# Regional Laboratory Policies

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# Regional Laboratory Procedures

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**TITLE: Specimen Rejection**

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

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

**Approved:** **CSHCC – Memorial**

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Laboratory Medical Director Date

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**TITLE: Laboratory Proficiency Testing**

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

Section: Laboratory
Number: LAB-104
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 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 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.
The Section Lead Technologist is responsible for storage of the completed survey response form, instrument printouts where applicable, etc.

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 and Laboratory Administrator or designee. 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 section Pathologist or Medical Director and Laboratory Administrator for review and signatures.
   b. Lack of consensus: The Section Lead Technologist will document that there was a lack of consensus on results and sign the survey results review sheet.
   c. 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). Once completed, the PTES response form and any accompanying documentation will be reviewed and signed by the Medical Director and submitted to the proficiency test provider.
   d. 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, along with any accompanying documentation where indicated, and given to the Laboratory Medical Director for review and signature. The signed PTES response form will be submitted to the proficiency test provider.

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. <u>List of Un-surveyed Analytes:</u>
   a. <u>Kleberg/Beeville Hematology</u>: Bleeding Time
   b. <u>Alice:</u> Stool reducing substance, stool pH
   c. <u>Memorial Chemistry:</u> Body fluid electrolytes (split survey with South), Body fluid lipase (split survey with Shoreline)
   d. <u>Shoreline Chemistry:</u> Body fluid lipase (split survey with Memorial), Urine Protein Electrophoresis (split samples between techs), Blood pH (split samples between techs)
   e. <u>Shoreline/Memorial Hematology:</u> Leukocyte alkaline Phosphatase
   f. <u>South Chemistry:</u> Body fluid electrolytes (split survey with Memorial)

2. <u>Proficiency testing procedure for performance of un-surveyed samples:</u>
   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 technical supervisor.
    b. All results must be compatible. Any discrepancies must be addressed immediately
    c. All results must be reviewed by the section Pathologist or Medical Director, Laboratory Administrator, or technical supervisor.
    d. All un-surveyed results and evaluations are kept on file for a minimum of two years.

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

**Approved:** **CSHCC – Memorial**

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**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

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

**Approved:** **CSHCC – Memorial**

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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:

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:**

**Approved:** **CSHCC – Memorial**

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**CHRISTUS SPOHN HEALTH SYSTEM**
**POLICY and PROCEDURE MANUAL**

**TITLE: Laboratory Document Control**

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

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. Personnel have read the policies/procedures relevant to their job activities
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:**

**Approved:** **CSHCC – Memorial**

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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:

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:**

**Approved:** **CSHCC – Memorial**

Dr. Joe Lewis _03/27/13__
Laboratory Medical Director Date

Alan Wells _03/27/13__
Laboratory Administrator Date

**CSHCC – Shoreline**

Dr. Joe Lewis _03/27/13__
Laboratory Medical Director Date

Jason Naranjo _03/27/13__
Laboratory Administrator Date

**CSHCC – South**

Dr. Joe Lewis _03/27/13__
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Manuel Tamez _03/27/13__
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**CSH – Alice**

Dr. Randall Simonsen 04/01/13___
Laboratory Medical Director Date

Jessica Mercer _03/28/13__
Laboratory Administrator Date

**CSH – Beeville**

Dr. Randall Simonsen 04/01/13___
Laboratory Medical Director Date

Barbara Herro 04/01/13___
Laboratory Administrator Date

**CSH – Kleberg**

Dr. Randall Simonsen 04/01/13___
Laboratory Medical Director Date

Tina Vargas 04/01/13___
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:

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:**

**Approved:** **CSHCC – Memorial**

Dr. Joe Lewis 03/27/13
Laboratory Medical Director Date

Alan Wells 03/27/13
Laboratory Administrator Date

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Dr. Joe Lewis 03/27/13
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Dr. Joe Lewis 03/27/13
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Dr. Randall Simonsen 04/01/13
Laboratory Medical Director Date

Tina Vargas 04/01/13
Laboratory Administrator Date

**CHRISTUS SPOHN HEALTH SYSTEM**
**POLICY and PROCEDURE MANUAL**

**TITLE: Laboratory Reference Laboratory Selection**

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

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:**

**Approved:** **CSHCC – Memorial**

Dr. Joe Lewis _03/20/13__
Laboratory Medical Director Date

Alan Wells _03/27/13__
Laboratory Administrator Date

**CSHCC – Shoreline**

Dr. Joe Lewis _03/20/13__
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Dr. Randall Simonsen 04/01/13___
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Tina Vargas 04/01/13___
Laboratory Administrator Date

**TITLE: Laboratory Continuing Education Program**

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

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:**

**Approved:** **CSHCC – Memorial**

Dr. Joe Lewis 03/14/13
Laboratory Medical Director Date

Alan Wells 03/27/13
Laboratory Administrator Date

**CSHCC – Shoreline**

Dr. Joe Lewis 03/14/13
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Jason Naranjo 03/27/13
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Dr. Joe Lewis 03/14/13
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Manuel Tamez 03/27/13
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Dr. Randall Simonsen 04/01/13
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Dr. Randall Simonsen 04/01/13
Laboratory Medical Director Date

Tina Vargas 04/01/13
Laboratory Administrator Date

**CHRISTUS SPOHN HEALTH SYSTEM**
**POLICY and PROCEDURE MANUAL**

**TITLE: Laboratory – Intra-Laboratory Communication**

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

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:**

**Approved:** **CSHCC – Memorial**

Dr. Joe Lewis 03/17/13
Laboratory Medical Director Date

Alan Wells 03/27/13
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Dr. Randall Simonsen 04/01/13
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Dr. Randall Simonsen 04/01/13
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Barbara Herro 04/01/13
Laboratory Administrator Date

**CSH – Kleberg**

Dr. Randall Simonsen 04/01/13
Laboratory Medical Director Date

Tina Vargas 04/01/13
Laboratory Administrator Date

**CHRISTUS SPOHN HEALTH SYSTEM**
**POLICY and PROCEDURE MANUAL**

**TITLE: Laboratory – Technical Procedure Review**

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

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:**

**Approved:** **CSHCC – Memorial**

Dr. Joe Lewis 03/27/13
Laboratory Medical Director Date

Alan Wells 03/27/13
Laboratory Administrator Date

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Dr. Joe Lewis 03/27/13
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Jason Naranjo 03/27/13
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Dr. Randall Simonsen 04/01/13
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Dr. Randall Simonsen 04/01/13
Laboratory Medical Director Date

Tina Vargas 04/01/13
Laboratory Administrator Date

**TITLE: Laboratory Reporting of Results - PROCEDURE**

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

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

**Approved:** **CSHCC – Memorial**

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Laboratory Medical Director Date

Alan Wells 03/27/13
Laboratory Administrator Date

**CSHCC – Shoreline**

Dr. Joe Lewis 03/27/13
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Dr. Randall Simonsen 04/01/13
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Barbara Herro 04/01/13
Laboratory Administrator Date

**CSH – Kleberg**

Dr. Randall Simonsen 04/01/13
Laboratory Medical Director Date

Tina Vargas 04/01/13
Laboratory Administrator Date

**TITLE: Laboratory Critical Results, Notification and Documentation - PROCEDURE**

Date Issued: 10/01
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
Date(s) Reviewed: 09/11, 05/12, 03/13

Section: Laboratory
Number: LAB-106-P
Originator: Laboratory

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

## PURPOSE:

To establish standardized critical values for laboratory test procedures which require notification of Physicians/LIPs and/or Nursing personnel. Critical values have been determined with the use of appropriate laboratory journals and in consultation with Administrative Laboratory Directors, Lead Technologists, and Laboratory Medical Directors.

## 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 Nursing personnel and/or Infection Control for certain microbiology values.

## PROCEDURE:

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 re-checked immediately, as necessary, then called to the ordering Physician/LIP and/or Nursing personnel.

    c. A verification “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 appropriate Nursing personnel is notified of the critical values. Microbiology critical values may require direct Physician/LIP notification and/or notification to Infection Control where indicated.

    e. REFERENCE LABORATORY: Test results that have been referred to the laboratory from reference laboratory hospital clients, nursing homes, and skilled nursing facilities will be called to the appropriate Nursing personnel of that respective facility.

    f. OUTPATIENTS: The ordering Physician/LIP, Physician/LIP’s nurse, or other authorized party shall be notified of critical values for CHRISTUS Spohn Health System outpatients not specified above. In the event none of the aforementioned person(s) can be reached the pathologist on call shall be notified.

    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 appropriate Nursing personnel.

2. **Documentation:**

    a. Documentation of notifications will be entered into the laboratory computer system and will include:
        i. Date
        ii. Time
        iii. Name of person (first and last name) and title to whom the results are given

    b. Documentation of successful "read-backs" will be entered into the computer system with the critical value result.

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

**Reviews:**
09/11, 03/13

**Critical Laboratory Results Requiring Notification**

| **CHEMISTRY** | | | |
|---|---|---|---|
| Assay (Serum, unless otherwise specified) | Units of Measure | Critical Low | Critical High |
| Bilirubin Total Neonatal From 0 - 5 Days | mg/dL | none | 12.0 |
| Bilirubin Neonatal From 6 Days | mg/dL | none | 15.0 |
| 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 |
| 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.* | | | |

| **THERAPEUTIC / NON-THERAPEUTIC DRUGS** | | | |
|---|---|---|---|
| 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 Random From 0 Days | mcg/mL | none | Greater than 40.0 |
| Phenobarbital Random From 12 Years | mcg/mL | none | Greater than or equal to 55.0 |
| Phenobarbital Trough From 0 Days to 11 Years | mcg/mL | none | Greater than 40.0 |
| Phenobarbital Trough From 12 Years | 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 to 11 Years | mcg/mL | none | Greater than 20.0 |
| Theophylline Trough From 12 Years | mcg/mL | none | Greater than 25.0 |
| Theophylline Random From 0 Days to 11 Years | mcg/mL | none | Greater than 20.0 |
| Theophylline Random From 12 Years | 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 |

| **BLOOD BANK** (Applies to CSHCC – Memorial and CHSCC – South ONLY) | | | |
|---|---|---|---|
| Test | Units of Measure | Critical Low | Critical High |
| Neonatal DAT (From 0 days) | Reactions graded from negative to 4+ positive | N/A | Positive |
| XM-Inability to find compatible units | | | |

| **HEMATOLOGY** | | | |
|---|---|---|---|
| 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 |
| Neonatal 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 Information System but will be called upon admission only. This applies to all CHRISTUS Spohn Hospital – Corpus Christi facilities.

| **MICROBIOLOGY** |
|---|
| ♦ Positive Blood Culture |
| ♦ Positive CSF Culture/Gram Stain |
| ♦ Positive Sterile-Site Body Fluid/Tissue Culture or Gram Stain |
| ♦ Positive AFB Smear/Culture (Smear, Preliminary, and/or Final) (Requires additional notification to Infection Control) |
| ♦ Positive Genital Group B Culture (OB post-partum patients only) |
| ♦ Vancomycin Resistant Enterococci (VRE) (Requires additional notification to Infection Control) |
| ♦ Positive Stool Pathogens (Requires additional notification to Infection Control) |
| ♦ Positive C. difficile Toxin (Requires additional notification to Infection Control) |

Identification of Critical Test/Procedure: **Frozen Section** – Frozen section is considered a critical test/procedure and Pathologist report results immediately to the requesting Physician/LIP.

**Approved:** **CSHCC – Memorial**

Dr. Joe Lewis _03/27/13__
Laboratory Medical Director Date

Alan Wells _03/27/13__
Laboratory Administrator Date

**CSHCC – Shoreline**

Dr. Joe Lewis _03/27/13__
Laboratory Medical Director Date

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**CSHCC – South**

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Laboratory Medical Director Date

Jessica Mercer _03/28/13__
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**CSH – Beeville**

Dr. Randall Simonsen 04/01/13___
Laboratory Medical Director Date

Barbara Herro 04/01/13___
Laboratory Administrator Date

**CSH – Kleberg**

Dr. Randall Simonsen 04/01/13___
Laboratory Medical Director Date

Tina Vargas 04/01/13___
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

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

**Approved:** **CSHCC – Memorial**

Dr. Joe Lewis _03/27/13__
Laboratory Medical Director Date

Alan Wells _03/27/13__
Laboratory Administrator Date

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Manuel Tamez _03/27/13__
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Barbara Herro 04/01/13___
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Dr. Randall Simonsen 04/01/13___
Laboratory Medical Director Date

Tina Vargas 04/01/13___
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**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

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

Approved By: Pamela S. Robertson, President, CEO

Dr. C. Volk, Chief Medical Officer

Doug Dippel, Chief Nurse Executive

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

## 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 Instructions for Completing Form FDA 3500
      MedWatch 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

**Approved:** **CSHCC – Memorial**

Dr. F. Parks 09/15/11
Laboratory Medical Director Date

Alan Wells 09/15/11
Laboratory Administrator Date

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Dr. J. Lewis 09/14/11
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Todd Cooper 09/14/11
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Laboratory Medical Director Date

James Joffrion 11/02/11
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Dr. R. Simonsen 11/01/11
Laboratory Medical Director Date

Barbara Herro 10/31/11
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:

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:**

**Approved:** **CSHCC – Memorial**

Dr. Joe Lewis _03/27/13__
Laboratory Medical Director Date

Alan Wells _03/27/13__
Laboratory Administrator Date

**CSHCC – Shoreline**

Dr. Joe Lewis _03/27/13__
Laboratory Medical Director Date

Jason Naranjo _03/27/13__
Laboratory Administrator Date

**CSHCC – South**

Dr. Joe Lewis _03/27/13__
Laboratory Medical Director Date

Manuel Tamez _03/27/13__
Laboratory Administrator Date

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Dr. Randall Simonsen 04/01/13___
Laboratory Medical Director Date

Jessica Mercer _03/28/13__
Laboratory Administrator Date

**CSH – Beeville**

Dr. Randall Simonsen 04/01/13___
Laboratory Medical Director Date

Barbara Herro 04/01/13___
Laboratory Administrator Date

**CSH – Kleberg**

Dr. Randall Simonsen 04/01/13___
Laboratory Medical Director Date

Tina Vargas 04/01/13___
Laboratory Administrator Date

**CHRISTUS SPOHN HEALTH SYSTEM**
**POLICY and PROCEDURE MANUAL**

**TITLE: Laboratory Patient Complaints - PROCEDURE**

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

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:**

**Approved:** **CSHCC – Memorial**

Dr. Joe Lewis _03/27/13__
Laboratory Medical Director Date

Alan Wells _03/27/13__
Laboratory Administrator Date

**CSHCC – Shoreline**

Dr. Joe Lewis _03/27/13__
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Dr. Randall Simonsen 04/01/13___
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Tina Vargas 04/01/13___
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:

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.

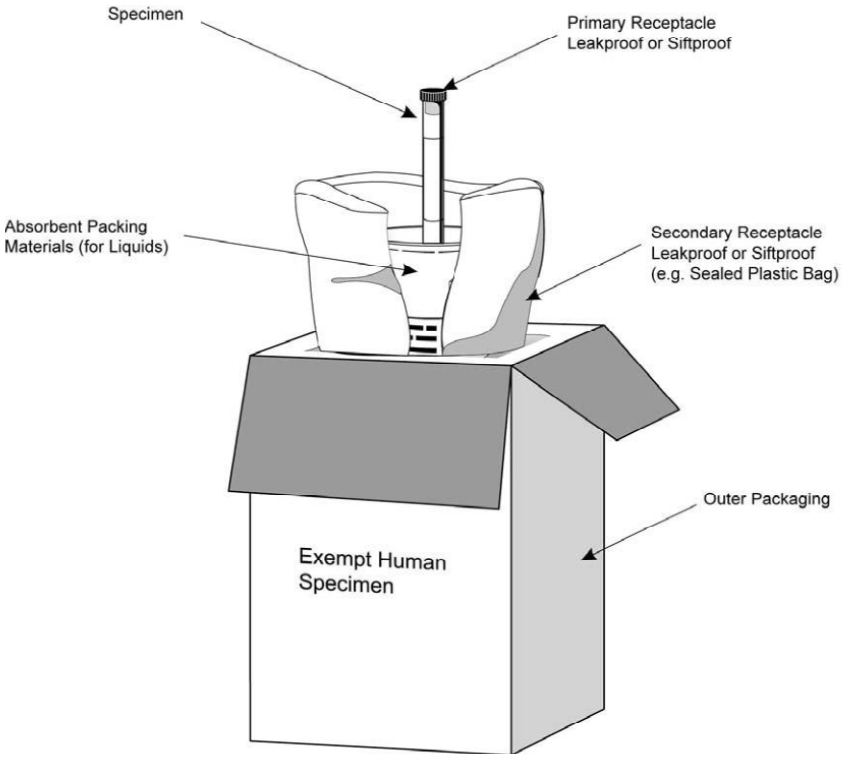
**PROCEDURE:**

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**

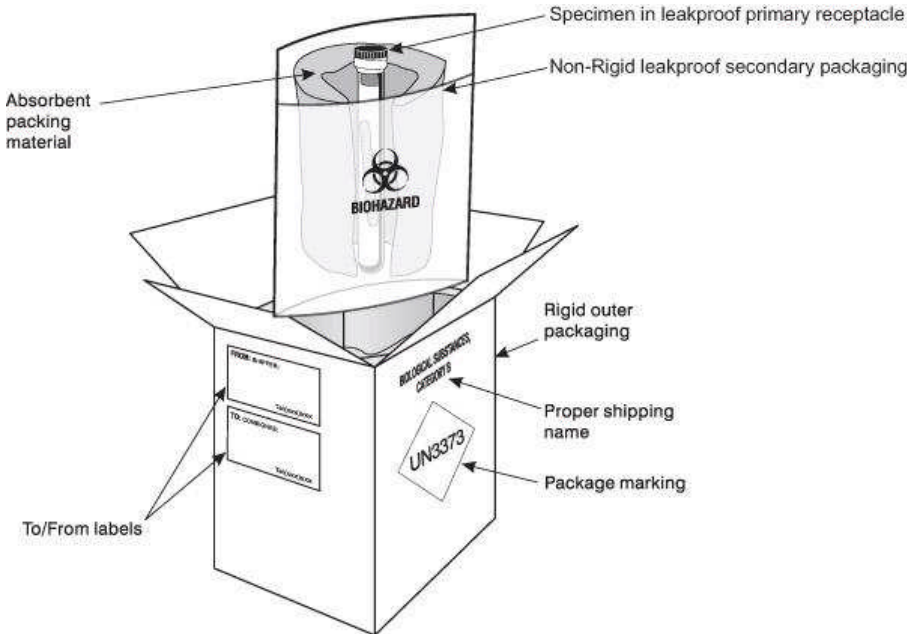


4. Follow the established process for sending out the specimen for transport including provision of the Site Batch with the specimens to be sent.

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:**

**Approved:** **CSHCC – Memorial**

Dr. Joe Lewis _03/27/13__
Laboratory Medical Director Date

Alan Wells _03/27/13__
Laboratory Administrator Date

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Dr. Joe Lewis _03/27/13__
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Manuel Tamez _03/27/13__
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**CSH – Alice**

Dr. Randall Simonsen 04/01/13___
Laboratory Medical Director Date

Jessica Mercer _03/28/13__
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**CSH – Beeville**

Dr. Randall Simonsen 04/01/13___
Laboratory Medical Director Date

Barbara Herro 04/01/13___
Laboratory Administrator Date

**CSH – Kleberg**

Dr. Randall Simonsen 04/01/13___
Laboratory Medical Director Date

Tina Vargas 04/01/13___
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:

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:**

**Approved:** **CSHCC – Memorial**

Dr. Joe Lewis _03/24/13__
Laboratory Medical Director Date

Alan Wells _03/27/13__
Laboratory Administrator Date

**CSHCC – Shoreline**

Dr. Joe Lewis _03/24/13__
Laboratory Medical Director Date

Jason Naranjo _03/27/13__
Laboratory Administrator Date

**CSHCC – South**

Dr. Joe Lewis _03/24/13__
Laboratory Medical Director Date

Manuel Tamez _03/27/13__
Laboratory Administrator Date

**CSH – Alice**

Dr. Randall Simonsen 04/01/13___
Laboratory Medical Director Date

Jessica Mercer _03/28/13__
Laboratory Administrator Date

**CSH – Beeville**

Dr. Randall Simonsen 04/01/13___
Laboratory Medical Director Date

Barbara Herro 04/01/13___
Laboratory Administrator Date

**CSH – Kleberg**

Dr. Randall Simonsen 04/01/13___
Laboratory Medical Director Date

Tina Vargas 04/01/13___
Laboratory Administrator Date