Quest Diagnostics

TRAINING UPDATE

Lab Location:	GEC, SGAH & WAH	**Date Distributed:**	5/14/2012
Department:	Technical staff	**Due Date:**	6/14/2012

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:	
Clerical Errors, Detection and Resolution	**GEC.L21, SGAH.L23, WAH.L23 v002**
Repeat Testing Requirement	**GEC.L12, SGAH.L14, WAH.L14 v002**
Description of change(s):	

Clerical Errors, Detection and Resolution
Section 5: update PI form to Quality Variance form, add read back process to item B.1

Repeat Testing Requirement
Section 5 - update translation of code QNSR, add call documentation

EMPLOYEE SIGNATURES

I have read and understand the procedure described above:

Name	**Signature**	**Date**

Employee signatures are not necessary. Document your compliance with this training update by taking the quiz in the MTS system.

Approved draft for training all sites (version 002)

Non-Technical SOP

Title	**Clerical Errors, Detection and Resolution**	
Prepared by	Leslie Barrett	Date: 3/18/2009
Owner	Robert SanLuis, Jean Buss	Date: 4/23/2012

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

12 month (or new) management review and approval: Signature acknowledges SOP version remains in effect with NO revisions.		
Print Name	**Signature**	**Date**

Form revised 3/31/00

TABLE OF CONTENTS

1. PURPOSE

This policy is intended to aid in the reduction of clerical errors and provide instructions for correction of clerical errors when identified.

2. SCOPE

Applies to all aspects of laboratory testing, including specimen collection, lab orders, test performance and resulting.

3. RESPONSIBILITY

All technical and non-technical staff involved in data entry must comply with this procedure.
Laboratory managers and supervisors must ensure training and compliance with this procedure.

4. DEFINITIONS

Clerical error - transposed letters/numbers, misplaced scientific notations (decimal points), improper abbreviation, and incorrect spelling or mistranslated computer data entry.

LIS – Laboratory Information System

5. PROCEDURE

A. Prevention and Detection of Clerical Errors

1. Requisition slips that are processed in the department are reviewed for completeness and accuracy of data. Information on the slip must match those in the LIS. If there are discrepancies, the ordering process must be halted, and the originating unit or department must be contacted for clarification. When appropriate, fill out a Quality Variance form indicating action taken.

2. Before affixing computer generated labels to any specimen, slides, document, **verify the Name and Medical Record number**.

3. Upon review of instrument/analyzer printouts, make sure that data is legible and is consistent with tests requested.

4. When performing manual entry of results into the LIS or documenting as hard copy, carefully re-read text to verify content accuracy and modify if necessary. Retype the entry if an error is found on reviews. A Quality Variance form must be completed with a copy of the corrected report attached. This is given to the supervisor or designee to review and sign.

5. If calculators are used to perform numeric calculation, verify initial results by repeating calculation. Take care when transcribing calculated results into units reported as set up in the LIS. Verify decimal placing, and look for flagging by the LIS for any invalid entries.

B. Correction of Clerical Errors

1. As soon as a clerical error is identified, the correct result or information is to be relayed to the ordering provider, nurse-in-charge or the appropriate individual immediately. All verbal results must be confirmed by the read back process (the person receiving the results will verify the results, by repeating back the patient name, test name, test results, to the laboratory personnel).
   a. A Corrected report is to be generated indicating:
      - the previous and corrected result
      - Name of the person to whom the corrected report is given
      - Date and Time of the notification
      - **CBACK (call to and read back by)** must be included in the documentation
   b. All pertinent information is to be documented in the LIS under the test being corrected.
   c. The corrected report is generated and attached to the Quality Variance form and submitted to the supervisor or designee for review and possible follow up.

2. All Corrected reports are tracked via a PI database. Reports are retained as specified in the Retention of Records and Materials policy.

Form revised 3/31/00

6. RELATED DOCUMENTS

Process for Documentation Technique Training and Competency Assessment, QA policy
Quality Variance Forms, QA procedure
Retention of Records and Materials, Laboratory policy

7. REFERENCES

None

8. REVISION HISTORY

Version	Date	Reason for Revision	Revised By	Approved By
		Supersedes SOP L039.001		
000	3/24/2010	Updated owner	L. Barrett	L. Loffredo
001	4/23/2012	Updated owners Section 4: add LIS Section 5: update PI form to Quality Variance form, add read back process to item B.1	L. Barrett	L. Loffredo

9. ADDENDA AND APPENDICES

None

Approved draft for training all sites (version 002)

Non-Technical SOP

Title	**Repeat Testing Requirement**	
Prepared by	Leslie Barrett	Date: 1/22/2009
Owner	Lori Loffredo	Date: 1/22/2009

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

12 month (or new) management review and approval: Signature acknowledges SOP version remains in effect with NO revisions.		
Print Name	**Signature**	**Date**

Form revised 3/31/00

TABLE OF CONTENTS

1. PURPOSE

To ensure accurate and reliable test results.

2. SCOPE

All abnormal laboratory testing is reviewed and retested, utilizing the criteria outlined in this procedure.

3. RESPONSIBILITY

Knowledge of this process is the responsibility of all technical laboratory staff.

4. DEFINITIONS

AMR - The Analytical Measurement Range is the range of analyte values that a method can directly measure on the specimen without any dilution, concentration, or other pretreatment not part of the usual assay process

CRR - The Clinically Reportable Range is the range of analyte values that a method can report as a quantitative result, allowing for specimen dilution, concentration, or other pretreatment used to extend the direct analytical measurement range.
The establishment of the CRR is a medical judgment made by the Laboratory director, and is based in part on the assay technology.

5. PROCEDURE

Out of reportable range, and unusual test results must be repeated. Before reporting any of these results or when results meet one or more of the following described criteria, the technologist must retest the patient sample.

- Any result which falls outside the reportable range of an assay. If the assay SOP instructs you to perform a dilution, then the dilution qualifies as the repeat.
- Any result with an attached instrument error code, which specifies repeat testing.

- Any result that exceeds any parameter for repeat testing as specified in the assay SOP.
- Any result that fails a delta check, refer to Delta Check procedure.
- Only critical values that fall outside of the CRR or AMR of an assay.

RESULTS EVALUATION:

1. All repeats must replicate the original result within 10% or the expected analytical accuracy of the assay, which ever is greater.
2. For specimens that exceed the reportable range of the assay, the diluted specimen must not exceed or be within 10% of the upper limit of linearity.
3. For specimens outside of the reportable range of the assay, where dilution or increased sample volume for testing is not an option, the repeat test must confirm the initial finding.
4. Report a numeric answer in preference over a 'greater or less than value' answer.

TROUBLESHOOTING:

1. If the duplicate answer does not agree with the original answer, repeat the assay again in duplicate using the primary or aliquot tube as the specimen source.
2. Re-make all manual dilutions if not performed on-line by the instrument.
3. Check all on-line instrument dilution reservoirs to ensure that they contain the correct diluents.
4. Report the answer that confirmed by the repeat.
5. Notify the supervisor of any problems with specimens that do not repeat.

REPORTING:

1. Indicate as a comment using canned text that the result was repeated.
2. If you are unable to retest because of a QNS specimen, report the original answer with the comment code QNSR which translates to -

   'Due to limited sample size the laboratory is unable to confirm this result by repeat analysis. If the result is inconsistent with clinical symptoms please recollect and submit to confirm analytical findings.'
3. Call the result to the ordering unit or physician.
   - All verbal results must be confirmed by the read back process (the person receiving the results will verify the results, by repeating back the patient name, test name, test results, to the laboratory personnel).
   - Document the notification in the LIS. Name of the person to whom the report is given, Date and Time of the notification and **CBACK** (call to and read back by) must be included in the documentation

6. RELATED DOCUMENTS

Delta Check, Quality Assurance policy

7. REFERENCES

N/A

8. REVISION HISTORY

Version	Date	Reason for Revision	Revised By	Approved By
		Supersedes SOP L044.001		
000	2/1/2010	Updated owner Section 4 – added AMR and CRR Section 5 – revised critical value repeat criteria	L. Barrett	L. Loffredo
001	5/9/2012	Section 5 - update translation of code QNSR, add call documentation	L. Barrett	L. Loffredo

9. ADDENDA AND APPENDICES

None