

APPENDIX 13

All sites will participate in the pilot phase of this study for testing of Influenza and RSV Serology. The pilot phase includes collecting one gold top tube from patients at visits Baseline, Weeks 4, 10, End of Study (EOS). Patient samples should be collected and frozen for batch shipping to WFU.

In order for each site to receive specimen kits:

WFU CCOP RB sites fax a copy of their institution's IRB approval letter must be faxed to the WFU Infectious Diseases Clinical Trials Unit at (336) 716-3356. Following receipt of the IRB approval letter, a specimen collection kit will be shipped directly to the address provided by each site. (Submission of this letter is in addition to each sites normal IRB notification process.)

CTSU sites complete and fax the "Specimen Kit Shipping Information for CTSU Sites" document prior to enrollment of their first patient. The form and fax information is located under the Site Registration Documents section of the WFU-07-02-03 web page.

Each specimen should be labeled with patient's initials, date, actual collection time, and protocol identification number. This should be documented on the completed Serology Form. (Page 3 of Appendix 13)

If there are any questions about lab kit contents, please contact Abbie Beltz at (336) 716-9134

Blood:

Blood collection:

Collect 5 ml blood sample in:

- 5 ml **gold** top tube

Blood processing:

Gold top:

- *Allow gold* top tube to clot approximately 15 minutes. When gold top tube has clotted, centrifuge at 2000 X g for 10 minutes (to separate the cellular elements from the serum).
- Transfer and divide serum into (TWO) screw-capped polypropylene transfer tubes.
- Document on tubes patient's initials, date, collection time, and protocol identification number.
- *Immediately* freeze and store both screw-capped polypropylene transfer tubes in -20°C freezer.
- All specimens for all patients must be batched and shipped at the end of study (May 2009).

Serology Shipment:

Frozen container:

- (2) Frozen screw-capped polypropylene transfer tubes - each individually placed in separate 3 X 5 Ziploc bags.
- Place (2) frozen specimens in each 7 X 11 IATA approved Therapak bag.

Note: The shipment of human tissues to WFUHS must comply with appropriate regulations as specified by the carrier. At a minimum, all samples must be packaged within two containers with absorbent material between containers to control any potential spill or leakage. The outer container must be puncture resistant (e.g. cardboard mail tube or corrugated cardboard box.)

Note: A biohazard sticker must be affixed to both the inner and outer container.

Shipping:

1. All 4 samples for each patient will be shipped at the end of the study.
2. Notify Abbie Beltz, PhD, Director, Infectious Diseases Clinical Trials Unit at 336-716-9134 prior to shipment.
3. **Samples should be shipped overnight FedEx for AM delivery. They should not be sent to arrive on a Saturday, Sunday, or holiday.**
4. The frozen samples are to be placed in an insulated container with enough dry ice to maintain them in a frozen state for two days.
5. A copy of the **Serology Form** on the following page should be included in each shipment for each patient.
6. All specimens are to be shipped to:

Attention: Abbie Beltz
Wake Forest University Health Sciences
Infectious Diseases Section, 3rd Floor Grey Building
Medical Center Boulevard
Winston-Salem, NC 27157-1042
Phone: (336) 716-9134
Fax: (336) 716-3356

Blood Draw kit contains:

- (6) storage tubes (4 for serum, 2 extra)
- (6) transfer pipettes (4 for serum, 2 extra)
- (2) 3 X 5 Ziploc bags (2 for serum)
- (2) 7 X 11 IATA approved Therapak bag (2 specimens per bag)
- 6 Cryo-babies specimen labels
- (6) 5 ml gold top tube (including 2 extra)

Frozen insulated container contains: ****Will be shipped at a later date** (Note- Sites must provide dry ice)**

- **Outer Box** – 15 3/8 x 13 3/4 x 12 3/4”
- **Insulated Chest** – ID 11 5/8 x 10 x 8”
- Inner Box – ID 6 1/2 x 6 1/2 x 8”
- Disposable 2-part Secondary Pressure Vessel, Medium (2)
- 250 mL Absorbent Strip (2)
- 12 x 12” Saf-T-Rap® Bubble Wrap (2)
- Consignee Address Marking
- Dry Ice Marking
- UN 3373 Marking

Other items:

- 9 x 12 Ziploc bag for Serology Form
- (1) Return shipping label for overnight shipping and FedEx account number

Pharmacology Form for Influenza and RSV Serology

INSTRUCTIONS: This form is to be completed and submitted as required by protocol. Submit a copy to the CCCWFU Data Management Center and send another copy with samples to the laboratory. Protocol required sample time points are baseline, 4 week, 10 week, and end of study visits (EOS).

Patient's Last Initial, First Initial _____ Protocol ID# _____ Institution ID# _____

Baseline Serology (before any study drug)

Date and time of baseline serology sample:

M		D		Y		H m	

4 Week Serology

Date and time of 4 week serology sample:

M		D		Y		H m	

10 Week Serology

Date and time of 10 week serology sample:

M		D		Y		H m	

End of Study Serology (EOS)

Date and time of end of study serology sample:

M		D		Y		H m	

Please look at special processing and shipping information requirements.

Name of person sending samples: _____ Phone no. or pager no.: _____

Institution name: _____ Email address: _____

FOR LAB USE ONLY

Sample Receipt + Condition Information

- Usable (1-no, 2- yes)
- Tubes intact? (1-no, 2-yes)

Date sample received ____/____/____

Name of analyst _____

Sample Analysis Information

Sample Time Points

- Baseline serology _____
- 4 week serology _____
- 10 week serology _____
- End of study serology _____