TRAINING UPDATE

Lab Location:	GEC, SGMC & WAH	**Date Distributed:**	2/23/2016
Department:	Technical Mgmt, Tech Specialist & QA	**Due Date:**	3/14/2016
		Implementation:	**3/15/2016**

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

Process for Comparison of Intra/Interlaboratory Test Results GEC/SGAH/WAH.QA16 v1

Description of change(s):

Update title page, remove Nichols Institute in header
Section 5: Add use of recurring calendar (step F)
Section 9: Add reference to EDCS
Section 10: App G updated

This revised SOP will be implemented on March 15, 2016

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

Approved draft for training (version 1)

Non-Technical SOP

Title	**Process for Comparison of Intra/Interlaboratory Test Results**
Prepared by	Susan Kanter Date: 5/10/04
Owner	Quality Assurance Best Practice Team

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 and Title	**Signature**	**Date**

Form revised 3/31/00

TABLE OF CONTENTS

1. PURPOSE

This document sets forth the process for periodic instrument and/or method comparison in Quest Diagnostics laboratories. It defines the process for verifying that an acceptable relationship exists between test results using the same or different methodologies or instruments within a laboratory as well as test results from Rapid Response Laboratories (RRL) vs. the main laboratory.

2. SCOPE

- This process applies to Clinical Pathology departments in the main lab and Rapid Response Laboratories at which test procedures are performed:
  - At the main laboratory and at a Rapid Response Laboratory
  - On multiple instruments within the same laboratory
  - Using more than one method within the same laboratory

  Note: Examples of systems that require method comparison are:
  - Automated vs. manual ABO, Rh, and antibody screening
  - Total PSA on the Bayer Centaur vs. total PSA on the Beckman Access
  - Multiple microbiological ID and sensitivity systems
  - Multiple chemistry, hematology, coagulation, etc. analyzers
  - Multiple ELISA microtiter plate readers
  - Specific gravity on an Atlas™, Clinitek™, dipstick

  Note: Considerations for determining applicability are:
  - Same Analyte: Target analyte is similar, e.g., Estradiol by RIA and Centaur.
  - Same Specimen Type: For purposes of this SOP, serum and plasma are considered as the same specimen type.
  - Sensitivity: Test methods under consideration should detect the target analyte at approximately the same concentration.

- This process does not apply to tests where specimen stability could be exceeded prior to testing at the main laboratory and RRL, e.g., ESR and sperm motility.
- This process does not apply to Anatomic Pathology departments.

3. RESPONSIBILITY

- The **Department or RRL Supervisor** is responsible for ensuring compliance with this process in his/her department or Rapid Response Laboratory.
- The **Technical Supervisor/Technical Consultant** is responsible for implementing this process in the department for which he/she is responsible and for reviewing all comparison data and initiating corrective action, as he/she deems necessary.
- The **Quality Assurance Manager** is responsible for ensuring that all laboratories within the Business Unit participate in this process at the defined frequency.
- The **Laboratory Director** is responsible for the approval of the initial document and any subsequent revisions.

4. DEFINITIONS

Allowable Total Error (TEa): The amount of error that can be tolerated without invalidating the medical usefulness of the analytical result or the maximum amount of error defined for successful performance in proficiency testing.

Analytical Measurement Range (AMR): The AMR 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.

Estimate of Bias: The difference in results obtained by two different methods. It is calculated as the difference in the mean values from multiple analyses of each method.

Grand mean: The average value of all samples run on all instruments or by all methods. The grand mean can be used as a target value to estimate bias when compared to the instrument/method mean.

Instrument/method mean: The average value of multiple samples run on a single instrument or by a single method.

Sample mean: The average value of the same sample when analyzed on multiple instruments or by multiple methods.

5. PROCESS

A. Inter-laboratory Process

1) Select a minimum of five (5) patient specimens that are appropriate for the test method.
   Note: Contact the main lab for assistance if support is needed in obtaining an adequate number of specimens.

2) If possible, for quantitative methods obtain patient specimens with results that span the assay's AMR (low, medium, high).

3) If possible, for qualitative methods obtain patient specimens with positive and negative results.

4) If possible, for semi-quantitative methods obtain patient specimens with positive, negative and equivocal (when applicable) results.

5) An aliquot of the specimen is submitted from the RRL to the main laboratory under conditions required to maintain specimen stability. If preferred, specimens may be sent from the main lab to the RRL.

6) Testing is performed at the RRL and main lab.

7) The designated individual retrieves the main lab and RRL data.

8) The data is submitted to the RRL Laboratory Director, or designee, for evaluation and review.
   Note: Appendices A thru F are provided to assist in the data evaluation.

9) The RRL Laboratory Director, or designee, provides a written summary report to the main laboratory's Medical Director and the main laboratory's QA Manager.

B. Intra-laboratory Process

1) The department selects a minimum of five (5) specimens that are appropriate for the test method.

2) For quantitative methods obtain specimens with results that span the assay's AMR (low, medium, high).

3) For qualitative methods obtain specimens with positive and negative results.

4) For semi-quantitative methods obtain specimens with positive, negative and equivocal (when applicable) results.

5) If possible, analyze the same aliquots on all instruments and by all methods on which the test is performed.

Note: If the use of the same aliquots is not possible due to a large number of instruments and the specimen volume needed, e.g. numerous hematology analyzers, the following scenario is suggested:

a) Divide the instruments into "groups" (i.e., 5 Coulter Gen-S = Group #1)
b) Perform the comparison study within the instrument groups using a different set of specimens for each instrument group.
c) Select one (1) instrument from each instrument group and using a different set of specimens perform the comparison study across the instrument groups on the selected instruments.
d) Continue until all instruments have been compared.

6) Data is submitted to the Technical Supervisor, or designee, for evaluation and review.

C. Data Evaluation Criteria

Application	Individual Result Evaluation	Estimate of Bias
Same Analyte Same / Equivalent Instrument Model* Same Reference Range Two Instrument Comparison **Consult on a case-by-case basis with the BPT if different models from the same vendor are being evaluated.*	Quantitative: 1) Select one instrument as the reference for purposes of comparison. 2) The difference between individual sample results should be < TEa. Qualitative: Results are expected to achieve 100% concordance. 1) An equivocal specimen is acceptable if it remains equivocal or reads "high" negative or "low" positive. a) A high negative is defined as a result that is not < 70% of the cutoff signal b) A low positive is defined as a result that is not > 130% of the cutoff signal 2) Semi-Quantitative results that are converted from an OD or Index (specimen signal ÷ cutoff signal) to a qualitative result are evaluated as qualitative results. 3) Results with a titered or graded result should duplicate within one (+/-1) dilution or grade.	Quantitative: The difference between the instrument/method means should be $\leq$ TEa/4. For example: If the instrument/method means from two (2) instruments are 100 and 106 and the TEa = 24: 1) TEa/4 = 6 and 2) The difference in instrument/method means = 6. 3) The result comparison passes.

Form revised 3/31/00

Application	Individual Result Evaluation	Estimate of Bias
Same Analyte Same / Equivalent Instrument Model* Same Reference Range Three or More Instruments **Consult on a case-by-case basis with the BPT if different models from the same vendor are being evaluated.*	Quantitative: Each individual result must be within the sample mean +/- TEa. For example: If the results from the same specimen on four (4) instruments are 120, 122, 124, and 126, the results are evaluated in this manner. 1) The sample mean for that specimen is 123. 2) The difference of each result from the sample mean should be no greater than the TEa. Qualitative: Results are expected to achieve 100% concordance. 1) An equivocal specimen is acceptable if it remains equivocal or reads "high" negative or "low" positive. a) A high negative is defined as a result that is not < 70% of the cutoff signal b) A low positive is defined as a result that is not > 130% of the cutoff signal 2) Semi-Quantitative results that are converted from an OD or Index (specimen signal ÷ cutoff signal) to a qualitative result are evaluated as qualitative results. 3) Results with a titered or graded result should duplicate within one (+/-1) dilution or grade.	Each instrument/method mean must be within grand mean +/- TEa/4. For example: If the instrument/method mean from all samples from each of four (4) instruments is 100, 106, 108, and 110, the bias is evaluated in this manner. 1) The grand mean across all instruments is equal to 106. 2) Each instrument/method mean should agree with the grand mean within TEa/4.

Form revised 3/31/00

Application	Individual Result Evaluation	Estimate of Bias
Same Analyte Different Instrument/Method Same Reference Range	Quantitative: 1) Select one instrument/ method as the reference for purposes of comparison. a) For intra-laboratory evaluations, select the instrument/method having the higher test volume. b) For inter-laboratory evaluations, the main lab will be the reference method. 2) The difference between individual samples should be < TEa. Qualitative: Results are expected to achieve 100% concordance. 1) An equivocal specimen is acceptable if it remains equivocal or reads "high" negative or "low" positive. 2) A high negative is defined as a result that is not < 70% of the cutoff signal 3) A low positive is defined as a result that is not > 130% of the cutoff signal 4) Semi-Quantitative results that are converted from an OD or Index (specimen signal ÷ cutoff signal) to a qualitative result are evaluated as qualitative results. 5) Results with a titered or graded result should duplicate within one (+/-1) dilution or grade.	1) Intra-Laboratory: Select the data from the instrument/method having the higher test volume as the reference method. The alternate instrument/method mean must be within TEa/3 of the reference instrument/ method mean. For example: If the instrument/ method mean for the reference method is 100 and the instrument/ method means for the alternate method using three (3) instruments are 106, 108, and 110, the bias is evaluated in this manner. a) The grand mean across all instruments is equal to106. b) Each instrument/method mean should agree with the reference method grand mean within TEa/3. 2) Inter-Laboratory: The RRL instrument/method mean must be within the main lab instrument/ method mean within TEa/2. For example: If the instrument/ method mean from the RRL is 100 and the instrument/method mean from the main lab is 110, the bias is evaluated in this manner. a) The difference in instrument/ method means is equal to 10. b) The TEa/2 should be ≤ 10.

Form revised 3/31/00

Application	Individual Result Evaluation	Estimate of Bias
Same Analyte Different Method Different Reference Range *Applies to quantitative analysis only.*	Individual results from alternate platform must be within main platform results +/- TEa, after adjustment for the known bias.	The observed bias for the alternate platform should be within the instrument/method mean +/- TEa/2, after adjustment for the known bias.

Note #1: TEa Specifications
Current TEa tables are available on the Quest Diagnostics Intranet under "Units & Functions", "Medical Quality", "Quality Control", "QC SOPs" or in QLS pathway 10,7,6,2 (QC Allowable Total Error List).

If the TEa has not been defined for the analyte, it can be determined by either of the following methods:

1) Calculated based on ¼ of the reference interval (Tonk's Criteria)
   e.g., The reference interval for a test with a reference range of 100-160 is 60. That is 160 (the highest normal) minus 100 (the lowest normal).
   - In this case, the TEa is 15, i.e. ¼ of 60.
   - At the upper limit of the reference interval, the criterion in percentage calculates to be 15/160 X 100 or 9.4%. Apply the percentage criteria for specimens with results that are above the reference interval.

2) Calculated Based TEa on Interlab QC data
   Since CLIA General Chemistry PT requirements are specified for the more routine analytes, for non-regulated obtain the Interlab QC data for that peer group. Use the target +/- 3 SD or +/- 3 CV. This is the general criterion used by CMS in CLIA 88 and by CAP for those tests that have defined PT limits. The value of 3 SD or 3 CV becomes the TEa.

D. Frequency
   The minimum frequency for result comparison is every six (6) months.

E. Corrective Action
   1) Same Analyte, Same/Equivalent Instrument Model, Same Reference Range:
      Service the instrument as needed to bring the comparison data into specifications.

   2) Same Analyte, Different Instrument/Method, Same Reference Range:
      Initiate appropriate corrective action that may include instrument/method replacement.

   3) Same Analyte, Different Method, Different Reference Range:
      Corrective action is not needed if the known relationship remains as expected.

Form revised 3/31/00

If the relationship varies from the expected, initiate an investigation to determine which method is at fault. Implement corrective action to bring the methods into specifications.

4) Patient testing will not be performed on any analyte using any test system that does not provide acceptable comparison data.

F. Documentation

1) Documentation will be maintained of the result comparison studies as well as any corrective action that is required should the comparison study not meet the acceptability requirements.
2) The QA Recurring Calendar is utilized as a tool to facilitate this process.

6. RECORDS MAINTENANCE

Records are maintained according to the requirements for "Laboratory Operations Management Reports" available on the Quest Diagnostics intranet under "Units & Functions," "Legal & Compliance," "Policies & Procedures," "Records Management Program," "Retention Schedule by Function," "Laboratory Operations."

7. REFERENCES

1. *Federal Register*, Part III, Department of Health and Human Services, 42 CFR Part 493, January 24, 2003, 493.1281 (a)

2. Appendix C "Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services" Published by CMS on January 12, 2004

3. Garber CC and Carey RN, "Evaluation of Method" *in Clinical Chemistry: theory, analysis and correlation*. Kaplan LA and Pesce AJ, eds., Mosby Co., St. Louis, 2003, 4th Edition, Ch 22, pages 402-426.

8. REVISION HISTORY

Version	Date	Reason for Revision	Revised By	Approved By
Corp	5/18/09	Minor adjustment to format to meet QDNI-Chantilly SOP format requirements. Supersedes SOP QA209.000	L Barrett	C Bowman-Gholston

000	2/5/16	Update title page, remove Nichols Institute in header Section 5: Add use of recurring calendar (step F) Section 9: Add reference to EDCS Section 10: App G updated Footer: version # leading zero's dropped due to new EDCS in use as of 10/7/13.	L Barrett	C Bowman-Gholston

9. PROCEDURE RETIREMENT

Version	Date	Reason for retirement/superseded by	Name
		Refer to the SmartSolve EDCS.	

10. APPENDICES

Appendix	File Name	Title
A	AppAInstCompare2.xls	Instrument to Instrument Comparison Study: 2 Instrument (Same or equivalent instrument, same reference range, 2 instruments)
B	AppBInstCompare3.xls	Instrument to Instrument Comparison Study: ≥3 Instruments (Same or equivalent instrument, same reference range, 3 or more instruments)
C	AppCMethodCompareLab.xls	Instrument to Instrument Comparison Study: Intra-Lab (Different method, same reference range, within laboratory)
D	AppDMethodCompareRRL.xls	Instrument to Instrument Comparison Study: Inter-Lab (Different method, same reference range, main lab vs. RRL)
E	AppEInstCompareFactor.xls	Method to Method: Known Bias, Different Method
F	AppFQual-Semi-Quant.xls	Qualitative/Semi-Quantitative Comparison Study
G	AppGTestAnalyzerList.doc	Test and Analyzer List

TEST and ANALYZER LIST

Chemistry - Dimension Analyzers

ACTM	Acetaminophen
ALTI	Alanine Aminotransferase
ALB	Albumin
ETOH	Alcohol (Ethyl)
ALPI	Alkaline Phosphatase
AMM	Ammonia
AMY	Amylase
AST	Aspartate Aminotransferase
DBIL	Bilirubin, Direct
TBIL	Bilirubin, Total
CA	Calcium
CRBM	Carbamazepine
CTNI	Cardiac Troponin-I
CL	Chloride
HDLC	Cholesterol, HDL
CHOL	Cholesterol, Total
CRP	C-Reactive Protein
CKI	Creatine Kinase
CREA	Creatinine
DGNA	Digoxin
CO2	Enzymatic Carbonate
FERR	Ferritin
FOLAC	Folate
FT4	Free T4
GGT	Gamma Glutamyl Transferase
GENT	Gentamicin
GLUC	Glucose
HA1C	Hemoglobin A1C

HCG	Human Chorionic Gonadotropin
IRON	Iron
TIBC	Iron Binding Capacity, Total
LA	Lactic Acid (Lactate)
LDI	Lactic Dehydrogenase
LIPA	Lipase
LITH	Lithium
MG	Magnesium
MMB	Mass Creatine Kinase MB Isoenzyme
MYO	Myoglobin
PHNO	Phenobarbital
PTN	Phenytoin
PHOS	Phosphorus
K	Potassium
PRALB	Prealbumin
PSAT	PSA Total
SAL	Salicylate
NA	Sodium
THEO	Theophylline
TSH	Thyroid Stimulating Hormone
TOBR	Tobramycin
TP	Total Protein
TGL	Triglycerides
BUN	Urea Nitrogen
URCA	Uric Acid
VALP	Valproic acid
VANC	Vancomycin
VB12	Vitamin B12

QUAL	AMPH	Urine Amphetamine/Methamphetamine Screen
	BARB	Urine Barbiturate Screen
	BENZ	Urine Benzodiazepines Screen
	COC	Urine Cocaine Metabolite Screen
	OPI	Urine Opiates
	PCP	Urine Phencyclidine Screen (PCP)
	THC	Urine Cannabinoids Screen (THC)

UR	CREA	Creatinine, Urine
	K	Potassium, Urine
	NA	Sodium, Urine
	UCFP	Protein, Urine and CSF
	GLUC	Glucose, Urine

Calc	% Iron Sat	% Iron Saturation
	A/G Ratio	A/G Ratio
	IBIL	Bilirubin, Indirect
	AGAP	Anion Gap
	ALDL	Cholesterol, LDL

Other Chemistry

BNP	Triage vs. Centaur
CTNI	Xpand vs. iSTAT (GEC only)

Hematology

LH750

WBC	White Blood Cell
RBC	Red Blood Cell
HGB	Hemoglobin
HCT	Hematocrit
MCV	Mean Cell Volume
MCH	Mean Corpuscular Hemoglobin
MCHC	Mean Corpuscular Hemoglobin Concentration
RDW	Red Cell distribution Width
DIFF	Differential Count
PLT	Platelet
MPV	Mean Platelet Volume
RETIC	Reticulocyte Count

Manual vs. Automated	
PLT	Platelet Count
ESR	Sed Rate

Coagulation

Stagos

PT	Prothrombin Time and INR
APPT	Activated Partial Thromboplastin Time
Fibro	Fibrinogen
D-Dimer	D Dimer
TT	Thrombin Time (WAH only)

GEC only	
	LH vs. back up analyzer

Urinalysis

Manual vs Automated

Glucose
Bilirubin
Ketone
Blood
Protein
Nitrite
Leukocytes
Specific Gravity (Refractometer, Iris, Dipstick)
pH
Urobilinogen
UA Microscopic
Iris Body Fluid

Miscellaneous

Qual HCG kit comparison