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| **Topic** | **Review Information** |
| **Why do we have to do this task?** | This is a CAP requirement  CAP Standards for New Reagent Lot Confirmation of Acceptability requires that new reagent lots and shipments be checked against previous reagent lots or with suitable reference material before or concurrently with being placed into service. |
| **What tests requires Lot-to-Lot comparison** | **Lot-to-Lot Comparison Definition**:  The comparison of testing results with new lots of lab reagents, which are *received as a kit* (multiple reagents for the testing), to the lot currently in use to ensure that testing results are comparable.   * Fetal Bleed Screen * Hemoglobin S |
| **How will we do this task?** | Follow SOP  <https://iuhealth-pathlab.policystat.com/policy/4904320/latest/> |
| **When do we complete Lot to Lot Comparison?** | We **log** the reagent in per procedure, **store** the new lot in the reagent quarantine with worksheet and then **test** the new lot at the time the current lot is expiring.  **A reminder to complete this Lot to Lot Comparison will be placed on the Reagent Log in Page for Fetal Bleed Screen and Hemoglobin S** |
| **How do we complete this comparison**  ***This is a summary of the SOP for training purposes***  **Follow the SOP steps** | * Receive new lots/shipments of FMH RapidScreen and Sickledex reagents * Do not mark these reagents as "Okay to Use” * Start the Lot-to-Lot Comparison Worksheet. * Place the form and the new lot of reagent in the reagent quarantine location. * When the current lot is expiring, *or at any time before put into use*, then obtain the new lot of reagent with the Lot-to-Lot Comparison Worksheet from the reagent quarantine location. * Perform Quality Control testing following the SOP/package insert for the test system *with this modification*: * Test the new lot of reagent and the CURRENT QC material. * The QC material must come from the current lot-in- use rather than the corresponding new lot of QC material. * Document the current lot number of QC material on the Lot-to-Lot worksheet. * Document QC results and interpretation on Lot to Lot Worksheet. * If the results were valid, then the new lot of reagent is acceptable for use. * Forward the Lot-to-Lot Worksheet to a supervisor for review and retention. * When lot-to-lot comparison is complete and acceptable, document in the Remarks column of the [Reagent Receiving Log](https://iuhealth-pathlab.policystat.com/policy/4186854/latest/) that the lot is **OK to use.** |