

Frederick National Laboratory for Cancer Research <small>sponsored by the National Cancer Institute</small>	HPV Serology Laboratory Standard Operating Procedure	
Serum Sample Procedure		
Document ID: HSL_LAB_003	Version 2.0	Page 1 of 8

Released by/Date Effective:

Author Name	Title	Signature/Date

Approver Name	Title	Signature/Date

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<p>Document ID: HSL_LAB_003</p>	<p>Version 2.0</p>	<p>Page 2 of 8</p>

1. PURPOSE

- 1.1. The purpose of this procedure is to describe how to separate serum from blood samples.

2. SCOPE

- 2.1. This procedure applies to the HPV Serology Laboratory located at the Advanced Technology Research Facility, Room C2007.

3. REFERENCES

- 3.1. HSL_LAB_003.01: Serum Separation Procedure Form
- 3.2. HSL_GL_001: Waste Disposal at the Advanced Technology Research Facility
- 3.3. HSL_GL_003: Good Documentation Practices for the HPV Serology Laboratory
- 3.4. HSL_GL_006: Reagent Preparation for the HPV Serology Laboratory
- 3.5. HSL_GL_007: Reagent and Chemical Expiry in the HPV Serology Laboratory
- 3.6. HSL_GL_008: Laboratory Flow and Gowning Procedures for the HPV Serology Laboratory
- 3.7. HSL_GL_009: HPV Serology Laboratory BSL-2 Procedures
- 3.8. HSL_GL_010: Control and Request of Documents in the HPV Serology Laboratory
- 3.9. HSL_EQ_001: Biosafety Cabinet (BSC) Use and Maintenance
- 3.10. HSL_EQ_003: Use and Maintenance of the Thermo Fisher Sorvall Legend XTR Centrifuge in the HPV Serology Laboratory
- 3.11. HSL_EQ_007: Use and Maintenance of a 2-8°C Refrigerator in the HPV Serology Laboratory
- 3.12. HSL_EQ_008: Use and Maintenance of -80°C Freezers in the HPV Serology Laboratory
- 3.13. HSL_EQ_012: Use and Maintenance of Pipettes in the HPV Serology Laboratory

4. RESPONSIBILITIES

- 4.1. The Research Associate, hereafter referred to as analyst, is responsible for reviewing and following this procedure.
- 4.2. The Scientific Manager or designee is responsible for training personnel in this procedure and reviewing associated documentation.

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<p>Serum Sample Procedure</p>		
<p>Document ID: HSL_LAB_003</p>	<p>Version 2.0</p>	<p>Page 3 of 8</p>

- 4.3. The Quality Assurance Specialist is responsible for quality oversight and approval of this procedure.

5. REAGENTS, CHEMICALS AND EQUIPMENT

- 5.1. Biosafety Cabinet II (BSC)
- 5.2. -80°C Freezer
- 5.3. 2-8°C Refrigerator
- 5.4. Thermo Fisher Sorvall Legend XTR Centrifuge
- 5.5. 1.5 mL Tubes (Thomas Scientific, Cat # 1228H20 or equivalent)
- 5.6. 15 mL Tubes (Warehouse, Cat # 66401479 or equivalent)
- 5.7. 50 mL Tubes (Warehouse, Cat # 66401493 or equivalent)
- 5.8. Serologic Pipette and Pipette Tips
- 5.9. Pipettes and Pipette Tips
- 5.10. Ice Pan (Thomas Scientific, Cat # 1200R42 or equivalent)
- 5.11. Wet ice
- 5.12. Parafilm (Warehouse, Cat # 66401356 or equivalent)
- 5.13. 2" Box and 81 position insert (Warehouse, Cat # 81150001 and 81150004 or equivalent)

6. HEALTH AND SAFETY CONSIDERATIONS

- 6.1. Proper safety precautions should be taken while working in a laboratory setting. This includes, but is not limited to, proper protective equipment such as lab coats, safety glasses, closed-toe shoes, and non-latex gloves.
- 6.2. Refer to the respective SDS when working with any chemicals.
- 6.3. Refer to "HSL_GL_001: Waste Disposal at the Advanced Technology Research Facility" regarding waste disposal processes at the ATRF.
- 6.4. All contaminated BSL-2 level liquid waste must be decontaminated using 10% Clorox bleach (final concentration) with a minimum contact time of 30 minutes before sink disposal.
- 6.5. All serum work should be performed inside of a Class 2 Biosafety Cabinet (BSC).

Frederick National Laboratory for Cancer Research <small>sponsored by the National Cancer Institute</small>	HPV Serology Laboratory Standard Operating Procedure	
Serum Sample Procedure		
Document ID: HSL_LAB_003	Version 2.0	Page 4 of 8

7. DEFINITIONS

Term	Definition
BSC	Biosafety Cabinet
FME	Facilities, Maintenance and Engineering
HPV	Human Papillomavirus
HSL	HPV Serology Laboratory
RCF	Relative Centrifugal Force
SDS	Safety Data Sheets
SOP	Standard Operating Procedure

8. SERUM SEPARATION PROCEDURE

- 8.1. Record all data on HSL_LAB_003.01: Serum Separation Procedure Form.
- 8.2. Allow the blood to clot for a minimum of 30 minutes to a maximum 60 minutes upright at room temperature until centrifugation. However, if the blood cannot be centrifuged immediately after the clotting time, the tubes should be refrigerated at 2-8°C for up to 4 hours.
- 8.3. A minimum of 6 labels will be required, per sample. If more vials are needed, continue numbering sequence as needed. For example, see table below.

Tube Number	Sample Type
001	500 µL
002	500 µL
003	1000 µL
004	1000 µL
005	Remaining Serum (15 or 50 mL Tube)
Variable	Affix to HSL_LAB_003.01

- 8.4. Label at least five (5) tubes per sample with appropriate HSL Sample ID. Place labelled 1.5 mL tubes in a rack and larger tubes, on wet ice.
- 8.5. The label should include HSL Sample ID, Tube Number, Date, Analyst Initials, Sample type, and Volume in µL. See Attachment 1: Serum Sample Aliquot Labels, for more details.

Note: Samples should arrive to HSL with an assigned ID from the source, but should also be assigned a unique ID (SSxxx) for individual identification. I
- 8.6. Centrifuge blood samples for 20 minutes at 1300 x g at room temperature.
- 8.7. After centrifugation, the serum layer will be at the top of the tube. Carefully collect the serum layer with a pipette without disturbing the buffy coat layer then place serum into a 15 or 50 mL conical tube depending on the total volume of serum collected. Vials from a single donor may be pulled together.

<p>Frederick National Laboratory for Cancer Research <i>sponsored by the National Cancer Institute</i></p>	<p>HPV Serology Laboratory Standard Operating Procedure</p>	
<p>Serum Sample Procedure</p>		
<p>Document ID: HSL_LAB_003</p>	<p>Version 2.0</p>	<p>Page 5 of 8</p>

- 8.8. Mix the pooled serum by inverting the 15 mL or 50 mL tube 10 times.
- 8.9. Pipette the serum into appropriate sized aliquots in labeled vials:
 - 8.9.1. Two (2) 500 µL aliquots and two (2) 1000 µL aliquots per participant. This process should be completed within 1 hour after centrifugation and with all tubes on ice.
 - 8.9.2. The remaining serum will be stored in the 15 mL or 50 mL tube with para film wrapped around the lid.
- 8.10. Initially, place serum in 1.5 mL tubes into designated box while the remaining serum stored in either 15 mL or 50 mL tubes should be placed into a rack. Store the serum samples at -80°C freezer. Within 48 hours, transfer the 15 mL or 50 mL tubes placed in a rack into designated box containing donors 1.5 mL serum tubes.
- 8.11. Record final aliquot storage location on HSL_LAB_003.01: Serum Separation Procedure Form.

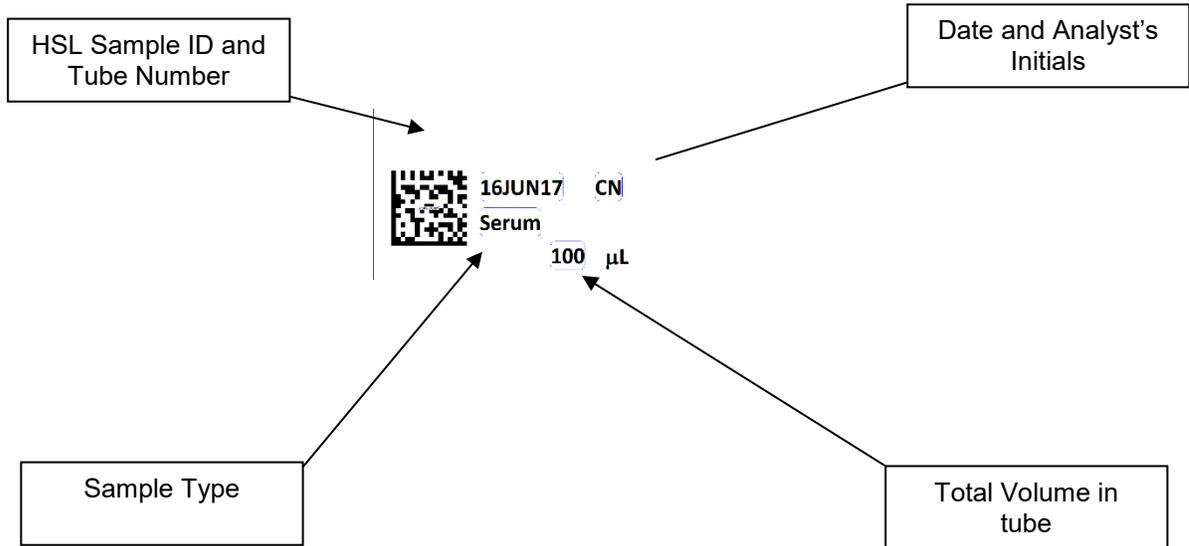
Note: A box label template file is available for generating box labels. See Attachment 2: Box Label Example, for label layout and placement.
- 8.12. Document sample storage information, once aliquoted, on HSL_LAB_003.01: Serum Separation Procedure Form.
- 8.13. Document sample location on the -80°C freezer inventory file.

9. ATTACHMENTS

- 9.1. Attachment 1: Serum Sample Aliquot Labels
- 9.2. Attachment 2: Box Label Example

Frederick National Laboratory for Cancer Research <small>sponsored by the National Cancer Institute</small>	HPV Serology Laboratory Standard Operating Procedure	
Serum Sample Procedure		
Document ID: HSL_LAB_003	Version 2.0	Page 6 of 8

Attachment 1: Serum Sample Aliquot Labels



Frederick National Laboratory for Cancer Research <small>sponsored by the National Cancer Institute</small>	HPV Serology Laboratory Standard Operating Procedure	
Serum Sample Procedure		
Document ID: HSL_LAB_003	Version 2.0	Page 7 of 8

Attachment 2: Box Label Example

Study: *OHS SS001 (RDP ID)*
Sample Type: *Serum*
Date: *27AUG17*
Initials: *TK*
Box 1 of 1



Frederick National Laboratory for Cancer Research <small>sponsored by the National Cancer Institute</small>	HPV Serology Laboratory Standard Operating Procedure	
Serum Sample Procedure		
Document ID: HSL_LAB_003	Version 2.0	Page 8 of 8

10. REVISION HISTORY

Revision Start Date	Version #	Changes	Reasons
22Mar17	New	Create new SOP for Serum sample procedure.	Currently no SOP.
15Aug17	1.0	Update ID for Serum. Update equipment information.	To identify repeat draws. Easier for analysts.

Frederick National Laboratory for Cancer Research <small>sponsored by the National Cancer Institute</small>	HPV Serology Laboratory Standard Operating Procedure	
Serum Separation Procedure Form		
Form ID: HSL_LAB_003.01 Associated SOP: HSL_LAB_003	Version 2.0	Page 1 of 1

Sample Information

Participant ID		
HSL ID		
Draw Date/Time		
Received in HSL Date/Time		
Aliquot Completed Date/Time		Total Aliquots: Estimated Total Volume:

Equipment Information

Equipment Name	Equipment ID	Calibration Due Date
BSC	<input type="checkbox"/> HSL_007 <input type="checkbox"/> HSL_008 <input type="checkbox"/> HSL_009 <input type="checkbox"/> Other:	
2-8°C Refrigerator	<input type="checkbox"/> HSL_029 <input type="checkbox"/> Other:	
Sorvall Legend XTR	<input type="checkbox"/> HSL_033 <input type="checkbox"/> Other:	
-80°C Storage Freezer	<input type="checkbox"/> HSL_022 <input type="checkbox"/> Other:	
	Shelf #:	Rack #:
_____ µL Pipette		

Aliquot Label:	Comments:
<input type="checkbox"/> N/A	<input type="checkbox"/> N/A

Performed By/ Date:	
Reviewed By/ Date:	