TRAINING UPDATE

Lab Location:	GEC, SGAH & WAH	**Date Distributed:**	7/10/2014
Department:	Core	**Due Date:**	8/11/2014
		Implementation:	**8/12/2014**

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:
Repeat Testing Requirement GEC.L12, SGAH.L14, WAH.L14 v3
Description of change(s):
Section 4: add Tea, Lookback, unexpected results Section 5: add investigation of unexpected result Section 6: add QC Program, Critical Value & HIL policies Section 9: add unexpected results flow chart This revised SOP will be implemented on August 12, 2014

Document your compliance with this training update by taking the quiz in the MTS system.

Approved draft for training all sites (version 3)

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:	

Review:		
Print Name	**Signature**	**Date**

Form revised 3/31/00

TABLE OF CONTENTS

1. PURPOSE

To ensure accurate and reliable test results.

2. SCOPE

Laboratory results are assessed to determine the need for repeating testing 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.

TEa - The Total Allowable Error is the amount of error that can be tolerated without invalidating the medical usefulness of the analytical result.

Lookback - the term used for the process to determine the accuracy of prior reported test results, after discovery of an “out of control” analytical run (1:3S or 2-levels >2SD). Qualitative methods require look back when QC falls outside of the acceptable range.

Unexpected Results - Biologically improbable results

5. PROCEDURE

When results meet one or more of the following described criteria, the technologist must retest the patient sample.

- Any result that is biologically improbable
- Any result which falls outside the reportable range of an assay as defined per SOP. 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.
- Result that fail delta check may require repeat testing, refer to Delta Check SOP.
- 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 the expected TEa/2 of the assay.
2. Report a numeric answer in accordance with each assay procedure.
3. Use the following guidelines to

INVESTIGATION OF UNEXPECTED RESULTS:

1. Utilize the Unexpected Results Flowchart (see Addendum) to investigate the validity of unexpected results.
2. Examine the results for trends of other lab values from the same analyzer.
3. Trends present: repeat patient testing on the second analyzer, when available.
4. No trends from the initial analyzer: review the patient's prior lab result and review history.
5. Verify QC and instrument operation (Run QC – If QC range does not test suspect performance range pull previous samples and utilize TEa/2 for acceptability criteria).
6. Perform a visual inspection to assess sample integrity, i.e. clots, dilution, sample volume, adequate centrifugation. Inspect instrument syringes for gel and/or signs of damage.
7. Check for interfering substances as reflected in the instrument data transfer or printout via instrument flags or errors.
8. If QC is determined to be the root cause, **stop the process** perform appropriate troubleshooting and repeat the assay. Perform a lookback if required.
9. If root cause is determined to be preanalytic or interference, **stop the process. Alert other lab sections to the specimen problem.**
10. Contact the patient's caregiver about the need to recollect the sample.
11. Cancel the order, reorder in the LIS, and dispatch a phlebotomist to redraw specimen.
12. Notify the laboratory supervisor/manager of the issue or contact the pathologist as necessary.
13. If the root cause cannot be linked to QC, instrument performances, preanalytic, or interfering substances, contact the primary care giver to verify the potential validity of the result, with the patient's clinical presentation.

14. If patient history and presentation support validity of results, **report and follow critical value policy.**
15. If patient history and presentation do not support validity of results, repeat above steps 10 through 12.

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 the result was repeated by appending a canned text comment in the LIS.
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
Critical Values, Laboratory policy
Hemolysis, Icteria and Lipemia Interference, Laboratory policy
Quality Control Program, 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
002	5/16/2014	Section 4: add Tea, Lookback, unexpected results Section 5: add investigation of unexpected result Section 6: add QC Program, Critical Value & HIL policies Section 9: add unexpected results flow chart Footer: version # leading zero's dropped due to new EDCS in use as of 10/7/13.	L. Barrett C Bowman L Loffredo	N. Cacciabeve

9. ADDENDA AND APPENDICES

Unexpected Results Flowchart

Unexpected Results Flowchart