## Objective

To describe the role of, and to specify the services provided by Microbiology Services Laboratory – Virology

### Changes in this version

Replaced the word “should” with “must” where relevant, updated section 7.8, 8, 10.1, removed the word “serum” where relevant.

Information added to section 5.2 to action CR77552 – volume of sample required

Information added to section 6 to action CR77094 – explanation of testing schedule

# Contents

UKAS MEDICAL

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Microbiology Services Laboratory – Virology
NHS Blood and Transplant
Charcot Road
Colindale
London
NW9 5BG

# 1 Introduction

## 1.1 About Microbiology Services Laboratory - Virology

Microbiology Services Laboratory (MSL) consists of Virology and Bacteriology based at NHSBT's Colindale site. MSL is part of the Testing and Scientific Development Team which sits in the Blood Supply Directorate of NHSBT. The role of MSL - Virology is to provide a specialist virology, microbiology serology and molecular service throughout NHS Blood and Transplant (NHSBT). Core areas of activity are:

- The investigation of blood and non-blood donors found reactive in the mandatory screening tests performed by NHSBT Testing laboratories
- Donation screening for the release of deceased donor tissue, surgical tissue, and stem cell products
- Testing of solid organ donors
- Responsible for the lot release testing of all new manufacturers' lots of serology and nucleic acid screening tests used within NHSBT for donation screening
- Providing organisation-wide advice, support and guidance in those aspects of the field of Transfusion & Transplantation Microbiology that it has expertise in

In addition to these core activities, the laboratory provides an advice and trouble-shooting service for any matters that may be virological in nature. The laboratory also plays a leading role in evaluations and validations of test kits and systems, and in procurement exercises involving serology and NAT systems for mandatory marker screening and confirmation.

For the MSL – Bacteriology User Guide refer to SPN201.

## 1.2 Blood Supply Directorate Responsibilities & Accountabilities

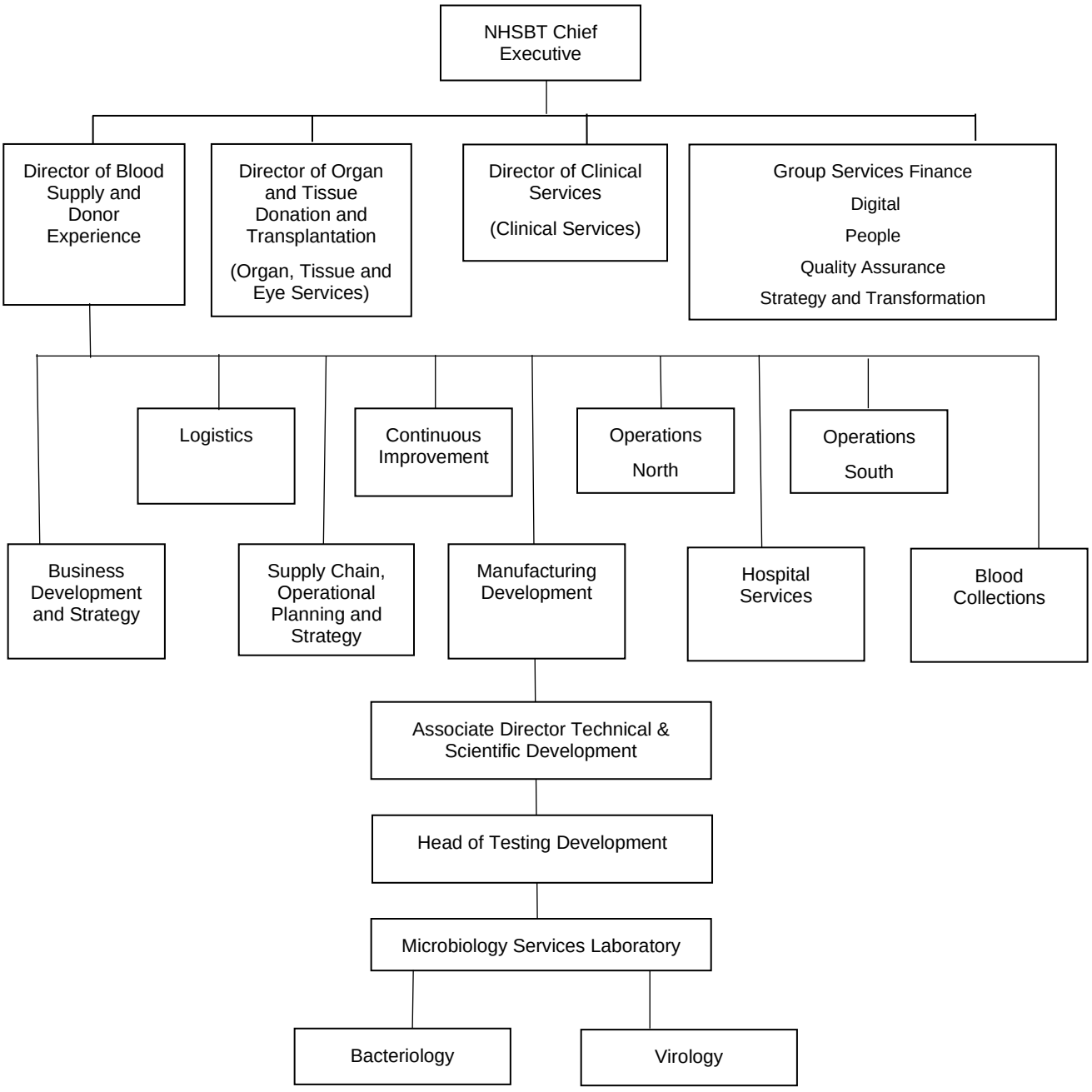
There are four main directorates: Blood Supply, Organ and Tissue Donation and Transplantation, Group Services and Clinical, which are supported by a further six directorates: Quality and Governance, Finance, Digital Data and Technology Services, Strategy and Transformation, Communications and Engagement/ Donor Experience and People.

The Director of Blood Supply delegates professional direction to individual associate/assistant directors, managers and heads of function.

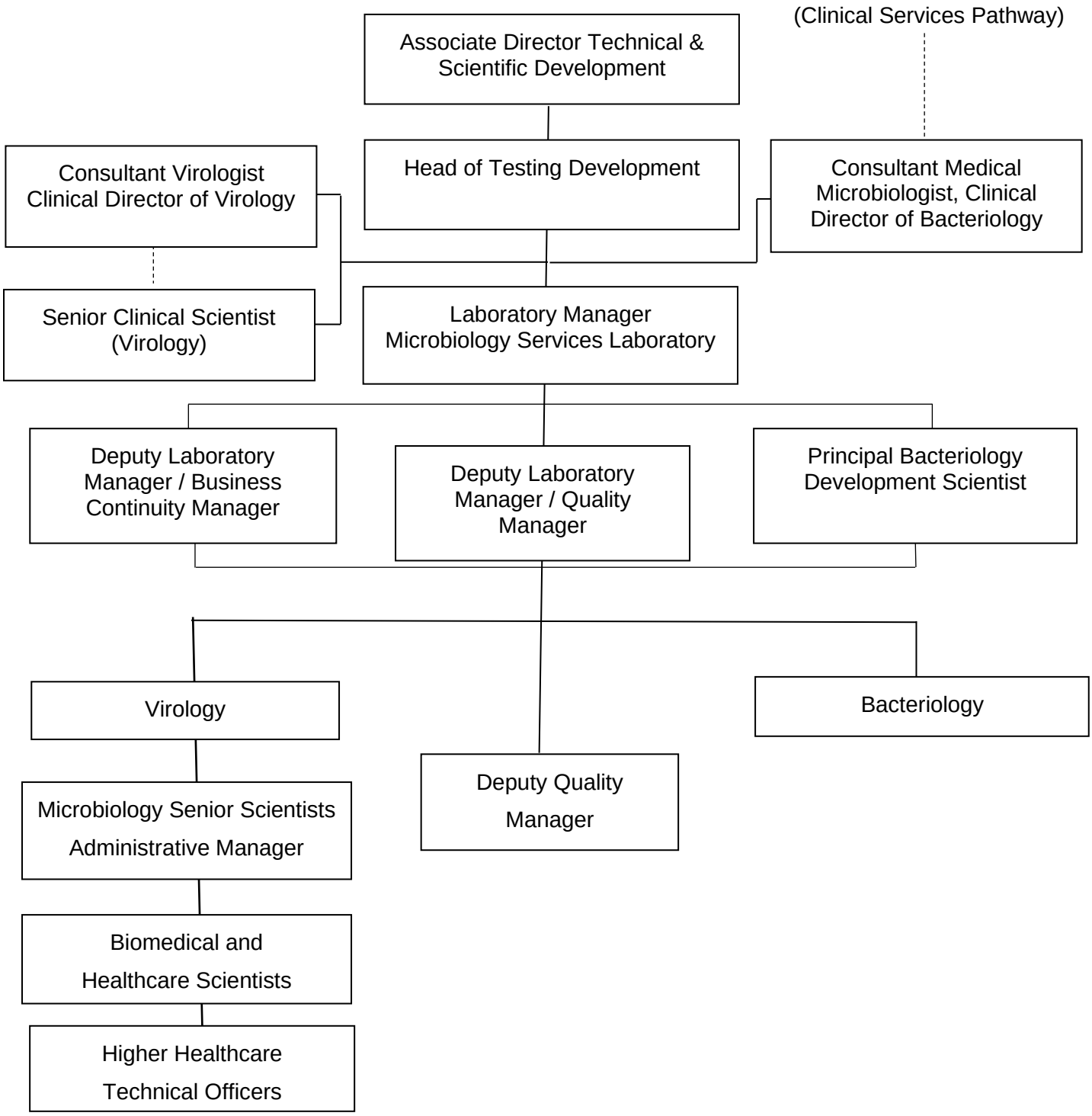
The Chief Medical Officer delegates clinical, nursing, scientific, and research and development direction to the respective individual associate medical directors.

Responsibility for Quality and Regulatory Compliance is delegated to Lead Quality Specialists who are accountable to the Assistant Director of Quality Assurance and Regulatory Compliance who is in turn accountable to the Director of Quality. Responsibility for the Quality Management System is delegated to regional Quality Assurance Managers.

### 1.2.1 Organogram: Relationship of MSL to overall structure of NHSBT



### 1.2.2 Structure of MSL and relationship to the Clinical Services directorate



# 2 Virology Staffing

The laboratory currently has the following clinical and senior scientific and administrative staff:

| | |
|---|---|
| Dr Ines Ushiro-Lumb | Consultant Virologist and Clinical Director of MSL - Virology |
| Mhairi Webster | Laboratory Manager – Microbiology Services Laboratory (Clinical Scientist) |
| Holly Sawyer (prev Ciesielczuk) | Deputy Laboratory Manager & Quality Manager – Microbiology Services Laboratory (Clinical Scientist) away on secondment until Nov 2026 |
| Pravesh Dhanilall | Deputy Laboratory Manager & Business Continuity Manager – Microbiology Services Laboratory (Biomedical Scientist) |
| Victoria Maddox | Senior Clinical Scientist (Fire Marshal) |
| Lynn Rossetti | Microbiology Senior Scientist (Biomedical Scientist, IBMS laboratory-based Registration Portfolio co-ordinator) |
| Iryna Andrade | Microbiology Senior Scientist (Biomedical Scientist) |
| Marita Smit | Microbiology Senior Scientist (Biomedical Scientist/ Fire Marshal) |
| Ruwanika Kothalawala | Microbiology Senior Scientist (Biomedical Scientist) |
| Mina Madhaparia | Microbiology Senior Scientist (Biomedical Scientist) |
| Nazow Azim | Microbiology Services Deputy Quality Manager, Delegated quality assurance advice (Biomedical Scientist) |
| Anne Dale | Administrative Manager |

# 3 Contact information

## 3.1 Telephone numbers

| | |
|---|---|
| Laboratory contact number | 020 8957 2816 |
| Office contact number | 020 8957 2733 |

### 3.1.1 Clinical enquires and advice

| | |
|---|---|
| Dr Ines Ushiro-Lumb | 07764 280297 |
| Microbiology Services Clinical Office | 020 8957 2988 |

### 3.1.2 Administration

| | |
|---|---|
| Anne Dale | 020 8957 2733 |

### 3.1.3 Senior Scientists

Victoria Maddox (Senior Clinical Scientist) 07790 315963

Marita Smit, Mina Madhaparia and Iryna Andrade (Sample Reception, Serology Screening, Serology Confirmatory Testing, including Lot Release Testing) – 020 8957 2816

Lynn Rossetti and Ruwanika Kothalawala (NAT screening and Molecular Reference including Lot Release Testing) – 020 8957 2722

#### 3.1.4 Laboratory Management

| | |
|---|---|
| Mhairi Webster | 020 8957 2896 or 07385 384868 |
| Holly Sawyer | 020 8957 2883 or 07385 388119 |
| Pravesh Dhanilall | 020 8957 2896 or 07385 388258 |

### 3.2 E-mail

The laboratory may be contacted by e-mail to NTMRL@nhsbt.nhs.uk. Individual Virology staff may be contacted by e-mail as follows: firstname.surname@nhsbt.nhs.uk. **For routine enquiries, the laboratory email is preferable as it is checked regularly throughout the day, individual staff may be absent and their emails may therefore not be read for a few days.**

### 3.3 Laboratory Opening Hours

The Virology laboratory core hours are 08:00 to 16:00 from Monday to Friday (excluding bank holidays when there will be no staff onsite), although the laboratory itself is usually staffed from 07:00 on most working days. Outside of these hours the office number (020 8957 2733) is re-directed to the laboratory answer machine (020 8957 2816) for the next working day.

# 4 Summary and guidelines

MSL - Virology focuses on undertaking the appropriate confirmatory investigations on the samples referred to determine the status of the donors from whom the samples originate. Virology is also responsible for product release screening of a range of non-blood donations, where the department has either the unique expertise or the specific/specialist facilities needed to undertake such screening; currently Virology is responsible for the screening of deceased tissue donors. This service is provided to both NHSBT and to any external laboratories that require such a service. Virology is also responsible for the lot release of all serological and molecular screening kits used within NHSBT.

The laboratory focuses on determining whether the donor is infected or in the case of blood donors, may potentially be suitable for reinstatement to the active donor panel. The laboratory performs donor/donation screening in a manner that mirrors, as far as can reasonably be achieved, that performed by the operational screening laboratories.

The provenance of referred samples is out of the control of the department, and thus its quality systems are based upon the assumption that each sample referred has been identified correctly by the referrer, stored and transported correctly, in accordance with Transportation of Dangerous Goods (TDG) regulations, and that the correct investigation(s) has(have) been requested.
In line with ISO 15189 requirements, our Users should ensure the following: sample collection activities should maintain sample integrity, the sample should be labelled for unequivocal identification of the donor/recipient and site (if applicable), each request form represents an agreement between the User and MSL and Users should periodically review their transport systems and notify MSL of any issues.

For all donation/donor investigations the original sample tubes are preferred and should be referred when available.

All samples referred to Virology are booked into the department's database and allocated a laboratory accession number which identifies the sample within Virology. All samples referred for confirmatory testing are booked individually even if the sample is an additional volume for a sample already referred, e.g., archive or an additional sample tube. A full audit trail of every sample received is maintained.

It is assumed that all NHSBT and other UK Blood Services laboratories referring screen reactive samples will follow extant Red Book (UK Transfusion Guidelines) instructions, performing initial and any repeat screening on the same sample.

Most samples referred for confirmatory testing will be from donations found to be repeatedly reactive on screening at some stage, and the confirmatory algorithms developed will reflect this. Nonetheless they will be broadly appropriate for any clinical diagnostic or other investigations performed. Additional or different investigations may be performed if reasonably required/requested by the referring laboratory and/or relevant clinical information is provided and if considered valid by senior Virology staff, or if dictated by circumstances.

Results and reports issued are authorised by the senior scientific staff of the laboratory. The exceptions are reports on confirmatory samples which are confirmed negative at the primary investigation stage, and non-blood screening reports where all the mandatory tests requested are negative (with no discretionary testing requested). These negative reports are generated automatically and not individually signed. Screening and confirmatory results on NHSBT blood and tissue donors are transmitted directly to Pulse. Users should be aware that different units of measurement are used for different assays, which may differ to what our Users are used to and could result in misinterpretation of results.

Virology reports the results of the confirmatory investigations performed on all NHSBT donor samples to Microbiology Services Surveillance. Otherwise, non-NHSBT confirmatory and screening results are reported back to the referring laboratory/site as entered on the referral form. If the report needs to be sent to a different location, that location should be entered onto the referral form as the referring site.

### 4.1 General Data Protection Regulation (GDPR)

NHSBT's policies on GDPR can be found here:

https://nhsbloodandtransplant.sharepoint.com/sites/InformationGovernance/SitePages/General-Data-Protection-Regulation.aspx

To obtain more information or ask specific questions about data held by NHSBT please contact customer services at customer.services@nhsbt.nhs.uk or the Data Protection Officer at dpofficer@nhsbt.nhs.uk.

## 5 Sample Quality Requirements for Screening Samples

Samples referred to MSL - Virology for the screening of non-blood donors/donations must be collected, stored and transported within timescales and temperatures as indicated in the individual Instructions for Use (IFU) for the tests requested. Failure to ensure this may compromise the accuracy and reliability of the screening results generated. All Virology users must be aware of the sample storage and shipping requirements and need to ensure that all samples sent to Virology are handled appropriately and arrive in the department in a timeframe that enables the laboratory to be able to undertake the screening requested before the age of the samples exceeds the assay storage times (Table 1).

It is an HTA requirement that all samples referred must include both the time and location of where the sample was drawn. Ideally this information must be included on the sample tube, however, if there is insufficient space the time and location must be included on the referral form instead.

All samples referred to Virology for screening must meet the requirements set out in Table 1 together with the following:

- Samples must be whole blood or separated plasma collected into EDTA. Samples for Molecular screening must be plasma.
- Samples must not be lipaemic or grossly haemolysed (Hb > 500mg/dL). However, Virology will always assess carefully any apparently unsuitable samples before rejecting them.

**Samples referred are deemed to have been handled by the referrer according to the sample storage and handling requirements in Table 1 and are thus considered to be suitable for testing**

Any sample not meeting the sample storage and quality requirements upon receipt in Virology, unless there is a formal written request for concessionary testing, cannot be tested. Samples received not meeting the sample age requirements, but for which a request for concessionary testing is to be made will be stored frozen, including red cells, to protect sample integrity whilst awaiting the completed concessionary documentation. Service users will be contacted regarding any issues with sample or request form received in Virology.

### 5.1.1 Table 1: Storage and shipping requirements for samples referred to Virology for screening

| Screening required | Sample storage requirements from point of bleed to testing (maximum time)[1] | Sample shipping requirements |
|---|---|---|
| Standard triplex molecular screen (HBV DNA, HCV RNA, HIV RNA), | Post-mortem:<br>8 days @ 2-8°C OR<br>14 days @ <-70°C<br><br>Pre-mortem:<br>13 days @ 2-8°C OR<br>15 months @ <-20°C | Samples may be shipped at between 2 to 25°C if:<br>Freshly collected<br>OR previously stored at 2-8°C<br>OR previously stored frozen<br>Must arrive within:<br>• 72 hours of draw for pre-mortem samples<br>• 24 hours of draw for samples collected post-mortem<br>If shipping will take longer than 24 hours, temperature-controlled shipping (2-8°C or frozen on dry ice as appropriate) is required.<br>Sample storage requirements must not be exceeded. |
| Procleix HEV assay,<br>WNV RNA,<br>CMV DNA, | Post-mortem:<br>8 days @ 2-8°C<br><br>Pre-mortem:<br>13 days @ 2-8°C | Samples may be shipped at between 2 to 25°C if:<br>Freshly collected<br>OR previously stored at 2-8°C<br>Must arrive within:<br>72 hours of draw |
| Malaria DNA | 10 days @ 2-8°C | Samples may be shipped between 2-25°C if<br>Freshly collected<br>OR previously stored at 2-8°C |

| | | |
|---|---|---|
| | | OR previously stored frozen<br><br>AND arrive within 24 hours<br><br>If shipping is longer than 24 hours, temperature-controlled shipping (2-8°C or frozen on dry ice as appropriate) is required.<br><br>Sample storage requirements must not be exceeded. |
| Standard serology screen (HBsAg, HIV Ag/Ab, HCV Ab[2], HTLV Ab, Syphilis Ab, HBc Ab) | 6 days @ 2-8°C | Samples may be shipped at between 2 to 25°C if:<br><br>Freshly collected<br><br>OR previously stored at 2-8°C<br><br>OR previously stored frozen<br><br>AND arrive within 24 hours<br><br>If shipping is longer than 24 hours, temperature-controlled shipping (2-8°C or frozen on dry ice as appropriate) is required.<br><br>Sample storage requirements must not be exceeded. |
| Malaria Ab, Toxo IgM, HAV IgM and total | 7 days @ 2-8°C | |
| anti-HBs, CMV IgG[2] and IgM | 14 days @ 2-8°C | |
| EBV VCA IgG, Toxoplasma total antibodies | 5 days @ 2-8°C | |
| EBV VCA IgM | 2 days @ 2-8°C | |
| *T. cruzi* Ab | Post-mortem:<br><br>7 days @ 2-8°C<br><br>Pre-mortem:<br><br>14 days @ 2-8°C | Samples may be shipped at between 2 to 25°C if:<br><br>Freshly collected<br><br>OR previously stored at 2-8°C<br><br>OR previously stored frozen<br><br>AND arrive within 72 hours<br><br>If shipping is longer than 72 hours, temperature-controlled shipping (2-8°C or frozen on dry ice as appropriate) is required. Sample storage requirements must not be exceeded. |

[1] Unless otherwise stated in Table 1, all plasma samples separated from the red cells may be stored indefinitely at ≤ -20°C prior to testing

[2] Plasma samples separated from the red cells may be stored at ≤ -20°C for ≤ 3 months prior to testing. A concession request must be made to test samples which have been stored at ≤ -20°C for >3 months. (See section 5.5)

## 5.2 Referred samples (Screening and Reference) – type and volume

The sample type for all testing within MSL – Virology is EDTA plasma, with the exception of HTLV I/II pro-viral DNA detection and for Malaria DNA detection that require whole blood collected into EDTA tube. Sample collection activities must ensure the integrity of the sample is maintained, where possible.

All sample tubes collected for the sample to be investigated must be referred. At least 2ml of plasma is required for most reference investigations; white cells may also be needed for some investigations. However, for more complex and lengthy investigations and for screening a larger volume of sample, a full EDTA tube is required (at least 8ml whole blood). Exceptions to this volume requirement are made where the sample has come from a deceased paediatric or low weight (< 30kg) donor where a low volume sample can be tested. An aliquot of the sample from such a donor will be diluted for molecular testing to preserve sample volume to allow full mandatory marker testing (both serology and molecular).

All samples referred must be in good condition, free from gross haemolysis, non-lipaemic and be compliant with the requirements set out in Table 1. Unsuitable samples will not be tested.

Regarding HTA licensable referrals, it is the referrers responsibility to be aware of and comply with guidance re: haemodilution in HTA-GD-020 HTA guide to Quality and Safety Assurance for Human Tissue and Cells for Patient Treatment section 2. The haemodilution level of such referrals must be recorded on the referral paperwork.

## 5.3 Completion of Virology referral form

FRM1208 must be used to refer NHSBT blood donor samples from Testing Manchester and Filton; FRM7890 must be used to refer all other blood and non-blood donor samples; FRM5025 must be used for OTDT routine screening samples, FRM7029 must be used for Scottish OTDT samples and FRM7233 can be used to refer samples for specialist, non-routine clinical investigations. The sample request form represents an agreement between the service User and MSL. Previously agreed alternative paperwork for non-NHSBT sites, must be completed for each sample referred to Virology (one form for each investigation required for confirmatory referrals). Samples not accompanied by their original paperwork or accompanied by incomplete, incorrect, illegible, or otherwise poor-quality paperwork, will not be processed until the correct and properly completed original paperwork has been received.

The referral form contains boxes to include patient name and hospital number which may be used when referring routine clinical samples or where the referrer considers this additional information necessary. NHSBT samples are booked using the donation number and donor ID as primary identifiers.

The referrer must complete the referral form, entering the following information as the minimum requirement:

- Investigations required
- Referring site

- Donation/sample number
- Donor ID (number or full name)
- Date sample bled
- Time sample bled *
- Location of where sample was bled *
- If donor has received blood products/components
- Pre-transfusion or Post-transfusion sample
- If deceased donor, whether the sample was collected pre- or post-mortem
- If sample has been stored frozen until despatch to Virology
- Name and contact details of the person referring the sample
- Any other information relevant to the screening required or the sample handling

Blood donation and Tissue donation samples (where possible) require a barcoded G number on the tubes.

Non-barcoded NHSBT/ non-NHSBT samples requires 3 identifiers that match on tube and paperwork.

A minimum of 3 identifiers are required on the sample tube, 3 identifiers can be; DOB; ODT number; hospital number; NHS number, donor/patient name, donation number, donor id number and date of birth.

The sample tube details must be unequivocally matched to the donor details on the referral form.

Any discrepancies in the above may result in a delay in testing.

* It is an HTA requirement that all samples referred must include both the time and location of where the sample was drawn. Ideally this information must be included on the sample tube, however, if there is insufficient space the time and location must be included on the referral form instead.

## 5.4 Despatch of Samples to MSL - Virology

The referral of samples to Virology is the responsibility of the referrer. Samples must be shipped in accordance with extant NHSBT and UK HSE regulations and with the relevant Transportation of Dangerous Goods (TDG) regulations.

Samples must be despatched under conditions which ensure that they meet the storage and shipping requirement within Table 1. It is the responsibility of the referrer to meet this requirement.

It is the responsibility of the referrer to ensure that, if required, mechanisms are in place to confirm delivery of samples to the Virology. Virology cannot routinely confirm receipt of samples in the laboratory. Service users must periodically review their sample transport processes and notify MSL of any issues/findings.

Samples received outside of Virology working hours and at weekends will be stored as indicated on the outer packaging. If samples will arrive outside of normal working hours' storage instructions must be present on the outer packaging.

Sample despatch must consider time for transport and likely arrival time in Virology to ensure that sample storage and shipping requirements are adhered to.

Samples must not be dispatched if they are likely to be received in Virology after 12:00pm on a Friday unless they will still be within the sample storage times outlined in Table 1 on the following Monday.

MSL-Virology DX details are - DX number: 6531000 Exchange: Colindale 92 NW

### 5.5 Concessionary testing if sample storage conditions have not been met

If the sample storage conditions outlined in Table 1 have not been met, the sample may still be tested if the related product(s) is/are critical for patient care and no other samples are available. If the sample has been stored under the appropriate conditions and the referrer understands that the age of the sample exceeds that stated in the assay IFU, the referrer may request testing under a concession. Within NHSBT a concessionary process has been defined and must be followed (SOP5224). External customers may utilise the NHSBT concessionary procedure or may initiate their own process. In all cases, however, written evidence of the request (via email) for concessionary testing must be provided to Virology prior to any testing taking place. In addition, samples referred for concessionary testing will still require to be reviewed by Virology staff to ensure that the sample is generally suitable for testing in terms of volume, general condition etc.

Although a concessionary testing route is available to ensure that there is a mechanism for dealing with irreplaceable samples from donors of products of high clinical value and in limited supply, it is the responsibility of the referrer to ensure their samples are handled such that this route rarely needs to be utilised.

### 5.6 Additional/Further Examinations

Requests for additional/further examinations will be accepted by e-mail only (NTMRL@nhsbt.nhs.uk) providing that there is sufficient volume remaining. Archived samples are stored at -40°C for at least 10 years.

## 6 Testing services available

Virology currently offers a range of confirmatory and screening services both serological and molecular. The core services offered are described below but the department may be able to provide a wider range of additional tests as required, to support the needs of stakeholders. Please contact the Laboratory Manager, or Deputies, or Senior Clinical Scientist to discuss specific needs.

All laboratory investigations will normally follow the algorithms formulated for each infectious agent. The basis of the confirmatory algorithms is the initial use of alternative assays followed by a larger range of other assays, including blots and line assays, to determine the donor's true status.

Although the defined algorithms are followed, it is recognised that the investigations performed within Virology may involve different assays and procedures to reach a valid scientific conclusion. Such investigations cannot be totally pre-determined, and some flexibility is necessary and expected, provided that it is scientifically valid.

Serology Screening is performed daily, and NAT screening is performed 4-5 days/week depending on sample numbers. Primary and Secondary confirmatory tests are batched and performed weekly. Prioritisation is dependent on number of referrals and any requests for urgent testing. If urgent testing is performed this may impact the planned schedule of tests

## 6.1 Confirmatory testing

Confirmatory testing for HBV, HBc, HCV, HIV, syphilis, HTLV, CMV, WNV, HEV, Malaria, and Chagas' disease is performed on samples referred by NHSBT Testing or other screening laboratories. The aim of the confirmatory testing performed is primarily to determine the true status of the donor and thus be able to either refer the donor for clinical intervention if infection is confirmed or manage the donor with the aim of re-instatement to active status if not confirmed.

The initial testing of samples referred for confirmatory testing will normally follow the defined algorithms and will be performed within a formal quality system appropriate for such a laboratory and such activities. Samples will be investigated as appropriate, depending on the reason for referral. The results generated will be interpreted and the appropriate conclusions drawn. Confirmatory testing will utilise both serological and molecular investigations as required and appropriate.

## 6.2 Donor/donation screening

MSL Virology carries out serological and molecular screening of all NHSBT tissue donations from deceased donors, some surgical tissue and stem cell donations, and HEV NAT (and discretionary testing where applicable) on all NHSBT solid organ donations. MSL facilitates HHV8 screening for OTDT samples performed at an external laboratory. Virology provides both serological and molecular screening for a number of external users. This screening includes the mandatory donor/donation screening, and any additional discretionary screening required (see current UK Transfusion Guidelines and current SaBTO guidelines which detail the screening required).

All samples referred for serological screening will be screened using the assay or assays selected by Virology unless previously agreed with the referring laboratory. These assays will have been approved by the NHSBT Kit Evaluation Group (KEG) for use for donor/donation screening within NHSBT. The current serology platform used for most of the donor/donation screening within Virology is the Architect i1000SR system, supplemented with specific plate-based enzyme immunoassays or other automated platforms. The appropriate quality controls are included with each batch of testing performed.

The current molecular platform used for routine molecular donor/donation screening within Virology is the Grifols Panther system, running the Ultrio Elite triplex assay for HBV, HCV, HIV nucleic acids, and Procleix HEV assay for HEV RNA. In addition, validated commercial and in-house techniques for HTLV proviral DNA, CMV DNA, Malaria DNA, WNV RNA, HEV RNA and HBV quantification are also used.

**Samples required**: at least one full original EDTA tube (appropriate to the age/size) of the donor, compliant with the requirements set out in Table 1 and accompanied by the properly completed referral form. If multiple markers are requested, more than one full EDTA tube must be referred to ensure sufficient sample volume for testing. A lower volume of 800µl plasma can be accepted when the referral form indicates that the donor is a deceased paediatric or low weight (<30kg). Under these circumstances the sample for molecular testing will be diluted however the sensitivity of the tests will be reduced.

## 6.3 Post-transfusion infections

All actual or suspected cases of post-transfusion viral or parasitic (Malaria/Chagas disease) infection reported to NHSBT are investigated by Virology. Investigations are designed to firstly determine if the blood components or tissue/cell products transfused could have been the source of infection and secondly to try to determine how or why the routine donation screening didn't identify the index donation. Archive index samples from the implicated donations are tested for the presence of viral nucleic acid (for appropriate infectious agents) and/or by the appropriate serology if sufficient sample remains.

Samples from previous donations from the implicated donors are investigated serologically depending upon the outcome of the nucleic acid testing and the screening results for index donations.

**Samples required**: as defined at the outset of the investigation, according to the national post transfusion infection (PTI) guidelines, with a completed referral form including the PTI reference number.

### 6.4 Lot release testing

See section 11.

### 6.5 Miscellaneous screening

A range of miscellaneous screening tests may be performed for either NHSBT and/or non-NHSBT users when infectious disease screening/testing support is required. In all cases the requirements are agreed in advance between Virology and the referring laboratory/organisation, and the results reported directly to the referrer.

**Samples required**: sample(s) of sufficient volume, compliant with the requirements set out in Table 1 with a completed Virology, or previously agreed alternative, referral form.

### 6.6 Measurement of Uncertainty

Measurement of Uncertainty is calculated for the assays performed and is available upon request.

### 6.7 Definitions of final confirmatory result interpretations

**Positive**

Clear and irrefutable evidence of either the presence of an infectious agent or of previous infection. Generally, a concluded result from several individual assays used to investigate the true status of an individual.

**Reactive**

Reactive screening test, usually repeatable, that may determine the fate of a donation, but which requires additional (confirmatory) testing to determine whether the reactivity reflects true infection.

**Negative**

No evidence of infection or presence of a specific marker with the tests performed.

**Indeterminate/Inconclusive**

Some evidence indicating possible exposure, but insufficient to confirm infection. Further samples may be requested to try to determine donor status.

## 7 Investigations currently performed/available

### 7.1 UKAS ISO 15189 accreditation

Refer to section 9.1 for details of accreditation

All markers are in scope of the UKAS accreditation (unless denoted with a *).

Those markers denoted with a * are not currently in scope and an extension to scope has been or will be requested, except for those tests used for research purposes only.

### 7.2 Hepatitis B virus

HBsAg

anti-HBc (Total/IgM)

HBeAg

anti-HBe

anti-HBs (quantitative and semi-quantitative)

HBV DNA (qualitative and quantitative)

HBV genotyping and sequencing available as required via UK Health Security Agency

### 7.3 Hepatitis C virus

anti-HCV

anti-HCV blot/line assay

HCV Ag/Ab

HCV RNA (qualitative)

HCV genotyping available as required via UK Health Security Agency

### 7.4 Human Immunodeficiency Virus

anti-HIV 1+2+gpO

HIV Ag/Ab

HIV RNA (qualitative)

HIV Ab avidity via UK Health Security Agency

### 7.5 Syphilis

anti-TP (Total /IgM)

anti-TP blot/line assay

TPHA*

RPR

## 7.6 Human T cell leukaemia virus

anti-HTLV I/II

anti-HTLV I/II blot/line assay

HTLV I/II pvDNA (qualitative)

## 7.7 Others

Antibodies to CMV (total/IgG/IgM) – Liaison assays not within UKAS scope*

Antibodies to EBV [VCA/EA] (IgG/IgM)

Antibodies to Toxoplasma (total Ab/IgM)

Antibodies to *T. cruzi* (IgG)

Antibodies to malaria [*falciparum* and *vivax*] (total Ab)

Antibodies to malaria [*falciparum*] (IgG)

Antibodies to WNV (IgG/IgM) via UK Health Security Agency

Antibodies to HEV (IgG/IgM)

Antibodies to HAV (total Ab and IgM)*

CMV DNA (qualitative)*

Plasmodial DNA - separate qualitative assays for *falciparum* and combined *vivax/ovale/malariae/knowlesi*

WNV RNA (qualitative)

HEV RNA (qualitative and quantitative)

Antibodies to HHV8 and/or HHV8 DNA via UK Health Security Agency (for organ donors only)

Tropical virus screening* (Zika, Chikungunya, Dengue) available on request after discussion with the Consultant Virologist and provided via UK Health Security Agency

Samples requiring genotyping, sequencing, or avidity testing are referred to the Virus Reference Department at UK Health Security Agency

## 7.8 Sample Type

The sample type for all tests (except HTLV I/II pro-viral DNA and Malaria DNA detection) is EDTA plasma. The tests for HTLV I/II pro-viral DNA and Malaria DNA detection require whole blood collected on EDTA. Virology is accredited under ISO 15189 by UKAS to perform testing on plasma (or whole blood for HTLV and Malaria DNA) only.

# 8 Reporting

Virology results are reported by hard copy and/or electronic transfer to Pulse depending upon sample type and source.

| Sample type | Result type | Source | Report type |
|---|---|---|---|
| Reference | Primary negative, some anti-HCMV | NHSBT | Direct electronic transfer to Pulse, and hard copy when required |
| Reference | Primary reactive, some anti-HCMV | NHSBT | Hard copy and direct electronic transfer to Pulse |
| Reference | All | Non-NHSBT | Hard copy only |
| Screening | All | NHSBT | Direct electronic transfer to Pulse, and hard copy when required |
| Screening | All | Non-NHSBT | Hard copy only |
| Other | All | NHSBT | Hard copy. Direct electronic transfer to Pulse if NHSBT sample and Pulse set-up to receive results |
| Other | All | Non-NHSBT | Hard copy only |

The printed reports contain the sample identifiers, date bled and date received, lists the tests performed and the results obtained. Where appropriate, numerical optical density values are expressed as signal/cut-off ratios, cut-off/signal ratios for competitive assays, and in most cases a ratio ≥1 (except Vircell Chagas where a ratio of >=11.0 is positive) is positive. Results generated on the Liaison XL are expressed and interpreted according to extant assay instructions. Non-numerical results are expressed as positive/negative/indeterminate as appropriate.

The individual test results are given in accordance with the manufacturer's instructions. Screening results are reported directly based on the specific results obtained. Reference results include a final concluded result based upon the overall picture from all the individual test results and which also takes into account any relevant clinical history/other information provided.

The primary sample type referred to MSLV must be plasma/whole blood; therefore, no comment on this is made in the report. However, in the case of a serum sample being referred for testing where no plasma/whole blood sample is available, this will be noted in the comment section of the report along with a statement that the tests performed are not UKAS accredited.

Unless specifically requested interim reports will not be issued.

In all cases there is no need to enquire about results unless there is an urgent clinical need.

Service User(s) will be informed that an amended report is being issued and the reason for the amendment. Details of the amendment will be included as a comment in the report.

### 8.1 Turnaround time

The normal target turnaround times, from receipt of sample in the laboratory by Virology to reporting of results are as follows. Please note that these times are based upon referral for a single investigation type (i.e., reference or screening).

#### 8.1.1 Reference investigations:

99% of results within 20 working days of receipt of sample in VIROLOGY

#### 8.1.2 Screening (serology):

99% of results within 8 working days of receipt of sample in VIROLOGY

#### 8.1.3 Screening (molecular):

99% of results within 15 working days of receipt of sample in VIROLOGY

For samples referred on by Virology to an external laboratory the turnaround time will be based on that laboratory's stated turnaround time and the marker/infectious agent under investigation. All efforts are made to expedite such samples, but this is dependent upon the workload and turnaround times of the external investigating laboratory.

Monitoring of turnaround times is performed as part of the laboratory's standard quality indicators (key performance indicators). MSL continue to calculate 90% TAT for our own identification of laboratory delays, trends and actions.

### 8.2 Reporting routes

Standard reporting process is to send reports by e-mail (to secure address). Download of results to Pulse is performed at the same time as the reports are authorised.

**Verbal reports are not provided.**

### 8.3 General report enquiries and queries

There may be occasions when referring sites may wish to know the status of investigations, chase overdue results or other information regarding the samples referred. Please contact Virology by email as and when appropriate at ntmrl@nhsbt.nhs.uk

## 9 Accreditation

### 9.1 ISO 15189

MSL is a UKAS accredited medical laboratory No. 8783. The Schedule of Accreditation is available here:

https://www.ukas.com/wp-content/uploads/schedule_uploads/00007/8783-Medical-Single.pdf

### 9.2 MHRA

The laboratory is subject to inspection by the MHRA as part of the Blood Safety and Quality Regulations 2005 and Blood Establishment Authorisation (BEA):25335 for the Colindale site. The laboratory was last inspected by the MHRA on 19 – 22 June 2023.

The laboratory is named on MIA (IMP) 25224 license from MHRA.

### 9.3 HTA

The laboratory is subject to inspection by the HTA as part of the HTA licence for NHSBT. The laboratory was last inspected by HTA in March 2024.

### 9.4 NHSBT audits

The laboratory is subject to NHSBT internal audit (Self Inspection). The outcomes of these may be obtained from the Quality Assurance Department at NHSBT Colindale. The last Quality Self Inspection – Colindale ISO 15189 was in January 2026 There are regular monthly Quality reviews by the local Quality Assurance Department.

### 9.5 Internal audits

The laboratory has an internal audit schedule that meets the requirements of ISO 15189.

## 10 EQA and IQA

### 10.1 EQA

The laboratory is registered with the UK NEQAS for Virology (UKHSA Colindale). The UKHSA scheme includes:

ANTI-HBS DETECTION, HEPATITIS B SEROLOGY, HEPATITIS B DNA QUANTIFICATION, EBV DETECTION, HEPATITIS C SEROLOGY, HIV SEROLOGY, SYPHILIS SEROLOGY, BLOOD DONOR SCREEN, TOXOPLASMA SEROLOGY, HEV SEROLOGY, MALARIA DNA, PARASITE SEROLOGY

The laboratory is registered with Quality Control for Molecular Diagnostics (QCMD). The QCMD scheme includes HCV RNA, HIV RNA, HBV DNA, HEV RNA, WNV RNA, CMV

The laboratory is registered with Lab Quality. The Lab Quality scheme includes: CMV serology (IgG, IgM), HTLV serology, HAV serology.

In-house EQA for Malaria. This service is also provided to the Testing sites at Filton and Manchester, and also to the other UK Blood Services.

EQA for HTLV DNA detection is provided by an in-house scheme provided by Imperial College London

### 10.2 IQA

The laboratory undertakes IQA on a weekly basis.

## 11 Lot release testing

Lot release testing of all new manufacturers lots of screening kits supplied to the NHSBT (serological and molecular) is the responsibility of MSL - Virology. This activity is either performed by Virology or by one of NHSBT's Testing Laboratories using the panel(s) supplied by Virology. In all cases the results are analysed by Virology and the outcome determined. A release letter is sent to the supplier and then posted onto the Intranet in the Blood Supply section.

Under normal circumstances no action is required from the Testing sites, but in the event of any problems with the site-based delivery acceptance testing, any national procedures must be followed, and Virology contacted to discuss the problem and possible solutions.

# 12 Complaints

Any complaints or other issues identified with the results provided or any other aspects of the service of the MSL - Virology must be addressed in the first place to the Laboratory Manager, Microbiology Services Laboratory in writing.

Internal (NHSBT) complaints must be made using the national Quality Management System on Q-Pulse.

All formal complaints, not logged on the national QMS, will be acknowledged within 48 hours of receipt of the written complaint, logged on to the national QMS and then investigated. A written response will be provided within 14 days of receipt of the written complaint. Complaints logged on the national QMS will be managed through Q-Pulse.

In the unlikely event of any dissatisfaction with the investigation of the complaint, or the response received, representation must then be made to Amanpreet Dhesi, Associate Director - Manufacturing Development at the following address:

Amanpreet Dhesi

Associate Director – Technical and Scientific Development

NHS Blood and Transplant

Charcot Road

Colindale

London

NW9 5BG

Email: amanpreet.dhesi@nhsbt.nhs.uk

# 13 Service Level Agreements

## 13.1 Establishment of Service Level Agreements

A Service Level Agreement (SLA) is drawn up between Virology and any establishment which purchases a service(s) from Virology. The SLAs are drawn up and the original signed copy kept by the NHSBT Contracts Department. The index of SLAs with external users is maintained by the Contracts Department.

## 13.2 Review of service agreements

The review period is specific to each Service Level Agreement (SLA). It is the responsibility of the NHSBT Contracts Department to notify the Laboratory Manager in advance when a contract requires review or renewal. Virology are responsible for ensuring that the content of the technical specification for each SLA is appropriate and up to date.

Should any changes/amendments be required to these contracts mid-term then communication takes place between Virology and the relevant establishment(s). The NHSBT Contracts Team is instructed to make the necessary changes and a revised SLA is issued.

## 14 Contingency

MSL – Virology has a Business Continuity Plan which details the department's response to critical incidents which threaten service delivery. There are contingency measures in place to ensure that testing can continue by either using alternative platforms or assays within the department, or by sending samples to Manchester Testing for living donors or other UK Blood Services for deceased donor testing. The latter is covered by an SLA. In the event of a major incident that impacts on all service delivery (e.g., a pandemic) the services provided by Virology will be prioritised in consultation with Users.