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Laboratory Document Management and Record Retention Procedure

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Document Type: Procedure

I. PURPOSE AND OBJECTIVE:

The purpose of this document is to provide instruction for creating and maintaining laboratory procedures, forms, manuals, and good document practices. Refer to Corewell Health Policy on Policies for details on the process for development, approval and maintenance of documents using the policy management system.

II. RESPONSIBILITY / AUTHORITY:

It is the responsibility of department managers to monitor and maintain quality, effective and controlled-documents. Management includes: Operations Director, individual Medical Directors, Technical Directors, Managers, Supervisors and Lead Techs.

III. DEFINITIONS:

A. Document – *Information and its supporting medium* (ISO 9000) (CLSI QMS02-A6).

B. Form – *A paper or electronic document on which the results from the performance of a procedure or other information are captured; a completed form becomes a record. (CLSI QMS02-A6).*

C. Policy – *A written statement of overall intentions and directions defined by those in the organization and endorsed by management.*

D. Procedure – *A specified way to perform an activity.* ***NOTE:*** *For a quality system, a procedure is a set of instructions that describe the stepwise actions to be taken to complete activities identified in processes.*

E. Process – *Set of interrelated or interacting activities that transform inputs into outputs.* ***NOTE:*** *It may be documented as flowcharts or tables that describe the path of operational work flow in the laboratory.*

F. Substantial Revisions to policies/procedures. A major revision is a modification made to an existing procedure that significantly impacts the procedure or policies or that consists of the addition, removal or change of a significant portion of the procedure. **This includes, but not limited to:**

1. Modifications that are the result of new technology, new instrumentation, medical advances, improvements to the standard of care, patient safety concerns, regulatory requirements, etc.
2. Modifications directed by manufacturers, such as changes in volume, temperature, time or speed, which may affect the way a procedure is performed.
3. Modifications that may require staff training.
4. Substantial (major) revisions require sign-off by the Medical Director. Outreach Policies/Procedures require approval by the Outreach Medical Director.

IV. DOCUMENT CONTROL SYSTEM:

A. A document control system is composed of two major processes:

1. To identify, review, approve and archive documents.
2. To create, review, file, and store records.

B. Corewell Health East Laboratory document control system includes:

1. The Quality System manual
2. Quality Procedure manuals
3. Administration manuals
4. Laboratory department procedures
5. Operational (work instructions) procedures
6. Records
7. Forms
8. Supporting documents

V. PROCEDURE:

A. Quality System Manual

1. The Corewell Health East Laboratory Quality System manual (QS) is maintained by

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the Operations Specialists.

2. Records are established and maintained to provide evidence of conformity to requirements and of the effective operations of the quality management system.
3. The Laboratory Medical Director reviews, at least biennial (every two years), the contents of the QS manual for its continuing adequacy and effectiveness. This review includes assessing the need for improvement and/or change. The Operations Specialist maintains documented records of these ongoing reviews.

B. Clinical Laboratory Operational Procedures Manuals

1. Each section of the laboratory provides documented instructions, in the form of procedures, for all the sequential activities included with the pre-analytical, analytic and post-analytic processes of testing. These procedures, policies and processes are designed and written to build the required level of quality into the laboratory work and to minimize medical error. The operational (technical) procedure manuals and the quality system manual are designed to complement each other toward establishing a complete quality system. Both sets of manuals are considered "controlled documents" and should not be copied without supervisory authorization.
2. Written procedures should include steps of the entire process, start-to-finish. Steps performed by different people at different times (e.g. Lab Assistant at processing versus Medical Technologist at testing) should also be included.
3. A complete procedure manual should be available in a paper-based, electronic or web-based format at the workbench or in the work area.
4. The use of inserts (provided by manufacturers) is not acceptable in place of a procedure manual. However, such inserts may be used as part of a procedure description if the insert accurately and precisely describes the procedure as performed in the laboratory. Any variation from this printed procedure must be detailed in the procedure manual. In all cases, appropriate reviews must occur.
5. A manufacturer's procedure manual for an instrument reagent system may be acceptable as a component of procedures. Any modification to, or deviation from, the procedure manual must be clearly documented.
6. Card files or similar systems that summarize key information are acceptable for use as quick reference at the workbench provided that:
    a. a complete manual is available for reference
    b. the card file or similar system corresponds to the complete manual and is subject to document control
7. Electronic (computerized) manuals are fully acceptable. There is no requirement for paper copies to be available for the routine operation of the laboratory, so long as the electronic versions are readily available to all personnel. Such electronic versions are subject to proper document control (i.e., only authorized persons may make changes, changes are dated/signed). Current paper copies of electronically stored procedures should be available at the time of the College of American Pathologists (CAP) inspection, or rapidly generated at the request of the Inspector.
8. At a minimum and as applicable, laboratory procedures should include: Title,

purpose or principle, clinical significance, criteria for specimen rejection and acceptability, labeling, storage, preservation, required reagents, special safety precautions, calibration, quality control, corrective action to take when calibration or control results do not meet the laboratory's criteria for acceptability, test limitations, procedure instructions, calculations, pertinent literature, reference intervals (normal values), interpretation, guidelines for entering results into the lab computer system, guidelines for the documentation and reporting of panic (life-threatening) values, author and approval signatures, as applicable.

C. Approval Signatures

1. The Laboratory Medical Director must approve, sign/electronic approval and date each new and/or **substantially** revised policy and procedure before it is placed in use. This responsibility cannot be delegated.
2. Following a change in laboratory directorship, the new laboratory director approves the laboratory policies and procedures within three months of the change of directorship. If the procedure approval process is going to exceed three months, document a written plan to complete the procedure review process.
3. Each Laboratory Medical Director should include policies within their site(s) procedure manual, which clearly identifies the *designee(s)* for each section.
4. A single signature on the Title page or Index of all procedures is **not acceptable**. This practice does not significantly document that each procedure has been carefully reviewed.
5. Signature (or initials) on each page of a procedure is not required.
6. Each policy and procedure must reflect documentation of at least every two years by the current Laboratory Medical Director or *"designee."*
7. It is the responsibility of the Laboratory Medical Director to verify the collection of policies and technical procedures are complete, current and have been thoroughly reviewed by a knowledgeable person.

D. Procedure Manual Review / Modification. Follow these guidelines to review or modify a procedure:

1. Section manager(s) define, for each respective section, which persons are approved to:
    a. Write procedures
    b. Revise old procedures
    c. Archive obsolete procedures
2. **Modifications** include as follows. These five modifications do not require the approval or immediate signature of the Laboratory Medical Director for implementation. These modifications can be signed off by the section manager/ supervisor and approved by the Laboratory Medical Director or designee during the procedural review process performed every two years. Identify revisions as "major" or "minor" on the sign off page/document changes in the policy management system.

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a. Corrections to clerical (typing) errors, which do not change the sentence meaning (e.g. errors of spelling, a missing word, language-based errors, verb-noun types of errors).

b. Changes directed by the manufacturer (e.g. volume changes, temperature, time or speed changes), which do not otherwise change the procedure.

c. Changes in cited literature.

d. Attachments which do not change the content of the procedure.

e. Changes in procedures directed by manufacturers as to reagents, supplies or equipment, which do not otherwise change the procedure.

E. Revised / New Procedures

1. **New procedures** require the approval and signature/electronic approval of the Laboratory Medical Director prior to implementation. This responsibility cannot be delegated.

2. **Revised Procedures:** Procedures which require the elimination of procedural steps and/or major changes (not listed in the Modified Procedures section above) are considered **revised procedures**. Revised procedures must be approved and signed/ electronic approval by the Laboratory Medical Director and Laboratory Chair prior to implementation. This responsibility cannot be delegated.

F. Additional Good Documentation Practices

1. Recording Data. Note: This includes, but is not limited to, QC data, temperature logs and intermediate test results or worksheets.

a. For corrections to paper and/or electronic records:

i. Original (erroneous) entries must be visible (no erasing or use of correction fluid or tape) or accessible (audit trail for electronic records)

ii. Corrected data, including the identity of the person changing the record and when the record was changed, must be accessible to audit

b. Do not use ditto marks (") to record the same data.

c. For fields, which do not require data, enter N/A.

d. If additional information is required on forms, enter simple, complete sentences. Include facts and actual observations only.

e. Pencils and non-indelible ink pens are not acceptable. Use only black or blue ink pens. The use of "black-out" or "white-out" is unacceptable. Draw a single line through the error and initial and date the change.

f. When recording multiple entries of the same type, you may draw an arrow from the first entry line to the last entry. Initial and date. Do not use ditto marks.

g. Do not use post-it notes for documentation.

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h. Missing data: Do not fill in past missing data.

i. Immediately notify your leader.

ii. Leader: Review error with staff involved. Initial and date next to missing information with *note of follow up completed or add to corrective section.

2. Substitute Signatures

a. For persons who are approved to substitute-sign a procedure, print the name of the original person where the original person would sign, then the substitute person signs their name. Date the entry.

b. It is **not** acceptable to sign someone else's name to a document unless accompanied by that of the signatory (your name). See the following Acceptable when properly authorized example:

Approval:

_____

Mary Jones, Supervisor Date

3. Date & Time Entries

a. Use *standard* date and time entries.

b. The Corewell Health East Laboratory standardized date format is: 06/20/2020

c. The pattern of day/month/year is not acceptable when using numeric.

d. Acceptable time formats include: 2:15 PM or 1415 (military time)

e. Backdating is **not** acceptable. If a signature is added at a later date, include an explanation for the delay in dating.

G. Archived Procedures

1. Refer to the Corewell Health Policy on Policies procedure for details on the archiving process within the policy management system.

2. For revised or retired documents managed within the laboratory, the copy of the previous version is moved into the designated archive file within the laboratory section. This archived version is labeled as such (by stamp or handwritten) and is initialed and dated by the archiver. The archived original copy is placed in the designated location (varies by section) and is stored as required by regulatory/accreditation agency(ies).

H. Notification of Staff for New, Revised or Modified Procedures

1. Each section of the laboratory has a system to document that all personnel are *knowledgeable about the contents of procedure manuals relevant to the scope of their testing activities*. Both new and revised procedures are addressed by this system. An annual procedure sign-off by testing personnel is not required. The exact approval for the approved system is at the discretion of the Laboratory Medical Director and Laboratory Chair. Refer to Laboratory Education - Employee Training Procedure for guidance on the employee review process of new and/or

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revised procedures.

VI. FORMS:

A. A "form" is defined as *"a paper or electronic document on which results from the performance of a procedure or other information are captured; a completed form becomes a record."*

B. Form documents should contain the following:

1. Corewell Health logo and Corewell Laboratory, [site]
2. A title that is directed to the form's purpose
3. An effective date
4. Appropriate fields within which to record the necessary information
5. A means of identifying the form to its respective procedure

C. Form types include those which are:

1. created by the section (internal)
2. created by the department (internal)
3. created by the hospital (external)
4. created by external agencies (e.g. Centers for Disease Control and Prevention (CDC))

D. Form examples include: Quality Control (QC) forms, Continuing Education (CE) forms, training and competency assessment forms, employment application forms, counseling forms, tuition-reimbursement forms, termination (on-line) forms, purchasing (on-line) forms.

VII. POSTED DOCUMENTS:

A. A posted document is defined as any policy and/or procedure (standard work document) that is posted for employee information.

B. Cheat sheets (shortened versions of an official policy or procedure): It is preferred these are not used. If used, cheat sheets must include the procedure name of the official policy or procedure.

C. Policies:

1. Stamp document as Uncontrolled or when printed from the policy management system, the document will have a "Copy" watermark on the printed document.
2. Needs to be reviewed at least every other year
3. Once reviewed,
    a. If the document is up-to-date, the reviewer initials and dates the document again.
    b. If the document is not up-to-date, the document is removed.

D. It is the responsibility of the section manager to monitor and maintain any other type of posted documents within his/her section.

E. It is the responsibility of individual staff to monitor and maintain any other type of posted

documents within his/her workstation.

VIII. RECORD RETENTION:

A. Corewell Health East Laboratory record retention policy must meet regulatory, accreditation and organizational retention requirements. Refer to both the Complete Health Organization Record Retention Guide (Michigan) and Table 1 - Laboratory Record Retention schedule, which covers laboratory specific items not detailed in the Complete Health Organization Record Retention Guide (Michigan).

B. Contact the site Operations Specialist or recordretention@corewellhealth.org to request the most up-to-date version of the Complete Health Organization Record Retention Guide (Michigan).

C. All records, whether paper or electronic, must be stored in a manner to maintain integrity, accessibility and to facilitate retrieval.

D. Additionally, the confidentiality of patient-specific information must be assured.

E. Should this laboratory cease operation, all records, slides, blocks and tissues are retained and available for the required amount of time for each type of record. Please refer to the Complete Health Organization Record Retention Guide (Michigan) and Table 1, Record Retention Schedule.

IX. REFERENCES:

A. College of American Pathologists (CAP) Lab General Checklist (current version)

B. CMS, Department of Health & Human Services. Part 493 – *Laboratory Requirements: Clinical Laboratory Improvement Amendments of 1988.* Code of Federal Regulations, Title 42, Subparts J.K., U.S. Government Printing Office. Revised annually.

C. Record Management, Retention and Destruction Policy.

D. Record Storage and Destruction Procedure.

E. CLSI QMS02-A6: 2013 Quality Management System: Development and Management of Laboratory Documents, 6th edition, CLSI eCLIPSE Ultimate Access site. Accessed September 11, 2018.

F. Retention of Laboratory Records & Materials, CAP References, Resources & Publications, CAP e-site, September 2016.

Attachments

Table 1 - Laboratory Record Retention Schedule.pdf

Approval Signatures

Step Description	Approver	Date
CLIA Site Licensed Medical Directors	Muhammad Arshad: Chief, Pathology	9/27/2024
CLIA Site Licensed Medical Directors	Jeremy Powers: Chief, Pathology	9/26/2024
CLIA Site Licensed Medical Directors	Ann Marie Blenc: System Med Dir, Hematopath	9/26/2024
CLIA Site Licensed Medical Directors	Hassan Kanaan: OUWB Clinical Faculty	9/23/2024
CLIA Site Licensed Medical Directors	Ryan Johnson: OUWB Clinical Faculty	9/16/2024
CLIA Site Licensed Medical Directors	Subhashree Mallika Krishnan: Staff Physician	9/16/2024
CLIA Site Licensed Medical Directors	Masood Siddiqui: Staff Pathologist	9/16/2024
CLIA Site Licensed Medical Directors	John Pui: Chief, Pathology	9/16/2024
CLIA Site Licensed Medical Directors	Kurt Bernacki: System Med Dir, Surgical Path	9/16/2024
Policy and Forms Steering Committee Approval (if needed)	Michele Sedlak: Lab Quality Coord	9/16/2024
	Sarah Britton: VP, Laboratory Svcs	9/9/2024
Operations Directors	Joan Wehby: Dir, Lab Services	9/3/2024
Operations Directors	Elzbieta Wystepek: Dir, Lab Services	8/20/2024
Operations Directors	Brittnie Berger: Dir Sr, Lab Operations	8/14/2024
Operations Directors	Amy Knaus: Dir, Pathology Service Line	8/9/2024
Operations Directors	Christopher Ferguson: Dir, Lab Services	8/9/2024
	Michele Sedlak: Lab Quality Coord	8/8/2024

Applicability

Dearborn, Farmington Hills, Grosse Pointe, Royal Oak, Taylor, Trenton, Troy, Wayne

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GEN.20375, GEN.20377, GEN.20425, GEN.20450

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TABLE 1. RECORD RETENTION SCHEDULE*

Refer to Complete Health Organization Record Retention Guide (Michigan) for the comprehensive list of retention guidelines.
The table below contains laboratory specific items not detailed on that list.

*Times listed are minimum retention times		Regulatory / Accreditation Organization		
	Beaumont Laboratory	CLIA	CAP	Joint Commission
Types of Records	RETENTION PERIOD			
Employee initials documentation	10 years			
Equipment calibration/maintenance records	Blood Bank: Life of the instrument, plus 10 years All other labs: Life of the instrument, plus 2 years	2 years	2 years Blood Bank: 10 years	
Paper copies of test results from reference labs	Date resulted into LIS, plus 2 years			
Software verification	Paper: For at least 7 years Electronic: Indefinitely		Life of the system, plus 2 years	
Training & Competency Records	Active employment plus 7 years			
Training & Competency supporting documents	Inspection cycle (2 years)			
Test method verification	Life of the method, plus 2 years			
Cell blocks	11 years			
IHC batch controls	2 years		2 years	
Reports of outside consultations on laboratory cases	10 years		10 years	
Chromosomal microarray data	Original scan for at least 2 weeks after final report and at least two years of sufficient original data to support primary results generation and re-analysis (CYG.32700)		2 years	