TRAINING UPDATE

Lab Location:	GEC, SGMC & WAH	**Date Distributed:**	8/19/2019
Department:	Technical Specialists, Mgmt & QA	**Due Date:**	9/15/2019
		Implementation:	**9/15/2019**

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

Comparison of Intra-laboratory Test Results SGMC.QA978 v1

Instrument to Instrument Comparison Study for 2 Equivalent Instruments (Same or equivalent instrument, same reference range, 2 instruments) AG.F458

Instrument to Instrument Comparison Study: Intra-Lab (Different method, same reference range, within laboratory) AG.F459

BNP Comparison Study AG.F460
Method to Method: Known Bias, Different Method Comparison AG.F461

Qualitative/Semi-Quantitative Comparison Study AG.F462

Description of change(s):

Header: Updated parent facility, changed WAH to WOMC
Section 2: Replaced Iris with AUWi PRO
Section 5: Updated references to worksheets
Section 6: Added worksheets
Section 9: Moved worksheets to 'forms'; Added POCT comparison studies

Note: The forms are NOT attached.
They are excel worksheets that perform the necessary calculations & are nearly identical to the QD versions. They will be placed on the G drive and emailed.

This SOP and Forms will be implemented on September 15, 2019

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

Non-Technical SOP

Title	**Comparison of Intra-laboratory Test Results**	
Prepared by	Leslie Barrett	Date: 9/28/2017
Owner	Cynthia Bowman-Gholston, Robert SanLuis	Date: 9/28/2017

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 describes the process for periodic instrument and/or method comparison by providing the steps for verifying that an acceptable relationship exists between test results using the same or different methodologies or instruments within a laboratory.

2. SCOPE

This procedure applies to test procedures that are performed

- On multiple instruments within the same laboratory
- Using more than one method within the same laboratory
- Using the same or a different method to test an analyte in point of care and the main laboratory

Note: Examples of systems that require method comparison are:

- Automated vs. manual ABO, Rh, and antibody screening
- BNP on the Centaur vs. BNP by Triage Meter
- Multiple chemistry, hematology, coagulation, etc. analyzers
- Specific gravity by refractometer, dipstick, Clinitek, AUWi PRO

3. RESPONSIBILITY

The Technical Supervisor/Technical Consultant is responsible for implementing this process, ensuring it is performed at the defined frequency and for reviewing all comparison data and initiating corrective action, as necessary.

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.

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. PROCEDURE

A. 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 insufficient samples that span the assay range are available, then 'simulated' (analyte-spike) specimen samples may be used. For example, positive specimens for urine drugs of abuse.
6. If possible, analyze the same aliquots on all instruments and by all methods on which the test is performed.
7. Data is submitted to the Technical Supervisor, or designee, for evaluation and review. Refer to appendices for worksheets with calculations.

B. Data Evaluation Criteria

1. Same Analyte and Same / Equivalent Instrument Model with Same Reference Range, Two Instrument Comparison

Quantitative (use AG.F458 worksheet)
Individual Result Evaluation: 1) Select one instrument as the reference for purposes of comparison. 2) The difference between individual sample results should be < TEa.
Estimate of Bias: The difference between the instrument / method means should be < TEa/4. For example: If the from two (2) instruments are 100 and 106 and the TEa = 24: 1) TEa/4 = 6 and 2) The difference in means = 6. 3) The result comparison passes.

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Qualitative (use AG.F462 worksheet)
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.

2. Same Analyte by Different Instrument / Method with Same Reference Range

Quantitative (use AG.F459 or BNP-specific worksheet [AG.F460])
Individual Result Evaluation: 1) Select one instrument / method as the reference for purposes of comparison. 2) The difference between individual sample results should be < TEa.
Estimate of Bias: 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.
Qualitative (use AG.F462 worksheet)
Qualitative: Results are expected to achieve 100% concordance. 1) Semi-Quantitative results that are converted from an OD or Index (specimen signal ÷ cutoff signal) to a qualitative result are evaluated as qualitative results. 2) Results with a titered or graded result should duplicate within one (+/-1) dilution or grade.

3. Same Analyte Different Method with Different Reference Range

Quantitative (use AG.F461 worksheet)
Individual Result Evaluation: Individual results from alternate platform must be within main platform results +/- TEa, after adjustment for the known bias
Estimate of Bias: The observed bias for the alternate platform should be within the instrument/method mean +/- TEa/2, after adjustment for the known bias.

C. Frequency

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

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D. Corrective Action

1. Same Analyte, Same/Equivalent Instrument Model, Same Reference Range:
Service the instrument as needed to bring the comparison data into specifications. If troubleshooting does not bring data info specification, estimate bias at TEA/3 and obtain approval from the medical director.

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. 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.

E. 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. RELATED DOCUMENTS

Current Allowable Total Error Specifications at
http://questnet1.qdx.com/Business_Groups/Medical/qc/docs/qc_bpt_tea.xls

Instrument to Instrument Comparison Study for 2 Equivalent Instruments (Same or equivalent instrument, same reference range, 2 instruments) (AG.F458)
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BNP Comparison Study (AG.F460)
Method to Method: Known Bias, Different Method Comparison (AG.F461)
Qualitative/Semi-Quantitative Comparison Study (AG.F462)

7. REFERENCES

Process for Comparison of Intra/Interlaboratory Test Results, Quality Assurance Best Practice Team, 6/30/2005

8. REVISION HISTORY

Version	Date	Reason for Revision	Revised By	Approved By
		Supersedes SGAH/WAH/GEC.QA16.1		
0	8/8/19	Header: Updated parent facility, changed WAH to WOMC Section 2: Replaced Iris with AUWi PRO Section 5: Updated references to worksheets Section 6: Added worksheets Section 9: Moved worksheets to 'forms'; Added POCT comparison studies	L Barrett S Codina	R SanLuis C Bowman-Gholston

9. ADDENDA AND APPENDICES

Appendix	Title
A	Point of Care Comparison Studies
B	Test and Analyzer List

Appendix A

Point of Care Comparison Studies

Step	Action
1	Point of care meters will be compared to laboratory instruments at least once every six months if a particular analyte is tested in both locations.
2	A single meter will be compared to a single laboratory instrument that performs equivalent testing using this procedure. Additional meters will be compared to the test meter.
3	When performing comparisons using the Roche AccuChek II glucose and Abbott iStat meters, a specimen will be collected in a vacutainer tube containing lithium heparin. The specimen will be tested on the point of care meter using whole blood first. Then, the specimen will be centrifuged and the plasma will be tested using the laboratory method.
4	Point of care comparisons will be reported using the POCT Instrument Comparison Approval Form.

Appendix B

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

Sysmex

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 Instruments	
	Sysmex body Fluid

GEC only	
	Sysmex vs. back up analyzer

Urinalysis

Manual vs Automated Instruments

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

Coagulation

Stagos

PT	Prothrombin Time and INR
APPT	Activated Partial Thromboplastin Time
Fibro	Fibrinogen
D-Dimer	D Dimer