

# **GSTS Pathology**

## ***STANDARD OPERATING PROCEDURE***

**Title: Specimen Reception**

**Subject: Sample Acceptance**

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## 1. Introduction

### 1.1 Scope

- 1.1.1 This document covers sample and request form labelling, including incorrect sample types for tests requested, and serves GSTS Pathology as a whole.
- 1.1.2 Exceptions to this policy will be made at a local laboratory level and attached as addendums at location.

### 1.2 Reference sources

- 1.2.1 This policy is created as per Guidance on Acceptance and Rejection of Samples for GSTS Pathology December 09. Guidance followed includes the following references:
- i Institute of Biomedical Sciences
    - July 09 Professional Guidance: Patient Sample and Request Form Identification Criteria
  - ii Royal College of Pathologists
    - May 2005 Code of Practice for Haematology departments
    - May 2005 Code of Practice for Histopathology
    - May 2005 Code of Practice for Clinical Biochemistry
  - iii CPA Standards for Medical Laboratories
    - Version 2.01 March 2009
  - iv BCSH Guidelines
    - BCSH Guideline on Administration of Blood Components (2009)
    - BCSH Guidelines on Pre Transfusion Compatibility Procedures in Blood Transfusion Laboratories (2004)
  - v GSTT Trust Policy
    - GSTFT Blood Transfusion Policy (2007)

### 1.3 Rationale

- 1.3.1 Following recent reported increases in the number of rejected samples, GSTS Pathology has undertaken a review of the current policies across all operational areas. The review highlighted inconsistent and subjective approaches to sample acceptance criteria
- 1.3.2 This policy and procedure aims to provide an overarching process to sample rejection to help balance the 'requirement to process' against the 'risk to patient safety'.
- 1.3.3 The procedure outlines a consistent approach to acceptance of samples and identifies escalation routes and validation stages such that the decision to reject

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a sample is made appropriately and reported consistently, in light of sample type, ability to obtain a repeat sample and clinical history.

- 1.3.4 The procedure introduces a disclaimer option that will help manage risk and allow samples that are currently rejected but which cannot be repeated to be processed.
- 1.3.5 The term “defect” will be used to refer to an inconsistent data match between a request form and its received samples and samples that do not meet the minimum labelling criteria.

## 2. The Policy

- 2.1. GSTS will seek to manage and minimise the number of rejected samples and requests.
- 2.2. GSTS Pathology will adopt a set of Mandatory Labelling Requirements, three unique identifiers, for accepting a sample(s) for testing (see Section 4.1 for list of mandatory requirements)
- 2.3. Blood Transfusion is the only unit which does not have any exceptions to the policy and will follow all BCSH and GSTT Trust regulatory requirements (See 1.2.1 iv and v)
- 2.4. The request form will always be the principle reference of information against which information on samples received will be compared.
- 2.5. If the requesting sample has either a PIMS or PMI entry, the PIMS or PMI information will be the principle reference against which information on both the request form and samples received will be compared.
- 2.6. All samples and request forms will be compared against mandatory criteria at the point of receipt.
- 2.7. Where GSTS is satisfied that the sample and request meet the mandatory criteria, we will process the sample and request.
- 2.8. Where GSTS is NOT satisfied that the sample and request meet the mandatory criteria, we will NOT process the sample and will reject it.
- 2.9. All other samples / requests which fail to meet the mandatory criteria will be pulled out of the system to prevent disruption to the sample flows, becoming defect samples.
- 2.10. Under extreme circumstances where a defect sample is considered to pose a high risk to patient safety, if processed GSTS Pathology reserves the right to reject and discard the sample without disclaimer.
- 2.11. All defect samples / requests will then be sent to a dedicated area for sample triage to be individually assessed by a HPC registered BMS and/or Scientist.
- 2.12. All reasons for defects will be logged and recorded for audit purposes. The results of quarterly audits will be shared with users of the GSTS Pathology service. (See Section 0 for explanation of audit)

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### 3. Process

- 3.1.1 Following triage – defect samples / requests that are accepted for processing will have an appropriate comment added to the final report identifying any defect, where it does not meet the acceptance criteria. (See 0)
- 3.1.2 Following triage – samples / requests that fail the criteria but that cannot be repeated or that are time or event dependant will only be processed after obtaining a disclaimer from the requestor, faxed or emailed to the triage unit for authorisation to continue processing.
- 3.1.3 Following triage - samples / requests that do not meet the criteria for acceptance and/or have not received an instruction from the requestor with a disclaimer attached, will be rejected and discarded with an appropriate reporting comment identifying the reason for the rejection.
- 3.1.4 Samples will be stored for seven days in the laboratory before being discarded. If the sample becomes unsuitable for testing during the seven day storage period, testing will not be carried out even on receipt of a disclaimer.
- 3.1.5 Requestors are not allowed to manually alter the original sample/ request label following defective identification. Should they wish to correct the original label they will be asked to perform one of the following:
- Supply a new label with correct patient details
  - Stick the new label on the sample – ensuring the original defect information is still visible.
  - Sign a disclaimer
- 3.1.6 All actions will be documented and comments added to the final report.
- 3.1.7 This would only be done on samples which are perceived to be unrepeatabe.

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## 4. Labelling criteria

### 4.1 Labelling Criteria for Samples and Request Forms

#### 4.1.1 Mandatory Labelling Criteria for Samples and Request Forms (See Policy 2.1):

The mandatory three unique identifiers are:

- First Name
- Family Name
- Date of birth

Patient details on samples should match the details written on the request form.

Request forms should be dated and signed by those taking the sample.

#### 4.1.2 Additional identifiers can be supplied WITH the mandatory identifiers are:

- Hospital Number
- NHS Number
- Gender

#### 4.1.3 Request forms should contain requestor and location information

- Internal Request – location (ward code) and clinician details/code
- External Request – addressograph label/ surgery and GP details

Samples/ requests where full names are substituted by initials will immediately be treated as defect samples/ requests and a disclaimer will be issued.

## 4.2 Exceptions

### 4.2.1 Histopathology, Cytology, Oral Pathology and Dermatopathology

- As per local SOPs within the above mentioned laboratories, the rejection of a sample can only be authorised with the consent of a respective consultant pathologist.

### 4.2.2 Blood Transfusion

As per BCSH guidelines for labelling of samples and request forms, the mandatory details for all blood transfusion samples and requests are:

- Handwritten labelled samples
- Full Name - correctly spelled
- Date of Birth

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- Hospital Number
- Date sample was taken
- Gender (desirable)
- Time sample was taken (desirable)
- Signature of veneselector on sample (desirable)

If any of the mandatory details for Blood Transfusion samples and requests are omitted, the escalation procedure will follow Blood Transfusion laboratory protocol (See SOP BSBT 021-March 2010)

### 4.3 Anonymous/Uniquely Identified Samples and Requests (eg.GUM)

Where patient identification details are intentionally hidden or substituted with particular ID numbers:

#### 4.3.1 Clinical Trial Samples

- In a clinical trial usually only the trial number will be provided and is acceptable as the only identifier.
- Due to clinical trial subject should not normally be identified by name

#### 4.3.2 Chlamydia Swabs

- Tigris specific swabs for Chlamydia require only the first name and family name to be accepted for testing

#### 4.3.3 NHS Numbers

- In some circumstances NHS commissioners require the use of the NHS number and have instructed laboratories not to handle specimens where this number has not been used.
- The decision to accept or reject these specimens will be made by the relevant laboratory.

If any of these exceptions present any defective information (See 0), these samples will be treated as defects and follow the escalation process within this document. (See 4.6)

### 4.4 Categories for Defects

Information will be taken from the request form to the sample, NOT from the sample to the request form.

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Samples that fail to meet the mandatory criteria represent a significant risk to patient safety and raise serious concerns of sample integrity. Repeat samples will be requested for such defects. Where no repeat sample is possible then samples will only be processed with a disclaimer.

The mandatory information required is:

- First Name
- Family Name
- Date of Birth

A “Reasonability Test” will be applied to Mismatch, Misspelled and Poor Handwritten Defects (See 4.6.3)

## 4.5 Reasonability Test

### 4.5.1 Missing Mandatory Information

- Missing information can be obtained from the requestor and added to the sample / request with a signed disclaimer from the requestor.

### 4.5.2 Mismatch of Mandatory Information

- Information on the sample does not match the information on the request form
- Undergoes the “Reasonability Test” (See 4.6.3)

### 4.5.3 Misspelling of Mandatory Information

- Omission or Substitution of letters in names written on samples / requests
- Will undergo the ‘Reasonability Test’ (See 4.6.3)

### 4.5.4 Poor Hand Writing

- Many samples / requests are hand written and poor handwriting is a common reason for the defect.
- In such cases, every effort will be made to affirm that the sample / request details match through the “Reasonability Test” (See 4.6.3)

### 4.5.5 Inappropriate samples

- Samples which are received in the incorrect containers required for the requested tests and cannot be processed
- GSTS will make every effort to use duplicate samples or shared samples to minimise the rejection of requests.

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- If no substitute samples are available, the samples will be rejected with appropriate comments on the report.

#### 4.6 Escalation Procedure (See **Error! Reference source not found.** – Escalation Process Flowchart)

##### 4.6.1 Patient record checking

- All defect samples will be looked up on the LIMS systems to identify any previous history
- Should there exist a previous entry on the LIMS system, details will be compared on LIMS versus request form versus sample details and noted on the request.

##### 4.6.2 Log of defect data into Defects Spreadsheet

- All defect samples and requests data will be logged into “Defects Spreadsheet”
- The function of this spreadsheet will be to collect data on all defect samples identified for audit and requestor engagement purposes.

##### 4.6.3 The ‘Reasonability Test’ will used to assess defects. (See 0):

- Questions:
  - i Is the defect consistent with an alternate spelling of the same sounding name?
  - ii Is the defect only individual letters or missing repeated letters but that does not affect the pronunciation of the name?
  - iii Could the defect be poorly written?
  - iv Have two or more people assessed the defect and are in agreement?
- Pass: YES to all four questions – continue processing
- Fail: NO to any question – issues a disclaimer to authorise continuation of processing.

#### NOTES

- Samples /requests that pass this will be processed with comments added to the report.
- Samples that fail the ‘Reasonability Test’ will require a disclaimer signed by the requestor prior to processing.

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- Where a repeat sample cannot be obtained, and fails the “Reasonability Test”, the sample will be processed with a signed assessment from a HPC registered BMS/ senior scientist.
- Should any doubt remain, a disclaimer will be issued to the requestor for clarification.

#### 4.6.4 Log of disclaimer samples into Disclaimer Spreadsheet

- Details of all samples and request which require a disclaimer to be sent out to the requestor will be logged into the “Disclaimer Spreadsheet”
- All actions, comments and outcomes will be logged into spreadsheet
- The function of this spreadsheet will be to manage the disclaimer and requestor engagement process.

#### 4.7 GSTS Phlebotomy defects

- These are defects originating from GSTS Phlebotomy Department
- Disclaimer will not be issued.
- Apology will be sent on behalf of GSTS Pathology, and request a new sample to be sent.

#### 4.8 Sample Integrity and Storage

- Following failure of the “Reasonability Test” the defect sample will be prepared for storage (i.e. SST tubes will be spun down)
- Samples will then be stored in appropriate conditions, determined by the test requested
- Samples / requests where a repeat sample can be obtained will be stored appropriately for 7 days rejected and discarded if a disclaimer cannot be obtained from the requestor.

#### 4.9 Disclaimer Request

- A disclaimer will be issued following the failure of the “Reasonability Test” by a sample / request
- This disclaimer is sent to the requestor via email to provide consent and authorise the continued processing of the sample / request.

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- Should a disclaimer not be returned and where a repeat sample cannot be obtained, the sample will be processed with a signed assessment from a HPC registered BMS/ senior scientist.

#### **4.10 Audit of data**

- All data entered into the “Defects spreadsheet” will be used for audit purposes.
- All data will be reviewed monthly for trend analysis.
- Results of analysis will be fed back to requestors quarterly

#### **4.11 Secure Communications**

- Ensuring communications with internal and external requestors will be through secure networks, in accordance with GSTS Data Security Policy.
- Disclaimers will only be sent via email.
- Disclaimers can be received via email or fax.

#### **4.12 Report comments**

- Comments regarding any actions undertaken will be documented and printed at the end of each report.

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