Titer	86593	Reactive	T. Pallidum Particle Agglutination	86781
Urine Drug Screen	**varies by drug class	Positive	Reference Laboratory confirmation if requested by physician	**varies by drug class
HIV Combo	86703	Reactive	HIV1-HIV2 MS (Multispot)	86689
MICROBIOLOGY				
Rapid A Strep	87880	Negative	Throat Culture	87070

3. **Composite Testing:** A **composite order** is a testing protocol used to identify additional and significant diagnostic information, medically necessary for quality patient care.

Initial Test	CPT	Composite Order	CPT
BLOOD BANK			
Fresh Frozen Plasma	P9017	ABO, Rh and Antibody Screen	86901,86900,86850
Cryoprecipitate	P9012		
Platelets	P9031/P9033		
Pheresis Platelets	P9035/P9036		
HEMATOLOGY			
Urinalysis	81003	Clinitest for patients < 2 years of age	81002
MICROBIOLOGY			
AFB Culture	87116	AFB Smear	87206
AFB Smear (1st specimen)	87206	AFB Culture	87116
Body Fluid Culture Respiratory Culture CSF Culture Surgery Culture Wound Culture Eye Culture	87070 87070 87070 87070 87070 87070	Gram Stain	87205 87205 87205 87205 87205 87205
Fungal Culture	87102	Fungal Smear	87210
Fungal Smear (sterile site)	87210	Fungal Culture	87102
Stool Culture	87045	Enrichment Broth Campylobacter Cult EColi O157H7 Cult Shiga Toxins A&B	87015 87046 87046 87427x2

Reviews: 02/14, 05/14, 01/16, 01/17

Approved: CSHCC-Memorial

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CHRISTUS SPOHN HEALTH SYSTEM

TITLE: Bedside Blood Glucose Monitoring, Point of Care Testing - PROCEDURE

Date Issued: 10/07
Date(s) Revised: 06/10, 09/10, 07/12,05/14
Date(s) Reviewed: 06/10, 09/10, 07/12, 03/13,05/14

Section: Laboratory
Number: LAB-101-P
Originator: Laboratory

Approved By: *See last page for Laboratory Medical Director/Administrator approvals
(Original with signatures archived in Document Control)

PURPOSE:

The Nova StatStrip Meter is a hand held, battery powered, in vitro diagnostic laboratory instrument that works in conjunction with Nova Biomedical glucose electrochemical test strips to measure glucose in a whole blood sample. Glucose is measured amperometrically using an enzyme based test strip. Bedside blood glucose monitoring is performed as ordered by a physician or anytime, a Registered Nurse's assessment indicates that a blood glucose test is warranted.

PRINCIPLE:

1. Competency
    a. Blood glucose testing will only be performed by CHRISTUS Spohn Associates that have valid competency documentation.
    b. To be certified competent and considered a valid operator, Associates must complete the Healthstream Nova computer based training and training with a designated trainer.
        i. This will consist of hands-on training and successfully completing the validation checklist, passing the written test, performing a patient test, and running a set of quality control.
        ii. To remain a valid operator, competency will be assessed by reviewing the current procedure on SharePoint, successfully completely the Healthstream test annually, performing two patient tests, and successfully completing two sets of quality controls on an annual basis.
    c. All training is under the direction of the Laboratory Director or designee.
    d. Competency records for all certified operators will be maintained by the Point-of-Care Testing (POCT) Department.

2. Unit manager or designee is responsible for their respective unit's testing activity. These responsibilities include the following:
    a. Review of data reports and appropriate corrective action if necessary.
    b. Monitoring expiration date of test strips and appropriate disposal if not used within six months of opening.
    c. Assuring availability of reference material on the unit.
    d. Insuring annual re-certification for all glucometer operators on their respective units.
    e. Performing initial troubleshooting of meters prior to contacting the Laboratory Point-of Care Testing (POCT) Department.

3. The Laboratory Point-of-Care Coordinator will manage the daily operations of all Nova StatStrip glucometers. Responsibilities include the following:
    a. Providing operational direction and development of policies and procedures.
    b. Providing policy and procedure manuals to all nursing units and reviewing manual annually.
    c. Serve as a resource for unit managers when problems arise.
    d. Serve as the resource for meter repair or replacement.
    e. Supervise units regarding quality control data, operator variances, operator competencies, and issue periodic reports documenting supervision.
    f. Confirm compliance with all applicable regulations.
    g. Supervise the maintenance of the NovaNet Database including entry of vertified operators into the operator database, entry of test strip and quality control lot numbers

into the reagent database, and setting parameters in the database to conform to current procedure.

4. The Director named on the CLIA certificate will be responsible for the following:
    a. Periodic review of this document.
    b. Determining the context in which this test is utilized.
    c. Approving staff as qualified to perform each role defined in this procedure.
    d. Approving training for all staff.
    e. The overall operation of the glucometer program.

SPECIMEN:
Type: Whole blood: capillary, arterial, and/or venous.

Handling Conditions:
1. When not analyzing from a lancing device, whole blood should be analyzed within 30 minutes of collection. Storing samples on ice is not recommended.
2. Sodium, lithium, and ammonium heparin are the recommended anticoagulants when sampling with syringes or vacutainer tubes.
3. Serum or plasma must NOT be used in the Nova StatStrip glucometer.

REAGENTS/EQUIPMENT:
Nova StatStrip Glucometer
StatStrip test strips (available from Central Supply)
StatStrip Control Solutions, Level 1 and Level 3 (available from Central Supply)
Single use, auto-disabling finger stick device
Alcohol pads and gauze
Germicidal disposable wipe (available from Central Supply)
Disposable gloves

Reagents must be stored at room temperature and away from heat and light in the original bottles. Strips should be tightly capped and only the strips that will be utilized immediately should be removed from the bottle. All reagents must be dated upon opening. StatStrip control solutions (Levels 1 and 3) expire 90 days after opening, on the last day of the month and year of the date stamped on the bottle if unopened or the shorter of the 2 dates. Use only Nova reagents with the Nova glucometers.

Clean the meter with a cloth that has been dampened with a 10% bleach solution or a disinfectant wipe. Immediately follow with a water-dampened cloth to remove all cleaning residue. Dry thoroughly with a soft cloth or lint-free tissue.

CAUTION: **DO NOT** immerse the meter or hold meter under running water.
DO NOT spray the meter with a disinfectant solution.

PROCEDURE:
Operator Login:
After initial power up, an operator must touch the screen to "wake" the meter up. The associate may then log in to access the following functions of the meter. To log in, proceed as follows:
1. From the "Welcome" screen, press the "Login" soft key at the bottom middle of the screen.
2. The "Enter Operator ID" screen appears.
3. To use the barcode scanner, press the "Scan" soft key on the screen. (Operator ID's may not be manually entered.)
    NOTE: When an invalid ID is entered, the screen will display the following message: "is not a valid Operator ID; Try again."
4. Press the "Accept" soft key at the bottom of the screen.
5. After the Operator ID is accepted, the "Patient Test" screen appears. The meter is now ready to run patient and QC tests.

Quality Control (QC)
QC must be performed once every 24 hours of patient use. The meters are set to lockout and will not perform patient testing until QC is performed. The QC will include two levels of liquid control. Prompts on the meter will guide the operator through the process. The meter must be checked for cleanliness. The meter should be cleaned and disinfected with a germicidal disposable wipe immediately after each patient use. Thorough cleaning and disinfection between patients will prevent transmission of bloodborne pathogens among patients. The meter may need to be cleaned as part of a troubleshooting process. All parts of this meter may be cleaned with a germicidal disposable wipe.

Quality Control Test:
The following section explains how to run a Quality Control Test with one of the two StatStrip Glucose Control Solutions.

1. From the Patient Test screen, press the "QC" soft key.
2. The "Enter Strip Lot" screen displays. Enter the strip lot number by scanning the barcode on the bottle. To scan the barcode, press the "Scan" soft key.
   NOTE: If the strip lot number is invalid, the screen displays "is not a valid Strip Lot; Try again."
3. If the strip lot number is valid, the "Enter QC Lot" screen appears. Enter the QC lot number by scanning the barcode on the bottle. To scan the barcode, press the "Scan" soft key.
   NOTE: If the QC lot number is invalid, the screen displays "is not a valid QC Lot; Try again."
4. If the QC lot number is valid, the "Insert Strip" screen appears. Insert the Nova StatStrip test strip face up into the meter.
5. With the test strip correctly inserted, the "Apply Ample" screen appears.
6. Gently mix the StatStrip Glucose Control Solution before each use by gentle inversion to avoid bubble formation.
7. Discard the first drop of control solution from the bottle to avoid contamination and to ensure there are no bubbles that will cause flow errors.
8. Place a drop of the control solution from the bottle at the end of the test strip until the solution is drawn into the well of the test strip. (Do not place the drop on the top of the test strip.) When enough sample has been drawn into the strip, an audible beep is sounded by the meter and the countdown timer begins.
9. The "Testing Sample" screen is displayed. The screen shows a clock with seconds remaining below the clock.
10. When the meter completes the test, the "QC Result" screen appears with the result, either "Pass" or "Fail."
    NOTE: Do not test patient samples until both control solutions are within expected range.
11. To add a comment to the result, press the "Comment" soft key. Press the "Accept" soft key to accept the comments and return to the "QC Result" screen.
12. To accept the result, press the "Accept" soft key.
13. Repeat steps 1 through 13 with the second level of control solution.

PATIENT TESTING PROCEDURE:

NOTE:

1. QC must be performed before patient testing. Meter will not allow patient testing until QC is completed and acceptable.
2. Gloves must be worn at all times while handling specimens in compliance with the CHRISTUS Spohn Standard Precautions Policy.
3. Patient owned glucose meters may not be used for glucose testing at CHRISTUS Spohn facilities.
4. Sharing of operator ID is **NOT ALLOWED** under any circumstances.

1. Check patient identification using the patient armband and two patient identifiers as required under The Joint Commission Patient Safety Guidelines. The standard for Point-of-Care testing is the patient's name and account number or date of birth.
2. Clean the patient's finger. An alcohol pad may be used to clean the puncture site if hand washing is not possible. The site must be completely dry before proceeding. Prepare the single-use, auto-disabling lancet device. Properly perform the finger stick following appropriate CHRISTUS Spohn collection protocol. (Be sure to wipe away the first drop of patient blood following the finger stick.)
3. Touch the screen to "wake" the Nova meter on.
4. From the "Patient Test" screen, press the "Accept" soft key.
5. The "Enter Strip Lot" screen displays. Enter the strip lot number by scanning the barcode on the bottle. To scan the barcode, press the "Scan" soft key.
6. If the strip lot number is valid, the "Enter Patient ID" screen appears.
7. The patient's ID is the account number on the patient's armband. From the "Enter Patient ID" screen, the patient's account number can be entered by scanning the barcode on the patient's armband or by manually entering the account number. To scan the barcode on the patient's armband, press the "Scan" soft key. To manually enter the patient's ID, use the alphanumeric soft keys on the screen. Once entered, press the "Accept" soft key.
   NOTE: If the patient does not have an active account number, enter the patient's last name and as much of the first name as will fit in the meter display (e.g. THOMPSONJENN). For newborns without account numbers, enter the mother's last name and baby boy or girl (e.g. JONESBABYBOY).
8. The "Insert Strip" screen is displayed. Insert a test strip as shown on the screen.
9. Once the Nova test strip is inserted properly, the "Apply Sample" screen is displayed. When the blood drop appears, touch the end of the test strip to the blood drop until the well of the test strip is full. The meter will beep once enough blood has been drawn up into the strip and the countdown will begin.
   WARNING: The test strip must fill completely upon touching the blood droplet. If the test strip does not fill completely, do not touch the test strip to the blood droplet a second time. Discard the test strip and repeat the test with a new strip.
10. The test results will appear in 6 seconds.
11. The "Patient Result" screen is displayed.
12. To add a comment, press the "Comment" soft key. Select the appropriate comments and press the "Accept" soft key and return to the "Patient Result" screen.
13. To accept the result, press the "Accept" soft key. To reject the result, press the "Reject" soft key.
    NOTE: A single up arrow is displayed for abnormal high results and 2 up arrows are displayed for critical high results. A single down arrow is displayed for abnormal low results and 2 down arrows are displayed for critical low results.

PRECAUTIONS AND LIMITATIONS

1. A patient result above 600 mg/dl ("HI") should be verified by the Laboratory
2. A patient result below 50 mg/dl should be verified by the Laboratory
3. Physicians must be notified whenever bedside glucose results are below 35 or above 200 for neonates, and below 50 or above 400 for adults, unless physician notes otherwise.
4. For test results less than 70mg/dl, refer to Delegated Orders: Hypoglycemia or applicable policy.
5. Only hospital-owned meter results may be utilized for patient treatment.
6. If the patient suffers from dehydration, shock, low oxygen levels, or has factors that affect the peripheral circulation, such as vasoactive drugs or Raynaud's Disease laboratory glucose testing methods should be considered.
7. The reportable range for neonatal patients is 0-200 mg/dl, with a hematocrit level of between 25-65%. Laboratory testing should be considered when results or conditions are outside these limits on neonates.

RANGES TO BE REPORTED WITH THE TEST RESULTS

Normal	
0-28 days	35-60 mg/dl
Adult	70-110mg/dl
Critical	
0-28 days	Less than 35 mg/dl or Greater than 200 mg/dl
Adult	Less than 50 mg/dl or Greater than 485 mg/dl

LIMITATIONS OF THE PROCEDURE:

1. If needed, sodium, lithium, and ammonium heparin are the recommended anticoagulants for use with the Nova StatStrip Glucose Meter.
   a. Depending on the amount of heparin used in the collection syringe and whether it is filled to capacity with blood, the concentrations of heparin may be 20 I.U. per mL to over 100 I.U. per mL. When liquid heparin is present in excess, it may cause dilution errors.
   b. A lyophilized lithium heparin giving a final concentration in blood of not more than 20 I.U. per mL is acceptable.
2. EDTA, citrate, oxalate, and sodium fluoride are not recommended for use.
3. **Glucose Interferences**
   The Nova StatStrip Glucose Meter exhibits no interference from the following substances up to the following concentration levels:

Interfering Substance	Concentration Level
Acetaminophen	10.0 mg/dL
Ascorbic Acid	10.0 mg/dL
Bilirubin	15.0 mg/dL
Cholesterol	500.0 mg/dL
Creatinine	6.0 mg/dL
Dopamine	10.0 mg/dL
Ephedrine	0.9 mg/dL
D(+) Galactose	350.0 mg/dL
Hematocrit (RBC)	< 20% or >65%
Ibuprofen	48.0 mg/dL
L-Dopa	100.0 mg/dL
D(+) Maltose Monohydrate	240.0 mg/dL
D(+) Maltotetraose	240.0 mg/dL
D(+) Maltotetriose	240.0 mg/dL
Methyl-Dopa	1.0 mg/dL
Oxygen	All concentrations
Salicylate	30.0 mg/dL
Tetracycline	30.0 mg/dL
Tolazamide	15.0 mg/dL
Tolbutamide	45.0 mg/dL
Triglycerides	750.0 mg/dL
Uric Acid	20.0 mg/dL

GLUCOMETER COMMENT MESSAGES

The following comment messages are to be utilized in order to establish a standardized method to prevent testing errors from being reported in the patient's medical record. They are also to be used to document critical error notification. Glucometer operators must attach comment messages to test results as indicated in the Procedure section of this document.

NOTE: This procedure is to be used when an error is known **before** completion of testing. For errors discovered after testing is complete use the Glucometer Error reporting Form.

Attach comment messages to test results using the "Enter Notes" function as indicated in the following situations:

- **Procedure Error:** (wrong control, wrong strip lot, wrong patient etc.) Use this comment message for quality control and patient testing errors when the error is realized **before** testing is complete. Use of this comment message prevents the result from being reported in the patient's medical record.
- **To be Repeated:** (results are not consistent with the clinical observations or for test results that require confirmation.) Use this comment message when additional testing will be performed. Use of this message will prevent duplicate test result reporting.
- **Notify MD/RN:** Use this comment message when critical test results are reported to the appropriate physician or RN. This serves as required documentation for accreditation.
- **Received Meds:** Use this comment message to document intervention after a specific test result.
- **Confirm with Lab:** Use this comment message as documentation that the result will be verified with a laboratory test.
- **Chart this result:** Use when the result is to be sent to the patient medical record
- **Do not chart this result:** Use this comment when the result should not be sent to the medical record.

The manager of the patient care unit, or designee, is responsible for daily testing, quality control, and accreditation compliance.

The POCT Coordinator, or designee, is responsible for QC review.

References:

1. Burtis, Carl A. and Ashwood, Edward R., ed 1999. Tietz Textbook of Clinical Chemstry. Philadelphia, PA: W. B. Saunders Co.

2. NOVA Biomedical Instruction for Use Manual, Printed in the U.S.A. Copyright 2011, Nova biomedical Corporation, Waltham, MA 02454-9141.

Reviews:
03/13, 05/14

Approved: **CSHCC – Memorial**

Joe A. Lewis, M.D. _____
Laboratory Medical Director Date

Raymond Ramos _____
Laboratory Administrator Date

CSHCC – Shoreline

Joe A. Lewis, M.D. _____
Laboratory Medical Director Date

Jason Naranjo _____
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Joe A. Lewis, M.D. _____
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Manuel Tamez _____
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Randall Simonsen, M.D. _____
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Aamer Qidwai _____
Laboratory Administrator Date

CSH – Beeville

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Barbara Herro _____
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CSH – Kleberg

Randall Simonsen, M.D. _____
Laboratory Medical Director Date

Aamer Qidwai _____
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CHRISTUS SPOHN HEALTH SYSTEM
POLICY and PROCEDURE MANUAL

TITLE: Laboratory Reporting of Results - PROCEDURE

Date Issued: 06/04
Date(s) Revised: 08/11, 03/13
Date(s) Reviewed: 08/11, 03/13, 03/15

Section: Laboratory
Number: LAB-102-P
Originator: Laboratory

Approved By: *See last page for Laboratory Medical Director/Administrator approvals
(Original with signatures archived in Document Control)

PURPOSE:

To provide useful clinical data in the form of legible, accurate test results with units of measure and/or reference intervals (normal ranges) where appropriate in a timely manner. In order to achieve this, CHRISTUS Spohn Health System Laboratory Associates shall demonstrate knowledge of (e.g. documentation of policy/procedure, SOP review, direct observation, verbal communication) and thereby comply with the following provisions set forth to achieve our purpose:

1. Provide the pertinent healthcare information necessary to satisfy its access and do so promptly
2. Define content required in laboratory result reports, and to retain results in accordance with CAP guidelines
3. Provide notification of a delay in testing
4. Establish a turnaround time for all laboratory tests and procedures
5. Provide a mechanism to ensure that test methodologies are available to clients upon request

PROCEDURES:

1. All laboratory reports generated by the laboratories of CHRISTUS Spohn Health System shall include the following elements:
    a. Name and address of testing laboratory
    b. Patient name and identification number, or unique patient identifier
    c. Name of physician of record, or legally authorized person ordering test, as appropriate
    d. Date and time of specimen collection, when appropriate
    e. Date of release of report, if applicable (if not on the report, this information should be readily accessible)
    f. Time of release of report, if applicable (if not on the report, this information should be readily accessible)
    g. Specimen source, when applicable
    h. Test result(s) and units of measurement, when applicable
    i. Reference intervals, as applicable
    j. Conditions of specimen that may limit adequacy of testing

2. Patient results are readily retrievable via the computer system in accordance with CAP record retention guidelines. See Record Retention Policy for additional details.

3. Access to results and healthcare information is restricted to persons authorized by documented employment job description duties, by law, or other legally acceptable party in adherence with HIPPA regulations. The process is designed to ensure that only those healthcare personnel authorized to review test result and/or access PHI, are granted access to do so (see CHRISTUS Health System "Computer User Security Agreement" form). A random audit of users' access (i.e., HIPPA compliance) is conducted annually or as indicated to monitor compliance to include documentation for record. Any infringements are dealt with on a case by case and per hospital policy for PHI/HIPAA breaches.

4. The LIS provides the means to track the Analyst ID on all tests performed and resulted. For tests performed in-house, the mnemonic identifier of the individual performing and resulting the test, along with the instrument used for analysis, as applicable, is automatically entered by the computer system,

using the mnemonics of the associate signed onto the resulting computer. For reference laboratory tests, the identity of the person performing the test is most commonly determined through direct communication with the reference laboratory.

5. Test Delay Notification – In the event of a delay in testing or resulting that could impact patient care, the laboratory will promptly notify the appropriate party – physician, patient care unit nursing personnel, physician's office, or other. Reference laboratory result reporting delays are also communicated to the appropriate party when clinically significant. Laboratory personnel will enter an internal or external comment into the computer system, depending on the circumstances, that documents the testing/reporting delay notification.

6. Turnaround Times – Clinical Pathology
    a. The laboratory has defined turnaround times (i.e. time elapsed between specimen receipt into the laboratory to time of results reporting) for each of its tests/procedures based upon the ordered priority of the test, as determined by the ordering physician. These turnaround times were established in consultation with the laboratory medical directors, staff pathologists, and in accordance with reputable journals of laboratory medicine as well as in consultation with the medical staff. All tests offered by the laboratory, whether done in-house or as a send-out to a medical director approved reference laboratory or other facility, are listed alphabetically in the online laboratory test directory. This comprehensive listing includes specimen collection requirements, special instructions where indicated, and other pertinent test/collection information. In addition to the online laboratory test directory, estimated turnaround times for most in-house test/procedures are established in the laboratory test/procedure dictionaries within the computer system. General turnaround times for in-house clinical laboratory test or procedure are as follows, defined according to order priority as determined by the patient's healthcare giver:
        1. STAT: 1 hour
        2. Urgent: 4 hours
        3. Routine: 8 hours or same day

       This excludes most microbiology tests as well as any other test/procedure that cannot be reasonably performed within the times stated above. Microbiology turnaround times are located and defined in the online Laboratory Test Directory and the microbiology procedure dictionary in the computer system.
    b. Emergency department (ED) and Surgery (OR) turnaround times

       Our laboratory internal ED TAT criterion is that dashboard assays are resulted and issued within 40 minutes from the time of receipt into the laboratory to result 90% of the time. Our laboratory external ED TAT criterion is that dashboard ED assays are resulted and issued within 60 minutes from the time or order to result 90% of the time. O.R. specimens such as blood, STAT gram stain or others capable of completion within 60 minutes or less must adhere to the same standards described above.
    c. Turnaround times – Anatomic and Cytopathology

       All surgical pathology and cytopathology reports are required to be signed out within 48 hours of specimen processing, unless additional procedures (e.g., special stains) or outside consultation is necessary. Autopsy reports are signed out within 30 days of completion unless it is a category II autopsy case (i.e. requiring additional procedures and/or outside consultation), and if so, is signed out within 60 days. The average turnaround time for autopsy reports is two weeks.

7. Provision of Client Information – Test/Procedure Methodologies

   The laboratory will provide physicians and/or patient clients with information on test methodologies for all procedures, whether performed in-house or sent to a reference laboratory, along with the clinically appropriate reference ranges and other performance

specification where applicable, and all laboratory test procedure results are reported with units of measure. The various testing/procedure methodologies of in-house tests and procedures are contained within each laboratory technical section's procedure manuals and are available upon request.

8. Issuance of Corrected Reports

When errors are detected in patient reports, the laboratory must promptly notify the appropriate clinical personnel. All revised reports are identified as corrected and the original data is clearly identified as "previously reported". If there is a need for multiple sequential corrections of a single test result, all corrections are referenced in sequential order on subsequent reports.

Reviews:
08/11, 03/13, 03/15

Approved: **CSHCC – Memorial**

Dr. Joe Lewis 04/24/15
Laboratory Medical Director Date

Sylvia Buentello 04/22/15
Laboratory Administrator Date

CSHCC – Shoreline

Dr. Joe Lewis 04/24/15
Laboratory Medical Director Date

Jason Naranjo 04/24/15
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CSHCC – South

Dr. Joe Lewis 04/13/15
Laboratory Medical Director Date

Manuel Tamez 04/20/15
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CSH – Alice

Dr. Randall Simonsen 04/13/15
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Dr. Randall Simonsen 04/13/15
Laboratory Medical Director Date

Barbara Herro 04/07/15
Laboratory Administrator Date

CSH – Kleberg

Dr. Randall Simonsen 04/13/15
Laboratory Medical Director Date

Aamer Qidwai 04/07/15
Laboratory Administrator Date

TITLE: Laboratory Critical Results, Notification, and Documentation-Procedure

Date Issued: 10/01 Section: Laboratory
Date(s) Revised: 10/04, 05/05, 06/06, 02/07, 07/08, 05/09
04/10, 04/11, 09/11, 05/12, 03/13, 07/16 Number: LAB-106-P
Date(s) Reviewed: 09/11, 05/12, 03/13, 12/13, 04/15, 06/16, 07/16 Originator: Laboratory

Approved By: *See last page for Laboratory Medical Director / Administrator approvals
(Original with signature archived in Document Control)

PURPOSE:

To establish standardized critical values for laboratory test procedures which require notification of Physician/LIP (Licensed Independent Practitioner) and/or other appropriate licensed caregiver*, e.g. RN, Respiratory Therapist. Critical values have been determined with the use of pertinent Clinical Laboratory Science journals and in consultation with Administrative Laboratory Directors, Lead Technologists, and Laboratory Medical Directors and other Medical Staff as indicated.
**Only licensed caregivers are authorized to receive critical test results*[1]

DEFINITION:

Critical Values: those values that fall outside of the predetermined high and low critical limits and which therefore require immediate notification of the Physician/LIP and/or other authorized licensed caregiver and/or Infection Control for certain Microbiology values.

SECTION 1.01 Procedure for Notification and Documentation

1. **Notification**:

   a. A list of critical values requiring notification is attached to this document for reference.

   b. If a patient testing value is obtained that falls into the critical value range, the result will be called to the ordering Physician/LIP and/or other appropriate licensed caregiver immediately.

   c. A "read-back" of the result by the person to whom the result is given is required for successful completion of notification.

   d. For Inpatients: The ordering Physician/LIP or appropriate licensed caregiver is notified of the critical value(s).

   e. External Laboratory: Test results that have been referred to the laboratory from outside, intra-System Laboratory hospital clients, nursing homes, and/or skilled nursing facilities will be called to the appropriate Physician/LIP/other authorized caregiver of the patient.

   f. Other: For discharged, clinic or other outpatients not mentioned above, the ordering Physician/LIP, Physician/LIP's nurse, or other authorized party shall be notified of critical values in accordance with hospital policy H-143-P[1], "CSHS Critical Values Policy," Procedures #6 and #7, excerpted below for convenience:

      6. For a discharged patient the critical values are called directly to the ordering physician or on call physician within one hour.

      7. All Critical diagnostic test results received by the patient's nurse will be reporting according to the following sequential notification system:
         a. First call to MD/LIP #1 (ordering or on call)
         b. If no response after 15 minutes, call MD/LIP #1 again
         c. After 30 minutes, escalate notification by contacting the ED Physician and subsequently document the variance on the ordering physician.

g. Patient values determined by the Laboratory testing personnel to exhibit significant trends affecting patient care will be called to the Medical Director, Physician/LIP and/or licensed caregiver as defined in H-143-P[1] and accordingly herein.

2. **Documentation:**

a. Documentation of notification for critical results will be entered into the Laboratory computer system and the report will include:

i. The patient's full name (first and last name) ***with two patient identifiers*** of the patient for whom critical result(s) are being called, e.g. the patient's DOB, and/or the patient's hospital account number

ii Date of call

iii. Time of call

iv. Name (first and last name) and title of person to whom the result(s) are given

b. Documentation of successful "read-backs" will be entered into the Laboratory computer system with the critical value result. ***In order to be successful, the read-back must include at least two patient identifiers*** **–** the patient's full name (first and last name), *and* the patient's DOB, and/or the patient's hospital account number. ***A patient's room number is NOT a valid patient identifier.***

c. Should all attempts for proper notification fail, successful read-backs can include sufficient documentation of faxed results to the outpatients'/discharged patients' Physician/LIPs via a fax transmission confirmation report.

Reviews:
09/11, 03/13, 12/13, 04/15, 06/16, 07/16

Reference:
[1] CHRISTUS Spohn Health System Policies and Procedures Manual, "Administrative Policies and Procedures, Section H – Patient Care, H-143-P, 'CSHS Critical Values Policy'"" procedure steps 6 and 7. Available at: CSHS CHRISTUS Connect Intranet: http://christusconnect.echristus.net/regions/spn/OSandGuidelines/Pages/Spohn-PoliciesAndProceduresPage.aspx.

Critical Laboratory Results Requiring Notification

SECTION 1.02 CHEMISTRY CRITICAL VALUES			
Assay (Serum, unless otherwise specified)	**Units of Measure**	**Critical Low**	**Critical High**
Calcium From 0 Days	mg/dL	6.6	13.0
Ionized Calcium From 0 Days	mmol/L	0.82	1.55
Chloride From 0 Days	mmol/L	74	125
CO2 From 0 Days	mmol/L	10	40
Glucose Neonatal From 0 Days – 11 Months	mg/dL	35	200
Glucose From 1 Year	mg/dL	50	485
CSF Glucose From 0 - 4 Days	mg/dL	35	435
Magnesium Neonatal From 0 - 4 Days	mg/dL	1.1	5.0
**Magnesium From 5 Days	mg/dL	1.2	5.0 **OB 7.0
Osmolality, Serum From 0 Days	mOsm/kg	250	325
Phosphorous Neonatal From 0 Days – 1 Year	mg/dL	1.2	9.6
Phosphorous From 2 Years	mg/dL	1.2	8.9
Potassium Neonatal From 0 - 7 Days	mmol/L	2.5	7.9
Potassium From 8 Days – 12 Years	mmol/L	2.8	6.2
Potassium From 13 Years	mmol/L	3.0	6.0
Sodium From 0 Days	mmol/L	120	160
Troponin-I* From 0 Days	ng/mL	none	0.5
Troponin-T* From 0 Days	ng/ml	none	0.10
**Troponin notification will only be performed upon initial critical value and with a subsequent spike during the same admission.*			
***For OB Patients on magnesium therapy only: Critical magnesium levels of >=7.0 mg/dL will be called to RN and documented per protocol. A standardized canned text result comment citing this critical values policy revision will be added in these circumstances for OB patients on magnesium therapy only.*			

SECTION 1.03 THERAPEUTIC / NON-THERAPEUTIC DRUGS CRITICAL VALUES			
Assay (Serum, unless otherwise specified)	**Units of Measure**	**Critical Low**	**Critical High (Toxic Level)**
Acetaminophen	mcg/mL	none	Greater than or equal to 50
Amikacin Random	mcg/mL	none	Greater than 8.0
Amikacin Trough	mcg/mL	none	Greater than 8.0
Amikacin Peak	mcg/mL	none	Greater than or equal to 35.0
Carbamazepine	mcg/mL	none	Greater than or equal to 20.0
Digoxin	mg/mL	none	Greater than 2.0
Ethyl Alcohol	mg/dL	none	Greater than or equal to 400
Gentamicin Random	mcg/mL	none	Greater than 2.0
Gentamicin Trough	mcg/mL	none	Greater than 2.0
Gentamicin Peak	mcg/mL	none	Greater than10.0
Lithium	mmol/L	none	Greater than or equal to 1.2
Phenobarbital	mcg/mL	none	Greater than 40.0
Random From 0 Phenobarbital Random From 12	mcg/mL	none	Greater than or equal to 55.0
Phenobarbital Trough From 0 Days	mcg/mL	none	Greater than 40.0
Phenobarbital Trough From 12	mcg/mL	none	Greater than or equal to 55.0
Phenytoin	mcg/mL	none	Greater than or equal to 30.0
Salicylate	mg/dL	none	Greater than or equal to 30.0
Theophylline Trough From 0 Days	mcg/mL	none	Greater than 20.0
Theophylline Trough From 12	mcg/mL	none	Greater than 25.0
Theophylline Random From 0	mcg/mL	none	Greater than 20.0
Theophylline Random From 12	mcg/mL	none	Greater than 25.0
Tobramycin Random	mcg/mL	none	Greater than 2.0
Tobramycin Trough	mcg/mL	none	Greater than 2.0
Tobramycin Peak	mcg/mL	none	Greater than 10.0
Valproic Acid	mcg/mL	none	Greater than or equal to150.0
Vancomycin Random	mcg/mL	none	Greater than 20.0
Vancomycin Trough	mcg/mL	none	Greater than 20.0
Vancomycin Peak	mcg/mL	none	Greater than or equal to 50.0

SECTION 1.04 TRANSFUSION SERVICES				
Test		**Units of Measure**	**Critical Low**	**Critical High**
Neonatal DAT (From 0 days)	Reactions graded from negative to 4+ positive	N/A		Positive
Crossmatch - Inability to find compatible units				

SECTION 1.05 HEMATOLOGY CRITICAL VALUES			
Test	**Units of Measure**	**Critical Low**	**Critical High**
WBC*	$x10^3/\mu L$	Less than 2.0	Greater than 35
Neonatal WBC (0-7 days)	$x10^3/\mu L$	Less than 2.0	Greater than 50
Hemoglobin	g/dl	Less than 7.0	N/A
eonatal Hemoglobin	g/dl	Less than 9.5	Greater than 25
Hematocrit	%	Less than 20.0	N/A
Neonatal Hematocrit	%	Less than 29.0	Greater than 75
Platelets*	$x10^3/\mu L$	Less than 50	Greater than 1,000
PT (non-Coumadin)	Seconds	N/A	Greater than 25
PT (Coumadin) **	INR	N/A	Greater than or equal to 4.5
PTT (non-heparin)	Seconds	N/A	Greater than 68
PTT (heparin) **	Seconds	N/A	Greater than 120
Fibrinogen	mg/dL	Less than 100	N/A
CSF WBC	WBC/cumm	N/A	Greater than 10

* For Oncology patients, WBC and platelet count critical values are called upon admission only; rechecks are performed on all subsequent results.
**PT and PTT critical values for patients not on anticoagulants will not be flagged in the Laboratory LIS but will be called upon admission only. This applies to all CHRISTUS Spohn Hospital – Corpus Christi facilities.

SECTION 1.06 MICROBIOLOGY CRITICAL VALUES
Positive Blood Culture (non-contaminated)
Positive CSF Culture or Gram Stain
Positive CSF Cryptococcal Antigen
Positive Sterile-Site Body Fluid Culture or Gram Stain
Positive Sterile-Site Tissue Culture or Gram Stain
Positive AFB Smear or Culture*
Positive *Mycobacteria tuberculosis* identification*
Positive Ocular Culture with: • *Bacillus* species • *Neisseria gonorrhoeae* • *Pseudomonas aeruginosa* • Staphylococcus aureus • Acanthamoeba species
Positive Stool Culture Pathogens (*Salmonella, Shigella, Campylobacter, Shiga Toxin producer, E.cole 0157.H7*)*
Positive Herpes Simplex Virus from Newborns (up to one year of age)

*Also requires notification to Infection Control Department

The following Microbiology results ("notifiable conditions") are required by state and/or federal law to be reported to the appropriate authorized party. The Microbiology Department calls the following conditions upon the first occurrence of each patient admission, directly to the nursing unit for in-house patients only. The Infection Control Department is also notified of the same conditions via the HIS Infection Control Report. Infection Control personnel notify state authorities with communicable disease reports as required by state law.

SECTION 1.06.a. MICROBIOLOGY NOTIFIABLE CONDITIONS (ALERTS, NOT CRITICAL VALUES)
♦ Methicillin Resistant Staphylococcus aureus (MRSA)
♦ Vancomycin Resistant Enterococcus (VRE)
♦ Extended Spectrum Beta Lactamase producing Enterobacteriaceae (ESBL)
♦ Carbapenem Resistant Enterobacteriaceae (CRE)
♦ Multidrug Resistant Acinetobacter
♦ Multidrug Resistant Pseudomonas aeruginosa
♦ Pan-Resistant Organisms
♦ Toxigenic Clostridium difficile
♦ Select Agents and other highly pathogenic organisms (*Bacillus anthracis*, *Brucella spp.*, *Burkholderia mallei, Burkholderia pseudomallei*, *Coccidiodes immitis*, *Francisella tularensis, Yersinia pestis*, and *C. diphtheriae*, *Salmonella typhi, Vibrio cholera*)*

Section 1.07 Anatomic Pathology Critical Procedure
Frozen Section: A frozen section is considered a critical test/procedure and the Pathologist reports results immediately to the requesting Physician/LIP.

Approved: **CSHCC – Memorial**

Joe A. Lewis 08/30/16
Joe A. Lewis, M.D, Laboratory Medical Director Date

George Bost 08/30/16
George Bost, Laboratory Administrator Date

CSHCC – Shoreline

Joe A. Lewis 08/30/16
Joe A. Lewis, M.D., Laboratory Medical Director Date

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Randal L. Simonsen 08/31/16
Randal L. Simonsen, M.D., Laboratory Medical Director Date

Barbara Herro 08/31/16
Barbara Herro, Laboratory Administrator Date

CSH – Beeville

Randal L. Simonsen 08/31/16
Randal L. Simonsen, M.D., Laboratory Medical Director Date

Barbara Herro 08/31/16
Barbara Herro, Laboratory Administrator Date

CSH – Kleberg

Randal L. Simonsen 08/31/16
Randal L. Simonsen, M.D, Laboratory Medical Director Date

Barbara Herro 08/31/16
Barbara Herro, Laboratory Administrator Date

CHRISTUS SPOHN HEALTH SYSTEM
POLICY and PROCEDURE MANUAL

TITLE: Laboratory Associate Communication of Concerns - PROCEDURE

Date Issued: 02/05
Date(s) Revised: 05/11, 09/11, 03/13
Date(s) Reviewed: 09/11, 03/13, 04/15

Section: Laboratory
Number: LAB-107-P
Originator: Laboratory

Approved By: *See last page for Laboratory Medical Director / Administrator approvals
(Original with signatures archived in Document Control)

PURPOSE:

To provide Laboratory Associates a defined procedure for alerting management to safety concerns.

PROCEDURE:

1. Laboratory Associates with concerns, complaints and/or suggestions about the safety or quality of Laboratory operations, may report these concerns to Laboratory Management (immediate supervisor, Laboratory Service Director, and/or Laboratory Director).

2. Concerns, complaints or suggestions may be submitted to Laboratory Management in any of the following ways: direct verbal communication, written, e-mail, suggestion box item, or anonymous memorandum.

3. Laboratory Management will promptly review and investigate the concerns and initiate action in the form of appropriate redress.

4. All Laboratory Associate concerns regarding testing quality and/or laboratory safety that cannot be immediately resolved, involve healthcare entities outside of the lab, or may have resulted in patient/Associate harm will be escalated and documented using the Risk Management Variance Report.

5. Escalated events will be investigated and reviewed by the Laboratory Manager and a representative from the CHRISTUS Spohn Health System Risk Management Department to ensure a thorough investigation and appropriate correction action have been completed and documented.

6. The Risk Management Department and Laboratory Management should be contacted immediately if bodily injury to a patient or Associate has occurred in the Laboratory, or due to laboratory operations.

Reviews:
09/11, 03/13, 04/15

Approved: **CSHCC – Memorial**

Dr. Joe Lewis ___
Laboratory Medical Director Date

_____ ___
Laboratory Administrator Date

CSHCC – Shoreline

Dr. Joe Lewis ___
Laboratory Medical Director Date

Jason Naranjo ___
Laboratory Administrator Date

CSHCC – South

Dr. Joe Lewis ___
Laboratory Medical Director Date

Manuel Tamez ___
Laboratory Administrator Date

CSH – Alice

Dr. Randall Simonsen ___
Laboratory Medical Director Date

Aamer Qidwai ___
Laboratory Administrator Date

CSH – Beeville

Dr. Randall Simonsen ___
Laboratory Medical Director Date

Barbara Herro ___
Laboratory Administrator Date

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Dr. Randall Simonsen ___
Laboratory Medical Director Date

Aamer Qidwai ___
Laboratory Administrator Date

CHRISTUS SPOHN HEALTH SYSTEM
POLICY and PROCEDURE MANUAL

TITLE: Laboratory Medical Device Related Adverse Event Reporting and Notification from Vendors - Procedure

Date Issued: 02/05
Date(s) Revised: 05/11, 09/11
Date(s) Reviewed: 09/11, 10/14

Section: Laboratory
Number: LAB-108-P
Originator: Laboratory

Approved By: Pamela S. Robertson — President, CEO
Dr. Charles Volk — Chief Medical Officer
Estela Chapa — Chief Clinical Officer
(Original with signature archived in Document Control)

PURPOSE:

To provide Laboratory Associates a defined procedure for alerting management to safety concerns and guidelines for handling vendor notifications regarding defects or issues with supplies or software that may affect patient care.

DEFINITIONS:

Medical Device-Related (MDR) Event: "Information that reasonably suggests that a laboratory instrument, reagent or other device utilized by the laboratory (e.g., phlebotomy collection supplies) has or may have caused or contributed to a patient serious injury or patient death."

PROCEDURE:

1. Laboratories of CHRISTUS Spohn Health System, in accordance with FDA MDR requirements, will report any occurrence of patient adverse events that are related to medical devices, as defined below; and will investigate and address vendor notifications regarding product defects or issues with supplies or software that may affect patient care.
2. All laboratory associates must immediately report the MDR event to laboratory management and the FDA, using the following procedure:
    a. Determine what is reportable per FDA guidelines, view link below:
    How to Report a Problem (Medical Devices)
    b. Report MDR Events Immediately. Associates must report all MDR events to his or her lead tech/supervisor no later than 10 days after the time of such an event. This report must be directed to laboratory administration who will forward to Risk Management.
    c. Fill Out FDA Form 3500 per Instructions with link to forms below:
    Voluntary MedWatch — Instructions for Completing Form FDA 3500 / Reporting Form FDA 3500
    Mandatory — Instructions for Completing Form FDA 3500A / MedWatch Reporting Form FDA 3500A
3. All laboratory personnel are required to be knowledgeable of the above procedure; documentation of education is maintained on-line in the HLC Education System.
4. Vendor notifications regarding defects or issues with supplies or software that may affect patient care may be received via mail, email, fax, or through the RASMAS electronic notification system. These notifications are forwarded to the appropriate leadership team member for investigation and corrective action. Documentation of notices, investigations, and corrective actions is maintained in the appropriate laboratory section.

Reviews: 09/11, 10/14

Approved:

CSHCC – Memorial

Joe A. Lewis, M.D. — 12/22/14
Laboratory Medical Director — Date

Raymond Ramos — 12/4/14
Laboratory Administrator — Date

CSHCC – Shoreline

Joe A. Lewis, M.D. — 12/22/14
Laboratory Medical Director — Date

Jason Naranjo — 12/4/14
Laboratory Administrator — Date

CSHCC – South

Joe A. Lewis, M.D. — 12/22/14
Laboratory Medical Director — Date

Manuel Tamez — 12/1/14
Laboratory Administrator — Date

CSH – Alice

Randall Simonsen, M.D. — 10/27/14
Laboratory Medical Director — Date

Aamer Qidwai — 11/5/14
Laboratory Administrator — Date

CSH – Beeville

Randall Simonsen, M.D. — 10/27/14
Laboratory Medical Director — Date

Barbara Herro — 10/21/14
Laboratory Administrator — Date

CSH – Kleberg

Randall Simonsen, M.D. — 10/27/14
Laboratory Medical Director — Date

Aamer Qidwai — 11/5/14
Laboratory Administrator — Date

CHRISTUS SPOHN HEALTH SYSTEM
POLICY and PROCEDURE MANUAL

TITLE: Laboratory Direct Access Testing (DAT) - PROCEDURE

Date Issued: 03/13
Date(s) Revised:
Date(s) Reviewed: 03/15

Section: Laboratory
Number: LAB-109-P
Originator: Laboratory

Approved By: *See last page for Laboratory Medical Director / Administrator approvals
(Original with signatures archived in Document Control)

PURPOSE:

To establish the administrative and pre-analytical requirements necessary to initiate Direct Access Testing.

PROCEDURE:

1. Direct Access Testing will be initiated by the patient by completing the Laboratory DAT Requisition Form and the Consent for Treatment Form. All portions of the consent form except those designated "For Laboratory Use Only" must be completed in the Admitting Department prior to registration. Only the tests requested by the consumer will be ordered and performed by the laboratory.

2. Payment is due at the time of the test requisition and will be collected in the form of cash, check, debit card, or credit card. No insurances will be billed as DAT testing does not meet the medical necessity criteria for most insurance companies.

3. Following payment, the patient will present to the laboratory with the requisition form and proof of payment. Specimen collection or testing will not be performed until payment has been submitted to a Patient Access Representative.

4. A short registration method will be used with the Laboratory Medical Director as the ordering physician. "DAT Testing" and the patient's phone number should be entered into the "Reason for Visit" section during registration.

5. Any tests requested after a specimen has been collected will require a new DAT Requisition and Consent Form and an additional specimen collection. Tests will not be added onto previous specimen collections.

6. **Department Responsibilities:**
    a. Admitting
        i. Verify completion of the Laboratory Requisition Form
        ii. Collect payment
        iii. Generate a receipt of payment
        iv. Post credits to the appropriate GL Account
    b. Laboratory
        i. Patient Registration
        ii. Order Tests in Meditech
        iii. Specimen Collection

7. Result Distribution:
    a. Upon final verification of Direct Access Test results, a broadcast report will print to a dedicated laboratory printer. A Laboratory Associate will match the report with the Laboratory DAT Requisition Form.

    b. Non-critical laboratory results will be sent by mail or pickup.

    c. They will be provided to the patient by the method selected on the requisition form.

d. Results will be mailed to the address provided at the time of registration within 24 - 48 hours of broadcasting. All critical results will be called directly to the patient.

e. Patient results may be picked up in person during normal business hours with proper identification. Results will only be released to the patient or guardian whose name appears on the requisition form.

8. Critical Value Reporting:
    a. If during the course of patient testing, a value is obtained that falls into the critical value range, the result will be promptly called to the patient by a Laboratory Associate or Administrator.

    b. The patient will be notified of the critical value and instructed to contact their primary care physician or a local healthcare provider as soon as possible to aid in test interpretation and determine if follow-up actions are required.

    c. Notification of critical values will be documented in the LIS test comment section and will include the date, time, the Associate making the phone call, the person notified, and proper read back documentation. Documentation should occur as soon as possible and all results called should be read back by the patient as confirmation.

9. Record Retention:
    a. Records will be held indefinitely in the LIS system and all requisition and consent forms will be held by the Laboratory for one year.

    b. Release of any confidential information to a third party will only be done by the Healthcare Information Management department. The consumer may release this information by contacting HIM directly or by having their healthcare provider fax the required documentation.

Reviews: 03/15

Approved: **CSHCC – Memorial**

Dr. Joe Lewis 04/24/15
Laboratory Medical Director Date

Sylvia Buentello 04/22/15
Laboratory Administrator Date

CSHCC – Shoreline

Dr. Joe Lewis 04/24/15
Laboratory Medical Director Date

Jason Naranjo 04/22/15
Laboratory Administrator Date

CSHCC – South

Dr. Joe Lewis 04/24/15
Laboratory Medical Director Date

Manuel Tamez 04/23/15
Laboratory Administrator Date

CSH – Alice

Dr. Randall Simonsen 04/13/15
Laboratory Medical Director Date

Aamer Qidwai 04/07/15
Laboratory Administrator Date

CSH – Beeville

Dr. Randall Simonsen 04/13/15
Laboratory Medical Director Date

Barbara Herro 04/15/15
Laboratory Administrator Date

CSH – Kleberg

Dr. Randall Simonsen 04/13/15
Laboratory Medical Director Date

Aamer Qidwai 04/07/15
Laboratory Administrator Date

Patient Information			FOR LABORATORY USE ONLY	
NAME	SS#	☐ MALE ☐ FEMALE	COLLECTED BY:	DATE:
ADDRESS		DATE OF BIRTH	PAYMENT RECVD BY:	TIME:
CITY/STATE/ZIP CODE		PHONE	☐ FASTING	☐ NON-FASTING
PAYMENT METHOD: ☐ DEBIT/CREDIT CARD ☐ CASH ☐ CHECK _____#			RELEASE RESULTS BY: ☐ PICKUP ☐ MAIL	

LAB TEST	Fee	√	Lab Test	Fee	√
BLOOD TYPING ABO/RH (TYPE)	$27		CHOL, TRIG, HDL, LDL (LIPID)	$28	
BASIC METABOLIC PANEL (BMP)	$24		*PREGNANCY TEST URINE (HCGQUALU)	$22	
HEPATIC FUNCTION PANEL (HFP)	$23		*PREGNANCY TEST BLOOD (HCGQUALS)	$22	
CBC WITH CELL DIFFERENTIAL (CBCAD)	$22		PROSTATE SPECIFIC AG (PSAS)	$35	
COMPLETE METABOLIC PANEL (CMP)	$30		PROTHROMBIN TIME / INR (PT)	$11	
GLUCOSE (GLU) or (GLUF)	$7		RENAL FUNCTION PANEL (RFP)	$25	
HEMOGLOBIN A1C (GLYHGB)	$28		THYROID STIMULATING HORMONE (TSH)	$33	
TB SKIN TEST (PPD)	$15		URINALYSIS (UA)	$12	
**URINE DRUG SCREEN (DAUP)	$32		***URINE DRUG SCREEN (DAU-TRIAGE)	$32	
*performed on adults only **performed on adults at Alice only ***performed on adults at Beeville and Kleberg only			**TODAY'S TOTAL**		

PARTICIPANT INFORMED CONSENT

I understand that the CHRISTUS Spohn Health System and the testing facility disclaim any liability for any costs, claims, injuries, actions or damages suffered by an individual, no matter what their relationship, as a result of participation in Direct Access Testing. Participation in Direct Access Testing is strictly voluntary, and any injuries suffered in conjunction with such participation shall not be subject to reimbursement under any applicable law. I agree to release the CHRISTUS Spohn Health System, the testing facility and any other person associated with these tests from any liability whatsoever in connection with testing procedures, or any other aspect of this screening.

I understand that the results of these tests will be mailed directly to me using the contact information provided on this form only. Critical laboratory test values will be promptly called to me. I understand it is my responsibility to contact my physician regarding these critical results.

I understand that these tests are for screening purposes only, and the results are preliminary and should in no way be considered conclusive. Moreover, by providing these results, the CHRISTUS Spohn Health System and testing facility are not giving medical advice. For a better understanding of the results of these tests, for more conclusive measures, and for any additional medical advice and treatment, I understand that it is my responsibility to contact my own personal physician. Any minors under the age of 18 must have a legal guardian sign this consent.

Signature:_____ Date: _____ Time: _____

Legal Guardian: _____ Date: _____ Time: _____

Alice Laboratory	Beeville Laboratory	Kleberg Laboratory	Memorial Laboratory	South Laboratory
2500 E. Main Street	**1500 E. Houston Way**	**1311 Gen. Cavazos Blvd.**	**2606 Hospital Blvd.**	**5950 Saratoga Blvd**
Alice, Tx 78332	**Beeville, Tx 78102**	**Kingsville, Tx 78363**	**Crp Christi, Tx 78405**	**Crp Christi, Tx 78414**
361-661-8121	**361-354-2012**	**361-595-9743**	**361-902-6519**	**361-985-5012**
Mon-Fri 7:30am–5:00pm	**Mon-Fri 8:00am–5:00pm**	**Mon-Fri 8:00am–5:00pm**	**Mon-Fri 7:30am–5:00pm**	**Mon-Fri 8:00am–4:30pm**

CHRISTUS SPOHN Health System

PLACE PATIENT LABEL HERE

CHRISTUS SPOHN HEALTH SYSTEM
POLICY and PROCEDURE MANUAL

TITLE: Laboratory Patient Complaints - PROCEDURE

Date Issued: 03/13
Date(s) Revised:
Date(s) Reviewed: 04/15

Section: Laboratory
Number: LAB-111-P
Originator: Laboratory

Approved By: *See last page for Laboratory Medical Director / Administrator approvals
(Original with signatures archived in Document Control)

Purpose:

To improve patient/customer satisfaction by providing a systematic process for addressing, resolving and documenting concerns reported by patients, families, physicians, visitors and other customers concerning laboratory quality and safety.

Policy:

The Laboratory will document, address, and resolve quality or safety concerns reported by patients, families, physicians, visitors and other customers in a timely manner. All complaints regarding quality or safety that cannot be resolved at the point of service will be escalated to a grievance and documented using the Risk Management module in Meditech. These grievances will be investigated and reviewed by the Laboratory Manager and a representative from the CHRISTUS Spohn Health System Risk Management department to ensure a thorough investigation and appropriate corrective actions have been documented.

All laboratory complaints and grievances will be addressed in compliance with the guidelines found in CHRISTUS Spohn Health System Policy A-115, Patient Complaint/Grievance Process.

Definitions:

Patient Complaints: A “patient complaint” is an expression of dissatisfaction with some aspect of care and/or service. Most complaints will have simple and obvious causes that can be promptly addressed to the patient’s satisfaction at the level of service between the patient, hospital associate, management or Guest Services representative.

Patient Grievance: A “patient grievance” is a formal or informal written or verbal complaint that is made to the hospital by a patient or patient’s representative, regarding the patient’s care (when the issue is not resolved at the time of the complaint by the staff present), abuse or neglect, issues related to the hospitals compliance with the CMS Hospital Conditions of Participation (COP’S), or a Medicare beneficiary billing complaint related to rights and limitations provided by 42 CFR 489.

Reviews: 04/15

Approved: **CSHCC – Memorial**

Dr. Joe Lewis 04/24/15
Laboratory Medical Director Date

Sylvia Buentello 04/22/15
Laboratory Administrator Date

CSHCC – Shoreline

Dr. Joe Lewis 04/24/15
Laboratory Medical Director Date

Jason Naranjo 04/22/15
Laboratory Administrator Date

CSHCC – South

Dr. Joe Lewis 04/24/15
Laboratory Medical Director Date

Manuel Tamez 04/23/15
Laboratory Administrator Date

CSH – Alice

Dr. Randall Simonsen 04/13/15
Laboratory Medical Director Date

Aamer Qidwai 04/07/15
Laboratory Administrator Date

CSH – Beeville

Dr. Randall Simonsen 04/13/15
Laboratory Medical Director Date

Barbara Herro 04/30/15
Laboratory Administrator Date

CSH – Kleberg

Dr. Randall Simonsen 04/13/15
Laboratory Medical Director Date

Aamer Qidwai 04/07/15
Laboratory Administrator Date

CHRISTUS SPOHN HEALTH SYSTEM
POLICY and PROCEDURE MANUAL

TITLE: Laboratory Packaging, Shipping and Transportation of Specimens - PROCEDURE

Date Issued: 03/13
Date(s) Revised:
Date(s) Reviewed: 03/15

Section: Laboratory
Number: LAB-116-P
Originator: Laboratory

Approved By: *See last page for Laboratory Medical Director / Administrator approvals
(Original with signatures archived in Document Control)

Purpose:

The laboratory departments of CHRISTUS Spohn Hospitals have established a standardized protocol for packaging and labeling diagnostic specimens for transport that is in accordance with federal, state, and local regulations. By signing this procedure, we attest that we regularly review regulatory packing/shipping requirements for regulatory compliance.

Definitions:

Exempt Human Specimens – Exempt human specimens are those for which there is "minimal likelihood there are pathogens present."

Examples of such specimens include urine or serum to be tested for routine laboratory testing.

Category B Specimens – A Category B substance is defined by IATA as "an infectious substance which does not meet the criteria for inclusion in Category A." Category B substances are not in a form generally capable of causing disability, life-threatening illness, or fatal disease. Examples of such specimens include:

1. Typical clinical, diagnostic, or patient specimens, e.g., blood, biopsies, swab specimens, excreta, body fluids, tissues, etc.
    a. Being shipped for routine culturing or other testing for non-Category A infectious microorganisms or
    b. Suspected of containing a non-Category A microorganism.
2. Typical clinical laboratory cultures (usually on solid or in liquid media) of routinely encountered non-Category A microorganisms grown and used in clinical microbiology laboratories.

Category A Specimens – A Category A substance (pathogen or agent) is "an infectious substance which is transported in a form that, when exposure to it occurs, is capable of causing permanent disability or life-threatening or fatal disease to otherwise healthy humans or animals. Examples of such specimens include but are not limited to agents of bioterorrism such as *Bacillus anthracis, Francisella tularensis, Yersinia pestis* and highly pathogenic organisms such *as Mycobacteria tuberculosis* and *Coccidiodes immitis*. *Category A substances are not shipped between hospital facilities.*

Note: A clinical, diagnostic, or patient specimen suspected of containing or being tested for a "Culture Only" Category A substance may be shipped as a Biological Substance, Category B because the suspected Category A substance is not in culture form, e.g., sputa being tested for *M. tuberculosis* and serum to be cultured for HIV.

Training:

1. All laboratory associates who prepare and send specimens for shipment, including between facilities, are trained in appropriate safety and packaging procedures suitable to specimen type and distances transported upon hire and every 2 years thereafter using the MTS "Specimen Transport" training module.

2. Lab associates who process infectious specimens for transport complete certified packaging and shipping training every 2-3 years using ARUP online.

3. All couriers are required to complete training specific to their job role.

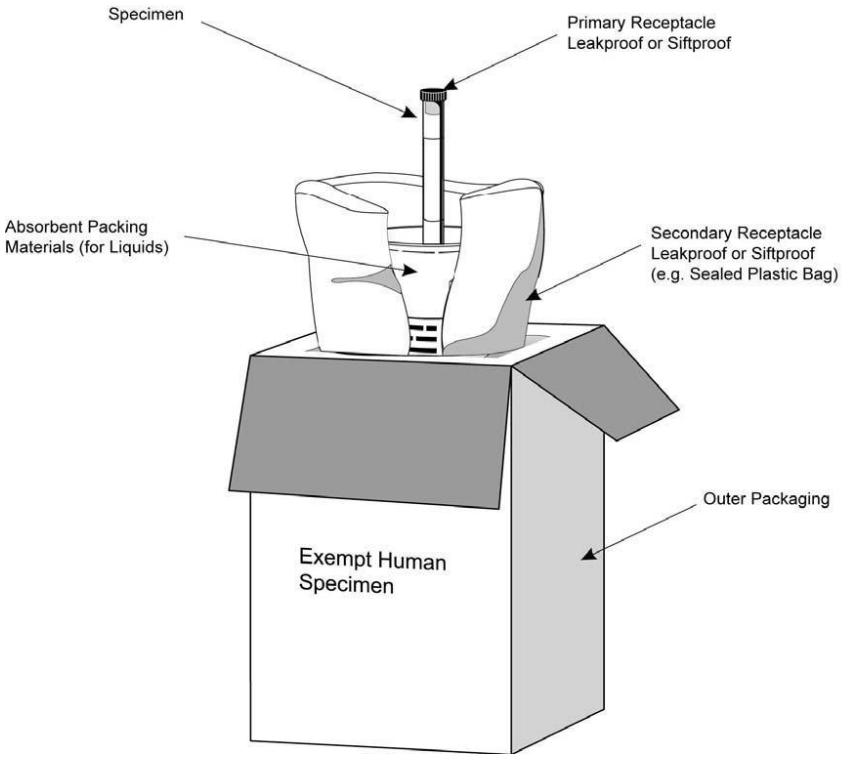
PROCEDURE:

A. **Inter-Facility Transport of Specimens**
   1. Create an LIS site batch of all specimens to be sent offsite.

   2. Place the primary specimen receptacle in a secondary leak proof packaging such as a biohazard bag or plastic jar.
      a. Liquid specimens - Place an absorbent material in the secondary receptacle. The absorbent must be sufficient to absorb the entire liquid contents, should a spill occur. Liquid samples cannot exceed 1L.
      b. Solid specimens – both the primary and secondary receptacles must be siftproof.
      c. If transporting fragile primary receptacles, they must be separated in a way to prevent contact.
      d. Include cold pack in the secondary receptacle if needed.

   3. Place the secondary packaging in a rigid outer packaging such as a box. The outer packaging must not contain more than 4L or 4kg. Consult the histology department for proper shipping of body parts, whole organs, or whole bodies. The outer packaging must have a minimum dimension of 4in x 4in. The entire package must be capable of passing a "drop test".
      a. If the specimen is classified as exempt, the overpack must be labeled "Exempt human specimen".
      b. If the specimen is classified as a Category B Infectious Substance, the overpack must be labeled properly in accordance with UN number UN3373 (Biological Substance, Category B).

Example of Packing and Marking for Exempt Specimens

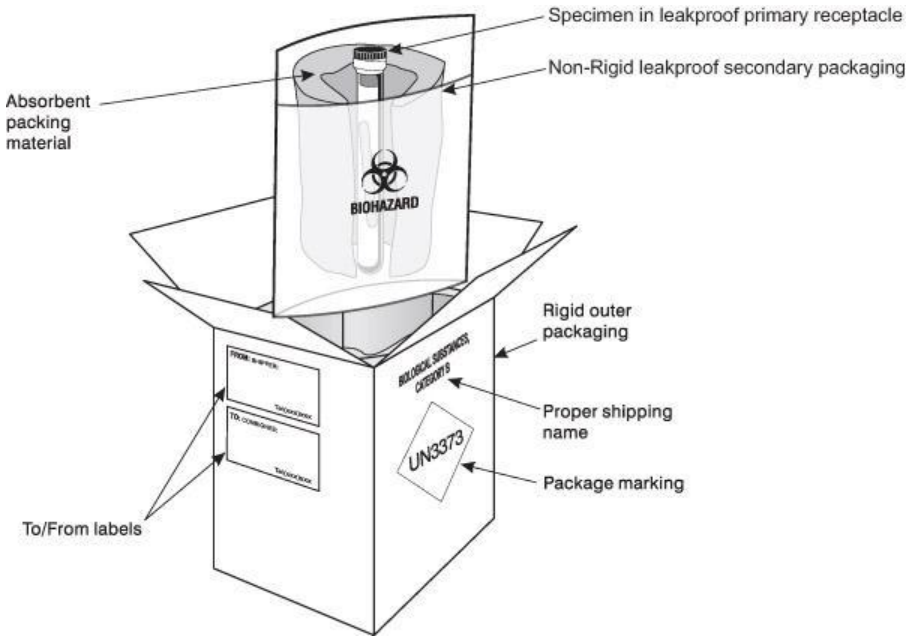


4. Follow the established process for sending out the specimen for transport including provision of the Site Batch with the specimens to be sent.

5. Upon receipt at the testing laboratory, the specimens are verified against the enclosed site batch and the site batch is received. Follow-up action to the sending facility is required for missing specimens and/or improperly collected, labeled and/or improperly preserved specimens.

B. **Category A Infectious Substance Shipping**
Each facility has a select group of associates who have completed category A packaging and shipping training. Only these associates may package and ship samples of this nature. For complete details on shipping category A substances, utilize Sentinel Laboratory Guidelines for Suspected Agents of Bioterrorism and Emerging Infectious Diseases. The document can be accessed on the internet at: http://www.asm.org/images/pdf/Clinical/ps11-15-10final.pdf

Example of Packing and Marking for Category B Infectious Substances



C. **Reference Lab Transport**
The laboratory follows the specific reference lab guidelines for packaging and shipping exempt human specimens and category B infectious substances, all of which are in accordance with federal, state, and local regulations.

References:

1. International Air Transport Association - www.iata.org
2. US Department of Transportation Pipeline and Hazardous Materials Safety - http://phmsa.dot.gov/hazmat
3. Sentinel Laboratory Guidelines for Suspected Agents of Bioterrorism and Emerging Infectious Diseases - http://www.asm.org/images/pdf/Clinical/ps11-15-10final.pdf

Reviews: 03/15

Approved: **CSHCC – Memorial**

Dr. Joe Lewis 04/24/15
Laboratory Medical Director Date

Sylvia Buentello 04/22/15
Laboratory Administrator Date

CSHCC – Shoreline

Dr. Joe Lewis 04/24/15
Laboratory Medical Director Date

Jason Naranjo 04/22/15
Laboratory Administrator Date

CSHCC – South

Dr. Joe Lewis 04/24/15
Laboratory Medical Director Date

Manuel Tamez 04/22/15
Laboratory Administrator Date

CSH – Alice

Dr. Randall Simonsen 04/13/2/15
Laboratory Medical Director Date

Aamer Qidwai 04/07/15
Laboratory Administrator Date

CSH – Beeville

Dr. Randall Simonsen 04/13/15
Laboratory Medical Director Date

Barbara Herro 04/15/15
Laboratory Administrator Date

CSH – Kleberg

Dr. Randall Simonsen 04/13/15
Laboratory Medical Director Date

Aamer Qidwai 04/07/15
Laboratory Administrator Date

CHRISTUS SPOHN HEALTH SYSTEM
POLICY and PROCEDURE MANUAL

TITLE: Laboratory Downtime - PROCEDURE

Date Issued: 03/13
Date(s) Revised:
Date(s) Reviewed: 03/15

Section: Laboratory
Number: LAB-118-P
Originator: Laboratory

Approved By: *See last page for Laboratory Medical Director / Administrator approvals
(Original with signatures archived in Document Control)

PURPOSE:

The following procedure outlines the management of laboratory orders, test result documentation, and result reporting during a Laboratory Information System (LIS) downtime.

PROCEDURE:

Laboratory Orders

1. In case of an unannounced (emergency) LIS outage the Help Desk must be notified immediately.

2. Orders will be transcribed by the ordering unit using downtime requisitions.

3. Requisitions and specimens will be delivered to the lab for processing and analysis.

4. Specimens without Meditech labels will be given a unique downtime number. This will be the specimen ID number until the patient is registered and a label can be generated.

5. Scheduled downtime will be handled in the same manner with the added task of stopping all interfaces 15 minutes prior to the announced downtime.

Test Resulting

1. Instrument printouts will be used as result documentation when possible.

2. Department specific LIS downtime forms will be used for all other test results.

3. Critical value documentation and other necessary comments or information are documented on the result form, result copy or requisition.

4. Copies of all results will be sent to the ordering department, client or Physician via fax, pneumatic tube system, or hand delivery during LIS downtime.

5. All original patient and QC results, comments required for regulatory purposes, and requisitions are kept and entered into the LIS when functionality is restored. Documentation is made to acknowledge the testing was performed during LIS downtime. (Example: Comment result “Test performed by ___ during Meditech downtime”)

6. All QC is performed as required and documented accordingly. Those tests with QC records maintained in Meditech will be handled according to Department downtime policy.

Records Keeping

1. Copies of all requisitions logs and manual lab reports will be kept for a minimum of two years.

Reviews: 03/15

Approved: **CSHCC – Memorial**

Dr. Joe Lewis 04/24/15
Laboratory Medical Director Date

Sylvia Buentello 04/22/15
Laboratory Administrator Date

CSHCC – Shoreline

Dr. Joe Lewis 04/14/15
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Jason Naranjo 04/22/15
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CSHCC – South

Dr. Joe Lewis 04/24/15
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Manuel Tamez 04/23/15
Laboratory Administrator Date

CSH – Alice

Dr. Randall Simonsen 04/13/15
Laboratory Medical Director Date

Aamer Qidwai 04/07/15
Laboratory Administrator Date

CSH – Beeville

Dr. Randall Simonsen 04/13/15
Laboratory Medical Director Date

Barbara Herro 04/15/15
Laboratory Administrator Date

CSH – Kleberg

Dr. Randall Simonsen 04/13/15
Laboratory Medical Director Date

Aamer Qidwai 04/07/15
Laboratory Administrator Date

CHRISTUS SPOHN HEALTH SYSTEM
POLICY and PROCEDURE MANUAL

TITLE: Laboratory – Medical Director Authority, Responsibility and Designation of Duties

Date Issued: 2001
Date(s) Revised: 05/11, 04/13
Date(s) Reviewed: 05/11, 04/13, 05/15

Section: Laboratory
Number: LAB-123
Originator: Laboratory

Approved By: (Original with signatures archived in Document Control)

The authority and responsibility of the Medical Director of Laboratory Services encompass oversight of the Laboratory as a whole. He/she is responsible for ensuring that all Laboratory personnel, via evaluation against CLIA-88 standards, are deemed competent to perform their duties. The circumference of the Medical Director of Laboratory Services' scope of authority, responsibilities, and designation of duties are outlined herein.

This includes the person(s) he/she has designated for administrative responsibilities, such as General Supervisor (CLIA) or Administrative Directors of Laboratory Services as well as the technical supervisors (CLIA) or Lead Technologist of each Laboratory section and Laboratory Coordinators as applicable (LIS, Clinical, and/or Performance Improvement).

Outline of the Medical Director of Laboratory Services' Authority, Responsibilities, and Designations (as includes, but not limited to, the following):

1. Ensures that the Performance Improvement Program is implemented as designed
2. Ensures the quality of testing procedures, results, and safety are all in compliance with regulatory Standards
3. Ensures proficiency testing, quality control and quality improvement programs are established and maintained with appropriate reviews to ensure the quality of Laboratory Services provided
4. Ensures the review and approval of the following:
    a. Laboratory Organizational Chart
        i. The Organization chart for each facility identifies each Laboratory site's managers, section Technical Supervisors (CLIA), and Coordinators (i.e. LIS, Clinical, and Performance Improvement). The individuals named on the Laboratory Organizational Charts serve as the designees of the Medical Director of Laboratory Services for review of the following, unless a new policy, procedure, test methodology, LIS system to included but not limited to LIS report/report format or other document format or major procedural change of any kind. For biennial reviews and/or other minor changes, those individuals named in the Laboratory Organizational Chart serve as the Medical Director's designees
    b. Laboratory Policies and Procedures
        i. All Laboratory general administrative and section policies and procedures upon origination or major revision are reviewed and approved by the Medical Director and biennially by appropriate designee
5. Ensures that testing systems developed and used for each of the tests performed provide quality Laboratory Services for all aspects of test performance, which include pre-analytic, analytic and post-analytic phases of testing
6. Ensures that the physical plant and environmental conditions of the Laboratory are appropriate for the
testing performed and provide a safe environment in which Laboratory associates are protected from physical, chemical and biological hazards
7. Ensures that equipment and test methodologies selected have the capability of accuracy, precision and other pertinent performance characteristics of the methods
8. Ensures that Laboratory personnel are performing the test methods as required for accurate and reliable results

9. Ensures that the Laboratory is enrolled in a CMS-approved proficiency testing program for the testing performed and that
   a. The proficiency testing samples are tested as required, i.e. treated as patient samples
   b. The results are returned within the time frames established by the proficiency testing program
   c. All proficiency testing reports received are reviewed by the appropriate Laboratory personnel to evaluate performance and identify any problems that require corrective action
   d. An approved corrective action plan is followed when any proficiency testing result(s) is found to be unacceptable or unsatisfactory, such as

   College of American Pathologists' Troubleshooting Guide for Proficiency Testing Data: http://www.cap.org/apps/docs/proficiency testing/troubleshooting guide for pt data.pdf . Clinical and Laboratory Standards Institute (CLSI). *Using Proficiency Testing to Improve the Clinical Laboratory; Approved Guideline – Third Edition. C* LSI document GP27-A2. 2012.

10. Designation of Technical Supervisors (Lead Technologists) to assume responsibility for the following:
    a. The Lead Technologists have been designated to oversee their respective technical areas, up to and including QC review, proficiency testing review and follow-up documentation where appropriate, and initial selection of new Laboratory equipment and instrumentation, then presentation of requisite information to the Technical Procedure Review Process
    b. The section Lead Technologists are responsible for ensuring that their staff meet these criteria and carry out the policies and procedures as defined
    c. The Lead Technologist of each section is the designee of the Medical Director and charged with ensuring all personnel are evaluated for competency initially, at six months after and annually thereafter
    d. The Lead Technologists are responsible for the design and implementation of their section's QC program, compliance with proficiency testing protocol, section standard operating procedures and procedure manuals
    e. The Lead Technologists review each section's procedures biennially and show evidence by written or electronic signature/initials and date
11. Medical Director Off-Site Responsibilities
    a. The Medical Director is responsible for the periodic visiting of off-site Laboratories within the System Laboratory wherein he/she does not office on a full-time basis. Visitation frequency is as scheduled by the Medical Director and at least once per calendar year
    b. A record or log of the Medical Director's visit date, duration and activities carried out while at the off-site Laboratory
    c. Ensure Documentation/Record of off-site visits is maintained at off-site Laboratory and contains elements of visit, such as the following (see Attachment LAB-123F[1]**)**
       1. Date of off-site visit
       2. Duration of off-site visit
       3. Activities carried out during off-site visit

1 Attachment –LAB-123F Medical Director Off-Site Visit Record Template

CHRISTUS SPOHN Health System

Medical Director's Off-Site Visit Record[1]

Medical Director: _____

Date and Time: _____

Others in Attendance:_____

_____

Activities during Off-Site Visit:

Other (as applicable):

Any Questions and/or Concerns Reported (During off-site visit)

Additional Topics of Discussion (During off-site visit)

Medical Director's Signature _____ Date _____

Laboratory Manager/Attendee's Signature: _____ Date _____

[1] Attachment to LAB-123 Medical Director's Authority, Responsibility, and Designation of Duties

CHRISTUS SPOHN Health System

Policy/Procedure Title: Laboratory Test Requisition Handling

SOP Number:		**Creation Date:**	5/07/2015
Department:	Lab General	**Effective Date:**	5/11/2015
Policy (P), Procedure (PR)or Both (P/P):	P/P	**Version:**	01

Applicable Standards	
Standard	Organization
GEN.40930	CAP
GEN.40932	CAP
GEN.40935	CAP
GEN.40938	CAP
Related Documents	
CHRISTUS Policy 3.140	

Version History		
Version	Effective Date	Deactivation Date
01	5/11/2015	

Review History (Up to the Last 15 Occurrences)			
Date	Version	Revision Type	Review By
5/11/2015	01	New Policy/Procedure	

Distribution
CSHCC-Memorial, Shoreline, South Laboratory General

Policy/Procedure Title: Laboratory Test Requisition Handling

Purpose:
To delineate who can order laboratory tests, whom in the laboratory can accept verbal orders in relation to laboratory testing, the authentication process for verbal orders, and the requirement and process for confirming unclear test orders.

Policy:

- The laboratory performs testing only at the written or electronic request of authorized persons.
- The provider must be appropriately credentialed through the Medical Staff Office.
- In accordance with CHRISTUS Health Corporate Policy 3.140 verbal orders are to be utilized only in emergency situations when the physician is unable to take attention away from the patient to physically write an order.
- Within the Laboratory, Medical Technologists are authorized to accept verbal and telephone orders in relation to laboratory testing.
- All orders, including verbal and telephone orders, must be authenticated by the provider within 48 hours as per state guidelines.

Note: In Texas, individuals other than credentialed providers may order some laboratory tests on themselves without a physician's referral; this is referred to as direct-to-consumer testing or direct-access-testing (DAT). Refer to Lab-109P for Regional Direct Access Testing Procedure. The statements and procedures referred to in this "Laboratory Test Requisition Handling" policy refer to physician ordering on patients and are not applicable to direct access testing.

Procedure:
Verbal and Telephone Orders
Laboratory staff shall request orders be entered electronically or provided in written fashion prior to the initiation of verbal or telephone orders. When written or electronic orders are not yet available the following actions will be performed:

1. As verbal orders are taken, authorized laboratory personnel will transcribe:
    a. the entire laboratory test/procedure order
    b. the date and time of the order
    c. the full name of the authorized prescribing provider.
2. The Medical Technologist must read back the entire order to verify accuracy of transcription.
3. The Medical Technologist will enter the order into the LIS via the Order Source field as TELEPHONE or VERBAL which will send the order to the Provider's e-Signature queue for authentication. Note: When entering the Requisition the ordering physician's name must be accurate in the LIS under the Submit Dr**.** field.

Unclear Test Orders

1. In the occasion of unclear test orders (e.g. orders using non-standard or non-specific terms or illegible written orders) test orders must be clarified with the ordering individual/Provider.
2. If in the course of clarification a new/different test procedure is initiated the technologist will utilize an order source of TELEPHONE or VERBAL which will send the order(s) to the e-Sign queue.

CHRISTUS SPOHN Health System

Policy/Procedure Title: Laboratory Associate Competency Assessment

SOP Number:	LAB-126	**Effective Date:**	05/11/2015
Department:	Lab Gen	**Revision Date:**	
Policy (P), Procedure (PR)or Both (P/P):	P/P	**Version:**	01

Applicable Standards	
Standard	Organization
GEN.55450	CAP
GEN.55500	CAP
GEN.55525	CAP
GEN.57000	CAP
Related Documents	

Version History		
Version	Effective Date	Retired Date
01	05/11/2015	

Review History (Up to the Last 15 Occurrences)			
Date	Version	Revision Type	Review By/Initials & Date
05/07/2015	1	New Policy/Procedure	Joe A. Lewis, M.D. (on file)

Distribution
CSHCC – Memorial, Shoreline, South Laboratory General

Purpose: In order to establish and maintain competency of Laboratory associates the following training and competency assessment methods are employed.

A list of skills and procedures relevant to particular job description/duties are utilized for initial training. Each technologist is thoroughly trained by a qualified instructor in each item of the checklist. Individuals performing competency assessments are qualified through education and experience to meet the defined regulatory requirements associated with the complexity of the testing.

Prior to starting patient testing and prior to reporting patient results for new methods or instruments, each individual must have training and be evaluated for proper test performance. Retraining and reassessment of employee competency must occur when problems are identified with employee performance.

Elements of competency assessment include but are not limited to:

1. Direct observations of routine patient test performance, including, as applicable, patient identification and preparation; and specimen collection, handling, processing and testing
2. Monitoring the recording and reporting of test results, including, as applicable, reporting critical results
3. Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records
4. Direct observation of performance of instrument maintenance and function checks
5. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and
6. Evaluation of problem-solving skills

Many of the elements of competency assessment listed above are performed during routine review of an employee throughout the year. Documentation of these elements, including adherence to laboratory policies and procedures, observation of test performance, results reporting, instrument maintenance, review of worksheets, recording QC, performance of PT, and demonstration of taking appropriate corrective actions are examples of daily activities that can be used to demonstrate competency. Competency assessment during routine review is documented via checklist(s).

Competency Assessment Frequency:
Laboratory staff are assessed on their competency to perform testing at 3 months and 9 months after the initial hire date. Annual assessment of competency occurs thereafter on the schedule defined by Human Resources.

Corrective Action for Failed Competency:
If it is determined that there are gaps in the individual's knowledge, the employee will be re-educated and allowed to retake portions of the assessment that fell below the laboratory's guidelines. If, after re-education and training, the employee is unable to satisfactorily pass the assessment, then further action will be taken which may include supervisory review of work, reassignment of duties, or other actions deemed appropriate by laboratory administration.

Continuing Education
Continuing Education for maintenance and enhancement of competency is stressed in the department via the use of reference material, audio conferences, online training programs, CAP final critiques, and other references for continued learning. The Med Lab Training (MTS) Online Training and Competency Program is an excellent resource for training, competency assessment and continuing education and is available to all CHRISTUS Spohn Health System Lab associates.

Invalid and Positive Newborn Screen Result Handling

SOP Number:		**Effective Date:**	04/27/2015
Department:	GEN LAB	**Revision Date:**	
Policy (P), Procedure (PR)or Both (P/P):	PR	**Version:**	1.0

Applicable Standards	
Standard	Organization
GEN.41325	CAP
Related Documents	

Version History		
Version	Effective Date	Retired Date
01	04/27/2015	

Review History (Up to the Last 15 Occurrences)			
Date	Version	Revision Type	Review By
04/22/2015	01	New Policy/Procedure	Dr. Joe A. Lewis, M.D.

Distribution
CSHCC-South Lab General

Invalid and Positive Newborn Screen Result Handling

Purpose

Due to the urgent nature of newborn screening, a process is established to handle invalid and positive newborn screening reports for samples submitted to the Texas Department of State Health Services laboratory (TDSHS)

Unsatisfactory Report

TDSHS will only notify the submitting facility of an unsatisfactory specimen.

An unsatisfactory report for a specimen initiates a recall to the patient for a redraw or coordinating with the patient's current healthcare provider to ensure that a satisfactory newborn screening specimen is collected.

At the physicians discretion, if a baby has two newborn screens and one was "unsatisfactory", see the table to determine necessity of a third screen:

1st screen	2nd screen	3rd screen necessary?
unsatisfactory	normal	No, if full term baby with a birth weight ≥2,500g
		Yes, if low birth weight or premature baby with a birth weight of <2,500g
normal	unsatisfactory	Yes, up to 12 months of age
unsatisfactory	abnormal	Please follow recommendations received from DSHS Newborn Screening Clinical Care Coordination Team.
abnormal	unsatisfactory	Please follow recommendations received from DSHS Newborn Screening Clinical Care Coordination Team.

If a baby has an unsatisfactory screen, we will take the following steps:

1. If the patient is still in-house, notify the nurse or caregiver to recollect.
2. If the patient is discharged, we will attempt to notify the parent/guardian to recollect.

Tracking Requests for Repeat Testing

All notification attempts must be documented in the LIS under the unsatisfactory test order. If unsuccessful after multiple attempts to reach parent/guardian and/or healthcare provider, a risk variance notification will be submitted.

Follow-up, Reporting, and Record Keeping on Abnormal Screening Results and Confirmed Cases

Out of range results are followed by the TDSHS Clinical Care Coordination Group for Newborn Screening. Action taken on positive determinations includes notifying the PCP. TDSHS will notify the hospital when assistance is necessary to follow-up on individuals at risk for any disorder.

References

www.dshs.state.tx.us/lab/nbsFAQ.shtm

Email from davidr.martinez@dshs.state.tx.us, 07/21/2011, RE: DSHS CCC Follow up protocols
Department of State Health Service Texas Newborn Screening Clinical Care Coordination Out-of-Range Results July 2011

Ref. Texas Administrative Code, Title 25, Part 1, Chapter 37 Maternal and Infant Health Services, Subchapter D Newborn Screening Program, Rule 37.58 Follow-up, Reporting, and Record Keeping on Abnormal Screening Results and Confirmed Cases.

CHRISTUS SPOHN Health System

Policy / Procedure Title: **CHRISTUS Spohn Hospital Autoverification**

SOP Number:	RG010	**Effective Date:**	6/24/2015
Department:	Regional	**Revision Date:**	3/31/2016
Policy (P), Procedure (PR)or Both (P/P):	Procedure	**Version:**	02

Applicable Standards	
Standard	Organization
	CAP
Related Documents	

Version History		
Version	Effective Date	Retired Date
01	6/24/2015	3/31/2016
02	3/31/2016	

Review History (Up to the Last 15 Occurrences)			
Date	Version	Revision Type	Review By
6/24/2015	01	New Policy/Procedure	Joe A Lewis MD
3/31/2016	02	Minor Revision	Joe A Lewis MD
3/31/2016	02	Minor Revision	Randall L Simonsen MD

Distribution
Laboratory Sharepoint
Shoreline Chemistry

Intended use

Autoverification is the process by which patient results are generated from interfaced instruments and sent to the LIS, where they are compared against laboratory-defined parameters. If the results fall within these defined parameters, the results are automatically released to patient reporting formats without additional laboratory staff intervention. Any data that fall outside the defined parameters is reviewed by laboratory staff prior to reporting.
Autoverification is a process whereby computer-based algorithms automatically perform actions on a defined subset of laboratory results without the need for manual intervention by a laboratorian. The computer-based action could be immediate verification of a result, repeat analysis, reflexive testing, addition of comments, or suggested manual steps including (but not limited to) manual review of the result. By automatically performing actions on results that meet well-defined criteria, more time is made available for manual processing of those results that require special attention. Autoverification ensures that every result consistently receives the same review process. Additionally, computer-based autoverification algorithms provide the opportunity to develop more sophisticated algorithms that incorporate more extensive data than would be possible for a laboratorian to perform in a consistent, timely, and accurate manner.

Policy

Before implementing autoverification with laboratory result reporting, each analyzer sending results to be autoverified must be thoroughly tested with the LIS. Each analyzer has unique capabilities that must be accounted for when planning the algorithms to be written and used during the autoverification process. Some analyzers are very simple and may not require algorithm use at all. Other analyzers have the capability of sending myriad error flags and can even manipulate data prior to traveling thru the interface via data managers. In short, each situation is unique; requiring validation plans that are designed specifically for the analyzer/LIS combination.
A validation plan for autoverification per interface must be developed prior to implementation and approved by Laboratory Director and Medical Director. Autoverification must be tested at least annually and whenever there is a change to the system that could affect the autoverification logic. The range of results for which autoverification is acceptable must be defined for all patient tests subject to autoverification.

Instrument and LIS flags (delta, criticals, linearity, etc) should be incorporated into the autoverification process whenever appropriate or available. Any test that currently uses instrument and LIS flags-should also use them during the autoverification process. Not all laboratory tests require the use of delta checks or critical limits. Autoverification may still be used with these tests, but there must be some method of validating that only correct results are autoverified.

QUALITY/ CONTROL: For all results subject to autoverification, the laboratory ensures that applicable quality control samples have been run within an appropriate time period and all QC is acceptable. This requirement will be met by the computer system automatically checking against quality control status prior to autoverification. If the computer system cannot automatically disable the test, it will be manually disabled until the QC is acceptable.

PROCEDURE:

SETTING UP AUTOVERIFICTION

1. Map each test that will be autoverified. Include all flags; delta, critical, abnormal, normal, linearity, etc; that are currently set on the test. These flags will probably be incorporated into algorithms for the autoverifiction of test results.

2. List all instrument flags/error codes that may accompany results. Determine which of these flags or errors should prevent results from being autoverified, which require review, and which may allow autoverification.

3. If a Data Manager is used, determine how the data manager can be used to sort results prior to shipping to the LIS. In some instances, the Data Manager can stop results that should not be autoverified from even shipping to the LIS.

4. Determine how QC will be handled. Will the QC autoverify or not? Determine how to keep patient test results from autoverifing if QC should either fail or not be performed within a specific time period. Many analyzers can now be programmed to run QC at defined time intervals; preventing patient tests to run if the QC has not been performed.

5. Create a test plan for the analyzer. The test plan should include each test to be autoverified with each flag /error assigned as allow, reject, review.

6. Create and implement algorithms for the LIS and/or Data Manager.

7. Test every test per the Autoverification Plan.

8. When testing is completed, present data to the Medical Director for authorization to perform autoverification.

9. When first activated, monitor the autoverification to determine that it is working properly.

10. Annually or after system changes that might affect the autoverification logic, revalidate that autoverifictaion is functioning properly.

SUSPENSION OF AUTOVERIFICATION

Steps for suspending autoverification:

- LAB ANALYZER TYPE / DICTIONARY
    1. LIS DICTIONARIES
    2. LAB DICTIONARY
    3. ANALYZER TYPE
    4. ENTER/EDIT
    5. Enter analyzer name: ex- SHCOBAS1,SXCOBAS

6. at the AUTOFILE? prompt – enter N
7. F12

- LAB ANALYZER DESKTOP
  1. Select interface
  2. Click STATUS
  3. Click STOP

- When, multiple Data Manager feed single LIS interface, autoverification may be rapidly halted by turning off the HOST communication parameter in the Data Manager instead of a complete shutdown of LIS Analyzer Type AUTOFILE prompt.

RESULT INTERPRETATION/ REPORTING RESULTS:

1) Results are checked for flags or warnings prior to autoverification. The mere presence of a flag may not disqualify a result from autoverification, but any flag that is not specifically recognized by the autoverification program must cause the flagged result to be held for manual review.
2) Results are compared with appropriate range of acceptable values prior to autoverification. Appropriate comparisons include checking patient results against absurd and critical results requiring manual intervention.
3) The autoverification process includes all delta-checks that the laboratory performs prior to the manual release of test results. This requirement does not require delta-checking for all autoverified results, but the laboratory's delta-checking procedures should be the same for manually released and autoverified test results.
4) An audit trail in the computer system identifies all test results that were autoverified, and date/time of autoverification. All test results that are autoverified display "INFCE" or "AUTOINS" as the entering and verifying technologist when viewed or printed from Internal Inquiry. This information is not included on the charted patient results or in the EMR.

REFERENCES:

CAP General Checklist stds – GEN.43878, 43881, 43884, 43890
Autoverification of Clinical Laboratory Test Results;Approved Guideline – CLSI – AUTO10-A; Vol. 26 No. 32.

FILENAME:S:\Lab Manuals STE-STM\Computer\Autoverification_01-15.doc

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Effective date

Effective date for this procedure:_____

Author

Brenda A. Davila MT (ASCP)

Designee Authorized for annual Review

See Annual Procedure manual Review Policy.

TECHNICAL PROCEDURE MANUAL

CHRISTUS Spohn Hospital

Autoverification