

## TRAINING UPDATE

**Lab Location:** GEC, SGMC & WAH  
**Department:** Core

**Date Distributed:** 8/3/2016  
**Due Date:** 8/23/2016  
**Implementation:** 8/23/2016

### DESCRIPTION OF PROCEDURE REVISION

<b>Name of procedure:</b>
<b>New Reagent Lot or Shipment Comparison Study (Quant) Form AG.F217.3</b>
<b>Description of change(s):</b>
<p>Revised the cell for Reagent Lot Number to also include Expiration Date.</p> <p>When using the form, record the lot # <b>AND</b> expiration date for both the current and new reagents in the space provided.</p> <p><b>This revised FORM will be implemented on August 23, 2016</b></p>

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

**New Reagent Lot or Shipment Comparison Study Form**  
**QUANTITATIVE RESULTS**

**Instructions:** Fill in all blue sections.

**NOTE:** QC are required for all New Ship Dates, whereas QC **plus** patient's samples are required for lot changes.

Analyte: Method:

Reagent Lot number <b>and Exp Date</b>	Received Date:	Room Temperature (20 - 25° C)	Reason for Calibration (Put an X in box)		
			New Lot / Shipment	<input type="checkbox"/> Instrument Related	QC Problem
			Calibration Due		

Current    
 New  

**Allowable Total Error**

TEa (percent):	%
Units:	
TEa/2 %	0.0%
TEa/2 Units	0.0000

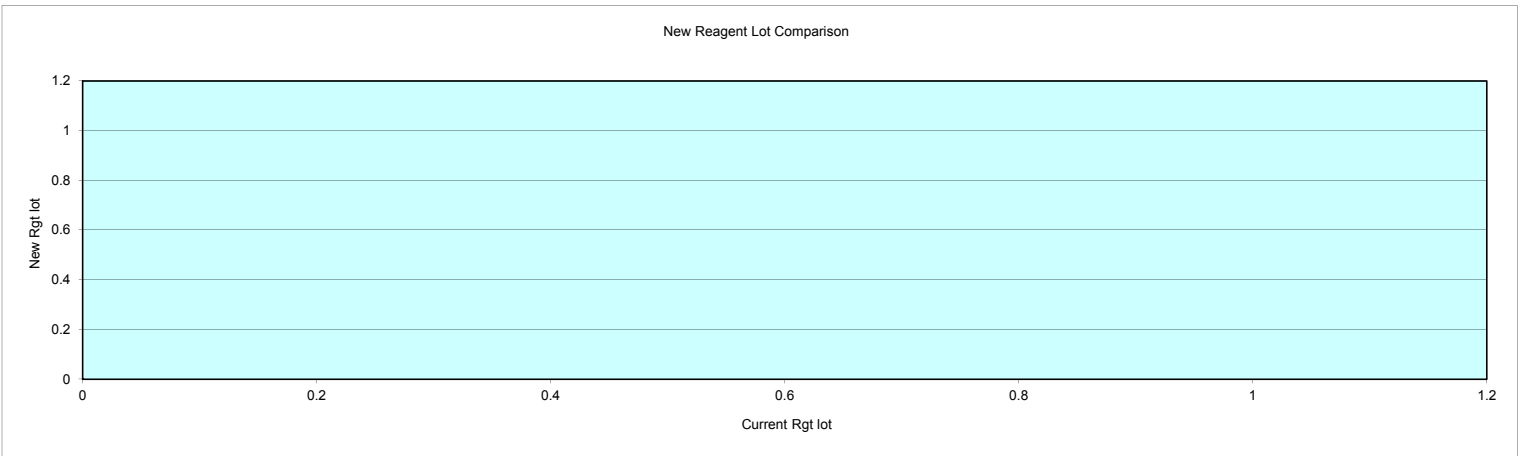
Calibrator Lot & Exp. Date:	QC 1 Lot & Exp. Date:	
	QC 2 Lot & Exp. Date:	
	QC 3 Lot & Exp. Date:	
	QC 4 Lot & Exp. Date:	

Sample #	Sample ID	Current Reagent Lot	New Reagent Lot
Patient 1	1		
Patient 2	2		
Patient 3	3		
Patient 4	4		
Patient 5	5		
Patient 6	6		
Patient 7	7		
Patient 8	8		
Patient 9	9		
Patient 10	10		

Reference Value	Difference for Individual Samples		Low Limit Evaluation	High Limit Evaluation
	MIN TEa/2 Acceptable	MAX TEa/2 Acceptable		
0.000	0.000	0.000	Accept	Accept
0.000	0.000	0.000	Accept	Accept
0.000	0.000	0.000	Accept	Accept
0.000	0.000	0.000	Accept	Accept
0.000	0.000	0.000	Accept	Accept
0.000	0.000	0.000	Accept	Accept
0.000	0.000	0.000	Accept	Accept
0.000	0.000	0.000	Accept	Accept
0.000	0.000	0.000	Accept	Accept
0.000	0.000	0.000	Accept	Accept

Count	0	0
Mean	#DIV/0!	#DIV/0!
Bias %:		#DIV/0!
Bias units:		#DIV/0!
TEa/4 in %:		0.000%
TEa/4 in units:		0.000
Estimate of Bias:		#DIV/0!

	Current Reagent QC		New Reagent QC	
	Expected Mean	Expected SD	New lot result	SDI
QC1				Accept/Fail
QC2				
QC3				
QC4				



**Individual difference:** Difference between results with old and new reagents must not exceed the allowable total error (Tea/2) for the assay.  
**Estimate of Bias:** Mean value for the new reagent must not vary from the old reagent by more than TEa/4.  
**QC results:** QC results for new reagent lot should fall within range for old lot of reagent.  
*If above criteria are not met (indicated in red), review data with lab director or designee before releasing results.*

Comments:

Tech Code:   
 AG.F217.3

Date:

Reviewed by:

Date:   
 Rev 8/2016