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. sdH_2O: Sterile distilled water

E. PROCEDURE:

1. 0.5 % Ammonia Solution

   a. Materials:
      aa. 5% Ammonia solution 1 part
      bb. sdH_2O 9 parts
      cc. Autoclaved brown dropper bottles (30ml)

   b. Procedure:
      aa. Dilute the 5% ammonia solution 1:10 in sdH_2O 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 (sdH_2O)	1L
cc.	Autoclaved glass bottle (stock)	

b. Procedure:

aa. Dissolve tablets in sdH_2O

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 (sdH_2O)	1L
ee.	pH paper (1-12 pH)	
ff.	Autoclaved glass bottle (stock)	

b. Procedure:

aa. Dissolve the chemicals in 900ml of sdH_2O.

bb. Bring to a final volume of 1L with sdH_2O 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 dH_2O (sdH_2O)

a. sdH_2O 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 sdH_2O Reagent Log Sheet. Record the required information.

c. If the appropriate results are not obtained, discard, review the procedure and obtain new sdH_2O.

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. dH_2O

a. Fill a stock carboy with dH_2O 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 each month with dH_2O from the carboy.

b. Replace in the stock bottle labeled with the lot # (date of preparation), control date and examiner's initials and store at room temperature.

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

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:

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. 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.