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

E. PROCEDURE:

1. 0.5 % Ammonia Solution

   a. Materials:
      aa. 5% Ammonia solution 1 part
      bb. Distilled water (dH_2O) 9 parts
      cc. Brown dropper bottles (30ml)

   b. Procedure:
      aa. Dilute the 5% ammonia solution 1:10 in dH_2O and place into a dropper bottle.

      bb. Test the diluted solution before use according to 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. 10 % Sodium Hydroxide Solution

a. Materials:
   aa. Sodium Hydroxide
   bb. Distilled water (dH_2O)
   cc. Glass bottle (stock)

b. Procedure:
   aa. Make a 1:10 weight/volume solution with dH_2O and place in a glass bottle.

   bb Record the required information on the 10% Sodium Hydroxide Reagent Log Sheet.

   cc. Test the new solution <u>before</u> use according to SOP-FB-16 (Test for Creatinine) and the Jaffe Test Reagent Log Sheet. Record the required information.

   dd. If the appropriate results are not obtained, discard the solution, review the procedure and make a new solution.

   ee. If the solution is suitable for use, record the solution, lot # (date of preparation), control date and examiner's initials on the stock bottle and store in the refrigerator.

   ff. Discard after one (1) year.

3. Phosphate Buffered Saline

<u>Tablets</u>

a. Materials:

aa.	Phosphate Buffered Saline tablets	5 tablets
bb.	Distilled water (dH_2O)	1L
cc.	Glass bottle (stock)	
dd.	Brown dropper bottles (30ml)	

b. Procedure:
   aa. Dissolve tablets in dH_2O
   bb. Place in a glass bottle and dropper bottles.

E. 3. <u>Alternative Method</u>

a. Materials:
   - aa. Sodium Phosphate (Monobasic, Monohydrate) 5.38g
   - bb. Sodium Phosphate (Dibasic, Heptahydrate) 16.35g
   - cc. Sodium Chloride 9.00g
   - dd. Distilled water (dH_2O) 1L
   - ee. pH paper (1-12 pH)
   - ff. Glass bottle (stock)
   - gg. Brown dropper bottles (30ml)

b. Procedures:
   - aa. Dissolve the chemicals in 900ml of dH_2O.
   - bb. Bring to a final volume of 1L with dH_2O and check for final pH 7.
   - cc. Place in a glass bottle and dropper bottles.

PBS

a. Test the new solution before use according to SOP-FB-07 (Screening Tests for Blood), SOP-FB-11 (Screening Test for Semen) and the PBS Reagent Log Sheet. Record the required information.

b. If the appropriate results are not obtained, discard the solution, review the procedure and make a new solution.

c. If the solution is suitable for use, record the solution, lot # (date of preparation), control date and examiner's initials on the stock bottle and dropper bottles. Include the fill date on the dropper bottles. Store in the refrigerator.

d. Discard after six (6) months.

4. Glacial Acetic Acid and Saturated Picric Acid Solution
   a. These acids are purchased from outside vendors and are tested/used as received.

   b. Test the new lots before use according to SOP-FB-16 (Test for Creatinine) and the Jaffe Reagent Log Sheet. Record the required information.

   c. If the appropriate results are not obtained, review the procedure, repeat the test and replace the chemical if necessary.

   d. If the lots are suitable for use, record the date received, date opened and examiner's initials on the stock bottles.

   e. Store glacial acetic acid at room temperature. Place in a brown dropper bottle labeled with the chemical, lot #, fill date and examiner's initials.

E. 4. f. Store picric acid in the refrigerator. Place in a glass bottle and record the chemical, lot #, manufacturer's expiration date, fill date and examiner's initials on the bottle. Discard according to the manufacturer's expiration date.

5. 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.

6. 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.

   d. Store at room temperature.

7. 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.

E. 7. 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.

8. 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.

9. 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.

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.

10. New 20% bleach is made up each month. Replace in the stock bottle labeled with the lot # (date

of preparation), control date and examiner's initials and store at room temperature. Replace in all wash bottles and label with the lot # (date of preparation), control date, fill date and examiner's initials.

11. dH_2O and sterile dH_2O (sdH_2O) are provided by the DNA Unit.

    a. Place the dH_2O in a stock carboy labeled with the lot # (date received) and examiner's initials. Store at room temperature and replace as needed. Fill and label wash bottles and dropper bottles with the lot # (date received), fill date and examiner's initials.

    b. Store the sdH_2O in the refrigerator and replace as needed. Label the bottle with the date received, date opened and examiner's initials.

12. 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. Replace the chemicals as needed or according to the manufacturer's expiration date.

13. New chemicals, reagents and kits are purchased according to SOP-GL-6 (Purchasing). For additional information, refer to the Biological Inventory Appendix.

F. REFERENCES:

1. Kristaly, A., Smith, D.A.S. Validation of the One step ABAcard® HemaTrace® for the rapid Forensic identification of human blood. 1999.

2. Connecticut State Forensic Science Laboratory, ABAcard HemaTrace Internal Validation, 2004.

3. Independent Forensics Rapid Stain Identification of Human Blood (RSID™ - Blood) provided Technical Information and Protocol sheet.

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.

F. 7. Connecticut State Forensic Science Laboratory, ABAcard p30 Internal Validation, 1998.

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. 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.

12. SOP-GL-2 (Safety Manual).

13. SOP-GL-6 (Purchasing).

14. Material Safety Data Sheets.