Beaumont Laboratory
Clinical Pathology
Royal Oak

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Related Documents:

GENERAL POLICIES FOR QC/QA AND QI IN AUTOMATED CHEMISTRY AND URINALYSIS

RC.CH.LOP.QCQA.PR.009.r05

Purpose

This policy describes the structure of pre-analytic and post-analytic phases of testing in the Automated Chemistry Lab, as related to quality assurance and quality improvement.

Policy

Quality Control

General quality control procedures are described in the "Method Quality Control" protocol (RC.CH.LOP.QCQA.PY.08). This protocol includes information on:

- Requirements, i.e. type of material and frequency of use
- Preparation of QC materials
- Establishment of QC ranges, their evaluation and review
- Corrective action
- Checks on water used in reagent/control preparation
- Temperature checks

Proficiency Testing

Policies relating to proficiency testing are outlined in "Proficiency Testing" (RC.QM.011).

Pre-analytical Phases of Testing

1. Specimen Collection:
Samples of blood or body fluids (other than urine) are collected by phlebotomy, nursing or medical staff. Guidelines for blood collection, specimen labeling and transport are included in the "*Specimen Collection Manual*" (*Inside Beaumont*). Nursing or laboratory staff oversees collection of urine samples such that appropriate preservatives are used and labeling is correct.

2. Patient Identification:
All specimens submitted to Automated Chemistry or Urinalysis should be labeled with:

a) Patient's last name and first name
b) Actual date and time of collection of specimen
c) Seven (7)-digit hospital number
d) Order number assigned by computer
e) Name of test(s) or acceptable abbreviations

3. Unlabeled or Improperly Identified Specimens:
If an incompletely or improperly labeled specimen is received, the nursing unit will be notified. If a new properly labeled specimen can be obtained at no great inconvenience to the patient, this should be done. If the specimen cannot be duplicated or the patient would be seriously inconvenienced or jeopardized, then it is the responsibility of the individual who collected the specimen to properly identify it. The individual who assumes the responsibility for labeling an unlabeled specimen or correcting the identification of the submitted specimen must be the individual who collected it. He or she must indicate in the "Clinical Pathology Specimen Re-label Record" that:
"This specimen was collected by me and I certify that it is correctly identified."
Signed: _____ Date: _____
An external variance report is generated from the Laboratory for mislabeled specimens that are identified as such.
(See "Proper Handling of Unlabeled/Mislabeled Specimens" RC.OP.PR.007).

4. Specimen Integrity:
Specimens must be of the appropriate sample type (serum, plasma, urine, etc) and of sufficient volume to perform the test as described in the corresponding procedure and in the Laboratory Test Directory (*Inside Beaumont*). Special collection and/or handling of the sample are specified in the Procedure Manual and Laboratory Test Directory. Lipemic, hemolyzed and/or icteric specimens should be noted. Use of such specimens is permissible if indicated in the specific procedure. Criteria for unacceptable specimens can also be found in the Procedure Manual and Laboratory Test Directory. If it is not clear whether a sample is acceptable, a supervisor, clinical chemist or pathologist should be consulted. If a test is performed on such a specimen, the report should specify the condition of the specimen and any appropriate comment about how the test results may be affected.

5. Phone orders
If any personnel in Automated Chemistry or Urinalysis receive a phone order for a lab test, the individual receiving the request must read back the entire order to verify accuracy of transcription.

Analytical Phase of Testing

General:
The general protocol for sample analysis is described in the "Performance Guidelines for Analytical Methods" (RC.CH.LOP.QCQA.PY.002). This includes information on:

- Standard preparation
- Calibration of method
- Reasons for recalibration
- Calibration verification
- Analytical measurement range
- Clinically reportable range
- Reagent preparation and use

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Sample Storage and Add-On Policy:
Once testing is complete, samples should be capped, archived and stored appropriately:

- Serum/plasma – 7 days refrigerated for Core Lab and Stat Lab
- Urines for urinalysis – 24 hrs refrigerated
- Urines (non-UA) – aliquot refrigerated 4 weeks
- CSF – refrigerated 4 weeks
- Other bodily fluids – refrigerated 4 weeks

Add-on testing is allowed for general chemistry testing, except in the following circumstances:

- Electrolytes or potassium where specimen is greater than 18 hours post-collection
- Specimen is QNS
- During significant LIS downtime
- For Stat chemistries, when both Stat Lab Chemistry Analyzers are inoperable

Reporting of Results

General:
All patient results must be verified for acceptability prior to reporting, whether they are entered manually into the computer or uploaded automatically from an interfaced analyzer. The lab technologist is expected to use LIS chart review to trend previous results of the same test or other related tests whenever an unusual result is observed. A delta check may also alert the technologist to changes in the patient results that are significant and require a technologist to review. The technologist reporting results documents that the result has been reviewed, or repeated if necessary. If there are sample conditions that are causing interference in testing the tech will refer to "Processing Difficult Specimens" (RC.CH.LOP.SH.PR.006) to resolve the problem. If auto-verification is in effect, results that satisfy established rules may be released without review by the operator. In the absence of auto-verification, the person performing the test must review results. Results that are entered manually into the computer must be reviewed by another individual. If a "Corrected" report needs to be sent out, the corrected value overrides the first value. The new value will be in chart review labeled "corrected." The floor, office or BRL will be notified of the corrected result. To complete the documentation of corrected result, click on Call Box and under Person/Msg Type Corrected__(insert analyte) **called to** _____ (insert employee badge number of call recipient).
(See RC.OP.PR.008 "Patient Laboratory Results: Resolution of Errors).

Urinalysis:
Most urinalysis results are uploaded from interfaced analyzers. Whenever results are entered manually (e.g. microscopic review of sediment warrants edits to instrument generated results), the technologist is responsible for reviewing all results and correlating the dipstick and microscopic report before release. The LIS allows for edits if a transcription error occurs. It is unreasonable to expect that all manual entries in Urinalysis be reviewed by a second individual.

Test Turn-Around-Time:
Expected turn-around times for reporting of results are included in Laboratory Test Directory (*Inside Beaumont)*. When significant delays are anticipated (e.g. instrument downtime, computer downtime), a policy is in place to inform the Emergency Center (charge nurse on

duty) the in-patient nursing units and the BRL Reference Lab. Details of contacts are posted at the reporting terminals in Beaumont Outreach and the Core Lab.
(See "Notification Procedure of Instrument Downtime" RC.CH.LOP.LIS.PY.002 and "Turn-Around-Time Guidelines for Automated Chemistry" RC.CH.LOP.QCQA.RG005)

Critical Values:
All critical values are to be verified or repeated prior to reporting. Critical values are called to the nursing unit or physician. In general, such results are automatically forwarded (electronically) to the Beaumont Outreach personnel who are then responsible for contacting the appropriate unit or physician. However, technologists reserve the right to call critical values when they see fit. The critical value lists are included in the "*General Policy and Procedure Manual*" and are also available on the Laboratory Services Website (*Inside Beaumont*). Details of the critical value reporting processes are included in the Automated Chemistry General Policy and Procedure Manual.
(See "Policy and Procedure for Reporting Critical Values" RC.CH.LOP.QCQA.PY.003)

Quality Improvement

General:
The assurance of quality in the performance and reporting of laboratory tests is fundamental to providing appropriate patient care. Personnel involved in any aspect of sample testing (pre-analytic to post-analytic) are expected to be vigilant for any sources of error that could in any way affect test results. Should any such source be identified, notification of a supervisor, clinical chemist or pathologist is expected.
(See "Patient Laboratory Results: Resolution of Errors" RC.OP.PR.008 and documentation folder - S:/Automated Chemistry/ Corrected Reports).

Quality Assurance Monitors:
Monitors are prepared monthly by a supervisor, pathologist or clinical chemist. These are designed to track problems associated with sample testing and may include factors such as turn-around time, sample integrity, sample labeling or appropriate use of laboratory services. Monitors should include a description of specific problems, ways to rectify these, and results of attempts to improve and correct the problem.
See "AutoChem QA Monitors" binder in supervisor's office and current monitors posted on Lab bulletin board.

Internal Quality Monitor Program-Patient Safety Variances:
The laboratory technologists are encouraged to initiate on-line variance reports that are clear, brief, factual, and non-judgmental. Problems include delayed TAT, floor failure to follow standard operating procedures, inappropriately shared specimens etc. Variance types are tabulated monthly by our Lab Quality Coordinator. All variances are investigated by supervisors for resolution.

Authorized Reviewers

Section Medical or Technical Director

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Document Control

Location of Master: Master electronic file stored on the Beaumont Laboratory server under S:/AutoChemistry/DocControl/NEW/LOP/QCQA
Master printed document stored in Automated Chemistry Procedure Manual, Core Lab
Number of Controlled Copies posted for educational purposes: 0
Number of circulating Controlled Copies: 2
Location of circulating Controlled Copies:
Automated Chemistry General Policy and Procedure Manual, Stat Lab
Urinalysis Procedure Manual

Document History

Signature	Date	Revision #		Related Documents Reviewed/ Updated
Prepared by: E. Sykes, MD Medical Director	2006			
Approved by: E. Sykes				
Reviewed by: (Signature)	**Date**	**Revision #**	**Modification**	**Related Documents Reviewed/ Updated**
E. Sykes	01/03/2008	r01	Edits into Doc Control format	
Raymond E. Karcher	12/08/2008			
E. Sykes, MD	01/09/2009			
Raymond E. Karcher	12/07/2009			
Vivek Kumar, PhD	12/07/2010			
E. Sykes, MD	02/16/2012			
Elizabeth Sykes, MD	01/31/2014			
Elizabeth Sykes, MD	01/05/2015	r02	Updates to policy numbers, add PSQI Variance Reports	
Revised: Robin Carey-Ballough	10/27/2015	r03	Added use of call box for corrected reports.	
Elizabeth Sykes, MD	10/27/2015			
Kenneth Simkowski, PhD	11/03/2017			
Revised by: Amber M Macumber MLS(ASCP)^{cm} Approved by: Kenneth Simkowski, PhD	12/07/2017 12/08/2017	r04	Removed reference to retired procedure of readback orders and results.	
Elizabeth Sykes, MD	02/02/2018			
Revised by: Robin Carey-Ballough, MT(ASCP) Approved by: Kenneth Simkowski, PhD	5/14/2018	r05	Added delta check policy and reference to Processing Difficult Samples.	