**Description of Non-conformance:**

Two Forensic Biology staff members used an expired reagent in the extractions of four proficiency tests. Because the expired reagent was not labeled with its expiration date and was not inside the kit box that it was a part of, the staff members did not properly identify it as being expired.

**Additional Information/Follow-Up:**

N/A
Summary of Root Cause Analysis:
Note: Incidents are documented for tracking purposes and trend analysis. Root Cause Analysis is not required for incidents.

There were two contributing factors identified as root causes for this nonconformance: the Forensic Biology staff's practice of utilizing a plastic bin for reagents and an unreliable mechanism of verifying expiration dates. Forensic Biology staff utilize a plastic bin to organize some of their extraction room reagents. The kit reagents are sometimes placed in this plastic bin instead of being placed back inside of the kit box. Once a kit reagent is placed in the plastic bin, it is not clear which kit it belongs to and/or what its expiration date is. In addition, once a reagent is removed from the kit, it no longer meets the reagent labeling criteria (since the expiration date is not listed on the tube itself). Once a kit is expired it is taken out of circulation for casework and placed in a "training only" location. But, because some of the reagents may have been removed from the kit box and placed into the plastic bin, those removed reagents are not identified as being part of the expired kit and consequently are never transferred to the "training only" location. Forensic Biology staff had an unrealistic expectation that all available reagents were part of the current lot, however, this information was not readily verifiable in the extraction room.

In addition, for reagents prepared by the Forensic Biology laboratory, staff primarily relied on unverified notes as a means of checking that the reagents they were using were not expired. These notes were uncontrolled and were not verified, creating a risk that expired reagents may be used in casework and/or the respective lot numbers, QC dates and/or expiration dates may not be accurate. Because these reagents are now being individually labeled (as opposed to the tubes containing a symbol referencing back to the labeled rack), the need for staff to create and rely on any notes has been mitigated. Also, when staff are recording and/or verifying reagent information, they are now required to use the information provided on only the reagent tube, the outer reagent storage container or the quality control forms because these sources have been verified for accuracy.

Actions Taken:

Forensic Biology staff were instructed to always check the reagent lot numbers and expiration dates prior to use. The items that were extracted with expired proteinase K were re-portioned and re-extracted. The affected items have the following report statement: "A sample preparation error occurred with this item; therefore, no results will be reported. See Quality Report 2019-007". As a direct result of this nonconformance the Forensic Biology laboratory discussed the details of how all reagents were labeled. The sticker that is placed on the EZ1 kit box has now been revised to include the kit lot number and each component’s lot number. And, each EZ1 kit reagent component now has a label with the EZ1 kit lot number listed on it (so that a reagent can then be readily tied back to the kit that it came from) as well as its expiration date. Even with the new labeling, Forensic Biology staff were instructed to always return the kit reagents back into the appropriate box after use. There are two reagents (cRNA and DTT) that are stored in the freezer and while the racks that hold these reagents have the lot numbers, QC dates and expiration dates written on them, the individual reagent tubes do not. When staff records the lot number, QC date and expiration date information in the laboratory information management system (LIMS), they do not have this information readily available to them. This has created the practice of transcribing the reagent information onto a post-it note and then populating the necessary information from the post-it note into LIMS. If an error occurs in the creation of the post-it note, the error is then potentially repeated numerous times because the post-it note is then typically affixed to the computer terminal for others to use. These notes are uncontrolled, and the content of these notes is not formally verified for accuracy. It was also determined that the allelic ladder lot number was being recorded, but it’s QC date and expiration date were not. Like the proteinase K reagent, the allelic ladder is purchased as part of a kit but once the allelic ladder is removed from its kit, it is not clear which kit it belongs to. The allelic ladder label has now also been revised to include the kit lot number so that it can be readily associated with the kit it is a part of. In addition, the lot number and expiration date were not being...
recorded for the HiDi formamide or the LIZ 600 size standard. On 2/21/19 the laboratory started recording the lot number, QC date (when applicable) and expiration dates for all three reagents (allelic ladder, HiDi formamide and LIZ 600 size standard) and having this information verified by a second staff member. While this nonconformance was being investigated a discrepancy was observed in the documentation of the QC date for the DTT reagent on the extraction worksheets in at least three training binders. While the error was observed in training, the laboratory recognizes that there is a possible risk that the incorrect QC date may have been recorded in casework (please see workflow ID# 47766/2019-043 for further information). However, in this circumstance, the error would only extend to the documentation of the correct QC date and there is no risk that an expired reagent was used in casework. An allelic ladder was then discovered as being labeled with the wrong QC date. The incorrect date was determined to have been taken from a supply chain management worksheet which had been incorrectly populated. The QC date was then corrected. Moving forward, when labeling the allelic ladder, the QC date must be supplied from the DNA Amplification Reagent Quality Control form. All other reagents must now only have their in-house created label information provided from their respective quality control forms. Lastly, the cRNA, DTT and HiDi formamide reagents are all stored frozen but they were not labeled with their storage conditions as is required by the Quality Manual. The racks that these reagents are stored in now have the storage conditions included on their labels. The Forensic Biology laboratory purchased a label maker in order to assist in the labeling of reagents. During the Technician Meeting on 6/11/19, the Assistant Technical Leader presented on the new reagent labeling procedure. The PowerPoint presentation outlined why reagents are now being labeled, how and with what information to label the reagents. The presentation is available to all Forensic Biology staff to refresh their recollection of the reagent labeling procedure. On 07/10/19 and 07/11/19, the Operations Supervisor demonstrated the appropriate procedure for the label maker to all applicable staff.