YALE-NEW HAVEN HOSPITAL	TITLE: Handling of Specimens Suspected of Containing Hemorrhagic Fever Viruses		DEPT OF LAB MEDICINE Policy and Procedure Manual
			DOCUMENT # Admin Safety 4.0
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This procedure is internal to YNHH. Sample processing is performed in the BSL3 TB lab using BSL3 practices with sample inactivation if possible, which exceeds current CDC recommendations.

Transmission of Ebola in clinical samples is **via contact or injection with blood and body fluids**. Hemorrhagic fever viruses are enveloped and **inactivated by routine disinfectants**.

NOTE: The most current instructions should be obtained from the www.cdc.gov website for the particular pathogen suspected, and from the CDC and CT DPH directly as needed.

Testing should be kept to the minimum required for patient management and infection control. Questions regarding medical necessity should be referred to the Laboratory's Medical Director.

No testing will be performed in Satellite Laboratories. Rather patients will be referred to York Street and blood drawn and transported by personnel using PPE, according to CDC guidelines.

4.1 Purpose

The purpose of this policy is to define departmental guidelines for the safe handling of laboratory specimens that potentially may contain hemorrhagic fever viruses (VHF). This policy is applicable to all Laboratory Medicine employees.

4.2 Background

The term viral hemorrhagic fever (VHF) refers to the illness associated with a number of geographically restricted viruses. This illness is characterized by fever and in most severe cases, by shock and hemorrhage. Although a number of other viral infections may produce hemorrhage, only the agents of Lassa, Marburg, and Crimean-Congo hemorrhagic fevers are known to have caused significant outbreaks of disease with person to person transmission. Therefore, these recommendations specifically address these agents. However, newly recognized VHF viruses about which little information is available, such as the Sabiá virus, should be handled under the same guidelines. If a patient is suspected of having any of the above-mentioned VHF viruses including Sabiá, the handling of the patient within the hospital will be coordinated through the Hospital Epidemiology Department and the Centers for Disease Control.

Due to several recent epidemics, valuable information has been gained regarding the transmission of VHF. It is recommended that the same precautions be taken as those with blood and other body fluids from patients infected with hepatitis B virus or HIV, combined with barrier nursing. Transmission has been associated with the reuse of unsterile needles and syringes and the administration of patient care without the use of appropriate barrier

precautions to virus-containing blood and body fluids. The risks associated with various body fluids have not been well defined since most caregivers who acquired infection had multiple contacts with multiple fluids. Airborne transmission involving humans has never been documented.

Classification and Geographic Distribution of Hemorrhagic Fever Viruses with Documented Person-to-Person Transmission

Family	Virus	Distribution
Arenavirus	Lassa Fever Sabiá*	West Africa South America
Filoviridae	Marburg Ebola	Sub-Saharan Africa
Bunyaviridae	Congo-Crimean HF	Africa, Asia, Southern USSR

* Person-to-person transmission is not documented; of only 3 human infections reported, 2 were laboratory acquired.

4.3 Reporting

4.3.1 All suspected cases of hemorrhagic fever virus should be immediately reported to both the local and state health departments and to the Centers for Disease Control as follows:

New Haven Health Department
Contact: Mario Garcia, M.D., MSC, MPH
Director of the Heath Department
Telephone: 203-946-6999 (Monday-Friday)

Connecticut State Health Department:
Contact: Philip Sommers, PhD, Director of the
Division of Biological Sciences
Telephone: 860-920-6506

Contact: Matthew L. Cartter, M.D., Ph.D.
Epidemiology Program Coordinator
CT. Dept. of Public Health
Telephone: 860-509-7995

Centers For Disease Control and Prevention
24/7 Emergency Operations
Telephone: 770-488-7100

Viral Special Pathogens Branch
Telephone: 404-639-1115

4.3.2 Specimens for virus-specific diagnostic tests should be sent to CDC as rapidly as possible according to the instructions provided when contact is made.

4.4 Recommendations

4.4.1 Diagnosis in the initial stages of the disease is difficult since many of the symptoms are non-specific. Two critical studies should be done for any patient who has recently returned from the tropics and has a fever. These are a blood film examination for malaria and blood cultures. If the clinician feels that VHF is a likely diagnosis, he/she should take two immediate steps: 1) isolate the patient, and 2) notify Hospital Epidemiology, local and state health departments and CDC.

4.4.2 The following criteria can be used to screen patients with fevers. **The likelihood of acquiring VHF is considered extremely low in persons who do not meet these criteria**. The following recommendations apply to patients who, within 3 weeks before onset of fever have either:

4.4.2.1 Traveled in the specific local area of a country where VHF has recently occurred.

4.4.2.2 Had direct contact with blood, other body fluids, secretions, or excretions of a person or animal with VHF.

4.4.2.3 Worked in a laboratory or animal facility that handles hemorrhagic fever viruses.

4.4.3 The aim of management is to provide optimal care to the patient with the least hazard to the staff. Because of the potential risks associated with handling infectious materials, **laboratory testing should be kept to the minimum necessary for diagnostic evaluations and patient care**.

4.4.4 **Meticulous adherence to barrier procedures and precautions to prevent contact with blood and other body fluids are fundamental to the protection of the staff.**

Technologists should wear enhanced PPE when handling <u>inactivated</u> samples: fluid resistant or impermeable gowns, double gloves, surgical mask to cover nose and mouth, full face shield or goggles, pants (no bare legs) and solid shoes.

4.4.5 Aerosol generating procedures should be avoided though no human transmission via aerosol has been documented.

4.4.6 Laboratory tests must be done by trained staff using the precautions outlined in guidance documents provided by the CDC..

Prior guidance (1988, 1995, 2005) recommended 1) <u>inactivation</u> of specimens using Triton X-100, especially on automated instruments, 2) <u>BSL 3 practices</u>, although testing could be performed at BSL 2.

The latest 2014 guidelines require use of a class II biosafety cabinet for processing, the enhanced PPE specified above, and routine instrument decontamination only. **To exercise an abundance of caution, YNHH will continue to use Triton X inactivation and BSL 3 for sample processing.**

4.4.5 As much as possible, essential testing will be done at the beside. A basic Chemistry panel (glucose, BUN, creatinine, electrolytes), hematocrit, blood gases and lactate can be done on the iSTAT and INR on the Hemachron Elite. These hand-held instruments will need to be obtained from their current locations (e.g. Adult ED) and brought to the patient. Testing is performed in disposable cartridges and transport of samples to the laboratory is averted. The Laboratory Medicine Point of Care Coordinator can assist in locating instruments and training personnel.

4.5 Laboratory Overview

Responsibility and Core Specimen Receiving

4.5.1 The clinician(s) in charge of the patient are responsible for notifying the laboratory that there is a suspected case of hemorrhagic fever virus **before any samples are sent**. The Virology Laboratory will be the initial contact during operating hours (688-3524) and will initiate notification of other laboratories (see Phone tree in Appendix). When Virology is closed, the Laboratory Medicine Resident on-call will be the initial contact (860-340-3411).

4.5.2 All specimens should be collected in **plastic tubes or containers** and care taken not to contaminate the external surfaces of the container.

4.5.3 **Laboratory staff should be alerted to the arrival of the specimen and the types of tests requested.** All specimens should remain in the custody of a designated person until testing is done.

PPE and plastic transport containers are located in PS539 in **Specimen Receiving** and the following protocol should be followed (more details are available in Core Receiving protocols):

When notified that a suspected VHF specimen is coming to the lab, designated Laboratory Associate will

1. Don the required PPE, accept the sample container, and bring it directly to the hood
2. Log on to the terminal located at the Urine Bench
3. Take samples from the container, but not remove them from the biohazard bags
4. Scan the specimens through the bags to collect and receive
5. Separate the samples under the hood into:
    a. One transport container for Hematology specimens only
    b. One transport container for all other specimens

6. After placing specimens into the plastic transport containers seal top properly before removing from the hood
7. notify all the affected labs (if staffed) of sample arrival and transfer to the TB Lab.
8. Deliver the Hematology container to the technologist designated to receive this specimen who should be wearing the same PPE.
9. Deliver the container with all other specimens to the 6th floor BSL3 TB Laboratory (PS 624).

4.5.4 Upon notification of the receipt of specimens, laboratories should prepare to move any necessary equipment required for processing to the negative pressure environment. The TB Laboratory has centrifuges with safety buckets.

Note: If testing is not urgent, samples can be stored in a designated container in the TB refrigerator until staff are available to perform testing.

4.5.5 The Laboratory Managers of the respective laboratories will work with the Microbiology Laboratory Manager and/or the TB/Mycology Supervisor to arrange for time and space. Call ahead to discuss with the TB/Mycology Supervisor, or, in his or her absence, the technologist working in that area.

TB personnel will orientate all users to the safe use of the hood and schedule time when the hood could be made available. Off-shift staff who need to use the hood will be oriented annually on the safe use of the hood.

4.6 Specimen Handling

Although a BSL3 facility is not required, handling and processing of all specimens, submitted to the YNHH clinical laboratories will be handled in one centralized location, the BSL3 TB laboratory.

This laboratory has directional airflow (negative pressure) and a class II biological safety cabinet equipped with a HEPA filter, which exhausts to the outside. The TB laboratory is currently the only biosafety level 3 area in the Department of Laboratory Medicine.

The main purpose of BSL3 is to protect against aerosol transmission. VHF viruses in clinical samples have not been transmitted by aerosol. The CDC assumes processing will occur in a routine BSL2 facility. In the past BSL3 practices were recommended as an extra precautionary step and we will continue those precautions as we have a BSL3 facility on site.

4.6.1 A centrifuge, hood and supplies are labeled for use in “R/O Ebola” cases.

Make sure the blower in the biosafety hood is on. It should be kept on at all times. Turn the cabinet lamp from ultraviolet to fluorescent light using the switch above the upper right corner of the window. Adjust the height of the sash (about 10” opening). Place all needed materials in the hood.

4.6.2 All personnel should be wearing a **double pair of disposable gloves**, a gown and a surgical mask. These are also available in the TB Laboratory.

4.6.3 Place hands within the hood and wait 30 seconds for air currents to stabilize. Do not go into and out of the hood while working.

4.6.4 After completion of processing, the materials under the hood as well as the outer pair of gloves should be removed and discarded in an autoclave bag within the hood. The inner pair of gloves should be removed only after the autoclave bag containing all the waste has been disposed of. There is an autoclave in the negative pressure room for this purpose.

4.7 Specimen Processing

4.7.1 Plasma or serum used in laboratory tests should be pretreated with polyethylene glycol p-tert-octylphenyl ether (Triton® X-100). **Treatment with 10 µl of 10% Triton® X-100 per 1 ml of serum for 1 hour** reduces the titer of hemorrhagic fever virus in serum. Triton X is stored in the Chemistry section in the 4th floor fume hood in the AA area and in the TB Laboratory.

4.7.2 Centrifugation of Specimens

4.7.2.1 If patient samples need to be centrifuged they must be centrifuged in swinging buckets with containment lids closed. There is a centrifuge of this type located in the TB Laboratory.

4.7.2.2 **The containment lids should be opened only under the hood** and the specimen and balance tubes should be placed in the buckets and the bucket lids are to be secured while the buckets are still under the hood.

4.7.2.3 The outer gloves worn to place the specimen tubes in the buckets are to be removed under the hood.

4.7.2.4 Fresh gloves are to be put on and the closed buckets are to be placed in the centrifuge.

4.7.2.5 **After centrifugation the buckets are to be placed in the hood before the lids are opened.**

4.7.3 Blood smears are not infectious after fixation in solvents.

4.7.4 Routine procedures can be used for automated analyzers, however they should be disinfected after use as recommended by the manufacturer, or with a 1:100 solution of bleach. Each laboratory should refer to their policy to disinfect their instruments.

4.7.5 Environmental surfaces or inanimate objects minimally contaminated with blood, other body fluids, or excretions can be cleaned and disinfected using

standard procedures with a 1:100 solution of household bleach. However, for grossly soiled surfaces use a 1:10 dilution of household bleach.

4.7.6 After completion of work, place all cleanup materials etc. into the biohazard container; clean the surface with a 1:100 solution of bleach; remove the inner gloves, and put all the supplies back to where they originated.

4.8 Laboratory Specific Instructions and Procedures

The following are procedures developed by each laboratory:

4.8.1 Microbiology

4.8.1.1 Processing of specimens such as urine, sputum, etc. are to be handled under the biosafety hood in the TB Laboratory. Once the culture media have been inoculated, agar plates can be incubated and safely worked up using routine procedures.

4.8.1.2 Blood culture bottles that turn positive on the Bactec FX instrument should be subcultured onto appropriate plates using the biosafety hood in the TB Laboratory, since it is not known how long the virus might survive in the bottles.

4.8.2 Immunology

The Immunology Laboratory does not perform essential testing relevant to VHF patients and thus would not be expected to receive specimens. However, if a request is received, the Immunology Medical Director will assess the medical necessity and the appropriate action will be taken.

4.8.3 Blood Bank

NOTE: The following process for Blood Bank is only to be performed if the Blood Bank Director determines that there is sufficient staff available to do the required testing in the TB Laboratory. Otherwise, transfusion support for suspected VHF patients will follow the emergency release protocol (Group O un-crossmatched red cells, Group A or AB plasma) until the testing can be performed.

4.8.3.1 The Triton® X-100 cannot be used for blood samples as the lysing of cells may be a problem.

4.8.3.2 No automated equipment is to be used.

4.8.3.3 All routine procedures should be performed in the biosafety hood located in the TB Laboratory.

4.8.3.4 Place the following equipment and supplies on a cart and take it to the TB Laboratory:

1) One Immufuge and head
2) 1 magnifying mirror
3) 1 test tube rack
4) 1 squeeze bottle of saline
5) 1 box of 10 x 75 test tubes
6) 1 box of blood bank droppers
7) 1 rubber bulb
8) 2 small white buckets
9) One set of reagents (anti-A, -B, -A and B and screening AHG and Coombs control cells).
10) One magic marker

4.8.3.5 Handle and centrifuge samples as in general policy.

4.8.3.6 Place the immufuge, test tube rack and a sufficient number of tubes and droppers to do a type and screen, and one white bucket containing one inch of bleach in the bucket on the cart.

4.8.3.7 Place the reagent bottles, saline, magic marker and rubber bulb in the other white bucket on the cart. Use the reagents in the hood, then place them back in the bucket on the cart.

4.8.3.8 Do the type and screen in the hood. Place the test tube rack holding the screening tubes in the designated area in the Microbiology incubator. Incubate for 30 minutes and read reactions macroscopically ONLY. Discard all tubes, droppers and wash saline in the white bucket containing bleach.

4.8.3.9 Follow clean up procedures under Specimen Processing (pages 5).

4.8.3.10 Place the clean immufuge and rack on the cart and leave it in the TB Laboratory.

4.8.3.11 Place the reagent vials and saline bottle in the white bucket on the cart and return the bucket to the Blood Bank. Store in walk-in refrigerator. When the episode is over, discard all reagent vials and saline bottles in the contaminated trash.

4.8.3.12. If the patient needs Red Cross transfusions, repeat the ABO and Rh type on the donor and issue type specific blood. (Do Not crossmatch). Repeat the screening as often as usual procedure requires.

4.8.3.13 If the patient has an antibody, do all the necessary testing in the TB Laboratory hood. Refer to the Blood Bank supervisor or attending to determine what must be done.

4.8.4 Virology

NOTE: For more detailed protocols, refer to Virology BSL 3 Policy (P.SAF.2).

4.8.4.1 Respiratory virus testing by DFA or culture will not be performed on patients suspected of VHF.

4.8.4.2 Viral culture for samples from suspected VHF patients is not permitted as culture requires a BSL 4 facility.

4.8.4.3 Viral serology testing can be performed as long as samples are pre-treated for 1 hour with 10% Triton X-100 (10 µl of 10% Triton X-100 per 1.0 ml serum). Automated analyzers will be decontaminated after performing testing on these patients per CDC recommendations. Test turn-around-times may be affected. Note: Treatment with Triton X-100 reduces infectivity of hemorrhagic fever viruses in serum, but 100% efficacy should not be assumed.

4.8.4.4 Molecular testing can be performed on patients with suspected VHF as long as sample processing occurs in PS 625 (BSL 3) and samples are placed in guanidine lysis buffer while in the BSL 3 area.

4.8.4.5 *C difficile* testing on patients with suspected VHF will consist of screening using C. Diff Chek Complete instead of C. diff Chek-60 EIA and cytotoxicity. Stool filtrates will have Triton X-100 pretreatment as stated above for serology. If the GDH antigen screen is positive and toxin is negative, *C difficile* cytotoxicity testing cannot be performed as this would require a BSL 4 facility. A positive *C difficile* GDH antigen can be confirmed by *C difficile* PCR if needed.

4.8.4.6 Virology will assume primary responsibility for referring diagnostic samples to the CDC. Virology will contact both the State of CT Epidemiology and CDC Emergency Operations, confirm shipping category (A or B)* and arrange sample transportation. All necessary packaging and shipping material will be inventoried and stored by the Virology laboratory. Virology will obtain instructions and forms from the CDC website and contact the Special Pathogens Branch.

*Initial specimens are usually B; confirmed Ebola are A.

Samples to collect will vary with the suspected VHF agent. Virology will confirm samples to collect by consulting the CDC website for the specific pathogen. In general, acute

blood samples for PCR and virus isolation and acute and convalescent sera for antibody are collected. Plastic containers with screw-tops (i.e. cryovials) must be used.

4.8.4.7 Testing to determine an alternate etiology in patients with suspected VHF should be kept to the minimum necessary to support patient care and infection control practices until VHF is ruled out. Questions of medical necessity should be referred to the Virology Medical Director.

4.8.5. Hematology

The Hematology Laboratory has recommendations for the safe handling of potential virus containing specimens such as blood for CBC, malaria smear, prothrombin, and urine for urinalysis.

The technologist must wear all required PPE as described in 4.4.4. as the sample is not inactivated.

Other personnel working in the lab and not wearing enhanced PPE must leave clearance of 10 ft whenever a spill or splash is possible.

4.8.5.1 CBC

Do not add Triton® X-100 for CBC as it will lyse cells.

Using Abbott Sapphire (automated cell counter), the specimen will be analyzed in closed mode only. The only acceptable specimen is 3.0 mL EDTA tube filled 2/3 volume.

a) Place blood specimen into Sapphire auto sampler rack by itself

b) Place rack on Sapphire and click on “Run Loader”

c) Verify results in SoftLab

d) Bag specimen in biobag, label bag with “Suspect Hemorrhagic Virus”, place in secondary container, and place in designated refrigerated area in the TB Lab.

e) Place 10% fresh bleach solution into all Sapphire pots (do not swirl with Q tips or remove bleach)

f) Immediately perform instrument autoclean with 10% bleach

g) After autoclean is completed, perform instrument prime in Special Protocols

h) Verify background acceptable and run patient references

i) Clean work area with 10% bleach

j) Remove and discard gloves

4.8.5.2 Blood smears and malaria smears

Note: If any instrument data/suspect flags warranting smear review occur, smear needs to be made and fixed in methanol in the TB hood and all materials disposed in accordance with policy below.

Only BinaxNow will be performed for malaria, using the BL3 hood.

For clot assessment, smear preparation or BinaxNow testing:

a) Print patient result sheet from Sapphire and circle data that needs follow-up review

b) Biobag specimen tube, zip close, and place specimen in secondary container

c) Remove outer gloves and discard

d) Obtain needed supplies: i) clot assessment- 5 applicator sticks; smear- ten 3 x 1 glass slides and 5 applicator sticks, paper dispo urinetek cup with methanol to alcohol fix slide; ii) malaria- BinaxNow test kit, plastic tube with 10 drops of developing reagent and plastic transfer pipet

e) Bring bagged blood and needed supplies to TB lab. Access to TB lab keypad code 1234#

f) Place blood and supplies in hood

g) Double glove and place hands in hood, waiting 30 seconds for air flow to stabilize.

h) Perform needed test(s)

i) Place biobagged blood in designated container in TB Lab with other VHF patient samples

j) Discard all materials and outer pair of gloves in an autoclave bag within hood

k) Remove inner gloves only after the autoclave bag of waste is disposed in autoclave bag in TB room.

l) Bring slides back to Hematology Lab, label and place on stainer.

4.8.5.3 Prothrombin Time

NOTE: The automated PT instrument uses an potentially infectious open blood tube, so it is not done.

a) Instead, a PT should be done with the Hemachron Elite at the bedside using a disposable cartridge. Testing can be arranged by the Point of Care Coordinator.

b) Manual PT is no longer performed.

4.8.5.4 Urinalysis

Dipstick testing at bedside recommended. If needed, urinalysis can be done in the TB Lab as described below.

a) Take double-bagged urine, a plastic bucket and lid, Labstix (the ones with specific gravity on the pad), glassslides, coverslips, disposable sterile pipettes, nail polish, amphyl and blank lab slip to record results to the TB Laboratory.

b) For specimen processing, follow instructions on page 5

c) Dip the urine (save cap), record results, including specific gravity. If all results are normal there is no need for a microscopic exam. If any of the parameters are abnormal, centrifuge urine according to instructions on page 5, specimen processing, for 5 minutes at 1800 RPM.

d) Return centrifuge bucket to hood, open cover and unload. Pour supernatant in waste container with 10% Clorox. Prepare coverslip for wet prep over this bucket, then seal with nail polish! Let dry for 20 minutes, then read using microscope on the counter.

e) Discard all waste into waste bucket under hood. Switch hood light to UV light when you leave.

f) For clean-up refer to section under specimen handling and processing.

4.8.6. Chemistry

Refer to 4.4.4 and 4.4.6 for appropriate PPE. Once samples are inactivated, enhanced PPE will still be used, though not required.

4.8.6.1 The Roche Modular DPP in the Chemistry Laboratory has been engineered to minimize aerosol formation, but this cannot be eliminated. Because of the possibility of aerosol transmission, specimens must be inactivated with Triton® X-100 before analysis as detailed below. Prior to inactivation, they must be handled only in closed containers or in a biosafety hood.

4.8.6.2 The following tests have validated lack of interference of Triton® X-100 when run on the Roche Modular DPP:

Plasma:
Sodium, Potassium, Chloride, Calcium, Urea Nitrogen, Creatinine, Glucose, Magnesium, Phosphate, AST, ALT, Alkaline Phosphate, Total Bilirubin, Direct Bilirubin, Amylase, Lipase, CK, LDH, Uric Acid, Total Protein, Albumin, Cholesterol, Triglyceride, Troponin T, C-Reactive Protein.

CSF (Spinal Fluid):
Protein, Glucose.

4.8.6.3 Refer to the section on handling and processing specimens on pages 5- 7.

4.8.6.4 Spin the chemistry samples for 15 minutes at 3000 rpm in a sealed rotor in the TB laboratory. The longer centrifugation time and the use of a plasma separator gel will minimize white cells in the plasma specimens.

4.8.6.5 Using a 1.0 ml adjustable pipette, transfer 1.0 mL of the specimen deep into a 13 X 100 mm plastic tube. Mix with 10μL of Triton® X-100 by gently transferring the serum back and forth from the pipette to the carrier. Do not bubble air through the plasma during this process. If any of the plasma spilled, it should be immediately diluted with 10% bleach. Decontaminate the hood as mentioned in the section specimen handling.

4.8.6.6 Place disposable pipette into small biohazard bag. Cap aliquot tube and recap the primary specimen. Double bag the primary specimen. Reseal the buckets. Wait one minute to allow clearance of any aerosol. Remove your outer glove leaving the glove protecting the hand in place. Invert them and place into biohazard bag with disposable pipette. Seal the bag. Remove the materials from the biosafety cabinet and turn on the ultraviolet light.

4.8.6.7 Allow the capped plastic tube to stand 1 hour at room temperature in the hood in the TB lab.

4.8.6.8 Return the aliquot specimen to Chemistry in the designated protected container for analysis. Uncap the specimen using a disposable gauze square. Place the uncapped plastic tube on the instrument. Run only validation approved assays (see section: 4.8.6.2) according to (section 4.4.4 PPE) protocol.

4.8.7 Spill and Exposures

Every precaution should be taken to avoid spills by keeping especially non-inactivated blood tubes in sealed carriers when not working in a BSC.

4.8.7.1. Handling

Any spill of patient samples outside of the hood in the BSL3 TB Lab must be decontaminated by personnel wearing an N95 filter mask following the protocol for decontaminating *M. tuberculosis* spills. A "biohazard spill kit" for this purpose is located in the cabinet labeled "Biohazard Spill Kit" near the Biosafety cabinet inside the TB Laboratory.

Spills of inactivated material do not require evacuation of the room for 30 min, but protective clothing below should be worn.

a. Leave the room for at least 30 minutes to permit the air handling system to evacuate most of the aerosol.

b. Wear protective clothing (impermeable gown, N95 mask, face shield, double gloves) to reenter the room and clean up the spill.

c. If the spill contains broken glass or other objects, these should be removed and discarded, without contact to the hands, into a white bucket labeled "glass" on the lid and filled with 10% (1:10 dilution) household bleach. Rigid sheets of cardboard used as a "pusher" and "receiver" may be used to handle such objects and discarded with the objects into an appropriate biohazard container.

d. If the spill is large and/or there is potential of contaminating the worker's shoes, water impermeable shoe covers should be worn.

e. Since most disinfectants are less active, or even ineffective, in the presence of high concentrations of protein as are found in blood and serum, the bulk of the spilled liquid should be absorbed prior to disinfecting.

f. Absorb the spilled material by covering the spill with paper toweling immediately to prevent further aerosolization.

g. Soak the covering cloth with disinfectant (10% Clorox) to wet the area. Pour around the periphery of the spill and then into the center. Avoid any splashing. Let the Clorox sit for 20 minutes.

h. Place all cleanup materials into the biohazard bag and autoclave all biohazardous waste using the small autoclave in the TB biocontainment area.

4.8.7.2. Exposure to Personnel

a. Any person exposed with percutaneous or mucocutaneous exposures to blood, body fluids, secretions, or excretions from a patient suspected of having VHF should immediately wash the affected skin surfaces with soap and water. Mucous membranes (e.g. conjunctiva) should be irrigated with copious amounts of water of eyewash solution.

b. The exposed person(s) should immediately receive medical evaluation in Occupational Health Services. On off-shifts the person should be taken immediately to the Emergency Room for evaluation.

4.9. Shipping Instructions for Specimens to CDC

4.9.1. The Virology Laboratory is responsible for shipping samples to either the State or to CDC and will contact the appropriate persons prior to shipment. No samples can be sent without prior consultation and approval. For Special Pathogens Branch call (404) 639-1510 or (404) 639-1115). Instructions for Ebola can be found at http://www.cdc.gov/ncezid/dhcpp/vspb/specimens.html

4.9.2. Shipping containers (both category A and B) for transporting VHF specimens are located in the Virology Laboratory.

4.9.3. The shipping of specimens of VHF to CDC requires special handling. The United Nations and the International Air Transport Association (IATA) have implemented regulations governing the identification, packaging, and shipping of “Dangerous Goods” via air transport. Federal Express and Airborne Express are IATA member airlines and must follow these regulations. The Department of Transportation (DOT) also regulates transport of “Hazardous Materials” in the U.S.

4.9.4. These regulations refer to “Infectious Substances” category (Division 6.2), which are materials known or expected to contain a pathogen. Infectious Substances are divided into two categories, A and B. Initial diagnostic samples for VHF are usually considered **Category B, and confirmed Ebola Category A** but CT DPH and CDC should be consulted to confirm the shipping category for each specific case**.**

4.9.5. The shipment of samples from suspected patients should follow **packing instructions 620** as follows (more detailed documents in Virology):

a. The use of Performance-oriented packaging: This packaging has been tested and certified to withstand special degrees of trauma. This packaging can be purchased many suppliers, including:

Berlin Packaging (previously All Pak)
Corporate One West
1195 Washington Pike

Bridgeville, PA 15017-2854
Telephone number: 412-257-3000 or 800-245-2283
(Attn: Bill Barger)
Infectious Substance Packaging

b. The use of leakproof primary receptacles, secondary packaging, containing absorbent material, enclosed in a sturdy outside container of specific requirements and bearing the UN specification markings.

c. The Name and Telephone number of a person responsible for the shipment marked on the outside.

d. An itemized list of contents placed between the secondary and outside packaging.

e. An Infectious Substance Label.

f. A Shippers Declaration for Dangerous Goods.

g. Advance arrangements must be made between the shipper and the operator before each shipment takes place.

h. If the package is instead delivered by courier to CT DPH, DOT forms must be filled out to accompany the package. These forms can be obtained from Virginia Kristie at the Center For Emergency Preparedness at Hartford Hospital. 860-545-1213, or Virginia.Kristie@hhchealth.org

4.10 References

4.10.1 Original Documents

Edberg, S. C., S.H. Fischer, M. Klassen, Plans for Processing Patient Specimens Requiring Special Handling Precautions (Potentially Sabiá Virus Infected Materials) in the Microbiology Laboratory, August 8, 1994.

McPhedran, P., Hemorrhagic Procedures for Prothrombin, Cell DYN CBC, and Urinalysis, August, 2003

Protection of Laboratory Workers from Infectious Diseases Transmitted by Blood, Body, Fluids, and Tissue, Second Edition, NCCLS, Doc. M29-T2, Vol. 11, No. 14, Sept. 1991.

Rainey, P., Procedure for Specimens Containing Sabiá Virus, August, 1994.

Management of Patients with Suspected Viral Hemorrhagic Fever, U.S. Department of Health and Human Services, Centers for Disease Control, 37:S-3, February 26, 1988.

Update: Management of Patients with Suspected Viral Hemorrhagic Fever- United States, U.S. Department of Health and Human Services, Centers for Disease Control, 44: No. 25, June 30. 1995

4.10.2 Current documents:

4.10.3 Interim Guidance for Managing Patients with Suspected Viral Hemorrhagic Fever in U.S. Hospitals, May 19, 2005 http://www.cdc.gov/vhf/ebola/exposure/index.html

4.10.4 Interim Guidance for Specimen Collection, Transport, Testing, and Submission for Patients with Suspected Infection with Ebola Virus Disease August 6, 2014: http://www.cdc.gov/vhf/ebola/hcp/interim-guidance-specimen-collection-submission-patients-suspected-infection-ebola.html

4.10.5 Viral Special Pathogens Branch (VSPB) Specimen Submission Information http://www.cdc.gov/ncezid/dhcpp/vspb/specimens.html#guidelines

4.10.6 Guidelines for Evaluation of US Patients Suspected of Having Ebola Virus Disease August 1, 2014 http://emergency.cdc.gov/han/han00364.asp

4.10.7 Information for Healthcare Workers http://www.cdc.gov/vhf/ebola/hcp/index.html

4.10.8 Biosafety in Microbiological and Biomedical Laboratories, 5th Edition, December 2009

4.11 **Appendix**

Guidelines Regarding Inter-Laboratory Communication of Potential Ebola/VHF Samples

Suspected Ebola patients will generally be seen first in the ED. The ED should contact:

1) The Clinical Virology Laboratory at 688-3524.
2) The Laboratory Medicine Resident on-call on beeper 860-340-3411 when Virology is closed.

If the patient is at SRC, the clinician or the SRC Laboratory should notify the York St campus as above.

Information requested by Laboratory personnel (see form below)**:**

1) Patient name and MR number*
2) If admission is likely and if the inpatient ward is known*
3) What samples are being sent to which laboratories. *Only essential testing recommended.*
4) The name of the person providing the information
5) Remind the caller that samples must be hand-carried to lab

**This information should be kept at the specimen receiving area in each laboratory.*

Laboratory Phone Tree

1) Each laboratory should be called and the information above given to the Laboratory Manager or, if not available, to the supervisor on-duty, or if not available, to a medical technologist.
2) The name of the person taking the information and the date/time of the call should be recorded.
3) The phone tree below should be followed, according to the time of the call.
4) Each Laboratory should notify their Director and Manager.

When Virology is open

1) Virology (688-3524) notifies Core Specimen Receiving (688-7041), Microbiology (688-2649), Point of Care (beeper 203-412-7505), Pete Marone (cell 203-809-6652), and the Resident on call if after 5 PM.
2) Microbiology notifies Immunology (688-5648) and the Microbiology fellow
3) Immunology notifies Flow Cytometry (688-8179) and Molecular Diagnostics (688-2654)
4) Specimen Receiving notifies Chemistry (688-3713) and Hematology (688-8827).
5) Chemistry notifies the Blood Gas Lab (785-5046) and SRC (203-789-3060).
6) Hematology notifies Blood Bank (688-2443).

When Virology is closed

1) The Laboratory Medicine Resident notifies Specimen Receiving, Microbiology, and Virology to activate the phone tree above, as well as Point of Care and Pete Marone.

Suspected Ebola samples arriving without the above notification process

If a laboratory receives a sample from a suspected Ebola patient without prior notification as above, that laboratory should activate the communication process by calling either the Virology Laboratory or the Laboratory Medicine Resident, as appropriate, as well as the laboratories they would ordinarily notify as outlined above.

Yale-New Haven Hospital
Department of Laboratory Medicine

Suspected Viral Hemorrhagic Fever Case Information

Date/Time of Contact	
Patient Name	
MRUN	
Patient Location	
Potential Inpatient Location	
Testing Being Sent to the Laboratory	
Name/Position/Service of Caller	
Person Receiving Call	
Phone Tree- Labs notified	
Lab Director and Manager contacted	

*Remind clinician to HAND-CARRY samples in sealed transport carrier; the tube system should not be used.