Public Health England
National Infection Service

National Mycobacterium Reference Service-South (NMRS-South) user manual
About Public Health England

Public Health England exists to protect and improve the nation’s health and wellbeing, and reduce health inequalities. We do this through world-leading science, knowledge and intelligence, advocacy, partnerships and the delivery of specialist public health services. We are an executive agency of the Department of Health, and a distinct delivery organisation with operational autonomy to advise and support government, local authorities and the NHS in a professionally independent manner.

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Sustainable Development Goals
# Contents

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>About Public Health England</td>
<td>2</td>
</tr>
<tr>
<td>Contents</td>
<td>3</td>
</tr>
<tr>
<td>Introduction</td>
<td>4</td>
</tr>
<tr>
<td>Personnel and contact details</td>
<td>7</td>
</tr>
<tr>
<td>Summary of NMRS-South services</td>
<td>8</td>
</tr>
<tr>
<td>NMRS-South services and turn around times</td>
<td>9</td>
</tr>
<tr>
<td>Key factors affecting specimen performance</td>
<td>11</td>
</tr>
<tr>
<td>NMRS-South pricelist April 2017 to March 2018</td>
<td>15</td>
</tr>
<tr>
<td>Specimen and sample submission guidelines</td>
<td>16</td>
</tr>
<tr>
<td>Guidance on packaging and transport</td>
<td>19</td>
</tr>
<tr>
<td>Reports</td>
<td>22</td>
</tr>
<tr>
<td>Submitting tissue samples from deceased people</td>
<td>23</td>
</tr>
<tr>
<td>Complaints</td>
<td>24</td>
</tr>
<tr>
<td>Caldicott recommendations</td>
<td>25</td>
</tr>
<tr>
<td>References</td>
<td>26</td>
</tr>
</tbody>
</table>
Introduction

The National Mycobacterium Reference Service-South (NMRS-South) is an accredited constituent reference laboratory of the National Infection Service (NIS) of Public Health England (PHE). With its sister laboratory the National Mycobacterium Reference Service – Central & North (NMRS-Central & North) based in Birmingham, it provides Mycobacterial Reference services to the NHS in England. NMRS works closely with Mycobacterial Reference services in the Devolved Administrations.

The principal activities of the unit include: a primary isolation service including microscopy and culture and a Fastrack (PCR) Service for detection of *M. tuberculosis* complex and rifampicin (and multidrug) resistance in clinical specimens and reference samples; molecular based rapid identification of Mycobacterium sp isolates; drug susceptibility testing for first line and reserve drugs; and molecular epidemiological typing and support of outbreak investigations/contact tracing. Interferon Gamma Release Assays for detection of latent infection and diagnosis are also carried out.

The NMRS-South provides information and advice to clinical and public health teams for the identification and investigation of outbreaks and TB transmission. Our activities support surveillance activity for TB in the UK.

The NMRS-South is moving towards provision of a Mycobacterial Reference Service based on Whole Genome Sequencing (WGS) for identification of Mycobacterium sp isolates, prediction of drug susceptibility and resistance and determination of relatedness for detection of transmission and investigation of outbreaks. This will be a phased introduction:

**Phase 1:** As of 22 December 2017 the NMRS-South will no longer provide MIRU VNTR typing and will instead sequence samples involved in ongoing clusters of public health importance and laboratory contamination events. WGS provides improved discrimination based on single nucleotide polymorphism (SNP) differences between all sequenced isolates.

**Phase 2:** WGS will be introduced for all mycobacterial cultures, replacing current tests for identification and resistance prediction from early 2018. Users will be advised when a date is determined.

**Phase 3:** First line phenotypic sensitivity testing for those samples genotypically sensitive to first line anti-tuberculous therapy is under review pending an evaluation of the performance of sensitivity prediction using WGS.
By implementing WGS within a single management structure across both laboratories in the Mycobacterial Reference service for England the new service will improve the diagnosis, treatment and public health management of TB and plays a significant role in delivering England’s TB strategy.

NMRS-South has been working towards this transition for some time so we would not anticipate any reduction in service, although we accept that it will take some time for users to establish similar familiarity with report formats.

Clinical and scientific support will be available from the NMRS-South to guide you through the changes.

There will be no cost implications resulting from the change for reference mycobacterial services initially, but as this is a new service, costs will be reviewed once the service is implemented and periodically thereafter.

The WGS service will include: identification of mycobacterial cultures, sensitivity/resistance prediction and phenotypic susceptibility testing of members of *M.tuberculosis* complex, and determination of relatedness between *M.tuberculosis* complex isolates (typing). Identification of non-tuberculous mycobacteria (NTM) will continue to be a core part of our service, and WGS provides more accurate identification of these organisms. In response to recommendations (2015 TB services review, BTS NTM treatment guidelines, NICE guidance for management of Cystic Fibrosis), we are working to standardise our testing methods and costs across the service including drug sensitivity testing.

We will be monitoring turnaround times as part of the introduction of the service. Full WGS results are predicted to be reported within 7 working days from receipt of positive cultures.

The unit is a World Health Organization (WHO) Supranational Reference Laboratory for *M. tuberculosis* DST; together with centres in Germany, Sweden and Belgium, it co-ordinates EQA for DST across the EU and non-EU states in the WHO Euro region. It is also a member of the WHO Global Laboratory Initiative involved with the development of WHO/IUATLD strategies for management of mycobacterial diseases and participates in international EQA schemes receiving samples and dispatching to designated regions. The NMRS-South, with the ECDC, co-ordinates the European Reference Laboratory Network for mycobacterial disease.
Delivery address

Address:

Public Health England
National Mycobacterium Reference Service-South
National Infection Service
61 Colindale Avenue
London
NW9 5HT

DX Address:

PHE Colindale
NMRS-South
DX 6680700
COLINDALE NW

Telephone: +44 (0)20 832 76957

Email: nmrl@phe.gov.uk
       phe.nmrs-south@nhs.net

Web: https://www.gov.uk

Hours of service

Services will be provided between 09.00 to 17.00 hours, Monday to Friday (excluding bank holidays).
Personnel and contact details

<table>
<thead>
<tr>
<th>Name</th>
<th>E-mail</th>
<th>Telephone</th>
</tr>
</thead>
<tbody>
<tr>
<td>General enquiries</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><a href="mailto:nmrl@phe.gov.uk">nmrl@phe.gov.uk</a></td>
<td>020 832 76957</td>
</tr>
<tr>
<td></td>
<td><a href="mailto:phe.nmrs-south@nhs.net">phe.nmrs-south@nhs.net</a></td>
<td></td>
</tr>
<tr>
<td>Clinical enquiries</td>
<td>Dr Eliza Alexander</td>
<td><a href="mailto:eliza.alexander@phe.gov.uk">eliza.alexander@phe.gov.uk</a></td>
</tr>
<tr>
<td>Laboratory manager</td>
<td>Mrs Norah Easy</td>
<td><a href="mailto:norah.easy@phe.gov.uk">norah.easy@phe.gov.uk</a></td>
</tr>
<tr>
<td>Senior Clinical Scientist</td>
<td>Dr Vlad Nikolayevskyy</td>
<td><a href="mailto:vlad.nikolayevskyy@phe.gov.uk">vlad.nikolayevskyy@phe.gov.uk</a></td>
</tr>
<tr>
<td>Clinical Scientist</td>
<td>Dr Simon Warwick</td>
<td><a href="mailto:simon.warwick@phe.gov.uk">simon.warwick@phe.gov.uk</a></td>
</tr>
<tr>
<td>Safety officer</td>
<td>Mrs Melanie Kemp</td>
<td><a href="mailto:melanie.kemp@phe.gov.uk">melanie.kemp@phe.gov.uk</a></td>
</tr>
<tr>
<td>Quality Manager</td>
<td>Ms Helen Liddy</td>
<td><a href="mailto:helen.liddy@phe.gov.uk">helen.liddy@phe.gov.uk</a></td>
</tr>
</tbody>
</table>

General results enquiries are addressed by our administrative staff initially who will direct clinical and technical enquiries to the appropriate staff. There is daily cover for clinical and technical issues. Complex cases are discussed further internally and the advice returned will often be a product of this discussion not just the opinion of the person answering the call. We record the advice given for continuity. We must know the identity both of the patient and the caller.
Summary of NMRS-South services

- Identification of mycobacterium sp. isolates (a rapid molecular DNA-amplification based identification service provided free to the NHS)
- Drug susceptibility testing for *M. tuberculosis* complex (phenotypic culture based for first-line drugs on solid media and liquid culture based for reserve drugs; this is provided free to the NHS)
- Drug susceptibility testing for Non-Tuberculous Mycobacteria (NTM) (phenotypic culture based testing for clinically significant NTM isolates; this is free of charge for NHS patients under 18 years old)
- Molecular epidemiological service (eg outbreak investigations, laboratory cross-contamination, provided free to the NHS)
- Interferon gamma release assay (latent TB infection diagnosis)
- Primary isolation service (including microscopy and culture)
- Fastrack (PCR) service (molecular detection of *M. tuberculosis* complex and rifampicin resistance or multi-drug resistance in primary specimens and cultures)
- Scientific and technical advice
- Clinical advice for case and outbreak investigation and management
- Computerised database on laboratory confirmed cases
- Archived collection of mycobacterium isolates for epidemiological analysis
- Training
- Research and development

For further information concerning services or matters of interest visit the PHE website at https://www.gov.uk/government/organisations/public-health-england
NMRS-South services and turn around times

Please note all turnaround times are dependent upon the receipt of a pure culture containing sufficient bacteria for analysis. At least 90% of all samples will be available at the turnaround times listed below. We endeavour to assist laboratories by treating contaminated cultures to purify mycobacteria rather than returning them to the sender.

<table>
<thead>
<tr>
<th>Service</th>
<th>Description</th>
<th>Turnaround time</th>
</tr>
</thead>
<tbody>
<tr>
<td>REFERENCE SERVICE: Identification of AFB Positive Cultures</td>
<td>Rapid identification of M. tuberculosis complex &amp; common Non-Tuberculous Mycobacteria (NTM) using molecular techniques</td>
<td>Only cultures received by 9:30 am are processed the same day, all other cultures are processed the following day</td>
</tr>
<tr>
<td></td>
<td>Whole genome sequencing may be performed when clinically indicated and identification is not possible by the above method.</td>
<td>Reported within 2 working days of culture receipt</td>
</tr>
</tbody>
</table>

Phenotypic M. tuberculosis sensitivity

<table>
<thead>
<tr>
<th>First Line Antibiotics</th>
<th>Isoniazid, Rifampicin, Ethambutol, Pyrazinamide</th>
<th>Reported within 2-3 weeks of culture receipt</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reserve Antibiotics</td>
<td>Ofloxacin, Moxifloxacin Amikacin, Kanamycin, Prothionamide, Capreomycin</td>
<td>Reported within 2-3 weeks of request for reserve sensitivities, Identification of rifampicin resistance or MDR-TB in referred cultures</td>
</tr>
<tr>
<td>Additional Antibiotics</td>
<td>Linezolid PAS (this is rarely performed and the exact correlation with clinical efficicacy is unclear)</td>
<td>Reported within 2-3 weeks of request for these sensitivities or identification of XDRTB</td>
</tr>
</tbody>
</table>

Non-tuberculous mycobacteria (NTM) sensitivity*

<table>
<thead>
<tr>
<th>Rapid growers</th>
<th>Co-trimoxazole, Linezolid, Ciprofloxacin, Moxifloxacin, Cefoxitin, Amikacin, Doxycycline, Clarithromycin and Tobramycin, Imipenem</th>
<th>Reported within 1-2 weeks of culture receipt</th>
</tr>
</thead>
<tbody>
<tr>
<td>Slow growers</td>
<td>Clarithromycin, Ethambutol, Rifampicin</td>
<td>Reported within 2-3 weeks of culture receipt</td>
</tr>
</tbody>
</table>

*Please note the antibiotic panel tested for NTM will vary depending on the organism identified.
<table>
<thead>
<tr>
<th>Service</th>
<th>Turnaround time</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>PRIMARY SERVICE</strong></td>
<td></td>
</tr>
<tr>
<td>Fluorescence microscopy on clinical samples</td>
<td>Reported within 1 working day of specimen receipt</td>
</tr>
<tr>
<td>Culture of clinical samples (including blood and bone marrow) on liquid and solid media</td>
<td>Final negative result reported after 6 weeks (or 8 weeks for blood and CSF samples)</td>
</tr>
<tr>
<td>NB. Cultures that are negative at 6 or 8 weeks which were positive on either FastTrack or microscopy are incubated further for a total of 12 weeks. A report is only issued if the culture subsequently becomes positive. A further incubation comment is also added to the report for such cases</td>
<td></td>
</tr>
<tr>
<td><strong>MOLECULAR EPIDEMIOLOGY SERVICE</strong></td>
<td></td>
</tr>
<tr>
<td>VNTR-MIRU analysis</td>
<td>Final report within 4 weeks of receipt of a suitable culture (stop date 22 December 2017)</td>
</tr>
<tr>
<td>Confirmation of rapid fingerprinting by further VNTR-MIRU analysis</td>
<td>Final report within 6 weeks of receipt of a suitable culture (stop date 22 December 2017)</td>
</tr>
<tr>
<td><strong>FASTTRACK PCR SERVICE</strong></td>
<td></td>
</tr>
<tr>
<td>Rapid detection of <em>M. tuberculosis</em> complex and Rifampicin/Isoniazid resistance</td>
<td>Positive cultures received by 9:30 am are analysed on the same day and results communicated to the sending laboratory within 1 working day.</td>
</tr>
<tr>
<td>Rapid detection of <em>M. tuberculosis</em> complex and Rifampicin resistance detection in pulmonary and CSF samples</td>
<td>Clinical Samples received by 9:30 am are analysed on the same day and results communicated to the sending laboratory. Pulmonary/CSF 1 day turn around time and non-pulmonary 2 weeks turn around time.</td>
</tr>
<tr>
<td>NB. A minimum CSF (NOT supernatant) volume of 0.5ml is required for Fastrack. If culture is specifically requested, we will also culture the residual material but the minimum volume required would be &gt;0.5ml</td>
<td></td>
</tr>
<tr>
<td>Detection of <em>M. tuberculosis</em> complex and rifampicin resistance detection in non-pulmonary samples</td>
<td>Clinical samples received before 9:30 am Wednesday, results communicated to sending laboratory by Friday</td>
</tr>
<tr>
<td>NB. For paraffin wax embedded samples, the whole wax block must be sent. Wax shavings or shaved sections are not accepted. The block MUST always be submitted with a diagram/slide indicating the area where AFB/granuloma were see otherwise the sample will not be processed. If no diagram/slide is received within 2 weeks the block will be sent back to the referring laboratory</td>
<td></td>
</tr>
<tr>
<td>NB. The NMRS-South proactively analyses cultures produced at NMRS-South from specimens submitted to our national Fastrack molecular diagnostic service. If rifampicin resistance mutations (predictive of MDRTB) are detected we will automatically set up cultures for first-line and reserve drugs at no further cost to the NHS</td>
<td></td>
</tr>
<tr>
<td><strong>INTERFERON GAMMA RELEASE ASSAY</strong></td>
<td></td>
</tr>
<tr>
<td>Quantiferon assay</td>
<td>Reports sent out within 10 working days of receipt of sample</td>
</tr>
<tr>
<td><strong>ADVISORY SERVICE</strong></td>
<td></td>
</tr>
<tr>
<td>Clinical and technical advice</td>
<td>Available Monday-Friday 9:00 to 17:00</td>
</tr>
</tbody>
</table>
Key factors affecting specimen performance

PLEASE NOTE: If a specimen is submitted to NMRS-South for an investigation that we do not offer we will temporarily archive the sample/isolate and issue a report to the sender explaining the reasons for the sample’s rejection. The specimen can be sent back to the referring laboratory if requested.

Reference service for positive mycobacterial cultures

Turnaround times for bacterial identification and drug susceptibility tests is dependent upon the receipt of unmixed viable cultures. Cultures that require purification or that cannot be retrieved because they are no longer viable and necessitate a second isolate may increase turnaround time significantly.

Our approach is to assist you wherever possible by not rejecting contaminated cultures. However, submitting a second culture minimises further delay.

If an aliquot of a liquid culture is to be sent then a concentrated sample is required. Transfer 3ml of the concentrated sample to a sterile universal for transport, and store the rest of the sample (1-2ml) at your laboratory.

Leaking cultures will not be processed and a report will be issued informing the user of this.

Primary service

Clinical specimens submitted for culture should be as fresh as possible, we strongly recommend that specimens are refrigerated if any delays in submission to the NMRS-South are likely.

Do not add diluent to specimens. When small pieces of tissue are submitted sterile saline or sterile water may be added to prevent desiccation. Do NOT use formalin as this will kill the mycobacteria.

Blood samples and bone marrow samples (minimum volume of 3ml) for culture should be sent in a vacutainer containing lithium-heparin or sodium citrate NOT EDTA (Mycobacterial survival is lower in EDTA tubes).
We do not routinely perform microscopy on blood, bone marrow or urine specimens; we only culture early morning urine specimens.

If you wish to send samples of non-human origin please contact NMRS-South before sending.

**Fastrack service**

This service offers rapid molecular detection of *Mycobacterium tuberculosis* complex and rifampicin resistance, from primary samples.

Ideal specimens are smear positive primary specimens. Other specimens have lower sensitivities for detection (1, 2).

Generally smear positive samples are more likely to be successfully analysed as they have a higher Acid Fast Bacilli (AFB) load. As part of Fastrack, the NMRS-South pro-actively analyses specimens shown to be rifampicin resistance for isoniazid resistance and any resulting cultures from specimens containing MTBC with rifampicin/isoniazid resistant mutations (predictive of MDRTB) are pro-actively set up for first line and reserve drugs at no further cost to the NHS.

In general fluid samples such as CSF, pleural fluid and ascites have much lower sensitivities; the minimum amount of CSF that will be examined is **0.5ml (not supernatant)**. However, submitting the largest possible volume of CSF and other fluids will increase the sensitivity.

For paraffin wax embedded samples, the **whole wax block** must be sent, wax shavings or shaved sections are not accepted. The block **MUST** always be submitted with a **diagram/slide** indicating the area where AFB /granuloma were see otherwise the sample will not be processed. If no diagram/slide is received within 2 weeks the block will be sent back to the referring laboratory. Wax blocks will also be returned to the referring laboratory on successful completion of the test.

Lysed blood or heavily bloodstained samples can interfere with PCR based reactions. DNA in specimens requesting molecular tests may degrade if stored for too long before referral.

**Interferon gamma release assay**

Blood should be collected in the tubes provided (follow instructions) and **MUST** be incubated within 16 hours of collection at 37°C for 16-24 hours, before sending. Samples must reach NMRS-South within 72 hours post incubation.
Referral of specimens/cultures

No specimens or cultures are referred by the NMRS-South to other laboratories. If other investigations are required at another laboratory then it is strongly recommended that a further specimen/culture is sent directly to that laboratory.
Requesting additional tests

Fastrack service

Additional requests for Fastrack testing must be accompanied by a Fastrack request form (N2) (https://www.gov.uk/government/publications/nmrl-fastrack-request-form)

Requests can be processed, on receipt of sufficient and suitable material, with in the time periods specified below:

1. **CSF samples**: Within 1 day of specimen receipt
2. **Sterile samples (except CSF)**: within 2 weeks of specimen receipt
3. **Smear negative sputum**: within 1 day of specimen receipt
4. **Smear positive sputum**: up to 1 week of specimen receipt
5. **Positive culture**: up to 3 weeks of culture receipt

*M. tuberculosis* sensitivity

All first isolates of *M. tuberculosis* will be processed for first line sensitivity testing. All new MDRs will be processed for reserve drug sensitivity testing. Sensitivities will be repeated on isolates more than 2 months apart.

Additional sensitivity testing on *M. tuberculosis* isolates must be discussed with the NMRS-South laboratory staff before requests are submitted. Appropriate additional sensitivity testing requests can be processed up to 6 weeks after culture receipt.

Non-tuberculous mycobacteria (NTM) sensitivity

All repeatedly clinically significant NTM isolates, will be set up for the appropriate panel, based on the organism identification and the patient’s clinical status. Full completion of the request form with clinical details aids this process.

Additional sensitivity testing on NTM isolates must be discussed with the NMRS-South laboratory staff before requests are submitted. Appropriate additional NTM sensitivity testing requests can be processed up to 6 weeks after culture receipt.
### NMRS-South pricelist April 2017 to March 2018

Please note all environmental and animal samples will be charged the non-NHS price

<table>
<thead>
<tr>
<th>METHODS</th>
<th>REQUEST</th>
<th>NHS/PHE PRICE * (per isolate/sample)</th>
<th>NI/SC/CI PRICE** (per isolate/sample)</th>
<th>NON-NHS PRICE ** (per isolate/sample)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Identification of submitted cultures and first line drug testing on solid media</td>
<td>ID and Sensitivity</td>
<td>£0</td>
<td>£68.92</td>
<td>£91.89</td>
</tr>
<tr>
<td>Reserve drugs susceptibility testing</td>
<td>Extra Sensitivities</td>
<td>£0</td>
<td>£51.69</td>
<td>£68.92</td>
</tr>
<tr>
<td>Molecular epidemiology of TB cultures ***</td>
<td>Molecular Epidemiology</td>
<td>£0</td>
<td>£43.65</td>
<td>£57.43</td>
</tr>
<tr>
<td>Non-Tuberculous Mycobacteria (NTM) DST</td>
<td>ID and Sensitivity</td>
<td>£60.34</td>
<td>£60.34</td>
<td>£78.03</td>
</tr>
<tr>
<td>Primary specimen culture into liquid and solid media</td>
<td>Culture</td>
<td>£37.90</td>
<td>£37.90</td>
<td>£51.69</td>
</tr>
<tr>
<td>Fastrack: PCR identification of <em>M. tuberculosis</em> complex and molecular rifampicin testing (includes culture and identification of resulting cultures)</td>
<td>Fastrack</td>
<td>£142.71</td>
<td>£142.71</td>
<td>£206.12</td>
</tr>
<tr>
<td>Quantiferon Plus for diagnosis of latent infection and active tuberculosis (based on purchase of 10 tests at a time)</td>
<td>IGRA</td>
<td>£47.50</td>
<td>£47.50</td>
<td>£47.50</td>
</tr>
<tr>
<td>Further Molecular Identification (sequencing)</td>
<td>ID and Sensitivity</td>
<td>£142.70</td>
<td>£142.70</td>
<td>£206.12</td>
</tr>
</tbody>
</table>

**NOTE:** Where samples are unsuitable for testing (leaking, incorrect container, unlabelled specimen) or are submitted with no or incomplete request forms, a fixed administrative charge of £14.93 will be applied

* = Internal Recharging (NHS/PHE)  
** = External Recharging  
*** = Outside of outbreak investigations we do not analyse non NHS/PHE cultures without prior agreement

*Please note all above prices are subject to VAT*
Specimen and sample submission guidelines

Specimens **MUST** be labelled with the following:

1. Surname/forename, or other unique patient identifier
2. Sender’s sample number/reference number
3. Date of birth

**Request Forms MUST** match the corresponding specimen and include the above information on the sample as well as details listed below. The Name and contact information of the requester (telephone number vital for urgent requests) should also be included.

1. Tests required
2. Sample type
3. Specimen/Isolation site
4. Date of dispatch
5. NHS number
6. Sex
7. Full patient address including postcode
8. Date and time of collection of specimen
9. Relevant clinical information
10. Reference number
Request forms to accompany specimens/cultures

There are four NMRS-South request forms, these are as follows:

1. Mycobacterium Referral Form (primary samples and positive cultures) (N1)
2. Fastrack Request Form (N2)
3. Molecular Epidemiology Request Form (N3)
4. QuantiFERON®-TB Gold PLUS test (N4)

- NMRS-South request forms can be downloaded from the following website: [https://www.gov.uk/government](https://www.gov.uk/government), or ordered pre-labelled with the requestor code and address from the PHE LIMS department via e-mail (LimsHelpdesk@phe.gov.uk), the latter may reduce clerical error

- please ensure the appropriate NMRS-South request from is fully completed for the sample being submitted with the required information as stated above (1-13) as well as the correct telephone number, particularly for Fastrack requests

- each sample must be accompanied by an individual request from, even if more than one sample is submitted from the same patient
- the PHE NMRS-South laboratory advises users where forms are poorly completed
- NMRS-South advises its users when rejecting referred specimens and cultures
- wherever possible the NMRS-South supports its users by not rejecting referred specimens and cultures
- the space marked “For NMRS-South Use Only” is intended for use by NMRS-South staff, please do not write in this space

**Urgent specimens**

If a reference service is required urgently, please contact the NMRS-South to discuss prior to dispatch. Always mark ‘URGENT’ clearly on the request form.
Guidance on packaging and transport

A small but significant proportion of samples received by the PHE National Infection Services are poorly or inappropriately packaged. This often leads to samples leaking or being damaged during transport, therefore posing a serious risk to PHE staff handling them. PHE hopes to eliminate this risk by helping laboratories to understand basic packaging requirements.

The following guidelines are intended to cover the transport of clinical samples from humans, or cultures of micro-organisms isolated from such samples to another laboratory for diagnostic or other clinical testing within the UK where the micro-organisms suspected of causing the disease are all either hazard groups two, three or four.

The terms Category A and Category B are limited to classifying samples/microbial cultures being transported to another laboratory.

These guidelines are not intended as a substitute for reading the advice given by DfT and DoH.

<table>
<thead>
<tr>
<th>Sample description</th>
<th>Packaging requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Category A samples are known or suspected to contain a microbial agent with the following definition: &quot;an infectious substance which is transported in a form that if exposure to it occurs, is capable of causing permanent disability, life-threatening or fatal disease to humans or animals.&quot; (see indicative list) The majority are Hazard Group 3 or 4.</td>
<td>Assign to UN2814 (Humans) Packaging Instructions PI620 Supporting documentation as per ADR Transport as category A ADR licensed courier</td>
</tr>
<tr>
<td>For practical reasons to allow referral / reference services to continue a limited number of Category A agents have exempted from being transported as Category A. These are Vero-cytotoxin producing <em>Escherichia coli</em> (VTEC), <em>Mycobacterium tuberculosis</em> and <em>Shigella dysenteriae</em> 1.</td>
<td>Assign UN3373 Packaging instruction PI650 Send by courier Royal Mail will NOT accept</td>
</tr>
<tr>
<td>Category B samples are those that do not meet the definitions of Category A.</td>
<td>Assign UN3373 Packaging instruction P1650. Send by Post or courier Royal Mail WILL accept</td>
</tr>
</tbody>
</table>
Use the links below for further information:

- https://www.gov.uk/shipping-dangerous-goods/overview
- http://www.icao.int
- http://www.unece.org

Reporting incidents during transportation that may affect the safety of personnel:

- the NMRS-South will report any leaking containers and improperly packaged parcels to users
- leaking cultures will not be processed by the NMRS-South, users will be informed and a repeat sample requested
- repeated offences will be referred to the PHE Safety Committee who may refer to the Health and Safety Executive

Label the specimen/culture bottle with the name of the patient (or unique identifier) and the laboratory number. All specimens/cultures sent to the NMRS-South must be packed in accordance with IATA regulations 650/602:

1. The top of the specimen/culture bottle must be fixed on firmly so that there is no chance of leakage. It may be necessary to use parafilm to ensure that the top remains on tight during transport. This will also prevent desiccation of the specimen/culture in transit which will compromise successful culture. Wrap the bottle in absorbent material and seal inside a minigrip bag. The NMRS-South will endeavour to process primary material if leakage occurs but this is likely to compromise the chance of successful culture, and we will request the user to send us an additional specimen. Leaking cultures will NOT be processed and a repeat sample will be requested.
2. Do not submit positive cultures on agar plates. These will be discarded and not processed.
3. Place the specimen/culture inside a leak proof plastic container with enough absorbent material to be able to absorb all the contents of the bottle in case of leakage.
4. Place the plastic container inside a fibreboard box or approved DX plastic outer packaging.
5. Place the form between the plastic container and the outer cardboard box/plastic packaging. DO NOT PLACE IT INSIDE THE PLASTIC CONTAINER. In the event of leakage/breakage the whole shipment will be destroyed without opening.
Specimens may be sent by Royal Mail or courier

We recommend that to minimise delays specimens, especially those sent for our Fastrack molecular diagnostic service, are sent by routine courier e.g. DX or other specialised courier. Please ensure that the courier is able to reach the NMRS-South before 17:00h.

Cultures can only be sent by courier.
Reports

The NMRS-South issues “acknowledgement of receipt” reports on the date of receipt of the samples.

NMRS-South reports are routinely sent out via PHE-eLab. Printed reports will only be sent out if the referring laboratory is not registered to PHE-eLab. PHE-eLab details can be found on https://phe-elab.phe.org.uk/Authentication

Users can access archived reports on PHE-eLab using the search function for up to 2 years.

It is our policy that reports containing patient data should not be sent by routine email. Emails cannot be relied on to guarantee security of patient data because they can be intercepted by a third party on route (unless encrypted).
Submitting tissue samples from deceased people

Compliance with the Human Tissue Act

The PHE Microbiology Services is licensed by the Human Tissue Authority (HTA) (Licence number 12459) to store tissues from deceased people for scheduled purposes. Post mortem samples are submitted to PHE National Infection Service by coroners or pathologists for examination to help them determine the cause of death.

As part of our public health remit, we sometimes need to retain these samples for the purpose of public health monitoring which is defined as a scheduled purpose within the Human Tissue Act 2004. Further analysis of these samples may help determine the cause of an outbreak due to an infectious disease or may allow identification of new strains of infectious agents at a later date.

Obtaining consent to remove, store and use human tissues for a scheduled purpose is one of the underlying principles of the Human Tissue Act. PHE Microbiology Services receives post-mortem samples from Coroners’ post-mortems or from NHS establishments across the UK and therefore we are not in a position to either seek consent ourselves or have arrangements in place to confirm that the requirements of the Act have been complied with by the sender.

We would ask coroners and pathologists who send post mortem samples to PHE Microbiology Services to provide us with details of consent, and would also ask that consent includes retention of the samples for the purpose of public health monitoring.

When tissue samples from deceased people are received at the PHE Microbiology Services they are retained securely and confidentiality is maintained in compliance with Caldicott principles as are all samples received at this centre. It is normal practice for tissue samples from the deceased to be disposed of in the same way that all others clinical samples we receive are disposed of. However, we will adhere to any specific requirements regarding disposal or returning tissue samples if requested by the sending coroner or pathologist.
Complaints

Please refer complaints by post, email or telephone to Dr Eliza Alexander, Interim Clinical Lead or Mrs Norah Easy, Laboratory Manager of the NMRS-South using the contact details provided on Page 7. All complaints will receive a final response within 20 days of receipt of the complaint.
Caldicott recommendations

The recommendations of the Caldicott report (1997) have been adopted by the Public Health England (PHE). These recommendations relate to the security of patient identifying data (PID) and the uses to which they are put.

The PHE observes Caldicott guidance in handling PID and has an overall Caldicott Guardian who is the Director of Health Protection and Medical Director who reports through the Information Governance and Caldicott functions and onwards to the National Executive.

The PHE Microbiology Services has a Caldicott guardian who advises the Director of Microbiology Services on confidential issues and is responsible for monitoring the physical security of PID in all parts. This also applies to the transfer of results of investigations to and from PHE Microbiology Services whether by mail services; telephone or email. The value of ‘safe haven’ arrangements or other means of the sender and receiver information identifying themselves to each other before data is transferred is emphasised.

The PHE is anxious to audit the security of its PID in collaboration with its customers. Customers are invited to review our arrangements in conjunction with individual laboratory directors and/or the Caldicott Guardian. Customers are also asked to draw to the Caldicott Guardian’s attention any instances where PID security has been threatened or has broken down.

Any uses that PID are put to outside the clinical diagnostic services generally allow patient identifiers to have been removed before hand, and when PID is used for research purposes the proposals are considered first by the appropriate Ethics Committee. All enquiries regarding the security and use of PID should be addressed to the Caldicott Guardian at: nmrl@phe.gov.uk
References
