TRAINING UPDATE

Lab Location:	GEC, SGMC & WAH	**Date Distributed:**	8/31/2016
Department:	Core	**Due Date:**	9/20/2016
		Implementation:	**9/20/2016**

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:
New Reagent Lot or Shipment Comparison Study (Quant) Form AG.F217.4
Description of change(s):
Changed acceptability criteria for QC comparison to SDI of 1.5 (current form has 1.0) Added TEA table to last tab This revised FORM will be implemented on September 20, 2016

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

APPENDIX A Bench Level Approval

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 and Exp Date	Received Date:	Room Temperature (20 - 25° C)	Reason for Calibration (Put an X in box)			
				New Lot / Shipment	□ Instrument Related	QC Problem	Calibration Due
Current							
New							

Allowable Total Error

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

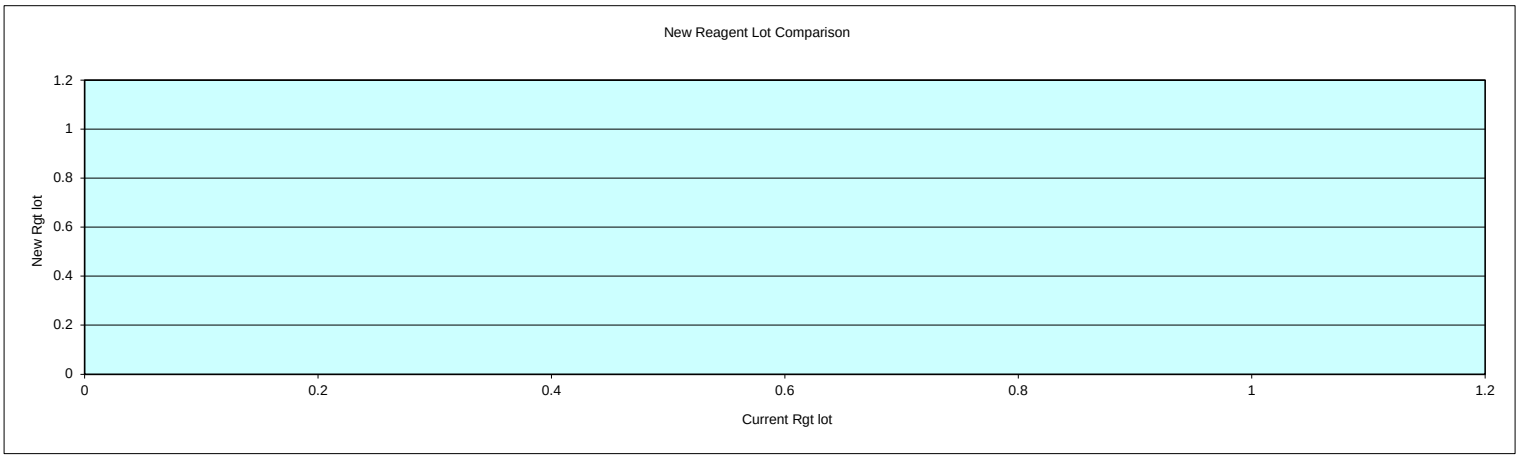
Calibrator Lot & Exp. Date:	QC 1 Lot & Exp. Date:	
	QC 2 Lot & Exp. Date:	
	QC 3 Lot & Exp. Date:	
	QC 4 Lot & Exp. Date:	

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		

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!

	MIN TEa/2	***MAX Tea/2***	***Difference for Individual Samples***	
Reference Value	Minimum Acceptable	Maximum Acceptable	Low Limit Evaluation	High Limit Evaluation
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

	Current Reagent QC		New Reagent QC		
	Expected Mean	*Expected SD*	*New lot result*	SDI	Accept/Fail
QC1					
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: **Date:** **Reviewed by:** **Date:**

Quest Diagnostics™

TEa Table

Germantown Emergency Center
Shady Grove Medical Center
Washington Adventist Hospital

Chemistry

Method	TEa (percent)	Absolute Value (TEa Units)	Units
ALB	10	0.4	g/dL
ACTM	25	4.8	ug/mL
ALC (ETOH)	25	9	mg/dL
ALPI	30	10	U/L
ALTI	20	10	U/L
AMON (AMM)	25	12	umol/L
AMY	30	10	U/L
AST	20	10	U/L
BNP	30	30	pg/mL
BUN	9	2	mg/dL
CA	6	0.5	mg/dL
CHOL	10	6	mg/dL
CKI	30	10	U/L
CL	5	4	mmol/L
CRBM	25	1	ug/mL
CREA (CRE2)	15	0.3	mg/dL
CREA (CRE2), Urine	17	4	mg/dL
CRP	30	0.4	mg/dL
CTNI	30	0.2	ng/mL
CO2	30	5	mmol/L
DBIL	20	0.15	mg/dL
DGNA	20	0.2	ng/mL
Ferrtin	20	9	ng/mL
Folate	30	2	ng/mL
FT4	22	0.2	ng/dL
GENT	25	0.4	ug/mL
GGT	30	10	U/L
GLUC	10	6	mg/dL
HCG	20	2	mIU/mL
HDLC	17	4	mg/dL
Hemoglobin A1C	6	0.4	%
iPTH	30	10	pg/mL

Chemistry

Method	TEa (percent)	Absolute Value (TEa Units)	Units
Iron	20	10	ug/dL
K	0.5	0.5	mmol/L
K, Urine	29	4	mmol/L
Ketone (β-Hydroxybutyrate)	10	0.5	mmol/L
LA	30	1.8	mmol/L
LDI	20	10	U/L
LITH	20	0.3	mmol/L
LIPL	30	10	U/L
MG	15	0.4	mg/dL
MMB	20	3	ng/mL
MYO	30	10	ng/mL
NA (Sodium)	4	4	mmol/L
NA (Sodium), Urine	26	6	mmol/L
PHNO	20	2	ug/mL
PHOS	11	0.3	mg/dL
PreAlbumin	25	5	mg/dL
PTN	25	1	ug/mL
SAL	20	22	mg/dL
TBIL	20	0.4	mg/dL
TGL	25	8	mg/dL
THEO	25	1	ug/mL
TIBC	20	10	ug/dL
TOBR	25	0.4	ug/mL
TP	10	0.4	g/dL
TP, Urine	30	6	mg/dL
TPSA	22	0.2	ng/mL
TSH	15	0.06	uIU/mL
UCFP (TP, Fluid)	20	10	mg/dL
URCA	17	1	mg/dL
VALP	25	4	ug/mL
VANC	25	1.6	ug/mL
Vitamin B12	30	70	pg/mL

Hematology

Method	TEa (percent)	Absolute Value (TEa Units)	Units
WBC	15	0.5	thous/uL
LY%	15	1	%
MO%	25	1	%
NE%	7.5	1	%
RBC	6	0.4	Mill/uL
HGB	7	0.6	g/dL
MCV	6	0	fL
RDW	6	0	%
PLT	25	9	thous/uL
Retic	21	0.75	%
ESR	40	10	mm/hr

Coagulation

Method	TEa (percent)	Absolute Value (TEa Units)	Units
aPTT	15	0	sec
D-Dimer	30	0.125	ug/mL
Fibrinogen	20	0	mg/dL
INR	20	0	
PT	15	0	sec
Thrombin Time	15	0	sec