TRAINING UPDATE

Lab Location:	GEC, SGMC & WAH	**Date Distributed:**	5/16/2016
Department:	Core	**Due Date:**	6/13/2016
		Implementation:	**6/14/2016**

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

Reagent Parallel Testing GEC / SGAH / WAH.QA37 v1

New Reagent Lot or Shipment Comparison Study (Quant) Form AG.F217.2

Description of change(s):

SOP -

Section 4: add TEA

Section 5.1: add documentation description

Section 5.2: specify wording on green label

Section 5.2.1: add use of orange label

Section 5.2.2: add use of blue & orange date labels

Section 5.3: add calculations done by quant form, add corrective action

FORM –

- Has 4 tabs (TEA/4, TEA/3, TEA/2 & TEA); heading at top of each specifies approval level.
- Info & data is entered on TEA/4 tab (the other tabs will pre-populate from it).
- If testing is NOT acceptable at TEA/4, review TEA/3 tab and seek appropriate approval if that is acceptable. If not, proceed to TEA/2 tab and so forth.

The revised SOP & FORM will be implemented on June 14, 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	**Reagent Parallel Testing**	
Prepared by	Jean Buss, Robert SanLuis	Date: 4/7/2011
Owner	Cynthia Bowman-Gholston	Date: 4/7/2011

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

TABLE OF CONTENTS

1. PURPOSE

This procedure defines the process for validation of new lots, new shipments, and new batches of reagent before or concurrent with use for patient testing.

2. SCOPE

This SOP applies to all personnel who perform assay/sample testing.

3. RESPONSIBILITY

The Supervisor is responsible for ensuring compliance with this SOP and that documentation of results is filed appropriately in each department.

The senior QA specialist is responsible for content and review of this procedure.

4. DEFINITIONS

New Lot to Old Lot comparison: New reagent lots are checked against prior lots or known standards before or concurrent with being placed in use.

Same Lot comparison: Same lots received on different dates checked against prior lot or known standard before or concurrent with being placed in use.

TEa: Total Allowable Error; TEa is the amount of error that can be tolerated without invalidating the medical usefulness of the analytical result.

5. PROCEDURE

5.1 General Information

A. The verification of reagent performance is required for all new shipment dates (even if the lot number is the same) and every time the lot number changes. Reagent parallel testing must be documented.

B. A comparison of kits is performed to ensure that a new kit lot does not alter the performance of the tests.
   1. For qualitative tests, this is accomplished by running kit controls to confirm the manufacturer's ranges, and by running External Controls to check for bias between the kits.
   2. For quantitative tests, this is accomplished by running kit controls to confirm the manufacturer's ranges, by running External Controls to check for bias between the kits and by testing at least 2 patient samples run simultaneously on both kits to check for equivalency.

C. Documentation
   1. Comparisons for quantitative tests are recorded on the New Reagent Lot or Shipment Comparison Study (Quant) Form. Results are recorded on the Comparison (TEA/4) tab. The form will perform all calculations.
   2. The Lot to Lot Cross Check Log is used for qualitative test comparisons.
   3. An alternative log may be used as specified in the test SOP (i.e. PFA-100, Coag lot conversion).

5.2 Reagent Testing

5.2.1 Parallel testing when a new lot of reagent is received in the laboratory

All new lot of reagents, kits and controls must be labeled with an orange "Do Not Use This Lot Number" sticker and be logged on the electronic receipt log.

A. For Qualitative Analysis Reagents / Kits / Controls

1. For kits that contain the controls
   a. Run the controls from the old kit on the new reagent and the controls from the new kit on the old reagent
   b. Label the kits with the green "This Lot is Ready to Use" sticker.

2. For kits with controls external to the kit
   a. Run the external positive and negative controls on both the old and new kit.
   b. Label the kits with the green "This Lot is Ready to Use" sticker.

3. For test with 'onboard' or 'built in controls'
   a. Run the external positive and negative controls.
   b. Positive and negative external and 'onboard' controls must be definite positive or negative.
   c. Label the kits with the "This Lot is Ready to Use" stickers.

Form revised 3/31/00

4. Controls
   a. Controls will be run with reagents that have already been tested.
   b. Positive and negative controls must be definite positive and negative. Any borderline results are not accepted.
   c. Label with the green "This Lot is Ready to Use" sticker.

B. For Quantitative Analysis Reagents / Controls

1. Reagent
   a. Reagent validation for those analytes that are new lot numbers will be performed in conjunction with Calibration.
   b. Calibration material (not otherwise in use as a calibrator), control material of known performance, and patient samples may be used for crosschecking reagents.
   c. See the Calibration procedure for each analyzer for the detailed procedure.
   d. Label reagent with the green "This Lot is Ready to Use" sticker.

2. Controls are run as per the Quality Control Program policy.

5.2.2 Reagents / Kit / Control of the same lot number that is presently being used with different ship and/or receipt dates

Reagents/Kit/Control of the same lot number with different ship and/or receipt date must be labeled with both a blue sticker and an orange date label, and must be logged on the electronic receipt log.

A. For Qualitative Analysis Reagents / Kits / Controls

1. For kits that contain the controls
   a. Run the controls from the old kit on the new reagent and the controls from the new kit on the old reagent
   b. Label the kits with the green "This Lot is Ready to Use" sticker.

2. For kits with controls external to the kit
   a. Run the external positive and negative controls on both the old and new kit.
   b. Label the kits with the green "This Lot is Ready to Use" sticker

3. For test with 'onboard' or 'built in controls'
   a. Run the external positive and negative controls
   b. Positive and negative external and 'onboard' controls must be definite positive or negative.
   c. Label the kits with the green "This Lot is Ready to Use" stickers.

4. Controls
   a. Controls will be run with reagents that have already been tested.
   b. Positive and negative controls must be definite positive and negative. Any borderline results are not accepted.
   c. Label controls with the green "This Lot is Ready to Use" stickers.

B. For Quantitative Analysis Reagents / Controls

1. Reagent
   a. Run the current lot of controls using the new reagent.
   b. The control values should be within the 2SD limit for that analyte.
   c. Label the reagent with the green "This Lot is Ready to Use" sticker.

2. Controls
   a. Run all levels of the control with the current lot of reagent.
   b. The control values should be within the 2SD limit for that analyte.
   c. Label the controls with the green "Ready to Use" stickers.

5.3 Analyze Data

5.3.1 Quantitative results of reagent cross checks must be evaluated according to statistical methods ~~and will have an acceptable target range within the TAe, exhibit results within the acceptable calibration criteria and control range for the analyte, with results documented and reviewed.~~ The New Reagent Lot or Shipment Comparison Study (Quant) Form performs the calculations.

- Individual difference between results with old and new reagents must not exceed half 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 one fourth of the TEa (TEa/4).
  - The technical supervisor or above may approve a variation between old and new lot of one third of the TEa (TEa/3).
  - The technical director or above may approve a variation between old and new lot of one half of the TEa (TEa/2).
  - Only the medical director can approve the variation at straight TEa.
  - **Note**: Data entered on the TEA/4 tab of the comparison form will pre-fill the other tabs (TEA/3, TEA/2 and TEA).
- QC results for new reagent lot should fall within range for old lot of reagent.

5.3.2 Positive controls must be Positive and Negative controls must be Negative. Any borderline results are not acceptable and must be repeated. Patient results should match prior results.

5.3.3 Corrective action for failures

A failed lot-to-lot requires additional troubleshooting including but not limited to the following:

- How is the current reagent lot QC running against the peer?
- Was there a performance shift with the implementation of the current lot?
- Was there a recent calibration performed with a new lot of calibrator that caused a shift in performance?
- Is the same lot of calibrator being used or is it a new lot number?
- Has one of the other system labs already worked through this new lot implementation with or without issue?
- How does the current lot perform instrument to instrument how is the current QC performance instrument to instrument?

After considering the above questions, if all looks well then recalibrate and repeat the lot-to-lot comparison.

If the above criteria are not met, then perform an extended lot-to-lot comparison as well as an instrument to instrument comparison as needed utilizing our instrument to instrument criteria to decide our next steps.

- If the extended comparison passes and the instrument to instrument is acceptable, then QC ranges may be adjusted slightly as needed.
- If the extended studies fail, then proceed to extended troubleshooting and contact the manufacturer to work through the problem.

6. RELATED DOCUMENTS

Analyte/Test technical SOPs
Appropriate Analyzer Calibration procedures
Quality Control Program, QA procedure
Reagent Labeling and Handling, QA procedure
Coagulation Reagent Lot Conversion
Lot to Lot Cross Check Log (AG.F104)
New Reagent Lot or Shipment Comparison Study (Quant) Form (AG.F217)
SOP specific Cross Check forms

7. REFERENCES

Department-specific Checklists, College of American Pathologists, Laboratory Accreditation Program, Northfield, IL 60093

8. REVISION HISTORY

Version	Date	Reason for Revision	Revised By	Approved By
		Supersedes SOP L048.001		
000	4/8/16	Section 3: update job titles Section 4: add TEa Section 5.1: add documentation description Section 5.2: specify wording on green label Section 5.2.1: add use of orange label Section 5.2.2: add use of blue & orange date labels Section 5.3: add calculations done by quant form, add corrective action Section 6: add forms and Coag SOP Footer: version # leading zero's dropped due to new EDCS in use as of 10/7/13	L Barrett	C Bowman

9. ADDENDA AND APPENDICES

None

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	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	

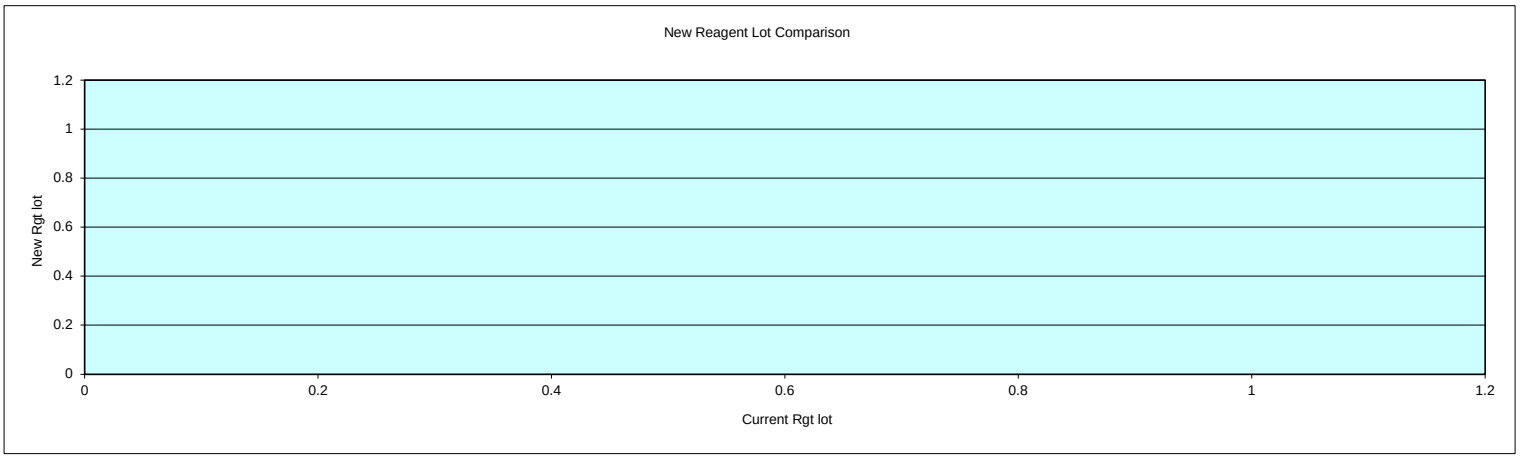
Calibrator Lot & Exp. Date:	QC 1 Lot & Exp. Date:	
	QC 2 Lot & Exp. Date:	
	QC 3 Lot & Exp. Date:	
	QC 4 Lot & Exp. Date:	

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:**

APPENDIX A Technical Supervisor or above 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:** 0

	Reagent Lot number	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	0	0					
New	0	0	0	**0**	**0**	**0**	**0**

Allowable Total Error

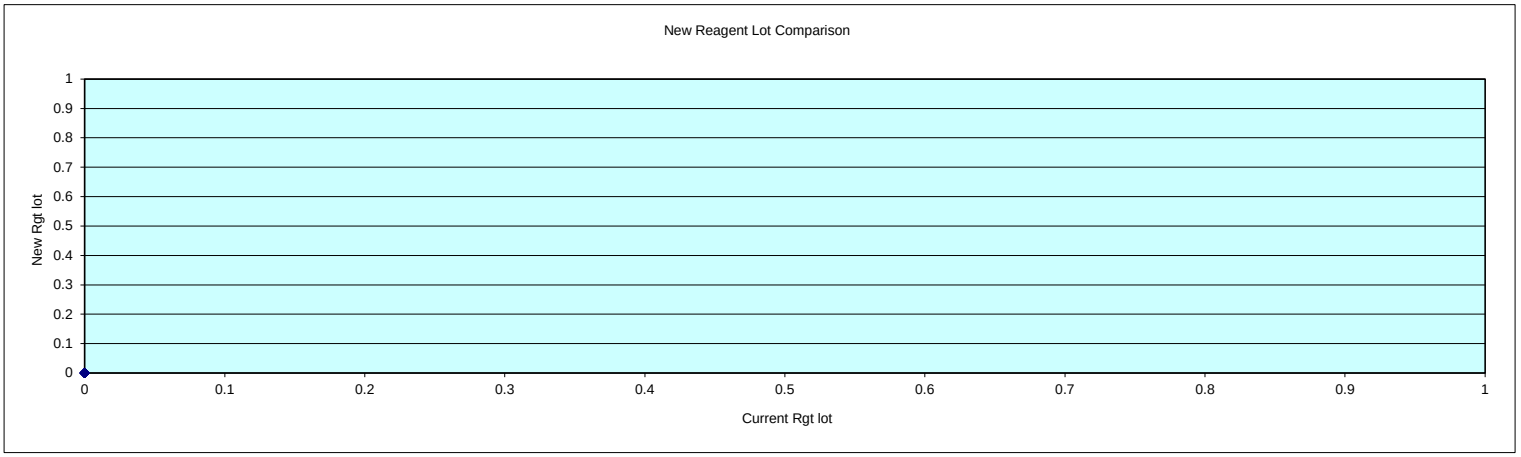
TEa (percent):	0.00%	%
Units:	0	0
TEa/2 %	0.0%	
TEa/2 Units	0.0000	

Calibrator Lot & Exp. Date:	QC 1 Lot & Exp. Date:	0
	QC 2 Lot & Exp. Date:	0
	QC 3 Lot & Exp. Date:	0
0	QC 4 Lot & Exp. Date:	0

Sample #	**Sample ID**	***Current Reagent Lot***	***New Reagent Lot***	***MIN TEa/2***	***MAX TEa/2***	***Difference for Individual Samples***	
				Reference Value	Minimum Acceptable	Maximum Acceptable	Low Limit Evaluation	High Limit Evaluation
Patient 1	1	0	0	0.000	0.000	0.000	Accept	Accept
Patient 2	2	0	0	0.000	0.000	0.000	Accept	Accept
Patient 3	3	0	0	0.000	0.000	0.000	Accept	Accept
Patient 4	4	0	0	0.000	0.000	0.000	Accept	Accept
Patient 5	5	0	0	0.000	0.000	0.000	Accept	Accept
Patient 6	6	0	0	0.000	0.000	0.000	Accept	Accept
Patient 7	7	0	0	0.000	0.000	0.000	Accept	Accept
Patient 8	8	0	0	0.000	0.000	0.000	Accept	Accept
Patient 9	9	0	0	0.000	0.000	0.000	Accept	Accept
Patient 10	10	0	0	0.000	0.000	0.000	Accept	Accept

Count	10	10
Mean	0.000	0.000
Bias %:		#DIV/0!
Bias units:		0.000
TEa/3 in %:		0.000%
TEa/3 in units:		0.000
Estimate of Bias:		#DIV/0!

	Current Reagent QC		New Reagent QC		
	Expected Mean	*Expected SD*	*New lot result*	SDI	Accept/Fail
QC1	0.000	0.000	0.000	#DIV/0!	#DIV/0!
QC2	0.000	0.000	0.000	#DIV/0!	#DIV/0!
QC3	0.000	0.000	0.000	#DIV/0!	#DIV/0!
QC4	0.000	0.000	0.000	#DIV/0!	#DIV/0!



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/3.

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:**

APPENDIX A Technical Director or above 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:** 0

	Reagent Lot number and Expiration:	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		0					
New		0	0	**0**	**0**	**0**	**0**

Allowable Total Error

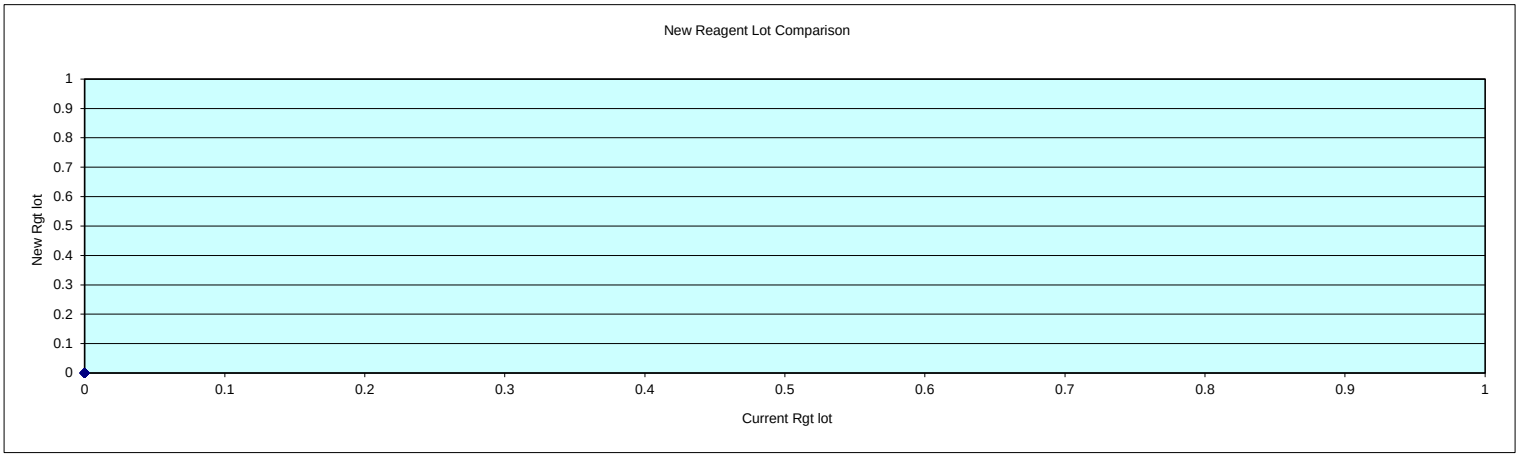
TEa (percent):	0.00%	%
Units:	0	0
TEa/2 %	0.0%	
TEa/2 Units	0.0000	

Calibrator Lot & Exp. Date:	QC 1 Lot & Exp. Date:	0
	QC 2 Lot & Exp. Date:	0
	QC 3 Lot & Exp. Date:	0
0	QC 4 Lot & Exp. Date:	0

				MIN TEa/2	***MAX TEa/2***	***Difference for Individual Samples***	
Sample #	**Sample ID**	***Current Reagent Lot***	***New Reagent Lot***	Reference Value	Minimum Acceptable	Maximum Acceptable	Low Limit Evaluation	High Limit Evaluation
Patient 1	1	0	0	0.000	0.000	0.000	Accept	Accept
Patient 2	2	0	0	0.000	0.000	0.000	Accept	Accept
Patient 3	3	0	0	0.000	0.000	0.000	Accept	Accept
Patient 4	4	0	0	0.000	0.000	0.000	Accept	Accept
Patient 5	5	0	0	0.000	0.000	0.000	Accept	Accept
Patient 6	6	0	0	0.000	0.000	0.000	Accept	Accept
Patient 7	7	0	0	0.000	0.000	0.000	Accept	Accept
Patient 8	8	0	0	0.000	0.000	0.000	Accept	Accept
Patient 9	9	0	0	0.000	0.000	0.000	Accept	Accept
Patient 10	10	0	0	0.000	0.000	0.000	Accept	Accept

Count	10	10
Mean	0.000	0.000
Bias %:		#DIV/0!
Bias units:		0.000
TEa/2 in %:		0.000%
TEa/2 in units:		0.000
Estimate of Bias:		#DIV/0!

	Current Reagent QC		New Reagent QC		
	Expected Mean	*Expected SD*	*New lot result*	SDI	Accept/Fail
QC1	0.000	0.000	0.000	#DIV/0!	#DIV/0!
QC2	0.000	0.000	0.000	#DIV/0!	#DIV/0!
QC3	0.000	0.000	0.000	#DIV/0!	#DIV/0!
QC4	0.000	0.000	0.000	#DIV/0!	#DIV/0!



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/2.

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:**

APPENDIX A Medical Director approval required.

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:** 0

	Reagent Lot number	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	0	0					
New	0	0	0	**0**	**0**	**0**	**0**

Allowable Total Error

TEa (percent):	0.00%	%
Units:	0	0
TEa %	0.0%	
TEa Units	0.0000	

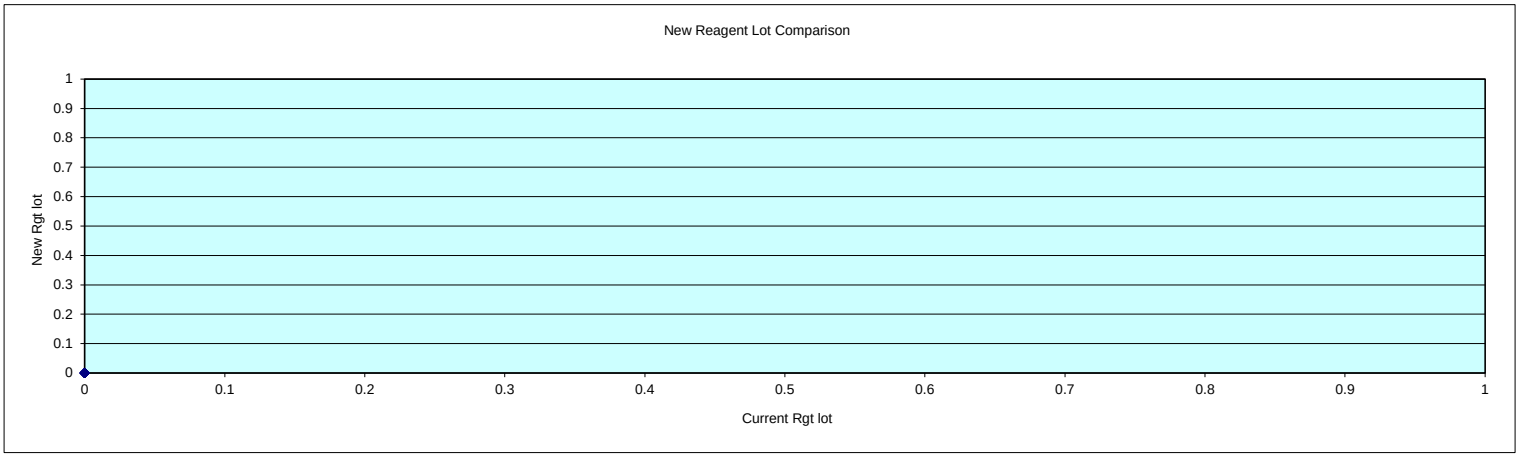
Calibrator Lot & Exp. Date:	QC 1 Lot & Exp. Date:	0
	QC 2 Lot & Exp. Date:	0
	QC 3 Lot & Exp. Date:	0
0	QC 4 Lot & Exp. Date:	0

Sample #	**Sample ID**	***Current Reagent Lot***	***New Reagent Lot***
Patient 1	1	0	0
Patient 2	2	0	0
Patient 3	3	0	0
Patient 4	4	0	0
Patient 5	5	0	0
Patient 6	6	0	0
Patient 7	7	0	0
Patient 8	8	0	0
Patient 9	9	0	0
Patient 10	10	0	0

			MIN Tea	***MAX TEa***	***Difference for Individual Samples***	
			Reference Value	Minimum Acceptable	Maximum Acceptable	Low Limit Evaluation	High Limit Evaluation
Patient 1	1	0	0.000	0.000	0.000	Accept	Accept
Patient 2	2	0	0.000	0.000	0.000	Accept	Accept
Patient 3	3	0	0.000	0.000	0.000	Accept	Accept
Patient 4	4	0	0.000	0.000	0.000	Accept	Accept
Patient 5	5	0	0.000	0.000	0.000	Accept	Accept
Patient 6	6	0	0.000	0.000	0.000	Accept	Accept
Patient 7	7	0	0.000	0.000	0.000	Accept	Accept
Patient 8	8	0	0.000	0.000	0.000	Accept	Accept
Patient 9	9	0	0.000	0.000	0.000	Accept	Accept
Patient 10	10	0	0.000	0.000	0.000	Accept	Accept

Count	10	10
Mean	0.000	0.000
Bias %:		#DIV/0!
Bias units:		0.000
TEa in %:		0.000%
TEa in units:		0.000
Estimate of Bias:		#DIV/0!

	Current Reagent QC		New Reagent QC		
	Expected Mean	*Expected SD*	*New lot result*	SDI	Accept/Fail
QC1	0.000	0.000	0.000	#DIV/0!	#DIV/0!
QC2	0.000	0.000	0.000	#DIV/0!	#DIV/0!
QC3	0.000	0.000	0.000	#DIV/0!	#DIV/0!
QC4	0.000	0.000	0.000	#DIV/0!	#DIV/0!



Individual difference: Difference between results with old and new reagents must not exceed the allowable total error (Tea) for the assay.

Estimate of Bias: Mean value for the new reagent must not vary from the old reagent by more than TEa.

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:**