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| **S:\Marketing and Communications\Logos\Children's Minnesota Logo\JPG\Childrens_MN_2015_logo_2c_RGB_800x257.jpgReagent Lot Verification** |
| **Purpose** | To confirm that the use of new reagent lots and shipments do not affect patient results. New reagent lots and shipments are checked against previous reagent lots or with suitable reference material before or concurrently with being placed in service on chemistry instrumentation.Matrix interferences between different lots of reagents may impact the calibration status of instruments and consistency of patient results. Improper storage conditions during the transport of reagents may have an impact on their ability to perform or exhibit the same levels of reactivity as intended.  |
| **Policy** | **Quantitative Testing:** Manufactured 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 may help confirm the absence of matrix interference.One of the following requirements must be met for the materials being used for reagent lot verification according to COM.30450:1. QC materials with peer group established means based on interlaboratory comparison that is method specific and includes data from at least 10 laboratories;
2. Patient samples tested on a previous lot;
3. Reference materials or QC products provided by the method manufacturer with method specific and reagent lot specific target values;
4. Proficiency testing materials with peer group established means;
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.

**Qualitative Testing:** Examples of suitable reference materials include:1. Positive and negative patient samples tested on a previous lot;
2. Previously tested proficiency testing materials;
3. External QC materials tested on a previous lot;
4. If none of the above options is available, control material provided by the assay manufacturer with the new lot is acceptable.

Follow the actions in the table below to verify New Lots/Shipments of reagents for Chemistry instrumentation.  |
| **Procedure** | **Step** | **Action** |
|  | 1 | All chemistry reagents received will be marked with a received date while being put away. |
|  | 2 | All reagents will contain a sticker over the opening of the box.**Minneapolis:** Use round red stickers that say ‘DO NOT USE.’**St. Paul:** Use ‘New Lot’ stickersIndicate if it is a **new lot** or **same lot/new shipment** using a black Sharpie on the top-most accessible box. |
|  | 3 | Place new lot/shipment of reagent on analyzer.  |
|  | **If:** It is a new lot of reagent | **Then:** Calibrate the new lot of reagent on the analyzer. Perform Quality control on serum and urine assays when applicable. |
|  | **If:** It is the same lot that is a new shipment | **Then:** Perform quality control on serum and urine assays when applicable. On the Vista and RxL, you will need to remove the current reagent flex to ensure QC is being run on the new shipment flex. |
|  | 4 | Obtain the reagent lot verification form [CH 2.15.f1](https://starnet.childrenshc.org/References/labsop/chem/forms/ch-2.15.f1-reagent-lot-verification-form.pdf) on StarNet Intranet in the Chemistry Manual under the Forms section. |
|  | 5 | Indicate if it is a New Lot or the Same Lot/New Shipment by checking the corresponding box. (Top middle of form) |
|  | 6 | Fill out the appropriate boxes at the top of the worksheet. (i.e. Analyzer, lot numbers, expiration dates, date new lot/shipment was received and amount received in boxes) |
|  | 7 | Locate Peer Mean and calculate the Standard Deviation (SD) from the Coefficient of Variation (CV). (If there is no peer, see Limitations section below.)1. In Unity Real Time, select Advisors> Westgard…
2. Find and highlight the desired lot number of quality control on the left side of the active screen.
3. Highlight the appropriate analyte at the top of the screen under the Analyte column
4. Click the Group Statistics tab in the bottom right of the active screen
5. Record the Peer Monthly Mean on your worksheet and use the Peer Monthly CV data to calculate the SD.
6. To calculate the SD: Multiply the CV first by 0.1 and then by the Peer Monthly Mean to arrive at the SD, as shown below:

 **CV x 0.1 x Peer Monthly Mean= SD** |
|  | 8 | Record serum QC and urine QC, when applicable, on the [CH 2.15.f1](https://starnet.childrenshc.org/References/labsop/chem/forms/ch-2.15.f1-reagent-lot-verification-form.pdf) worksheet. Write the name of the control being tested. (Note: If the reagent does not have urine tests, leave blank.) For those tests that have 3 levels of serum QC, cross out the low urine level and write in the third level of QC. Record the QC results obtained from calibration of the new lot of reagent or shipment in the ‘reagent result’ column. |
|  | 9 | New lot/new shipment results must be within 2 Standard Deviations of the Peer Monthly Mean. Multiply the SD calculated above by 2 to arrive at the range above and below the mean where the data points must fall for acceptability.  |
|  | **If:** The reagent result is within 2 SDs of the peer mean | **Then:** Reagent has been verified. A. Circle ‘Yes’ on reagent verification worksheet. B. Enter in Unity Real Time (URT): As shown by the green arrow below, double-click the A and chose the action to match the outcome of the verification from the box. Click apply. C. As shown by the purple arrow below, double click the C to enter a free text comment. The following information must be recorded in URT: Lot number, expiration date, how many boxes received, date of receipt. NOTE: In case of a failure, any and all troubleshooting must also be free-texted in this box. D. Sign the form and have a second tech review the calculations. E. The second reviewer files the form.  |
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|  | **If:** The value is out by more than 2 SDs of the peer mean | **Then:** Troubleshoot in this order1. Rerun QC once
2. Recalibrate and repeat QC. If the reagent is still not acceptable, continue on with the investigation.
3. Perform Vista Crossover studies using previously reported patient samples (See Vista iGuide procedure for steps). Crossover Acceptability: SD must be within 2SD of peer mean and CV should be within 7%. Contact Siemens or Chemistry Technical Specialist for deviations.
4. Run 3-5 patients that were previously run on the current lot/shipment. (Choose patients that span in the clinical reportable range) Compare values with new lot/shipment. Results should be within ±10%.
5. Run proficiency testing samples only from testing where results have been returned, per CAP regulations. Results should be within ±10%

If values exceed ±10%, the Chemistry Technical Specialist must review all data to determine further investigatory actions. |
|  | 11 | **‘Yes’** or **‘No’** should be circled on the reagent lot verification form. |
|  | 12 | Sign off on ‘Verification Performed By’ on reagent lot verification form. |
|  | 13 | A second tech must review the form for correct calculations and sign ‘Verification Reviewed by.’ |
|  | 14 | File worksheets:* Vista – Staple reagent lot verification form to calibration printout and file in the appropriate file per campus.
* RXL – Place reagent lot verification form in the same file/folder as the Vista calibrations.
* DiaSorin Liaison XL: File in the same drawer as Vista on the St. Paul campus
* Abbott Architect and IDS iSYS: file in appropriate calibration binders in Minneapolis.
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|  | 15 | Re-Label each box of new lot/new shipment of reagent with a ‘This lot is ready for use’ sticker. Initials of person who performed the verification and date verified should be marked on each label. |
| **Limitations** | 1. If there is no peer mean, such as with Beta Hydroxybutyrate, Lamotrigine, IgG Subclasses, or Methotrexate, utilize the current QC lot cumulative mean from Westgard Advisor.

 * + In Unity Real Time: Advisors> Westgard Advisor> select lot number> on the right side, select the Group Statistics Tab. The top line shows the cumulative data.
1. Manufactured materials, proficiency testing (PT) or QC materials may be affected by matrix interference between different reagent lots. If matrix interference is suspected use patient sample to resolve problem.
2. This does not apply to qualitative tests, such as Borrelia/Lymes or HIV. The manufacturer’s package insert range and quality control are used to verify new lots of reagent. If the positive QC result is positive and the negative QC result is negative, accept the verification. New lot information should be recorded in Unity Real Time Actions and Comments sections in lieu of paper forms using the documentation steps described above in step 9. For additional information on entering actions and comments, see procedure [CH 2.17 Unity Real Time QC Review, General User](https://starnet.childrenshc.org/References/labsop/chem/quality/ch-2.17-unity-real-time-qc-review-general-user.pdf).
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| **References** | 1. All Common Checklist, College of American Pathologists, Northfield, IL. August 2018.
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| **Historical Record** | **Version** | **Written/Revised by:** | **Effective Date:** | **Summary of Revisions** |
| 1 | Kelsi Brown, Erin Bartos, Stephen Gripentrog | September 26, 2017 | Initial Version |
|  | 2 | Erin Bartos | July 15, 2019 | Updated for URT |