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Quality Control, Quality Assurance and Quality Improvement in Automated Chemistry and Urinalysis - Royal Oak

Document Type: Policy

I. PURPOSE AND OBJECTIVE:

A. 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.

II. POLICIES:

A. **QUALITY CONTROL (QC)**

1. General quality control procedures are described in Quality Control for Automated Chemistry-Royal Oak. This procedure includes information on:
    a. Requirements, i.e. type of material and frequency of use
    b. Preparation of QC materials
    c. Establishment of QC ranges, their evaluation and review
    d. Corrective action
    e. Checks on water used in reagent/control preparation
    f. Temperature checks

B. **PROFICIENCY TESTING**

1. Policies relating to proficiency testing are outlined in Proficiency Testing for Automated Chemistry-Royal Oak.

C. **PRE-ANALYTICAL PHASES OF TESTING**

1. **Specimen Collection**

a. 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". 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**
   a. 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: _____
   b. An external variance report is generated from the Laboratory for mislabeled specimens that are identified as such. (See Correction of Information on Specimen Labels: Proper Handling of Unlabeled/ Mislabeled Specimens).

4. **Specimen Integrity**
   Specific information on the following can be found in the corresponding test procedure and in the Laboratory Test Directory:
   a. Specimens must be of the appropriate sample type (serum, plasma, urine, etc) and of sufficient volume to perform the test.
   b. Special collection and/or handling of the sample
   c. Lipemic, hemolyzed and/or icteric specimens should be noted. Use of such specimens is permissible if indicated in the specific procedure.
   d. Criteria for unacceptable specimens. 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.

D. **ANALYTICAL PHASE OF TESTING**

1. **General**
   The general protocol for sample analysis is described in Laboratory Performance Guidelines for Analytical Methods. This includes information on:
   a. Standard preparation
   b. Calibration of method
   c. Reasons for recalibration
   d. Calibration verification
   e. Analytical measurement range
   f. Clinically reportable range
   g. Reagent preparation and use

2. **Sample Storage and Add-On Policy**
   a. Once testing is complete, samples should be capped, archived and stored appropriately:
      i. Serum/plasma – Core Lab outpatients and Stat Lab 7 days refrigerated. Core Lab inpatients 4 days refrigerated.
      ii. Urines for urinalysis – 3 days refrigerated
      iii. 24 hour Urine – aliquot refrigerated 4 weeks
      iv. CSF (cerebrospinal fluid) – refrigerated 4 weeks
      v. Other bodily fluids – refrigerated 4 weeks
   b. Add-on testing is allowed for general chemistry testing, except in the following circumstances:
      i. Electrolytes or potassium where specimen is greater than 72 hours post-collection
      ii. Specimen is QNS (quantity not sufficient)
      iii. During significant LIS (laboratory information system) downtime
      iv. For Stat chemistries, when both Stat Lab Chemistry Analyzers are inoperable

3. **Reporting of Results**
   a. **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 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 (Beaumont Reference Laboratory) will be notified of the corrected result. To complete the documentation of corrected result, click on Comm Log and under Topic select "Result Correction". In the comment box type the full name or employee identification number of the person notified of the correction. (See Notification of Corrected Laboratory Results).

b. **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.

c. **Test Turn-Around-Time**
Expected turn-around times for reporting of results are included in Laboratory Test Directory. 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 Beaumont Reference Lab. (See Notification Procedure of Instrument Downtime and Turn-Around-Time for Automated Chemistry)

d. **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 "Chemistry Policy and Procedure Manual" and are also available on the Laboratory Website. Details of the critical value reporting processes are included in

the Reporting Critical Results procedure.

E. **QUALITY IMPROVEMENT**

1. **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 Corrected Laboratory Results and documentation folder - S:/Automated Chemistry/ Corrected Reports).

2. **Quality Assurance (QA) 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" folder in supervisor's office and current monitors posted on Lab bulletin board.

3. **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.

Approval Signatures

Step Description	Approver	Date
Medical Director	Ann Marie Blenc: System Med Dir, Hematopath	5/18/2023
Lab Chemistry Best Practice Committee	Caitlin Schein: Staff Physician	5/17/2023
Lab Chemistry Best Practice Committee	Qian Sun: Tech Dir, Clin Chemistry, Path	5/11/2023
Policy and Forms Steering Committee Approval (if needed)	Colette Kessler: Mgr, Division Laboratory	5/11/2023
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