Molecular Surveillance

Operations Manual Version 2: September 2007

Blood Center Participants:

- The Blood Center of Wisconsin, Milwaukee, WI
- Blood Centers of the Pacific- University of California- San Francisco, CA
- Hoxworth Blood Center and the University of Cincinnati Medical Center, Cincinnati, OH
- Institute for Transfusion Medicine and LifeSource Blood Services, Pittsburgh, PA
- American Red Cross Biomedical Services, Scientific Support Office
- New York Blood Center
- United Blood Services

Coordinating Center:

Westat, Rockville, MD

Central Repository:

SeraCare BioServices, Gaithersburg, MD

Central Laboratory:

Blood Systems Research Institute (BSRI), San Francisco, CA
Blood Systems Laboratory (BSL), Tempe, AZ

Sponsored by:
The National Heart, Lung, and Blood Institute (NHLBI)
National Institutes of Health (NIH)

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RESEARCH CORPORATION

MEMORANDUM

TO: List* October 4, 2007

FROM: Danielle Carrick
Deborah Todd
Tesa Kochie

SUBJECT: MS Manual of Operations - Version 2

Attached please find Version 2 of the REDS-II Molecular Surveillance (MS) Manual of Operations (MOP). This version replaces MOP Version 1, September 2006 that you received. This MOP is also available for download in PDF format on the REDS-II website under Documents/MOP.

A brief summary of the major changes to MS MOP Version 1 is listed below. Please consult the appropriate chapters and its accompanying exhibits for more detailed explanations and directions.

- **Specimen Processing**
  BSRI has developed aliquoting and specimen labeling procedures. See section 2.3 and Appendix, Exhibits G and H.

- **STS Users Guide**
  The STS Users Guide has been added. See Appendix, Exhibit F.

  If an import .csv file is used to enter data into the STS instead of scanning the aliquots individually into the system, run a test import of all of the files on the Beta/training STS site to identify possible errors in the files. https://sts-beta.reds-ii.org

- **Specimens to send to BSRI**
  We are no longer requesting that you send BSRI specimens from donations that were First Time-Prevalent HCV or First Time-Prevalent HBV positive.

  As specified in the protocol, we are asking that you continue to save and send BSRI specimens from donations that were HIV positive (FT or Repeat), Incident HBV positive (FT or Repeat), and Incident HCV positive (FT or Repeat).

  Please see Appendix, Exhibit B for the updated Schedule of Deliverables.

- **Data to send to Westat**
  As in the past, we are requesting that you send us demographic data via the MS P&I Data Form on ALL donations that are considered to be HIV, HBV, and/or HCV positive (regardless of incident/prevalent or FT/Repeat donation status or whether specimens were sent to BSRI). **Prior to specimens being sent to BSRI, the MS P&I Data Form (see Chapter 4) should be sent to Westat.**

The annual summary data should be sent to Westat according to the timetable in Appendix, Exhibit B for the Schedule of Deliverables.

- **Shipping Schedule**

  A revised shipping schedule has been developed for shipping 2007 donations. See Appendix, Exhibit B for the Schedule of Deliverables.

- **BSRI Supply Request Form**

  See Appendix, Exhibit I for a template BSRI supply request form.

* List	Cc
Anne Guiltinan Beth Slikas David Krysztof Deborah Bunch Deborah Kessler Eric Delwart Erik Scott Hany Kamel Ingrid Wilson Jerome Gottschall Leslie Tobler Linda Banks Lisa Milan Benson Michael Bush Pam D'Andrea Ram Kakaiya Sherri Cyrus Susan Stramer Susan Wilkinson Teresa Lin Val Winkelman Yefim Katz	Danielle Carrick Deborah Todd George Nemo George Schreiber Melissa King Simone Glynn Tesa Kochie Traci Mondoro

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1. INTRODUCTION

1.1 REDS-II Overview

The Retrovirus Epidemiology Donor Study- II (REDS-II) is a National Heart, Lung, and Blood Institute (NHLBI) multicenter study. The purpose of REDS-II is to conduct laboratory and epidemiological research to aid in improving blood safety and availability in the U.S. To this end, multiple protocols will be performed under the REDS-II umbrella. The Molecular Surveillance (MS) study is one such protocol being implemented.

Six blood centers, a coordinating center, a central laboratory, and a central repository participate in the REDS-II program. Below is a list of participating sites and their role:

- Blood Centers:
  - The Blood Center of Wisconsin, Milwaukee, WI;
  - Blood Centers of the Pacific- University of California- San Francisco, CA;
  - Southern Region - American Red Cross and Emory University, Atlanta, GA;
  - Hoxworth Blood Center and the University of Cincinnati Medical Center, Cincinnati, OH;
  - New England Region - American Red Cross, Dedham, MA; and
  - Institute for Transfusion Medicine and LifeSource Blood Services, Pittsburgh, PA..

To increase yield to obtain adequate sample size for the purposes of this study, additional blood centers have been asked to participate. These blood centers are:

  - American Red Cross Biomedical Services, Scientific Support Office
  - New York Blood Center
  - United Blood Services

- Coordinating Center:
  - Westat, Rockville, MD
- Central Laboratory:
  - Blood Systems Research Institute (BSRI), San Francisco, CA

- Central Repository:
  - SeraCare BioServices, Gaithersburg, MD

1.2 MS Study Background and Overview

All blood donations in the U.S. are screened for HIV, HCV, HBV, and other infectious disease viruses to help ensure the safety of transfusion with regards to the transmission of these viruses. There are several strains of each virus and they are not all indigenous to the U.S. For example, HIV-1 group M subtype B is the most common in North America whereas world-wide, it is subtype C (http://hiv-web.lan1.gov). While other subtypes are relatively infrequent in the U.S., there is some evidence to show that the variety and numbers of these being detected is increasing.[1,2,3] With the globalization of the world economy, it is important to monitor the spread of these other strains in the U.S.

In addition, the sensitivity of screening assays that detect and quantify HIV, HCV, and HBV viruses can be reduced by certain strains of those viruses. Thus, molecular surveillance of the phylogenetic clade and subtype distribution of HIV, HCV, and HBV infections in blood donors is critical to ensuring that blood screening and related assays are sensitive to the current strains of blood-borne viruses. Certain viral strains may also alter the efficacy of anti-viral treatments, and monitoring the distribution of these actively transmitted viral strains will be an important guide to future anti-viral treatment and vaccine research in the United States[4].

Current blood donation screening in the U.S. includes nucleic acid testing (NAT) which can identify infectious blood donations prior to the development of anti-viral antibodies. This testing strategy not only decreases transfusion-transmitted risks for these viruses [5-8], but in terms of this study, presents a unique opportunity to examine the viral subtypes that have been recently acquired (incident infections) and compare them to more remotely acquired (prevalent infections) strains. The MS study will capitalize on this by evaluating the phylogenetic clade and subtype distribution of incident and prevalent HIV, HCV, and HBV infections in U.S. blood donors. Further, monitoring the viral subtypes in incident and prevalent infections over time will allow the molecular epidemiology of these viruses to be tracked.

The main objectives of the MS study are to:

- measure the frequency of distinct viral lineages in incident and prevalent blood donor infections;

- measure the frequency of anti-viral drug resistance mutations in HIV and HBV in incident and prevalent blood donor infections; and
- using residual volume from the characterized specimens, create a linked repository for future HIV, HBV, and/or HCV studies.

The secondary objectives are intended to further contribute to the public health surveillance goals of this study by evaluating whether the distributions of viral variants 1) vary by demographics and geographic location (the US Census geographic areas [Regions]commonly referenced by the CDC); 2) change over time; and 3) are different in infected donors than in other populations as reported in the literature.

To meet these secondary objectives, laboratory data will be merged with donor demographics such as age, gender, and race/ethnicity. Additionally, the US Census Regions associated with the donors' place of residence will be included. All REDS-II blood centers routinely provide this information to the coordinating center. For the additional participating sites, this information will be provided along with summary statistics on all annual blood donations. Summary statistics will include the total number of donations by donations status (first-time versus repeat), gender, age, race/ethnicity, and US Census region. The US Census region will be derived using the state of residency and age will be derived from DOB and date of donation. Upon completion of these derivations, state of residency and DOB will be stripped from the dataset and all analyses will only include US Census regions and age.

The MS study involves testing blood specimens from volunteer blood donors identified as positive for HIV, HCV, and HBV during routine infectious disease testing by participating blood centers between January 2006 and June 2009. In addition to the six REDS-II blood centers, New York Blood Center (NYBC), United Blood Services (UBS), and all American Red Cross (ARC) centers have agreed to participate. Note that two of the REDS-II centers are part of ARC (Emory University and ARC Southern Region; ARC New England Region) and one is part of UBS (UCSF/Blood Centers of the Pacific). Participation by the additional non-REDS-II blood programs (NYBC, UBS, and all of ARC) provides a broader catchment area, enabling a nationally representative study with a larger sample size and more diverse donor population to evaluate the frequency of viral clades and subtypes. This is critical for monitoring the spread of viral types in the U.S.

Specimens will be obtained from surplus blood collected at the time of routine blood donation. As previously mentioned, donated blood is routinely tested by the blood centers for HIV, HCV, and HBV. Thus, blood centers will send blood samples from HIV, HCV, and HBV incident and prevalent

positive donors to the REDS-II central laboratory, Blood Systems Research Institute (BSRI), for evaluation of the phylogenetic clade and subtypes of these viruses. Westat will coordinate the transfer of data and specimens, and analyze resulting data from BSRI.

We will retain residual volume for these characterized samples in a small linked repository. From past REDS-I experience, we have found that small repositories of this nature are very valuable, and would allow for additional studies of HIV, HBV, and HCV. Such repository studies, if conducted in the future, could be either anonymized or not, and would necessitate separate OSMB and IRB approvals.

References

1. Bennett, D. (2005). HIV genetic diversity surveillance in the United States. *J Infect Dis* **192**(1)**,** 4-9.

2. Delwart, E. L., Orton, S., Parekh, B., Dobbs, T., Clark, K., and Busch, M. P. (2003). Two percent of HIV-positive U.S. blood donors are infected with non-subtype B strains. *AIDS Res Hum Retroviruses* **19**(12)**,** 1065-70.

3. Sides, T. L., Akinsete, O., Henry, K., Wotton, J. T., Carr, P. W., and Bartkus, J. (2005). HIV-1 subtype diversity in Minnesota. *J Infect Dis* **192**(1)**,** 37-45.

4. Delwart, E., Kuhns, M.C., and Busch, M.P. (2006). Surveillance of the genetic variation in incident HIV, HCV, and HBV infections in blood and plasma donor: Implications for blood safety, diagnostics, treatment, and molecular epidemiology. *J of Medical Virology* **78**, S30-S35.

5. Offergeld, R., Faensen, D., Ritter, S., and Hamouda, O. (2005). Human immunodeficiency virus, hepatitis C and hepatitis B infections among blood donors in Germany 2000-2002: risk of virus transmission and the impact of nucleic acid amplification testing. *Euro Surveill* **10,** 2.

6. Stramer, S. L., Glynn, S. A., Kleinman, S. H., Strong, D. M., Sally, C., Wright, D. J., Dodd, R. Y., and Busch, M. P. (2004). Detection of HIV-1 and HCV infections among antibody-negative blood donors by nucleic acid-amplification testing. *N Engl J Med* **351**(8)**,** 760-8.

7. Yoshikawa, A., Gotanda, Y., Itabashi, M., Minegishi, K., Kanemitsu, K., and Nishioka, K. (2005). HBV NAT positive blood donors in the early and late stages of HBV infection: analyses of the window period and kinetics of HBV DNA. *Vox Sang* **88**(2)**,** 77-86.

8. Busch, M. P., Glynn, S. A., Stramer, S. L., Strong, D. M., Caglioti, S., Wright, D. J., Pappalardo, B., and Kleinman, S. H. (2005). A new strategy for estimating risks of transfusion-transmitted viral infections based on rates of detection of recently infected donors. *Transfusion* **45**(2)**,** 254-64.

1.3 Specimen Tracking System (STS)

The STS is a web based specimen tracking system developed by Westat and customized for REDS-II studies. It is designed to track specimen storage and shipping activities. All specimens sent to BSRI from the centers should be entered and the shipment information will be recorded in the STS prior to shipping; details of how specimens and shipments will be entered into the STS are found in Appendix Exhibit F. The Central Laboratory will receipt the specimens into the STS and record when they have been shipped to the Central Repository for long term storage.

1.4 Study Timeline

This study is scheduled to run from 2006 through August 2009. The timeline in Table 1.4 indicates approximate dates (month/year) when certain activities are expected to be completed by the Blood Centers, Central Laboratory, and Coordinating Center.

Table 1.4 **Molecular Surveillance Timeline**

Item	Task	2006												2007												2008												2009												2010							
		Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug
1	All HIV positive donations (Incident & Prevalent) collected for the study																																																						
2	Prevalent HBV cases collected for the study																																																					
3	Prevalent HCV cases collected for the study																																																				
4	Incident HBV cases collected for the study																																																				
5	Incident HCV cases collected for the study																																																				
6	All HIV positive cases (Incident & Prevalent) shipped to BSRI																																																				
7	HBV prevalent donations Jan to Jun 2006 shipped to BSRI																																																				
8	HCV prevalent donations Jan to Jun 2006 shipped to BSRI																																																				
9	All Incident HBV donations shipped to BSRI																																																				
10	All Incident HCV donations shipped to BSRI																																																				
11	BSRI transfer of Repository Specimens to SeraCare																																																				
12	MS PIData Form to Westat: all prevalent and incident donations detected and demographics sent to Westat																																																				
13	Specimen selection lists (for release for testing) sent to BSRI by Westat																																																				
14	Testing conducted at BSRI - including detuned testing																																																				
15	Semi-Monthly Test Result Database sent from BSRI to Westat																																																				
16	Westat compiles testing results into database																																																				
17	Yearly summary statistics report sent to Westat																																																				
18	Data analysis and interpretation																																																				

BC = Blood Center/lab task B = BSRI task W = Westat task

2. SPECIMENS

2.1 Qualified Donations

Donations that are considered eligible for the MS study include all **allogeneic** donations from donors over the age of 17 and identified via confirmatory testing at the individual Blood Centers to be **HIV, HCV, and/or HBV positive between January 2006 and June 2009**. Specifically, all allogeneic donations identified between January 2006 and June 2009 that fall into the following categories should be considered "qualified" for the MS study:

Box 2A
Qualified Donations for the MS study

Descriptive categories				
HIV, HCV, or HBV **I= Incident; P= Prevalent**		**Testing Results**		**Allogeneic Donations**
		HIV NAT	HIV antibody	First time or Repeat*
HIV	I/P	negative	positive	*first-time* and *repeat*
HIV	I	positive	negative	*first-time* and *repeat*
HIV	I or P	positive	positive	*first-time* and *repeat*
		HCV NAT	HCV antibody	
HCV	I	positive	negative	*first-time* and *repeat*
HCV	P	positive	positive	*first-time* and *repeat*
		HBsAg	anti-HBc	
HBV	I	positive	non-reactive	*first-time* and *repeat*
HBV	P	positive	reactive	*first-time* and *repeat*

*First time donations – First donation given by the donor at a given center since June 1996.

2.2 Data to be recorded for all qualified donations listed in Box 2A

All eligible donations should be kept track of by each Blood Center. Specific information that should be recorded for each donation is described more fully in Chapter 4. Briefly, the following information should be recorded in the appropriate spreadsheet (see Chapter 4 for details) for **ALL** qualified donations at each Blood Center (see Box 2A for "qualified" donation). *Please note that regardless of whether specimens from donations that are qualified for the MS study (Section 2.1) are sent to BSRI for testing/placement in the repository, the following information should be recorded for all qualified donations*:

Box 2B
Data to be recorded for all qualified donations

For each confirmed HIV, HCV, and/or HBV donation, the following data should be recorded (see Chapter 4 for more details):

BUI / WBN
Organization
Date of donation
First Time/ Repeat Donor

Confirmatory test results for:
- HIV NAT
- HIV Ab
- HCV NAT
- HCV Ab
- HBsAg
- Anti-HBc

Date of birth
State of residency
Race/Ethnicity (if this information is available)
Sex

2.3 Specimens for the MS study

Specimens will consist of residual volume obtained from index donation tubes that were originally collected for NAT screening, HBsAg testing, or for serological testing.

2.3.1 Specimen Type: Plasma is preferable, while serum could also be sent, if available.

2.3.2 Specimen Volume: The plasma (or serum) specimen's minimal acceptable volume will be 1.0ml.

2.3.3 Specimen Storage at the Centers: All specimens should be stored at 4°C within 24 to 72 hours post donation. Specimens should then be aliquoted (see Appendix, Exhibit G) and stored at -20°C, but preferably at -80°C. Thawing and refreezing of the specimens should be avoided. Supplies have been provided by the Central Laboratory to store specimens in 1.0, 2.0, or 4.0mL cryovials. If specimens are stored in larger tubes, they should be re-aliquoted to small vials prior to shipping. **See Appendix, Exhibit G for aliquoting details**

2.3.4 Specimen Labeling: Specimens should be labeled with the appropriate BUI/WBN; a barcoded BUI/WBN label is preferable. All tubes should be labeled with an appropriate sequence number. **See Appendix, Exhibits G and H for labeling details**

2.3.5 Specimens to send to BSRI: While data should be recorded for <u>all</u> qualified donations (Section 2.2), only specimens from donations in specific categories should be stored and sent to BSRI. Specifically, all specimens from the following donation "descriptive categories" should be saved and sent to BSRI:

- <u>All</u> confirmed HIV allogeneic donations
- Confirmed HCV, incident allogeneic donations
- Confirmed HCV, first-time, prevalent allogeneic donations (identified between January and July 2006)
- Confirmed HBV, incident allogeneic donations
- Confirmed HBV, first-time, prevalent allogeneic donations (identified between January and July 2006)

Box 2D Specimens to be sent to BSRI for the MS Study

Descriptive Categories				HIV, HCV, or HBV I = Incident; P = Prevalent	2006 donations: Specimens saved, then sent to BSRI*	2006 – 2009 donations: Continue to collect and ship July 1, 2006 to June 30, 2009
HIV-EIA Positive	NAT- HIV Negative	Western Blot Positive	*First time & Repeat & Repeat*	I/P	Yes	Yes
HIV-EIA Positive	NAT-HIV Positive	Western Blot Positive, Negative, Indeterminate or Not Tested	*First time & Repeat*	I or P	Yes	Yes
HIV-EIA Negative	NAT-HIV Positive		*First time & Repeat*	I	Yes	Yes
HCV-EIA Positive	NAT-HCV Negative	RIBA Positive	*First time & Repeat*		No	No
HCV-EIA Positive	NAT-HCV Positive	RIBA Positive or Not Tested	*First time & Repeat*	P	Yes *(First-time)*	ARC Yes All others No
HCV-EIA Negative	NAT-HCV Positive	RIBA Negative or Not Tested	*First time & Repeat*	I	Yes	Yes
Anti-HBc non-reactive	HBsAg-EIA Positive	HBsAg neutralization Positive	*First time & Repeat*	I	Yes	Yes
Anti-HBc Positive	HBsAg-EIA Positive	HBsAg neutralization Positive	*First time & Repeat*	P	Yes *(First-time)*	No

***** Specimens should be stored according to the specifications in Section 2.3. Specimens should be sent to BSRI approximately every 5-6 months, following the shipping schedule and instructions outlined in Chapter 3 and Exhibit B Schedule of Deliverables. **When specimens are sent to BSRI, the MS Prevalence and Incidence Data Form (see Chapter 4) should be sent to Westat.**

****** Specimens from HCV FT (first time) prevalent and HBV FT prevalent donations should only be saved between January and July of 2006; all of these specimens will be sent to BSRI in the first shipment (see section 3.2). Data for **all** HCV FT prevalent and HBV FT prevalent donations at the centers should be recorded throughout the length of the study (see section 2.2 and Chapter 4).

******* Although specimens from HCV repeat prevalent and HBV repeat prevalent donations will not be sent to BSRI for testing, data for these donations should be recorded throughout the length of the study (see section 2.2 and Chapter 4).

2.4 Using the STS to record storage of the specimens

You may use the STS to record details about storage of the specimens at your Blood Center. For instance, you can record that a tube with 1.5ml plasma from a donation with BUI number 0912300 is currently stored in Row B, Column 5 of a box labeled “REDSII MS August 2006”. You can then use the STS to see what other MS specimens are stored in that box, as well as in other boxes at your center. See Appendix Exhibit F for instructions on how to use the STS.

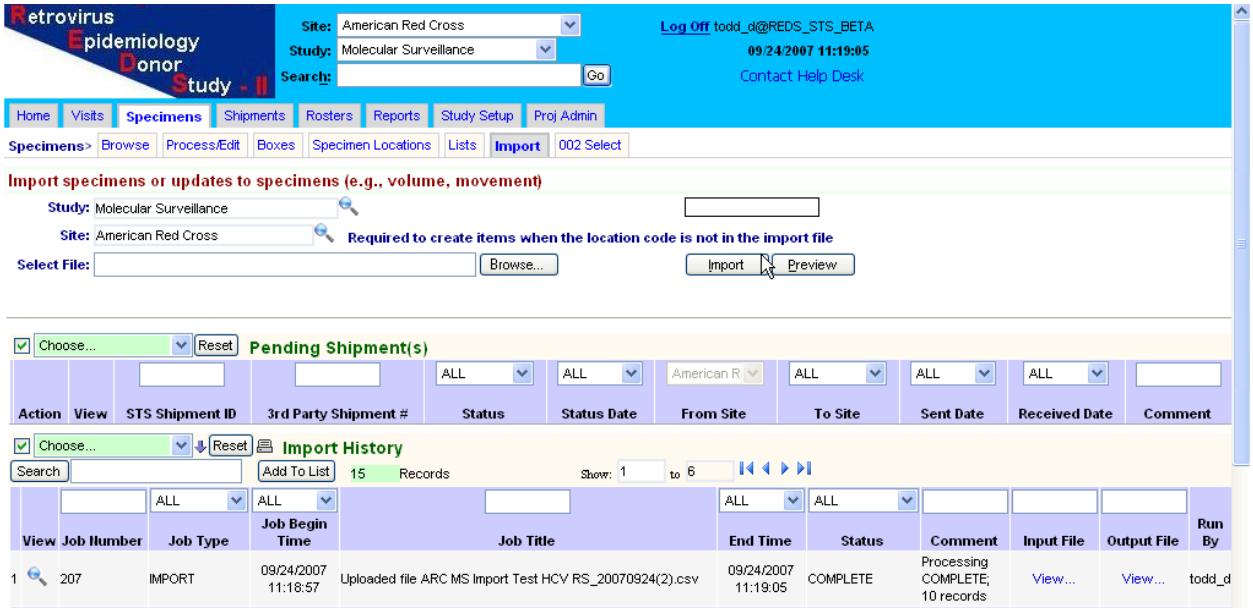
If you choose not to enter specimens into the STS individually at this point, you can enter the specimens into the STS all at once prior to shipping them by creating a shipment list csv file and importing the file into the STS. See Appendix Exhibit F for instructions on how to use the STS.

Tab = Specimens

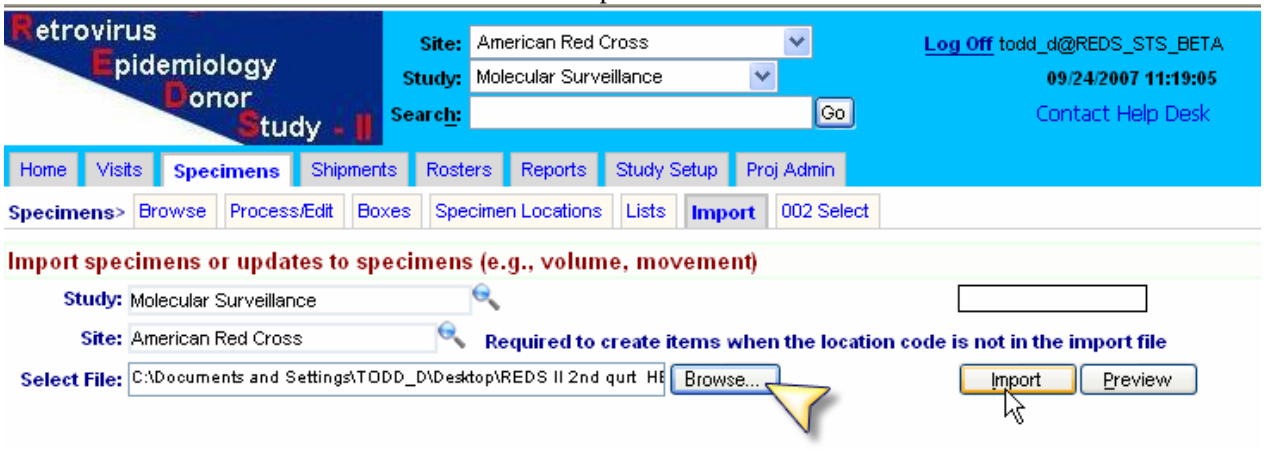
Sub Tab = Import

The Study must specify “Molecular Surveillance”

Site = Your Organization or location



Use the “Browse button” to locate the file to be imported



Press the “Import” button to upload your file.

3. SPECIMEN SHIPPING

3.1 Overview

Residual plasma volume from nucleic acid testing (NAT) or similar retention tubes will be the primary source of samples saved from donations meeting the testing parameters detailed in Chapter 2. Blood centers that are able to obtain additional plasma volume from FFP units can also be added for long term storage as will any available residual serum samples. Specimens for the MS Study will be collected following standard operating procedures at each blood center.

On a semi-annual basis, beginning in October 2006, the participating centers will enter information on specimens collected for the study into the Westat Specimen Tracking System (STS). The specimens will then be transferred to the REDS-II Central Laboratory BSRI for testing and temporary storage. Following completion of testing per the MS protocol, BSRI will send the remaining specimen volume to the NHLBI Central Repository SeraCare BioServices for long-term storage.

The MS STS Users Guide (Appendix Exhibit F) details the process for uploading files of information on the specimens being transferred to the Central Laboratory, preparing shipments and adding and removing any specimens and validating the contents of each freezer box and each shipment. Through the use of the STS shipping functions, the facility where the shipments are prepared as well as the facility where the shipments are received, it is possible to monitor the status of each shipment in real-time. When the shipment reaches its destination and is “Receipted” in the STS the facility from which the shipment was sent will also be able to see the notation that the specimens were received in good order or if any problems were encountered.

3.2 Shipping Schedules

A shipping schedule has been set up to cover the entire lifespan of the study from October 2006 through October 2009. Events that could cause an alteration to the following schedule are: if there are problems with weather or transportation events that are out of the control of study personnel, or staffing or other logistical problems that are unforeseen at this time. When alternate scheduling is required it will be devised on an ad hoc basis. All changes to scheduling should first be discussed with the Coordinating Center contact, Debbie Todd, to ensure that all parties are notified and are in agreement for the modified course of action.

The first shipments from the blood centers to BSRI are to take place the week of October 9, 2006. Dates for individual blood centers to send shipments to the REDS-II Central Laboratory, BSRI, are seen below in Table 3.1 and as Appendix Exhibit B. This first shipment will include all HIV positive (both incident and prevalent) allogeneic donations collected since January 2006. Subsequent shipments to take place in November 2006 are all incident and first-time prevalent HBV allogeneic donations and then in December 2006 HCV incident and first-time prevalent allogeneic donations that have been collected between January and July 1, 2006 (see Section 2.3.5, Box 2D for specimen requirement details).

Table 3.1 Blood Center shipping schedule for the first sets of samples.

Shipment	Marker	Blood Center	Blood Centers to BSRI
1	All **HIV** through July 1, 2006	ARC	Monday October 9, 2006
1	All **HIV** through July 1, 2006	BCW, ITxM HBC	Tuesday October 10, 2006
1	All **HIV** through July 1, 2006	BSL NYBC	Wednesday October 11, 2006
2	All **HBV** through July 1, 2006	ARC	Monday November 13, 2006
2	All **HBV** through July 1, 2006	BCW, ITxM HBC	Tuesday November 14, 2006
2	All **HBV** through July 1, 2006	BSL NYBC	Wednesday November 15, 2006
3	All **HCV** through July 1, 2006	ARC	Monday December 4, 2006
3	All **HCV** through July 1, 2006	BCW, ITxM HBC	Tuesday December 5, 2006
3	All **HCV** through July 1, 2006	BSL NYBC	Wednesday December 6, 2006

See Appendix Exhibit B for 2007, 2008, and 2009 shipment schedule.

2007, 2008, and 2009 shipments will consist of all HIV positive (both incident and prevalent) donations collected, but only HBV and HCV incident donations, since all prevalent donations required for the study will already have been obtained and transferred to the Central Laboratory. With the smaller number of specimens collected after 2006, it will not be necessary to break shipments down over multiple days. As long as specimens are separated into distinct boxes by marker and testing versus storage purpose, all specimens for a 6 month period may be shipped in a single shipment. See Appendix, Exhibit B.

The Central Laboratory will be shipping residual volumes from tested samples as well as those samples volumes retained for future repository use to the NHLBI Central Repository, SeraCare.

3.3 Shipping Supplies

All supplies and costs related to the storage and shipping of specimens for the MS Study, except for the dry ice, will be borne by the recipient of the shipment. At the request of the Blood Centers, the Central Lab, BSRI, will supply each of the Blood Centers with aliquot storage tubes, freezer boxes, labels for the freezer boxes, shipping containers, any related supplies and shipping labels prior to the first shipment of specimens to the facility as well as any time that the demand for supplies dictates this. See Figure 3-1 for an example of the shipping containers provided. Exhibit I is the order form from BSRI for supplies related to the storage materials for the study.

3.4 Instructions for Shipping to the REDS-II Central Laboratory (BSRI)

3.4.1 Record Details of the Shipment in the STS

When preparing to ship frozen samples to BSRI, record the details of the shipment and its contents in the STS (see Appendix Exhibits E and F). This will allow you to prepare an electronic shipment manifest and track whether the specimens were received in good order of if any problems were encountered. This will also allow BSRI and Westat to monitor the status of each shipment in real-time.

3.4.2 Shipping of Frozen Samples to BSRI

BSRI Contact Information

Blood Systems Research Institute
ATTN: Simon Ng
270 Masonic Ave.
San Francisco CA 94118
(415) 901-0751
Fax: (415) 775-3859
Email: ltobler@bloodsystems.org and sng@bloodsystems.org

Schedule: Shipments may be made Monday through Wednesday Only

Figure 3-1. Example of the items provided with Saf-T-Pak STP 320 (Diagnostic Specimens).

The STP 320 will arrive at the Blood Center with the following items:

- Dry ice label (Class 9 label). There is space on this label for the amount of dry ice contained in the shipment, the shipper's name and address and the consignee's name and address
- A STP 111 Inner box
- Two STP 710 white secondary containers (envelope system)
- Two 250 mL absorbent strips
- Rubber bands (at least ¼" thick)

Procedures Using the Saf-T-Pak STP 320

The Saf-T-Pak STP 320 shipping containers will be shipped to the Blood Center by FedEx ground and will be covered with brown paper. The empty shipping container will contain the labels listed above.

Preparing Shipment:

1. Remove polystyrene lid from polystyrene inner cooler.
2. Place White Absorbent Strip around Freezer box.
3. Place Rubber bands (at least ¼" thick) around Freezer Box.

4. Place Freezer box(es) in Clear Biohazard bag and seal according to instructions on the bag.

5. Place Clear Biohazard bag in White Envelope and seal envelope according to the instructions on the envelope.

6. Place White Envelope(s) in inner brown box (this inner box can hold 3-2" Freezer boxes or 2-3" Freezer Boxes) and tape the inner container shut.

7. Place inner box in reusable outer box containing polystyrene cooler.

8. Add dry ice to bring total amount to the same level as the top of the inner box. Note that the total amount of dry ice used will be ~16 lbs or 9 kg. The STP 320 shipping container will maintain a temperature of between 0^0 C and minus 44^0 C for 83 hours when using 7.8 kg of dry ice.

9. Place the Styrofoam lid onto the inner polystyrene container (do not tape the Styrofoam lid.

10. A paper copy of the Shipping Manifest must be included in the shipment; it can be downloaded from the STS or you may generate your own spreadsheet. You may also attach this to the email or fax notifications.

11. Seal the cardboard box with shipping tape.

12. Complete the FedEx Airbill with your shipping address and the amount of Dry Ice placed in box:

    a. Section 2 - The Internal Billing Reference Section must have the following information " REDS-II, Diagnostic Specimens UN 3373"

    b. Section 4a - Check the "FedEx Priority Overnight" box

    c. Section 5 - Check the "other" box

    d. Section 6 - Check the box that says, "Yes Shipper's Declaration not required". Check the "Dry Ice box" and write "1" in the first blank line and the "kg" of dry ice used on the second line; i.e., 1 x 9 kg

    e. Section 7 - Check Recipient. The account number is pre-printed on the FedEx airbill provided by BSRI.

13. Fill in the Dry Ice Label on box with the amount of dry ice used, the sender's and consignee's name and address.

14. Please complete and fax a copy of the REDS-II MS Study - Shipping Notification (Appendix Exhibit C) **prior to the shipment** to Simon Ng at (415) 775-3859 at Blood Systems Research Institute. You may do this either by using a traditional hard copy fax or electronically through the STS (see Appendix Exhibit F, the STS User's Guide – attachments such as the shipping manifest can also be included with this method).

15. Send an e-mail **prior to the shipment** to REDSIICC@westat.com. You may do this either electronically formatted through the STS (see Appendix Exhibit F the STS User's Guide) or by using your own email system.

16. Include the following information in your e-mail.

    a. Subject Line of E-mail should read: REDS-II (Blood Center Name), MS Study, FedEx, "insert tracking number", "insert date of shipment":

    b. Shipper's Name:

    c. Shipper's Address:

    d. Shipper's Phone:

    e. Shipment Date:

    f. Courier:

    g. Tracking Number (no spaces):

If you should have any questions regarding these instructions please contact BSRI or Westat using the contact information above.

4. BLOOD CENTER DATA SUBMISSIONS

4.1 Data and Demographics

Qualified donations meeting the protocol criteria are described in detail in Chapter 2 Section 2.1. At the time specimens are shipped to BSRI, data files detailing the viral marker test results and the donation demographics must also be sent to the Coordinating Center (Westat) from each of the participating organizations on all incident and prevalent cases irregardless of whether a specimen was submitted for the molecular surveillance study. This data includes the following information on each donation for viral marker test results and demographics: a blood unit identifier (BUI), date of donation, first time and repeat status, results of HIV, HCV and HBV nucleic acid & antibody tests, date of birth, race/ethnicity if available, gender, state of residence (this has been modified from the protocol which specified a 3-digit zip code) and a "flag" that indicates if this donation is represented by a specimen that was shipped to BSRI.

On an annual basis, in the second quarter of each year, additional files will also be transmitted to the REDS-II Coordinating Center for the yearly summary statistics on the total number of allogeneic donations screened at each blood center as well as demographic breakdowns on: number of donations by year of birth, gender, race/ethnicity if available, first time and repeat status, and the state of residence of blood donors.

4.2 Data Files Detailing Prevalent and Incident Donations

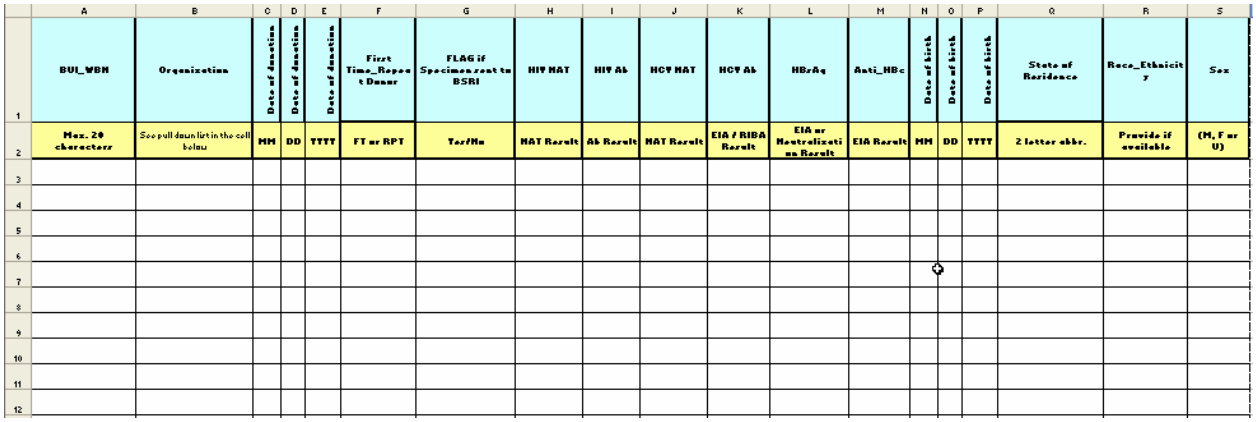
The initial MS Prevalence and Incidence Data Form (MS P and I Data Form) file from each center must contain information on all HIV positive donations: incident and prevalent, first time and repeat cases that were donated January 1, 2006 through July 1, 2006. Westat will compile and use the files to generate specimen selection lists for those donations requiring HIV LS-EIA testing at the Central Laboratory. This HIV LS-EIA (or detuning step) will assist in separating newly infected or incident donations from prevalent cases. The specimen selection list provided to the Central Lab identifies the viral marker type(s) reported as positive, BUI, organization, and sequence number as generated by the STS. It will not include demographic nor detailed viral marker test data. Westat will provide the specimen selection list to BSRI within 2 weeks of submission of the specimens and MS P and I Data Forms by the Blood Centers.

As the files are compiled by the Coordinating Center, the potentially identifying details for each donation will be converted from the date of birth to age at time of donation and the donor's state of residence converted to US Census Bureau geographic region division (9 divisions spread among the four regions of the US). The original MS P and I data files will then be deleted and the only link to this information will be the copy of the file maintained by the participating blood center that submitted the data.

Subsequent shipments and their related data files provided by the blood centers will similarly detail other HIV, HBV and HCV positive donations. **Please see the Appendix, Exhibit B for the 2007-2009 schedule for delivering the MS P & I Data forms to Westat for all qualified donations.**

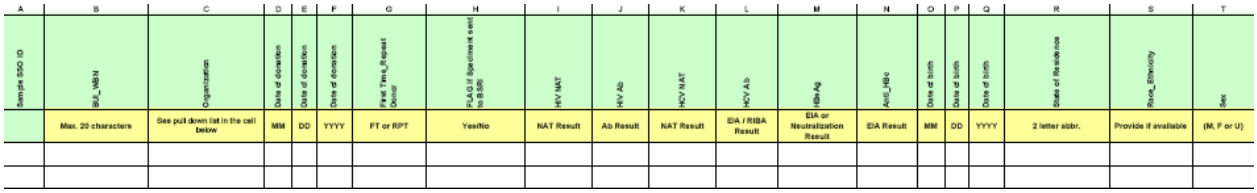
4.3 Instructions for Completion of the Molecular Surveillance Prevalence and Incidence Data Form

Materials and methods for blood center data reporting are described in this section. Two format options are allowed which will facilitate easy, rapid, standardized and accurate transfer of information into a compiled dataset once they are received at the Coordinating Center. The first option is submission of a study specific Excel template (see Figure 4.1 A & B and Appendix Exhibit D) which has pull down and quick fill fields. An electronic version of this file has been provided to you. The second option is utilizing indirect database reporting as described in Section 4.4. Table 4.1, the Data Layout Table, seen in Section 4.4 exactly corresponds with the options and characteristics found in the Excel spreadsheet seen below and can be used to create standardized comma delimited files for submission. Both of these options will be sent to Westat in a password protected .zip file (see Section 4.5).



	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q	R	S
1	BUI_WBN	Organization	Date of donation	Date of donation	Date of donation	First Time_Repeat Donor	FLAG if Specimen sent to BSRI	HIV NAT	HIV Ab	HCV NAT	HCV Ab	HBsAg	Anti_HBc	Date of birth	Date of birth	Date of birth	State of Residence	Race_Ethnicity	Sex
2	Max. 20 characters	See pull down list in the cell below	MM	DD	YYYY	FT or RPT	Yes/No	NAT Result	Ab Result	NAT Result	EIA / RIBA Result	EIA or Neutralization Result	EIA Result	MM	DD	YYYY	2 letter abbr.	Provide if available	(M, F or U)
3																			
4																			
5																			
6																			
7																			
8																			
9																			
10																			
11																			
12																			

Figure 4.1 A MS P & I Data Form



	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q	R	S	T
	Sample SSO ID	BUI_WBN	Organization	Date of donation	Date of donation	Date of donation	First Time_Repeat Donor	FLAG if Specimen sent to BSRI	HIV NAT	HIV Ab	HCV NAT	HCV Ab	HBsAg	Anti_HBc	Date of birth	Date of birth	Date of birth	State of Residence	Race_Ethnicity	Sex
		Max. 20 characters	See pull down list in the cell below	MM	DD	YYYY	FT or RPT	Yes/No	NAT Result	Ab Result	NAT Result	EIA / RIBA Result	EIA or Neutralization Result	EIA Result	MM	DD	YYYY	2 letter abbr.	Provide if available	(M, F or U)

Figure 4.1 B MS P & I Data Form for ARC

Open the file (this is provided to you electronically):
MS_Prev&Incid_DataCollectionTemplate_091206.xls.

Rename and save a copy of the file with a new name 1) to preserve a blank template for future use and 2) to have a clean file prepped for data entry for submission to the Coordinating Center.

To facilitate the automated file processes at Westat you must use a standardized naming convention, as shown below, for the files to be submitted.

Example: MS_HIVPIDATA_SITENUMBER_SITENAME_YYYYMMDD.xls
(i.e. MS_HIVPIDATA_270_ARC_20060925.xls)

This file name indicates this file is for the Molecular Surveillance study; it contains data on HIV prevalent and incident donations from the American Red Cross which has been assigned site number 270; and the file was prepared on Sept. 25, 2006. All gaps or spaces between words or abbreviations should be replaced with an underscore.

***Retain a copy of all data files submitted to the Coordinating Center.**

4.3.1 How to use the Excel Template

Step 1

Open the Excel spreadsheet and rename the file as suggested above.

Step 2

Row 1 is shaded in blue.
The titles are the variable names for columns A – S.
Row 2 is shaded yellow.
These fields are more descriptive information about the variables or the reporting format for the variables.

Row(s) 3 and beyond
This is the row where data will be entered for the reporting period.

Place your cursor over the data cell where you wish to enter data, and then left click once with the mouse. This will highlight the cell.

Some cells will display a gray downward pointing arrow along with a pop-up window on the right side of the cell. The pop-up window contains instructions specific to each cell and can be easily dragged around by holding the left button of your mouse if it appears in an inconvenient place.

If there is an arrow, by left clicking on the arrow you will see appearing below the cell, a pull-down list that is in a **standardized** format. You can scroll through the list with your mouse or use the down arrow on your keyboard to locate the appropriate response from which you can make your selection. Left click again on the response you wish to choose. TAB to the next column cell or you may highlight the cell in the next column by one click of the left mouse button.

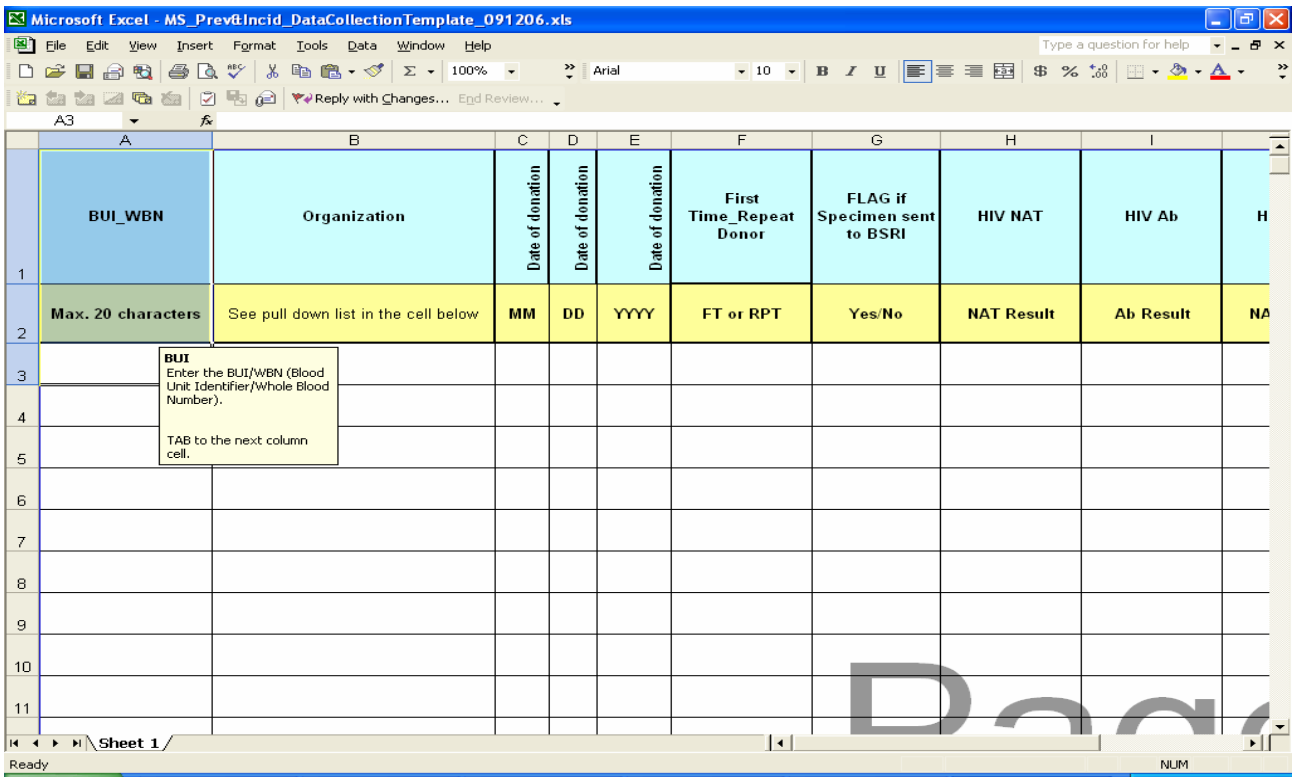
If there is no downward pointing arrow, the pop-up window contains instructions that ask you to enter information in a standardized format such as the number of digits or characters.

Use your mouse to click on cell **A3**.

Column A:

Blood Unit Identifier

Enter the BUI or WBN (10 characters preferred minimum, 20 characters maximum) for this donation. If you use a region code along with the 7 character donation ID please include this so that we do not get repetitive BUIs across blood centers/organizations.



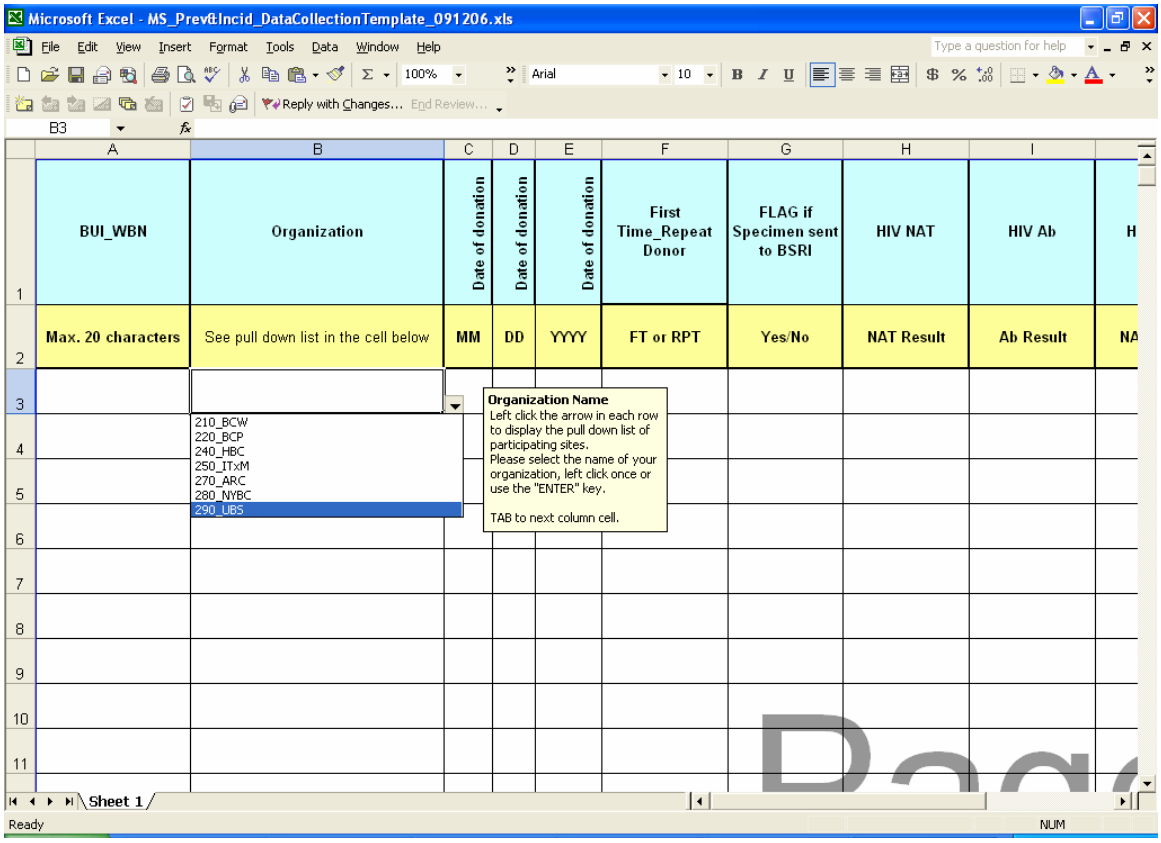
TAB to next column cell.

Cell **B3** should now be highlighted.

Column B:

Organization

In this pull down list there are sites listed with assigned Site Number and Abbreviated Organization Names.
Enter the assigned organization number and name (see below).
Left click the arrow in each row to display the pull down list of participating sites.
Please select your site, left click once or use the "ENTER" key.



The assigned site numbers and names are:

210_BCW	**for The BloodCenter of Wisconsin**
220_BCP	**for the Blood Centers of the Pacific**
240_HBC	**for University of Cincinnati/Hoxworth Blood Center**
250_ITxM	**for the Institute for Transfusion Medicine**
270_ARC	**for all American Red Cross Blood Services**
280_NYBC	**for the New York Blood Center**
290_UBS	**for the United Blood Services centers**

TAB to next column cell.

Cell **C3** should now be highlighted.

Columns C, D and E:

Date of Donation
MM is the two digit month format and has a pull down list from which to select 01-12.
DD is the two digit date format and has a pull down list from which to select 01-31.
YYYY is the four digit year format and has a pull down list from which to select 2006 or other current year.

TAB to each of the next columns to complete the donation date cells.

Cell **F3** should now be highlighted.

Column F:

First Time or Repeat Donor
Donors are considered First time (FT) if the blood center database does not have a donation since June 1996. If there is more than one donation after July 1, 1996 then select RPT for Repeat donor status.

TAB to the next column cell.

Cell **G3** should now be highlighted.

Column G:

FLAG if specimen sent to BSRI
Select "Yes" if specimen was shipped to BSRI or "No" if a specimen was not available for shipment and testing; data on the donation must be included for analytic purposes even if no specimen is shipped to BSRI.

TAB to the next column cell.

Cell **H3** should now be highlighted.

Column H:

HIV NAT
From the pull down menu choose result for the HIV NAT assay, NR if non-reactive and R if reactive. Choose NT of the specimen was Not Tested i.e. QNS.

TAB to the next column cell.

Cell **I3** should now be highlighted.

Column I:

HIV Ab
From the pull down menu choose result for the HIV1/2 EIA or if the EIA was reactive provide the WB result per manufacturer's package insert. Choose NT if Not Tested or QNS.

TAB to the next column cell.

Cell **J3** should now be highlighted.

Column J:

HCV NAT
From the pull down menu choose result for the HCV NAT assay, NR if non-reactive and R if reactive. Choose NT if the specimen was Not Tested i.e. QNS.

TAB to the next column cell.

Column K:

HCV Ab
From the pull down menu choose result for the HCV EIA or if the EIA was reactive provide the RIBA result per manufacturer's package insert. Choose NT if Not Tested or QNS.

TAB to the next column cell.

Column L:

HBsAg
From the pull down menu choose result for the HBsAg EIA or if the EIA was reactive provide the HBsAg Neutralization result per manufacturer's package insert. Choose NT if Not Tested or QNS.

TAB to the next column cell.

Column M:

Anti-HBc
From the pull down menu choose result for the Anti-HBc EIA test result. NR for Non-Reactive test results or R for Reactive per manufacturer's package inserts. Choose NT if Not Tested or QNS.

TAB to the next column cell.

Columns N, O and P:

Date of Birth
MM is the two digit month format and has a pull down list from which to select 01-12.
DD is the two digit date format and has a pull down list from which to select 01-31.
YYYY is the four digit year format and has a pull down list from which to select <1917 to >2000.

We have grouped donors who may be over the age of 89 to insure confidentiality. Donors must be 17 or older to be included in this study protocol.

If you are unable to provide the specific date of birth;

use month 01 and day 01 as a default,
providing only the actual birth year of the donor.
Example 01/01/1967.

TAB to the next column cell.

Column Q:

State of Residence
Donor's State of Residence
Use the pull down menu to enter the state in which the donor resides at the time of donation. If the donor resides outside the 50 states or the District of Columbia chose the final option "Other."

TAB to the next column cell.

Column R:

Race/Ethnicity

Please provide using the following options if this information is available.

Select:
W = White Non-Hispanic
B = Black Non-Hispanic
A = Asian
H = Hispanic
I = Native American
M = More Than One Race
O=Other Non-Hispanic
7 = Refused
8 = Not Sure
9 = Not Available

TAB to the next column cell.

Column S:

Sex
Donor Gender
Enter from the pull down menu either "M" for Male or "F" for Female or "9" if the gender is Unknown or Missing.

Go to Column A on the next row and repeat entries for each blood donation.

4.3.2 Additional Information

The Excel spreadsheet template is formatted for up to 1000 rows of data. If you require more than 1000 records we can assist you with formatting additional rows or you may find it more appropriate to prepare a comma delimited (.csv) file by utilizing the indirect database reporting methodology described in the next section.

The “Print Area” is currently set to print only the first page. Thus, if more printed pages are desired those parameters will need to be adjusted to suit your needs.

The spreadsheet should now be saved with a file name as described earlier on page 4-2.

4.4 Data Layout for Indirect Database Reporting

Some organizations may find it more expeditious to utilize the indirect database reporting approach to extract and report data on the donations for the Molecular Surveillance Study. This method is equally as acceptable as submitting the information in the Excel file format as long as the criteria match exactly the items in the table below. Table 4.1 below is a table displaying the variable names and characteristics that are also found in the Excel template and are required file specifications if using this method of data reporting. Files are then to be submitted in a comma delimited format (.csv) following the instructions in Section 4.5.

Table 4.1 Data Layout Table

Column	Variable Name	Variable Description	Type	Length	Values * Values that are **missing or unknown = 9**
A	BUI_WBN	BLOOD UNIT IDENTIFIER / WHOLE BLOOD NUMBER	A	20	
B	ORGANIZATION	SITE NUMBER AND SITE NAME	A	8	210_BCW 220_BCP 240_HBC 250_ITxM 270_ARC 280_NYBC 290_UBS
C	MM	MONTH OF DONATION	A	2	01-12
D	DD	DAY OF DONATION	A	2	01-31
E	YYYY	YEAR OF DONATION	A	4	2006-2008
F	FT OR RPT	FIRST TIME OR REPEAT DONOR	A	3	FT, RPT
G	FLAG	WAS A SPECIMEN SENT TO BSRI	A	3	YES, NO
H	HIV_NAT	DISCRIMINATORY HIV NAT	A	2	NR,NT,R
I	HIV_Ab	HIV 1/2 ANTIBODY EIA/WB TEST RESULT	A	10	NR,NT,R, POS,NEG,IND, INVALID, UNREADABLE
J	HCV_NAT	DISCRIMINATORY HCV NAT	A	2	NR,NT,R
K	HCV_Ab	HCV ANTIBODY EIA/RIBA TEST RESULT	A	10	NR,NT,R, POS,NEG,IND, INVALID, UNREADABLE
L	HBSAG	HEPATITIS B SURFACE ANTIGEN TEST RESULT	A	10	NR,NT,R, POS,NEG,IND, INVALID, UNREADABLE
M	ANTI_HBc	HEPATITIS B CORE ANTIBODY TEST RESULT	A	2	NR,NT,R
N	MM	MONTH OF BIRTH	A	2	01-12
O	DD	DAY OF BIRTH	A	2	01-31
P	YYYY	YEAR OF BIRTH	A	5	<1917 - (current year - 16)
Q	STATE	2 LETTER ABBR. STATE OF RESIDENCE OF DONOR	A	2	
R	RACE_ETHNICITY	RACE/ETHNICITY OF DONOR (FROM BLOOD CENTER DONOR REGISTRATION FORM)	A	1	A,B,H,I,O,W,M,7,8,9
S	SEX	SEX OF DONOR	A	1	M,F,9

4.5 Submission of Data Files to the Coordinating Center

The key element to the smooth transfer of data is that the naming convention conforms to the following format:

MS_HIVPIDATA_SITENUMBER_SITENAME_YYYYMMDD.xls
MS_HIVPIDATA_SITENUMBER_SITENAME_YYYYMMDD.csv

MS_HBVPIDATA_SITENUMBER_SITENAME_YYYYMMDD.xls
MS_HBVPIDATA_SITENUMBER_SITENAME_YYYYMMDD.csv

MS_HCVPIDATA_SITENUMBER_SITENAME_YYYYMMDD.xls
MS_HCVPIDATA_SITENUMBER_SITENAME_YYYYMMDD.csv

- The file(s) should be placed in a password protected .Zip file with the name:

  MS_HIVPIDATA_SITENUMBER_SITENAME_YYYYMMDD.**Z**

  - Sending the file with the extension .Z rather than .ZIP allows it to pass through our email system.

- Include in the email the number of records and columns contained in each file.

- A separate second email should be sent that contains the name of this file as well as the .zip file password. You may establish one password that can be used for each submission or provide a new password with each file. Whichever method is chosen, it must be communicated with the Coordinating Center.

- Submit files to: REDSIICC@WESTAT.COM

4.6 Yearly Summary Statistics

The participating organizations, the American Red Cross Blood Services, the New York Blood Center and the United Blood Services will also need to provide Westat with *yearly* summary statistical files that will include the total number of allogeneic donations screened from donors age 17 and older during the corresponding year (2006-2009) and the demographic distribution of allogeneic donations (age, gender, race/ethnicity if available, first time and repeat status, and geographic area). While the REDS-II centers/laboratories (The Blood Center of Wisconsin, the Blood Centers of the Pacific, Hoxworth Blood Center and the Institute for Transfusion Medicine) will need to provide Westat with a file containing information on center, donation date, BUI, and HIV, HCV and HBV overall test result interpretation for all qualified donations (see Chapter 2), the case-specific demographic information

for the 4 REDS-II centers may be directly extracted by Westat from the REDS-II donation database if it is not provided on the MS P and I Data Forms. The yearly summary statistics information for the 4 REDS-II centers will be directly extracted by Westat from the REDS-II donation database.

The yearly summary statistics Excel files should be provided in second quarter of 2007, 2008 and 2009 and will be broken down by first time, repeat and unknown donation type into the following demographic categories: age, state of residence, race/ethnicity, and gender. Please see the Appendix, Exhibit B for the 2007-2009 schedule for delivering the yearly summary statistics file to Westat.

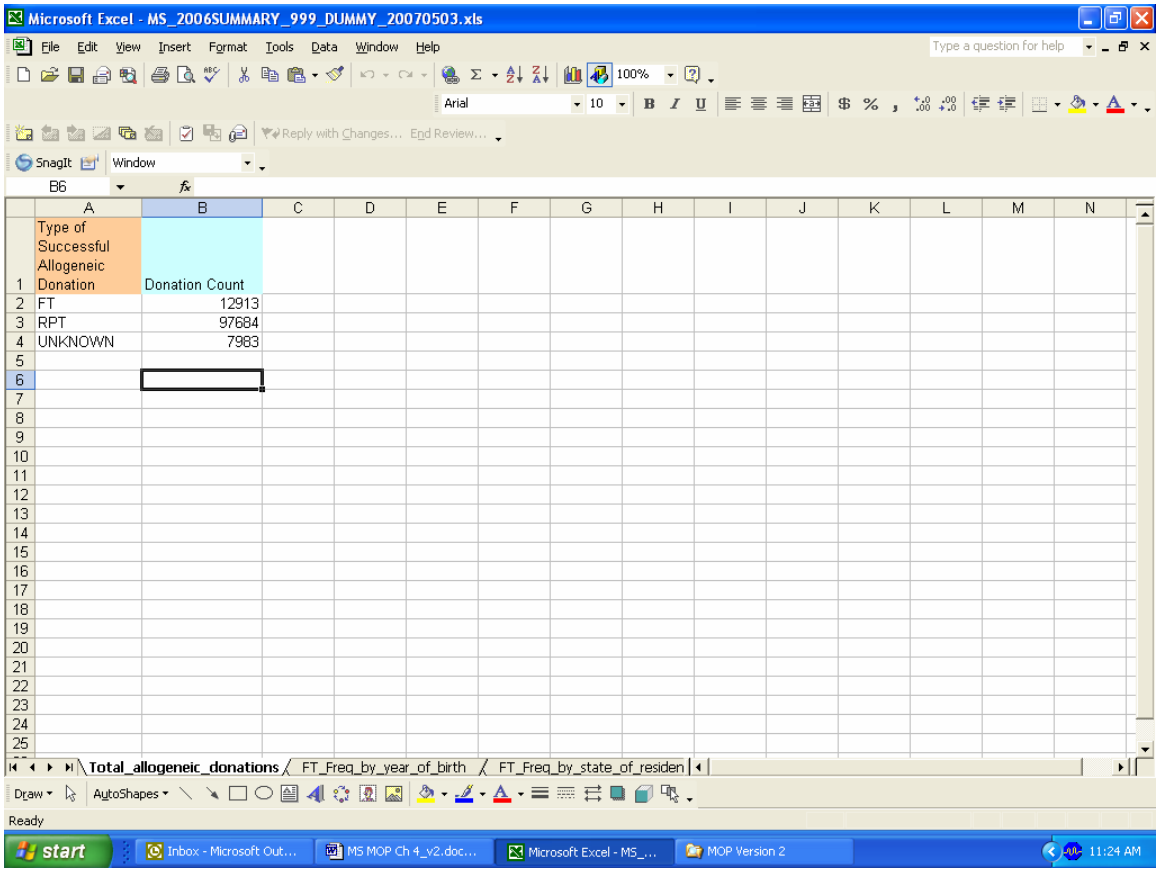
Worksheet 1:
Labeled **Total_allogeneic_donations - Total Allogeneic donations by donation type**

Column A:

Type of Successful Allogeneic Donation -
Use FT for First Time donor
RPT for Repeat Donor
Unknown if it is unknown whether the donor is a first time or repeat donor

Column B:

Donation Count -
Number of Donations



	A	B
1	Type of Successful Allogeneic Donation	Donation Count
2	FT	12913
3	RPT	97684
4	UNKNOWN	7983

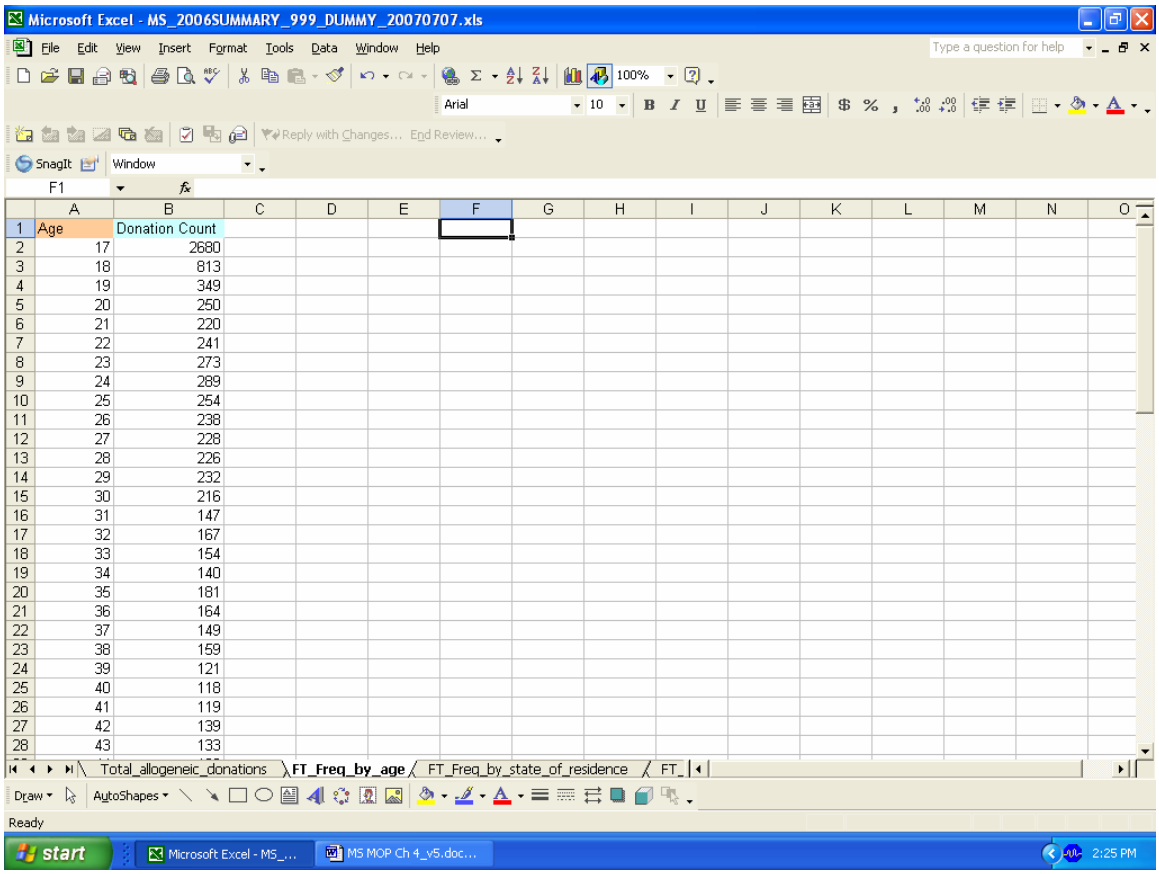
Worksheet 2:
Labeled **FT_ Freq_by_age – First time donations by age**

Column A:

Age -
Age at the time of the donation. “999” is used if the age can not be calculated.

Column B:

Donation Count -
Number of Donations



Age	Donation Count
17	2680
18	813
19	349
20	250
21	220
22	241
23	273
24	289
25	254
26	238
27	228
28	226
29	232
30	216
31	147
32	167
33	154
34	140
35	181
36	164
37	149
38	159
39	121
40	118
41	119
42	139
43	133

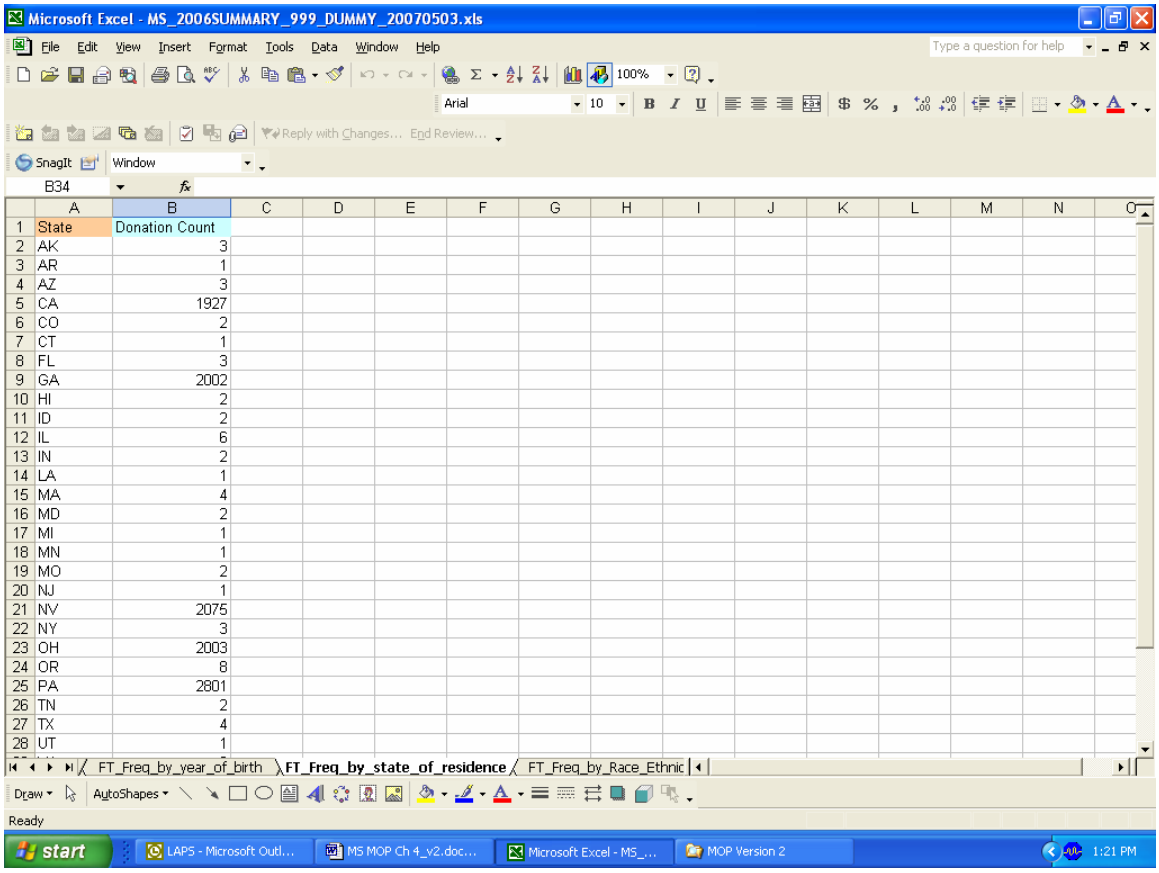
Worksheet 3:
Labeled FT_ Freq_by_state_of_residence – First time donations by state of residence

Column A:

State -
State of residence (if state of residence is not know, use the state of the donation blood center)

Column B:

Donation Count -
Number of Donations



	A	B
1	State	Donation Count
2	AK	3
3	AR	1
4	AZ	3
5	CA	1927
6	CO	2
7	CT	1
8	FL	3
9	GA	2002
10	HI	2
11	ID	2
12	IL	6
13	IN	2
14	LA	1
15	MA	4
16	MD	2
17	MI	1
18	MN	1
19	MO	2
20	NJ	1
21	NV	2075
22	NY	3
23	OH	2003
24	OR	8
25	PA	2801
26	TN	2
27	TX	4
28	UT	1

Worksheet 4: Labeled**FT_ Freq_by_Race_Ethnicity – First time donations by race and ethnicity**

Column A:

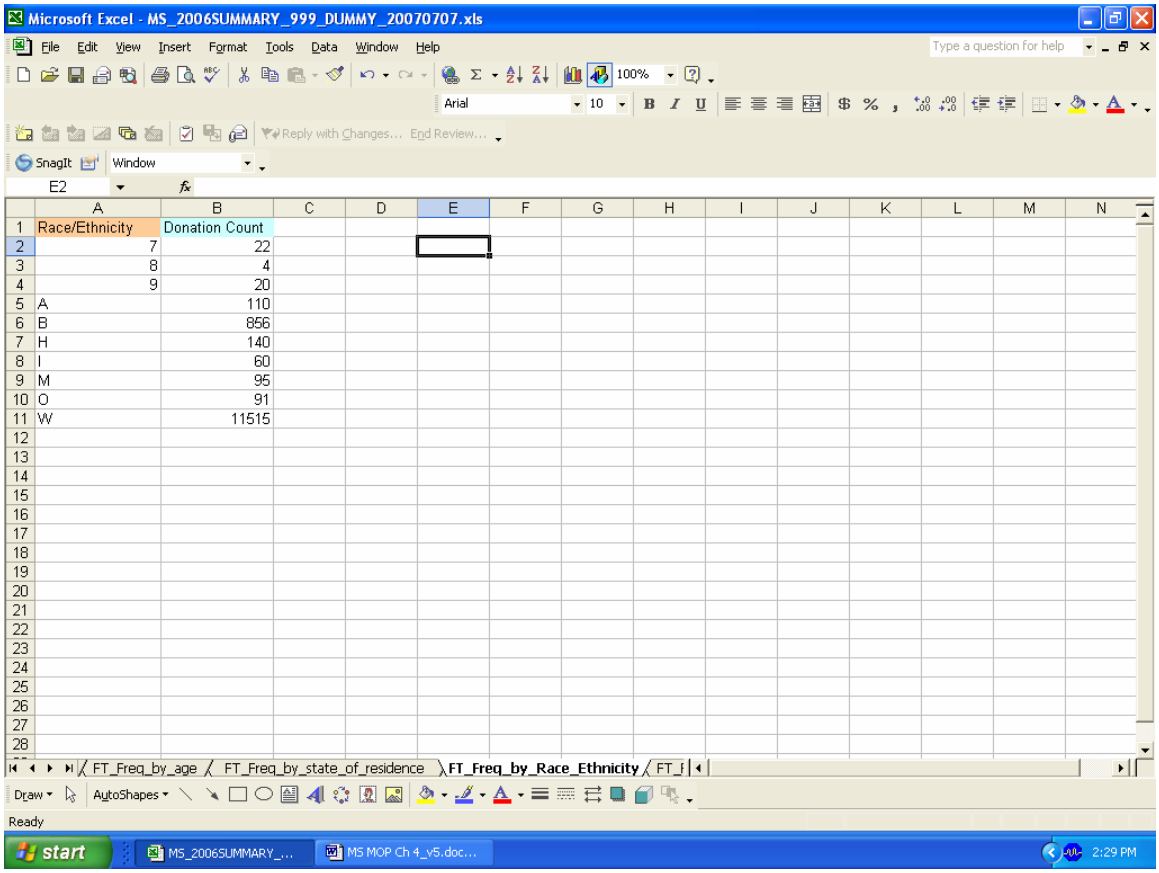
Race/Ethnicity -

Race values are: "A" = ASIAN
"B" = BLACK
"H" = HISPANIC
"I" = NATIVE AMERICAN
"O" = OTHER
"W" = WHITE
"M" = MORE THAN ONE RACE
"7" = REFUSED
"8" = NOT SURE
"9" = NOT AVAILABLE

Column B:

Donation Count -

Number of Donations



Race/Ethnicity	Donation Count
7	22
8	4
9	20
A	110
B	856
H	140
I	60
M	95
O	91
W	11515

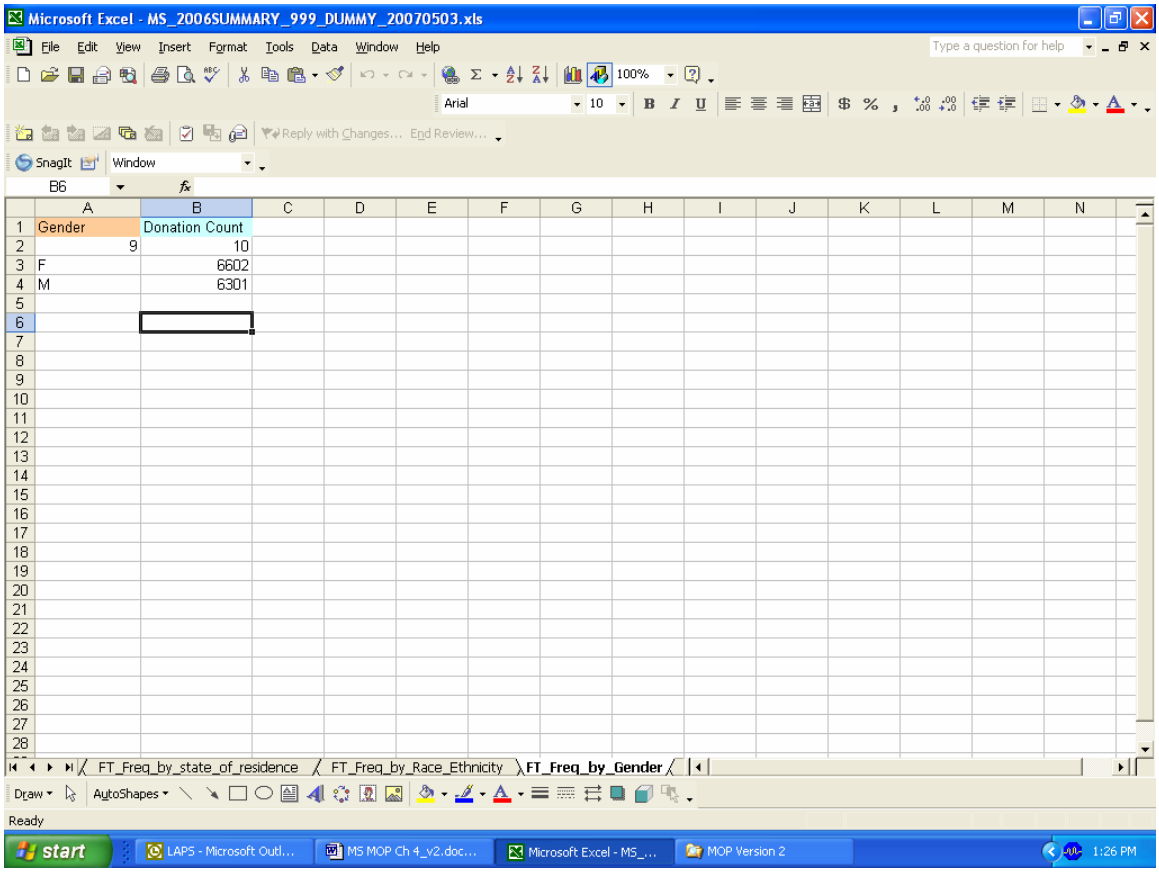
Worksheet 5: Labeled**FT_ Freq_by_Gender – First time donations by gender**

Column A:

Gender -
Gender values are: 9 – Unknown
F – Female
M – Male

Column B:

Donation Count -
Number of Donations



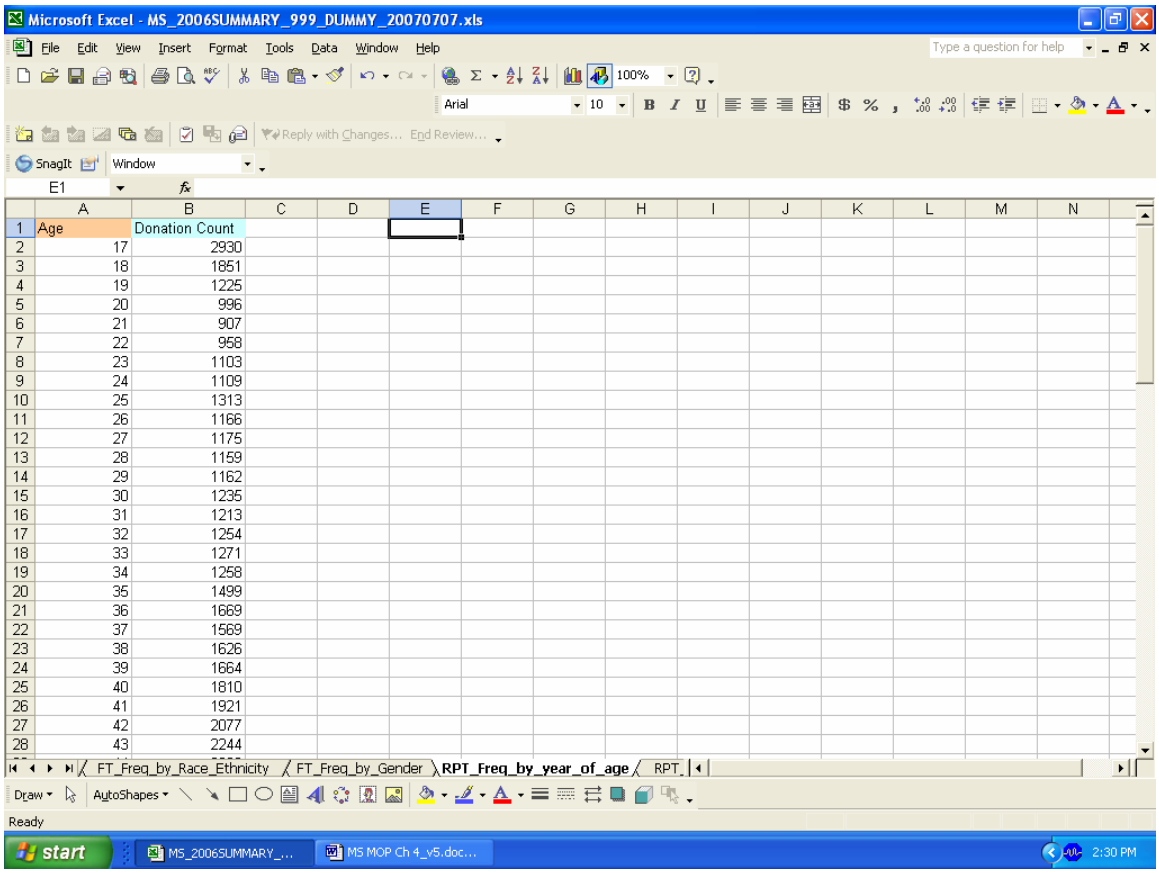
Worksheet 6: Labeled**RPT_ Freq_by_age – Repeat donations by age**

Column A:

Age -
Age at the time of the donation. “999” is used if the age can not be calculated.

Column B:

Donation Count -
Number of Donations



Worksheet 7: Labeled**RPT_ Freq_by_state_of_residence – Repeat donations by state of residence**

Column A:

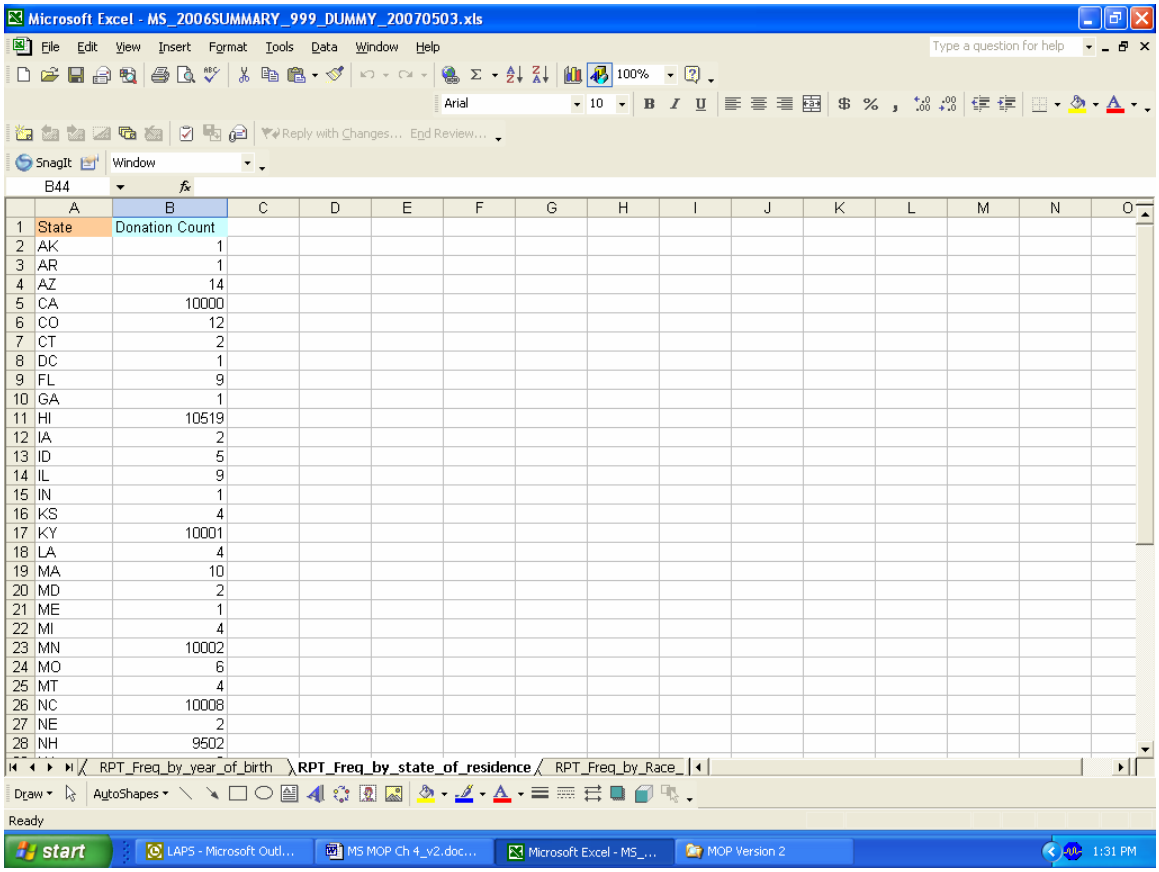
State -

State of residence (if state of residence is not know, use the state of the donation blood center)

Column B:

Donation Count -

Number of Donations



	A	B
1	State	Donation Count
2	AK	1
3	AR	1
4	AZ	14
5	CA	10000
6	CO	12
7	CT	2
8	DC	1
9	FL	9
10	GA	1
11	HI	10519
12	IA	2
13	ID	5
14	IL	9
15	IN	1
16	KS	4
17	KY	10001
18	LA	4
19	MA	10
20	MD	2
21	ME	1
22	MI	4
23	MN	10002
24	MO	6
25	MT	4
26	NC	10008
27	NE	2
28	NH	9502

Worksheet 8: Labeled**RPT_ Freq_by_Race_Ethnicity – Repeat donations by Race and Ethnicity**

Column A:

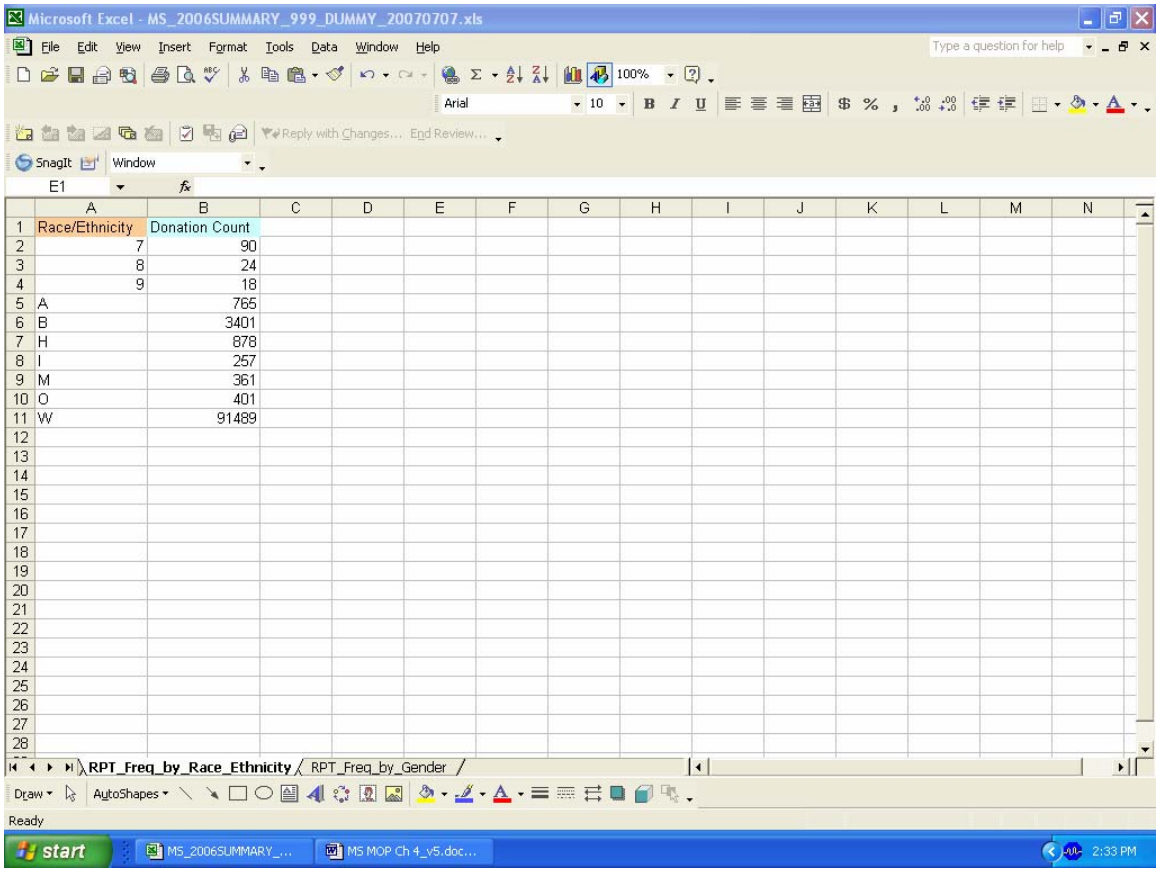
Race/Ethnicity -

Race values are: "A" = ASIAN
"B" = BLACK
"H" = HISPANIC
"I" = NATIVE AMERICAN
"O" = OTHER
"W" = WHITE
"M" = MORE THAN ONE RACE
"7" = REFUSED
"8" = NOT SURE
"9" = NOT AVAILABLE

Column B:

Donation Count -

Number of Donations



	A	B
1	Race/Ethnicity	Donation Count
2	7	90
3	8	24
4	9	18
5	A	765
6	B	3401
7	H	878
8	I	257
9	M	361
10	O	401
11	W	91489

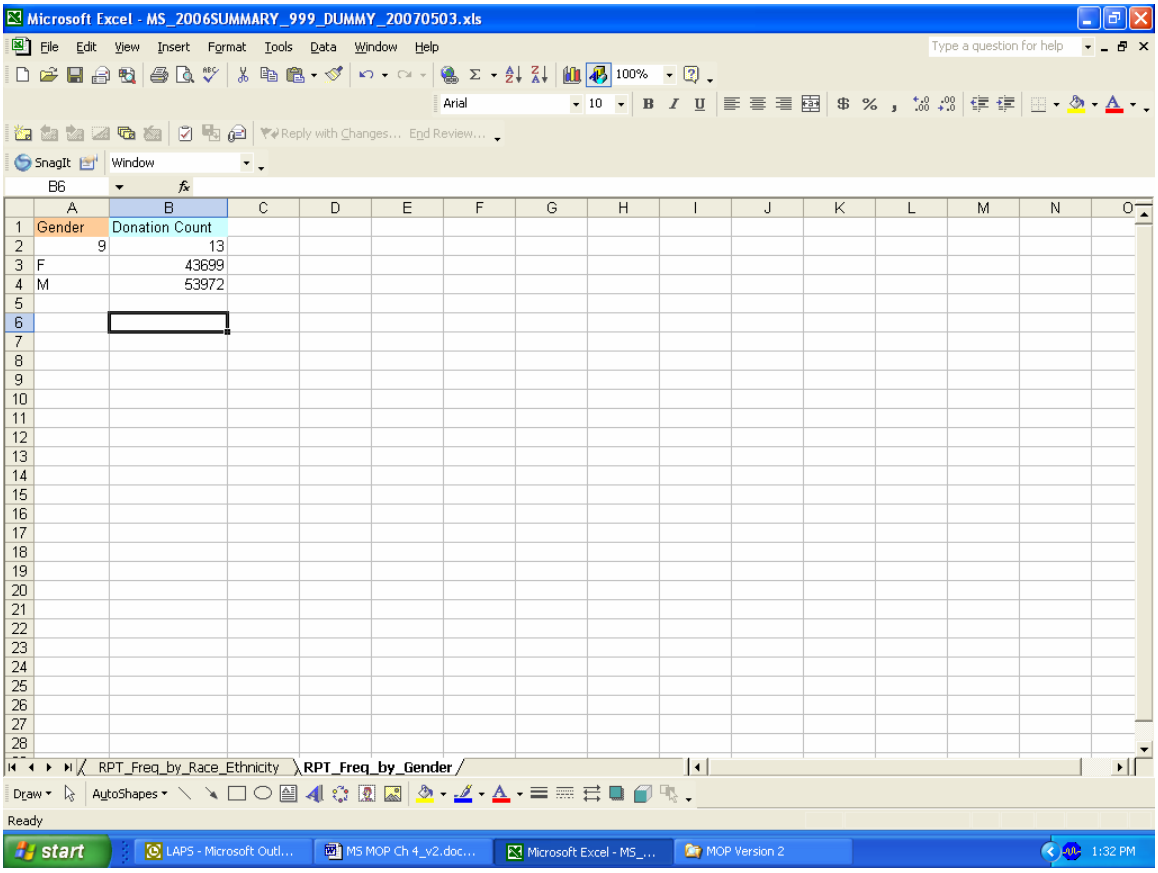
Worksheet 9: Labeled**RPT_ Freq_by_Gender – Repeat donations by gender**

Column A:

Gender -
Gender values are: 9 – Unknown
F – Female
M – Male

Column B:

Donation Count -
Number of Donations



The naming convention for annual summary statistics Excel file should conform to the following format:

MS_2006SUMMARY_SITENUMBER_SITENAME_YYYYMMDD.xls
MS_2007SUMMARY_SITENUMBER_SITENAME_YYYYMMDD.xls
MS_2008SUMMARY_SITENUMBER_SITENAME_YYYYMMDD.xls

- The file(s) should be placed in a password protected .Zip file with the name:

  MS_**YYYYSUMMARY**_SITENUMBER_SITENAME_YYYYMMDD.**Z**

- Sending the file with the extension .Z rather than .ZIP allows it to pass through our email system.

- A separate second email should be sent that contains the name of this file as well as the .zip file password. You may establish one password that can be used for each submission or provide a new password with each file. Whichever method is chosen, it must be communicated with the Coordinating Center.

- Please be sure that the donation totals within the demographic tabs match the totals on the first tab, total donations by donation type. For example, the total of column B on FT_ Freq_by_Race_Ethnicity tab should match the donation count for first time donations (cell B2) on Total_allogeneic_donations.

- Submit files to: REDSIICC@WESTAT.COM

Exhibit A
General Overview of the MS Study

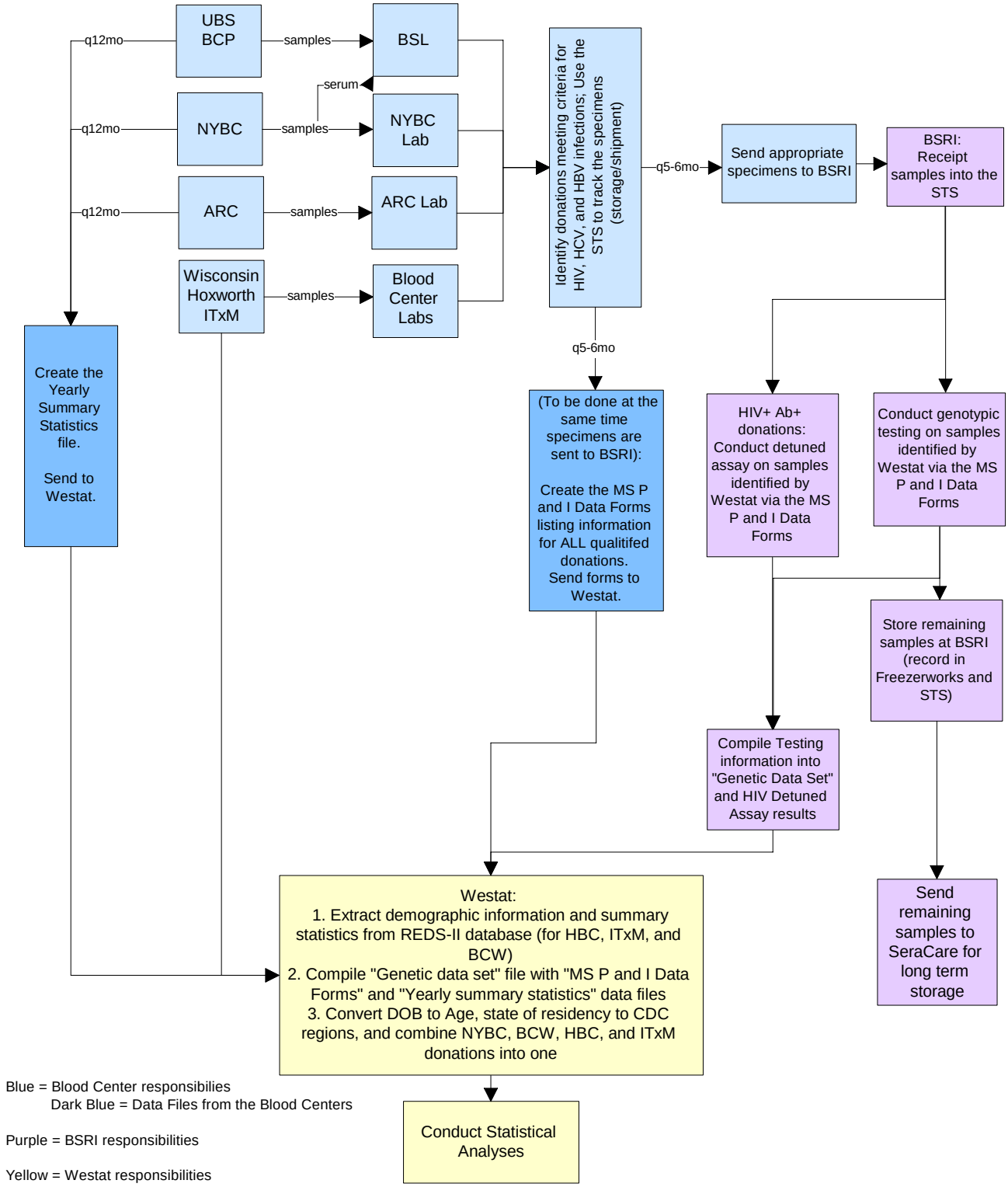


Exhibit B

Please confer with the Coordinating Center approximately 2 weeks prior to any shipments so that the necessary resources are informed and are in place on the exact dates negotiated by all parties.

REDS-II Molecular Surveillance Delivery: Schedule I

American Red Cross and New York Blood Center

Donations Collected	MS P&I Form (Demographic Data) Delivered to Westat All markers	Specimens Shipped to BSRI All markers	Annual Summary Data Delivered to Westat
January – June 2007	September 2007	September 2007	June 2008
July – December 2007	February 2008	February 2008	June 2008
January – June 2008	September 2008	September 2008	June 2009
July – December 2008	February 2009	February 2009	June 2009
January – June 2009 [1]	September 2009	September 2009	June 2010

REDS-II Molecular Surveillance Delivery: Schedule II

Blood Center of Wisconsin, Hoxworth Blood Center, Institute for Transfusion Medicine and United Blood Centers

Donations Collected	MS P&I Form (Demographic Data) Delivered to Westat	Specimens Shipped to BSRI All markers	Annual Summary Data Delivered to Westat
January – June 2007	October 2007	October 2007	June 2008
July – December 2007	March 2008	March 2008	June 2008
January – June 2008	October 2008	October 2008	June 2009
July – December 2008	March 2009	March 2009	June 2009
January – June 2009 [1]	October 2009	October 2009	June 2010

[1] These dates coincide with the NHLBI REDS-II extension but are pending approval of participants and all IRBs.

Please fax this form to:
(No cover sheet required)

Simon Ng, BSRI
Fax #: 1 (415) 775-3859

Page: _____ of _____

Date of Shipment: _____

Exhibit C:
REDS-II Molecular Surveillance Study - Shipping Notification

1. Fax this form to Simon Ng (BSRI- **1.415.775.3859**) the same day the specimens are sent to BSRI, this alerts our lab staff of sample's arrival the following day.
2. Include this form with shipment, fold and place inside box.

FedEx Tracking # 1: _____

FedEx Tracking # 2: _____

FedEx Tracking # 3: _____

Comments: _____ **shippers containing** _____ **boxes**

Scheduled Pick-Up Date:

Scheduled Delivery Date:

Blood Center: _____ **Blood Center Contact:** _____

Contact Phone: _____ **E-mail:** _____

Exhibit D

Data Reporting Form for
REDS-II Molecular Surveillance
Prevalent and Incident Donations

	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q	R	S
1	BUI_WBN	Organization	Date of donation	Date of donation	Date of donation	First Time_Repeat Donor	FLAG if Specimen sent to BSRI	HIV NAT	HIV Ab	HCV NAT	HCV Ab	HBsAg	Anti_HBc	Date of birth	Date of birth	Date of birth	State of Residence	Race	
2	Max. 20 characters	See pull down list in the cell below	MM	DD	YYYY	FT or RPT	Yes/No	NAT Result	Ab Result	NAT Result	EIA / RIBA Result	EIA or Neutralization Result	EIA Result	MM	DD	YYYY	2 letter abbr.	Provide if available	(M, F or U)
3																			
4																			
5																			
6																			
7																			
8																			
9																			
10																			
11																			
12																			
13																			
14																			
15																			
16																			
17																			
18																			
19																			
20																			

Exhibit D

Data Reporting Form for REDS-II Molecular Surveillance Prevalent and Incident Donations
SUPPORT SERVICES OFFICE AMERICAN RED CROSS / THE BLOOD CENTER OF WISCONSIN - VERSION 2

	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q	R	S	T
1	Sample SSO ID	BUI_WBN	Organization	Date of donation	Date of donation	Date of donation	First Time_Repeat Donor	FLAG if Speciment sent to BSRI	HIV NAT	HIV Ab	HCV NAT	HCV Ab	HBsAg	Anti_HBc	Date of birth	Date of birth	Date of birth	State of Residence	Race_Ethnicity	Sex
2		Max. 20 characters	See pull down list in the cell below	MM	DD	YYYY	FT or RPT	Yes/No	NAT Result	Ab Result	NAT Result	EIA / RIBA Result	EIA or Neutralization Result	EIA Result	MM	DD	YYYY	2 letter abbr.	Provide if available	(M, F or U)
3																				
4																				
5																				
6																				
7																				
8																				
9																				
10																				
11																				
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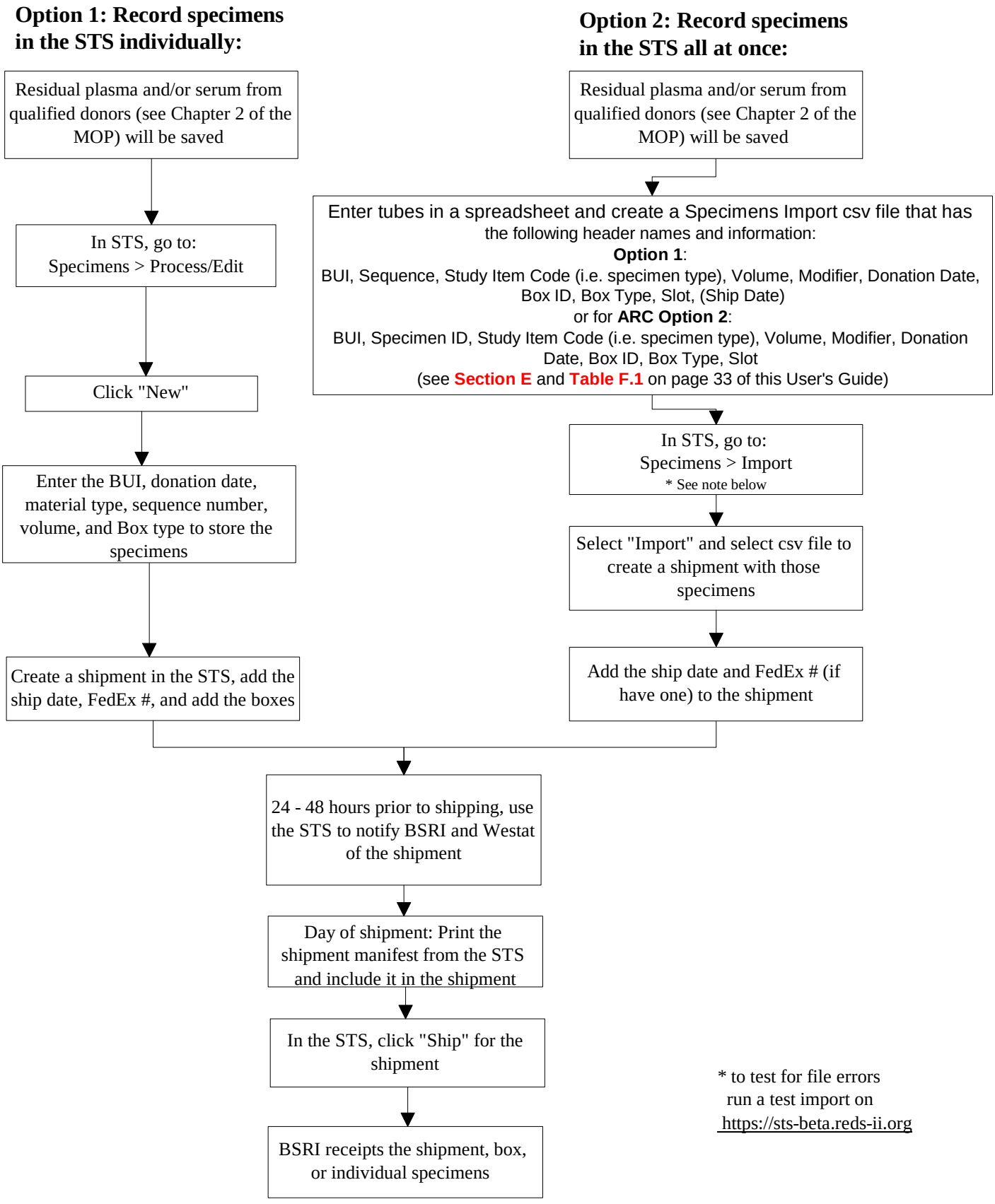
Exhibit E


Option 1: Record specimens in the STS individually:
Residual plasma and/or serum from qualified donors (see Chapter 2 of the MOP) will be saved
In STS, go to: Specimens > Process/Edit
Click "New"
Enter the BUI, donation date, material type, sequence number, volume, and Box type to store the specimens
Create a shipment in the STS, add the ship date, FedEx #, and add the boxes
Option 2: Record specimens in the STS all at once:
Residual plasma and/or serum from qualified donors (see Chapter 2 of the MOP) will be saved
Enter tubes in a spreadsheet and create a Specimens Import csv file that has the following header names and information:
Option 1:
BUI, Sequence, Study Item Code (i.e. specimen type), Volume, Modifier, Donation Date, Box ID, Box Type, Slot, (Ship Date)
or for ARC Option 2:
BUI, Specimen ID, Study Item Code (i.e. specimen type), Volume, Modifier, Donation Date, Box ID, Box Type, Slot
(see Section E and Table F.1 on page 33 of this User's Guide)
In STS, go to: Specimens > Import
* See note below
Select "Import" and select csv file to create a shipment with those specimens
Add the ship date and FedEx # (if have one) to the shipment
24 - 48 hours prior to shipping, use the STS to notify BSRI and Westat of the shipment
Day of shipment: Print the shipment manifest from the STS and include it in the shipment
In the STS, click "Ship" for the shipment
BSRI receipts the shipment, box, or individual specimens
* to test for file errors run a test import on https://sts-beta.reds-ii.org

Department of Health and Human Services (DHHS)
National Institutes of Health (NIH)
National Heart, Lung, and Blood Institute (NHLBI)

The Retrovirus Epidemiology Donor Study – II (REDS-II)

A Study on the Safety and Availability of the Nation's Blood Supply

Molecular Surveillance (MS) Study

SPECIMEN TRACKING SYSTEM (STS)

USER'S GUIDE

Version 3.0

Westat, September 2007

Molecular Surveillance (MS) Study

The following procedures for the MS study are to be used in conjunction with the Manual of Operations and Procedures (MOP) for the MS study.

*Please note that text in red denotes changes from previously distributed versions of this users guide.

*Text in green denotes ARC specific instructions.

Please contact the STS Help Desk, Danielle Carrick (DanielleCarrick@westat.com or 240-314-5896), Debbie Todd (DeborahTodd@westat.com or 301-738-8315) or Tesa Kochie (TesaKochie@westat.com or 240-314-2540 if you have any questions about using the STS.

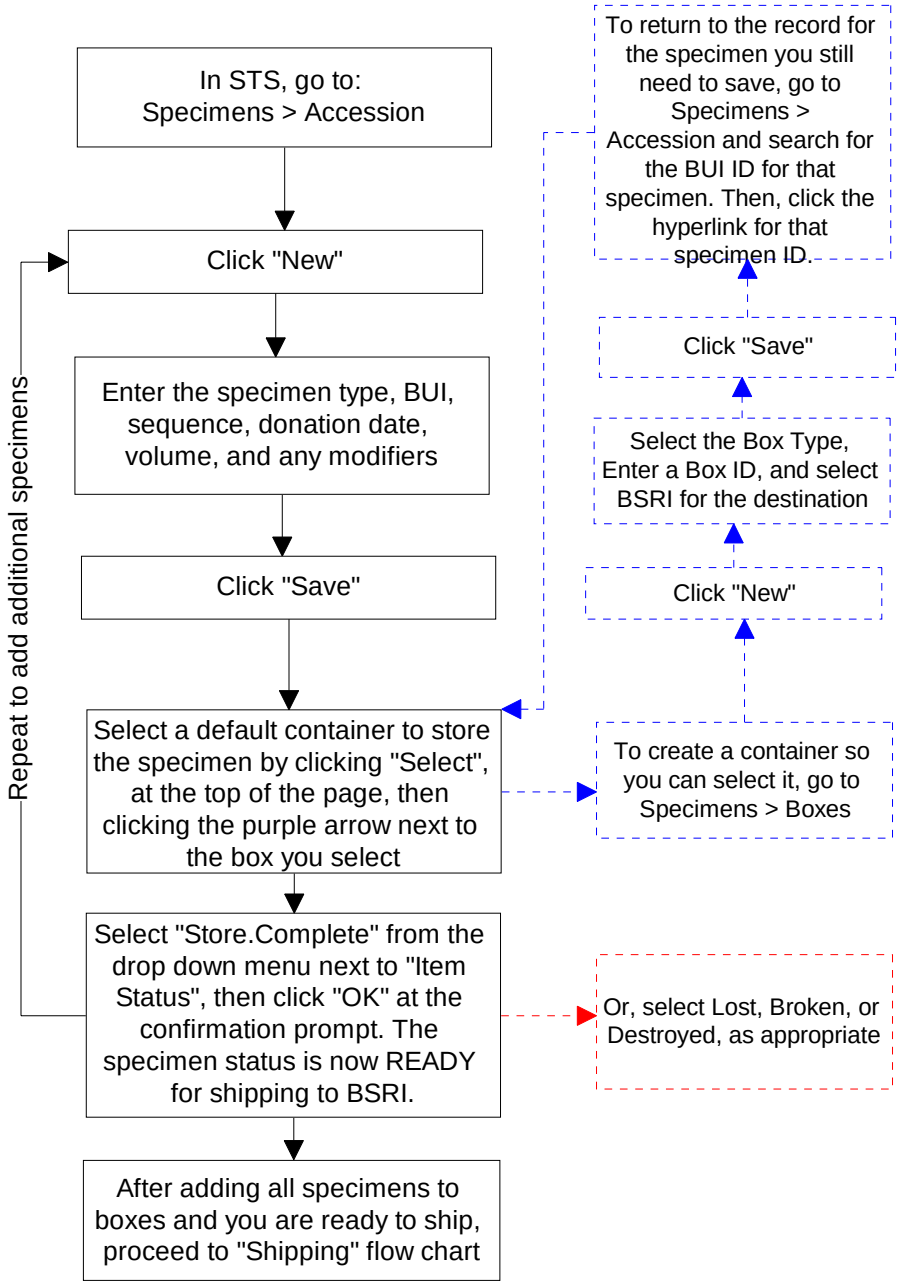
The STS and the MS Study

The STS was developed by Westat and customized for REDS-II. A full users guide for the STS can be opened and downloaded from the Home page on the STS website. The following flow charts provide an overview of how the STS will be used to track specimens for the MS study. Please feel free to explore the STS on your own. You will find that there is more than one way to conduct the necessary steps for the MS. However, the procedures detailed in this section are what we recommend.

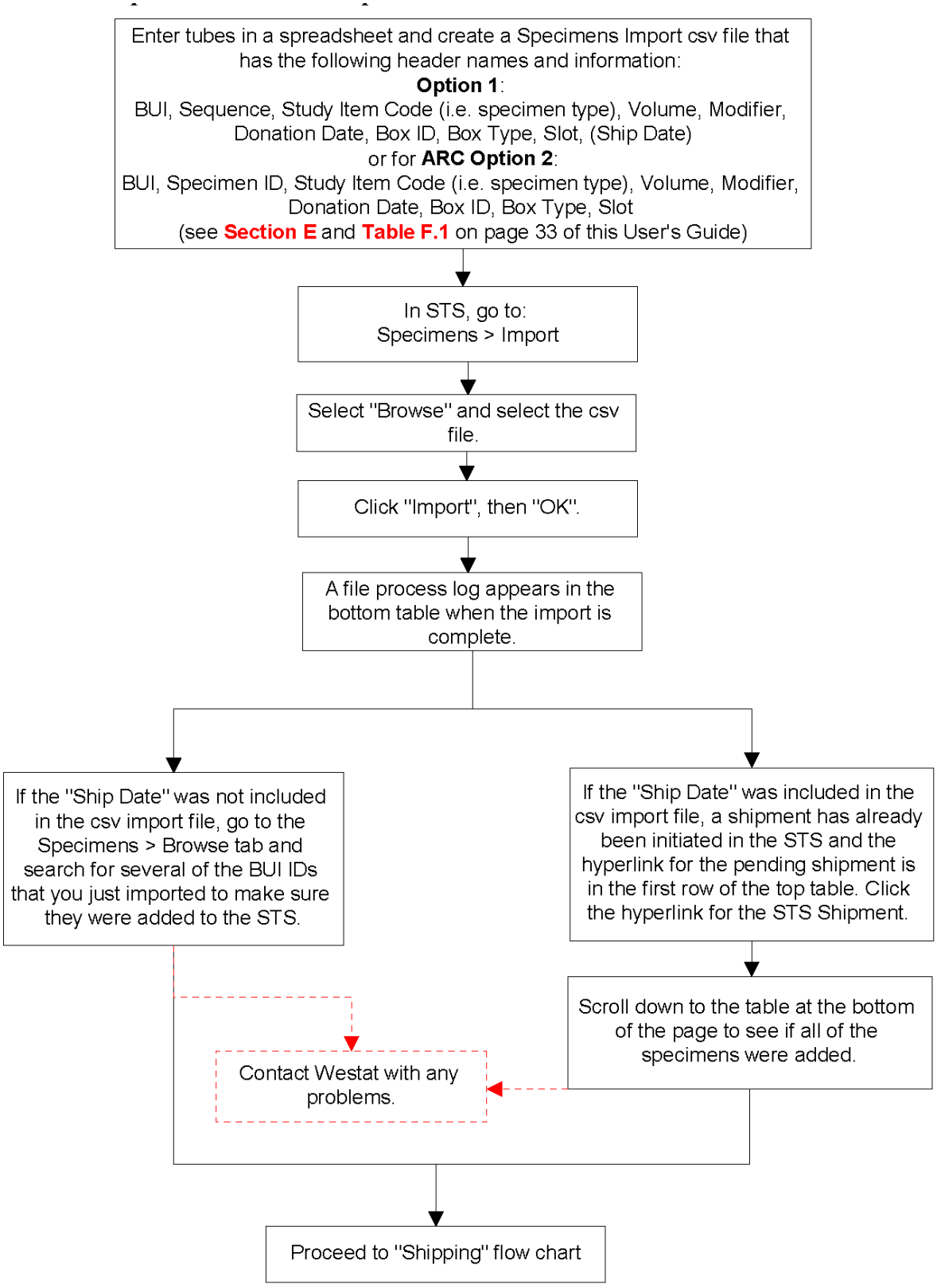
Table of Contents

A. STS Flow Charts

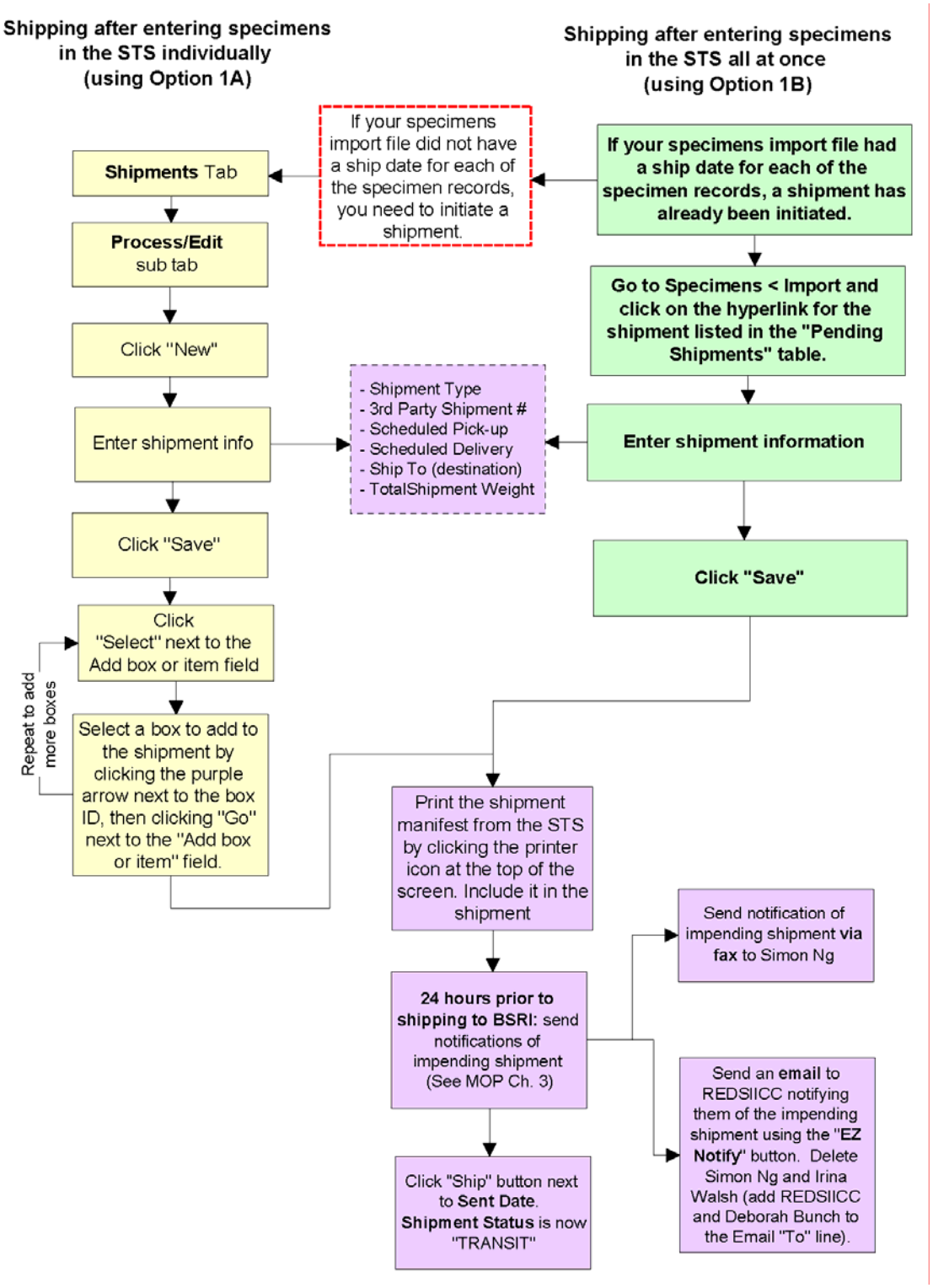
Step 1, Option A: Recording Specimens in the STS – Option 1A: Record specimens in the STS individually



Step 1: Recording Specimens in the STS
Option 1B: Record specimens in the STS all at once



Step 2: Recording Shipments in STS



B. Logging On to the REDS-II STS Website

Overview

- Two separate STS websites are available for you to use.
- The first site is a beta site (https://sts-beta.reds-ii.org), which you can use to test and train on.
- The second site is the true STS site (https://sts.reds-ii.org) for all REDS-II studies. All data that is entered in this site is retained in association with REDS-II.

Procedure

a. For testing and training, use the STS Beta site at:

   https://sts-beta.reds-ii.org.

b. Otherwise, use the "real" STS site for entering study data: https://sts.reds-ii.org.

c. Enter your login name and password.

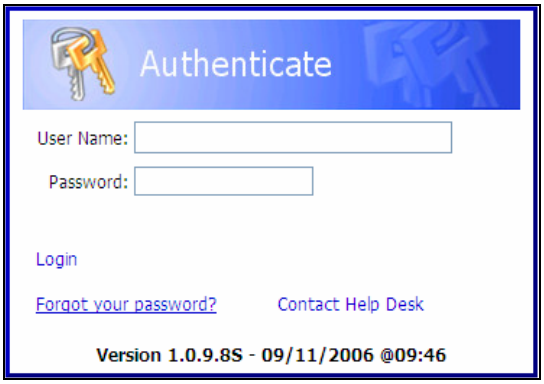


Figure 1: *Login dialog box*

d. Once you are logged in, select **Molecular Surveillance** from the **Study** drop down list at the top of the screen.

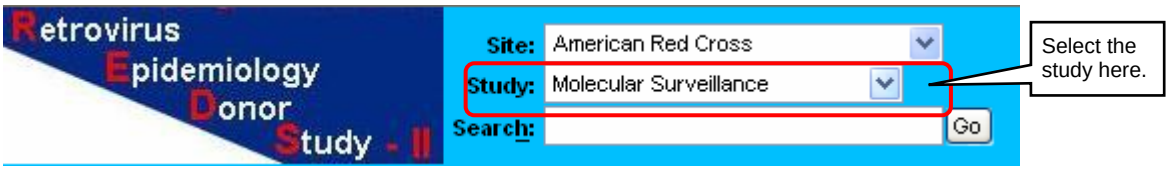


Figure F.2: *Study drop down list*

e. Select the name of the site for which you are recording information about specimens from the **Site** drop down list at the top of the screen.

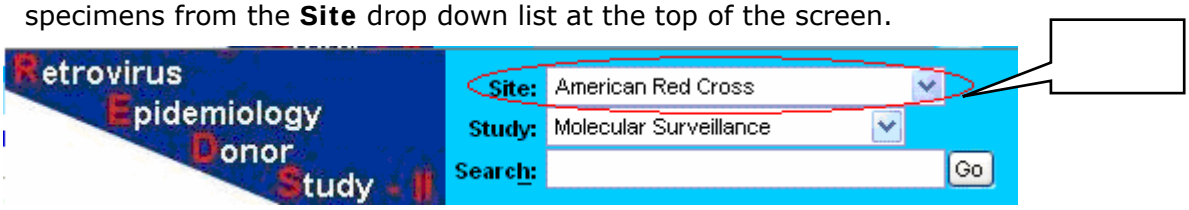


Figure F.3: *Site drop down list*

C. Step 1: Adding specimens to the STS

Overview

- You can add specimens to the STS using two methods:
  Option A: Add specimens individually
  Option B: Add specimens all at once (by importing a ..csv file)

**** Please note that there are additional instructions for ARC denoted in bolded-green text below. This is in order to accommodate the need to record the SSO# on the specimen vials, but the BUI/WBN on the MS P&I Data Form.**

Procedures

Option A: Add specimens individually

1) Place the cursor on the **Specimens** and select the **Accession** subtab.

Figure F.4: *Specimens and accession tabs*

2) Click **New**

Figure F.5: *Click New*

3) Select the appropriate **Specimen type** (default is plasma).

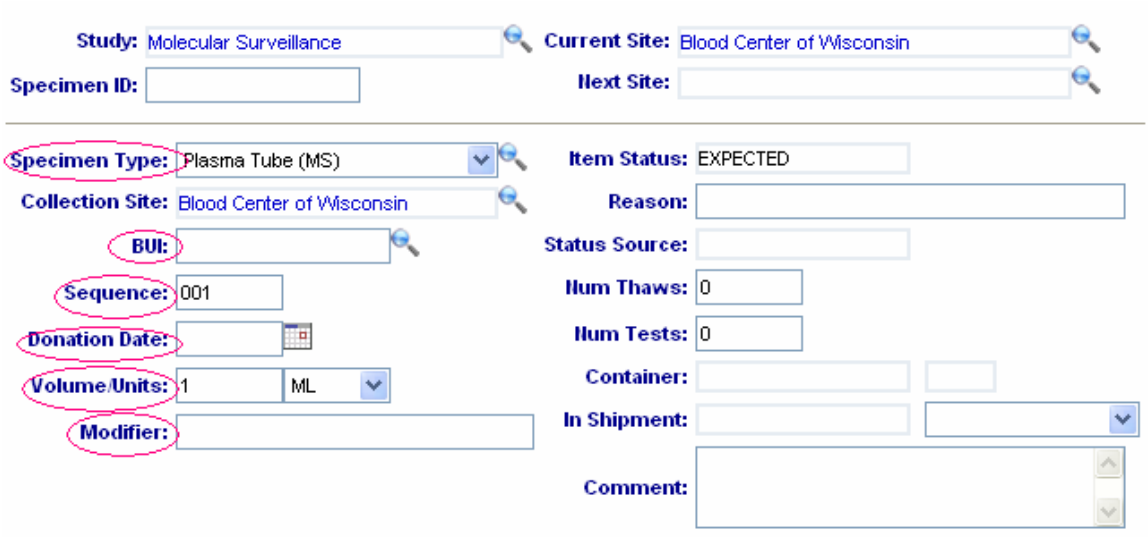


Figure F.6: *Specimen details*

4) Enter the **BUI*** (or WBN).

10 characters is the preferred minimum, while 20 characters is the maximum. If you use a region code along with the 7 character donation ID, please include this so that we do not get repetitive BUIs across blood centers/organizations.

5) Enter the **sequence** number (default is 001)*.

Three digit sequence numbers (**see the MS MOP, Amendment**) should be used in association with each tube entered into the STS.

###

For example: 001

Each tube entered into the STS needs to have a sequence number associated with it.

---

* The STS will combine the BUI ID with the sequence number to generate a **Specimen ID** (unless the **Additional instructions for ARC** are followed below).

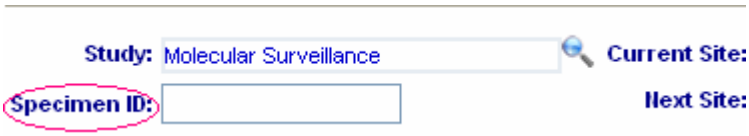


Figure F.7: *Specimen ID field*

**** Additional instructions for ARC:**

SpecimenID
Enter the Specimen ID into the Specimen ID field (see Figure F.7).

The Specimen ID is actually the SSO# plus the sequence#.

Therefore you should enter the following in the Specimen ID field for each vial:

SSO# + 3 digit sequence number

Ex.: 095x12345 001

(Please note that the space does not need to be included between the SSO# and the sequence number.)

6) Enter the **donation date**$^{\Omega}$.

$^{\Omega}$ If more than 1 specimen is entered for a single BUI ID, you do not need to keep entering the donation date.

7) Enter the **volume** of the specimen (in mL; default is 1.0mL).

8) If the specimen was hemolyzed, note this in the material **modifiers** field by keying in one of the following: pink or slightly pink

9) Click **Save**.

Figure F.8: *Click Save*

10) Select a **default container** for you to store the specimen in. Do this by clicking **Select** at the top of the screen. *If you need to create a box in the STS, proceed to step 13*.

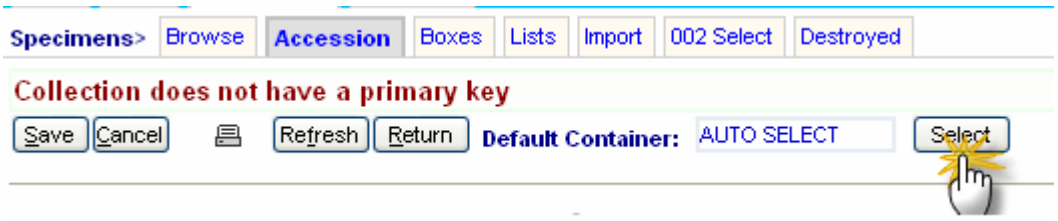


Figure F.9: *Click Select*

11) Then, click the purple arrow next to the box in which you want to store the specimens.

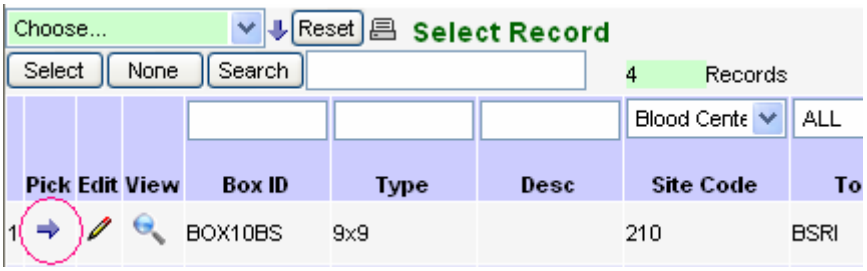


Figure F.10: Purple selection arrow

12) Select **STORE COMPLETE** from the Action drop down menu next to the item status field that appears. After creating a record for the specimen if the tube is misplaced select **"lost"** or other action as appropriate.

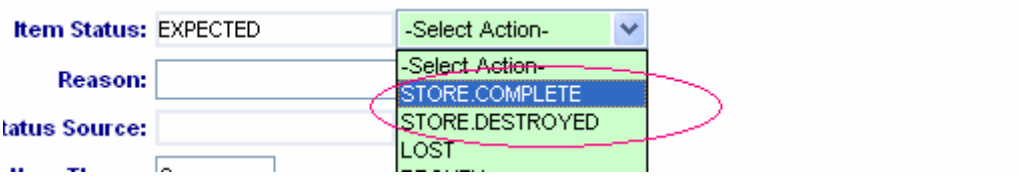


Figure F.11: *Drop down menu in the Action History table*

After selecting **STORE COMPLETE**, you will see that the **STORE** result is **COMPLETE** and the specimen status is changed to **READY** (i.e. "ready" for shipping to BSRI).

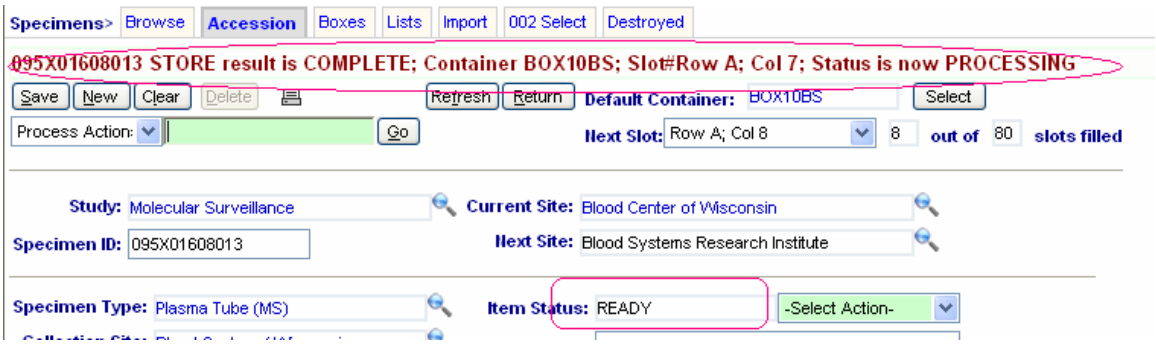


Figure F.12: *Completion message and updated specimen status*

13) If you need to **create a box**, click the **Boxes** subtab under the **Specimens** main tab.

14) Click **New**.

Figure F.13: *Boxes Subtab*

15) Select the **container type** from the drop down menu.

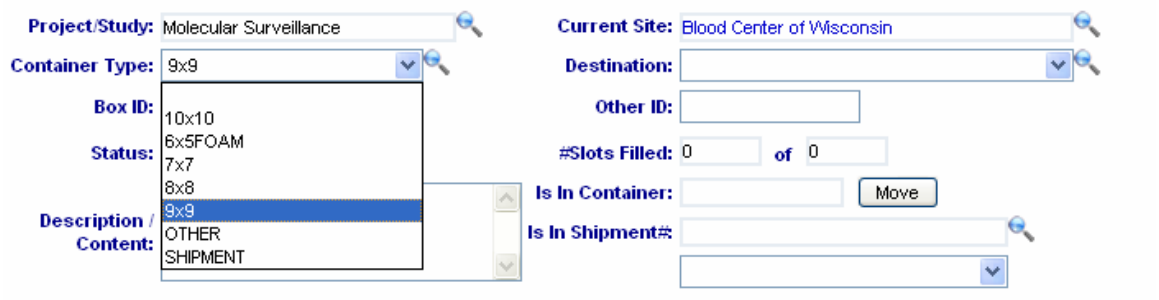


Figure F.14: *Container type drop down menu*

Descriptions of the boxes:
7x7 (has 49 slots; holds 48 specimens*)

8x8 (has 64 slots; holds 63 specimens*)

9x9 (has 81 slots; holds 80 specimens*)

10x10 (has 100 slots; holds 99 specimens*)

6X5 FOAM (has 30 slots for 50ml cryovials; holds 29 specimens*)

Other

*All containers should have the bottom right slot left empty

9x9 (Box Type) Labeling

	Col 1	2	3	4	5	6	7	8	9
Row A	1	2	3	4	5	6	7	8	9
B	10	11	12	13	14	15	16	17	18
C	19	20	21	22	23	24	25	26	**27**
D	28	29	30	31	32	33	34	35	36
E	37	37	39	40	41	42	43	44	45
F	46	47	48	49	50	51	**52**	53	54
G	55	56	57	58	59	60	61	62	63
H	64	65	66	67	68	69	70	71	72
I	73	74	75	76	77	78	79	80	⃠

Figure F.15: *Example layout of a 9x9 box type.*

C, 9 = Slot Num **27**

F, 7 = Slot Num **52**

The other box types follow a similar layout.

⃠ The lower right corner is always to be left empty.

16) Enter the **Box ID**.

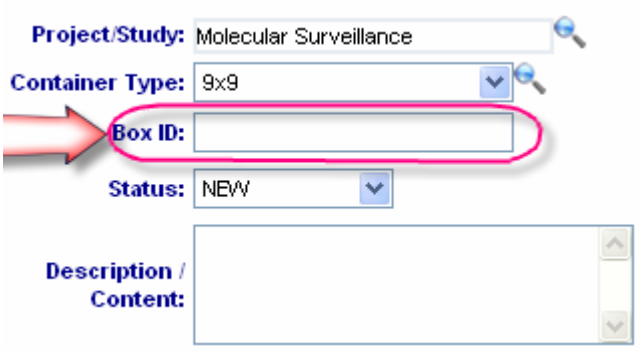
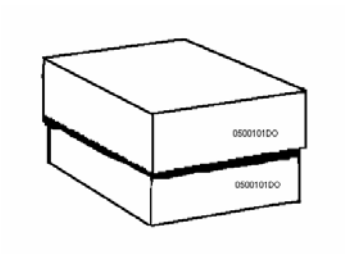


Figure F.16: *Enter a unique Box ID*

The Box ID should be unique to each container/box. BSRI has provided each center with Box ID labels. Please use those labels for the specimen boxes.

Both the bottom and top of the box should be labeled with the Box ID on the lower right corner:



17) Select **BSRI** as the **Destination** in the drop down menu at the right of the screen.

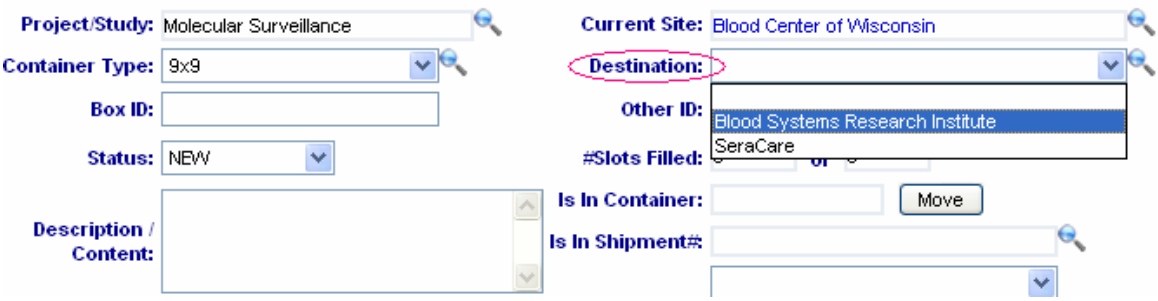


Figure F.17: *Destination drop down menu*

18) Click **Save.**

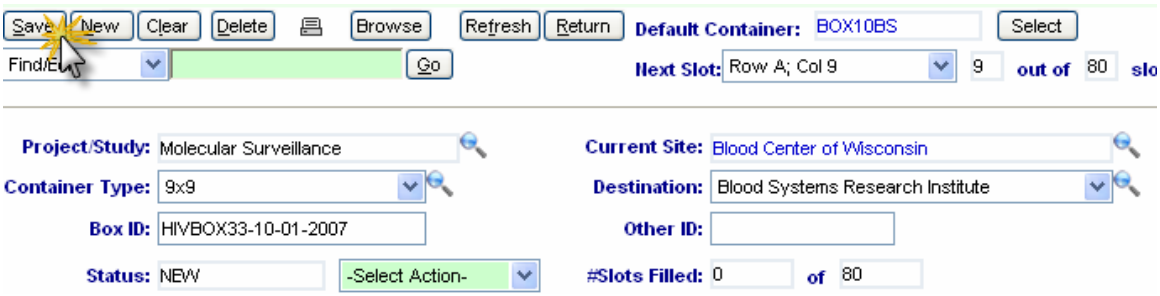


Figure F.18: *Click Save*

19) After creating a new box, return to the **Specimens**, **Browse** subtab.

Figure F.19: *Specimens > Browse subtab*

20) Click on the hyperlink for the **Specimen ID** that you need to save in a box. Alternatively, you can enter the BUI into field above the BUI column to filter the list, hit enter, then you can click on the hyperlink for the Specimen ID that you need to save in a box.

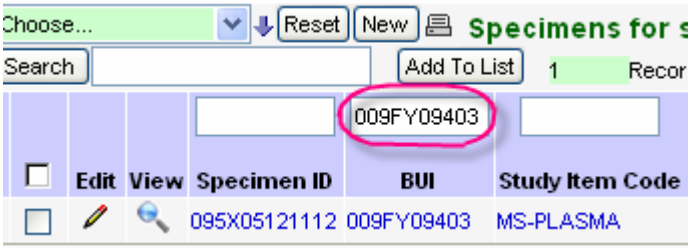


Figure F.20: *Hyperlink for the Specimen ID*

21) Proceed with steps 10 through 12 in this section.

22) To enter another specimen in the STS and record in which box it is stored, follow steps 2 through 12 in this section.

Option B: Add specimens all at once (by importing a .csv file)

1) Create a ..csv file according to the specifications (see section E, on Pg 28).
2) Log into the STS (see section B)
3) Select the **Specimens** tab and the **Import** subtab.

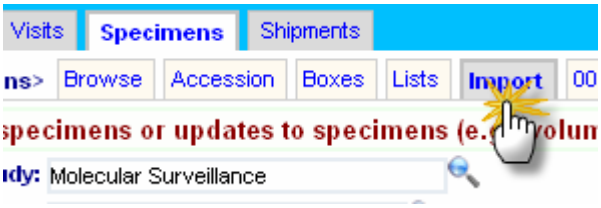


Figure F.21: *Specimens > Import subtab*

4) Click the **Browse** button and select your .csv file.

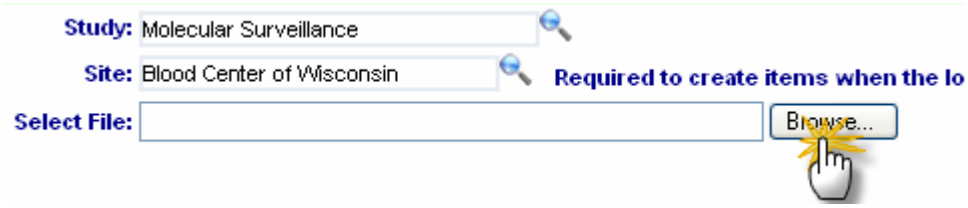


Figure F.22: *Browse button to select .csv file*

5) Click **Import**.

Figure F.23: *Click Import*

6) At the message prompt, click **OK**.

7) Once the import is complete, you will see a new screen that provides you with a log of whether the records were imported/updated in the STS.

```
)0001]: Column [4] StudyItemCode: Maps to StudyItemCode
)0001]: Column [5] Volume: Maps to Volume
)0001]: Column [6] Modifier: Maps to Modifier
)0001]: Column [7] DonationDate: Maps to SubjectCollection.CollectionDate
)0001]: Column [8] BoxID: Maps to Batch.BatchCode
)0001]: Column [9] BoxType: Maps to Batch.BatchTypeCode,Slot.BatchTypeCode
)0001]: Column [10] Slot: Maps to Slot.SlotDesc
)0001]: Column [11] ShipDate: Maps to BatchShipment.ScheduledPickUpDate
)0001]: ------------------------------------------------------------
)0001]:
)0002]: 009FY09403> WF:UPDATE: Status=PROCESSING; Updated Root ID; 009FY0
)0002]: 009FY09403001> New record inserted
)0002]: 009FY09403001> WF:CREATE: Status=EXPECTED; Created; 1
)0002]: 009FY09403001> WF:STORE: Status=READY; Storing in HIVBOX33-10-01-
)0002]: 009FY09403001:STORE> Action executed; result=COMPLETE
)0002]: 009FY09403001> Item added to container HIVBOX33-10-01-2007
)0003]: 009FY09403002> New record inserted
)0003]: 009FY09403002> WF:CREATE: Status=EXPECTED; Created; 1.5
)0003]: 009FY09403002> WF:STORE: Status=READY; Storing in HIVBOX33-10-01-
)0003]: 009FY09403002:STORE> Action executed; result=COMPLETE
)0003]: 009FY09403002> Item added to container HIVBOX33-10-01-2008
)0004]: 009FY09403003> New record inserted
)0004]: 009FY09403003> WF:CREATE: Status=EXPECTED; Created; 1
)0004]: 009FY09403003> WF:STORE: Status=READY; Storing in HIVBOX33-10-01-
)0004]: 009FY09403003:STORE> Action executed; result=COMPLETE
)0004]: 009FY09403003> Item added to container HIVBOX33-10-01-2009
)0004]:
)0004]: ------------------------------------------------------------
)0004]: Processing Summary for BCW tst import3.csv
)0004]: Processing COMPLETE
)0004]: > NUMBER OF LINES   : 4
)0004]: > NUMBER OF RECORDS: 3
)0004]: NO ERRORS encountered
)0004]: ------------------------------------------------------------
)0004]: End of process
)0004]: Closed log for session 0bq1b5ujqrjpp555mdwrke55: D:\Websites\reds
```

```
|:
|: RK000860002> ERROR: List/Group DuplicateEnrollees_BSRI_Destroy_20072908 was not found
|: RK000909002> ERROR: List/Group DuplicateEnrollees_BSRI_Destroy_20072908 was not found
|:
|: ------------------------------------------------------------
|: Processing Summary for D:\Websites\sts-reds-ll\Docs\tmp\DuplicateEnrollees_BSRI_Destroy.
|: Processing COMPLETE, but with 2 ERRORS
|: NUMBER OF LINES   : 3
|: NUMBER OF RECORDS: 2
|: NUMBER OF ERRORS : 2
|: ------------------------
|: End of process
```

Figure F.24: *Import process log*

****If you encounter errors during the import process call the Coordinating Center for assistance before processing.**

8) If you included the **Ship Date** field in the import file, then a shipment will automatically be created for all of the specimens/boxes in the import file. The pending shipment is listed in the **pending shipments** table.

Choose... Reset **Pending Shipment(s)**

	Action	View	STS Shipment ID	3rd Party Shipment #	Status	Status Date	From Site	To Site
					ALL	ALL	Blood Cente	ALL
1	-Select-		SHP000081-210-BSRI	...	TRANSIT	01/15/2007 10:09:41	210	BSRI
2	-Select-		SHP000088-210-BSRI	...	TRANSIT	05/08/2007 13:17:35	210	BSRI
3	-Select-		SHP000121-210-BSRI	30496867776	TRANSIT	09/07/2007 16:36:59	210	BSRI
	-Select-		SHP000125-210-BSRI	2039485767	BEGIN	09/17/2007 11:12:06	210	BSRI

Figure F.25: *Pending Shipments table*

9) To make sure that the specimens were added to the STS, click the **STS Shipment ID** hyperlink. Then scroll to the bottom of the page to see the boxes and contents of the boxes.

Figure F.26: *STS Shipment ID hyperlink*

10) Alternatively, to make sure that the specimens were added to the STS, go to the **Specimens** > **Browse** page and search for one of the **BUI** IDs that you just imported. You can do this by entering the BUI ID into the field above the BUI column and pressing enter. Adjustments may need to be done to remove spaced in the ID's that are not captured in the STS.

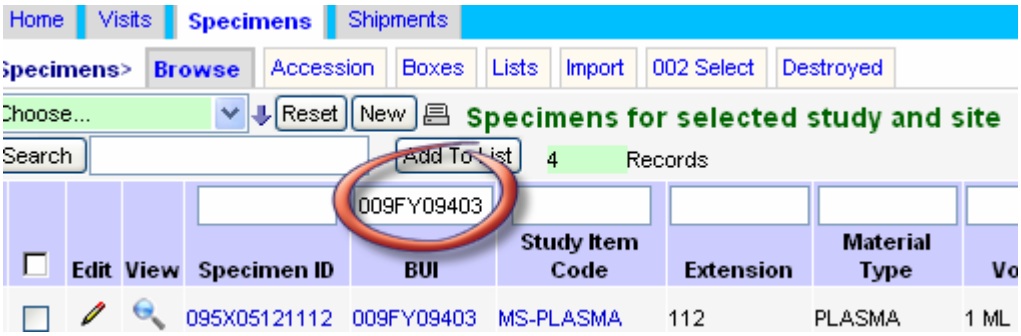


Figure F.27: *BUI search field under Specimens>Browse*

D. Step 2: Recording Shipments in the STS

Overview

- Depending on which manner you entered specimens into the STS, there are two different ways to record a shipment in the STS:
  - Option A. Shipping to BSRI after entering specimens into the STS individually
  - Option B. Shipping after entering specimens into the STS all at once (i.e. by importing a .csv file)

Option A. Shipping to BSRI after entering specimens into the STS individually

*Please follow the instructions in the MS MOP for details about how to prepare the physical shipment package to BSRI.

1) Click **Shipments** tab and the **Process/Edit** subtab.
2) Click **New**

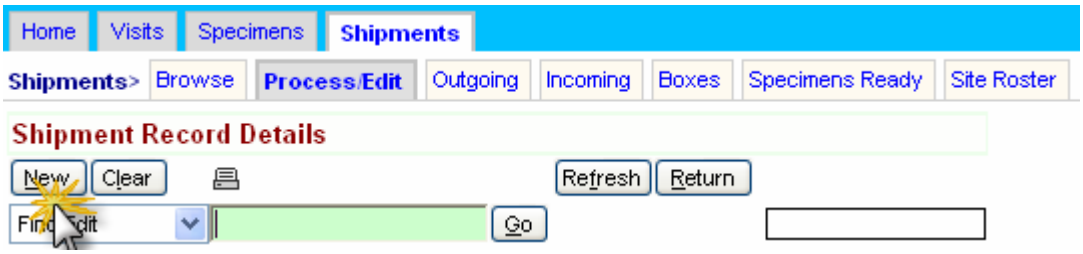


Figure F.28: *Shipments > Process/Edit and click New*

3) Enter the shipment information.
   a. Leave the **STS Shipment ID** field blank. It will be automatically populated by the STS.
   b. Enter the FedEx courier shipment number in the **3rd Party Shipment #** field. If another courier will be used, select the appropriate one from the Shipment Type drop down menu.
   c. Enter the **scheduled pick up** and **scheduled delivery** dates.
   d. Select **BSRI** from the drop down menu in the **Ship To** field.
   e. Enter the approximate weight of the entire package in the bottom right field, **Weight**.

(See next page for figure)

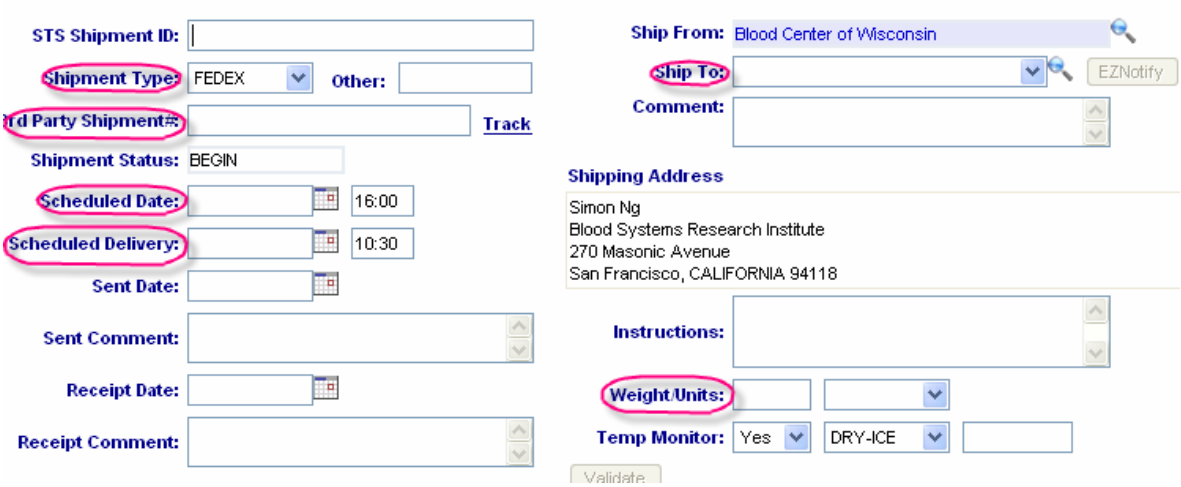


Figure F.29: *Enter the shipment information*

4) Click **Save**.

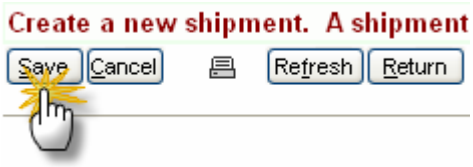


Figure F.30: *Click Save*

5) A green box at the bottom right of the screen now appears. Scan or key in the **Box ID** for the Box that you wish to add to the shipping container. Then, click **Go** next to the **Add box or item field**.

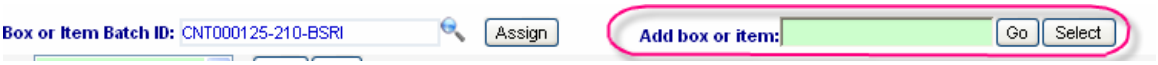


Figure F.31: *Add box or item field*

6) Alternatively, you can click the **SELECT** button to bring up a table of all of the boxes at your site (Note: this table also includes the shipment "box").

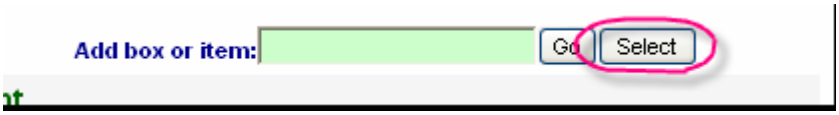


Figure F.32: *Select button to choose a box*

Then, click the **purple arrow** next to the box that you want to include in the shipment.

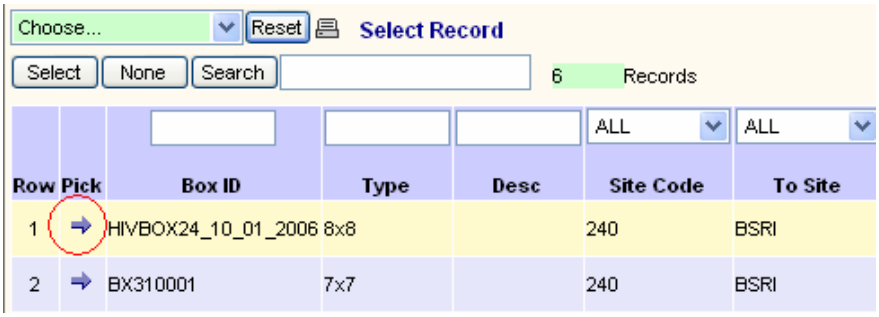


Figure F.33: *Purple selection arrow*

7) Then, click **Go** next to the **Add box or item field** by scanning or keying in box or Specimen ID.

Figure F.33.a: *Click Go.*

8) To add more boxes to the shipment, follow steps 5-6.

9) Scroll to the bottom of the screen to see a table of the boxes in the shipment as well as the content of each box.

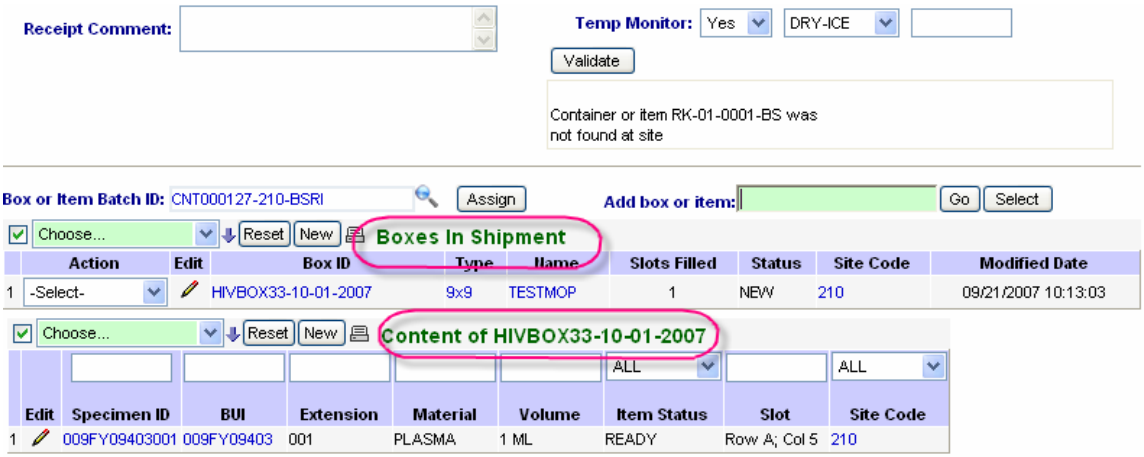


Figure F.33: *Tables showing shipment contents*

10) **Confirm that the Specimens are in the proper location in the box by spot checking the actual location of the vials in the box against the location in the STS.**

11) Print a shipment manifest to include in the actual shipping container by clicking the **printer icon** at the top right of the screen.

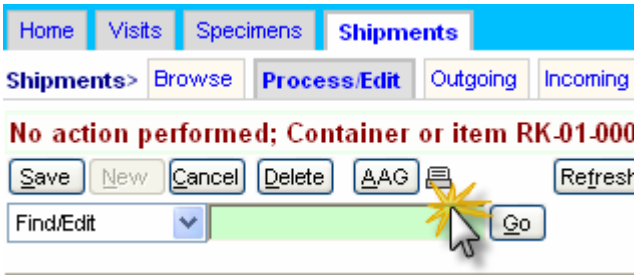


Figure F.34: *Printer icon*

Figure F.35: *EZ Notify button used to automatically generate an email message with the shipment manifest attached*

12) Click the **EZ Notify** button to generate an email message. Delete "IWalsh" from the "Email To" line, and add "REDSIICC" & Deborah Bunch to the "Select To" line of the email message. Send the email to REDSIICC@westat.com & dbunch@bloodsystems.org to notify the Coordinating Center and the Central Lab of the impending shipment.

13) On the day of shipment, click the **Ship** button.

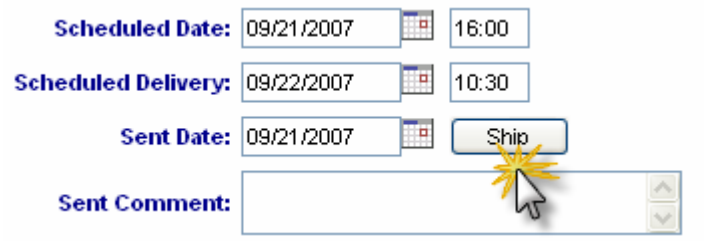


Figure F.36: *Ship button*

14) The shipment is now in **TRANSIT** and the **Ship Date** has been filled in. The status of the specimens and boxes are also now in **TRANSIT**.

You can no longer make changes to the specimens, boxes or shipments as they now "belong" to the recipient of the shipment.

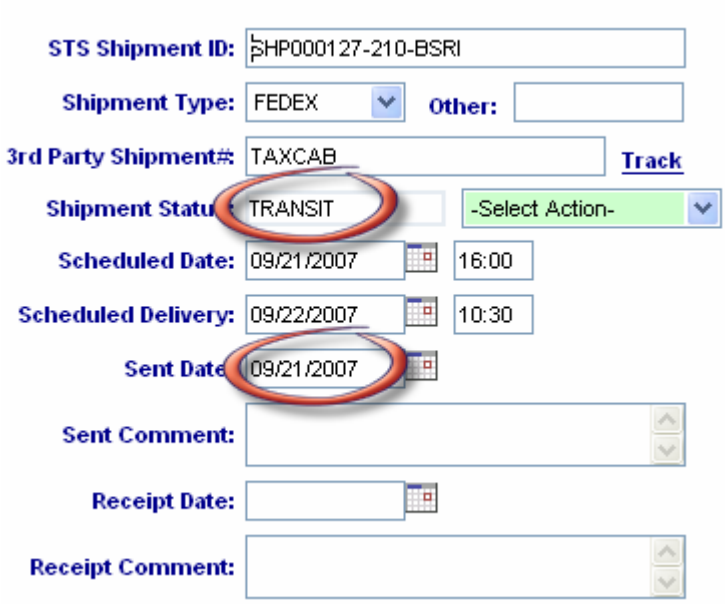


Figure F.37: *Updated Shipment Status and Sent Date*

15) Send a fax to Simon Ng at BSRI to notify him of the shipment. You can do this through the STS by going to the **Home** tab and the **Fax** subtab or you can use your own fax machine. You do not need to use both. Fill in all of the pertinent information and attach a completed fax notification form (Exhibit C).

Option B. Shipping after entering specimens into the STS all at once (i.e. by importing a .csv file)

*Please follow the instructions in the MS MOP for details about how to prepare the physical shipment package to BSRI.

1) If your imported file contained a **Ship Date** for each specimen, then the shipment has already been started and you should continue to step B.2 below. If your imported file did not contain a Ship Date for each specimen, then you need to follow the Shipping instructions for Option A.

2) The shipment is listed in the **Pending Shipments** table that appears on the **Specimens** > **Import** subtab.

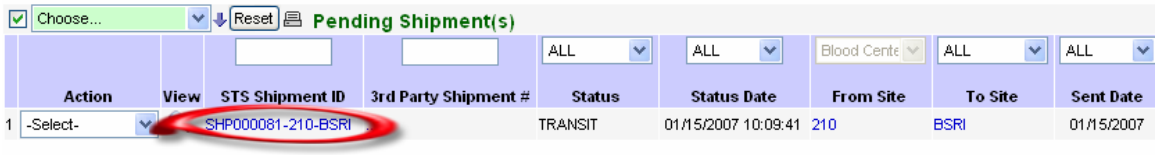


Figure F.38: *Shipment created from the import file*

3) Click the hyperlink for the **STS Shipment ID**.

4) Enter the shipment information.

a. The **STS Shipment ID** field has already been populated by the STS.

b. Enter the FedEx courier shipment number in the **3rd Party Shipment #** field. If another courier will be used, select the appropriate one from the Shipment Type drop down menu.

c. Enter the **scheduled pick up** and **scheduled delivery** dates.

d. Select **BSRI** from the drop down menu in the **Ship To** field.

e. Enter the approximate weight of the entire package in the bottom right field, **Weight**.

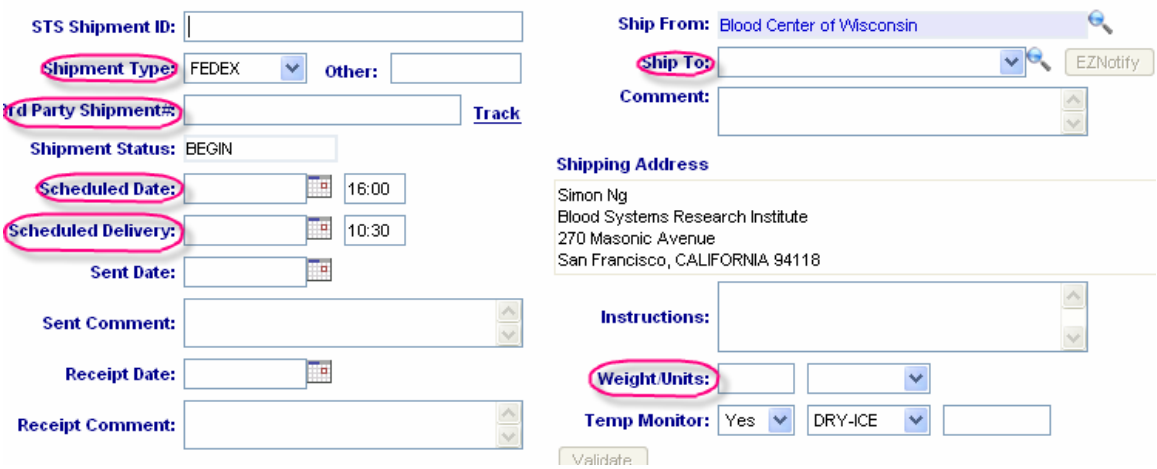


Figure F.39: *Enter the shipment information*

5) Click **Save**.

Figure F.40: *Click Save*

6) Scroll to the bottom of the screen to see a table of the boxes in the shipment as well as the content of each box.

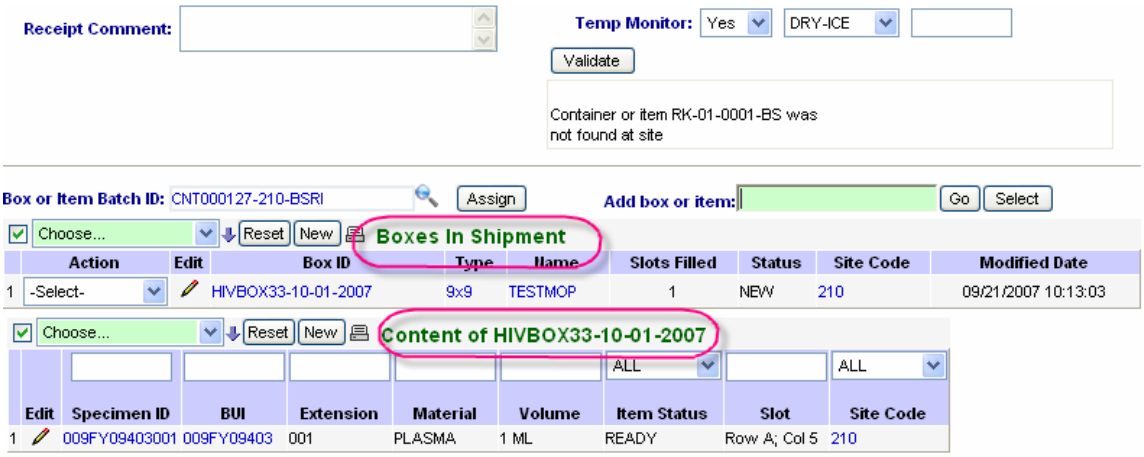


Figure F.41: *Shipment content tables*

7) Confirm that the Specimens are in the proper location in the box by spot checking the actual location of the vials in the box against the location in the STS.

8) Print a shipment manifest to include in the actual shipping container by clicking the **printer icon** at the top right of the screen.

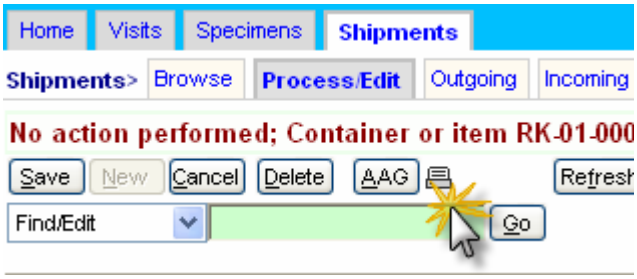


Figure F.42: *Printer icon*

9) Click the **EZ Notify** button to generate an email message. Delete "IWalsh" from the "Email To" line, and add "REDSIICC" & Deborah Bunch to the "Select To" line of the email message. Send the email to REDSIICC@westat.com & dbunch@bloodsystems.org to notify the Coordinating Center and the Central Lab of the impending shipment.

Figure F.35: *EZ Notify button used to automatically generate an email message with the shipment manifest attached*

10) On the day of shipment, click the **Ship** button.

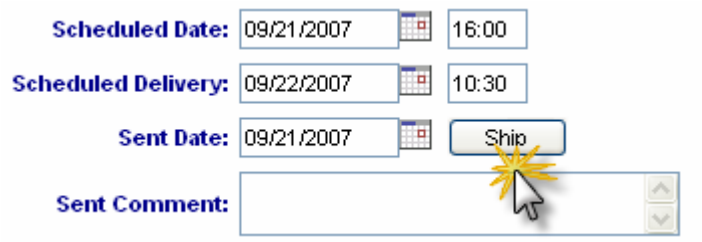


Figure F.36: *Ship button*

11) The shipment is now in **TRANSIT** and the **Ship Date** has been filled in. The status of the specimens and boxes are also now in **TRANSIT**.

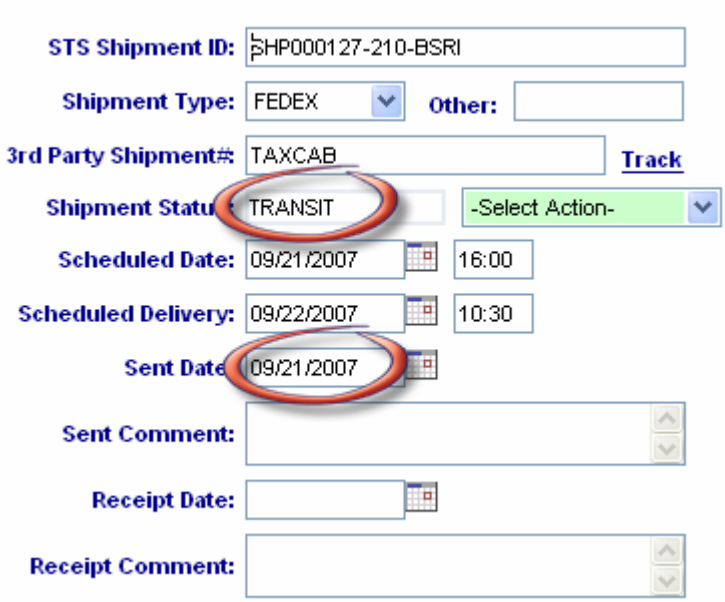


Figure F.37: *Updated Shipment Status and Sent Date*

12) Send a fax to Simon Ng at BSRI to notify him of the shipment. You can do this through the STS by going to the **Home** tab and the **Fax** subtab or you can use your own fax machine. You do not need to use both. Fill in all of the pertinent information and attach a completed fax notification form (Exhibit C).

E. Instructions for Completion of the Specimens Import File (for Step 1, Option B)

Overview:

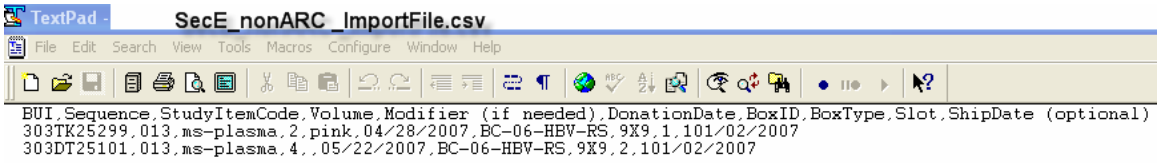
- Create a .csv file listing all of the specimens to be included in the shipment to BSRI.
- You can do this by creating an Excel file that has the variables listed in Table F.1 (at the end of this section) and saving it as a .csv file (Note: just renaming the file as a .csv file type will not work, it must be saved as a .csv file).
- Be sure to enter all of the numerical values as "**text**" values in order to maintain the leading zeroes.
- **The columns must be named exactly as specified in Table F.1.** However, the order in which the columns are placed is not essential.
- Instructions for importing the file into the STS are found in Section C.

**** Please note that there are additional instructions for ARC denoted in bolded-green text below. This is in order to accommodate the need to record the SSO# on the specimen vials, but the BUI / WBN on the MS P&I Data Form.**

Example .xls and ..csv files:
Note: Test import of ..csv files on Beta site.

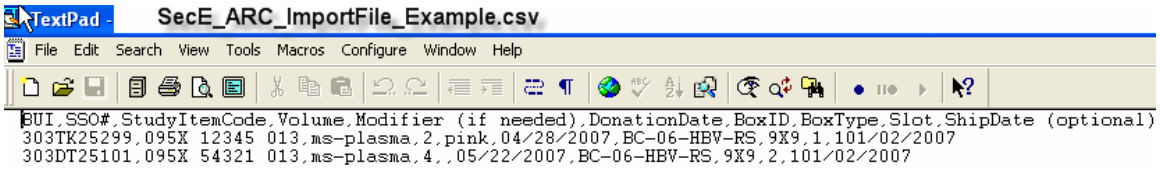
All centers except ARC

	A	B	C	D	E	F	G	H	I	J
1	BUI	SSO#	StudyItemCode	Volume	Modifier (if needed)	DonationDate	BoxID	BoxType	Slot	ShipDate (optional)
2	303TK25299	095X 12345 013	ms-plasma	2	pink	04/28/2007	BC-06-HBV-RS	9X9	1	101/02/2007
3	303DT25101	095X 54321 013	ms-plasma	4		05/22/2007	BC-06-HBV-RS	9X9	2	101/02/2007



ARC file:

	A	B	C	D	E	F	G	H	I	J
1	BUI	Sequence	StudyItemCode	Volume	Modifier (if needed)	DonationDate	BoxID	BoxType	Slot	ShipDate (optional)
2	303TK25299	13	ms-plasma	2	pink	4/28/2007	BC-06-HBV-RS	9X9	1	101/02/2007
3	303DT25101	13	ms-plasma	4		5/22/2007	BC-06-HBV-RS	9X9	2	101/02/2007



Variable descriptions:

BUI
Enter the BUI or WBN (10 characters preferred minimum, 20 characters maximum) for this donation. If you use a region code along with the 7 character donation ID, please include this so that we do not get repetitive BUIs across blood centers/organizations.

**** Instructions for ARC:**

SpecimenID
Add a column to the .csv file for the Specimen ID.

The title of the column should be: SpecimenID

The Specimen ID is actually the SSO# plus the sequence#.

Therefore you should enter the following in the Specimen ID column for each vial:

SSO# + 3 digit sequence number

Ex.: 095x12345 001

(Please note that the space does not need to be included between the SSO# and the sequence number.)

Sequence
Three digit sequence numbers (**see the MS MOP, Amendment**) should be used in association with each tube entered into the STS.

Each tube entered into the STS needs to have a sequence number associated with it. The sequence number must be in the following format in the .csv file **(please note that if you are entering this in Excel, which will then be saved as a .csv file, you should enter the sequence number as a "text" field so that the leading zeroes are not cut off)**:

###

For example: 001

StudyItemCode
This is the material type of the specimen. For MS, the only options are plasma and serum. Enter one of the following into this column for each specimen:

MS-Plasma
MS-Serum

Volume
The volume in the tube should be recorded in the STS. The default volume is 1.0 mL. If the volume in your tube is 1.0 mL, then you can leave the Volume variable out of the .csv file. However, if the volume in your tube is less than or greater than 1.0 mL, you need to indicate the approximate volume (in mL) in the tube.

For example: 1.5

Modifier
If the specimen is hemolyzed, note that in this field. Do this by entering one of the following for the Modifier variable field:

Pink
Slightly pink

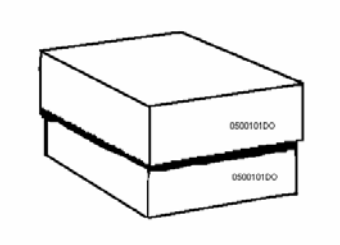
DonationDate
Enter the donation date from which the specimen was obtained from the donor. The format of the date needs to be:

MM/DD/YYYY

For example: 01/01/2006

BoxID
Each specimen entered into the STS must be stored in a container/box. Therefore, each specimen in the .csv file must have a Box ID associated with it. BSRI has prepared and sent each center Box ID labels. Please use those Box ID labels.

Both the bottom and top of the box should be labeled with the Box ID on the lower right corner:



BoxType
Each specimen entered into the STS must be stored in a container/box. Unless the particular container/box in which you will store the specimens already exists within the STS, you need to designate the Box Type along with the Box ID. Enter one of the following for the Box Type:

7x7
8x8
9x9
10x10
6X5 FOAM
Other

Descriptions of the boxes:

7x7 (has 49 slots; holds 48 specimens*)

8x8 (has 64 slots; holds 63 specimens*)

9x9 (has 81 slots; holds 80 specimens*)

10x10 (has 100 slots; holds 99 specimens*)

6X5 FOAM (has 30 slots for 50ml cryovials; holds 29 specimens*)
Other

*All containers should have the bottom right slot left empty

Slot

Each specimen entered into the STS must be stored in a container/box. The exact location (i.e. slot) in the box in which the specimen is stored should be recorded. The slot located in the lower right corner should always be left empty; it is used to help orient the direction of the box.

You can do this by recording the Slot in the .csv file as either a Row and Column*:

Ex. Row A; Col 1
Row A; Col 2
Row A; Col 3
Row A; Col 4

* The Row and Column designations must be in this exact format (Row X; Col #) for the STS to recognize it as a valid slot.

Or, you can do this by recording the Slot in the .csv file as a number:**

Ex. 1
2
3
4

** Please note that the slot number corresponds to a particular Row and Column:

1 = Row A; Col 1
2 = Row A; Col 2
3 = Row A; Col 3
4 = Row A; Col

	Col 1	2	3	4	5	6	7	8	9
Row A	1	2	3	4	5	6	7	8	9
B	10	11	12	13	14	15	16	17	18
C	19	20	21	22	23	24	25	26	**27**
D	28	29	30	31	32	33	34	35	36
E	37	37	39	40	41	42	43	44	45
F	46	47	48	49	50	51	**52**	53	54
G	55	56	57	58	59	60	61	62	63
H	64	65	66	67	68	69	70	71	72
I	73	74	75	76	77	78	79	80	⃠

Figure F.38. Example layout of a **9x9** box. The other box types follow a similar layout.

C, 9 = Slot Num 27

F, 7 = Slot Num 52

⃠ The lower right corner is always to be left empty.

ShipDate

This is the scheduled date for the shipment. A ship date does not need to be specified in the .csv file. However, if a ship date is specified, a shipment will automatically be created and the item will be put into the shipment. The format of the ship date should be:

MM/DD/YYYY

For example: 01/02/2006

Table F.1. Specimens Import File Specifications

***The order of the columns is not essential for the .csv file. However, the names of the variables should be kept exactly as specified in the variable column below.**

Column				
A	BUI	Blood Unit Identifier / Whole Blood Number	Up to 20	
B	Sequence	Three digit sequence numbers for specimen tubes from the same BUI	3	001 (up to 999)
C	StudyItemCode	Material Type (either serum or plasma)	9	MS-Serum MS-Plasma
D	Volume	Specimen volume in the tube (if it is less than or greater than 1.0mL)	3	
E	Modifier	Indicate whether the specimen was hemolyzed		Pink Slightly Pink
F	DonationDate	Date the donor donated blood	8	MM/DD/YYYY
G	BoxID	Id label on the box that stores the specimen		
H	BoxType	Type of box used to store the specimen The options are: 7x7 (has 49 slots; holds 48 specimens*) 8x8 (has 64 slots; holds 63 specimens*) 9x9 (has 81 slots; holds 80 specimens*) 10x10 (has 100 slots; holds 99 specimens*) 6X5 FOAM (has 30 slots for 50ml cryovials; holds 29 specimens*) OTHER *All containers should have the bottom right slot left empty	7	7x7 8x8 9x9 10x10 6X5 FOAM OTHER
I	Slot	The slot in the box in which the specimen is stored You can either record the slot as: Row A; Col 1 Row A; Col 2 OR 1 2 3 (in the latter case, the STS will associate slot "1" with Row A; Col 1)		1, 2, 3, (and so on until the slots in the box are filled) OR Row A; Col 1 Row B; Col 2 (and so on until the slots in the box are filled)
J	ShipDate	Scheduled date for the shipment. If a date is specified, a shipment will be created and the item will be put into the shipment.	8	MM/DD/YYYY
K	**SpecimenID**	**SSO# + Sequence number (ARC)** **Example: 095x12345 001**	**Up to 20**	**SSO# + Sequence#** **BUI + Sequence # (non ARC)**

Exhibit G

Instructions for Aliquoting and Labeling Specimens

- The aliquoting and labeling procedures have been revised by the Central Laboratory, BSRI, to address samples collected which may have more than the minimum volume of 1.0-mL described in the original protocol.

- The intent for the study is to receive adequate volume for designated testing and whenever possible to also save volume for long term storage and future testing capability. The original protocol stated to save 1.0-ml; however, when feasible the total optimal sample volume is 10mL (or more) to be aliquoted into 2 to 9 (or more) cryovials.

- It is not necessary to re-aliquot specimens for the first wave of shipments to the Central Laboratory but if at all possible, all subsequent shipments are to follow these guidelines.

G.1. Confirmed HIV Donations:

Aliquoting of confirmed HIV donations includes the use of 3 different types/sizes of cryovials as displayed in Table 1 below. The source material for these vial types can be either plasma or serum or both. In the event that there is not enough volume for all of the aliquots to be made, the priority is specified in the far left column in Table 1 shown below.

Table 1: Confirmed HIV donations

Cryovial Priority	Vial Sequence	Material type	Volume	Purpose
1	-001 or -101	Plasma or Serum	0.1mL	LS-EIA
2	-002 or -102	Plasma or Serum	0.5 to 1.0 mL*	Gen. Seq.
3	-003 or -103	Plasma or Serum	Up to 4.5mL**	Repository
4 etc.***	-004 etc. or -104 etc.	Plasma or Serum	Up to 4.5mL	Repository

* Since collection has already been performed, less volume is expected from the retrospective donors (January through June 2006) as opposed to the prospective donors in the following 2.5 years for which additional volume for aliquots may be available. The minimum volume for testing is 0.5mL, although 1.0mL is optimal when enough plasma or serum is available for the -002 or -102 series of cryovials. If only 1mL of source material is available, then place 0.5mL into a 2mL cryovial for testing and any residual volume into a 5mL cryovial for the repository.

** Sequence numbers -003 and -004 represent source material that will be placed in a HIV repository. The 5mL cryovials are for the repository; therefore, as much source material as possible should be collected. Aliquot residual volume between two or more 5.0mL cryovials, when more than 4.5mL[1] for one vial is available per source material.

*** If a large volume of material is available from the plasma unit for aliquoting, then a maximum of 7 cryovials, i.e. sequence numbers 003, 004, 005, 006, 007, 008 and 009, should be made.

1. Do not place more than 4.5mL into a 5mL cryovial, because the source material will expand during the freezing process.

Note: Knowledge of source material, designated by cap color, is important to track, but either source material is acceptable.

G.1.1. Processing Aliquots

Since only the BUI/WBN will be on the labels, sequence/suffix numbers will be determined by the color cap on the cryovial as well as recorded numerically in the STS. The sequence numbers are very important for specimen tracking and data analysis. The subsequent color scheme should be followed when placing the color caps on the cryovials:

Cryovial Color Scheme		
Purple cap =	Plasma 0.1mL	Sequence -001
Green cap =	Serum 0.1mL	Sequence -101
Yellow cap=	Plasma 0.5 – 1.0mL	Sequence -002
Blue cap =	Serum 0.5 – 1.0mL	Sequence -102
Clear cap =	Plasma 0.4 – 4.5mL	Sequence -003
Amber cap =	Serum 0.4 – 4.5mL	Sequence -103

G.1.2. Application of Labels to Aliquots

BUI/WBN labels with barcodes should be placed on cryovials with barcode lines running horizontally to top and bottom of cryovial, as shown below:

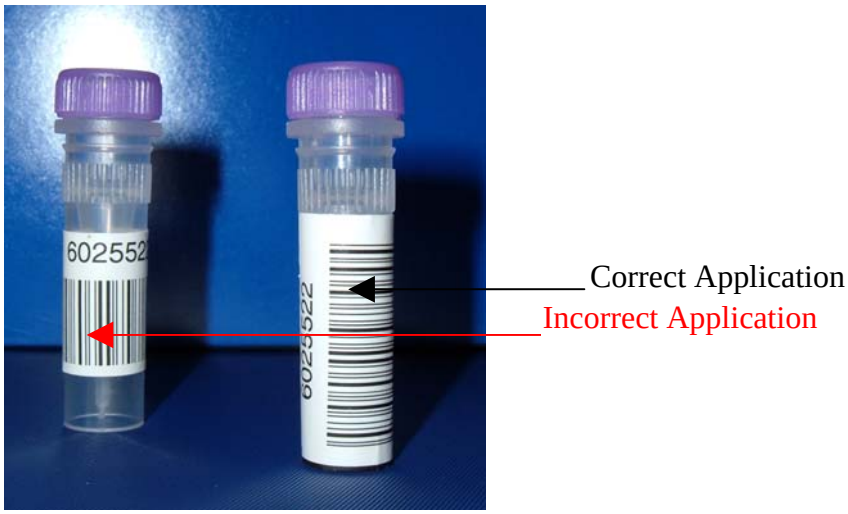
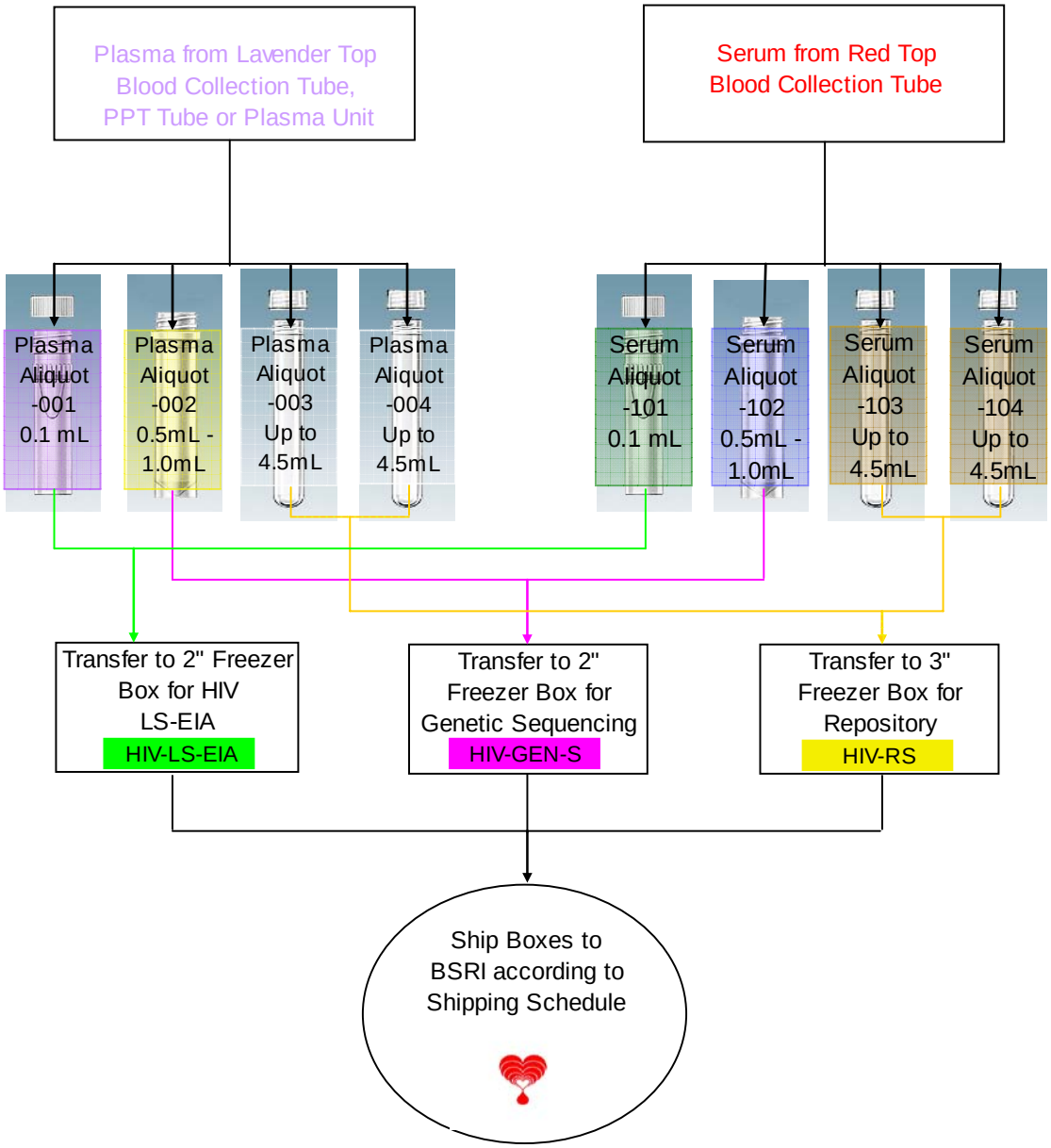


Figure 1: **HIV Aliquoting Flowchart**



See instructions given in section **3.4.2**

Specimens Chapter 2

G.2. Confirmed HBV and HCV Donations:

Since there is no additional testing for confirmed HBV and HCV donations as there is for HIV (LS-EIA), this requires only 2 different types of cryovials as opposed to the 3 for HIV, as displayed in Tables 2 and 3 below. Once again, the source material for these vials can be either plasma or serum or both. In the event that there is not enough volume for all of the aliquots to be made, the priority is specified in the far left column in the two tables shown below.

Table 2: Confirmed HBV donations

Cryovial Priority	Vial Sequence	Material type	Volume	Purpose
1	-012 or -112	Plasma or Serum	0.5 to 1.0 mL*	Gen. Seq.
2	-013 or -113	Plasma or Serum	Up to 4.5 mL* *	Repository
3 etc.***	-014 etc. or -114 etc.	Plasma or Serum	Up to 4.5mL	Repository

Table 3: Confirmed HCV donations

Cryovial Priority	Vial Sequence	Material type	Volume	Purpose
1	-022 or -122	Plasma or Serum	0.5 to 1.0 mL*	Gen. Seq.
2	-023 or -123	Plasma or Serum	Up to 4.5 mL* *	Repository
3 etc.***	-024 etc. or -124 etc.	Plasma or Serum	Up to 4.5mL	Repository

* Since collection has already been performed, less volume is expected from the retrospective donors (January through June 2006) as opposed to the prospective donors in the following 2.5 years for which additional volume and aliquots may be available. The minimum volume for testing is 0.5mL, although 1.0mL is optimal when enough plasma or serum is available for the -012 / -112 or -022/-122 series of cryovials. If only 1mL of source material is available, then place 0.5mL into a 2mL cryovial for testing and any residual volume into a 5mL cryovial for repository storage.

Specimens Chapter 2
** Sequence numbers 013/023 and 014/024 represent source material that will be placed in a HBV/HCV repository. The 5mL cryovials are for the repository; therefore, as much source material as possible should be collected. Aliquot residual volume between two or more 5.0mL cryovials, when more than 4.5mL[2] for one vial is available per source material.

*** If a large volume of material is available from the plasma unit for aliquoting, then a maximum of 7 cryovials, i.e. sequence numbers 013, 014, 015, 016, 016, 018 and 019, should be made. (The same sequence numbering should be followed for HCV except second digit should be a 2 as shown in Table 3).

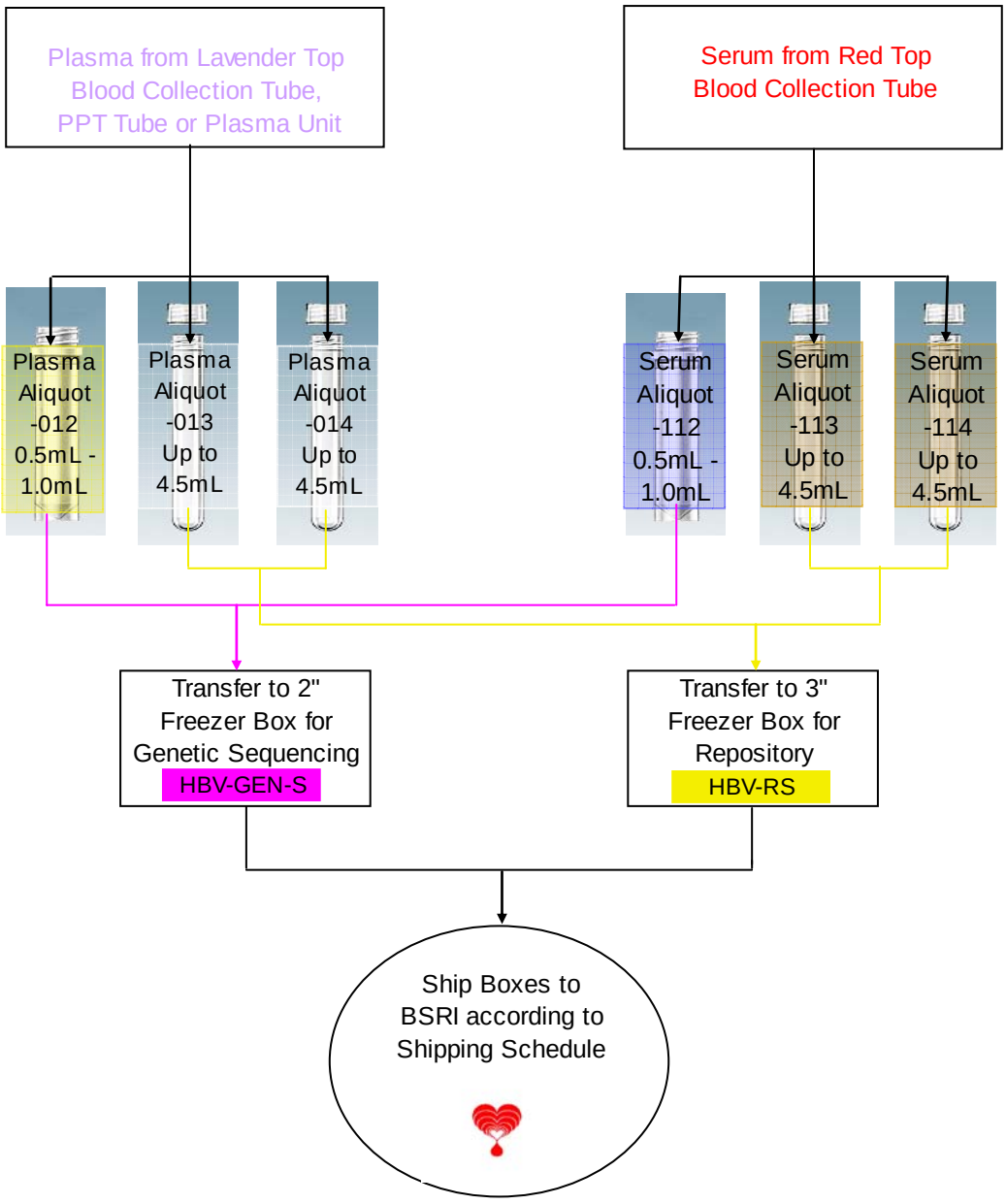
2. Do not place more than 4.5mL into a 5mL cryovial, because the source material will expand during the freezing process.

G.2.1. Processing Aliquots

Since only the BUI/WBN will be on the labels, sequence/suffix numbers will be determined by the color cap on the cryovial as well as recorded numerically in the STS. The sequence numbers are very important for specimen tracking and data analysis. The subsequent color scheme should be followed when placing the color caps on the cryovials (shown for both confirmed HBV and HCV donations respectively):

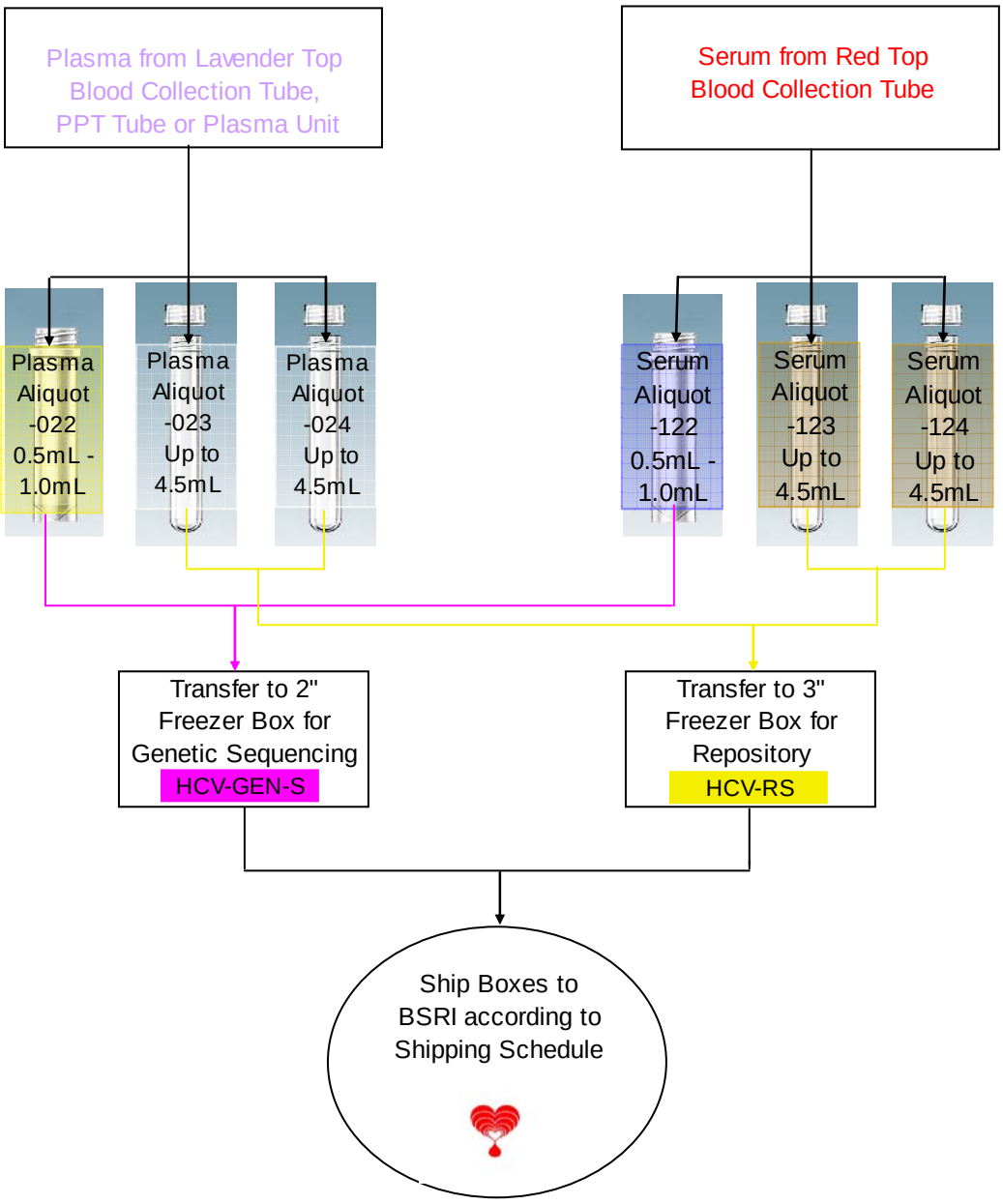
Cryovial Color Scheme		
Yellow cap=	Plasma 0.5 – 1.0mL	Sequence -012/-022
Blue cap =	Serum 0.5 – 1.0mL	Sequence -112/-122
Clear cap =	Plasma 0.4 – 4.5mL	Sequence -013/-023
Amber cap =	Serum 0.4 – 4.5mL	Sequence -113/-123

Figure 2: **HBV Aliquoting Flowchart**



See instructions given in section **3.4.2**

Figure 3: **HCV Aliquoting Flowchart**



See instructions given in section **3.4.2**

Exhibit H

Aliquoting Job Aids

H.1. HIV Aliquots for Molecular Surveillance Study

Cryovial Priority	Volume	Purpose
1	0.1mL	LS-EIA
2	0.5 to 1.0 mL	Gen. Seq.
3	Up to 4.5mL	Repository
4 etc.	Up to 4.5mL	Repository

Cryovial Color Scheme

	LS-EIA	Gen. Seq.	Repository	Repository	Repository
Color Cap Required	**Purple – Plasma** **Green - Serum**	**Yellow – Plasma** **Blue – Serum**	**Clear – Plasma** **Amber - Serum**	**Clear – Plasma** **Amber - Serum**	**Clear – Plasma** **Amber - Serum**
Volume Required	0.1mL	0.5 – 1.0mL	0.4 – 4.5mL	0.4 – 4.5mL	0.4 – 4.5mL
Sequence Number	0**0**1 – Plasma 1**0**1 - Serum	0**0**2 – Plasma 1**0**2 - Serum	0**0**3 – Plasma 1**0**3 - Serum	0**0**4 – Plasma 1**0**4 - Serum	0**0**5 – Plasma 1**0**5 – Serum
Boxing Requirements	2” Freezer Box HIV-LS-EIA	2” Freezer Box HIV-GEN-S	3”Freezer Box HIV-RS	3”Freezer Box HIV-RS	3”Freezer Box HIV-RS

Note: Continue Repository up to 7 aliquots if volume is available. The sequence number will end in 09.

Exhibit H

Aliquoting Job Aids

H.2. HBV Aliquots for Molecular Surveillance Study

Cryovial Priority	Volume	Purpose
1	0.5 to 1.0 mL	Gen. Seq.
2	Up to 4.5mL	Repository
3	Up to 4.5mL	Repository
4 etc.	Up to 4.5mL	Repository

Cryovial Color Scheme

	Gen. Seq.	Repository	Repository	Repository
Color Cap Required	**Yellow – Plasma** **Blue – Serum**	**Clear – Plasma** **Amber - Serum**	**Clear – Plasma** **Amber - Serum**	**Clear – Plasma** **Amber - Serum**
Volume Required	0.5 – 1.0mL	0.4 – 4.5mL	0.4 – 4.5mL	0.4 – 4.5mL
Sequence Number	012 – Plasma 112 - Serum	013 – Plasma 113 - Serum	014 – Plasma 114 - Serum	015 – Plasma 115 – Serum
Boxing Requirements	2” Freezer Box HBV-GEN-S	3”Freezer Box HBV-RS	3”Freezer Box HBV-RS	3”Freezer Box HBV-RS

Note: Continue Repository up to 7 aliquots if volume is available. The sequence number will end in 19.

H.3. HCV Aliquots for Molecular Surveillance Study

Cryovial Priority	Volume	Purpose
1	0.5 to 1.0 mL	Gen. Seq.
2	Up to 4.5mL	Repository
3	Up to 4.5mL	Repository
4 etc.	Up to 4.5mL	Repository

Cryovial Color Scheme

	Gen. Seq.	Repository	Repository	Repository
Color Cap Required	[redacted] **Blue – Serum**	**Clear – Plasma** **Amber - Serum**	**Clear – Plasma** **Amber - Serum**	**Clear – Plasma** **Amber - Serum**
Volume Required	0.5 – 1.0mL	0.4 – 4.5mL	0.4 – 4.5mL	0.4 – 4.5mL
Sequence Number	022 – Plasma 122 - Serum	023 – Plasma 123 - Serum	024 – Plasma 124 - Serum	025 – Plasma 125 – Serum
Boxing Requirements	2” Freezer Box HCV-GEN-S	3”Freezer Box HCV-RS	3”Freezer Box HCV-RS	3”Freezer Box HCV-RS

Note: Continue Repository up to 7 aliquots if volume is available. The sequence number will end in 29.

Exhibit I

BSRI Supply Request Form
REDS-II Molecular Surveillance Materials

Version: 9/20/2007

Email request to: dbunch@bloodsystems.org

Item	Company	Catalog #	Amount
Molecular Surveillance			
0.5 mL cryovial	Sarstedt	72.730.711	
2.0 mL cryovial	Sarstedt	72.664.711	
5.0 mL cryovial	Sarstedt	60.557	
Yellow caps	Sarstedt	65.716.002	
Green caps	Sarstedt	65.716.005	
Violet caps	Sarstedt	65.716.008	
Blue caps	Sarstedt	65.716.001	
Amber caps	Sarstedt	65.1121.008	
Clear caps	Sarstedt	Included with 0.5 mL cryovials	NA
BloodBlocs*	Fisher	06-670-35	
2" Freezer box	Sarstedt	95.064.981	
3" Freezer box	VWR	14230-204	
Freezer Box Labels	BSRI	HBV	Start # Stop #
Freezer Box Labels	BSRI	HCV	Start # Stop #
Freezer Box Labels	BSRI	HIV	Start # Stop #
Transfer pipets	Sarstedt	86.1171.020	

Transfer pipets	Sarstedt	86.1171.020	

Ship supplies to

Name: **Email**:

Address:

City: **State**: **Zip Code**:

Phone:

Date requested: **Estimated date supplies are required**:

Comments:

Exhibit J
REDS-II: Molecular Surveillance
Testing Flow Chart