FB SOP-21 General Chemical and Reagent QC Document ID: 2281

Revision: 7

Effective Date: 10/30/2024

Approved by Director: Dr. Guy Vallaro

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GENERAL CHEMICAL AND REAGENT QC

21.1 PURPOSE

To perform quality control testing on new chemicals to determine acceptability for use in casework.

21.2 RESPONSIBILITY

- 21.2.1: Test Procedure Personnel qualified to perform Forensic Biology duties.
- 21.2.2: Preparation/QC Procedure Personnel qualified to perform Forensic Biology duties.
 - A. Ordering information is maintained electronically and/or in a logbook in the Forensic Biology Unit.
 - B. New chemicals and reagents are purchased according to GL-6 (Purchasing).
 - C. An electronic reference containing reagent lot numbers and expiration dates will be maintained on the shared drive.
 - D. For additional information, refer to the Biological Inventory located in Appendix 3.

21.3 SAFETY

Use appropriate measures for the proper handling of bleach and hazardous chemicals according to GL-2 (Safety Manual) and the Safety Data Sheets.

21.4 PREPARATION/QC PROCEDURES

- 21.4.1: dH₂O (defined as deionized water, see DNA SOP-1: General Guidelines, section 1.1.9).
- A. dH₂O used to collect samples from evidence or for the preparation of a solution used for sample collection, will be obtained from and quality control tested by the DNA Unit prior to use.
 - Test the new lot before use according to FB SOP-08 (Screening Tests for Blood), FB SOP-12 (Screening Test for Semen), FB SOP-16 (Test for Amylase) and the dH₂O Reagent Log Sheet. Record the required information on the appropriate Quality Record Worksheet.
 - 2. If the appropriate results are not obtained, discard, review the procedure, obtain new dH₂O and retest. If the reagent still does not yield the appropriate results, then inform a Unit Lead to try to determine the root cause.
 - 3. If acceptable for use, label the containers received from DNA with the date opened and examiner's initials. Label containers filled in Forensic Biology with the lot #, control (expiration) date, fill date and examiner's initials.

The lot is acceptable for use when positive and negative results are obtained with the corresponding positive body fluid and negative blank controls according to the procedures listed above (21.4.1.A.1).

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4. Unopened containers of dH₂O may be stored at room temperature. Opened containers shall be stored in the refrigerator. Discard and replace according to the DNA expiration

- B. dH₂O used for other purposes will be obtained from the water filtration system in the DNA Unit.
 - 1. Fill and label a stock container with the lot # (date filled) and examiner's initials.
 - 2. Label containers filled in Forensic Biology with the lot #, fill date and examiner's initials.

<u>Note</u>: Containers filled for daily use (i.e. rinsing instruments after disinfecting) should be labeled with the name of the contents, fill date and initials.

3. Store at room temperature in a stock container and replace as needed.

21.4.2: Disinfecting Solutions

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date.

- A. 10% diluted bleach for daily use.
 - 1. Prepare a stock of 10% diluted bleach solution with dH₂O each day of use.
 - 2. Fill and label the stock container with the lot # (date of preparation) and preparer's initials. Fill and label other containers with the lot # (date of preparation) and examiner's initials.

<u>Note</u>: Containers filled for daily use (i.e. soaking instruments for disinfecting) should be labeled with the name of the solution, fill date and initials.

- 3. It is not necessary to track this daily preparation.
- B. 1:10 stabilized bleach may be used and is purchased by an outside vendor.
 - 1. Label the containers with the date received, date opened and examiner's initials. Include the fill date, initials and appropriate manufacturer's expiration date on the spray containers if re-used.
 - 2. Record the required information on the electronic order and/or reagent tracking log sheets.
 - 3. Store the stabilized bleach according to the manufacturer's instructions.
 - 4. Discard/replace as needed according to the manufacturer's expiration date or according to 21.4.3 below.

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21.4.3: New Chemicals

A. New chemicals received will be labeled with the date received, date opened and examiner's initials.

- B. Quality control information for chemicals used to prepare reagents will be included with each reagent prepared. Reagent QC is always conducted prior to use on case samples.
- C. Record the required information on the electronic order and/or reagent tracking log sheets.
- D. Store chemicals according to the manufacturer's instructions.
- E. Discard/replace chemicals according to the manufacturer's expiration date.
 - 1. The expiration date may be specified on the chemical container, the chemical Certificate of Analysis (CoA) or through a QR code on the container that provides a link to the CoA.
 - 2. If the manufacturer does not specify an expiration date, an expiration date of five (5) years from the date the chemical was received will be applied.
 - a. The chemical will be retested and QC'd during this (5) year period according to the control date of the reagent the chemical is used to prepare.
 - This will be documented on the appropriate reagent log sheet.
 - b. The chemical will be replaced before the end of the (5) year expiration.
 - 3. Manufacturer's expiration dates with only month and year indicated (i.e. 04/2014) expire the last day of the month noted.

21.5 REFERENCES

- A. GL-2 (Safety Manual)
- B. GL-6 (Purchasing)
- C. Safety Data Sheets