Objective

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

Changes in this version

Updated introduction; updated organogram and directorate in line with INF1060; staffing; sample acceptance/rejection criteria; note on large/swarming colonies; growth promotion TSB/Thio numbers and volume; responsibilities of users when samples do not meet specification; ISO 15189 standard; MHRA licenses; turnaround times; updated references; updated abbreviations. Added clinical trial samples and associated documentation.

Contents

1. INTRODUCTION

Microbiology Services Laboratory (MSL) consists of Bacteriology (MSL-Bacteriology) and Virology (MSL-Virology), 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 MSL, identification of action level/out of specification isolates from manufacturing sites and cleanroom facilities and follow-up investigative work
- Bacteriological investigation of patient adverse reactions to transfusion
- 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
- National confirmatory and reference work for the bacterial screening of platelets.
- Lot release testing of media for use within NHSBT
- Processing of aseptic validations and follow up growth promotions
- Validation of new disinfectants, products, media and processes within NHSBT
- Ad hoc screening requests

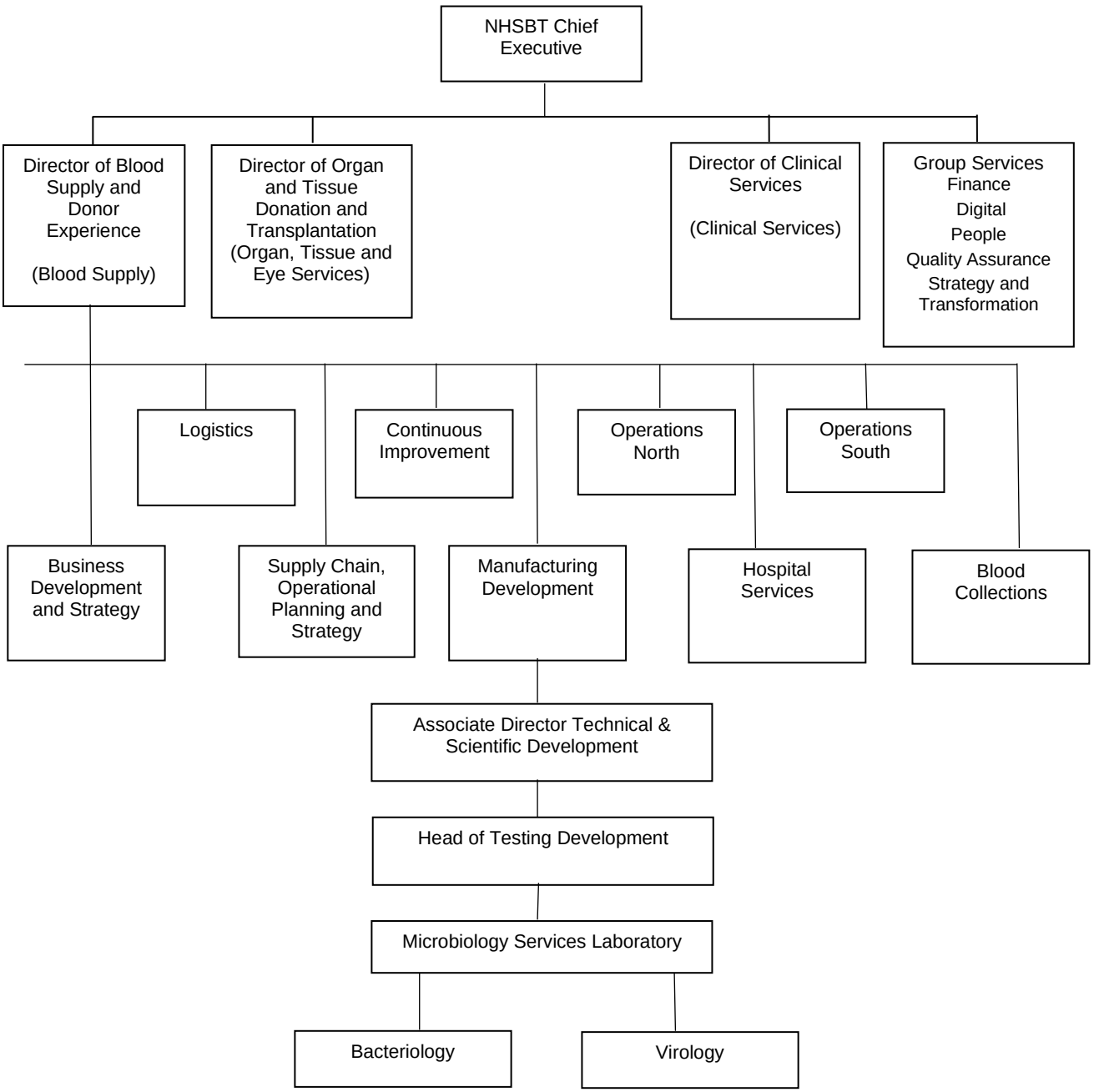
In addition to these core activities, the laboratory provides an advice and trouble-shooting service for any matters that may be bacterial in nature. The laboratory also plays a leading role in disinfection, from donor arm to disinfection of facilities or equipment. Investigations are continually undertaken 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

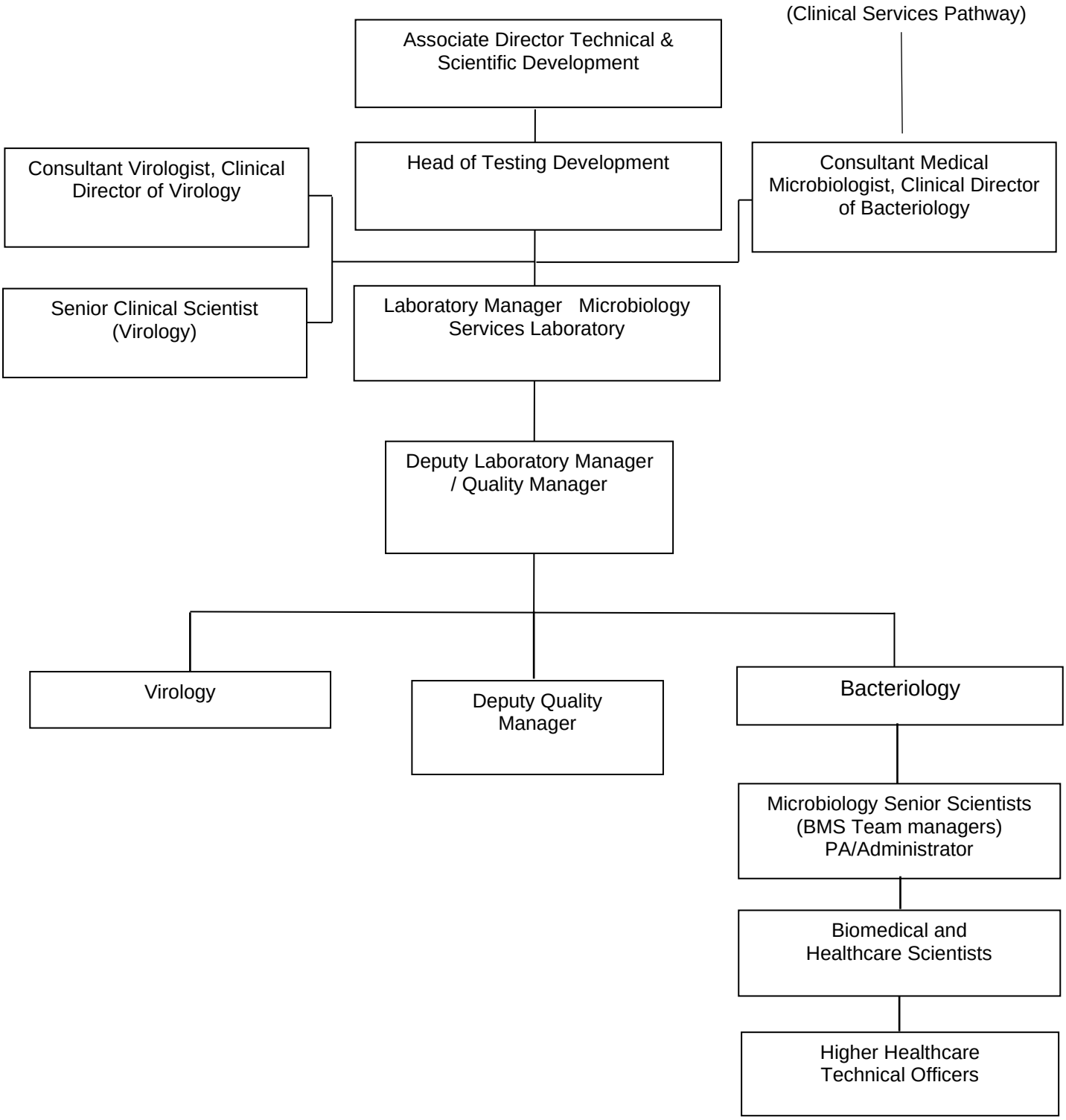
Microbiology Services Laboratory sits within the Blood Supply Directorate of NHS Blood and Transplant.

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. Organogram: Overall structure of NHSBT and relationship with MSL



1.3 Structure of MSL and relationship to the Clinical Services directorate



2. BACTERIOLOGY STAFFING

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

Dr Pasco Hearn	Consultant Microbiologist
Mhairi Webster	Laboratory Manager – Microbiology Services Laboratory (Clinical Scientist)
Holly Sawyer	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/Manual handling trainer/R&D Lead)
Becky Clare	Lead Specialist – Environmental monitoring and HACCP
Nazow Azim	Microbiology Services Deputy Quality Manager, Delegated quality assurance advice (Biomedical Scientist)
Dora Mangraviti	BMS Team Manager* (Biomedical 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)
Steffany Fairhurst	BMS Team Manager* (Biomedical Scientist/First aider)
Mfon Asuquo	MSL-Bacteriology Administrator

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

3. CONTACT INFORMATION

Laboratory Manager Mhairi Webster	020 8957 2896 07385 384868
Deputy Laboratory Manager / Quality Manager Holly Sawyer	020 8957 2883 07385 388119
Deputy Laboratory Manager / Business Continuity Pravesh Dhanilall	020 8957 2896 07385 388258
Consultant Medical Microbiologist Dr Pasco Hearn Please note: Available by email/phone on Wednesday mornings.	07392 315813
Principal Bacteriology Development Scientist Jennifer Bearne	07385 387950
Administrator Mfon Asuquo	020 8957 2787
General Laboratory	
Sample Reception	020 8957 2715
Senior Scientific Staff	020 8957 2963 020 8957 2959
Blood component 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 MSL-Bacteriology 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

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.

For National Committees it is recommended that all MSL Seniors and managers are contacted using MSLSeniors@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.

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-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.

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).

On 3-day Bank holiday weekends (i.e. Saturday – Monday) there will be one member of MSL staff to receipt samples only, on the Saturday. We recommend samples are put on the overnight run on the Thursday to ensure samples are incubated over the weekend.

On 4-day Bank Holiday weekends (i.e. Friday – Monday or Saturday – Tuesday), there will be two members of MSL staff to receipt and incubate samples on the Saturday. We still recommend samples are put on the overnight run on the Thursday to ensure samples are incubated over the weekend.

Please note that any samples that arrive outside of our stated working hours and fall outside of specification by our next working day are likely to be reported as 'Fail due to Non-conformance'

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, so where possible sample collection activities must ensure sample integrity is maintained:

- 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

MSL advises that BacT/ALERT bottles with visible damage or defects should not be used.

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 or where the age of the sample is expected to limit the relevance of results. For all cases, the referring laboratory will be contacted and advice will be sought from a senior member of staff.
Where samples are received outside of specification, it is the responsibility of the sender to raise a Quality Incident Report (QIR).

MSL requests that all Users notify us of samples being sent to us, with an email that includes the sample request form or consignment form, or by SIGN-APPS.

Sample Identifiers criteria

Sample request forms must be completed in full. Receipt of an incomplete FRM will delay testing. The sample request form represents an agreement between the service User and MSL.

Donation numbers must not be handwritten where possible, but if used may delay testing if these cannot be read. The sample must be labelled in such a way that it is unequivocally linked to the donor/donation and sample site, if not, the sample may be rejected and you will be required to raise an RPT.

The minimum identifiers per sample type are detailed below and must be present on the sample AND the respective FRM:

• Tissues:	Must have batch number
• Stem cells, Cords, ASE, other BacT/ALERT bottles:	Must have bottle ID AND donation number
• Environmental Monitoring:	Must have (your) lab sample number
• Lot Release Testing:	Must have Lot number
• Process Simulation:	Must have operator AND centre AND batch number/type (i.e. A, B, C or Re-qualification)
• Aseptic validations:	Must have Unique bag/bottle identifier
• Platelet Screening (PS)	Must have donation number on bottle and the SignApps notification (IR bottle) or on the packs and issue note (Index & Associated packs)
• Component investigation (CI):	Must have donation number
• Transfusion Reactions (TTI)	Must have donation number and FRM4544

Any deviation in the minimum identifiers must be discussed with MSL and will be reviewed on a case-by-case basis.
Any aberrations in minimum identifiers will be queried via email and you will have 3 working days to resolve the discrepancy. If no response is received in time we will reject the sample or report as failed due to non-conformance (whichever is applicable).

If we proceed with sample testing and a deviation was observed in the minimum identifiers (e.g. last digit of donation number missing) we will report the result with the comment 'Deviation in sample identifiers confirmed with sender'.

Sample acceptance and rejection criteria

It is the policy of MSL – Bacteriology to do all that is reasonably practicable to accept and process samples referred by users of the service.
Appropriate samples, should be received in a timely and safe manner. They should be properly labelled, properly packed and not leaking or damaged upon receipt. All solid and liquid media used must be within the expiry date for the testing period.

MSL advises that BacT/ALERT bottles with visible damage or defects should not be used. Where a user proceeds with using a BacT/ALERT bottle that is visibly damaged or has a defect, MSL will report as Fail due to non conformance (FDNC), but will continue to test, to allow for precious samples to be tested. For these samples reported as FDNC, users should perform a risk assessment for release of the product.

Further information regarding transit times and sample requirements can also be found in the table on the next page and the relevant specifications; SPN195 (Bacteriology Testing of Tissues), SPN196 (Bacteriology Screening of Samples sent to MSL in BacT/ALERT Bottles) and SPN415 (BacT/ALERT Culture Bottles, Screened Platelet Concentrates and Associated Units sent to MSL for Confirmatory Bacteriology Testing).

For all sample types please refer to the relevant specification and/or SOP for further information on specific sample acceptance and rejection criteria.

It is appreciated that samples referred to MSL-Bacteriology are usually unrepeatable. Therefore, samples that fall outside the specified criteria will be salvaged wherever possible. The advice of a senior member of staff will be sought. Where samples are received outside of specification, it is the responsibility of the sender to raise a QI.

Samples inappropriate to the investigation requested will not be accepted. The sender will be contacted and advice given.
Samples that are unlabelled will not be immediately accepted. Samples that are incorrectly labelled will be referred to a senior member of staff. The sender will be informed and MSL will request they raise a QI.

Any samples that are compromised by a laboratory error will be notified to the sender and a QI will be raised by MSL.

Any non-conformance or errors at receipt will be documented in the MSL-Bacteriology Sample Reception Error Log. The contents of this log is reviewed monthly and reported to the management team and all staff at the monthly meeting for the purpose of audit and trend analysis.

Any sample that does not meet the acceptance criteria, but are tested due to the importance of the sample must have a record of the justification within the laboratory report. This may be an attached communication or written evidence that a decision was made to proceed with processing. A comment describing the sample issue will be added to the final report noting the impact to the quality of the result.

For instances where the sample meets the acceptance and rejection criteria, but sample quality might compromise the examination result, a comment to this effect will be added to the final report.

Sample Transport criteria

Transport requirements and storage requirements prior to transport are detailed in the table below.
Samples arriving after a delay in transit will be accepted within reason, but the sender will be informed and they will be asked to raise a QI for this deviation.
Samples received damaged or leaking will be salvaged when possible, unless they pose a risk to the health and safety of MSL staff. Unsealed, leaking TxRx packs will not be processed due to the risk to MSL staff. Again, a QI will be raised and the sender informed.

Service Users should periodically review their sample transport processes and notify MSL of any issues.

Table 1. Transport requirements and relevant documents according to sample type

Test request	Transport conditions & requirements	FRM for test request	MSL documents for procedure
Environmental monitoring (see section 5.1)	Plates must be within individual specimen bags & secured with an elastic band, intact and undamaged. Must be received by MSL within 5 days of recording a non-compliant result. If not transported within 24 hours or 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 SOP255
TTI and CI investigation (see section 5.2)	Preferably at 2-8°C, within 10 working days of transfusion reaction/abnormality observed. CI cases must be received in accordance with DAT2940 and the type of abnormality must be specified by the sender. Packs must be received intact without leaks and must be accompanied by an issue note from the sender.	FRM4544 FRM7319	SOP914
Tissue testing (see section 5.3)	Samples must be sent in accordance with SPN195. Plates must be within individual specimen bags & secured with an elastic band, be intact and undamaged. For anaerobic plates the indicator should be confirmed to have passed. Broths must be sealed with parafilm and transported in specimen bags containing absorbent material. A maximum of 12 broths must be transported in one	FRM1133 FRM1431 (Liverpool TES) FRM7457 (for Corneas)	SOP1386, SOP1037 SPN195

	Biobottle (see note under table) All samples (except frozen femoral heads) must 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 (see section 5.4)	Samples must 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 and transit time should not exceed 48 hours. See note under table.	FRM1129 FRM3493 FRM3494	SOP1042 SOP1386, SOP3336 SPN196
Clinical trial samples (see section 5.10)	Samples must be sent in accordance with SPN196. BacT/ALERT bottles transported at ambient temperature or cooled conditions. Must be received within 2 days (ambient) or 5 days (cooled) of inoculation, however most clinical trial samples will require same day delivery or delivery to MSL within 24 hours. Prior to transport, store according to clinical trial requirements. Transit time should not exceed 48 hours. See note under table.	As per clinical trial: FRM1075 FRM3493 FRM3494 FRM6380 FRM6381 FRM6680	SOP6679
Serum eye drops & Saline Transfers (see section 5.5)	Samples must be sent in accordance with SPN196. BPA (4-10ml product) + BPN (4-10ml product) BacT/ALERT bottles transported at ambient	FRM1130 FRM1431 (Manufacturing)	SOP1386, SOP1043 SOP5252 SPN196

	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.		
Reagents (see section 5.6)	Transport reagents at ambient temperature or cooled conditions, within 7 days of contamination being identified.	FRM1181	SOP1044
Lot release testing of media (see section 5.7)	Transport according to manufacturer's storage conditions. Samples must be received intact without leaks and must be accompanied by the appropriate request form. Users must send a copy of the media QC certificate to MSL alongside the media for LRT.	FRM1078	SOP1009 SOP1011
Screened platelets and associated units (see section 5.8)	Samples must be sent in accordance with 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/SignApps alarm point. See note under table.	FRM163 (Testing/HS)	SOP3371 SPN415
Process simulations (see section 5.9)	Transport as per Tissues and/or serum eyedrop samples. Broths should be of the same lot number within each set and the broths should remain within expiry for the full period of testing. If expiry is within the first stage of testing, Users must have performed a risk assessment for the impact of expiry on this testing and results. See also note under table.	FRM968 FRM1130	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 must be packaged inside.

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

Note on large/swarming colonies: the presence of large and/or swarming colonies in a sample or media may prevent the detection of smaller, underlying microorganisms. Where mixed growth is visible, MSL will do all it can to distinguish and identify all microorganisms present, but some colonies could be missed.

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 DAT411.

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, SOP255, SOP976, 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 at QM labs or MSL.

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 ISO 15189:2022 under the provision of an approved technical or service level agreement.

Sampled media having isolates requiring identification by MSL-Bacteriology must be received by MSL within 5 days of documenting the non-compliant result. However, if not sent within 24 hours or 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.

EM plates received by MSL >5 days from recording a non-compliant result will be reported as 'Fail due to non-conformance', but identification of organisms will still be attempted. Where an isolate(s) cannot be identified, an appropriate comment will be added to the report after discussion with a Senior.

Reporting
EM reports are issued stating the genus and species (if applicable) of the isolates, along with any comments regarding the source of the contamination. Reports are generated in Hematos and emailed to users.

Where there is a discrepancy between the colony count reported by QM/sites and observed by MSL, which becomes actionable, Users will be notified so that this can be captured in their EM records.

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 results are issued to QA Direct, the Consultant in Epidemiology and Health Protection and the Microbiology Clinical Services team 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 which are returned to NHSBT due to a reported visual abnormality may be investigated in the same way to rule out microbiological contamination. The results of these investigations are not routinely issued back to the hospital except in rare cases where the unit had been transfused or there is a request for this information.

Sample presentation
Components must be sent to MSL-Bacteriology, preferably at 2-8°C. Where a component has been transfused, the giving set should remain in place and the end of the line sealed appropriately using a clamp, spigot or heat-sealer. If the giving set has been removed, the port must be adequately sealed with a spigot to avoid leaking in transit. Please note: leaking packs that pose a risk to staff will not be processed.

Testing criteria
Only platelet and red cell packs are tested routinely. FFP, intermediate plasma and cryoprecipitate unit are not tested and only performed on request by a consultant. Packs must be received by MSL for testing within 2 weeks (10 working days) of notification of a visual abnormality or transfusion reaction.
Components are tested in accordance with SOP914. Reports are generated and submitted to QA, Hospital services and the clinical team.

Reporting
TTI and CI reports are issued stating the genus and species (if applicable) of any isolates recovered, along with the overall result of the case: “Growth Detected” or “No Bacterial or Fungal Growth detected”. Reports are generated in Hematos and emailed to the relevant stakeholders described above.

5.3. Tissue Testing*

Currently the laboratory undertakes the testing of bone (live and deceased donors), amnion, meniscus, tendon, osteochondrals, 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 requirements for the process of providing and testing tissue samples are documented in 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 most up to date rejection organisms are detailed in a controlled spreadsheet located here: G:\001 National Share\001 Everyone\Validations Spreadsheet\Rejection organisms & EM organisms.

Reporting
Tissue screening reports are issued stating the overall result for the investigation for which there are three possible categories a) PASS, b) FAIL or c) FAIL BUT SUITABLE FOR IRRADIATION

The identification of any organisms isolated in the screening will only be released in the case of FAIL outcomes and this report with indicate the implicated rejection organism(s) and at what stage of the process (PRE or POST) they were isolated from.

For corneas, the final report states the genus and species (if applicable) of any isolates recovered, where they have been isolated from and an overall result for the tissue of "Growth Detected" or "No Bacterial or Fungal Growth Detected". Cornea samples received by MSL after 5 days will be issued with a comment indicating the delay in transport, to signify that recovery and identification of some organism might not be possible.

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 MSL-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 organisms 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 organisms 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 organisms 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 organisms 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/osteochondrals.
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/osteochondrals.
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 organisms 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 organisms 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.

Reporting
Cord blood reports are issued stating the genus and species (if applicable) of any isolates recovered, along with the overall result: Positive, Negative. Reports are generated by Hematos and emailed to users.
Stem cell results are entered into Hematos. Notification of positive stem cells and interim genus/species identifications are issued as interim reports as an email. Final genus/species and identifications and antibiotic susceptibility results are issued as final reports as an email. Negative stem cell results are only entered onto Hematos.

5.5. Autologous and Allogeneic Serum Eyedrops* & Saline Transfers

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.

Likewise, bacteriological testing is also performed on the packs of sterile saline that are used in TES for diluting serum eyedrop donations (see SOP5252).

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.

Reporting
ASE reports are issued stating the genus and species (if applicable) of any isolates recovered, along with the overall result: “Growth Detected” or “No Bacterial or Fungal Growth Detected”. Reports are generated by Hematos and emailed to users.

5.6. Reagents

The laboratory performs investigation of reagents from Laboratories within NHSBT that are suspected to be contaminated. All cases of suspected reagent contamination must be discussed with MSL-Bacteriology before sending.

Sample Presentation
Reagent samples may be 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/or fungal media according to appropriate SOPs. If the reagents sent are larger volume (>18ml, not including pre-dispense reagents), the reagent may also be inoculated into a pair of BacT/ALERT bottles and loaded onto the Bacteriology BacT/ALERT system to improve sensitivity of detection. A bespoke culture and incubation protocol is performed according to the reagent contaminated and the suspected cause of contamination. Samples may need to be referred externally for further investigation and identification.
All isolates are identified.

Reporting
Reagent reports are issued stating the genus and species (if applicable) of any isolates recovered. Reports are emailed directly to users.

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).

MSL verifies media is suitable for use by confirming it is able to support the growth of representative bacterial or yeast species, at known concentrations, according to British/European Pharmacopoeia.

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.

It is the responsibility of all departments to retain a copy of the relevant QC certificates for their media, in line with their requirements, as well as perform visual checks of all media before being put into use.

Sample Presentation
Batches of the media must be sent to MSL-Bacteriology for testing prior to routine use. Media must be sent to MSL under their normal storage conditions media and should be sent as received from the supplier, where possible. A copy of the relevant QC certificate must also be sent to MSL alongside the media. See FRM1078 for sample numbers required.

Testing Criteria
The media will be tested according to SOP1009 (liquid media) or SOP1011 (solid media). The media types are tested for their ability to grow selected organisms.

Reporting
Reports are generated by Hematos and made available at G:\001 National Share\001 Everyone\Validations Spreadsheet\2017 Reports Onwards - Lot Release Testing. The reports are issued with a final interpretive result of "Pass" or "Fail"

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 and/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/or BPA BacT/ALERT bottles are received already inoculated with 8 mls of sample and with FRM163. Index units and any associated units are sent to MSL-Bacteriology from other NHSBT sites or from Hospitals. Bottles and units must be sent to the laboratory preferably at $4 \pm 2°C$ for testing. All initial reactive BacT/ALERT bottles and blood units must be received within 5 working days of the alarm. Negative BacT/ALERT bottles and those still incubating, should not be sent to MSL.

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.

Reporting
Platelet screening reports are issued stating the genus and species (if applicable) of any isolates recovered, along with the overall result of the case: “confirmed positive”, “indeterminate positive”, “indeterminate negative” or “false positive”. Reports are generated in Hematos and emailed to the relevant Testing site.

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 MSL-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 their department or process manager. MSL-Bacteriology will develop and agree the process simulation/growth promotion requirements with the user to ensure it meets their needs.

Sample Presentation
Skin process simulation: Minimum 18 TSB and 12 Thio broth bottles containing piece of blue paper simulating a tissue. If 15 TSB and 9 Thio broths are received only, if we have a growth promotion failure, we will have no excess broths for repeat and the operator will need to repeat the whole process again.
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.

Where TSB bags are received, MSL-Bacteriology require a minimum of 50mL.

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.

Any samples not meeting the above criteria, must be agreed with MSL-Bacteriology before sending.

Spent ASE/Stem cell Media/Broth bags consists of liquid media that is passed through the normal processing instead of the real sample.
Simulation samples must 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, this may be performed by the user or MSL-Bacteriology. 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.

Reporting
Process simulation results are emailed directly to the technician being assessed and will be reported as pass or fail.

Sterile fills submitted as pre-inoculated BacT/ALERT bottles may be logged on Hematos. If so, these will be reported as "Growth Detected" or "No Bacterial or Fungal Growth Detected"

5.10. Clinical trial samples

MSL now performs sterility testing of clinical trial products under the MIA(IMP) license. Intermediates and/or final drug products are sent to MSL for screening using the BacT/ALERT. Samples for testing are sent directly from the NHSBT manufacturing site.

Sample presentation: Pairs of BacT/ALERT bottles (bottle type determined by clinical trial product and validation) are received already inoculated with the interim or final clinical trial product. BacT/ALERT bottles must be within their expiry date for the duration of the incubation period.

Testing criteria: BacT/ALERT bottes are incubated for 5-7 days, according to the clinical trial requirements, and are expected to be negative. Any positives detected will initiate investigation and completion of FRM7857.

Reporting: Results are reported according to the requirements of the specific clinical trial, as documented in SOP6679. Receipt, interim results and final results are all communicated via email to the user. Results are reported via Hematos or the appropriate clinical trial form. Any positive results will include the organism identification and be followed by antibiotic susceptibility results from the external reference laboratory, if required for the clinical trial.

5.11. MSL Research and Development

The R&D section provides a validation and research and development service for all bacteriological matters.

Examples include:
- Evaluation of antibiotic cocktails for tissue decontamination
- Validation of microbiological screening methods for tissues, stem cells, ATMPs, IMPs and blood components etc.
- Evaluation of donor arm and umbilical cord disinfection
- Evaluation of bacterial detection and pathogen reduction systems for platelets
- Validation of blood product and sample transport and storage
- Validation of bactericidal disinfectants for use with NHSBT (performed according to SOP5146)
- Validation of BacT/ALERT for screening products for contamination (performed according to SOP6483)
- Evaluation of equipment used to improve or maintain product safety, e.g., SCDs, flow cytometry

This list is not exhaustive and other areas of validation and/or research are also welcomed. Where the process is not covered by an SOP, MSL-Bacteriology will work with the requester to develop a bespoke protocol for approval by all parties before practical work commences. A formal scientific report will be issued on completion of the work.

Requests for bacteriological validation work must be emailed to Jennifer Bearne and Mhairi Webster on form FRM4577: MSL-Bacteriology Work Request Form as soon as possible once the need for assessment and/or MSL support has been identified. Requests will be reviewed and scheduled in-line with POL207: MSL-Bacteriology Validations.

Disinfection validation:

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 must be sent to the Disinfectant Working Group email address in the first instance, using FRM6143: Disinfectant Review Request.

5.12. HACCP Studies

Hazard analysis critical control point (HACCP) studies are performed by dedicated staff within MSL, according to MPD1358. Requests for a HACCP study should be made to HACCP&EMEnquiries@nhsbt.nhs.uk. HACCP studies identify all points in a process, including critical steps, and identify controls. From this study a HACCP plan will be created which will provide high level of assurance that there is protection from contamination within product manufacturing and processing.

6. AMENDED REPORTS

An amended report will be issued when information or a result on the original report was incorrect and required changing or additional information needed to be added, according to the national procedure for Amending an Authorised Hematos Report (SOP1350).

A comment will be added to the report stating that it is an amended report and indicating details of the amendment.
Service User(s) will be informed that an amended report is being issued and the reason for the amendment.

The same principles apply to the amendment and re-issue of reports that are issued outside of Hematos.

7. 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.

8. 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)

9. 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 5.2)

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 Osteochondrals / Menisci	25 days
Corneas	17 days

[¥] Identification may require referral to another laboratory for testing with expected 7-day TAT
[$] This refers to MSL laboratory testing only and not the turnaround time for the entire recall process

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

Saline transfers (see 5.5)

Final result (Pass or fail)	14 days

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

10. USE OF REFERENCE LABORATORIES

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 (TAT). 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 MSL-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:

Antimicrobial Resistance and Healthcare Associated Infections Reference Unit (AMRHAI)
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

11. ACCREDITATION AND REGULATION

UKAS MEDICAL 8783

United Kingdom Accreditation Service (UKAS)
MSL is a UKAS accredited medical laboratory No. 8783.
Accreditation is held in accordance with ISO 15189:2022.

The Schedule of Accreditation, which describes the Bacteriology activities covered under the scope of the accreditation, can be found at: https://www.ukas.com/download-schedule/8783/Medical/

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 (BSQR) 2005 and Blood Establishment Authorisation (BEA):25335 for the Colindale site. The laboratory was last inspected on the 19 – 23 June 2023.

The laboratory is also now subject to inspection by the MHRA as part of Manufacture of Investigational Medicinal Products - MIA (IMP) regulations. The frequency of these inspections are risk-based.

HTA
MSL is also subject to inspection by the Human Tissues Authority as part of the NHSBT Colindale HTA (Testing) licence 22600. The laboratory was last inspected by HTA on the 12 March 2024

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 or on password protected software.

12. INTERNAL QUALITY AUDITS

The laboratory is subject to internal BSQR (GMP) and ISO 15189 audits comprising of national and local self-inspections (SOP1480). National self-inspections take place biennially covering quality and safety regulations and are typically 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 ISO 15189 accredited functions, to be completed by internal auditors with training and knowledge of ISO 15189 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 (SOP2376).

13. 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. IQA processes are documented in SOP1027.

The laboratory participates in a Blood culture EQA scheme provided by BMS Micro. EQA processes are documented in SOP2375.

14. 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 QI system (SOP3406, Identifying and reporting an incident).

15. 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 must 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 Annual management review.

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 must 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 must 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

- **BEA –** Blood establishment authorisation
- **BMS** – Biomedical Scientist
- **BSQR** – Blood Safety and Quality Regulations
- **CBB** – NHS Cord Blood Bank
- **CI** – Component investigation
- **CMT** – Cellular and molecular therapies
- **CS** – Clinical scientist
- **DM** – dextran media
- **EM** – Environmental monitoring
- **EQA –** External quality assurance
- **FDNC –** Fail due to non conformance
- **GDPR** – General data protection regulation
- **HACCP** – Hazard analysis critical control point
- **HCPC** – Health and Care Professions Council
- **IMP** – Investigational Medicinal Products
- **IQA** – Internal quality assurance
- **MHRA** – Medicines and Healthcare Products Regulatory Agency
- **MIA –** Manufacture/importation of IMP
- **MSL** – Microbiology Services Laboratory
- **OCM** – organ culture media
- **PS** – Platelet screening
- **QI –** Quality incident
- **QIR** – Quality incident report
- **R&D** – Research & development
- **SAB** - Sabourard
- **SCI** – Stem Cell Immunotherapy
- **SHOT** – Serious hazards of transfusion
- **TAT** – turnaround times
- **TES** – Tissue and eye services
- **TSB** – Tryptic Soy Broth
- **TTI** – Transfusion transmitted reaction
- **TxRx** – Transfusion reaction
- **UKHSA** – UK Health Security Agency

Related Documents / References

- **DAT2254** – Disinfectants Validated for use in NHSBT by Microbiology Services Laboratory (Bacteriology)
- **DAT2940** – Hospital services visual abnormality actions
- **DAT411** – Reagents environmental monitoring sites
- **DAT453** – National Environmental Monitoring - Uncontrolled Rooms
- **FRM1075** – Ad hoc microbiological screening
- **FRM1078** – National Lot Release Testing
- **FRM1129** – MSL Bacteriology & NHS Cord Blood Bank: Microbiological screening of cord blood
- **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
- **FRM163** – Bacterial screening: Platelet referral request
- **FRM3351** – National Environmental Monitoring - Uncontrolled Rooms – Swab plates
- **FRM3493** – CMT donations: BacT/ALERT worksheet
- **FRM3494** – CMT BacT/ALERT consignment worklist
- **FRM4544** – Record of medical consultation
- **FRM4577** – MSL-Bacteriology work request form
- **FRM6143** – Disinfectant Review Request
- **FRM6380** – RESTORE bacteriology bottle consignment worklist for SCI-14
- **FRM6381** – RESTORE BacT/ALERT worksheet for SCI-14
- **FRM6680 –** RESTORE: radiolabelling process supernatant BacT/ALERT worksheet
- **FRM7319** – MSL Bacteriology form for Component Investigation
- **FRM7457** – MSL Bacteriology cornea request form
- **FRM7857** – MSL Clinical trial sample out of specification checklist
- **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

- **FRM968** – MSL-Bacteriology - Process Simulation Growth promotion test
- **MPD1358** – HACCP study protocol and plan
- **MPD1369** –The Management and Use of Disinfectants
- **MPD382** – National Environmental Monitoring System for Controlled Rooms
- **MPD383** – National Environmental Monitoring System for uncontrolled Rooms
- **POL2** – Confidentiality and Data Protection
- **POL207** – MSL-Bacteriology Validations.
- **POL84** – Testing of Tissues for Bacteria and Fungi, and their Acceptability for Clinical Use.
- **SOP1009** – Lot release testing of liquid media and BacT/ALERT culture bottles
- **SOP1011** – Lot release testing of solid media
- **SOP1027** – Internal quality assessment for MSL-Bacteriology
- **SOP1034** – Processing, identification and reporting of Environmental monitoring isolates by MSL-Bacteriology
- **SOP1037** – Reading, reporting and dispatch of tissue results
- **SOP1042** – Microbiological screening of cord blood
- **SOP1043** – Screening of autologous and allogeneic serum eyedrops for microbial contamination
- **SOP1044** – Microbiological screening of reagents and ad hoc BacT/ALERT testing
- **SOP1350** – Amending an Authorised Hematos Report
- **SOP1386** – Receipt and reconciliation of tissue and associated samples
- **SOP1480** – Internal quality audit – self inspection
- **SOP2375** – Testing and reporting of EQA samples
- **SOP2376** – MSL internal audit procedure
- **SOP254** – Environmental monitoring using contact plates
- **SOP255** – Environmental Monitoring Using Swab Plates
- **SOP3336** – Microbiological screening of stem cell samples
- **SOP3371 –** Confirmatory of screened platelets and associated packs
- **SOP3406** – Identifying and reporting an incident
- **SOP5146** – Validation of disinfectants
- **SOP5252** – Production of Saline Bags for Serum Eyedrops
- **SOP6483** – MSL validation of bacterial detection systems for microbiological screening of NHSBT samples not covered by the IFU
- **SOP6679** – Screening of clinical trial samples using the BacT/ALERT
- **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
- **SPN153** – Environmental monitoring materials
- **SPN195** – Bacteriology Testing of Tissue Samples.
- **SPN196** – Bacteriological Screening of Samples sent to MSL-Bacteriology in BacT/ALERT Bottles.
- **SPN415** – BacT/ALERT culture bottles, Screened Platelet Concentrates and Associated Units sent to the MSL-Bacteriology for Confirmatory Bacteriological Testing