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Area	Laboratory-Chemistry
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Proficiency Testing for Automated Chemistry - Royal Oak

Document Type: Procedure

I. PURPOSE AND OBJECTIVE:

A. This document provides technical staff with guidance and policies for Proficiency Testing (PT) in the Automated Chemistry section.

II. GENERAL INFORMATION:

A. External proficiency testing should be performed for each test in the laboratory at least twice annually. The Clinical Laboratory Improvement Amendments 1988 (CLIA '88) regulations require enrollment in a Centers for Medicare and Medicaid Services (CMS) approved PT program for all non-waived test methods.

B. Analytes that are regulated by the CMS require five PT challenges three times per year. A subscription to the College of American Pathologists (CAP), American Association of Clinical Chemistry (AACC), American Proficiency Institute (API) or other acceptable commercially available provider will satisfy this requirement. In the absence of commercial or professionally based programs, proficiency testing requirements can be satisfied by alternative means, such as assayed controls, samples shared with other laboratories, analysis by other in-house methods, clinical chart review or other method as defined by the section Medical Director.

C. Tolerance limits for acceptability of proficiency test results, if not specified by government or professional bodies must be defined by the Chemistry section pathologists. Results that exceed tolerance limits require repeat analysis (if possible) and corrective action by supervisory staff, with signed approval of the Chemistry section pathologists.

1. Laboratory sections will treat all proficiency samples in the same manner as they treat patient samples.
2. Employees performing the analysis are prohibited from inter-laboratory

communications concerning PT samples, until after submission deadline of data to the PT provider.

a. This includes proficiency testing records from the Laboratory Information System (LIS) or other common computer systems shared between laboratories. These values must be inaccessible to personnel of other laboratories.

3. The laboratory is prohibited from referring any proficiency testing sample to an outside laboratory for analysis.
4. The laboratory is not to test PT samples on more than one instrument/method unless that is how they test patient specimens. Repeated analysis of PT samples is not appropriate unless patient specimens are similarly tested.

III. PROCEDURE:

A. Automated Chemistry participates in multiple proficiency testing programs. With these, the laboratory is provided a PT challenge for each analyte that is performed.

1. **External Proficiency Testing Programs:** Surveys from external providers may be received each year and are scheduled for laboratory receipt throughout the year. Specific sample preparation directions vary with each shipment and are included with each delivery. Results, worksheets and samples (frozen) are maintained within the department section for two years.
    a. Examples of Proficiency Testing providers include:
        i. CAP: College of American Pathologists
        ii. API: American Proficiency Institute
    b. The list of survey providers changes as different analyte groups become available from the organizations.
2. **Internal Proficiency Testing Programs:** When an analyte is not available from a proficiency-testing provider, the laboratory confirms result accuracy, at least twice annually, by one of the following methods:
    a. Process assayed control material.
    b. Process pre-tested samples on an alternate in-house method.
    c. Send pre-tested samples to an alternate laboratory for comparison study. Alternatively, the samples may be received from an outside laboratory, such as ARUP, and tested again on one of our in-house procedures.
    d. Clinical validation by chart review.
3. **Worksheet requisitions**
    a. The technical staff incorporates the proficiency samples into the daily workload. The staff records the result(s) on a paper requisition. This process is similar to the downtime LIS reporting process. Instrument printouts and Quality Control (QC) records are maintained with the paper worksheet. An attestation statement provided from the external provider

must accompany each survey and is signed by all individuals involved in the testing process.

b. Worksheets are reviewed and initialed by the Medical Technologist (MT) Lead/designee and the section medical director/designee for the following:

i. Correct methodology and manufacturer information.

ii. Correct result interpretation, format and unit of measure.

iii. One supervisor/designee and one pathologist/designee will employ a read-back technique to match information between the Survey Result Form and original instrument printouts.

iv. The proficiency testing attestation statement is signed by the laboratory director or designee.

B. **Sample Identification and Test Orders**

1. **CAP Sample Identification:** Barcoded labels are prepared by the MT Lead or designee for CAP samples. The labels include a "downtime" number which is non-specific for LIS purposes, a barcode, and a CAP sample identifier/name that is handwritten by the MT Lead or designee. The MT Lead or designee will also place a downtime barcode label with CAP identifier/name on the back of the worksheet requisition for reference.

2. **CAP Test Orders:** For tests that are ordered in the automated chemistry middleware, the MT Lead or designee will use downtime barcode numbers. To make sure that nothing associated with the CAP sample/name is transferred to the LIS, only the downtime barcode number is entered into the middleware.

C. **Evaluation:** The laboratory section medical director or designee reviews the results of all proficiency tests.

1. **External Proficiency Testing Programs:** Survey results that are either graded or not graded are evaluated against the PT provider peer group. Dissimilar results will be investigated and documented in writing. The written evaluation will be reviewed and signed-off by the Section Medical Director / Associate Director or designee. If the result is considered "unacceptable" by the PT provider, the Chief of Clinical Pathology or Chair of Pathology must also sign the investigation conclusion. Decisions on what should be investigated should take into consideration:

2. Graded quantitative results must fall within 3 Standard Deviation Indices (SDI) of the peer group.

a. Non-graded results must agree with the majority of participants (i.e. results that are not graded due to lack of consensus, or because the lab submitted results after the CAP cut-off date). Occasionally, results of Educational Challenges are not graded but will still be compared to the peer group and documented.

b. Results should be assessed for trends and biases.

3. **Internal Proficiency Testing Programs:** Survey results are evaluated based on

unique criteria for each analyte. These unique criteria are displayed on the result worksheet. Unsatisfactory results are reviewed with the laboratory director or designee. Dissimilar results will be investigated and documented in writing. The written evaluation will be reviewed and signed-off by the Section Medical Director / Associate Director or designee

IV. REFERENCES:

A. Quality Control document for Automated Chemistry - Royal Oak

B. Laboratory All Common (Inspection) Checklist, College of American Pathologists. www.CMS.gov, Version 2021.

Approval Signatures

Step Description	Approver	Date
Medical Director	Ann Marie Blenc: System Med Dir, Hematopath	7/12/2022
Policy and Forms Steering Committee Approval (if needed)	Kelly Walewski: Medical Technologist Lead	7/11/2022
Policy and Forms Steering Committee Approval (if needed)	Gail Juleff: Project Mgr Policy	7/5/2022
Lab Chemistry Best Practice Committee	Qian Sun: Tech Dir, Clin Chemistry, Path	7/5/2022
Lab Chemistry Best Practice Committee	Caitlin Schein: Staff Physician	7/1/2022
	Colette Kessler: Mgr, Division Laboratory	6/22/2022
	Kelly Walewski: Medical Technologist Lead	6/22/2022