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# Amendment Procedure

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Each controlled document has a separate record of amendments detailed in this Amendment Procedure.

On issue of revised or new pages each controlled document should be updated by the copyholder.

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**1.0** **Introduction**

Patients will be risk assessed on the ward as being in one of 4 categories according to Public Health England’s [Viral Haemorrhagic Fevers Risk Assessment](http://www.hpa.org.uk/webc/HPAwebFile/HPAweb_C/1317135155050).

1. Unlikely to be infected with VHF
2. Low risk of Infection with VHF
3. High risk of infection with VHF
4. Confirmed VHF infection

The Pathology laboratories have risk assessed processing specimens from patients in categories 2-4 and decided due to the unknown infection status and the fact specimens are processed in the laboratory over several days, all specimens in the categories 2-4 will be considered high risk of infection.

Current guidance for these patients ([Management of Hazard Group 4 viral haemorrhagic fevers and similar human infectious diseases of high consequence. Advisory Committee on Dangerous Pathogens 2014](http://www.hpa.org.uk/webc/HPAwebFile/HPAweb_C/1194947382005)) states that in the first instance and whilst infection status is unknown, we will only be receiving a small number of samples into the laboratories plus blood samples to send to the Rare and Imported Pathogens Laboratory (RIPL)for rapid imported fever screening if this is deemed to be necessary.

**2.0 Communication Cascade**

Consultant Microbiologist will alert Blood Sciences and Microbiology laboratories on presence of patient suspected of VHF risk ( 2-4) 204 and to expect specimen types indicated in above guidance. Contact numbers are:

Blood science 2934 – out of hours Bleep 226

Microbiology 2962 – out of hours Switchboard

BMS dealing with the specimens will put an alert out on A- mail on IPS ( Mailing List code MICROALL) and post a notice on wipe boards on 3rd and 2nd floor.

The Haematology BMS will inform the chemistry BMS and put an alert out on A- mail on IPS ( Mailing List code CHEM, HAEMLAB, IMM)

Haematology and Chemistry BMS will call ‘ Second On’ to cover Blood Transfusion for the period of processing the VHF sample

 **3.0** **SPECIMEN TAKING AND TRANSPORT**

* Users must notify the laboratory/ Consultant Microbiologist before any specimens are sent to the any of the laboratories

The specimens will be taken as follows

Label the tubes and take blood from the patient. Double bag and label with High Risk Stickers

Take the specimens to the door of the isolation room. The ‘runner’ will be on the other side of the door with 3 containers

The nurse inside the isolation unit opens the door and places the specimens directly into the open containers being held by the runner



Take the following specimens and place in the containers as per table below

|  |  |  |  |
| --- | --- | --- | --- |
| Container 1 | Blood cultures EDTA Malaria screen  | Take to Microbiology  | Floor 3 Old Pathology Building |
| Container 2 | Red top EDTA and Brown top clotted for VHF Testing  | Take to Microbiology  | Floor 3 , Old Pathology building |
| Container 3  | Brown top clotted for U&E,LFT,CRP,GlucoseRed top EDTA for FBCGreen top citrate for Clotting  | Take to high throughput laboratory  | A2  |

* Runner screws the top on the containers and places containers 1 and 2 in a UN3373 compliant container (Green bag) for Old Pathology building and container 3 in a Green bag for A2
* Request forms must be filled on Outside of the isolation room and put into the pocket on the top of each green bag. Bar codes to be removed from Blood culture bottles and stuck onto request from before bloods are taken
* A member of the nursing team will be designated a ‘ runner’ to bring the specimens to the Blood Sciences laboratory ( A2) . On arrival at the laboratory specimens will be handed to a Biomedical Scientist (BMS). Runner and BMS will sign the required paperwork. BMS will sign paperwork in Microbiology
* The Haematology BMS will transport all samples to Microbiology Department (using the green transport bag) as soon as the second on BMS has arrived to cover the laboratory. The Haematology BMS must also take the slide transport box over to the microbiology lab to transport the malaria slides back to the A2 labs. A set of laboratory number barcodes must be taken for labelling the samples prior to centrifugation. The request form must be labelled with the appropriate barcode using clean hands.

**4.0 LABORATORY PROCEDURES**

**4.1 MICROBIOLOGY LABORATORY**

Samples for Microbiology ( Blood cultures ) VHF testing ( sent to Porton Down ) and Malaria screen will be processed in Microbiology. In addition samples for Biochemistry and Coagulation studies will be centrifuged.

*Once a patient is identified in one of the risk categories the laboratory will search the LIMS to ensure there are no specimens already in the laboratory which need to be handled under the protocol described below.*

All specimen received (except blood cultures) will be stored in a dedicated rack and kept for disposal under category A protocol.

**4.2 Containment Level 3 Protocol**

All samples received into Microbiology will initially be processed in the CL3 room.

Two members of BMS staff are required for processing specimens, Microbiology BMS and Haematology BMS.

**NB** *Lone working is not permitted in this room out of hours when processing category 3 or 4 pathogens*

Prior to taking samples into CL3 room,check request forms and obtain a blood culture number

Put the DO NOT ENTER sign on the door of the CL3 room and take the hands free phone into the CL3 room

Take the green transport bag into the CL3 room

Put on PPE as directed in Appendix A, each BMS acting as a ‘ buddy’ to the other to ensure PPE is fitted correctly .

Prepare disinfectant solution (10,000ppm chlorine) by adding 2 large haztabs to 500 ml of distilled water in container provided

Prepare a ‘ pot’ of 10,000 ppm chlorine by adding 8 large haztabs in 2 litres of water using white histology pot provided and leave this by the sink.

Turn on Safety cabinet and clear all items from within the cabinet except the white tray and the heating block

Place the following inside the cabinet

Blue absorbent pad on top of the white tray

Sharps container and lid

Disinfectant ( 500 ml)

Coplin jar with acetone

Malaria slide and buffer

Labelled blood film slides

Rack for Malaria specimen

Absorbent wadding for packaging specimen

Container with Specimens for Porton Down

Container with specimens for Malaria screen and Blood Cultures

Container with Specimens for A2

Outside the cabinet ( but within reach)

Rack for blood cultures

Small plastic transport container

Boxes of spare gloves

Plastic slide carrier for fixed malaria slides

Ensure large clinical waste container is ready containing double clinical waste bag and with lid readily available

Process the specimens in the following order

* + 1. **Specimens to be sent to Porton Down for VHF testing ( to be performed by Microbiology BMS)**

Open the container inside the cabinet

Do not remove the blood samples from the double bagging

Check that the specimens are labelled with patient details

Put back in Container and put the absorbent wading inside the container.

Put lid on the container and place in outside the cabinet

Package as per Appendix B

**4.2.2 Processing Blood Cultures ( to be performed by Microbiology BMS)**

* Inside the cabinet remove the blood cultures from the transport container
* If there is any blood contamination on the bottles they should be left in the bag and the Consultant Microbiologist notified. If specimens are irretrievably contaminated, they must be placed in the dedicated category A discard container awaiting disposal.

If specimens appear clean (small amounts of blood around the inoculation site are acceptable), immerse the bottles (**up to the neck**) in the 10,000 ppm chlorine solution.

Wipe the top of the bottles with the solution

Dry the bottles with the tissues and discard tissues into sharps container

***Remove the outer pair of gloves*** ( discard into sharps container)

Place the Blood Culture bottles in the rack OUTSIDE the cabinet.

 ***Put on another pair of gloves***

**4.2.3 Processing A2 Bloods ( to be performed by Microbiology BMS)**

**NB Do not process if tubes are outside of tubes are grossly contaminated with blood**

* Remove bloods from container and bags
* Wipe outside of blood tubes with disinfectant solution
* Dry with tissues

***Remove outer pair of gloves*** ( and discard into sharps container)

Place blood tubes in rack outside cabinet

***Put on another pair of gloves***

**Leave Cabinet**

* Centrifuge bloods using holders supplied by A2 in CL2 centrifuge
* Place all bloods in the small plastic transport container kept in the microbiology CL2 room Place the small transport container inside the new larger transport container
* Place transport container inside green bag and surround with tissue to maintain it in an upright position, ready for transport to A2

**4.2.4 Malaria Screen Procedure ( to be performed by Haematology BMS)**

Order of work**:**

**Prepare slides and then undertake rapid antigen test ( MIA) whilst slides are drying**

**Result of MIA to be phoned through to Torridge by Microbiology BMS**

***Thin Films***

***STEP ONE:***

***Place clean glass slide on a flat surface. Add one small drop of blood to one end.***

******

***STEP TWO:***

***Take another clean slide, and holding at an angle of about 45 deg, touch the blood with***

***one end of the slide so the blood runs along the edge of the slide by capillary action. Push***

***carefully along the length of the first slide to produce a thin smear of blood.***

******

***STEP THREE:***

***Make 2 smears, allow to air dry, and label clearly with patient surname and sample number on the frosted end of the slide.***

******

***Thick Films***

When making the thick film, place the blood spot close to the non-frosted end of the glass to ensure full exposure to stain. Label clearly with patient surname and sample number on the frosted end of the slide.

Using the corner of a clean slide, spread the drop of blood in a circle the size of a penny (diameter 1-2 cm). Do not make the smear too thick or it will fall off the slide. (You should be able to read newsprint through it.)



Wait until the thin and thick films are completely dry before fixing. They can be dries on the hotplate inside the cabinet.

 Fix the slides in Acetone for 10 minutes.

 ***Remove outer pair of gloves and put on a new pair***

Place the slides in a slide box , held outside the cabinet by Microbiology BMS.

**Leaving the Cabinet**

Discard absorbent paper into the Cat A sharps container.

Discard the specimen and any other items such as tissues / antigen test reagents etc into the Sharps container

Wipe down the cabinet, hot plate and coplin jar with Tristel and absorbent tissue, Discard into sharps container.

Place the disinfectant container outside the cabinet

Put the lid on the sharps container, and discard into the large Clinical waste bin

Discard the specimen transport containers into the Clinical waste bin

Discard disinfectant down the sink and discard this container into the Clinical waste bin

***Remove outer pair of gloves and put on a new pair***

 **4.2 5 Removal of PPE**

PPE is removed as per Appendix A, each BMS acting as ‘ buddy’ for the other to check correct removal process.

**Once the first buddy is free of PPE , then he/ she will put on a new pair of gloves in case they are required to assist their colleague in removal of PPE. These to be removed and hands washed prior to touching anything inside the room when second buddy has completed removal of PPE**.

Place PPE in Clinical waste bag inside the Clinical waste bin. Put the lid on the bin

**Take blood cultures and fixed malaria slide out of CL3 room and continue processing**

Blood cultures are to be placed into Fluids Section of Bact Alert and labelled with high risk stickers and

 **5.0 Procedure for Blood Sciences**

When the department is notified of imminent arrival of specimens, one member of BMS staff from Haematology and one member of BMS staff from Clinical Chemistry will put on PPE as directed in Appendix A. Each will act as a ‘buddy’ for the other to check that PPE is correct.

In the event of this occurring in the out of hours setting the ‘second on’ BMS for both haematology and chemistry must be called to attend the department. During weekend day sessions the blood transfusion BMS will act as the “second on” for haematology.

Specimen will arrive at A2 reception with runner.

BMS and runner will sign required paperwork, this document must be completed with the names of all blood sciences staff who have been involved in the processing of the samples. The document must be retained in Blood Sciences and handed to a blood sciences manager as soon as possible.

The equipment and PPE required for handling and processing high risk VHF samples can be found in the High Risk VHF box under the bench at the front reception desk. The contents of the box are described on the form BS-FORM- High Risk VHF.

 **5.1 Decontamination Protocol**

Take specimens out of green bag and take into small laboratory next to reception (A236)

Ensure you have a Category A waste container available and a box(es) of suitable gloves.

Place absorbent material on the designated tray and wipe outside of blood tubes with alcohol wipes

Place blood tubes in the designated rack

Take off outer pair of gloves and put on a clean pair

 **5.2 FBC and Clotting - BMS Haematology**

**FBC samples**

Place blood tube for FBC in the designated rack and take to analyser.

Specimens must be run on the analyser without any other specimens

Decontaminate the analyser by processing 3 tubes of diluted bleach (Hospec Thin Bleach ready diluted) followed immediately by 3 tubes of distilled water & shutdown for 30-60 minutes. This task should be performed by the “buddy”. Place sign on analyser to indicate that it is being decontaminated.

When the analyser has completed the test, place the rack and the specimen into the designated container labelled Category A specimen box.

Put this box in the designated area in A236. Specimens must be held here until result of VHF screen is known.

 **5.3 Coagulation samples**

10mls Terralin must be placed into the liquid waste of the coagulation analyser prior to specimen processing. Treated liquid waste is then safe to be disposed in a sink.

Prior to testing ensure that analyser is quality controlled and will not be required during testing of the high risk sample. Load sample onto analyser. The buddy must press button to move barcode reader. Rack is then loaded by BMS in PPE

When the analyser has completed the test , place the rack and the specimen into the designated container labelled Category A specimen box.

Decontamination of the analyser must be performed as follows.

 The buddy must perform all interactions with the analyser. Log on as user TOPCLOT password TOPCLOT. From the top of the screen select systems then diagnostics. In the cuvettes tab click “clear all cuvettes”.

The buddy must then open the cuvette waste drawer in order for the BMS in PPE to remove the cuvette waste including the plastic tray. The entire tray is then placed in a category A sharps bin. The buddy can then replace with a new plastic tray.

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The Coagulation analyser must be decontaminated using the enhanced clean for all probes routine in accordance with HASOPC-0024.

**Clinical Chemistry – BMS**

Specimen must not be put onto the PVT analyser.

Place the specimen in the designated rack (without other specimens) and load into the analyser stat port.

Uncap the specimen and place the cap into the category A sharps bin. Remove outer gloves and discard in the category A sharps bin and put on a clean pair.

When the specimen has finished processing, securely recap the tube using a spare Sarstedt SST tube, brown top, whilst still on the Modular system, remove the rack and place inside the Category A specimen container in A236 with the other specimens and racks

The analyser system must be decontaminated using following the Roche decontamination procedure. This should be carried out by a Roche LSC. Contact should be made with the LSC’s as soon as we are made aware that we are analysing a potential Ebola specimen. The analyser should be placed into standby and no other samples should be analysed until the decontamination is carried out.

When all testing has been completed and all samples and racks have been placed into the Category A specimen container in A236 the container should be sealed and the notice attached stating that the container has high risk VHF samples and should not be touched. The container must be left sealed, with the notice attached, until the VHF confirmatory testing has been completed and the results notified to the laboratory.

**5.4 Removal of PPE**

Remove PPE as per Appendix A, each BMS acting as buddy for the other to ensure correct procedure is followed.

Place in Clinical waste bag in A236. Place this inside another clinical waste bag and leave in A236 awaiting VHF result

 **6.0 Procedure for Blood Transfusion**

Due to the lack of closed automated testing procedures in the blood transfusion department, patients with high risk VHF will not have samples processed for group and save or crossmatch purposes. In the unlikely event of a high risk VHF patient requiring a transfusion of blood or blood components group O Negative red cells (issued uncrossmatched), group AB FFP and group A Negative platelets should be issued. The Consultant Haematologist and medical staff treating the patient must be informed that uncrossmatched blood has been issued in case of a transfusion reaction.

Requests for all blood and blood components must be made by telephone and documented on the relevant telephone request forms.

If the patient has an alert card stating that they have special requirements for blood (e.g. irradiated, antigen negative, HbS negative), these requirements should be met whenever possible but group O blood should be used as there will be no current sample for ABO confirmation.

To avoid unnecessary use of large quantities of group O Negative blood, O Positive may be used for males and females post child bearing age, on the advice of the Consultant Haematologist. Similarly, to conserve stocks of AB FFP and A Negative platelets, other blood groups may be issued on the advice of the Consultant Haematologist.

The IPS computer system requires a blood group to be entered in order to issue blood and blood components, therefore, in the absence of an historic group the patient should be given a provisional group of O Rh D negative. A lab note must be entered stating that the true blood group is unknown and a Special Interest Clinical note must be added as soon as possible (by a band 6 or above) confirming that a computer blood group has been assigned but the true blood group has not been confirmed.

In the event of a transfusion reaction, the Consultant Haematologist will advise on the actions to be taken but pre and post transfusion samples should not be tested locally.

 **7.0 Notification of change of Patient status**

It is the responsibility of the Medical staff/wards to ensure that the laboratory is kept up to date with any changes in patient risk status

* If a patient is confirmed as not infected then all specimens can be transferred to category 2 processing and waste disposed of by usual laboratory methods
* If a patient is confirmed VHF – all work on those samples in the laboratory must be immediately ceased. Any specimens / cultures will be saved in the event of Porton Down requiring these.

  **8.0 Waste Disposal**

Current guidelines state that waste from VHF patients can be autoclaved on site and after autoclaving the waste is rendered safe.

Dedicated waste containers will be used in the laboratory for this waste. The waste must be kept inside 2 containers, one of which must be leak-proof.

As for Containment level 3 all waste must be placed inside a plastic bin inside the yellow trolley and accompanied by a BMS to the autoclave.

All specimens from suspected VHF patients must be kept separately from other specimens and be kept until an autoclave run is organized.

If the patient is confirmed VHF positive then the samples racks must be discarded along with the samples and all other waste.

Waste from Blood sciences will be brought to Microbiology for autoclaving by a member of the blood sciences department. This will be pre- arranged with Microbiology.

**APPENDIX A**

**EBOLA - Use of Personal Protective Equipment (PPE)**

**PPE will only provide protection for staff if it is worn correctly.**

**It is just as important that PPE is removed in a way that avoids contamination of your eyes, mouth and nose during the removal process.**

**Before processing any work put on PPE in the following order:**

1. Disposable fluid resistant lab coat
2. Apron, over coat
3. Filter mask (FFP3)
4. Eye protection
5. Double gloves and gauntlets

Always get another member of staff to watch you put on your PPE and check that you have done so correctly.

**Before leaving isolation room remove items of PPE in this order and place each item (including paper towels) into a clinical waste bin for incineration:**

1. Apron
2. Remove gauntlets
3. **Wash hands (with gloves on) in the pot by the sink containing 10,000 ppm .Dry with paper towels**
4. Peel off gloves from one hand with other gloved hand and discard. Place ungloved fingers inside the other glove and peel off without touching the outside of the glove
5. Remove lab coat - use one hand to pull open across body and remove with help of colleague – avoid touching the outside of the coat. Roll into a bundle and discard.
6. **Wash hands( with gloves on) in the pot by the sink and dry with paper towels .**
7. Remove second pair of gloves
8. **Wash hands using sink**
9. Eye protection - pull forward away from face
10. **Wash hands using sink**
11. Filter mask – remove by breaking straps and pulling forward away from face
12. **Wash hands using sink**
13. Leave room
14. **Wash hands using sink**

**When both buddies have removed PPE , put the lid on the Clinical Waste Bin and place Cat A waste sticky label on it .**

**APPENDIX B**

**CATEGORY A SPECIMEN TRANSPORT PROCEDURE ( HAYSDX)**

**Contacting Porton Down Rapid Fever Screening Service**

Before organising transportation the following steps should have been taken:

* The Microbiology Laboratory will liaise with the Reference Laboratory (Microbiology Services Division – Porton Down Tel: 01980 612100) and arrange for the specimen to be transported there urgently
* Infection Consultant to arrange VHF screen with Imported Fever Service(0844 7788990

**Specimen requirements**

Specimens required for a VHF screen are 10mls of clotted blood (brown topped bottle) and 5mls EDTA (red topped tube).

**Courier Services**

For Category A samples contact PDP couriers on 01784 420466 (this number is 24/7) and quote reference RDE-NHS.

Packaging and labelling is supplied by PDP and this must be used otherwise they will not transport

For Category B samples contact City Sprint on 0844 888 4115 (this number is 24/7).

Use standard Category B packaging available in the laboratory

**Please note the drivers are not local. The PDP driver will take 2-3 hours to get here. Please bear this in mind if you are asked to do this on call- you will need to be here to hand the package to the driver so time your arrival to coincide with this.**

**For City Sprint – these are based in Plymouth so allow at least 1 hour for courier to get here.**