**Downtime Confirmation of Acceptability**

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| --- | --- | --- | --- |
| **Reagent:** |  | **Analyzer:** |  |
| **Lot:** |  | **CoA Date:**  **(Today’s date)** |  |
| **Exp. Date:** |  | **Tech:** |  |

Make sure to calibrate and run routine controls before performing the CoA. Do not run patient samples on the new reagent until CoA is complete. Only complete one of the three comparisons below. Submit form to TS after completion. See CH 2.99 Confirmation of Acceptability for guidance.

**Quantitative Assay Confirmation of Acceptability**

**Peer Comparison Data:** For Quantitative assays with > 10 peer labs. Compare routine QC results to URT Peer mean. Acceptable range is peer mean + 2 peer SD.

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| --- | --- | --- | --- | --- | --- |
| **QC Name** | **Peer Mean** | **Peer SD** | **Acceptable Range** | **Result** | **Within Range?** |
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**Sample Comparison Data**: For Quantitative assays with < 10 peer labs. Run 5 patient samples on new reagent and in-use reagent; attempt to have values near low, mid, and high ranges. Results must match within 10%.

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| --- | --- | --- | --- | --- | --- |
| **Sample ID** | **Original Result** | **New Lot Result** | **Absolute difference** | **Percent difference** | **Pass w/in 10%?** |
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**Qualitative/Semiquantitative Assay Confirmation of Acceptability**

**Qualitative/Semiquantitative Comparison Data:** Compare new reagent to in-use reagent patient, PT, or QC results; or run manufacturer QC. New reagent must match existing reagent/expected values.

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| --- | --- | --- | --- |
| **Sample ID** | **Expected Result** | **Result** | **Pass?** |
|  |  |  |  |
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**Is reagent acceptable for patient use?** **Yes**   **Yes, After Troubleshooting**   **No**

(Circle one)

Describe any troubleshooting needed to pass CoA: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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Place reagents that pass CoA into general use and label with green stickers. Reagents that fail CoA must be sequestered and labeled with red stickers. Notify TS of failures, if there is an impact to patient testing, notify operations supervisor.

**CoA Performed by/date**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_