Objective

To describe the role of, and to specify the services provided by Microbiology Services Laboratory - Bacteriology.

Changes in this version

Confirmed CR44294 incorporated at last review. Implemented CR50100, CR52647, CR54390, CR54509, CR54838 and CR55848. Tests within UKAS scope of accreditation have been indicated with an *. Expanded information of different testing performed for clarity. Updated staffing. Added in reference to GDPR policies.

Contents

1. INTRODUCTION

The Microbiology Services Laboratory (formerly National Transfusion Microbiology Laboratories) consists of Bacteriology (formerly National Bacteriology Laboratory) and Virology (formerly National Transfusion Microbiology Reference Laboratory), based at NHSBT's Colindale site. The Microbiology Services function is part of the Blood Supply directorate of NHSBT. The role of Bacteriology is to provide a specialist national bacteriological service throughout NHSBT. Core areas of activity are: -

- Environmental monitoring of Processing Laboratories and cleanroom facilities with identification of action level/out of specification isolates and follow-up investigative work
- Validation service for aseptic processing, disinfection and media
- Bacteriological investigation of patient adverse reactions to transfusion
- National monitoring of the bacterial contamination rate of blood components and tissues
- Bacterial screen testing of tissues for transplantation
- Bacterial screen testing of cord blood and stem cell samples
- Bacterial screen testing of autologous and allogeneic serum eyedrops
- Investigation of bacterial contamination of blood components and reagents
- Lot release testing of media for use within NHSBT
- National confirmatory and reference work for the bacterial screening of platelets.

In addition to these core activities, the laboratory provides an advice and trouble-shooting service for any matters that may be bacterial in nature. The laboratory also plays a leading role in disinfection, from donor arm to disinfection of facilities or equipment. Investigations are continually undertaken to achieve best practice, particularly in relation to testing tissues, cord blood, stem cells and preventing/reducing bacterial blood product transmissions.

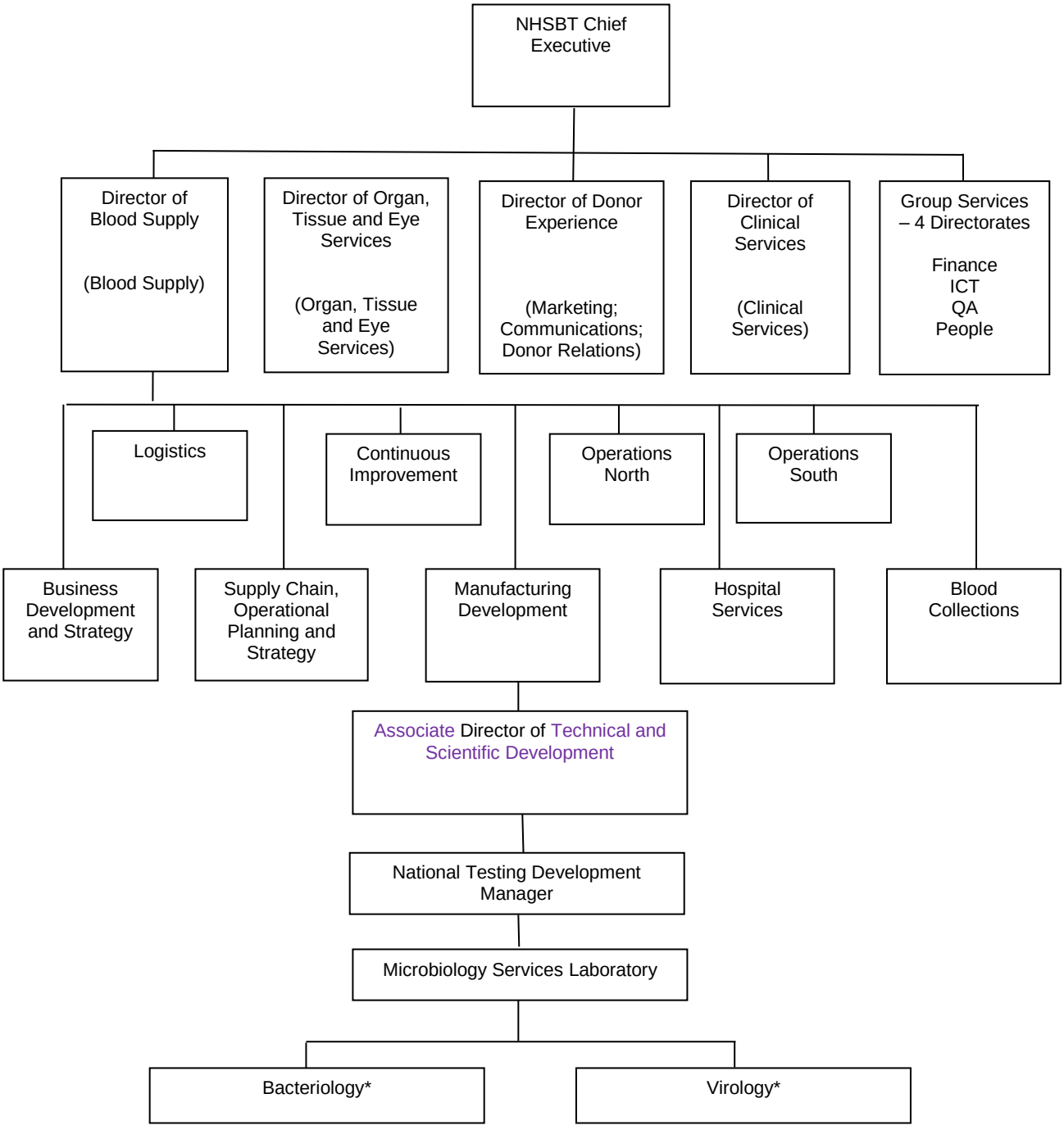
1.1. Blood Supply Directorate Responsibilities & Accountabilities

Microbiology Services Laboratory sits within the Blood Supply Directorate of NHS Blood and Transplant.

The Director of Blood Supply delegates professional direction to individual assistant and associate directors, managers and Heads of Function. Responsibility for Quality and Regulatory Compliance is delegated to the Lead Quality Specialists who are independently accountable to the Assistant Director of Quality Assurance and Regulatory Compliance. They, in turn, are accountable to the Director of Quality. Responsibility for the Quality Management System is delegated to Regional Quality Assurance managers, who are independently accountable to the Director of Quality. The Assistant Director of Health and Safety, who is independently accountable to the Director of People Directorate, provides professional health and safety advice. Professional financial management advice is provided by the Finance Business Partner team, which is divided into two divisions, each directed by a Divisional Finance Director. The Divisional Finance Directors are accountable to the Finance Director.

This group constitutes the Senior Management Team responsible for determining overall national policy, strategy and plans applied to the Directorate and NHSBT business as a whole.

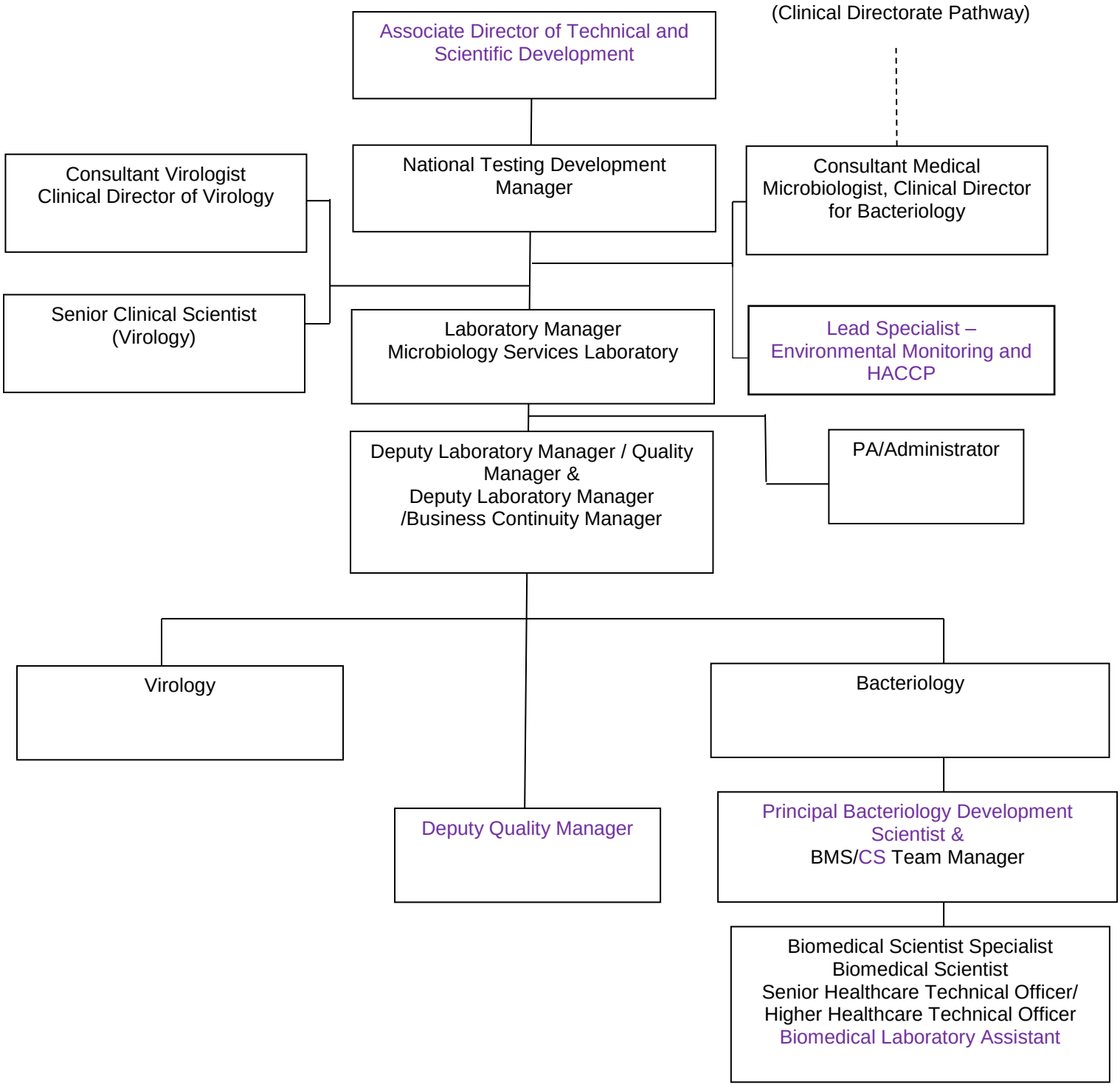
1.2. Organogram: Overall structure of NHSBT and relationship with MSL



Note *
Bacteriology – Previously National Bacteriology Laboratory
Virology – Previously NTMRL

1.3. Organisation within the Microbiology Services Function

The Function is headed by the Assistant Director of Technical and Scientific Development and has a management team responsible for the development, planning and delivery of its services in accordance with the policies, strategy and plans determined by National Management.



2. BACTERIOLOGY STAFFING

The laboratory currently has the following clinical, scientific, and technical staff:

Dr Pasco Hearne	Consultant Microbiologist
Mhairi Webster	Laboratory Manager – Microbiology Services Laboratory (Clinical Scientist)
Holly Ciesielczuk	Deputy Laboratory Manager & Quality Manager – Microbiology Services Laboratory (Clinical Scientist)
Pravesh Dhanilall	Deputy Laboratory Manager & Business Continuity Manager – Microbiology Services Laboratory (Biomedical Scientist)
Jennifer Bearne	Principal Bacteriology Development Scientist (Biomedical Scientist/Fire Marshal/First Aider)
Becky Clare	Lead Specialist – Environmental monitoring and HACCP
Yvonne Wilson	Programme Coordinator - HACCP & Environmental Monitoring
Nazow Azim	Microbiology Services Deputy Quality Manager, Delegated quality assurance advice (Biomedical Scientist)
Dora Mangraviti	BMS Team Manager* (Biomedical Scientist)
Anjana Roy	BMS Team Manager* (Clinical Scientist)
Adrian Lyons	BMS Team Manager* (Biomedical Scientist/Health & Safety Lead Co-ordinator)
Stephanie Worral	BMS Team Manager* (Biomedical Scientist)
Komal Khatri	BMS Team Manager* (Biomedical Scientist/Fire marshal/Mental Health Champion)
Ania Zuczkowska	BMS Team Manager* (Biomedical Scientist)
Chris Guttridge	Biomedical Scientist (Fire Marshal/First Aider)
Mohammed Zaman	Biomedical Scientist (Fire Marshal)
Joshua Obimma	Biomedical Scientist
Ernesta Kaktyte	Biomedical Scientist
Vivian Eze	Biomedical Scientist
Josip Krpan	Higher Healthcare Technical Officer
Alison Collins	Higher Healthcare Technical Officer
Chanka Ranatunga	Biomedical Laboratory Assistant
Yusra Hagos	Locum Healthcare Scientist
Mfon Asuquo	MSL-Bacteriology Administrator

*Please note, this is equivalent to Senior Scientists in MSL-Virology

3. CONTACT INFORMATION

Laboratory Manager 020 8957 2896
Mhairi Webster 07385 384868

Deputy Laboratory Manager / Quality Manager 020 8957 2883
Holly Ciesielczuk 07385 388119

Deputy Laboratory Manager / Business Continuity 020 8957 2896
Pravesh Dhanilall 07385 388258

Consultant Medical Microbiologist 07392 315813
(Joint Clinical Director for Bacteriology)
Dr Pasco Hearn
Please note: Available by email/phone on Thursday mornings.

Principal Bacteriology Development Scientist 07385 387950
Jennifer Bearne

Administrator Mfon Asuquo	020 8957 2787
General Laboratory	
Sample Reception	020 8957 2715
Senior Scientific Staff	020 8957 2963 020 8957 2959
PS/TTI bench	020 8957 2751
Validation / Research and Development	020 8957 2913

Laboratory enquiries (e-mail) baccol@nhsbt.nhs.uk

All Bacteriology staff have access to emails addressed to the National Bacteriology Lab Colindale. Use of the group email is preferable to ensure a timely response to general enquiries.

Individual staff may be contacted using the template firstname.surname@nhsbt.nhs.uk

For clinical calls please contact Dr Pasco Hearn and Dr Su Brailsford in the first instance. For urgent calls where there is no answer, please contact the Microbiology Services Clinical Office on 0208 957 2988 (open hours are 08:30 - 17:00 Monday - Friday)

Laboratory results will not be given over the telephone.
Printed reports will be issued electronically through Hematos or via email.

Queries relating to laboratory results must be referred to a BMS Team Manager for a response. If a BMS Team Manager is unavailable, queries should be referred to the Laboratory Manager, Deputy Laboratory Manager or Senior Clinical Scientist(s).

MSL-Bacteriology verbal communications with other NHSBT departments, hospitals and external institutions, relating to patients and donors or other laboratory matters, must be documented in a follow up email. The departmental email address baccol@nhsbt.nhs.uk must be included in the cc line.

Information relating to donors and patients and any paper-based investigation files will be held in MSL according to POL2 (Confidentiality and Data Protection Policy). Computer databases are password-protected. Information Governance training is mandatory for all staff.

NHSBT's policies on GDPR can be found here:
https://nhsbloodandtransplant.sharepoint.com/sites/InformationGovernance/SitePages/General-DataProtection-Regulation.aspx
and here:
https://peoplefirst.nhsbt.nhs.uk/my-personal-data.htm
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.

4. WORKING HOURS

The laboratory's core working hours are from 08:00 to 16.00 Monday to Friday. The laboratory also provides Saturday cover to receive samples sent by overnight transport services (skeleton cover).

5. SERVICES OFFERED

The laboratory offers a wide range of services, which are dependent upon service users providing appropriate samples as described in further detail in the sections below. A table summarising test request, transport conditions, FRM required, and SOPs is listed here for ease.

The following conditions have the potential to significantly impact on performance of the required examination process or the interpretation of results.

- Improper packaging or transport storage conditions
- Unlabelled or mislabelled samples, including mismatching, incomplete or missing paperwork
- Leaking or damaged samples
- Delays between sample collection and receipt at Bacteriology, including delays in transit.
- Insufficient sample volume

It is appreciated that samples referred to Bacteriology are usually unrepeatable. Therefore, samples that fall outside the specified criteria will be salvaged wherever possible, unless they pose a risk to the health and safety of Bacteriology staff. For all cases, the referring laboratory will be contacted, advice will be sought from a senior member of staff, and a Quality Incident Report (QIR) will be raised by MSL.

Further information regarding Bacteriology sample acceptance or rejection can also be found in the 'Sample Acceptance and Rejection' policy, POL58.

Test request	Transport conditions	FRM for test request	MSL documents for procedure
Environmental monitoring	Plates must be within individual specimen bags & secured with an elastic band Within 24 hours at ambient temperature or cooled conditions. If this will fall over a weekend or bank holiday, fridge at 2-8°C until next available transport.	FRM874 (controlled rooms) FRM875 (Grade B rooms) FRM876 (cleanrooms) FRM877 (contact plates) FRM878 (SCD bench) FRM879 (settle plates) FRM880 (SCD swab plates) FRM3351 (swab plates) FRM1165 (isolate)	SOP1034, SOP1386, SOP976
TTI and CI investigation	Preferably at 2-8°C, within 10 days of transfusion reaction/abnormality observed.	FRM4544	SOP914
Tissue testing	Samples should be sent in accordance with SPN195. Plates must be within individual specimen bags & secured with an elastic band Broths must be sealed with parafilm and transported in specimen bags containing absorbent material. A maximum of 12 broths should be transported in one Biobottle (see note under table)	FRM1133 FRM1431 (Liverpool TES)	SOP1386, SOP1037 SPN195

	All samples (except frozen femoral heads) should be received within 5 days from sampling, or within 5 days of the growth being detected for corneal cultures. Transit time must not exceed 48 hours, including cooled conditions and at ambient temperature. Samples can be kept refrigerated prior to transport for up to 4 days providing they are received on day 5 from sampling.		
Cord blood and stem cells	Samples should be sent in accordance with SPN196. Paediatric (0.5 - 4ml product) + BPN (0.5 – 8ml product) BacT/ALERT bottles transported at ambient temperature or cooled conditions. Must be received within 2 days (ambient) or 5 days (cooled) of inoculation. If cooled transport, must have been refrigerated prior to transit. See note under table.	FRM1129 FRM3493 (SCI) FRM3494 (CMT)	SOP1386, SOP3336 SPN196
Serum eye drops	Samples should be sent in accordance with SPN196. BPA (4-10ml product) + BPN (4-10ml product) BacT/ALERT bottles transported at ambient temperature or cooled conditions. Must be received within 2 days (ambient) or 5 days (cooled) of inoculation. If cooled transport, must have been refrigerated prior to transit and be in transit for ≤48 hrs. See note under table.	FRM1130 FRM1431 (Manufacturing)	SOP1386, SOP1043 SPN196
Reagents	Transport reagents at ambient temperature or cooled conditions, within 7 days of contamination being identified.	FRM1181	SOP1044
Lot release testing of media	Transport according to manufacturer's storage conditions	FRM1078	SOP1009
Screened platelets and associated units	Samples should be sent in accordance with SPN196.	FRM163 (Testing/HS)	SOP3371 SPN196

	Reactive BPA + BPN BacT/ALERT bottles (containing 8ml sample). Transport preferably at 4 ± 2°C. Must be received by MSL within 5 days of becoming reactive/alarm point. See note under table.		
Process simulations	Transport as per Tissues and/or serum eyedrop samples. TSB + Thio broths must be within the expiry date for the full period of testing. See note under table.	FRM975 (Tissues) or FRM1130 (eyedrops)	SOP985

Note: In one Biobottle, without a cold pack, a maximum of 24 broths or 16 BacT/ALERT bottles can be transported. If a cold pack is included within the Biobottle, a maximum of 12 broths or 8 BacT/ALERT bottles should be packaged inside.

All tests marked with an * in this section are UKAS accredited.

5.1. Environmental Monitoring

The laboratory provides an environmental monitoring service supporting the devising and implementation of national environmental monitoring programmes, the provision of training and advice and the validation of suitable media. Monitoring involves the use of contact, settle and swab plates, active air sampling and glove prints, undertaken by the facilities concerned. Standardised national programmes have been implemented throughout NHSBT, within which Bacteriology provides an identification and reference laboratory service. The programmes cover environmental monitoring in uncontrolled rooms, such as NHSBT Manufacturing Laboratories, and controlled rooms, such as NHSBT cleanroom facilities. Organisms isolated from out-of-specification monitoring in controlled rooms (clean areas) and from repeat non-compliant monitoring in uncontrolled rooms are identified to either genus or species level depending on the room grade, nature and clinical importance of the isolate(s).

Sample presentation

- Settle plate: Standard 90mm diameter plate containing growth media for the direct monitoring of the likely number of micro-organisms depositing on to a surface in a given time. Exposure times will be specified in national procedures but Bacteriology must be contacted regarding any deviations.
- Contact plate: 55mm diameter plate containing growth media with a convex surface for the direct sampling of flat surfaces. Media containing disinfectant neutralisers must be used for post disinfection sampling.
- Swab plate: Standard 90mm plate containing growth media that has been inoculated with a swab that has been used to sample a specified surface. EM swabs must be individually sterile wrapped, designed for EM and should only be used for sampling surfaces not suitable for the use of contact plates. Media containing disinfectant neutralisers must be used for post disinfection sampling.
- Active air sampling: For assessing the microbiological quality of air in controlled rooms. The air sampling device must be capable of sampling a $1m^3$ (1000L) volume of air and be compatible for use with pre-poured agar plates, capable of isolating a range of bacterial and fungal organisms.
- Glove print plate: Pre-poured ≥90mm nutrient agar plate (e.g. TSA) that has been inoculated with gloved fingers from the operator's left and right hands following aseptic processing in a grade A or B environment. All five digits of each hand must be sampled.

See SPN153 (Environmental monitoring materials) for more information. Please contact Bacteriology with any additional queries regarding EM.

Testing criteria

The Lead Specialist – Environmental Monitoring and HACCP will provide advice and support in the process for determining the sites to be monitored based on a risk management approach. Action and alert levels for controlled rooms are to be set in accordance with MPD382 (National Environmental Monitoring System for Controlled Rooms) and MPD383 (National Environmental Monitoring System for Uncontrolled Rooms). In uncontrolled rooms, action levels are to be set in accordance with DAT453 (National Environmental Monitoring - Uncontrolled Rooms). While environmental monitoring of reagents is described in DAT454.

SOPs have been implemented giving instructions for performing environmental monitoring and national forms are in place for recording details of media used, sites monitored and results (SOP254, SOP977, SOP978). An SOP has also been issued covering the processing of environmental monitoring samples at the Reading and Reporting Laboratories (SOP976).

Sampled media from environmental monitoring must be incubated within 48 hours from the time that the monitoring was performed. This timeframe includes the transit time from the point of dispatch (monitored facility) to receipt at the Reading and Reporting Laboratory, where applicable. Sampled media must have been maintained at room temperature between the time that monitoring was performed and the incubation of the plates.

Any repeat monitoring required in response to an initial non-compliant result must be performed as soon as possible within receiving the initial result from the Reading and Reporting Laboratory. National procedures are in place describing the action to be taken in response to out-of-specification results.

Colony growth from out-of-specification monitoring must be identified as part of the investigation to identify the possible source of the contamination, preferably through the service provided by MSL-Bacteriology. It is acceptable, however, for identification to be performed by a local UKAS accredited laboratory to ISO15189:2012 under the provision of an approved technical or service level agreement.

Sampled media having isolates requiring identification by MSL-Bacteriology must be dispatched within 24 hours of documenting the non-compliant result. However, if transport is not available within this period, such as at weekends and bank holidays, the plates with growth must be refrigerated at 2-8°C until the next available transport.

5.2. Investigation of Suspected Transfusion-Transmitted Bacterial Infections (Transfusion Reaction, TTI) and Visually Abnormal Blood Components (Component Investigation) *

Initiating a TTI or CI investigation:
In the event of a patient adverse event during or post transfusion, the relevant hospital staff must contact the NHSBT Duty Consultant for patients, which is done via the relevant NHSBT Hospital Services Department that supplies the hospital blood bank.

The Duty consultant will then advise on whether the case should be investigated (and pack/s sent back to NHSBT) and what investigations, if any, are required. They can also advise on the platelet screening results if required.

If an investigation is advised, the Duty consultant will complete a Record of Medical Consultation (FRM4544) for the case, recall any other associated components for the relevant donation(s) (as deemed necessary) and inform the relevant NHSBT investigating laboratory.

If a bacterial investigation is advised by the NHSBT Duty consultant, the hospital will be asked to send the transfused unit to NHSBT for investigation.

The investigation of possible TTIs is performed by culturing the implicated component and/or associated components. Should these cultures yield positive results, the source of the bacteria is sought, usually by investigating the donor(s). Isolates from the patient, the implicated unit and the donor are compared using molecular typing techniques in an attempt to confirm a chain of transmission. The molecular typing is currently performed by the UKHSA in Colindale.

All case files are forwarded on to the Consultant in Epidemiology and Health Protection who will send a report to the relevant hospital if appropriate. Investigations are reported into the Serious Hazards of Transfusion (SHOT) surveillance system.

Blood components suspected of being contaminated, but not transfused, are also investigated in the same way.

Sample presentation
Components should be sent to the laboratory, preferably at 2-8°C. Please note: leaking packs that pose a risk to staff will not be processed.

Testing criteria
Components are tested in accordance with SOP3371 and SOP914. Reports are generated and submitted to the relevant parties.

5.3. Tissue Testing*

Currently the laboratory undertakes the testing of bone (live and deceased donors), amnion, meniscus, tendon, osteochondrials, skin, corneas and cardiovascular grafts. Reports are sent to Tissue Services, Liverpool, and Filton Eye Bank (corneas only), with statements regarding the suitability for release for transplantation and sterilisation of individual tissues. The contamination rates of tissues are monitored on a regular basis.

The requirements for the process of providing and testing tissue samples are documented in the specification for the 'Bacteriology Testing of Tissue Samples', SPN195. Specifically, broths must remain within the expiry date for the duration of the incubation period.

The laboratory has developed national protocols for the testing of tissues and also advises on tissue sampling techniques. Research and development work is undertaken to investigate new technologies for the sterilisation / disinfection / testing of tissues to increase product safety.

The passing or failure of tissue donations is based on bioburden determination, presence of rejection organisms and/or detection of any organisms after exposure to decontaminating agents. Despite contamination, some tissues can still be approved for clinical use provided these donations undergo terminal sterilisation by irradiation, or where skin commensals are isolated from post-decontamination skin samples.

The rejection organisms are detailed in a controlled spreadsheet located here: G:\001 National Share\001 Everyone\Validations Spreadsheet\Rejection organisms & EM organisms

a) Frozen Femoral Head Donations from Live Donors:

Sample presentation
- Bone chips in Tryptic Soy Broth (TSB) and thioglycollate broths.
  The samples are taken in the operating theatre from live donors and kept frozen until delivered to Bacteriology.

Testing criteria
Organisms isolated from these donations are not identified.
- Donations with no growth (or a plate contaminant) are reported as "Pass" and are suitable for use as fresh frozen bone.

- Donations showing growth, excluding plate contaminants, are reported as “Fail”. All bone donations with results indicating “Fail” are suitable for use as processed bone after terminal sterilisation by irradiation.

b) Amnion:

Sample presentation

- Samples of amnion tissue in TSB and thioglycollate broths.
  Samples are sent before and after decontamination of amnion tissue in an antibiotic cocktail. These are referred to as Pre- or Post-decontamination samples.

Testing criteria

All bacteria isolated are identified.

- Donations with no growth in either broth are reported as “Pass” and are suitable for use.
- Donations with non-rejection organisms in the pre-decontamination samples only are reported as “Pass” and are suitable for use.
- Donations with rejection organisms isolated or non-recoverable organisms in the pre-decontamination samples are reported as “Fail” and are rejected for use.
- Donations with any growth or detection of non-recoverable organisms in post-decontamination samples are reported as “Fail” and are rejected for use.

c) Skin Donations:

Sample presentation

- Samples of skin tissue in TSB and thioglycollate broths.
  Samples are sent before and after decontamination of skin tissue in an antibiotic cocktail. These are referred to as Pre- or Post-decontamination samples.

Testing criteria

All bacteria isolated are identified.

- Donations with no growth are reported as “Pass” and are suitable for use.
- Donations with non-rejection organisms in pre-decontamination samples only are reported as “Pass” and are suitable for use.
- Donations with skin commensals in post-decontamination samples are reported as “Pass, in accordance with the tissue testing policy (POL84), tissue released despite the presence of skin commensal(s) in post decontamination samples”.
- Donations with rejection organisms isolated or non-recoverable organisms detected in either the pre- or post-decontamination samples are reported as “Fail but suitable for irradiation”.
- Donations with any growth other than skin commensals in post-decontamination samples are reported as “Fail but suitable for irradiation”.

d) Batches of Processed Bone or massive bone allografts from Deceased Donors:

Sample presentation

- Swab plates (aerobic blood agar, anaerobic blood agar and Sabouraud agar) are inoculated with swabs after sampling bone.

Testing criteria

Organisms isolated from these donations are not identified.

- Donations with no growth or less than semi-confluent growth on swab plates are reported as “Pass”.
  All bone donations with Pass results undergo terminal sterilisation by irradiation.
- Donations with semi-confluent to confluent growth on swab plates are reported as “Fail” and are rejected for use.

e) Tendon Donations for Irradiation:

Sample presentation

- Swab plates (aerobic blood agar, anaerobic blood agar and Sabouraud agar) are inoculated with swabs after sampling tendon.
  The tendon tissue is not chemically treated, nor decontaminated with antibiotic cocktail.

Testing criteria

Organisms isolated from these donations are not identified.

- Donations with no growth or less than semi-confluent growth are reported as “Pass”. All tendon donations with Pass results undergo terminal sterilisation by irradiation.
- Donations with semi-confluent to confluent growth are reported as “Fail and not suitable for irradiation”.

f) Decontaminated Tendon Donations:

Sample presentation

- Swab plates (aerobic blood agar, anaerobic blood agar and Sabouraud agar) are inoculated with swabs after sampling tendon. Swab plates are sent before decontamination of tendon tissue. These are referred to as Pre-decontamination samples.
- Broths (TSB and thioglycollate) are inoculated with swabs after sampling tendon.

Broths are sent before and after decontamination of tendon tissue in ethanol. These are referred to as Pre- or Post-decontamination samples.

Testing criteria

All bacteria isolated are identified.

- Donations with no growth on swab plates or broths are reported as “Pass” and are suitable for use.
- Donations with less than semi-confluent growth of non-rejection organisms on swab plates and / or growth of non-rejection organisms in pre-decontamination broths are reported as “Pass” and are suitable for use.
- Donations with any growth in post-decontamination samples are reported as “Fail but suitable for irradiation”.
- Donations with rejection organisms or non-recoverable organisms on swab plates and/or pre-decontamination broths are reported as “Fail but suitable for irradiation”.
- Donations with semi-confluent to confluent (heavy) growth on swab plates are reported as “Fail and not suitable for irradiation” and are rejected for use.

g) Cardiovascular Graft Donations (heart valves, femoral arteries, pericardium):

Sample presentation

- Swab plates (aerobic blood agar, anaerobic blood agar and Sabouraud agar) are inoculated with swabs after sampling cardiovascular grafts.

Swab plates are sent before decontamination of cardiovascular graft tissue. These are referred to as Pre-decontamination samples.

- Broths (TSB and thioglycollate) are inoculated with pieces of myocardium.

Broths are sent before and after decontamination of cardiovascular graft tissue in an antibiotic cocktail. These are referred to as Pre- or Post-decontamination samples.

Testing criteria

All bacteria isolated are identified.

- Donations with no growth on swab plates or broths are reported as “Pass” and are suitable for use.
- Donations with less than semi-confluent growth of non-rejection organisms on swab plates and / or growth of non-rejection organism in pre-decontamination broths are reported as “Pass” and are suitable for use.
- Donations with any growth or detection of non-recoverable organisms in post-decontamination samples are reported as “Fail” and are rejected for use.

- Donations with rejection organisms or detection of non-recoverable organisms on swab plates and/or pre-decontamination broths are reported as “Fail” and are rejected for use.
- Donations with semi-confluent to confluent growth of non-rejection organisms or detection of non-recoverable organisms on swab plates are reported as “Fail” and are rejected for use.

h) Meniscal cartilage and Osteochondral Donations:

Sample presentation

- Swab plates (aerobic blood agar, anaerobic blood agar and Sabouraud agar) are inoculated with swabs after sampling menisci/osteochondrials.

Swab plates are sent before decontamination of menisci/osteochondral tissue. These are referred to as Pre-decontamination samples.

- Broths (TSB and thioglycollate) are inoculated with swabs after sampling menisci/osteochondrials.

Broths are sent before and after decontamination of menisci/osteochondral tissue in an antibiotic cocktail. These are referred to as Pre- or Post-decontamination samples.

Testing criteria

All bacteria isolated are identified.

- Donations with no growth on swab plates or broths are reported as “Pass” and are suitable for use.
- Donations with less than semi-confluent growth of non-rejection organisms on swab plates and / or growth of non-rejection organisms in pre-decontamination broths are reported as “Pass” and are suitable for use.
- Donations with any growth or detection of non-recoverable organisms in post-decontamination samples are reported as “Fail” and are rejected for use.
- Donations with rejection organisms or detection of non-recoverable organisms from pre-decontamination broths are reported as “Fail” and are rejected for use.
- Donations with rejection organisms or semi-confluent to confluent growth of non-rejection organisms on swab plates are reported as “Fail” and are rejected for use.

i) Cornea donations:

Please note, testing of cornea donations is currently not within our UKAS scope.

Sample presentation

A combination of any of the below may be received for testing, depending on when and where growth is observed:

- Subculture plates (aerobic blood agar and/or Sabouraud agar plates) are inoculated with 1 drop of the cornea storage media (Organ Culture Medium (OCM) and/or Dextran Medium (DM)).
  These plates are incubated at the testing sites and sent to MSL for identification of any growth.
- Broths: Brain Heart Infusion (BHI) broths are inoculated with portions of the OCM or DM cornea storage media. SAB broths are inoculated with DM cornea storage media. The BHI and SAB broths will be incubated by the testing sites and sent to MSL for identification of any growth.
- The original bottles containing OCM and DM with the cornea may also be sent if growth is observed.

Testing criteria

All bacteria and yeasts isolated are identified.

- Results will be reported as Growth Detected or No Bacterial or Fungal Growth Detected.
- All microbial growth isolated will be identified and the organism ID included on the report.
- In the event of isolation of moulds, these will be referred for identification by a reference laboratory.

5.4. Cord Blood and Stem Cell samples*

The laboratory tests cord blood and stem cell samples for bacterial contamination using an automated microbial detection system, the BacT/ALERT 3D. Specific sample identification is maintained throughout the entire process.

Final product is tested post cryoprotectant and results are entered onto Hematos. Reports are dispatched to the Cord Blood Bank electronically, whilst SCI laboratories access results via Hematos.
Any Cord Blood isolates are identified to genus and/or species level. Identification to species level and antibiotic sensitivities are performed by the Oxford University Hospitals NHS Foundation Trust (stem cells only).

The requirements for the provision and bacteriological screening of samples sent in BacT/ALERT bottles are documented in specification SPN196. Specifically, BacT/ALERT bottles must remain within the expiry date for the duration of the incubation period.

Sample Presentation
Paediatric and BPN BacT/ALERT bottles are received already inoculated with 0.5ml of sample.

Testing Criteria
BacT/ALERT bottles are incubated on the BacT/ALERT system for 14 days for cord blood and 7 days for stem cell samples. All isolates are identified.

5.5. Autologous and Allogeneic Serum Eyedrops*

The laboratory performs bacteriological testing of autologous and allogeneic serum eyedrops using the BacT/ALERT 3D automated microbial detection system. Reports are dispatched to Liverpool Tissue Services electronically, via Hematos. Any isolates are identified to genus and/or species level.

The requirements for the provision and bacteriological screening of samples sent in BacT/ALERT bottles are documented in specification SPN196.

TES personnel fill the sampling bag with serum at the end of the first and last chains of vials. The sample is then divided equally between aerobic and anaerobic BacT/ALERT bottles and sent to MSL for testing.

Sample Presentation
Pairs of BPA BacT/ALERT and BPN BacT/ALERT bottles are received already inoculated with 5ml or 10ml of sample per bottle.

Testing Criteria
BacT/ALERT bottles tested for bacterial contamination by incubating on the BacT/ALERT system for 7 days.

All isolates are identified.

5.6. Reagents

The laboratory performs bacterial screening on reagents from Laboratories within NHSBT. This may be in response to a possible contamination incident or as part of their routine screening programme.

Sample Presentation
Reagent samples are received in dropper bottles, sterile universals, or if a bulk reagent requires testing, the entire pack/container is sent.

Testing Criteria
Reagents are cultured directly onto both bacterial and fungal media according to appropriate SOPs. If the reagents sent are larger volume (>18ml, not including pre-dispense reagents), the reagent is also inoculated into a pair of BacT/ALERT bottles and loaded onto the Bacteriology BacT/ALERT system to improve sensitivity of detection.

All isolates are identified. Reports are sent to relevant parties.

5.7. Lot Release Testing of Media

The laboratory performs validation of new batches of media for Bacteriology and other NHSBT sites (requested using form FRM1078, National Lot Release Testing). Types of media tested include BacT/ALERT 3D culture bottles, solid media (agar) and liquid media (broth).

With the exception of Bacteriology, lot release testing only needs to be performed on each batch of media **once**, regardless of the originating department. Departments can check whether the batch of media received has already been validated by accessing the Validations Spreadsheet (see "Validations Spreadsheet 2017 Onwards.xls") at G:\001 National Share\001 Everyone\Validations Spreadsheet.

Sample Presentation
Representative batches of the media are sent to the Bacteriology for testing prior to routine use. Media should be sent to the laboratory under their normal storage conditions.

Testing Criteria
The media will be tested according to the appropriate laboratory SOP. The media types are tested for both sterility and their ability to grow selected organisms. Reports are available at G:\001 National Share\001 Everyone\Validations Spreadsheet\2017 Reports Onwards - Lot Release Testing.

5.8. Confirmatory Testing of Screened Platelets and Associated Units*

All platelet components manufactured at the Manchester, Filton and Colindale Centres are screened on-site for bacterial contamination using the BacT/ALERT 3D automated microbial detection system.

All bottles that flag positive (initial reactive) are referred to MSL-Bacteriology for further investigation. Any isolates are identified to genus or species level.

Platelet units giving an initial reactive result (Index units) will be recalled and, if available, sent to MSL-Bacteriology for further testing. Associated units will also be re-called and, if available, sent to MSL-Bacteriology. Associated units will be tested if required.

The requirements for the sending of screened BacT/ALERT bottles, platelet components and associated units to MSL-Bacteriology and for the provision of confirmatory testing and results are documented in specification SPN415.

Sample Presentation
The initial reactive BPN and BPA BacT/ALERT bottles are received already inoculated with 8 mls of sample. Index units and any associated units are sent to MSL-Bacteriology from other NHSBT sites or from Hospitals. Bottles and units should be sent to the laboratory preferably at 4 ± 2°C for testing. All initial reactive BacT/ALERT bottles and blood units must be received within 5 days of the alarm.

Testing Criteria
Initial reactive bottles are cultured directly onto agar. Index units and associated component units are tested in duplicate. Units are sampled into BPN and BPA BacT/ALERT bottles and incubated for 7 days, using the BacT/ALERT automated microbial detection system. Bottles and units are tested in accordance with the appropriate SOPs.

All isolates are identified to genus and/or species level. Reports are generated electronically and submitted to the relevant parties via Hematos.

5.9. Process simulation(s)

Process simulations should be performed as part of the validation of aseptic processing, aseptic tissue processing and simulation broths for Cellular and Molecular Therapies (CMT). Where necessary, additional process simulations may be performed after discussion with Bacteriology.

New staff at Tissue Services (Liverpool), who process tissues, must complete an initial validation with three consecutive satisfactory simulation tests and a single re-qualification simulation test every 6 months thereafter. For Serum Eyedrop processing, personnel must pass the initial process simulation by achieving three successive passes and no requalification is required.

Staff performing process simulations for other processes (e.g. within CMT or for individual projects), should follow the timelines specified by the department or process manager.

Sample Presentation
Skin process simulation: 6 Thio and 6 TSB broth bottles containing piece of blue paper simulating a tissue. Gauze can be used in place of blue paper, but this has been associated with failures of process simulation/growth promotion.
If more than one lot number is used for the broths, these samples will be rejected, as it will not be possible to complete the growth promotion stage of testing.

Closed system dispensing of serum eyedrops: BacT/ALERT culture bottles for bacteriological testing: anaerobic (BPN) and aerobic (BPA) inoculated with 10ml of broth by the operator under test.

Spent ASE/Stem cell Media/Broth bags consists of liquid media that is passed through the normal processing instead of the real sample.
Simulations samples should be sent to the laboratory under their normal storage conditions.

Testing Criteria
Pre-inoculated BacT/ALERT bottles are incubated onto the BacT/ALERT system for 7 days or until bottle flags positive. These are reported as per the BacT/ALERT system result as negative or positive. No growth promotion testing is performed with these sample types.

All other simulations are incubated initially at 22 ± 2°C for 7 days followed by a further 7 days at 33 ± 2°C. Each broth is visually checked for turbidity after each incubation stage. Any turbid broths are examined for bacterial and fungal growth and isolates are identified to genus and/or species level (this is considered a fail). Growth promotion testing is performed on samples with no turbidity after the full 14-day incubation, to demonstrate the continued ability of the broth to support microbial growth. If the broths are due to expire during the initial 14-day incubation, the growth promotion stage will be performed at risk of the sender, as expired broths are not validated for this process. Reports will be issued with a comment to that effect.

A satisfactory simulation is indicated by the absence of turbidity in all the broth samples following incubation and evidence of growth during the final growth promotion test, or a negative result alone in the case of Bac/ALERT bottles. The presence of turbidity, or a positive BacT/ALERT test, is indicative of microbial contamination and hence failure of the simulation. Results are emailed to the relevant parties.

6. TROUBLE-SHOOTING

The laboratory provides a trouble-shooting service for problems that may have a bacterial cause, e.g. contamination of red cell reagents that no longer function or problems with cell culture lines.

7. CLINICAL ADVICE AND INTERPRETATION OF RESULTS

The laboratory provides a service for bacteriological advice and for the interpretation of results.

Clinical advice relating to bacteriological issues is provided by the management team, in liaison with the Consultant Medical Microbiologist.

Clinical advice relating to donors is provided through the Consultant in Epidemiology and Health Protection (contacted via the Microbiology Services Clinical Office on 020 8957 2988).

Urgent clinical calls requiring bacteriological advice should be directed to Dr Su Brailsford and Dr Pasco Hearn in the first instance. For urgent calls where there is no answer, please contact the Microbiology Services Clinical Office on 0208 957 2988 (open hours are 08:30 - 17:00 Monday - Friday)

8. DISINFECTION

The laboratory plays a leading role in the formulation of disinfection policies throughout the service. All disinfectants used by NHSBT to minimise the risk of bacterial contamination must be validated by Bacteriology prior to use, in accordance with MPD1369: The Management and Use of Disinfectants. Validated disinfectants for surface decontamination are listed in DAT2254: Disinfectants Validated for Use in NHSBT by Microbiology Services Laboratory (Bacteriology). Requests for consideration of new disinfectants to add to DAT2254 should be sent to the Disinfectant Working Group email address in the first instance, using FRM6143: Disinfectant Review Request.

In addition, separate validations have been performed by MSL-Bacteriology R&D section to assess the agents used during sample collection and processing, including donor arm disinfection procedures, cord disinfection and tissue decontamination.

9. RESEARCH AND DEVELOPMENT

The laboratory provides a validation/research and development service for all bacteriological matters.
Examples include:

- Antibiotic cocktails for tissue decontamination
- Donor arm and umbilical cord disinfection
- Evaluation of bacterial detection and pathogen reduction systems for platelets
- Blood product and sample transport and storage validations
- Validation of bactericidal disinfectants for use with NHSBT
- Validation of BacT/ALERT for screening products for contamination

Requests for bacteriological validation work should be emailed to Jennifer Bearne and Mhairi Webster on form FRM4577: *National Bacteriology Laboratory Work Request Form*, and in-line with POL207: *National Bacteriology Laboratory Validations*.

10. TURNAROUND TIMES

Stated are normal turnaround times for issue of reports: -

National Environmental Monitoring (see 5.1)

Final result	10 days

Investigation of Suspected Contaminated Blood Components (TTI and Visual abnormalities, see 4.2)

Final result	16 days

Tissues (see 5.3) ¥

Frozen Femoral Head (Bone from Live Donor)	22 days
Decontaminated Amnion	25 days
Decontaminated Skin	25 days
Batch of Bone from Deceased Donors	11 days
Tendon for Irradiation	11 days
Decontaminated Tendon	25 days
Decontaminated Cardiovascular Grafts	25 days
Decontaminated Osteochondrials / Menisci	25 days
Corneas	10 days

¥ Identification may require referral to another laboratory for testing with expected 7-day TAT

Stem Cell samples (Routine & Validation Samples)** (see 5.4)

Final result¥	14 days

¥ Identification and/or susceptibility testing are referred to another laboratory for testing with expected 7-day TAT

Cord Blood (Routine & Validation Samples)** (see 5.4)

Final result (including isolate identification)	21 days

Autologous Tears (Routine & Validation Samples)** (see 5.5)

Final result (including isolate identification)	14 days

Reagent Screening (see 5.6)

Final result	14 days

Lot Release Testing of Media (see 5.7)

Solid Media	7 days (samples are batched)
Liquid Media (TSB and Thioglycollate)	15 days (Samples are batched)
BacT/ALERT 3D media	15 days (Samples are batched)

Please note, LRT is batched and typically performed on Fridays for all samples received Monday-Thursday

Confirmatory Testing of Screened Platelets (see 5.8)

Final result	20 days

Process simulation (see 4.9)

Final result (Pass or fail)	28 days

** Refers to samples sent to Bacteriology in BacT/ALERT bottles for incubation

11. USE OF REFERENCE LABORATORIES

Occasionally, isolates may have to be referred to an external laboratory for identification or antibiotic susceptibility testing and this may lead to an increase in the published expected turnaround time. Whilst every effort is made to expedite such samples, this will be dependent upon the workload and turnaround times of the external investigating laboratory. Users will be notified of reference laboratory testing and the risk of an extended TAT.

Primary Reference Laboratories currently used by Bacteriology:

Micropathology Ltd – For Identification of bacterial and fungal isolates
University of Warwick Science Park,
Venture Centre
Sir William Lyons Road
Coventry
CV4 7EZ
United Kingdom

Oxford University Hospitals NHS Foundation Trust – For Identification and Antimicrobial Susceptibility testing of isolates from Stem Cell Samples and other ad hoc requests
Department of Microbiology
John Radcliffe Hospital
Headley Way
Oxford
OX3 9DU

Ad-Hoc Reference Laboratories available for use by Bacteriology:

Anaerobe Reference Laboratory
Public Health Wales Microbiology Cardiff
University Hospital of Wales
Heath Park
Cardiff
CF14 4XW

Antimicrobial Resistance and Healthcare Associated Infections Reference Unit (AMRHAI)
UK Health Security Agency
61 Colindale Avenue
London
NW9 5EQ

Gastrointestinal Bacteria Reference Unit (GBRU)
UK Health Security Agency
61 Colindale Avenue
London
NW9 5EQ

Respiratory and Vaccine Preventable Bacteria Reference Unit (RVPBRU)
UK Health Security Agency
61 Colindale Avenue
London
NW9 5EQ

UKHSA Mycology Reference Laboratory
National Infection Service
UKHSA South West Laboratory

Science Quarter
Southmead Hospital
Bristol
BS10 5NB

Animal and Plant Health Agency (For Exclusion of *Brucella* species from cultures)
Woodham Lane
New Haw
Addlestone
Weybridge
Surrey
KT15 3NB

National Mycobacterial Reference Service South
UK Health Security Agency
61 Colindale Avenue
Colindale
London
NW9 5EQ

12. ACCREDITATION AND REGULATION

United Kingdom Accreditation Service (UKAS)
MSL is a UKAS accredited medical laboratory No. 8783.
Accreditation is held in accordance with ISO15189:2012.

UKAS MEDICAL 8783

The Schedule of Accreditation, which describes the Bacteriology activities covered under the scope of the accreditation, can be found at:
https://www.ukas.com/wp-content/uploads/schedule_uploads/00007/8783-Medical-Single.pdf

Medicines and Healthcare Products Regulatory Agency (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.

HTA
MSL is also subject to inspection by the Human Tissues Authority as part of the NHSBT Colindale HTA (Testing) licence22600. The laboratory was last inspected by HTA on the 15th -17th March 2022.

The MSL-Bacteriology is governed by the Data Protection Act 2018, Human Rights Act 1998, the Computer Misuse Act 1990 and the Caldicott Principles. All records containing person identifiable data are stored in lockable cabinets.

13. INTERNAL QUALITY AUDITS

The laboratory is subject to internal BSQR (GMP) and ISO15189 audits comprising of national and local self-inspections. National self-inspections take place biennially covering quality and safety regulations and are scheduled on alternate years to the competent authority inspection. Local self-inspections should take place approximately 6 months prior to the expected dates of external inspections and focus on the standards applicable to the expected external inspection.

An annual horizontal audit will be planned to cover all ISO15189 accredited functions, to be completed by internal auditors with training and knowledge of ISO15189 standards. A series of vertical audits will be performed annually, designed to enable evaluation of a full range of processes as possible. Examination audits will also be performed on an annual basis, enabling areas not covered during previously performed vertical audits to be reviewed.

14. INTERNAL AND EXTERNAL QUALITY ASSESSMENT SCHEMES

The laboratory has developed and implemented internal quality assessment (IQA) programmes covering the bacteriological testing of tissues and surgical bone, screening of platelets, component investigation/TTI investigation, microbial detection and identification procedures and microscopy.

The laboratory participates in a national external quality assessment scheme (NEQAS) for microbial identification run in collaboration with UKHSA, Colindale.

15. LOGGING OF ERRORS

Any errors identified during the sample reception and data entry process are logged to monitor trends and, as required, will be reported through the QIR system (SOP3406, Identifying and reporting an incident).

16. COMPLAINTS

Any complaints with the results provided or any other aspects of the service of MSL-Bacteriology must be addressed in the first place to the Laboratory Director. Internal (NHSBT) complaints should be logged as an Occurrence on QPulse, after discussion with the Laboratory Director. External complaints (non-NHSBT) should be raised in writing, via email, to the Laboratory Director who will log the complaint on QPulse as an Occurrence. After complaint resolution, review of complaints is performed through the MSL User satisfaction survey (see also 4.1.2.6, 4.14.3).

All complaints will be managed through the QPulse system. All complaints will result in an investigation of which the root cause and corrective and preventative actions will be logged onto QPulse. The outcome(s) of the investigation will be fed back to the originator of the complaint via e-mail for both internal (NHSBT) and external (non-NHSBT) complaints.

In the event of dissatisfaction with the investigation of the complaint or the response received, the complaint should then be referred to the Associate Director for Testing and Scientific Development for investigation.

All incidents are documented within QPulse to enable MSL-Bacteriology, and NHSBT organisation-wide, to learn from mistakes, improve systems and provide a better service to all users.

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

Amanpreet Dhesi
Associate Director, Testing and Scientific Development
NHS Blood and Transplant
Charcot Road
Colindale
London
NW9 5BG

Email: **amanpreet.dhesi@nhsbt.nhs.uk**

Definitions

- **BMS** – Biomedical Scientist
- **BSQR** – Blood Safety and Quality Regulations
- **CBB** – NHS Cord Blood Bank
- **CI** – Component investigation
- **CS** – Clinical scientist
- **DM** – dextran media
- **EM** – Environmental monitoring
- **GDPR** – General data protection regulation
- **HACCP** – Hazard analysis critical control point
- **HCPC** – Health and Care Professions Council
- **MHRA** – Medicines and Healthcare Products Regulatory Agency
- **MSL** – Microbiology Services Laboratory
- **OCM** – organ culture media
- **PS** – Platelet screening
- **QIR** – Quality incident report
- **R&D** – Research & development
- **SAB** - Sabourard
- **SCI** – Stem Cell Immunotherapy
- **TES** – Tissue and eye services
- **TSB** – Tryptic Soy Broth
- **TTI** – Transfusion transmitted reaction
- **UKHSA** – UK Health Security Agency

Related Documents / References

- **DAT453** – National Environmental Monitoring - Uncontrolled Rooms
- **DAT454** – National Environmental Monitoring – NHSBT Reagents laboratory
- **DAT2254** – Disinfectants Validated for use in NHSBT by Microbiology Services Laboratory (Bacteriology)
- **FRM163** – Bacterial screening: Platelet referral request
- **FRM874** – Environmental monitoring – controlled rooms 'in process'
- **FRM875** - Environmental monitoring – controlled rooms Grade B daily
- **FRM876** - Environmental monitoring – cleanrooms weekly, monthly, quarterly
- **FRM877** - National Environmental Monitoring - Uncontrolled Rooms – Contact plates
- **FRM878** - National Environmental Monitoring - Uncontrolled Rooms – SCD bench monitoring
- **FRM879** - National Environmental Monitoring - Uncontrolled Rooms – Settle plates
- **FRM880** - National Environmental Monitoring - Uncontrolled Rooms – SCD swab plates
- **FRM975** – National Bacteriology Laboratory – Process simulation request
- **FRM1078** – National Lot Release Testing
- **FRM1130** – Autologous and allogeneic serum eyedrops: Bacteriology worksheet
- **FRM1133** – MSL Bacteriology testing request for tissue samples
- **FRM1165** – Environmental monitoring – Isolate(s) for identification
- **FRM1181** – Microbiological culture of reagents
- **FRM1431** – Bacteriology tracking
- **FRM1581** - Bacteriology Request Form For Investigation Of Suspected Contamination Of Blood Components
- **FRM3351** - National Environmental Monitoring - Uncontrolled Rooms – Swab plates
- **FRM3493** – SCI donations: BacT/ALERT worksheet
- **FRM3494** – SCI BacT/ALERT consignment worklist
- **FRM3700** – Bacterial screening of platelets: NBL investigation
- **FRM4544** – Record of medical consultation
- **FRM4577** – National Bacteriology Laboratory Validation Request.
- **FRM5398** – Pooled platelet confirmatory testing: Sample record
- **FRM6143** – Disinfectant Review Request
- **MPD382** – National Environmental Monitoring System for Controlled Rooms
- **MPD383** - National Environmental Monitoring System for uncontrolled Rooms
- **MPD1369** –The Management and Use of Disinfectants
- **POL2** - Confidentiality and Data Protection Policy
- **POL58** – Microbiology Services Laboratory -Bacteriology, Sample Acceptance and Rejection Copy
- **POL84** – Testing of Tissues for Bacteria and Fungi, and their Acceptability for Clinical Use.
- **POL207** – National Bacteriology Laboratory Validations.
- **SOP254** – Environmental monitoring using contact plates

- **SOP914 –** Microbiological investigation of transfusion reactions and visibly abnormal blood components
- **SOP976** – Incubation, reading and recording of Environmental monitoring samples and results
- **SOP977** – Environmental monitoring using glove prints
- **SOP978** - Environmental monitoring using settle plates
- **SOP985** – Process simulation and growth promotion testing
- **SOP1009** – Lot release testing of liquid media and BacT/ALERT culture bottles
- **SOP1034** – Processing, identification and reporting of Environmental monitoring isolates
- **SOP1037** – Reading, reporting and dispatch of tissue results
- **SOP1043** – Screening of autologous and allogeneic serum eyedrops for microbial contamination
- **SOP1044** – Microbiological screening of reagents
- **SOP3336** – Microbiological screening of stem cell samples
- **SOP3371 –** Confirmatory of screened platelets and associated packs
- **SOP3406** – Reporting and Managing Adverse Events
- **SPN153** – Environmental monitoring materials
- **SPN195** – Bacteriology Testing of Tissue Samples.
- **SPN196** – Bacteriological Screening of Samples sent to NBL in BacT/ALERT Bottles.
- **SPN415** – BacT/ALERT culture bottles, Screened Platelet Concentrates and Associated Units sent to the MSL-Bacteriology for Confirmatory Bacteriological Testing