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Beaumont

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Area	Laboratory-Chemistry
Applicability	Royal Oak

Technical Procedures in Automated Chemistry - Royal Oak

Document Type: Guideline

I. PURPOSE AND OBJECTIVE:

A. This document applies to technical procedures written in the Automated Chemistry department at Beaumont Laboratory, Royal Oak. Maintenance, training, and competency assessment documents are not addressed.

B. Before writing a new procedure, review whether a separate document is needed. Revision to a current document or work flow may be sufficient.

C. Procedure section headings for manual and automated test platforms are described below. New procedures must be drafted in document control format. All procedures (new and/or revised) are entered into the policy management system to be reviewed and approved before use. All copies should be “Controlled Copies”.

II. MANUAL / NON-AUTOMATED PROCEDURES: FORMAT AND SECTION HEADINGS:

A. Provide stepwise detail on pre-analytical, analytical, and post-analytical phases of testing under each of the following section headings, where applicable:

1. **Purpose and Objective**
2. **Clinical Significance**
3. **Definitions**
4. **Patient Preparation Required:** For example, fasting, dietary restrictions, posture, dosing of medications, etc.
5. **Specimen Collection and Handling Requirements:** Includes patient preparation,

specimen requirements, specimen storage requirements, rejection criteria, preservatives, stability, storage and sample volume for the test.

6. **Reagents and Supplies:** Describes source, if unusual, and preparation of essential reagents and supplies including name or molecular formula, acceptable grade, concentration, preservatives, stability and storage. Also indicates any special cleaning requirements for glassware or containers.
7. **Calibration**: Lists type and source of standards or calibrators, preparation, storage, calibration protocol and required frequency.
8. **Quality Control:** Quality control material, preparation, special containers or handling, frequency and criteria for acceptability. Procedure when controls are unacceptable.
9. **Safety Precautions**: Indicates known potential hazards associated with the procedure and directives for use of personal protective equipment.
10. **Procedure**: Stepwise description of how the test is performed. Includes details of specimen and reagent volumes, order of additions, instrument settings, timing requirements, blank requirements, calculations, and reporting of results.
11. **Analytical Measurement Range (quantitative tests):** Indicate maximum dilution allowed, approved diluent, and volumes to be used for dilutions
12. **Limitations and Interfering Substances:** Lists known interferences such as hemolysis, lipemia, icterus, etc.
13. **Reference Intervals (normal values):** Lists the reference intervals or therapeutic range and toxic level for a drug, if known. Includes the critical values, if defined.
14. **Interpretation**: Includes interpretive criteria for qualitative results and pertinent information about clinical use.
15. **References**: Cited or pertinent literature articles, books, manufacturer's publications, etc.:
    a. Article: Author(s), title, journal, year, volume, pages
    e.g., Gabhardt, et.al., A study of the lecithin/sphingomyelin ratio of amniotic fluid. Clin.Chim.Acta., 1975, 64: 133-42.
    b. Book: Author(s), title, edition, publisher location, publisher name, year published, pages
    e.g., Tietz, Textbook of Clinical Chemistry, 3rd ed., Philadelphia, W.B. Saunders, 1999, pp 1774-77.
16. Attachments: Related charts, tables, and/or documents that may support the procedure. Attachments are separate PDF documents that are attached to the associated document in the policy management system.

III. AUTOMATED PROCEDURES: TABULAR FORMAT FOR TEST PARAMETERS:

A. For each automated analyzer, the operation and maintenance steps specific to Beaumont Laboratory should be described in a standard operating procedure. The primary reference for

this will be the manufacturer's operator and reference manuals. This procedure should be consistent with or refer to relevant laboratory procedures, for example, quality control and backup procedures.

B. Individual procedures for each analyte on the test menu are not needed. However, a comprehensive, yet readable and useful table (e.g., Excel spreadsheet) should be created in document control format to provide staff with rapid access to important test information extracted and condensed from manufacturer package inserts / instructions for use.

C. The table must include at least the following information in concise form, where available from the test manufacturer or defined by the laboratory:

    1. Measuring principle/methodology
    2. Primary clinical utility
    3. Patient preparation
    4. Specimen requirements: acceptable sample types, stability, minimum volumes
    5. Reagents: storage, stability, preparation, manufacturer abbreviation and product number
    6. Calibration: Calibrators, calibration frequency
    7. Quality Control materials, Quality Control frequency
    8. External Quality Control (College of American Pathologists survey or other proficiency testing material)
    9. Safety precautions
    10. Analytical measuring range (in reporting units and decimal places)
    11. Material used for analytical measuring range verification
    12. Maximum dilution, automatic and manual
    13. Diluent and acceptable volumes for sample and diluent
    14. Reference intervals (in reporting units and decimal places)
    15. Critical values
    16. Manufacturer sensitivity claim, precision claims
    17. Interferences (both HIL and non-HIL)
    18. Reporting, including delta checks and calculations

D. *Wherever the laboratory establishes sample stability requirements, reference intervals, analytical measuring range, or other test parameters that differ from the manufacturer insert data, these should be clearly indicated.*

IV. REFERENCES:

1. College of American Pathologists All Common Checklist (2014)
2. Clinical and Laboratory Standards Institute (CLSI) document QMS02-A6. Quality Management System: Development and Management of Laboratory Documents (2013)

Approval Signatures

Step Description	Approver	Date
Medical Director	Ann Marie Blenc: System Med Dir, Hematopath	5/19/2023
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
	Colette Kessler: Mgr, Division Laboratory	5/11/2023