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All processes and procedures described herein are mandatory within the Black Country Pathology Services.

Contents

1 INTRODUCTION

The BCPS may receive specimens that are unlabelled, request forms or specimens with details that are either illegible or with insufficient information to carry out the investigation, and sometimes specimens with identification details that do not match those on the request form. Under Clinical Governance the BCPS has a duty of care to ensure that the results from specimens processed match the source patient and that investigations carried out are clinically relevant. Accurate identification of the source patient from whom the specimen is taken is essential. Therefore, to prevent an adverse event consequent to the receipt of these requests the following protocol has been adopted for the acceptance and rejection of pathology requests (PAT/RA/002).

It should be recognised that any specimen is potentially infectious, and it is therefore necessary to ensure that all specimens are safely contained and transported from the patient to the laboratory [PAT/SOP/043]. If a specimen is known to be high risk, then it is also important to label it in such a way that pathology staff can easily identify it and are thereby able to take the appropriate precautions.

These guidelines provide an overview of the requirements for reception, labelling and rejection of specimens and requests and are designed to meet the requirements of ISO 15189: 2022.

1.1 Scope and purpose

This SOP is aimed at all grades of staff working across all BCPS reception and sample processing areas both during and outside of normal working hours. The purpose is to provide define acceptance and rejection criteria to mitigate risk as far as possible to patient care.

1.2 Responsibility

It is the policy of the BCPS to ensure that all requests processed comply with the recommended guidelines on identification and supplementary information [Institute of Biomedical Sciences- Patient sample and request form identification criteria PAT/EXT/037]. The BCPS takes responsibility for all samples received.

The responsibility for requesting a pathology investigation lies with an authorised and trained practitioner (normally a clinician). It is the responsibility of the requester to ensure that samples are correctly labelled and request forms are completed to agreed standards.
Up to date information for users in order to facilitate proper use of pathology services is available on the BCPS website (link to Lab Tests online provided). The information includes instructions for specimen handling and completion of the request form and guidance for collecting samples.
If a request fails to meet the essential guidelines on identification, then the request may not be processed.

1.3 References and related documents

ISO 15189: 2022 Medical laboratories- Requirements for quality and competence [PAT/EXT/001]

Institute of Biomedical Sciences- Patient sample and request form identification criteria [PAT/EXT/037]

Other related documents include [PAT/SOP/012, PAT/FOR/043, PAT/FOR/040, PAT/FOR/048, IT/SOP/003, CYT/SOP/49 and CYT/SOP/65, CYT/NOT/58, PAT/RA/035, CHE/PRO/SOP/004, CHE/SOP/104]

BCPS website https://www.bcpathology.org.uk/

RWT CP50 Policy for the Management of Risks associated with Clinical Diagnostic tests and Screening http://trustnet/strategies-policies/clinical-policies-procedures-guidelines/clinical-practice-policies/cp50/

2 RECEPTION

2.1 Requesting

Each request form is considered an agreement. The primary mechanism and recommended method for requesting pathology investigations is via electronic requesting (e-Requesting/ order comms system OCS); e-requesting system in place for BCPS is ICE, alternatives systems are also used such as NPEX, refer to IT/SOP/003 for further detail. The e-Requesting systems are linked to the pathology laboratory information management systems (LIMS) thus data is transmitted electronically, mitigating the risk of transcription error. For further guidance on ICE requesting refer to [IT/SOP/006 and IT/SOP/007].

Access to e-Requesting for the purpose of making requests and receiving reports requires approval of the user and the issuing of a personal login and password. Requests can also be made using a paper request form (manual method). e-Requesting should be used as the primary requesting method.

The design and development of BCPS electronic request forms must be controlled through the BCPS IT LIMs change board.
Paper request forms are managed via Q-Pulse document module and cannot be released without prior approval.
Amendments are made by the BCPS IT team and/or Trust Medical Illustrations department via BCPS who require approval from the BCPS management. The Head of Pathology IT and Transformation is authorised to approve request forms on behalf of the BCPS; transfusion and antenatal forms are agreed through the Partner Trusts Hospital Transfusion Groups and the antenatal teams.

All samples for investigation must be accompanied by a completed request form. Instructions for the completion of the requests form are contained on the website.

Some specific tests require discussion with the appropriate pathology clinician and their agreement prior to the sample being taken to ensure efficient patient management e.g. discuss requests for TB spot with Microbiology Consultant.

2.1.1 Oral requests

Verbal requests for additional investigations than those originally requested on the request form (with the exception of transfusion) known as ‘add-ons’ are accepted for samples that have already been transported or accepted by the laboratory in some instances. Verbal requests must only be made by personnel authorised to request such tests. These requests are only processed if the sample is still suitable for testing; information regarding the time interval for requesting add-ons is available on the BCPS test database where appropriate. The test requested verbally must be recorded in the LIMs; clearly identifying it as a verbally requested test (add-on).

For all Microbiology tests, verbal requests are not carried out until an e-request or a signed manual request form is received. On receiving a verbal request inform the requestor of this requirement and

store the sample appropriately until the request form is received. On receiving such a request inform the Specimen Reception staff to expect it and that the sample is already in the laboratory.

In the event of electronic requesting being unavailable, the reverse of the carrier form can be used to manually request pathology investigations.

In the event of a major incident major incident, identification numbering system must be used in place of the NHS or Hospital number. Further guidance is available in [PAT/SOP/030].

2.2 Request information and specimen details required

Request and specimen details are categorised into essential and desirable information as shown in table 1. The NHS number should be used as the primary identifier. Requests that do not comply with the guidelines for essential information **may not be** processed, refer to rejected samples.
It is the responsibility of the requestor to ensure the patient information is accurate; Patient Administration System (PAS), national spine can be used to confirm patients' details.

Table 1 Acceptance criteria

SAMPLE	Essential date set	Desirable data set	Other

NHS number or Hospital number	X		Blood Transfusion will accept either NHS number OR hospital number. Non cervical screening Cytology requests require both identifiers.
First name and surname or approved unique identifier.	X		Approved unique identifiers include GUM identifier, Occupational health identifier, research trial identifier, Emergency Admission of unknown patient (gender must be provided).
Date of birth	X		
Date and time sample collected		X	Blood transfusion essential information. Essential for Quantiferon & Tryptase requests. Sometimes essential dependant on investigation.
Sample type and where appropriate anatomical site	Histology & microbiology	X	Essential if more than one sample per request. Histology and microbiology essential information.
Sample taker identifier		X	Blood transfusion essential information.
REQUEST FORM	**Essential date set**	**Desirable data set**	**Other**
NHS number or Hospital number	X		Blood Transfusion and Cytology require both identifiers.
First name and surname or approved unique identifier	X		Approved unique identifiers include: GUM identifier, Occupational health identifier, research trial identifier, Emergency admission of unknown patient (gender must be provided).
Date of birth	X		
Biological sex		X	
Patient's location and destination of report	X		
Patient's consultant, GP or name of requesting practitioner	X		
Investigation(s) required	X		
Sample type and where appropriate anatomical site	X		
Clinical information		X	Dependant on the request sometimes essential: relevant medication, recent travel.
Date and time sample collected		X	Blood transfusion & Cytology essential information.
Patient's address		X	
Practitioner's contact number		X	
Patient preparation (fasting, time of dose)		X	Dependant on the request sometimes essential.
Patients pregnancy status if appropriate	Cytology only		Cytology desirable: last LMP.
Patients EDD or number of weeks of pregnancy	BT only		Blood transfusion essential information.
Sample taker identifier	Cytology & BT only		Cytology essential sample taker name, PIN and address. Blood transfusion essential information.
Sample taker signature	BT only		Blood transfusion essential information.

Date & time blood products required (clinical diagnosis and reason for transfusion)	BT only		Blood transfusion essential information.
Previous transfusion history	BT only		Blood transfusion essential information.
Previous blood group and antibody history	BT only		Blood transfusion essential information.
Treatment with drugs known to effect Transfusion	BT only		Blood transfusion essential information.
Any special requirements	BT only		Blood transfusion: irradiated, CMV negative, HEV negative components.

Gynae Cytology refer to CYT/SOP/65

Please ensure that all details are legible and correct before sending the samples to Pathology. IMPACT OF NOT COMPLYING [PAT/RA/035]**:** Failure to provide essential / mandatory details will lead to the request being rejected; this may represent a risk to the patient and may compromise their safety. Non-repeatable specimens which do not comply with this guidance must be verified by the requesting practitioner. For urgent samples which do not comply with this guidance may be analysed at the discretion of the senior BMS or above.

2.3 Urgent requests

Urgent requests should be sent immediately to the appropriate BCPS laboratory. Samples should be easily identifiable as urgent to enable detection upon receipt by pathology reception areas. Red specimen bags should be used, and the request form should clearly indicate which test is required urgently. Red bags are issued to dedicated areas such as Accident and Emergency portals, Acute Medical Unit (AMU), Neonatal unit (NNU) and for specific tests such as CSF, Troponin and D-Dimers. If red bags are received not from areas or for tests stated above, then they are still processed as a priority over routine work received however are not prioritised above the pre-determined ‘urgent’ categories stated above. Some investigations required urgently require notice to be provided prior to the sample being taken or that it has been taken (out-of-hours), refer to the BCPS website for further details.

Urgent requests received should be accepted / entered into the LIMS and transferred to the appropriate laboratory immediately for analysis. Due to the volume of work received in blood science disciplines, a dedicated member of staff is responsible for ensuring urgent work is prioritised; generally, an MLA working on the ‘urgent bench’.

Urgent results should be reported as soon as possible and telephoned to the requestor (in preference) or requesting location, if appropriate.

2.4 Labelling for danger of infection

It is the responsibility of the person who requests a laboratory test to ensure that both the form and the specimen container are correctly labelled to indicate danger of infection. Sufficient clinical detail must be included on the request form to inform laboratory staff upon the safety precautions they need to take to process the specimen without risk of infection e.g. recent history of relevant foreign travel that may increase the likelihood of exotic agents being present. Although the warning label must be clearly visible, the clinical information need not be conspicuous to other people.

Danger of infection must be used identified for specimens that are suspected of containing a hazard group 3 or 4 agent. This includes labelling or highlighting samples suspected of HIV, Hepatitis, *Mycobacterium* species, *Salmonella typhi* or *Neisseria meningitidis* risk as being a danger of infection. For further advice on group 3 or 4 pathogens, contact senior staff in the Microbiology Department (01902 307999 ext. 88257). In keeping with international convention these labels use black print on a yellow background.

Samples for COVID-19 (SARS-CoV-2) are currently classed as a Hazard Group 3 agent and external packaging must be marked with a white label with red print stating:

Priority 10 for suspect patient sample

Priority 20 for presumptive positive patient sample, confirmed positive samples for follow up, contacts of known positive patients or cultured samples for research (cultured samples are category A dangerous goods classification).

If during patient intervention, further information becomes available that has implications for the safety of laboratory staff then this must be communicated immediately to the laboratory so that appropriate steps regarding containment can be taken.

The BCPS do not provide a diagnostic service for group 4 listed pathogens or Rabies virus. If infection with a group 4 pathogen or Rabies virus is suspected the clinician **must** inform the Duty Consultant/ Clinical Lead of the relevant laboratory **before** attempting to take samples for pathology investigations.

2.5 Labelling specimens that contain cytotoxic drugs

Specimens containing cytotoxic drugs should be clearly labelled as such.

2.6 Receipt of specimens

Only trained and competent pathology personnel such as Medical Laboratory Assistants or Biomedical scientists should receive specimens in accordance with the laboratory's safety rules. All specimens labelled 'High Risk', 'Danger of Infection', 'Priority 10 or 20' should be processed according to the laboratory's safety protocol. Universal precautions are to be used when handling samples regardless of whether the sample is labelled as high risk or not.

At BCPS reception the specimen(s) received must be checked against the associated request form and computer record. For the majority of requests, a specimen will be identified with both the patient's full name and coded identifier (the NHS number is to be used as the primary identifier) and date of birth. Greater stringency of identification is required for blood transfusion, refer to Table 1.

2.6.1 Receipt of samples from patients receiving radioactive iodine

For non emergency blood tests from patients who have received radioactive iodine in the previous 24 days of sample taking, the samples will be sent to the Nuclear Medicine Consultant, Jo Weekes (joanneweekes@nhs.net). This covers samples from WHT, RWT & DGFT. SWBH have their own procedure. The level of radiation in the blood will be measured and if safe will be sent to the lab for analysis.

2.6.2 Receipt of Cryoglobin requests

It is vital that requests for Cryogloblin are received in the testing laboratory at 37 degrees Celsius for accurate analysis. Patients should attend main OPD at RWT or Phlebotomy at RWT where all pre-warmed collection equipment (at 37°C) is available.
Prior to sample collection, service users are asked to contact the laboratory on extension: 82710 for New Cross hospital. See CHE/PRO/SOP/004 Cryoglobulins for more information.

2.7 Electronic requests

Once checked, the specimen and the e-Request form must be accepted as received on the LIMS. The e Requesting system creates a unique accession number that will identify the request and the associated sample(s). Samples received without request forms are to be scanned into the LIMS using the attached barcode. Information entered into the EPR by the service user will download into the LIMS. The data must be checked against the sample before accepting.

2.8 Manual request

Once checked, paper request forms and associated specimens must be identified by labelling with an appropriate laboratory barcode number. On data entry the patient's demographics and this identifier must be recorded in the LIMs. This will create a unique accession number that will subsequently identify the request and the associated sample(s).

2.9 Indexor

The Indexor system allows efficient tracking of sample tubes, allowing tubes to be registered, distributed to various laboratory areas and archived for long-term storage. For further information refer to CHE/SOP/104.

2.10 Rejection of request specimen

Rejection of requests will be made in circumstances where there is a failure to provide essential / mandatory details or the details are illegible, and the specimen is repeatable. Processing of these samples may represent a risk to the patient and may compromise their safety. If no tests have been requested a basic screen may be performed based on the sample type received to minimise risk to patient care, for example:

Investigation	**Sample type**
U&E	Serum gel tube (Gold top)
Glucose	Fluoride Oxalate tube (Grey top)
FBC	EDTA tube (Purple top)
INR	Sodium Citrate tube (Blue top)
Urine	Microscopy and culture

Precious (non-repeatable) specimens or potentially urgent samples which do not comply with this guidance may be analysed at the discretion of the senior BMS or above. The report should show a clear disclaimer detailing the shortcomings of the sample and/or request and alert the requestor to take responsibility for the results and for any action taken as a result of the report. Samples deemed to be precious include CSF, fluid, tissue, bone marrow, and paediatric samples.

If there is doubt as to whether a specimen can be rejected, advice must be sought from a senior member of the laboratory staff.

Specimens that are in a condition too hazardous to process will also be rejected.

Other stringent requirements may pertain to specific tests, such as time from collection to receipt and specimens may be rejected on this basis [PAT/RA/035], refer to BCPS website and local procedures for further information.

Recognised unique identifiers include the GUM patients, Occupational Health identifiers, prison number, this list is not exhaustive. In all these cases it is the details missing on the request form that are being highlighted; the information already in the LIMS need not be considered.

2.10.1 Reporting a rejected request

When a request is determined to be rejected in accordance with this policy, the receiving laboratory must issue a report which provides a comment giving the reason(s) why the request fails to meet the recommended criteria. Standardised rejection codes are to be used as appropriate in the LIMS, known as 'REJ' codes, these codes link to specific rejection comments. If the specimen is not

examined, it will be discarded. Rejection codes are built into the LIMs and should be selected for the appropriate reason, sample/department.
BT/SOP/004
HAE/FOR/110
CYT/SOP/64
IMM/SOP/053
MIC/SOP/083

If a sub-optimal request/sample is deemed appropriate to process a disclaimer comment must be issued as part of the report that results must be interpreted with care. Disciplines may use additional codes particularly for pre-examination comments; refer to departmental reception documents for further information.

2.11 Performance monitoring

BCPS IT team provide monthly performance monitoring including:

- Electronic requesting rates- incorporated into the BCPS Performance report which is shared with partner organisations and GP representatives.
- Filing of electronic reports- compliance data shared with RWT directorates.
- Quality of printed requests- a member of the IT team investigates sites where a high level of low-quality printing is identified (RWT GPs and Trust only).
- Rejection data shared with pathology disciplines.

2.12 Non-compliant requests in Cellular Pathology

If the details on the form and specimen do not match, then the specimen cannot be entered onto LIMS. In the worst-case scenario, the incident is error logged and the specimen and form are returned to the sender with a covering note (if the sender has come to the laboratory, they can be told why the specimen is not being accepted). If minor discrepancies are apparent, then the advice of a section leader or above (Band 7 or above) should be sought. Generally, the minimum acceptance criteria required on the request form and sample to enable positive identification is first name or initial, last name, date of birth or NHS number or hospital number, address, and sender.

In all cases there should be a request form for each specimen and all the details from both should match.

Specimens can arrive in reception via four ways:
1) Transport
2) Post
3) From Theatre by nurse, doctor or porter
4) Andrology specimens from patients

If problems arise when specimens are brought in by a nurse, porter, patient (semen) or doctor then the specimen should not be accepted, unless they are able to sanction the necessary amendments.

In the other instances whereby, specimens arrive via transport or post, several problems can occur:
a) Specimen or request form missing.
b) Information missing from form or pot.
c) Conflicting information between form and pot.

In the first instance contact should be made with the sender to inform them of the problem and inform a senior BMS. Sometimes it is necessary for the sender to come to the laboratory to amend the form or specimen; sometimes as in the case of GPs, information can be given over the phone but in all

cases, a note should be made on the back of the request form about the action taken and people spoken to. In the case of a missing form or pot, then this can be sent to the laboratory as soon as possible, again with a note made about the action taken.
Advice from the senior BMS should always be sought about which route to follow.
All serious errors need to be logged on DATIX and minor discrepancies can be entered as an appropriate in the LIMs record.

2.13 Cytology

Sample and request form must be compatible. For further information regarding acceptance criteria and sample management/ rejection refer to:
CYT/SOP/65 for cervical cytology specimens
CYT/SOP/49 for non-cervical cytology specimens

Cytology follow guidance from the NHS Cervical Screening Programme NHSCSP and local QARCs regarding specimen rejection and do not routinely discard samples with discrepancies.
IMPORTANT - All cervical cytology samples must be taken by a fully trained and authorised sample taker who will have been issued a valid smear taker PIN.