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| Confirmation of Acceptability |
| **Purpose** | This procedure provides instructions for confirmation of acceptability for new lots and new shipments of reagents. 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 Statements** | This procedure is intended for all personnel responsible for the confirmation of acceptability of new lots or new shipments of reagents.New reagent lots and shipments are checked against previous reagent lots or with suitable reference material before or concurrently with being placed in service.*NOTE: This requirement applies to reagents that provide a chemical or biological reaction to detect and/or measure a target analyte and would not apply to inert ingredients (eg, reagent water, saline) or materials used for specimen preparation.***Quantitative:** For quantitative nonwaived tests, patient specimens are preferred for comparing 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 specimens confirms the absence of matrix interference. The following materials may be used:* Patient specimens tested on a previous lot
* Reference materials or QC products provided by the method manufacturer with method specific and reagent lot specific target values
* Proficiency testing materials with peer group established means
* QC materials with peer group established means based on interlaboratory comparison that is method specific and includes data from at least 10 laboratories
* Third-party general purpose reference materials if commutable with patient specimens for the method (per package insert or method manufacturer)
* QC material in use with the current reagent lot to check a new shipment of the same reagent lot (There should be no change in potential matrix interactions with use of the same lot number of reagent and QC material).

**Qualitative:** For qualitative nonwaived tests, minimum cross-checking includes retesting at least one positive and negative specimen with known reactivity against the new reagent lot. Utilization of a weakly positive specimen is recommended for confirmation of acceptability.Examples of suitable reference materials for qualitative tests include:* Positive and negative patient specimens tested on a previous lot;
* Previously tested proficiency testing materials;
* External QC materials tested on the previous lot (eg, antigen testing kit controls, immunohematology antisera and reagent red cells)
* Control strains of organisms or previously identified organisms for microbiology reagents used to detect or evaluate cultured microorganisms;
* If none of the above options is available, control material provided by the assay manufacturer with the new test kit.

Follow the actions in the procedure below to confirm acceptability of new lots of reagents or new shipments of in-use reagents for Chemistry instrumentation.  |
| **Definitions** | **Confirmation of Acceptability (CoA)** – The process of confirming that a new shipment or lot of reagents is acceptable for use in patient testing. Also referred to as reagent verification, or new lot verification.**New reagent** – In the context of this procedure, a new reagent refers to any new lot or shipment of reagent that provide a chemical or biological reaction to detect and/or measure a target analyte.**In-use reagent** – In-use reagent is synonymous with current, old, or previous reagent that has previously been confirmed (verified) as acceptable for use. **Peer Lab** – Other laboratory running the same assay reagent on the same equipment. Data from peer labs provides a peer mean, peer SD, and peer CV for a given analyte.  |
| **Materials** |  |
|  | **Records/Forms/Documents** |
|  | * CH 2.99.f1 Confirmation of Acceptability Form (online)
* CH 2.99.f2 Downtime CoA Form (paper)
* CH 2.99.f3 Reagent CoA Guide Chart
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|  | **Materials** |
|  | * Green and red stickers
* Routine QC materials – Assay specific
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| **Procedure** |  |
|  | **Step** | Action | **Related Document** |
| 1 | Remove one set of reagent from the sequestered reagent area. Load reagent on analyzer, calibrate as applicable, and run routine QC. Fill out the appropriate form:* *CH 2.99.f1 Confirmation of Acceptability form is for routine verification of reagents.*
* *CH 2.99.f2 Downtime CoA is for use whenever computer systems are down, there is an error in the online form, or use of the online form is not possible for any other reason.*
 | [CH 2.99.f1 Confirmation of Acceptability Form](https://forms.office.com/Pages/ResponsePage.aspx?id=OpIKj12BPUaNw4KG0pTxPFEXQntFHYFFkShX7_KOSDpURVdQR0dOM05KN1Y2RTg3MEU3WlVWVDJSWiQlQCN0PWcu)[CH 2.99.f2 Downtime CoA Form](file:///C%3A/Users/CE165114/AppData/Local/Temp/1/MicrosoftEdgeDownloads/7e8dc609-661a-4954-ba20-c3d17c4fd450/V2%20CH%202.99%20Confirmation%20of%20Acceptability.docx) |
|  | 1a | Acceptability is confirmed by one of three protocols as follows:* Quantitative assay Peer Comparison: For quantitative assays with >10 peer labs, routine QC must be within 2 peer standard deviations of the peer mean.
* Quantitative assay Sample Comparison: For quantitative assays with <10 peer labs, a 5 patient sample comparison will be performed. New reagent results must match in-use reagent results within 10%.
* Qualitative/Semiquantitative Comparison: For qualitative or semiquantitative assays, routine QC must pass URT criteria. These QC materials are all either external QC tested on the previous lot, or manufacturer QC, or both.

These requirements are outlined in both the online and downtime CoA form. |  |
|  | 1b | For downtime forms, submit these to the chemistry lead tech or technical specialist. They will be added to the electronic record as soon as possible. |  |
|  | 2 | Reagents that pass CoA may be placed into general use for patient testing. Label all boxes from the lot/shipment with a green sticker and move to the in-use stock location. |  |
|  | 3 | Reagents that fail CoA must be kept in the sequestered reagent area. Label reagents that fail CoA with red stickers and notify TS immediately. Estimate time until the reagent is needed for patient testing (how long in-use reagent will last before running out). Arrange for a new order of reagent and/or to borrow reagent from alternate lab site to avoid cessation of patient testing, and notify operations supervisor if patient testing will be impacted.  |  |
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| **Calculations** | **Peer SD:** Where SD is the Peer SD, $\overbar{X}$ is the Peer Mean, and CV is the Peer CV$$SD=\overbar{X}\*\frac{CV}{100}$$**Acceptable range for Peer Comparison:** Where SD is the Peer SD, and $\overbar{X}$ is the Peer Mean$$Acceptable Range=\overbar{X}\pm 2SD$$**Acceptable range for Sample Comparison:** $$Acceptable Range=In Use Result\pm 10\%$$ |
| **Failure to Pass CoA** | With the assistance of the chemistry lead or technical specialist, a notice to the manufacturer may be placed with intent to refund/replace the product. Chemistry lead or technical specialist may suggest additional troubleshooting steps to take and to re-attempt confirmation of acceptability. If matrix interference is suspected, a patient comparison or other processes may be performed in place of a peer comparison.  |
| **Limitations** | Manufactured materials, proficiency testing (PT), or QC material may be affected by matrix interference between different reagent lots. If matrix interference is suspected, patient samples may be used to resolve problem. |
| **References** | 1. College of American Pathologists Chemistry and Toxicology Checklist
2. College of American Pathologists Lab General Checklist
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| **Historical Record** | **Version** | **Written/Revised by:** | **Effective Date:** | **Summary of Revisions** |
|  | Matt Johnson | 2/1/2023 | Initial Version |
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