DOCUMENT CONTROL

PURPOSE

To define the flow and control of policies, processes, procedures and forms within the laboratory.

POLICY

All documents-policies, processes, procedures and forms will be created and maintained using the stages defined by the document control process. Documents will exist in electronic and paper format. All changes will occur in the electronic version and then be printed for access at the bench.

CREATION OR REVISION OF DOCUMENTS

When the need for a new document or revision of an existing document is identified, the same process will be followed.

For **new** documents:

- All new policies and procedures are reviewed and approved by the laboratory medical director and director of operations prior to implementation.
- An electronic copy will be created and identified as a draft. It will remain a draft until completion and signatures are obtained.
- The proper location in the manuals will be determined based on the subject matter. Possible locations will be:
  - Administrative policies and procedures manual
  - Appropriate laboratory section technical manual
  - Quality assurance manual
- A suitable number will be chosen to assign to the document. The document will be identified as a draft until completion and signature is obtained.
- The document history pages must be signed be either the Director or designee.

For **revised** document,

- Major revisions to existing policies and procedures are reviewed and approved by the laboratory medical director and the director of operations prior to implementation.
- Minor revisions to existing policies and procedures are reviewed and approved by the director of operations prior to implementation. (Note: minor changes are defined as “spelling”, “grammar”, document formatting, and sentence changes that do not significantly alter the content, meaning or directions provided in the original documents.
- An electronic copy will be created and identified as a draft. It will remain a draft until completion and signature(s) are obtained.
- The document history pages must be signed by either the Director or designee.

DOCUMENT CONTROL

STANDARD FORMAT

Standardized templates will be used for policy, processes and procedures. As needed, this template will include the elements of:

- Principal and clinical significance
- Safety elements to bring attention to tasks that are capable of causing injury if not paid attention to.
- Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing and referral; and criteria for specimen rejection and acceptability
- Microscopic examination, including detection of inadequately prepared slides
- Step-by-step performance of the procedure, including test calculations and interpretation of results
- Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing
- Calibration and calibration verification procedures
- The analytic measurement range for test results, if applicable
- Analytic measurement range may not apply to qualitative or semi-quantitative tests
- Control procedures
- Corrective action to take when calibration or control results fail to me to let laboratories criteria for acceptability
- Limitations in the test and methodology, including interfering substances normal values critical values if applicable pertinent literature references the laboratory system for entry results in the patient record and reporting patient results including, when appropriate, the protocol for reporting critical results
- Description of the course of action to take a test system becomes inoperable

The standardized format will also include defined structures for headers and the addition of a history page. The history page is attached to track documents revisions and footers

DOCUMENT CONTROL

REVIEW SCHEDULE

Review of policies, processes, and procedures will occur every 2 years and be performed by the director or designee (as defined by CAP). Documents will be listed in the form of a table of contents and allow for individual document sign off.

CHANGE CONTROL DOCUMENTS

- All new and revised policies and procedures will be tracked using an electronic document control log. This listing will be maintained by the quality assurance coordinator or designee and recorded in the Document Control log.
- Policies and procedures will utilize a document history page to track approvals and revisions of the documents and will remain with the document until archived.
- Laboratory testing personnel are knowledgeable about new and revised policies and procedures that are relevant to the scope of their testing activities.
- Documentation of personnel knowledge may be accomplished by a signed training and education document, review and acknowledgement of document electronically in MTS or MediaLab, sign in sheets from discussion of changes in department huddles, read receipts of email or Relate newsletter containing documents or policy change information.

STORING AND ARCHIVING

Both electronic and paper copies of policies, processes, procedures and forms will be available. When electronic versions are updated, they will be moved to the appropriate archive folder in their section on the computer. When paper copies are updated, the older version will be “archived" and placed into the documents archive folder. The date and initials of the responsible party will also be documented. The archived copies will be sorted by section. History pages with applicable signatures will remain in the active procedure manual along with the active procedure.

When discontinuing a policy, process, or procedure, a paper or electronic copy is maintained for at least 3 years for general lab and 5 years for blood bank after discontinuation of use. The date of initial use and retirement need to be recorded on the document. The quality assurance coordinator and/or designee may be responsible for maintaining archived or discontinued documents.

DOCUMENT CONTROL

HISTORY PAGE

Type of Change: New Major, Minor	Description of Change(s)	Name of Responsible Person/Date	Operations Director, Area Laboratory Review/Date	CLIA Laboratory Director Review/Date	Date Change Implemented
New		Stephanie Prien 9/28/11	Stephanie Prien 9/29/11	Dr. Jana Pindur 10/3/11	10/3/11
Minor	Change from 2 yrs. to 3 yrs retention of revised/retired procedures. Added definition of minor change.	L. Padilla 10/30/13	Charles Park 11/3/13		11/4/13
Minor	Removed schedule of review "one 24th of the documents each month." Added document control log to track new and revised documents. Added designee to maintain listings or new and revised documents.	J. Remolar 6/8/17	Mary Lou Beaumont 6/8/17		6/8/17
Minor	Regional Template Update	Ruby Co 11/1/2018	Mary Lou Beaumont 11/1/18		11/1/18
Major	Added "document formatting" to minor change definition, explanation of methods of staff knowledge, format changes.	Mary Lou Beaumont 11/1/18	Mary Lou Beaumont 11/1/18	Dr. Jana Pindur 11/1/18	11/1/18
Minor	Moved to Quality	Judith Remolar 11/15/18	Mary Lou Beaumont		