QC Program - Pre-Analytical, Analytical and Post Analytical Considerations

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Revisions:

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The Biochemistry lab has implemented this policy to ensure quality throughout the pre-analytic, analytic, and post-analytic (reporting) phases of testing. The program is designed to detect problems in the laboratory systems and identify opportunities for improvement. This policy is an overview of the program within the Biochemistry department and more detailed workflows are defined in individual procedures where applicable.

Pre-Analytical Considerations

Samples are collected either by nursing, phlebotomy on the units or in Outreach. Patient preparation and the actual process of specimen collection will not be included in this lab specific program, much of which is included in the Phlebotomy Procedure Manual or the Laboratory Guide. Pre-analytical specimen handling guidelines are outlined in several of the Pathology Administrative policies such as:

1.4A Patient Identification and Verification
1.6 Sample Handling
1.7 Specimen Rejection

Only lab specific handling requirements are included in this policy.

A. Specimen Handling

- The requesting unit should be notified that the specimen is unacceptable unless the specific criteria detailed in 1.7-Specimen Rejection Policy are met.

- Original caps should not be replaced on tubes once they have been opened. Instead, they should be replaced with the provided plastic caps.

- Saving Specimens
  AU Testing – Sent to Rhode Island Hospital (RIH) and saved for 4 days (refrigerated)

- If a request is made to have a test performed Stat, which is only performed at RIH, we should contact NOW Courier for a Stat run at 401-729-4703. Notify them you would like a sample sent from East Greenwich Lab to RIH or The Miriam Hospital (TMH) with STAT status.

- All other specimens received for testing that will not be performed at East Greenwich should be handled according to the requirements for that specific test. All specimens will be sent to RIH and testing will be done there or sent out. If not performed at RIH or TMH, many of these can be found in the ARUP Laboratory Guide.

- If a complaint is received from an individual, who raises concerns about a current protocol or a specific incident, the event should be documented in SafetyNet.

- **Test system becomes inoperable:** In the event of an instrument downtime or any test system becomes inoperable, refer to the operator manuals that are specific for each system. Follow all shutdown, startup and operation procedures that are applicable. Tech support may need to be called. Patient specimens can be assessed and triaged before deciding to "workstation redirect" to the one of the other Lifespan sites or to initiate a downtime. Refer to Downtime procedure if applicable. Each situation is different, and a senior technologist or manager should be involved in decision making if it is for an extended period of time.

B. Specimen Receipt & Transport

- Specimens delivered to East Greenwich Lab will need to be Phlebotomy Received.
- Phlebotomy should notify Lab tech when specimen is STAT.
- Samples are transferred between affiliates by using NOW couriers. Except for LIS downtime, each shipment of specimens must be accompanied by a "Specimen Tracking List", required temperature noted, and that list must be "received" and verified by the receiving laboratory. Any discrepancies found, must be investigated fully and must involve the sending laboratory.

- Samples brought to the laboratory from Outreach sites are transported by NOW Couriers. These samples may or may not be registered and testing ordered in the system. Therefore, these do not arrive with a tracking list. Specimens coming from Outreach sites with Phlebotomists are monitored by Transport Lists which specify the number of tubes sent and patient specimens are wanded onto this list. These transport lists are then verified as to how many tubes / samples were received when arriving at the performing institution.

C. Cancellation of Testing

- A physician may request the cancellation of any procedure performed in this lab, until the point where the result is verified.

- Once the samples are received in lab, all cancellations requested, should be footnoted, to include the initials of the person requesting the cancellation and the time. This should be in the form of a chartable footnote in Soft.

- After an analyte has been verified, the results can be edited in Single Result Entry using the Cancel keypad and the aforementioned footnote.

- Testing will not be cancelled due to highly atypical results unless approved by the ordering physician or nurse caring for the patient, as per policy outlined later in this policy under Atypical Results.

Analytical Considerations

A. Specimen Analysis and Reporting

- All automated testing samples directed for the Beckman AU may be placed directly on the instrument.

- Specimens for rapid and point of care type testing will be handled according to individual procedures.

- If a test system or analyzer becomes inoperable, testing will be triaged. Any stat or critical and time sensitive tests will be sent to RIH laboratory for testing. If the testing is not time sensitive, it can be held and batched for testing once the issue has been resolved. As a courtesy, clinical manager and outreach managers can be notified of the delay with testing if it is not resolved within one hour.

- Specimens are analyzed using the Primary Sampling and Bar Code capability on the AU. The specimens need only be placed in a rack and then sampling turned "on". If the volume of a sample is inadequate to sample in this manner or if a dilution is required, the following procedure should be followed:

Pediatrics short draw: AU

- Reprint the LIS barcode and affix to 13x100 plastic aliquot tube
- Place a nesting cup directly into aliquot tube
- Verify that the patient and accession number on the reprinted label and original tube match
- Using a clean disposable pipette, transfer sample to nesting cup (or pour)
- Manually place into RED rack onto instrument using barcode with extension for downloading of patient information.

Adult short draw & Ammonia samples: AU

- Place nesting cup in original tube (13x100) with LIS barcode
- Using a clean disposable pipette, transfer sample to nesting cup (or pour)
- Manually place into RED rack onto instrument using barcode with extension for downloading of patient information.

Dilutions: General Protocol / Calculations

- A dilution may become necessary if the obtained result is outside the upper limit of the linear range on any given analyzer. Some analytes cannot be diluted, see specific procedures on how to proceed.
- If dilution of the analyte is permitted, the analyte has a specified diluent and information concerning the dilution protocol in its specific procedure.
- The calculations for all dilutions will vary depending upon the degree of dilution, but the general formula: Σ (Parts Sample + Parts Diluent) = Dilution Factor
- For example: If you were performing a "x5" dilution, you could use 1 part of sample and 4 parts of diluent, or 50 ul sample added to 200 ul of diluent.
- The Dilution Factor should be programmed directly into the AU and the result obtained from the instrument will be calculated.
- Many of the analyzers will automatically dilute and calculate results. The printed result will indicate that the test has been diluted and the reported result is acceptable, no further action is required. All manual dilutions are made with calibrated pipettors that use discrete disposable tips.

Manual Dilutions: AU

- Label nesting cup with the dilution factor (ex: x5)
- Dilute the sample directly into nesting cup
- Place nesting cup in original tube with LIS barcode
- Place on instrument using barcode for downloading of patient information
- Once completed be sure to discard diluted sample cup to prevent any addons from being run on this sample cup.

Pour-off Samples

- There are many instances in the laboratory when a specimen must be "poured off" into another container, whether urine, CSF or blood/plasma. When such instances occur, the barcode label must be reprinted and the patient's first and last name, along with the accession number, must be verified by checking that both the primary container and the pour off tube label are identical prior to the pour off. This check is necessary to prevent a possible specimen mix-up.
- Aliquots must not be returned to the original specimen container or be used for molecular-based testing, drug testing, HIV testing or any other restricted testing that has been defined by a department.
- Aliquoted samples can be used for addon tests that are deemed "routine" tests in chemistry, hematology, immunology, etc. unless it is stated otherwise in policies for individual assays. (11/12/21dn)

B. Critical Values

There is currently a list of critical values posted at workstations where results are reviewed and verified. The Critical Values are broken down into Critical Red Ranges and Critical Orange Ranges, each with their own specific guidelines which are detailed in the Critical Value Policy. In either category, the result should be reported appropriately to the requesting location and a chartable footnote stating the

first and last name of the person receiving the call, the unit/location, the date/time of the call and the name of the technologist.
Additionally, the caller should ask the person accepting the results to verify the results by reading the results back to include the patient's full name and DOB. This should also be captured in the footnote.
Critical Values on Outpatient Samples: Refer to complete guidelines contained in the "Critical Value Policy" to determine how to handle Outpatient providers as well as the notification algorithm if providers can not be contacted after hours.

Notes:

1. No critical values will be autoverified. They all require technologist review.
2. On the Beckman AU, most critical values will need to be repeated by the technologist.
3. All repeats must be logged on the Repeat Sheets, which are to be kept with the instrument printouts.
4. If the volume of the sample is insufficient to repeat (QNS), that fact should be reported along with the result.
5. A notification algorithm has also been developed for the Clinics at TMH and RIH and is located in the Administrative policy 1.8 Communication of Critical Values.
6. All steps and footnotes for difficult communication of results can be documented in the patient record as an internal "?" comment which can be helpful in audits and SafetyNet events.

C. Highly Atypical Results

Highly atypical results where the technologist has a high degree of suspicion that the results are somehow contaminated or not belonging to the patient identified should be handled in the following manner:

For Inpatients

- The sample should be repeated, if not already done.
- If the results are repeatable, the requesting unit should be called and the Nurse / Physician caring for the patient should be given the results with the information that lead the tech to believe the sample was contaminated. In the case of the Emergency Department, the physician caring for the patient must be spoken to and the situation explained.
- Questions surrounding whether the patient is on an IV should be detailed at this point.
- If by mutual agreement with the unit, the sample is deemed inappropriate, or not compatible with the condition of the patient, a screen print of the results should be generated, and the Canned Comment, "See Note" (See Note) should be entered for each analyte using the cancel keypad, depending on the actual analytes ordered. The actual results obtained should then be entered into the footnote in the appropriate locations, using the TAB key to move from one field to the next. The results will be available on the screen print which you

produced. If a test name appears in the footnote which was not ordered, backspace it out. Once all fields have been completed in the footnote, the result should be verified. If an additional assay name is needed, enter it at the end. A repeat sample should be requested. Save all documentation and forward for review and SafetyNet.

- You should bridge to OE so you can notify all other labs that the specimens associated with this order need to be cancelled.
- If the unit is willing to accept the results, they should be verified and the canned comment @ABN entered. The comment states "Abnormal results obtained on the specimen collected at this time. Lab requested redraw since specimen was suspected to be unsuitable for analysis. Called to __ at __ by __. "A repeat sample should be requested.

For Outpatients

- IV's are not typically present and therefore lack the availability of Delta checking
- The sample should be repeated if not already done.
- If results check after being reanalyzed, the technologist must confer with a Senior Technologist, Manager or Director on the appropriate course of action. If for any reason, this is not possible, the following guidelines should be followed:
- The requesting/ covering Physician will be called and presented with the results obtained and inquire if the results would match the clinical picture for that patient.
- If the physician deems the sample inappropriate, or not compatible with the condition of the patient, a screen print of the results should be generated, and the Canned Comment, "See Note" (See Note) should be entered for each analyte using the cancel keypad, depending on the actual analytes ordered. The actual results obtained should then be entered into the footnote in the appropriate locations, using the TAB key to move from one field to the next. The results will be available on the screen print which you produced. If a test name appears in the footnote which was not ordered, backspace it out. Once all fields have been completed in the footnote, the result should be verified. If an additional assay name is needed, enter it at the end. A repeat sample should be requested. Save all documentation and forward for review and SafetyNet.
- If the physician is willing to accept the results, they should be verified and the canned comment **"@ABN"** entered. The template states "Abnormal results obtained on the specimen collected at this time. Lab requested redraw since specimen was suspected to be unsuitable for analysis. Called to __ at __ by __." A repeat sample should be requested.

- **For all samples**: Notify other laboratory departments once a specimen is deemed contaminated. All samples on that Order Number should be considered contaminated and therefore cancelled by the other departments as well.

D. Delta Checking & Flagging

- Delta checking is a vital component to help eliminate problems with specimen identification or possible specimen contamination. It can also assist in avoiding clerical errors. Limits of acceptability have been entered into the Soft LIS where delta checking will be an automatically performed. The delta check limits, and process is at the director's discretion. Those failing the delta check limits will not be autoverified and will be noted on a LIS result verification screen where the result is followed by "aD" or "%D" . For more detailed information on the handling of these samples, see: Handling of Critical, Review and Delta Flags on the LIS, which can be found in the main Chemistry manual.
  The result may also have a postscript of "HH", "LL", indicating that the result is above (H) panic High (HH) or below (L) , panic low (LL), for a particular analyte. SoftLab also utilizes colors for flagging results and is defined in more detail in the above-mentioned policy.

D. Add-ons

Verbal Add-on's

- If an outreach physician calls to add on a test, the Outreach Department will request a written form from the physician's office or an electronic request via physician office interfaces prior to adding a test. The request will detail the testing requested and at least two patient identifiers. In either case, testing will not be ordered or performed until written or electronic authorization is received.
- **Electronic Add-ons**
  - Inpatients- Verbal requests are not accepted from inpatient units. The lab staff should instruct the caller to enter the request into Lifechart using the "Add-on" flow.

- A technologist always has the discretionary authority to repeat a sample which meets all the algorithms for result acceptance, yet they feel the results are questionable or the pattern of result change isn't consistent.

- **If a verified result is found to be in error**, the technologist MUST notify the requesting unit/ physician immediately of the error. The technologist, using Results Entry, must correct the result. A comment should then be entered and must include the name of the person receiving the call, the date/time the call was placed and the name of the technologist. A SafetyNet event should be entered.

- **Analytical Measurement Range**
  All assays have specified analytical range which should not be exceeded when reporting. For results outside this range, results will be reported as "<lower limit" or ">upper limit". Several assays have an extended AMR due to auto-dilution systems on the analyzers. Auto dilutions will be periodically verified throughout the year to

ensure the accuracy of the dilutions being made. Selected samples where auto dilution has been utilized will be manually diluted and the results compared. If the results are within ± 10% of each other, the verification will be accepted.

- **Clinical Reportable Range Summary:**
  - **All enzymes are to be diluted no more than 10X.** Results which are still above the reportable range should be reported as "> dilution factor x linear range upper limit", which are specified in the individual procedures and in the AU Ranges Information Sheets.
  - **Ammonia, Chloride, Potassium and Sodium are never diluted** and are reported out as "> upper limit of the reportable range".
  - For analytes on the AU, an upper limit of the Clinical Reportable Range has been determined. Refer to reportable range spreadsheets "bible' for details.
  - Any exceptions where values need to be diluted until numeric, refer to individual assay procedures along with a consult from Medical Director.

A. Reagents/Calibrators/Diluents/QC Materials

- All reagents, solutions, calibrators, stains, chemicals, and controls must be properly labelled as applicable with the following elements:
  1. Content and quantity, concentration or titer
  2. Storage requirements
  3. Date prepared, filtered or reconstituted by laboratory
  4. Expiration date and new expiration date if opening the container changes the expiration date, storage requirement, etc.
- When calibrators are reconstituted, the containers will be labeled as to the contents and lot #, if needed for cross-reference of calibration values, if not already on label.
- Reagent/Calibrators/Diluents will be stored according to manufacturer's recommendations and if not used, will be discarded when the expiration date is reached.
- If manufacturer does not specify an expiration date for a reagent, the vendor or contact number on SDS sheet should be called to confirm the open reagent stability. Once determined, that date should be marked on the container.
- Unless specified by the manufacturer, components of kits will only be used within a lot. Components from different lots will not be mixed.
- Calibrators-Only manufacturer recommended calibrators will be used.
- To determine **frequency of calibration**, manufacturer recommendations can be followed but may be modified based on assay performance.
- Once a bottle of Calibrator or QC material is opened, the expiration date of that opened bottle is sometimes different from the expiration date of the same material if it was unopened. If this is the case, the bottle/tube must be labeled with the date opened and the 'new'opened expiration date.

B. Quality Control

Overview

QC material are performed using the same methodologies as patient samples and are performed by the technologists who are approved to analyze those samples.

Beckman AU

The fundamental purpose of any quality control program is to ensure that the data that enters the patient's record or is communicated to the attending physician is an accurate measure of the requested analyte.

- Quality control for the AU is based on an internally consistent system. The instruments are calibrated with Beckman Calibrators/Validators. Following the procedures described in the AU manual, the Technologist will calibrate each analyte, as needed, using QC as the determinant factor of calibration acceptability. The QC used for most analytes will be the BioRad Multiqual Levels 1 and 3. Both levels of QC must be run after each calibration and each within lot calibration. Both levels must be found to be within the established ranges. If this is not the case, follow appropriate troubleshooting techniques outlined later in this manual. Once acceptable results have been obtained, the results of this will be maintained in QC log.

- Since it is not practical, precision and accuracy for all analytes is only determined during implementation of a new assay, or in the case of instrument failure with suspected issues related to precision. Correlations between the Lifespan AU analyzers will be performed at least twice per year and more often if the need arises.

- Instrument performance is continuously monitored via the stored statistics for each control analyte. From this data, the instrument calculates the mean, standard deviation and coefficient of variation for each analyte. Subsequently, as each analyte in the specified controls is measured, the variation of the result from the mean is calculated. Therefore, after repetitive analysis of the QC material on the analyzers, the laboratory has established acceptable limits for each of the analytes on all the controls. These limits are programmed into each instrument and become the limits that are to be used to accept or reject the performance of the instrument on each shift. We use the absolute QC acceptance rules where all levels assayed must be within acceptable limits, prior to the release of patient results, unless specifically released by a Senior technologist or Manager.

- Where available, QC data will be submitted for peer group analysis. The subsequent report provided will be reviewed comparing our Mean, SD and CV. Periodically, to test for imprecision, we will flag any CV which exceed 1.25 x Peer CV for that level QC and investigate as warranted, which will include comparing the most recent

period, to see if the issue still exists. Additionally, monthly QC Summary reports will be reviewed and deviations above what is expected will be investigated.

- **At least two levels of serum QC materials** to be performed on the AU, will be run daily at the beginning of the shift approximately 7:30AM, after the change of reagents (within lot or new calibration), after maintenance, or when a technologist determines its necessity.

- The typical duration for a "lot number" of Multiqual QC material is variable based on shipments. Data on each new lot number of QC that is used will be collected during a crossover period. The goal would be to obtain approximately 20 data points to establish a provisional range, which could then be adjusted as warranted.

- For all QC that is run, the results must be within established limits for the analyte before any patient results involving that assay are released. If the result for an analyte differs from the acceptable value by >2 SD a flag "Greater than 2 SD" will be printed in the remarks column. Any analyte with this flag requires corrective action before patient samples are run and verified. If, following corrective action, the repeat control is within acceptable limits, patient samples may be tested. **If the results of the QC are still not within acceptable limits after repeating the analysis once, if outside the Red Range limits, the same control material may not be repeated again. Repeat testing with new QC material must be performed. If the results are still outside the Red Range limits, the technologist should refer to the Procedure To Follow When Quality Control is "Out of Range", found later in this procedure.** Once resolved, the source of the error and the corrective action taken must be logged in the QC Incident Report sheet.

- To detect trends, the laboratory director or designee will review all QC daily (Monday through Friday). At the bench level, each tech verifies QC is acceptable after running it. Further, manager responsible for QC will then review this information monthly.

- When QC is complete, the performing technologist must check off and initial that QC has been performed, including repeats and within range. QC for all shifts **must be checked off** by the performing technologist. "Out" values must be appropriately dealt with by technologist noting corrective actions on the QC Out Values Sheet and in Unity. Technologist must initial off QC sheet verifying that QC has been performed and is within range.

- At least on a monthly basis, the cumulative QC data will be printed from each AU for each level of each QC. The data will be reviewed and the obtained means from each system. The manager in charge of QC will evaluate the data. Analytes where a significant difference in the observed mean value exists, will be further investigated. A Levy-Jennings plot may be generated to aid in determining the cause of the difference. After this review, any deviations will be deemed acceptable, or

recalibration of systems may be required to attempt to bring the values closed back toward mean.

New Reagent Lot Validation

There is a process to confirm that new lots of reagents respond to QC and patient values as the previous and/or current reagent lot before being placed into service. Two levels of QC material are run to confirm acceptability of the new reagent lot. The ideal acceptable QC values of the new lot should fall within the given 2SD range of the peer based mean of the assay. The purpose of this check is to confirm that the use of new reagent lots and shipments do not affect patient results.

Quantitative: For quantitative nonwaived tests, patient specimens should be used to compare a new lot against the previous lot, when possible. Manufactured materials, such as proficiency testing (PT) or QC materials may be affected by matrix interference between different reagent lots, even if results show no change following a reagent lot change. The use of patient samples confirms the absence of matrix interference. The following materials may be used:

1. Patient samples tested on a previous lot.
2. Reference materials or QC products provided by the method manufacturer with method specific and reagent lot specific target values.
3. Proficiency testing materials with peer group established means.
4. QC materials with peer group established means based on interlaboratory comparison that is method specific and includes data from at least 10 laboratories.
5. Third-party general-purpose reference materials if the material is affirmed in the package insert or by the method manufacturer to be commutable with patient specimens for the method.
6. QC material used to test the current lot is adequate alone to check a new shipment of the same reagent lot, as there should be no change in potential matrix interactions between the qc material and different shipments of the same lot number of reagents.

Procedure: Beckman AU's
Two levels of QC material are run to confirm acceptability of the new reagent lot. The ideal acceptable QC values of the new lot should fall within the given 2SD range of the peer-based mean of the assay.

1) Enter the new lot and/or calibrator in the New Lot Reagent Logbook.
2) Calibrate and/or Blank the new lot of reagent, run two levels of QC material and accept the reagent as valid if the QC falls within the 2SD range established and posted.
3) If the QC is outside the 2SD range, then attempt to troubleshoot so as get the QC within the 2SD range. Examples of troubleshooting steps include:

- change the reagent,
- change or repour the calibrator,
- change, or repour the QC
- clean the probes

4) If after troubleshooting, the QC is outside the 2SD range, but within the 3SD range, Rerun at least five patients that were performed on the previous lot of reagent. The new lot of reagent is acceptable if the patient results are within the spread of the 2SD range for that analyte. If the reagent is acceptable, then
    1. Enter these results in the reagent logbook as well as the QC obtained
    2. Relay this new lot information to a Senior technologist, Manager or Director
    3. Enter QC values on on QC Outlier sheet.
    4. Put a note to alert other Technologists of the QC situation with the new lot of reagent.

5) If the patient results are unacceptable, then, do not use this lot. Attempt to borrow or procure another lot of reagent. Follow the above procedure to alert users of the QC issue with the reagent on that instrument.

Qualitative: minimum cross-checking includes retesting at least one positive and negative sample with known reactivity against the new reagent lot. Examples of suitable reference materials for qualitative tests include:

1. Positive and negative patient samples tested on a previous lot;
2. Previously tested proficiency testing materials;
3. External QC materials tested on the previous lot
4. If none of the above options is available, control material provided by the assay manufacturer with the new test kit.

Frequency of QC

QC for Beckman AU, all AU assays, AU480 Biorad Multiqual Level 1 & 3 both run at the beginning of the shift (approximately 7:30AM).

Procedure to Follow When Quality Control is "Out of Range"

- Beckman AU: Two levels of QC material are run for all analytes on the following schedule:
    - AU480 Biorad Multiqual Level 1 & 3 Determine if QC Is acceptable by checking acceptable ranges for analyzer.
- If results are not acceptable, the "out of control" result should be recorded on the QC sheet.

- **Note**: If a new lot of reagent is in use, there could be as much as a 5% shift of QC means between lots.
- For the QC run at beginning of shift (Levels 1&3), the results must be within established limits, (usually ± 2 SD) for a particular analyte before any patient results involving that assay are released. On the AU's if the result for an analyte differs from the acceptable value by >2 SD a flag "Greater than 2 SD" will be printed in the remarks column on the AU printout. Any analyte outside of established acceptable ranges, requires corrective action before patient samples are run and verified. If, following corrective action, the repeat control is within acceptable limits, patient samples may be tested.
- **If the results of the QC are still not within acceptable limits after repeating the analysis once, the same control material may not be repeated again. A freshly poured aliquot of QC may be run now; if the results are now acceptable, patient testing may be resumed.**
- **If the results of this fresh QC are outside of the red ranges (Red Range list posted near workstations) patient testing must be suspended.**
- **Check/perform the items below to bring the analyte into proper control:**

  - Review Levy Jennings plots to see if trend has developed
  - Remove that reagent and recalibrate if necessary
  - Change lot number of reagent and recalibrate if indicated. Confirm the lot of calibrator is the same as what is installed on the instrument.
  -Check system parameters such as temperature and humidity
  -Is the analyzer operating properly? Refer to the specific troubleshooting section of Operator's Manual.
  - Check that the posted QC means are identical with those entered into the analyzer.
  - Repeat the QC after corrective action has been identified.
  - Document all corrective action in the QC incident binder.

- If the problem was resolved by one of the above procedures, document your resolution of the issue in the QC Incident Log Book for the AU, or directly on the QC sheet.

- **Backtracking of results: Once the analyte has been established to be "in control"** the technologist will be required to spot check patient results to ensure their accuracy. This process should begin with those most recently run and proceed backward in time until a point is reached where the repeated results agree with the initial result. At a minimum, five patient results spanning a significant portion of the reportable range should be found to check before the issue is thought to be resolved, unless a smaller number of patients were performed for that assay. The data should be reviewed by a Senior technologist, Manager or Director at the earliest possible time. If a Director or Manager is not immediately available, a reasonable process to determine if corrective action is needed is that the results should not change more than 15% or two SD on the comparable level

of QC material (whichever is greater). It is important to note that if patient retesting resulted in a significant difference and results need to be error corrected, those corrections need to be done immediately and all inpatient changes should be called to the unit. This includes outpatient (Outreach) result changes. Again, any changes that result in a value that then becomes a red critical, that value needs to be called irrespective of the time of day. Most importantly, if any question remains regarding the decision-making process, call the Manager/Senior technologist for assistance.

- If the problem was resolved by one of the above procedures, document your resolution of the issue in the QC Incident Log Book for the AU.

- If the problem still exists, contact Manager/Senior technologist, run on alternate instrument by sending specimens to RI Hospital (where applicable) and call field service.

Intermittent Testing is defined as tests that are taken out of production for a time (for example, seasonal testing for influenza). A test is considered to be taken out of production when (1) patient testing is not offered AND (2) PT or alternative assessment, as applicable, is suspended. When a test is put back into production, the following requirements must be met:

- PT or alternative assessment performed within 30 days prior to restarting patient testing
- Method performance specifications verified, as applicable, within 30 days prior to restarting patient testing
- Competency assessed for analysts within 12 months prior to restarting patient testing

Post-Analytical Considerations

Post analytical procedures are devised to check for possible clerical and analytical errors including patient misidentification, sample contamination and analytical errors. Any errors detected at this point must be treated as all others. The incorrect result should be amended, and notification of the requesting location/physician of the change will occur. A footnote detailing who was notified, using the template "CR" (corrected result called to) and a notation made in the patient report showing the original result and the corrected result. All significant errors must be entered in the hospital Safety Event reporting system.

A. Supervisor Reports

- The Supervisor Report is a listing of all results generated by each Workstation on the prior day and can be generated by the LIS each morning or configured for any time frame desired by the user. The Medical Director of laboratory, Manager or a designee will review these reports daily (Monday through Friday). The workload generated on weekends and holidays may be reviewed on the next regular shift (Monday through Friday).

- The report is checked for evidence of repeats, verifications, and footnotes to ensure that proper notification of physicians / staff of all critical values, unacceptable samples and error correction notifications were made. If deficiencies are found in this area, a copy of the patient's report is generated and given to the Manager of the area, who will notify the technologists of the situation and keep the documentation as a part of the technologist's annual review.

- The report will also be checked for day-to-day inconsistencies in patient results. This is easily seen by the presence of one or more delta check flags ("D") on the report. These may be investigated against previous results on the patient in the LIS. If necessary, stored samples may be repeated to ensure the accuracy of the results. To accomplish this, all samples are saved for a minimum of 72 hours. If an error is found, the process described above is followed.

- Once reviewed, a notation of the review is made on the daily log sheet, detailing any notable issues found.

B. Exceptions Report

- The Exceptions report lists all critical values, delta values, and any result modified after verification the Manager will be assigned the responsibility to check the Exceptions Report periodically. The information contained on this report will also be seen on the Supervisor Report, which is reviewed daily. The purpose of this daily review is for the detection and correction of significant clerical and analytical errors.
- This check is also to monitor tech competency, as to the frequency and type of errors that are occurring. If trends are noted either in frequency with a particular technologist or a certain type of error, action plans can be put into place to try and minimize its occurrence.
- This internal QA of tech performance is used in the annual review of the technologists.

D. Pending Report by Resulting Worklist

- A Pending Report should be generated at least once during each shift for the workstations. The purpose of this report is to indicate to the technologist all testing

for a Workstation or Template that has been received but has not yet been completed. This is particularly useful in "identifying" a sample which has been received but may not have been assayed in an appropriate timeframe.

F. Retention of Documentation

- All "Repeat Sheets" are saved for a minimum of two weeks as well as other pertinent laboratory documentation.