TRAINING UPDATE

Lab Location:	GEC, SGMC & WAH	**Date Distributed:**	11/19/2015
Department:	Technical Mgmt & QA	**Due Date:**	11/30/2015
		Implementation:	**12/1/2015**

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:
Reference Ranges GEC / SGAH / WAH.QA41 v2
Description of change(s):
Section 4: Add gender Section 5: Specify gender studies, add reporting for tests without ranges Section 6: Update SOP title This revised SOP will be implemented on December 1, 2015

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

Approved draft for training (version 2)

Non-Technical SOP

Title	**Reference Ranges**	
Prepared by	Leslie Barrett	Date: 2/3/2012
Owner	Cynthia Bowman-Gholston	Date: 2/3/2012

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:	

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

Form revised 3/31/00

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1. PURPOSE

This procedure outlines the process for determining reference ranges (normal values) and defining those values for tests performed at the hospital sites. The Quest Diagnostic Laboratories at Shady Grove Medical Center and Washington Adventist Hospital have opted to validate instrument and reagent manufacturer normal range studies whenever possible.

2. SCOPE

This procedure applies to all applicable assays and/or analytes tested at the hospital sites.

3. RESPONSIBILITY

The technical supervisor or manager verifies the reference range and ensures that it remains current for all applicable tested and reported analytes.

The Medical Director approves all reference ranges.

4. DEFINITIONS

Reference ranges - Ranges that provide fundamental guidelines for the clinician in making decisions about the “health” of the patient and allow a clinician to assess patient results within an appropriate population. These may also be referred to as normal values or normal ranges.

Adult - greater than 18 years
Child - less than 18 years
Neonate - 0-4 months

Gender – Ranges are defined in the LIS by patient gender (sex). Patients may be registered as male, female or unknown. The male reference range is utilized when gender is unknown.

5. PROCEDURE

A. Establishing the Reference Range Using Manufacturers Reference Range

1. Determine the pre-analytical and analytical factors of the original study, e.g., sex, age, race, etc. as provided by the manufacturer. This can be obtained from the literature published with the reference values or by calling the company's clinical support department.

2. Select 20 persons that satisfy the original study criteria from our healthy population. If the manufacturer provides separate ranges for gender, select 20 persons of each sex for the study.

3. After testing the 20 specimens, examine the results to make sure they represent a statistically homogeneous group of results, i.e., that none of the results appears to be an outlier. To test outliers, Reed's "one-third" rules should be applied. Any apparent outliers must be discarded and new patient specimens obtained to replace those results, so that 20 test results with no outliers are finally secured.

4. The manufacturer's reported reference values are valid for our application if not more than 2 of the 20 tests values (or 10% of the test results) fall outside of the original reported values.

5. If 3 or more test results fall outside these limits, another 20 reference specimens similar to the first 20 must be obtained, again free of outliers.

6. If no more than 2 of these new results fall outside the manufacturers reported reference values, the latter will be acceptable for use.

7. However, if 3 or more again fall outside the limits, validation of a patient population specific reference range must be performed.

8. Results of the study are included in the method validation and must be approved by the Medical Director prior to test implementation.

B. Establishing the Reference Range Using Published literature

Several assays have literature approved reference ranges that vary little among specific patient populations. Examples include glucose, cholesterol and PSA. Establishing these published ranges is acceptable with approval of the Medical Director.

C. Establishing the Reference Range Using the Patient Specific Population

In the instance where neither of the two methods of establishing a reference range as listed above is applicable, a series of 100 samples from healthy individuals representing a reasonable age and sex sampling from the population served by the laboratory is tested. After eliminating outlier points and replacing them with

additional samples to reach a total of 100, a distribution curve is prepared. Cut-offs of around 2SD on either side of the mean as approved by the Medical Director is performed.

D. Tests without Reference Ranges

If there is no established range or a range is not applicable, a comment must be attached to the result stating this unless LIS limitations prohibit it. Alternatively, a comment may be added with a clinical interpretation of the assay.

E. Reference ranges will be included on Laboratory reports when appropriate.

6. RELATED DOCUMENTS

Laboratory Method Validation for Quantitative and Semi-Quantitative Methods, QA procedure
Reference Range Chart (AG.F151)

7. REFERENCES

Clinical and Laboratory Standards Institute (CLSI) guideline C28-A2: How to Define and Determine Reference Intervals in the Clinical Laboratory, Wayne, PA, 2000.

8. REVISION HISTORY

Version	Date	Reason for Revision	Revised By	Approved By
		Supersedes SOPs QA27.000 & QA30.000		
000	10/31/13	Section 6: chart moved from Addenda. Range updated for total Cholesterol, free T4, GGT, CRP, Digoxin, TSH, Beta HCG quant, urine Sodium, urine Potassium, WBC, CBC Range removed for HBA1c, Iron, TIBC Range added for Hgb, Hct, KBT, Retic, WBC, CBC Footer: version # leading zero's dropped due to new EDCS in use as of 10/7/13.	L. Barrett	N. Cacciabeve
1	10/28/15	Section 4: Add gender Section 5: Specify gender studies, add reporting for tests without ranges Section 6: Update SOP title Footer: Version # leading zero's dropped due to new EDCS in use as of 10/7/13	L. Barrett	N. Cacciabeve

9. ADDENDA AND APPENDICES

None