

Document Title: Quality Control of Chemicals, Reagents and Rapid Immunoassay Kits

Controlled: Yes, with red stamp present

Controlled By: Quality Manager

Prepared By: _____ Date: _____

Approved By: _____ Date: _____

A. PURPOSE:

To quality control new chemicals, reagents and rapid immunoassay kits.

B. RESPONSIBILITY:

Forensic Science Examiners 1 and 2 in the Forensic Biology Section. Ordering information is maintained in a log book in the Forensic Biology Section.

C. SAFETY:

Use appropriate measures for the proper handling of glacial acetic acid, picric acid, sodium hydroxide, mercuric chloride and zinc chloride according to SOP-GL-2 (Safety Manual) and the Material Safety Data Sheets.

D. DEFINITIONS:

1. RSID™: Rapid Stain Identification
2. PBS: Phosphate Buffered Saline
3. ABACard®: Rapid Immunoassay
4. sdH₂O: Sterile distilled water

E. PROCEDURE:

1. 0.5 % Ammonia Solution

a. Materials:

- aa. 5% Ammonia solution 1 part
- bb. sdH₂O 9 parts
- cc. Autoclaved brown dropper bottles (30ml)

b. Procedure:

- aa. Dilute the 5% ammonia solution 1:10 in sdH₂O and place into a dropper bottle.
- bb. Test the diluted solution before use according to SOP-FB-07 (Screening Tests for Blood), SOP-FB-10 (Rapid Immunoassay Tests for Human Blood) and the 0.5% Ammonia Reagent Log Sheet. Record the required information.
- cc. If the appropriate results are not obtained, discard the 0.5% ammonia solution, review the procedure and make a new dilution.

- E. 1. b. dd. If the 0.5% ammonia is suitable for use, record the solution, lot # (date of preparation), control date and examiner's initials on the dropper bottles and store in the refrigerator.
- ee. Discard the 0.5% ammonia after six (6) months. Discard the 5% ammonia according to the manufacturer's expiration date.

2. Phosphate Buffered Saline

Tablets

a. Materials:

- aa. Phosphate Buffered Saline tablets 5 tablets
bb. Sterile distilled water (sdH₂O) 1L
cc. Autoclaved glass bottle (stock)

b. Procedure:

- aa. Dissolve tablets in sdH₂O
- bb. Place in a glass bottle.
- cc. Record the required information on the PBS Reagent Log Sheet.
- dd. Discard after six (6) months.

Alternative Method

a. Materials:

- aa. Sodium Phosphate (Monobasic, Monohydrate) 5.38g
bb. Sodium Phosphate (Dibasic, Heptahydrate) 16.35g
cc. Sodium Chloride 9.00g
dd. Sterile distilled water (sdH₂O) 1L
ee. pH paper (1-12 pH)
ff. Autoclaved glass bottle (stock)

b. Procedure:

- aa. Dissolve the chemicals in 900ml of sdH₂O.
- bb. Bring to a final volume of 1L with sdH₂O and check for final pH 7.
- cc. Place in a glass bottle.
- dd. Record the required information on the PBS Reagent Log Sheet.
- ee. Discard after six (6) months.

E. 3. Glacial Acetic Acid

- a. This chemical is purchased from an outside vendor and is used to prepare acid phosphatase reagent and acetate buffer.
- b. Record the date received, date opened and examiner's initials on the bottle.
- c. Record the required information on the Chemical Log Sheet.
- d. Store glacial acetic acid at room temperature according to the manufacturer's instructions.
- e. Place in a brown dropper bottle labeled with the chemical, lot #, fill date and examiner's initials.
- f. Replace as needed or according to the manufacturer's expiration date.

4. Phadebas[®]

- a. Materials:
 - aa. Phadebas[®] tablets
 - bb. Mortar and pestle
- b. Procedure:
 - aa. Crush tablets into a powder and return to original container.
 - bb. Test each new lot before use according to SOP-FB-15 (Test for Amylase) and the Phadebas[®] Reagent Log Sheet. Record the required information.
 - cc. If the appropriate results are not obtained, review the procedure, repeat the test and replace the chemical if necessary.
 - dd. If the lot is suitable for use, record the date received, date opened and examiner's initials on the bottle and store at room temperature.
 - ee. Discard according to the manufacturer's expiration date.

5. Mercuric Chloride and Zinc Chloride

- a. Test the new lots before use according to SOP-FB-17 (Test for Urobilinogen) and the Urobilinogen Reagent Log Sheet. Record the required information.
- b. If the appropriate results are not obtained, review the procedure, repeat the test and replace the chemical if necessary.
- c. If the lots are suitable for use, record the date received, date opened and examiner's initials on the bottles.

E. 5. d. Store at room temperature.

6. ABACard® HemaTrace® and ABACard® p30
 - a. Test the new lot before use according to SOP-FB-10 (Rapid Immunoassay Tests for Human Blood) or SOP-FB-14 (Rapid Immunoassay Tests for Human Semen) and the ABACard® HemaTrace® or ABACard® p30 Reagent Log Sheet and record required information.
 - b. If the appropriate results are not obtained, review the procedure, repeat the test and replace the lot if necessary.
 - c. If the lot is suitable for use, record the date received, date opened and examiner's initials on each box and store according to the manufacturer's instructions.
 - d. Discard according to the manufacturer's expiration date.
7. RSID™ - Blood and RSID™ - Semen
 - a. For RSID™ - Blood, test the new lot before use according to SOP-FB-10 (Rapid Immunoassay Tests for Human Blood) and the RSID™ - Blood Reagent Log Sheet. Record the required information.
 - b. For RSID™ - Semen, test the new lot before use according to SOP-FB-14 (Rapid Immunoassay Tests for Human Semen), the RSID™ - Semen Reagent Log Sheet and the ABACard® p30 Reagent Log Sheet. Record the required information.

In addition, test the Universal Buffer supplied with the new lot before use according to SOP-FB-15 (Test for Amylase) and the Phadebas Reagent Log Sheet. Record the required information.

 - c. If the appropriate results are not obtained, review the procedure, repeat the test and replace the lot if necessary.
 - d. If the lot is suitable for use, record the date received, date opened and examiner's initials on each box and the provided buffer bottles. Store according to manufacturer's instructions.
 - e. Each examiner should initial their own set of buffers for use.
 - f. Discard according to the manufacturer's expiration date.
8. RSID™ - Universal Buffer may be ordered separately.
 - a. Test the new lot before use according to SOP-FB-14 (Rapid Immunoassay Tests for Human Semen), SOP-FB-15 (Test for Amylase) and the RSID™ - Universal Buffer Reagent Log Sheet. Record the required information.

- E. 8. b. If the appropriate results are not obtained, review the procedure, repeat the test and replace the lot if necessary.

- c. If the lot is suitable for use, record the date received, date opened and examiner's initials on each bottle. Store according to manufacturer's instructions.
- d. Each examiner should initial their own buffer for use.
- e. Discard according to the manufacturer's expiration date.

9. RSID™ - Urine

- a. Test the new lot before use according to SOP-FB-16 (Rapid Immunoassay Test for Urine) and the RSID™ - Urine Reagent Log Sheet. Record the required information.
- b. If the appropriate results are not obtained, review the procedure, repeat the test and replace the lot if necessary.
- c. If the lot is suitable for use, record the date received, date opened and examiner's initials on each box and the provided buffer bottles. Store according to manufacturer's instructions.
- d. Discard according to the manufacturer's expiration date.

10. Sterile dH₂O (sdH₂O)

- a. sdH₂O is obtained from the DNA Section in bottles and then autoclaved.
- b. Test the new lot before use according to SOP-FB-07 (Screening Tests for Blood), SOP-FB-11 (Screening Test for Semen) and the sdH₂O Reagent Log Sheet. Record the required information.
- c. If the appropriate results are not obtained, discard, review the procedure and obtain new sdH₂O.
- d. If suitable for use, label the bottles with the lot # (date filled), control date and examiner's initials. Fill 50ml plastic tubes and dropper bottles labeled with the lot #, control date, fill date and examiner's initials.
- e. Store in the refrigerator. Discard and replace after six (6) months.

11. dH₂O

- a. Fill a stock carboy with dH₂O from the DNA Section and label with the lot # (date filled) and examiner's initials.
- b. Fill and label wash bottles and dropper bottles with the lot #, fill date and examiner's initials.

- E. 11. c. Store at room temperature and replace as needed.

12. 20% bleach

- a. Prepare fresh 20% bleach the day of use with dH₂O.
 - b. Fill and label containers with the lot # (date of preparation) and examiner's initials.
 - c. Discard any unused bleach from all containers at the end of the day of use.
 - d. Record the lot # (date of preparation) and examiner's initials on the electronic log sheet.
13. New chemicals received will be labeled with the date received, date opened and examiner's initials.
- a. Quality control for chemicals used to prepare reagents will be included with each reagent prepared.
 - b. Record the required information on the Chemical Log Sheet.
 - c. Store chemicals according to the manufacturer's instructions.
 - d. Replace the chemicals as needed or according to the manufacturer's expiration date.
14. New chemicals, reagents and kits are purchased according to SOP-GL-6 (Purchasing). For additional information, refer to the Biological Inventory Appendix.

F. REFERENCES:

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 4. Schweers, Dr. Brett A., Old, Dr. Jennifer, Boonlayangoor, Dr. P. W., Reich, Dr. Karl, Developmental Validation of a Novel Lateral Flow Strip Test for Rapid Identification of Human Blood, Rapid Stain Identification – Blood, RSID™ - Blood, p1-13.
 5. Connecticut State Forensic Science Laboratory, RSID-Blood Internal Validation, 2007.
 6. Abacus Diagnostics' *OneStep* ABACard p30 Test For The Forensic Identification of Semen provided Technical Information and Protocol sheet.
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8. Independent Forensics' Rapid Stain Identification of Human Semen (RSID™-Semen) provided Technical Information and Protocol sheets.
 9. Old, Dr. Jennifer, Schweers, Dr. Brett A., Boonlayangoor, Dr. P. W., Reich, Dr. Karl,

Developmental Validation Studies of RSID-Semen Lateral Flow Immunochromatographic Strip test for the forensic detection of Seminal Fluid, p 1-36.

10. Connecticut State Forensic Science Laboratory, RSID-Semen Internal Validation, 2010.
11. Independent Forensics, Rapid Stain Identification of Urine (RSID™ - Urine) Technical Information and Protocol sheet.
12. Old, Dr. Jennifer, Reich, Dr. Karl, Developmental Validation of RSID™ - Urine, p1-19.
13. Connecticut State Forensic Science Laboratory, RSID™ - Urine Internal Validation, 2012.
14. Metropolitan Police Forensic Science Laboratory. Biology Methods Manual. 1978, pp. 3-10 to 3-11, pp. 4-4 to 4-5 and pp. 4-7.
15. SOP-GL-2 (Safety Manual).
16. SOP-GL-6 (Purchasing).
17. Material Safety Data Sheets.