Adventist HealthCare

# TRAINING UPDATE

| | | | |
|---|---|---|---|
| **Lab Location:** | All sites | **Date Distributed:** | 5/30/24 |
| **Department:** | Core Lab | **Due Date:** | 6/5/24 |
| | | **Implementation:** | **6/4/24** |

## DESCRIPTION OF PROCEDURE REVISION

**Name of procedure:**

**AHC.QA37 Reagent Parallel Testing (v 5.0)**

**Related Document: New Reagent or Shipment comparison Study Form (AG.F217 v9.0)**

**Description of change(s):**

1. TEA values have been updated
2. We are no longer using Tea/4
3. Bench Level approval is Tea/3

**Once the new process becomes effective (6/4/24),** remove previous version of the form from your desktops or folders, and replace with the new version.

**Reviewers:** Make sure the techs are using the new form as of 6.4.24.

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

# AHC.QA37 Reagent Parallel Testing

## Copy of version 5.0 (approved, not yet effective)

| | |
|---|---|
| **Last Approval or Periodic Review Completed** | 5/22/2024 |
| **Next Periodic Review Needed On or Before** | 5/22/2026 |
| **Effective Date** | 6/4/2024 |

**Uncontrolled Copy** printed on 5/30/2024 9:30 AM

| | |
|---|---|
| **Printed By** | Demetra Collier (110199) |
| **Organization** | Adventist HealthCare |

### Approval and Periodic Review Signatures

| Type | Description | Date | Version | Performed By | Notes |
|---|---|---|---|---|---|
| Approval | Lab Director | 5/22/2024 | 5.0 | Nicolas Cacciabeve MD<br>Nicolas Cacciabeve | |
| Approval | QA Leader approval | 5/21/2024 | 5.0 | Cynthia Bowman-Gholston MT(ASCP) (104987) | |
| Approval | Lab Director | 5/18/2024 | 4.0 | Nicolas Cacciabeve MD<br>Nicolas Cacciabeve | |
| Approval | QA Leader approval | 5/17/2024 | 4.0 | Cynthia Bowman-Gholston MT(ASCP) (104987) | |
| Periodic review | QA Leader approval | 5/21/2024 | 3.0 | Cynthia Bowman-Gholston MT(ASCP) (104987) | |
| Periodic review | QA approval | 5/16/2024 | 3.0 | Demetra Collier (110199) | |
| Approval | Lab Director | 7/26/2022 | 3.0 | Nicolas Cacciabeve | |
| Approval | QA Leader approval | 7/25/2022 | 3.0 | Cynthia Bowman-Gholston (104987) | |
| Periodic review | QA Leader approval | 7/30/2020 | 2.0 | Cynthia Bowman-Gholston | |
| Periodic review | QA approval | 7/14/2020 | 2.0 | Leslie Barrett | |
| Periodic review Captured outside MediaLab | Designated Reviewer | 8/1/2018 | 2.0 | Cynthia Bowman-Gholston | Recorded on 5/14/2019 by Leslie Barrett (104977) when document added to MediaLab |
| Approval Captured outside MediaLab | Lab Director | 6/19/2016 | 2.0 | Nicolas Cacciabeve | Recorded on 5/14/2019 by Leslie Barrett (104977) when document added to MediaLab |

Approvals and periodic reviews that occurred before this document was added to the MediaLab Document Control system may not be listed.



### Version History

| Version | Status | Type | Date Added | Date Effective | Date Retired |
|---|---|---|---|---|---|
| 5.0 | Approved, Not Yet Effective | Major revision | 5/21/2024 | 6/4/2024 | Indefinite |
| 4.0 | Approved, Not Yet Effective | Major revision | 5/16/2024 | 6/4/2024 | 6/4/2024 |

| | | | | | |
|---|---|---|---|---|---|
| 3.0 | Approved and Current | Major revision | 7/25/2022 | 7/30/2022 | 6/4/2024 |
| 2.0 | Retired | First version in Document Control | 5/14/2019 | 8/9/2016 | 7/30/2022 |

**Linked Documents**

- AG.F104 Lot to Lot Cross Check Log
- AG.F106 KovaTrol Urine Qualitative Control Cross Check
- AG.F217 New Reagent Lot or Shipment Comparison Study (Quant) Form

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.* | | |
| | | |



## 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 Technical 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 is performed to ensure that a new 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 appropriate quality control and by testing at least **3** patient samples run simultaneously with both lots. The patient samples should span the analytical range (AMR) for the assay.

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/3) tab. The form will perform all calculations.
   2. The Lot to Lot Cross Check Log is used for qualitative test comparisons (AG.F104).
   3. An alternative log may be used as specified in the test SOP (i.e. PFA-100, Coag lot conversion, AG.F120).



### 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.

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. A minimum of 3 patient samples must be tested. Ideally, the samples should span the AMR.
   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. The New Reagent Lot or Shipment Comparison Study (Quant) Form (AG.F217) 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.
  **NOTE:** Full TEA allows the individual difference between old and new results to be compared at full TEA
- Estimate of bias
  - Mean value for the new reagent must not vary from the old reagent by more than one third of the TEa (TEA/3).

- The technical supervisor or above may approve variation between old and new lot of one half of the TEa (TEa/2).
- Only the medical director or designee can approve the variation at straight TEa.
- **Note**: Data entered on the TEA/3 tab of the comparison form will pre-fill the other tabs (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.

**Note:**

Refer to addendum for an example of troubleshooting lot to lot failures for chemistry reagents. This example is intended to promote a train of thought; it is not all inclusive nor is it meant to resolve all potential problems.



## 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 | 5/2/16 | Section 3: update job titles<br>Section 4: add TEA<br>Section 5.1: add documentation description<br>Section 5.2: specify wording on green label<br>Section 5.2.1: add use of orange label<br>Section 5.2.2: add use of blood & orange date labels<br>Section 5.3: add calculations done by quant form, add corrective action<br>Section 6: add forms and Coag SOP<br>Footer: version # leading zero's dropped due to new EDCS in use as of 10/7/13 | L Barrett | C Bowman |
| 1 | 6/28/16 | Header: add other sites<br>Section 5.1, 5.2.1: specify 3 samples across AMP<br>Section 5.3.3: add reference to addendum<br>Section 9: add addendum | R. SanLuis<br>L. Barrett | C. Bowman |
| 2 | 7/25/22 | Header: Changed site to All Laboratories<br>Footer: Changed prefix to AHC<br>Section 5.3.3, Section 9, and Addendum: Changed from "Vista" Lot to Lot to "Chemistry reagent" lot to lot. | D Collier | C Bowman |
| 3 | 5/15/24 | Section 3: Added "Technical" to supervisor title.<br>Section 5: Removed TEA/4. Replaced TEA/4 with TEA/3; updated approval levels for TEA/3 and TEA/2, Added form numbers.<br>Section 5.3.1: added note that for full TEA approval the individual result comparison is also set to full TEA (Medical Director or designee approval only).<br>5.3.3: Removed reference to addendum<br>Section 9 and Addendum: Removed the trouble-shooting flow chart. | D Collier<br>R SanLuis | C Bowman |
| 4 | 5/21/24 | Footer: Fixed Version number, now v5 | D Collier | C Bowman |

## 9. ADDENDA AND APPENDICES

None

**APPENDIX A** Bench Level

# 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** | | | | | | | |

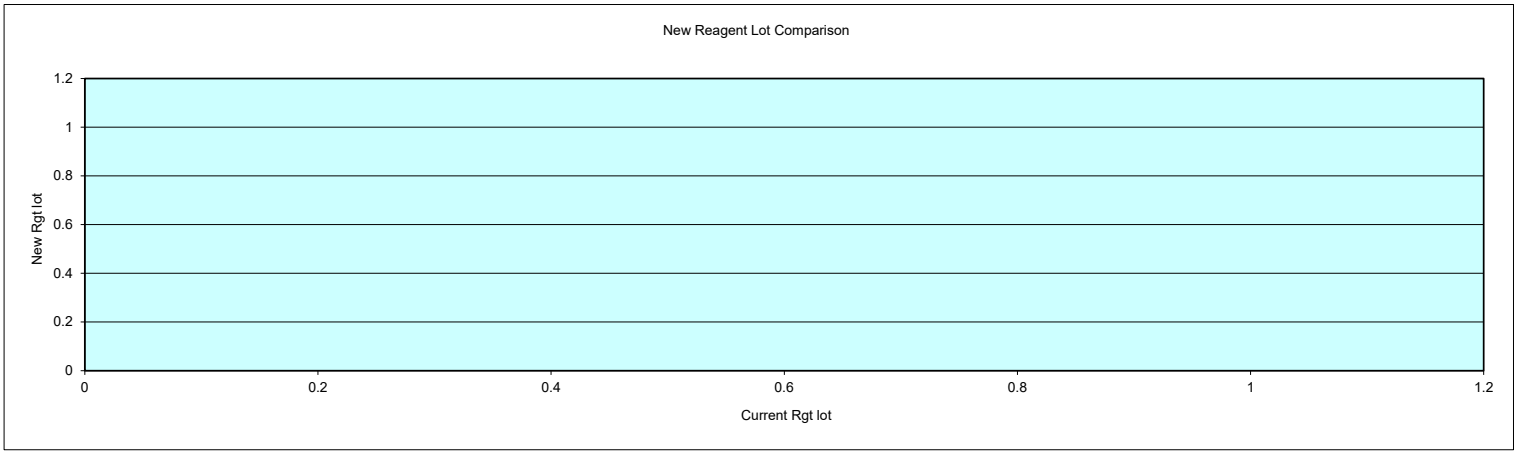
**Allowable Total Error**

| | |
|---|---|
| **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: | |

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

| | | | | Current Reagent QC | | New Reagent QC | | |
|---|---|---|---|---|---|---|---|---|
| | | | | *Expected Mean* | *Expected SD* | *New lot result* | SDI | Accept/Fail |
| **Count** | 0 | 0 | QC1 | | | | | |
| **Mean** | #DIV/0! | #DIV/0! | QC2 | | | | | |
| **Bias %:** | | #DIV/0! | QC3 | | | | | |
| **Bias units:** | | #DIV/0! | QC4 | | | | | |
| **TEa/3 in %:** | | 0.000% | | | | | | |
| **TEa/3 in units:** | | 0.000 | | | | | | |
| **Estimate of Bias:** | | #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:**

**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 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** | 0 | 1/0/1900 | | | | | |
| **New** | 0 | 1/0/1900 | 0 | **0** | **0** | **0** | **0** |

**Allowable Total Error**

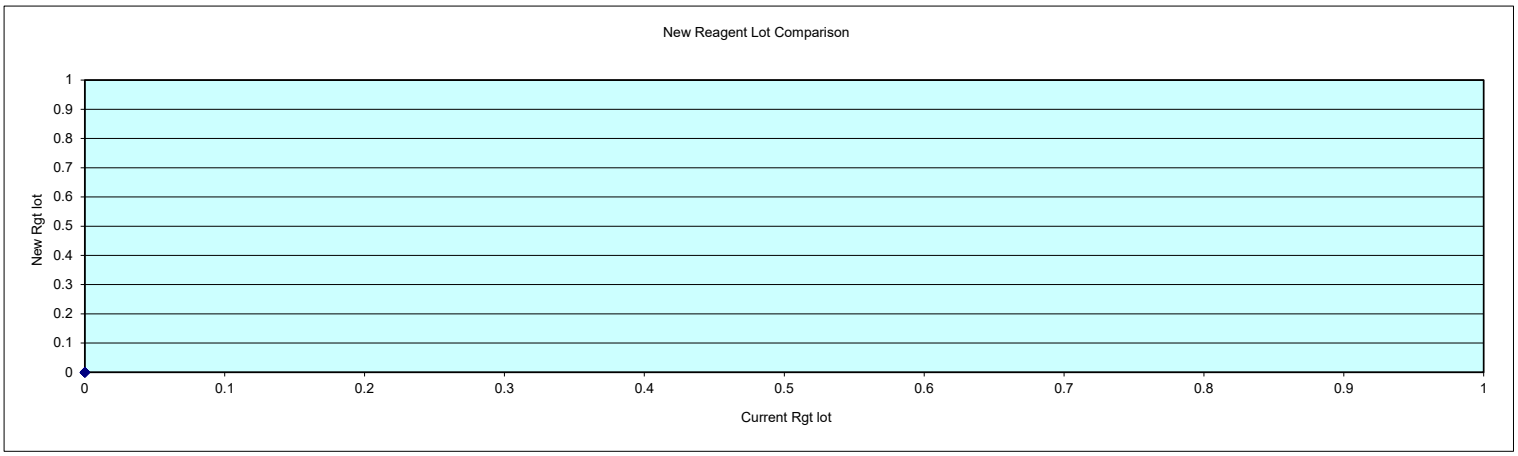
| | |
|---|---|
| **TEa (percent):** | 0.00% |
| **Units:** | 0 |
| **TEa/2 %** | 0.0% |
| **TEa/2 Units** | 0.0000 |

| 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 |

| | | *Current Reagent Lot* | *New Reagent Lot* | *MIN TEa/2* | *MAX TEa/2* | *Difference for Individual Samples* | |
|---|---|---|---|---|---|---|---|
| **Sample #** | **Sample ID** | | | 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 or designee 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 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** | 0 | 1/0/1900 | | | | | |
| **New** | 0 | 1/0/1900 | 0 | **0** | **0** | **0** | **0** |

**Allowable Total Error**

| | |
|---|---|
| **TEa (percent):** | 0.00% |
| **Units:** | 0 |
| **TEa %** | 0.0% |
| **TEa Units** | 0.0000 |

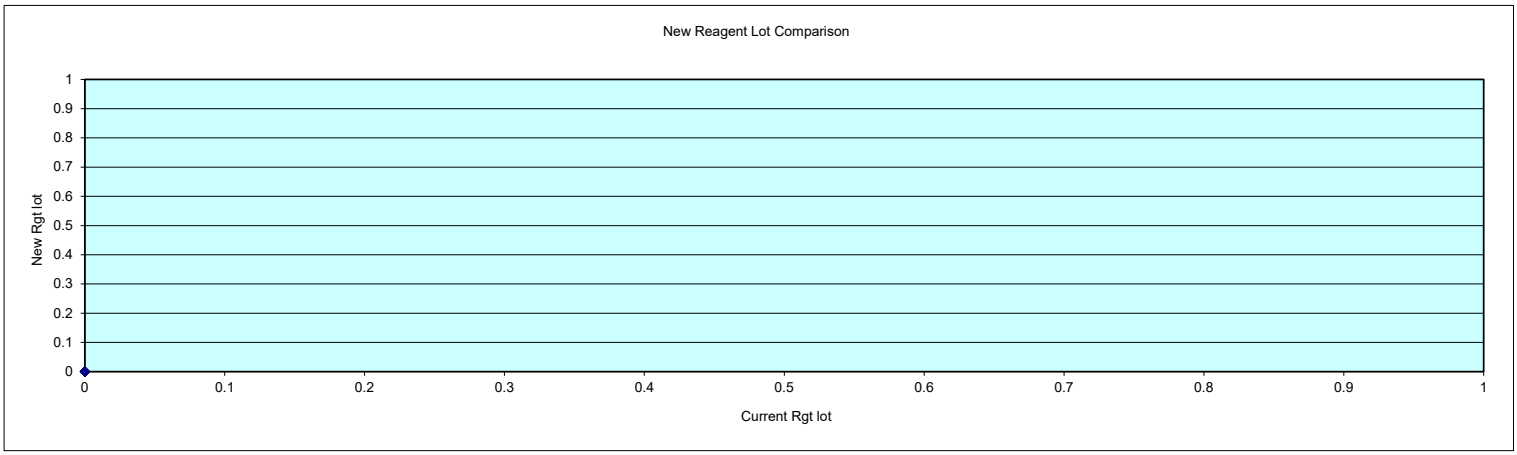
| Calibrator Lot & Exp. Date: | QC 1 Lot & Exp. Date: | 0 |
|---|---|---|
| | QC 2 Lot & Exp. Date: | 0 |
| | QC 3 Lot & Exp. Date: | 0 |
| 0 | QC 4 Lot & Exp. Date: | 0 |

| **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 |

| | | |
|---|---|---|
| **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! |

| | ***MIN Tea*** | ***MAX TEa*** | ***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 | 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:**

Adventist HealthCare

# TEa Table

Fort Washington Medical Center
Germantown Emergency Center
Shady Grove Medical Center
White Oak Medical Center

## Chemistry

| Method | TEa (percent) | Absolute Value (TEa Units) | Units |
|---|---|---|---|
| ALB | 8 | 0.3 | g/dL |
| ACTM | 15 | 3.0 | ug/mL |
| ALC (ETOH) | 20 | 7 | mg/dL |
| ALPI | 20 | 7 | U/L |
| ALTI | 15 | 6 | U/L |
| Amikacin | 25 | 1 | ug/mL |
| AMON (AMM) | 25 | 12 | umol/L |
| AMY | 20 | 7 | U/L |
| AST | 15 | 6 | U/L |
| BNP | 30 | 30 | pg/mL |
| BUN | 9 | 2 | mg/dL |
| CA | 6 | 0.5 | mg/dL |
| CHOL | 10 | 6 | mg/dL |
| CKI | 20 | 7 | U/L |
| CL | 5 | 4 | mmol/L |
| CRBM | 20 | 1 | ug/mL |
| CREA | 10 | 0.2 | mg/dL |
| CREA (CRE2), Urine | 10 | 4 | mg/dL |
| CRP | 30 | 0.4 | mg/dL |
| TNIH (troponin) | 30 | 200 | pg/mL |
| CO2 | 20 | 4 | mmol/L |
| DBIL | 20 | 0.15 | mg/dL |
| DGNA | 15 | 0.2 | ng/mL |
| Ferrtin | 20 | 9 | ng/mL |
| Folate | 30 | 1 | ng/mL |
| FT4 | 15 | 0.3 | ng/dL |
| GENT | 25 | 0.4 | ug/mL |
| GGT | 15 | 5 | U/L |
| GLUC | 8 | 6 | mg/dL |
| HCG | 18 | 3 | mIU/mL |
| HDLC | 20 | 6 | mg/dL |
| Hemoglobin A1C | 6 | 0.4 | % |
| PTH | 30 | 10 | pg/mL |

## Chemistry

| Method | TEa (percent) | Absolute Value (TEa Units) | Units |
|---|---|---|---|
| Iron | 15 | 8 | ug/dL |
| K | 0 | 0.3 | mmol/L |
| K, Urine | 12 | 3.3 | mmol/L |
| Ketone (β-Hydroxybutyrate) | 10 | 0.5 | mmol/L |
| LA | 30 | 1.8 | mmol/L |
| LD | 15 | 8 | U/L |
| LITH | 15 | 0.3 | mmol/L |
| LIPL | 30 | 10 | U/L |
| MG | 15 | 0.4 | mg/dL |
| MMB | 25 | 3 | ng/mL |
| MYO | 30 | 10 | ng/mL |
| NA (Sodium) | 0 | 4 | mmol/L |
| NA (Sodium), Urine | 5 | 4 | mmol/L |
| PCT (Procalcitonin) | 20 | 0 | ng/mL |
| Phnb | 15 | 2 | ug/mL |
| PHOS | 10 | 0.3 | mg/dL |
| PreAlbumin | 25 | 5 | mg/dL |
| PTN | 15 | 2 | ug/mL |
| SAL | 15 | 2 | mg/dL |
| TBIL | 20 | 0.4 | mg/dL |
| TGL | 15 | 5 | mg/dL |
| THEO | 20 | 1 | ug/mL |
| TIBC | 15 | 8 | ug/dL |
| TOBR | 20 | 0.3 | ug/mL |
| TP | 8 | 0.3 | g/dL |
| TP, Urine | 12 | 3.3 | mg/dL |
| TPSA | 20 | 0.2 | ng/mL |
| TSH | 20 | 0.2 | uIU/mL |
| UCFP (TP, Fluid) | 20 | 10 | mg/dL |
| URCA | 10 | 0.6 | mg/dL |
| VALP | 20 | 3 | ug/mL |
| VANC | 15 | 2.0 | ug/mL |
| Vitamin B12 | 25 | 30 | pg/mL |

## Hematology

| Method | TEa (percent) | Absolute Value (TEa Units) | Units |
|---|---|---|---|

## Coagulation

| Method | TEa (percent) | Absolute Value (TEa Units) | Units |
|---|---|---|---|

| | | | |
|---|---|---|---|
| WBC | 10 | 0.3 | thous/uL |
| LY% | 15 | 5 | % |
| MO% | 30 | 5 | % |
| NE% | 10 | 5 | % |
| RBC | 4 | 0.3 | Mill/uL |
| HCT | 4 | 0 | |
| HGB | 4 | 0.3 | g/dL |
| MCV | 6 | 0 | fL |
| RDW | 6 | 0 | % |
| PLT | 25 | 9 | thous/uL |
| Retic | 21 | 0.75 | % |
| ESR | 40 | 10 | mm/hr |

Highlighted Values Updated May 2024

| | | | |
|---|---|---|---|
| Anti - Xa | 30 | 0 | IU/mL |
| aPTT | 15 | 0 | sec |
| D-Dimer | 30 | 0.125 | ug/mL |
| Fibrinogen | 20 | 0 | mg/dL |
| INR | 15 | 0 | |
| PT | 15 | 0 | sec |
| | | | |