Policy for Documentation Technique

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Purpose

- Quest Diagnostics policy for proper documentation technique on **technical records**.
- These requirements are outlined to ensure our laboratories meet the requirements of regulatory compliance and good laboratory practice.
  - Lab technical records are important legal records.
  - We must provide detailed information regarding testing performed in our laboratories.
  - If a patient result or test is called into question, documentation must tell the whole story for everything that transpired through the course of obtaining the result.

Scope

- This policy applies to all Quest Diagnostics pre-analytic, analytic and post analytic departments that handle **technical records**.
- Departments included, but are not limited to the following:
  - Anatomic Pathology (AP)
  - Clinical Pathology (CP)
  - Client Services
  - Logistics
  - Referral Testing
  - Specimen Processing
  - Technical Operations
  - Warehouse

Overview

What is a **technical record**?

- A clinical laboratory document where the accuracy of the information recorded directly or indirectly affects patient test results and/or patient care.
- The following are examples (but not the only types) of technical records:
  - Standard operating procedures (SOPs)
  - Testing data (e.g., batch records, worklists, workcards, plate maps)
  - QA/QC activities (e.g., method validation, reagent verification, periodic quality control, preventive maintenance, calibration, proficiency testing)
  - Any other information that has a direct or indirect effect on the quality of patient test results

Overview

Why are **technical records** significant?

- They are evidence that work has been performed on a particular date.
- Documents reflect **who** did **what**, **when** and **why**.
- If no documentation can be produced, there is no evidence that work was performed.

General Requirements

Types of Documentation

- Recording information
- Voiding information
- Changing information

General Requirements

When recording, voiding or changing information:

- It must be dated with the current date.
- If relating to a past event,
  - It must clearly show the change was made on the current date.
  - There must be reference to the past date.
  - If applicable, an explanation for any oversight must be included
- It must be signed and dated on all pages. This includes any attachments.

General Requirements - additional

- The documented information must be traceable to the person making the entry.
- The identity of this person must be recorded as a signature, initials, code or other unique identifier.
- A department list of employees and unique identifiers is required.

General Requirements

It is **NEVER** acceptable to back-date an entry on a technical record.

Requirements for Recording Information

DO:

- Record information on standard approved forms, as applicable.
- Include a name, title, identifier that clearly reflects the contents of the record. This must be on all pages of the document
- Record information directly on the technical record.
- **Write legibly.** Letters, numbers and any symbols must be clear and decipherable.
- Make complete entries.
- Use permanent ink that does not smear. Blue or black ink is preferred.
- Define any abbreviations used in the legend or table. Or use abbreviations that are generally understood.
- Include a complete reference citation, if used for supporting information, so that the reference is retrievable.

Appropriate Recording Example

Fecal Immunochemical Test *Enterix* (InSure™)
Daily Quality Control Log

Performance Frequency: Each day of patient testing. Month: SEPT 2012

Controls	Expected Reactions	Acceptable Performance
Built in Positive Control:	*Pink line (Control line) appears on the test strip*	**Pos** = Control line present on all test strips (excluding those reported as invalid)
Built in Negative Control:	*Clear to light pink background*	**Neg** = Clear to light pink background on all test strips (excluding those reported as invalid)

Date	Tech	Test Strips		Buffer		Built in Control Results		Weekly Review
		Lot #	Exp. Date	Lot #	Exp. Date	Positive (Pos)	Negative (Neg)	
1	KC	732611	1/16/13	427992	4/2/13	+	—	
2	KC	732611	1/16/13	427992	4/2/13	+	—	
3	[illegible]	732611	1/16/13	427992	4/2/13	+	—	
4	TP	732611	1/16/13	427992	4/2/13	+	—	MB
5	TP	732611	1/16/13	427992	4/2/13	+	—	
6	BAG	732611	1/16/13	427992	4/2/13	+	—	
7	BAG	732611	1/16/13	427992	4/2/13	+	—	
8	BAG	732611	1/16/13	427992	4/2/13	+	—	
9	BAG	732611	1/16/13	427992	4/2/13	+	—	
10	[illegible]	732611	1/16/13	427992	4/2/13	+	—	
11	[illegible]	732611	1/16/13	427992	4/2/13	+	—	MB
12								
13								
14								
15								

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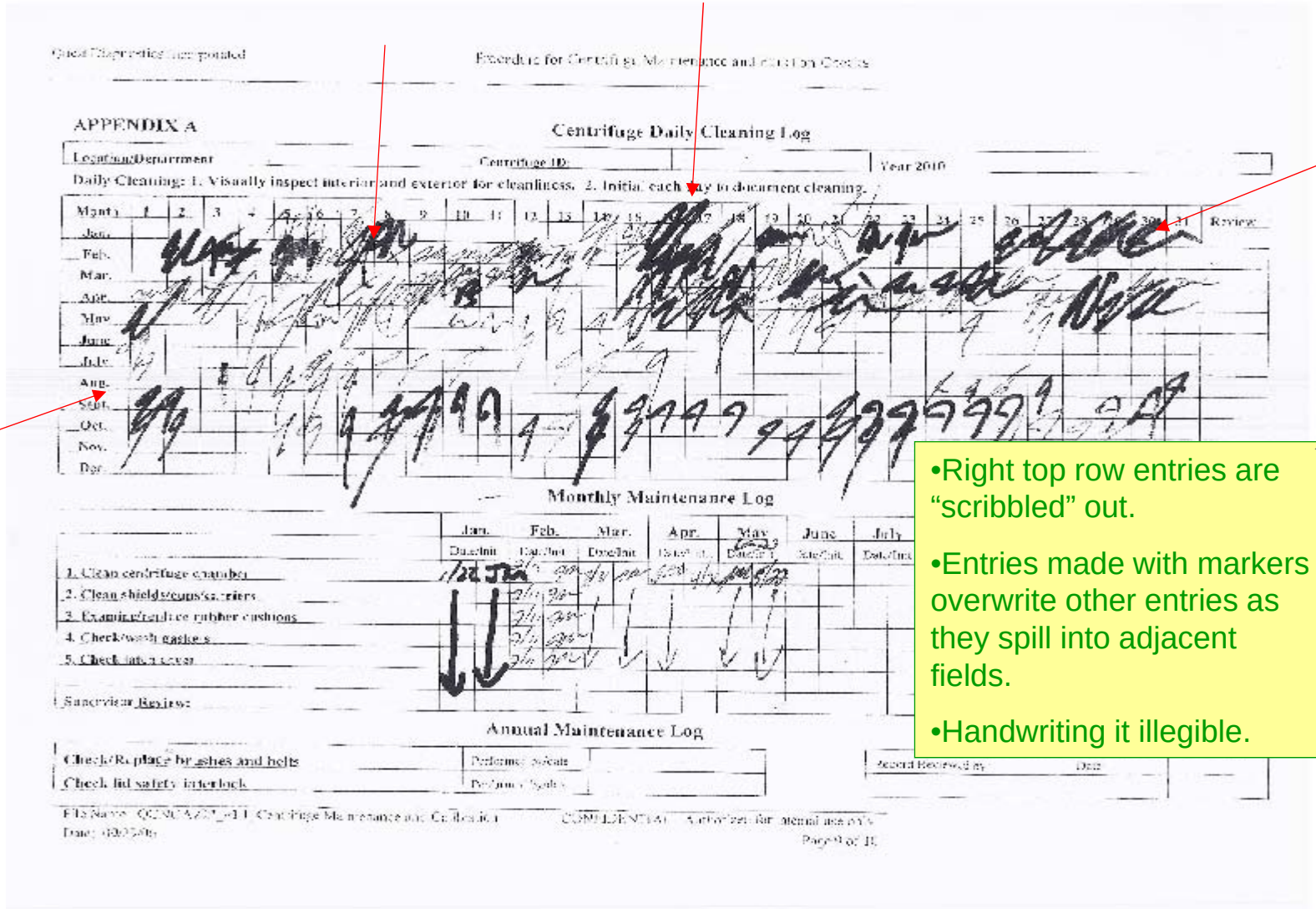
Requirements for Recording Information

DO NOT:

- Do not use a medium that is not part of the permanent record.
- Do not use:
  - Self-affixing notes (“stickies” or Post-It® Notes)
  - Small pieces of paper stapled, paper-clipped or otherwise attached to the technical record. If necessary, create a formal referenced attachment so it’s clear to which record it belongs.
- Do not use pencil.
- Do not use dark highlighters. These obscure information when it is faxed or copied.
- Do not use ditto marks to repeat information. Arrows are acceptable if it is completely clear what the arrows mean.

Poor Recording Example 1



Poor Recording Example 2

Microscope Maintenance Log

Month: October Year: 2009

Division: Infectious Diseases Department: MC / Virology Make/Model: Olympus LMS/CK - 40 Control No.: 1335 Serial No.: 1G06477

DAILY	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
CLEAN OBJECTIVES AND STAGE CONDENSER	/	–	/	/	–	/	–	–	–	/	/	–	–																		
CHECK FINE AND COARSE ADJUSTMENT	/	–	/	/	–	/	–	–	–	/	/	–	–																		
CHECK MECHANICAL STAGE	/	–	/	/	–	/	–	–	–	/	/	–	–																		
CHECK LIGHT ALIGNMENT	/	–	/	/	–	/	–	–	–	/	/	–	–																		
INITIAL		OK			OK		OK		OK			OK																		

Lead Tech/Supervisor Review	Week 1	Week 2	Week 3	Week 4	Week 5
Date	10-9-09				
Initial					

MONTHLY	Date	Initial
CLEAN ENTIRE EXTERNAL SURFACE		

SEMIANNUALLY	Date	Initial
CHECK CORD/PLUG		

AS NEEDED	Date	Initial
BULB CHANGE		

Reviewed by: _____

CODES: **C** – Equipment not functioning properly.
/ – Not in Use

Record Corrective Action on the Back of this Form.

S:\FORMS\Maintenance Logs\Microscope-Maintenance-(CI)-01-03-08-V1.doc 1 of 2

Documentation must match legend (Codes)

- Legend specifies /= Not in Use
- A line was used in each column to indicate microscope was not in use.

Poor Recording Example 3

This is an entry from a temperature chart.

Can you decipher what it says?

When Voiding Information

- Do not obscure the original information
- Draw a single horizontal line through the original information
  - The original entry must still be legible
- Do not use multiple cross out lines
- Do not use correction fluid (e.g. Wite-Out®) or correction tape of any kind
- Do not use a marker which can easily obscure the information
- The person voiding the entry must sign/initial and date the crossed out information.

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Voiding Example

Quest Diagnostics Incorporated
Site: Indicate here and make black

Title: **Evaluation and Interpretation of Lower Respiratory Tract Infections**

Only normal flora present	Growth of Normal Oropharyngeal Flora	**NORF**
Growth of a pathogen, and normal flora is also present:	Normal Respiratory Flora also present.	**NOAP**
Significant growth of a yeast	Yeast isolated. Please contact the laboratory within 3 days if further identification is desired.	**YISO**
Significant growth of a fungus	Fungus isolated. Please contact the laboratory within 3 days if further identification is desired.	**FISO**
~~Mixed morphologies of Gram rods~~	~~Mixed Gram negative growth~~	~~**MGNG**~~
Normal oral flora	No	**NORT**

DCM 3/2/11 message no longer in use.

- Single line through original information, dated and initialed by the Laboratory Director.

NOTE: Changes to SOPs are **not** permitted without Laboratory Director approval.

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When Changing Information

This a two step process.

1. Void the original entry
   - Draw a single horizontal line through the original information.
   - Follow the same process as described for Voiding Information.
2. Enter the new information
   - Enter the new information so that it is very clear which information it is replacing.
   - Do not obscure any original or voided information.
   - Review the changes to be sure that they are complete, accurate and legible.
   - Do NOT write over or through the original information.

- Document the reason for the change if it is not apparent
- The person making the change must sign/initial and date the entries.

Changing Example

Fecal Immunochemical Test *Enterix* (InSure™)
Daily Quality Control Log

Performance Frequency: Each day of patient testing. **Month:** SEPT 2012

Controls	Expected Reactions	Acceptable Performance
Built in Positive Control:	*Pink line (Control line) appears on the test strip*	**Pos** = Control line present on all test strips (excluding those reported as invalid)
Built in Negative Control:	*Clear to light pink background*	**Neg** = Clear to light pink background on all test strips (excluding those reported as invalid)

Date	Tech	Test Strips		Buffer		Built in Contr Results	
		Lot #	Exp. Date	Lot #	Exp. Date	Positive (Pos)	Nega (Ne
1	KC	732611	1/16/13	427992	4/2/13	+	—
2	KC	732611	1/16/13	427992	4/2/13	+	—
3	BA	732611	1/16/13	427992	4/2/13	+	—
4	TP	732611	1/16/13	427992	4/2/13	+	—
5	TP	732611	1/16/13	427992	4/2/13	+	—
6	BAG	732611	1/16/13	427992	4-2-13	+	—
7	BAG	732611	1/16/13	427992	4-2-13	+	—
8	BAG	732611	1/16/13	427992	4-2-13	+	—
9	BAG	732611	1/16/13	427992	4-2-13	+	—
10	[illegible]	732611	1/16/13	427992	4/2/13	+	—
11	[illegible]	732611	1/16/13	427992	4/2/13	+	—
12	KC	732611	1/16/13	427992	4/2/13 KC 9/12/12	+	—
13							
14							

- The year was entered incorrectly.
- A single line is drawn through that number and the correct number was entered.
- Since it is obvious from previous entries, no explanation is required.

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Non-Technical SOP

Title	**Policy for Documentation Technique**
Prepared by	Kathy Grimes Date: 10/1/12

Laboratory Approval	**Effective Date:**	
Print Name and Title	**Signature**	**Date**
Refer to the electronic signature page for approval and approval dates.		

Review		
Print Name and Title	**Signature**	**Date**

Corporate Approval	**Corporate Issue Date:**	
Print Name and Title	**Signature**	**Date**
Karen Rupke, Director of Quality Management – CP **Owner**	*On file*	11/2/2012
Stephen C. Suffin, M.D. **V.P and Chief Laboratory Officer**	*On file*	11/5/2012

Retirement Date:	*Refer to the SmartSolve EDCS*
Reason for retirement/replacement:	

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1. PURPOSE

This document sets forth the policy for proper documentation technique related to technical records and is in keeping with regulatory requirements and good laboratory practice.

2. SCOPE

This policy applies to all Quest Diagnostics pre-analytic, analytic and post-analytic departments in which personnel handle technical records. This includes but is not limited to testing departments in Anatomic Pathology (AP) and Clinical Pathology (CP), Client Services, Logistics, Referral Testing, Specimen Processing, Warehouse and Technical Operations.

3. RESPONSIBILITY

- The **Laboratory Director** is responsible for the approval of the initial document and any subsequent revisions.
- The **Laboratory Director or Designee** is responsible for the recurring review of this document.
- The **Technical Supervisor / Manager** is responsible for
  - Implementing this policy in the department for which he/she is responsible.
  - Ensuring compliance with the policy in the department for which he/she is responsible.
  - Ensuring all employees (Personnel) who handle technical records are trained at new hire and annually thereafter.
- All **Employees (Personnel) who handle technical records** must follow this policy.

4. DEFINITIONS

- **Technical Record:** a clinical laboratory document where the accuracy of the information recorded directly or indirectly affects patient test results and/or patient care. Technical record information includes but is not limited to standard operating

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procedures, testing data, record of QA/QC activities, workload records, or any other information that has a direct or indirect effect on the quality of patient test results.

5. POLICY

A. Overview

1) Technical records are evidence that work has been performed on a particular date.
2) Documents reflect who did what, when and why as applicable.
3) If no documentation can be produced, there is no evidence that work was performed.

B. General Documentation Requirements

1) There are three types of documentation
   a. Recording information
   b. Voiding information
   c. Changing information
2) Recording, voiding or changing information:
   a. Must be dated with the current date.
   b. If relating to a past event, an entry must:
      (i) Be clearly recognizable as having been made on the current date with a reference to the past date.
      (ii) Include an explanation for any oversight, if applicable trace
3) It is **never** acceptable to back-date an entry on a technical record.
4) All pages of a technical record, including attachments, must be signed/initialed and dated.
5) Documentation must be traceable to the person making, voiding or changing information on the record.
6) The employee/person must identify themselves by signature, initials, code, or other unique identifier.
7) All departments must maintain a list of employees and their unique identifier(s). The department must have a process to ensure it accurately reflects current personnel.

C. Requirements for Recording Information

1) Record information on approved forms.
2) All pages of a technical record must include a name, title, header or type of identification to clearly identify the contents of the record (or information recorded on the document).
3) Record information directly on the technical record.
4) Do not record information on a medium that is not an approved form or technical record.
5) Do not use self-affixing notes or small pieces of paper stapled, paper-clipped or otherwise attached to the technical record. If necessary, create a formal referenced attachment.
6) Use permanent ink (blue or black preferred) that does not smear.
7) Do not use pencil.
8) Avoid highlighters that obscure information if copied or faxed.

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9) Write legibly. Numbers and symbols must be clearly decipherable.
10) Use abbreviations that are generally understood or formally defined in a reference table or legend.
11) Make complete entries.
12) Do not use ditto marks to repeat information. The use of arrows is acceptable if it is entirely clear what the arrows mean.
13) When referencing supporting information, include a complete citation so that the reference is retrievable.

D. Requirements for Voiding Information

1) Entries must be voided in a way that does not obscure the original information.
   a. Draw a single horizontal line through the original entry being voided, so that the legibility of the original entry is maintained.
   b. Do not use correction fluid.
   c. Do not use correction tape.
2) The person voiding the information must sign/initial and date the entry.

E. Requirements for Changing Information

1) This is a two-step process, where voiding the original entry is separate from recording the new entry. Entries must not obscure the original information.
   a. Void the original entry by drawing a single horizontal line through the original entry being voided (See Section 5.D, Requirements for Voiding Information).
   b. Enter the new information so it is clear which information it is replacing. Do not obscure any existing or voided information (See Section 5.C, Requirements for Recording Information). Review the changes to ensure they are complete and accurate.
2) Do NOT write over or through original information.
3) Document the reason for the change, if it is not apparent to the reviewer.
4) The person changing the information must sign/initial and date the entry.

6. RECORDS MAINTENANCE

Records are maintained according to the requirements published in the Quest Diagnostics *Records Management Program Reference Guide*.

7. REFERENCES

- Title 21 (Food and Drug Administration), Code of Federal Regulations, Part 58--*Good Laboratory Practice for Nonclinical Laboratory Studies*, Section 58.130 (e).
- Technical Manual, American Association of Blood Banks, 17th Edition, AABB, 2011.
- Standards for Blood Banks and Transfusion Services, 28th Edition, AABB, 2012.

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8. DOCUMENT HISTORY

Version	Date	Section	Revision	Revised By	Approved By
1	11/5/12	All	QDNQA703 v1.0 renumbered as QDNQA707 to correct duplicate NQA SOP numbering	K. Grimes	K Rupke
1	12/7/12	Page 1	Add SOP type designation to reflect local terminology and electronic approval.	L. Barrett	C. Bowman
1.0A	10/31/16	Header Footer	Add other sites New local version numbering adopted per corporate policy change	L. Barrett	C. Bowman

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