| **Department of Clinical Laboratory Medicine** | East Lancashire Hospitals NHS NHS Trust |
|---|---|
| Document title | **Sample acceptance criteria** |
| Document reference : revision | PM/SAC : rev 011 |
| Active date of this revision | xx/xx/2024 |
| Document type | Quality Management |
| Owner of this revision | *Director of Pathology* |
| Author of this revision | *Quality Manager* |
| Approval required by | Director of Pathology |
| Area of standard | **ISO 15189:2022 7.2.6 Sample receipt**<br>ISO 15189:2012 5.4.6 Sample reception |

Purpose

To ensure that all requests for laboratory analysis are received with sufficient information to unambiguously identify the patient on the laboratory database.

Responsibility

All Trust staff and external users of the laboratory service are required to implement this policy.

It is the responsibility of the **person taking the sample** to identify the patient, label the sample and ensure that the information supplied on the request form and sample are accurate and match in each case.

The accuracy of the request is the responsibility of the **person making that request**. Specialised tests may require more detailed information. It is the responsibility of the requester to consult the laboratory for confirmation.

Laboratory staff have the responsibility for conducting analyses **only** on specimens that have been correctly identified.

Procedure

A request form (either written or electronic) with a plastic specimen bag attached is used for most samples.
A fully completed request form is designed to provide the necessary information to unambiguously identify the patient.
For in-patients the form should be completed at the bedside using the patient's wristband to confirm their identity.

**HIGH RISK SAMPLES**

All High Risk samples, request forms and transport bags **MUST** be labelled with appropriate "***Danger of Infection***" high visibility stickers and **double bagged** before transportation. Please also ensure that a "***Danger of Infection***" sticker is affixed to the outer bag to alert staff who may come into contact with this material.

**Sample acceptance criteria**

**Section 1: Blood Transfusion:**

| Samples | Request form |
|---|---|
| **MUST be labelled with the patients:**<br><br>✓ **FULL name** *or* unique coded identifier (note 1*)*<br>and<br>✓ **Date of Birth**<br>and<br>✓ **Hospital (e.g. RXR) number *or* NHS number or private unique identification number**<br>and<br>✓ **Date/time of request**<br>and<br>✓ **Requesters Signature**<br><br>*Note 1:*<br>**Confidential samples (Sexual Health)**<br>A unique identifier will be accepted in place of personal details where confidentiality is paramount e.g. sexual health specimens. The syntax and nomenclature for such labelling must be agreed by the laboratory management beforehand. | The request form data **MUST** match the sample information or be labelled with another suitable unique identifier.<br><br>Forms **MUST** include:<br><br>✓ the patient's **FULL** name or unique coded identifier<br>✓ the patient's date of birth<br>✓ Hospital (e.g. RXR) or NHS number<br>**Note - In the rare event that neither is available then the address must be supplied**<br>✓ the patient's location and a destination for the report (or a location code)<br>✓ an indication of the sample type(s) and the examination / tests required<br>✓ the consultant or GP identity (or identity code)<br>✓ name and signature of the requester<br>✓ date and time of request – should be changed to correct time if form printed in advance<br>✓ name and signature of sample collector/requester<br>✓ date and time of collection – should be changed to correct time if form printed in advance<br><br>**Note:**<br>**If preprinted labels are used on the request form, it is not necessary, however good practice that the transfusion passport number of the person taking the sample is also be supplied**<br><br>Forms **SHOULD** also have:<br><br>✓ the patient's gender<br>✓ all relevant clinical information<br>✓ a contact/bleep number for requester |
| **Note: UNKNOWN PATIENTS VIA EMERGENCY DEPT** :<br>For unknown patients the Hospital number or major trauma number and sex must be given | |

**Section 2: Blood Sciences:**

| Samples | Request form |
|---|---|
| **MUST be labelled with the patients:**<br><br>✓ **FULL name** *or* unique coded identifier (see note 1)<br>*and*<br>✓ **Date of Birth**<br>*or*<br>✓ **Hospital (e.g. RXR) number *or* NHS number or private unique identification number**<br><br>*Note 1:*<br>**Confidential samples (Sexual Health)**<br>A unique identifier will be accepted in place of personal details where confidentiality is paramount e.g. sexual health specimens. The syntax and nomenclature for such labelling must be agreed by the laboratory management beforehand.<br><br>**Note 2: Multiple samples:**<br>Samples taken from a patient at different times **MUST** be labelled with the time (24 hour clock) that each specimen was taken<br><br>**Note 3: Blood gas samples**<br>Samples for Blood Gas analysis in glass capillary tubes are unsuitable for labelling as described above. Please label the sample carrier/container correctly instead. | The request form data **MUST** match the sample information or be labelled with another suitable unique identifier.<br><br>Forms **MUST** include:<br><br>✓ the patient's **FULL** name or unique coded identifier<br>✓ the patient's date of birth<br>✓ Hospital (e.g. RXR) or NHS number<br>**Note - In the rare event that neither is available then the address must be supplied**<br>✓ the patient's location and a destination for the report (or a location code)<br>✓ the examination / tests required<br>✓ the consultant or GP identity (or identity code)<br>✓ name of the requester<br>✓ date and time of request – should be changed to correct time if form printed in advance<br>✓ name of sample collector<br>✓ date and time of sample collection - should be changed to correct time if form printed in advance<br><br>Forms **SHOULD** also have:<br><br>✓ the patient's gender<br>✓ all relevant clinical information<br>✓ a contact/bleep number for requester |
| **Note: UNKNOWN PATIENTS VIA EMERGENCY DEPT** :<br>For unknown patients the Hospital number or major trauma number and sex must be given | |

**Section 3: Microbiology**

| Samples | Request form |
|---|---|
| **MUST be labelled with the patients:**<br><br>✓ **FULL name** *or* unique coded identifier *(note 1)*<br>and<br>✓ **Date of Birth**<br>or<br>✓ **Hospital (e.g. RXR) number *or* NHS number or private unique identification number**<br><br>*Note 1:*<br>**Confidential samples (Sexual Health)**<br>A unique identifier will be accepted in place of personal details where confidentiality is paramount e.g. sexual health specimens. The syntax and nomenclature for such labelling must be agreed by the laboratory management beforehand. | The request form data **MUST** match the sample information or be labelled with another suitable unique identifier.<br><br>Forms **MUST** include:<br><br>✓ the patient's **FULL** name or unique coded identifier<br>✓ the patient's date of birth<br>✓ Hospital (e.g. RXR) or NHS number<br>**Note - In the rare event that neither is available then the address must be supplied**<br>✓ the patient's location and a destination for the report (or a location code)<br>✓ an indication of the sample type(s) and the examination / tests required<br>✓ the consultant or GP identity (or identity code)<br>✓ name of the requester<br>✓ date and time of request - should be changed to correct time if form printed in advance<br>✓ name of sample collector<br>✓ date and time of collection - should be changed to correct time if form printed in advance<br>✓ Full, relevant clinical information **including details of any recent foreign travel specifying location.**<br><br>Forms **SHOULD** also have:<br><br>✓ the patient's gender<br>✓ a contact/bleep number for requester |
| **Note: UNKNOWN PATIENTS VIA EMERGENCY DEPT** :<br>For unknown patients the Hospital number or major trauma number and sex must be given | |

**Section 4: Histopathology/Cytology**

| Samples | Request form |
|---|---|
| **MUST be labelled with the patients:**<br><br>✓ **FULL name** *or* unique coded identifier *(note 1)*<br>and<br>✓ **Date of Birth**<br>or<br>✓ **Hospital (e.g. RXR) number *or* NHS number or private unique identification number**<br><br>*Note 1:*<br>**Confidential samples (Sexual Health)**<br>A unique identifier will be accepted in place of personal details where confidentiality is paramount e.g. sexual health specimens. The syntax and nomenclature for such labelling must be agreed by the laboratory management beforehand. | The request form data **MUST** match the sample information or be labelled with another suitable unique identifier.<br><br>Forms **MUST** include:<br><br>✓ the patient's **FULL** name or unique coded identifier<br>✓ the patient's date of birth<br>✓ Hospital (e.g. RXR) or NHS number<br>**Note - In the rare event that neither is available then the address must be supplied**<br>✓ the patient's location and a destination for the report (or a location code)<br>✓ an indication of the sample type(s) and anatomical site(s)<br>✓ the consultant or GP identity (or identity code)<br>✓ name of the requester<br>✓ date and time of request - should be changed to correct time if form printed in advance<br>✓ name of sample collector<br>✓ date and time of collection - should be changed to correct time if form printed in advance<br>✓ Full, relevant clinical information<br>✓ Details of any relevant patient pathways – e.g. 2 week rule, etc.<br><br>Forms **SHOULD** also have:<br><br>✓ the patient's gender<br>✓ a contact/bleep number for requester |

## Sample acceptance: actions

If the Sample Acceptance Criteria above are not met, the laboratory reserves the right to take the following action in these instances:

<table>
<tr><td colspan="2">Samples which are deemed to be clinically critical or irreplaceable, precious, or unrepeatable may be processed at the discretion of Senior laboratory staff however, must be .<br><br>Where there are problems with:<ul><li>patient or sample identification – Specimen does not meet criteria.</li><li>sample instability due to delay in transport or inappropriate container(s)</li><li>insufficient sample volume</li></ul>and the laboratory chooses to process the sample, this event should be recorded including the name of the person authorizing processing. The final report MUST also include a comment to indicate the nature of the problem and, where applicable, that caution is required when interpreting the result.</td></tr>
<tr><td>Mislabeled or mismatched samples requesting Blood Transfusion</td><td>Samples must be repeated and correctly labelled by the requestor before any tests can be performed – there are no exceptions.</td></tr>
<tr><td>Unlabelled samples</td><td>Regardless of source, will be either<ul><li>returned to source stated on request</li><li>destroyed in cases where the origin cannot be guaranteed (e.g. where it has become detached from the request form)</li></ul></td></tr>
<tr><td>Partial details</td><td><ul><li>A report stating “mislabeling error” will be issued and the sample retained for up to 3 days.</li><li>If the requester is able to verify the sample identity within this time, an analysis may be carried out. Normally this will entail a visit to the laboratory.</li></ul></td></tr>
<tr><td>Lack of patient information</td><td>Although the minimum criteria are met, a lack of patient or sample information may result in the laboratory not conducting the analysis in certain cases:<br>Examples could include:<ul><li>no swab site indicated</li><li>no dates and times of sampling</li><li>no clinical details given</li></ul>In such situations it may not be possible to issue a report or to interpret the results<br>Appropriate comments will be made on the report in cases where one can be issued</td></tr>
</table>

**Additional Notes/Actions Pan-Pathology (where otherwise stated)**

- Specimen errors are logged within each discipline.
- Laboratory staff have been instructed NOT to amend details on the sample.
- Samples which have more than one component e.g. smears and fluid, each element should all meet the minimum criteria.
- Due to the large volume of specimens received it is not possible for laboratory staff to contact all users regarding mislabelled specimens. The onus is on the requester to contact the laboratory in the event of receiving an “unlabelled specimen” report.
- Any requests or supplementary requests made verbally should not be processed until a suitable request form has been received. The sample acceptance criteria must be met. Where a request must be carried out immediately due to urgency or sample stability, this must be recorded in specimen notepad.
- If there is a need to clarify an investigation requested (i.e. by contacting the requestor), then this needs to be recorded in specimen notepad or via other controlled paper method. Details should include investigation, who was spoken to, date, time, and staff member logging the occurrence.
- Any samples which are sent and do not meet defined criteria, such as volume, sample container or correct additive/preservative, should be logged (recorded) and the sample taker or department contacted. Appropriate action should be taken, as defined in local procedures such as specimen acceptance/reception SOPs, whilst considering factors, for example, precious/unrepeatable samples.
- Trends and patterns should be monitored and identified as part of local, management or audit reviews and findings raised in Q-pulse.
- Records must be kept of such events.
- Any samples which are deemed to be time-sensitive, such as Andrology specimens, MUST be checked on arrival to make sure that they meet the timescale criteria. Acceptance of the sample will be indicated, as a minimum, by date/time stamping and labelling of the specimen. Local procedures MAY also include signing log sheets/request form. This should be detailed in local departmental specimen acceptance/reception procedures.
- For any time-sensitive samples which do not meet the timescale criteria, the departments will have a defined process on how this should be handled (rejected and disposed or accepted and tested but notes in the report to clearly indicate). This should include when samples are precious and the process. A log should be kept in the event of any occurrence so that this can be reviewed for trends and patterns.
- For temperature sensitive samples, it may be difficult for the laboratories to monitor ALL samples to ensure they meet any temperature-sensitive requirements. However, the laboratories should have a process in place to ensure users are aware of the requirement and the potential ramifications if not met. The laboratory should also have audits in place as part of their schedule to audit transport pathways (where feasible). Any findings should be raised as a non-conformance and actioned.

## *Data Protection*

All data and patient information will be handled in line with Trust Policies ‘Guide to Data Protection’ and C077 ‘Confidentiality of Personal Information’.