



Manchester University  
NHS Foundation Trust

**Manchester Cytology Centre  
NHS Cervical Screening Programme**

**INFORMATION PACK  
FOR CERVICAL SAMPLE TAKERS  
August 2021**

The Manchester cervical screening laboratory is UKAS accredited to ISO15189:2012

Accreditation No. 8648

Q Pulse Identifier: CYQUALPRO22 v.12 (Previous Identifier CYT GEN 029) Date of issue: 27.08.2021

### SUMMARY OF CHANGES

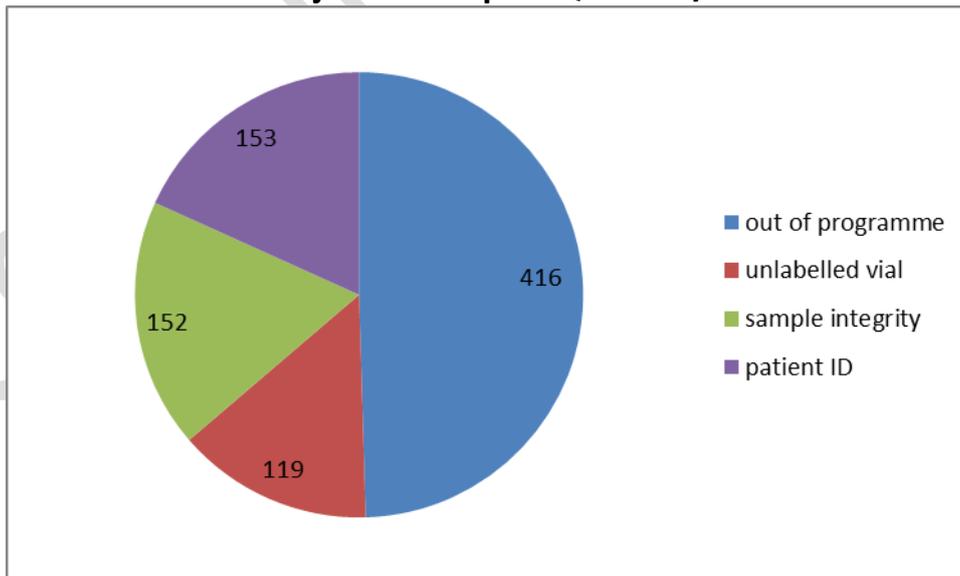
- The laboratory now provides a cervical screening service for Greater Manchester, Lancashire, Cumbria, and Cheshire and Merseyside, covering the North West region of England.
- Primary screening is undertaken by testing for high-risk Human Papillomavirus (HPV) with ThinPrep liquid based cytology (LBC) used as the reflex test
- The roll out of electronic requesting continues with a small number of practices continuing to use paper copy request forms.
- The department is now 'paperless' with the request form being scanned onto an archive system and is available to view electronically.

#### SAMPLE ACCEPTANCE POLICY:

A recent audit has shown that the most common reason for the laboratory to reject a sample is still an 'out of programme' sample and in particular early repeat tests i.e. the sample has been taken before a woman has been invited for screening.

We encourage all sample takers to check that a woman is due for her routine test before taking the cervical sample as the chart below shows that out of programme samples still account for the largest category of rejected samples

**Total rejected samples Q1: 2021/2022**



## CONTENT

<b>Section</b>	<b>Page</b>
<b>1</b> Introduction	4
Contact details	4
1.1 Clinical team	5
1.2 Senior management team	5
1.3 Medical secretariat	6
<b>2</b> Quality statement	7
2.1 Transport/LBC kits	8
<b>3</b> ThinPrep LBC cervical cytology sample collection and preparation	9
<b>4</b> Request forms	
Electronic requesting	10
<b>5</b> Sending the sample to the laboratory	12
<b>6</b> Reporting cervical screening results	12
<b>7</b> Patient management protocols	
7.1 Independent sector cervical screening samples	13
7.2 Inappropriate & 'Out of Programme' samples	13
7.2.1 Abnormal looking cervix	13
7.2.2 Young women with abnormal bleeding	14
7.2.3 Other inappropriate tests	14
7.2.4 Symptomatic women	14
7.3 Follow-up after total hysterectomy	15
<b>8</b> Cervical Sample Taker Database	16
<b>9</b> Direct referral to colposcopy	17
<b>10</b> Laboratory failsafe protocol	
10.1 Laboratory failsafe for colposcopy referrals	17
10.2 Suspected non-cervical glandular neoplasia	17
<b>11</b> Sample Acceptance	18
 APPENDICES	
Appendix A Cytology result codes and associated Read codes	20
Appendix B Sample acceptance policy – rejection categories	21

## 1 INTRODUCTION

The Manchester Cytology Centre was selected as the preferred bidder to deliver the cervical screening programme for the North West area using high-risk Human Papillomavirus (HPV) testing as the primary screening test.

The department is affiliated to the North of England Pathology and Screening Education Centre (Manchester). The Cytology and Virology departments and the regional Education Centre are situated within the Clinical Sciences Centre at Manchester Royal Infirmary.

The Manchester Cytology Centre is located on the first floor of the Clinical Sciences Centre. Virology is located on third floor. All visitors should access the departments via the central reception area on the ground floor

### Contact Us

#### Address

**Manchester Cytology Centre  
First Floor, Clinical Sciences Centre  
Manchester Royal Infirmary  
Oxford Road, Manchester  
M13 9WL**

#### Telephone enquiries

Urgent & general enquiries 0161 276 5111  
Clinic kits 0161 276 5172

**General email enquiries** [cyto.pathology@mft.nhs.uk](mailto:cyto.pathology@mft.nhs.uk)

**Patient-related email enquiries** [mft.mcc@nhs.net](mailto:mft.mcc@nhs.net)

#### Opening Hours

The department is open from 9.00am – 5.00pm, Monday to Friday (except bank holidays)

#### Clinical Advice

A Consultant Cytopathologist or Consultant Biomedical Scientist is available to answer gynaecological queries, discuss any aspect of the cytology report and provide advice on patient management from 9.00am – 5.00pm, Monday to Friday. Telephone 0161 276 5111

Clinical advice is also provided at multi-disciplinary team meetings. The clinical lead or cervical screening provider lead will respond to written enquiries.

## Technical Advice

Lead and Advanced Biomedical Scientists are available for technical advice, Monday to Friday 9.00am – 5.00pm. Telephone 0161 276 5111

## Visiting the laboratory

The Manchester Cytology Centre has an ‘open access’ policy for any clinicians or other screening programme staff who may want to visit the department and speak with staff to discuss any aspect of the service we provide.

Visits by medical staff can be arranged by contacting **Dr Miles Holbrook**

Informal visits by other clinical staff can be arranged by contacting the lead biomedical scientists

### 1.1 Clinical Team

Dr Miles Holbrook	Clinical lead, cervical screening Director of NEPSEC (Manchester)	0161 276 6475
Dr Durgesh N Rana	Consultant cytopathologist	0161 276 5108
Dr Louise Hesketh	Consultant clinical scientist Virology	0161 276 8853
Dr Alex Sargent	Clinical scientist HPV lead & pathway manager	0161 276 5174
Peter Heptinstall	Consultant biomedical scientist Manager of NEPSEC (Manchester)	0161 276 5118
Janet A Parker	Consultant biomedical scientist Cervical Screening Provider Lead (CSPL)	0161 701 0228
Steve Burrows	Consultant biomedical scientist Cytology deputy CSPL	0161 701 0228
Chris Evans	Consultant biomedical scientist Cytology deputy CSPL	0161 701 1443
Paul Hermansen	Consultant biomedical scientist	0161 276 5103
Nadira Narine	Consultant biomedical scientist	0161 701 7570
Angela Randall	Consultant biomedical scientist	0161 701 7904
Antonia Tweed	Consultant biomedical scientist	0161 701 1946

### 1.2 Senior Management Team

Jackie Medlock	Cytology Laboratory Manager	0161 276 5120
Adanna Ehirim	Lead biomedical scientist (BMS)	0161 276 5119

Q Pulse Identifier: CYQUALPRO22 v.12 (Previous Identifier CYT GEN 029) Date of issue: 27.08.2021

Peter Lloyd	Lead BMS	0161 276 5119
Sehrish Chaudhry	Lead BMS	0161 276 5119

### 1.3 Medical Secretariat

Helen Wilson	Medical secretary cytology	0161 276 6727
Katie Knapman	Medical secretary cytology	0161 276 5116
Jen Bradburn	Medical secretary cytology & NEPSEC	0161 276 8804

Controlled document

## 2 QUALITY STATEMENT

The Manchester Cytology Centre is fully accredited by UKAS to ISO15189:2012 – accreditation number: 8648. All cervical samples are processed and screened following NHS Cervical Screening Programme guidelines and the regional Screening Quality Assurance Services (SQAS) recommendations.

The Cytology department participates in the regional gynaecological and technical EQA schemes and the performance of all screening staff is monitored monthly following NHSCSP guidelines. HPV testing is undertaken by the Virology department who participate in two UK National EQA schemes.

The management and staff teams within the department are committed to providing a quality service to our users. We aim to continually improve our service through internal audit and annual feedback from users. If you do have a complaint, concern or compliment about any aspect of the service, this should be addressed to the Lead Biomedical Scientists or the Cytology Laboratory Manager.

Controlled Document

## **2.1 TRANSPORT AND LBC KITS**

### **Sample collection and transport**

The laboratory will deliver a supply of ThinPrep clinic kits to each practice/clinic. Local transport hospital services will collect samples from Practices/Clinics and deliver to local Trust hospital hubs. Arrangements are in place for collection of samples from hospital hubs by DLM and department contracted sample transport services for delivery at Manchester Cytology Centre. If there are any issues relating to the provision of LBC kits, please contact the department on 0161 276 5172

### **Posting LBC vials**

Occasionally it may be necessary to post a sample vial to the laboratory. If this is the case then please be aware that:

Royal Mail will only transport UN3373 diagnostic specimens if they are packaged following packaging instruction P650, and,

- Sent by first class post or special delivery to an inland address only
- The packet is marked with the sender's name, telephone number and address

### **LBC kits**

The laboratory uses a database to keep a record of the number of LBC kits used by each surgery and clinic to ensure that supplies are readily available. For any enquiry regarding LBC kits please contact the department on 0161 276 5172

### **LBC stock rotation**

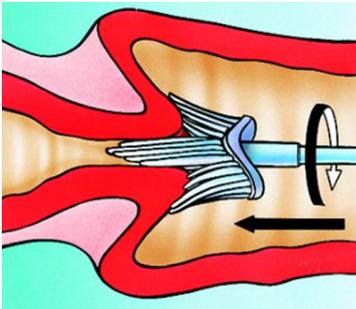
Please be aware that LBC vials have an expiry date and it is the sample takers responsibility to ensure that there is stock rotation and to check that the vials they are using have not passed the expiry date as printed labels containing patient details often obscure the expiry date once attached to the vial. Please ensure the expiry date on the vial is at least 14 days after the sample has been taken

## Manchester Cytology Centre

# PREPARING A THINPREP LBC SAMPLE

## IMPORTANT NOTICE

*If the broom head is left in the vial the sample will be reported as **inadequate***



OBTAIN an adequate sample from the cervix using a broom-like device. Insert the central bristles of the broom into the endocervical canal deep enough to allow the shorter bristles to fully contact the ectocervix. Push gently, and rotate the broom in a **CLOCKWISE** direction **FIVE TIMES**



RINSE the broom as quickly as possible into the PreservCyt® Solution vial by pushing the broom into the bottom of the vial **10 TIMES**, forcing the bristles apart. As a final step, swirl the broom vigorously to further release material. Examine the broom for residual material and repeat if necessary

**DISCARD THE BROOM – DO NOT LEAVE THE BROOM HEAD IN THE VIAL**



TIGHTEN the cap so that the torque line on the cap passes the torque line on the vial

Label the vial with the patient identifiers

- FORENAME
- SURNAME
- DATE OF BIRTH
- NHS NUMBER

For further copies please contact the laboratory or visit the CSTD:

**Manchester Cytology Centre**  
Manchester Royal Infirmary  
Oxford Road, Manchester  
M13 9WL  
Tel: 0161 276 5111

**Manchester Cervical Sample Taker Database**  
Type 'Manchester CSTD' into a web browser

Q Pulse Identifier: CYQUALPRO22 v.12 (Previous Identifier CYT GEN 029) Date of issue: 27.08.2021

#### 4 REQUEST FORMS

The national HPV primary screening implementation guide recommends the universal implementation of GP electronic test requesting as an opportunity to improve the transportation of samples and improve the tracking of samples between the primary care collection points and the centralised laboratory.

**Electronic requesting:** Please contact the Laboratory IT support team to set up electronic requesting in your practice/clinic.

Telephone 0161 276 4079 Email [labs.sd@mft.nhs.uk](mailto:labs.sd@mft.nhs.uk)

The provision of information relating to previous biopsies (punch, LLETZ/loop, cone etc) with histology grade and date of biopsy, as well as details of any treatment are ESSENTIAL to ensure correct patient management is given.

Cervical Screening Request Form		Central Manchester University Hospitals  NHS Foundation Trust
NHS Number:  NHS Number	GP	Order Number:  Order number
<b>Patient Details:</b>		<b>Requester Details:</b>
Surname:		Sample Taker:
Forename:		Contact No:
DOB:		GP/Clinician:
Sex:		Location:
Address:		Copy to GP:
<b>Request Details:</b>		
Date and Time of request:		Site:
LMP:		Condition:
Previous test date:		Appearance:
Reason for request:		Haemorrhage:
Sampler:		
<b>Clinical Details:</b>		
Signature:.....		
<b>Laboratory use only:</b>		
	Initials	Details or comments
Error code:		
Broom check:		
2 <sup>nd</sup> check – HPV 1 <sup>o</sup>		
Request allocated by:		
Exeter history check:		
Primary screener:		
Checker 1:		
Checker 2:		

**Paper request forms:** These are being actively phased out by the laboratory and should only be used when electronic requesting and the Open Exeter request form are not available due to IT issues. In this case the paper request form should be completed in full with information PRINTED legibly or a printed label containing patient demographics can be used.

**NHS number:** The NHS number **MUST** be used whenever it is available as this is the unique patient identifier. In addition, the full forename, surname and date of birth **MUST** be given.

**PIN codes:** The GMC, NMC or Physician Associate (PA) number is the unique sample taker identifier, or PIN code. This information **MUST** be provided on all request forms. The sample taker name should also be printed clearly. If a PIN code is not given, is illegible or the sample taker is not registered on the CSTD, this is reportable to the Screening & Immunisation Team so that enquiries can be made to determine if the sample taker is validated to take cervical samples.

Controlled document

## 5 Sending the sample to the laboratory

**Sample:** The label on the sample vial **must** record the forename (or initial), surname and date of birth, and the NHS number (if known) to allow matching of the vial with the request form. After labelling, the sample should be placed in the specimen bag and the request form securely attached to the bag using the second adhesive strip.

### Sample taking supplies



## 6 Reporting cervical screening results

The laboratory provides cervical screening results to over 1500 primary care locations who receive their results electronically. The result is sent to a nominated destination within the practice to ensure all reports are seen and actioned. Read codes for recording the result on GP clinical systems are given in **Appendix A**

The Cervical Screening Administration Service (CSAS) receive an electronic copy of the report to update the woman's cervical screening history on the Exeter system.

## **7 PATIENT MANAGEMENT PROTOCOLS**

### **7.1 INDEPENDENT SECTOR CERVICAL SCREENING SAMPLES**

All eligible women (aged from 25-64) will automatically receive their invitation letter from the CSAS to attend for screening. Women who have cervical samples taken outside the NHS cervical screening programme may contact their GP to say that they have had cervical screening in the private sector. The GP/practice should then advise the woman that her private cervical screening test results are not routinely captured in the NHS screening programme and that she is eligible for her routine test and should attend for this.

However, please be aware that there should be a 3-month interval between any private sample and one taken as part of the NHSCSP to ensure an adequate sample has been taken.

### **7.2 INAPPROPRIATE AND 'OUT OF PROGRAMME' SAMPLES**

#### **Recall intervals for cervical screening**

- Routine 3 yearly recall between the ages of 24 years, 6 months to 49 years inclusive <sup>(1)</sup>
- Routine 5 yearly recall between the ages of 50 to 64 years inclusive
- Cease cervical screening at age 65 years, only screen those who:
  - Have never had a screening test and now request one
  - Did not attend for their last test when aged 60 or over and now wish to have that final test
  - If the last 3 tests included an abnormal result and/or she is on follow-up for treatment of CIN/CGIN/invasive cancer
  - Over 65 and had fewer than 3 consecutive negative tests and patient has had a recall issued by CSAS

#### **7.2.1 Abnormal looking cervix**

If there is a clinical suspicion of cervical disease, a cervical screening test i.e. an HPV test is not the appropriate test to investigate the symptoms. The woman should be referred urgently to colposcopy for investigation under the two-week-wait rule <sup>(2)</sup>

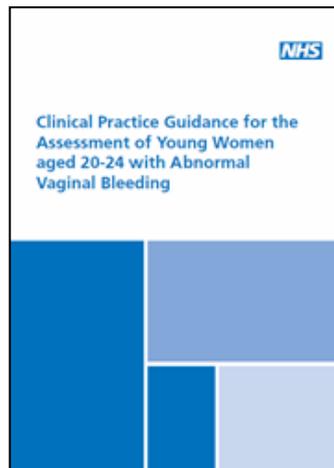
<sup>1</sup> The first invitation letter is sent at 24 years, 6 months.

<sup>2</sup> Women with an abnormal looking cervix should be referred for gynaecological examination and onward referral to colposcopy if cancer is suspected.

### 7.2.2 Young women with abnormal bleeding

Women below the screening age range who present with symptoms such as postcoital bleeding or intermenstrual bleeding should be managed as per the recommendations in “Clinical Practice Guidance for the Assessment of Young Women aged 20-24 with Abnormal Vaginal Bleeding”. Cervical screening does not form part of this management pathway. Note, this includes women under the age of 20 years.

[https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/436924/doh-guidelines-young-women.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/436924/doh-guidelines-young-women.pdf)



### 7.2.3 Other inappropriate tests

- On taking or starting to take an oral contraceptive
- On insertion of an intrauterine contraceptive device (IUCD)
- On taking or starting to take hormone replacement therapy (HRT)
- In association with pregnancy – either antenatally or postnatally, or after termination unless a previous screening test was abnormal
- Women with genital warts
- Women with a vaginal discharge
- Women with pelvic infection
- Women who have had multiple sexual partners
- Women who are heavy cigarette smokers

### 7.2.4 Symptomatic women

Women with symptoms of cervical cancer should be referred for gynaecological examination. Cervical screening i.e. an HPV test is not an appropriate investigation for:

- Postcoital bleeding
- Intermenstrual bleeding
- Postmenopausal bleeding

- Persistent vaginal discharge

### **7.3 Follow-up after total hysterectomy**

Women who need vaginal vault sampling following surgery are not included in the NHS Cervical Screening Programme. Vault samples should be taken in a hospital setting only and therefore women requiring this should be referred to colposcopy or remain at colposcopy until all necessary vault samples have been taken.

**The laboratory will reject vault samples taken in primary care.**

The clinical indications for taking a vault sample are given in 'Cervical screening: Programme and colposcopy management, February 2020'

<https://www.gov.uk/government/publications/cervical-screening-programme-and-colposcopy-management>

Controlled document

8 CERVICAL SAMPLE TAKER DATABASE (CSTD)



The CSTD was launched in April 2017. Staff in the laboratory have worked with the IT department and the Screening and Immunisation Teams to populate the database with sample taker details including the dates of sample taker training. Practice managers and sample takers can access reports on inadequate rates and the number of rejected samples via links to the CSTD. User guides have also been produced to enable both practice managers and sample takers make maximum use of the CSTD. The department now sends email reminders to sample takers when their next update training is due, hence the last training date is required for all sample takers.

Registration on the CSTD will become mandatory to support sample acceptance and unregistered sample takers may be reported to the Screening and Immunisation Teams to prevent screening incidents.

More information on the CSTD is given on the Division of Laboratory Medicine web page

<https://mft.nhs.uk/the-trust/other-departments/laboratory-medicine/cytology/cervical-sample-takers-database/>

This links provides access to the current CSTD user guides for:

- Training providers
- Practice managers or lead clinicians e.g. lead colposcopists
- Sample takers

## **9 DIRECT REFERRALS TO COLPOSCOPY**

The laboratory has well-established systems of direct referral to all the colposcopy units in Greater Manchester, Cumbria, Lancashire, and Cheshire and Merseyside. It provides details of the cervical screening result to allow efficient allocation of appointments to ensure women at highest risk get the earliest appointments.

All primary care samples and tests taken in hospital clinics (except colposcopy) where a recommendation for colposcopy assessment has been advised are included in the direct referral process.

Patient identifiable data and test results are sent via secure nhs.net to nhs.net email addresses.

## **10 FAILSAFE**

All colposcopy referrals are subject to laboratory failsafe and the guidance issued by the PHE Cervical Screening: cytology reporting failsafe (primary HPV).

<https://www.gov.uk/government/publications/cervical-screening-cytology-reporting-failsafe/cervical-screening-failsafe-guidance> [Updated 17 July 2019]

### **10.1 Laboratory failsafe for colposcopy referrals**

All colposcopy referrals are included in laboratory failsafe procedures and an enquiry is generated if a colposcopy outcome is not notified to the laboratory within the predetermined timescales. It is important that sample takers are aware that they still have overall responsibility for ensuring the patient attends colposcopy, even when direct referral is in operation and they should respond accordingly when a failsafe enquiry letter is sent. Any cases where an outcome is not available are audited by the laboratory CSPL.

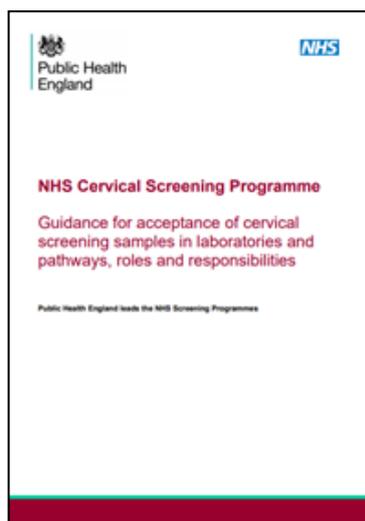
### **10.2 Suspected non-cervical glandular neoplasia**

The department has a separate protocol for the referral of suspected glandular abnormalities of non-cervical origin. This involves contacting the GP or sample taker prior to authorising the report to discuss the result and explain that an urgent referral to gynaecology is required. The GP must make the referral to gynaecology as there is no direct referral pathway for this group of women.

## 11 SAMPLE ACCEPTANCE

The national sample acceptance policy was published in April 2017 and implemented from 1<sup>st</sup> September 2017.

<https://www.gov.uk/government/publications/cervical-screening-accepting-samples-in-laboratories>



By following the national guidance and rejecting samples that fail to meet the sample acceptance criteria, the laboratory will ensure that:

1. The correct test result is issued to the correct women who attends for cervical screening
2. There is a reduction in the time taken to issue cervical screening results

Cervical screening samples must satisfy minimum requirements and any errors that compromise the safety of the patient will result in the sample being rejected.

Essential specimen data requirements are:

- Patient's full name i.e. at least first name and surname (2 identifiers)
- Patient's date of birth
- NHS number
- Patient address
- Name & address of GP
- Name and address of sender
- Sample taker personal ID – GMC, NMC or PA number

Q Pulse Identifier: CYQUALPRO22 v.12 (Previous Identifier CYT GEN 029) Date of issue: 27.08.2021

In order to link the form to the sample vial, at least 3 legible matching patient identifiers must be given on both the form and the vial, see bullet points:

Vial:	Form:
<ul style="list-style-type: none"> <li>• Full forename or initial</li> <li>• Full surname</li> <li>• Date of birth</li> <li>• NHS number</li> </ul>	<ul style="list-style-type: none"> <li>• Full forename</li> <li>• Full surname</li> <li>• Date of birth</li> <li>• NHS number</li> </ul> <p>Request form must also contain the patient address</p>

All rejections are coded in the laboratory with the relevant error code. This provides the laboratory with a means of auditing rejected samples and providing feedback to the Screening and Immunisation Teams

### Minor discrepancies

Minor discrepancies will be accepted as the patient identity is known

1. Spelling error in patient name but the name sounds the same (homonyms)
2. Transposition of a single digit within the date of birth or NHS number
3. Specimen without form, or vice versa – contact the sample taker to seek an explanation
4. Request form without sender details – check Open Exeter and phone GP to confirm

### Major discrepancies

Major discrepancies constitute a serious risk as the patient identity is uncertain and the sample must be rejected.

1. Absence of two or more essential data items
2. Mismatch between the vial and the form
3. Two or more minor discrepancies
4. Unlabelled vial

**See Appendix B – rejection categories**

**Appendix A Cytology result codes and associated Read codes**

<b>Cervical screening report terminology</b>	<b>Result code on Exeter</b>	<b>Read code</b>
Inadequate/ High-risk Human Papillomavirus (HR-HPV) Unreliable	1	4K21
Negative	2/N	4K22
Borderline change in squamous cells	8/B	4K290
Borderline change in endocervical cells	9/E	4K291
Low-grade dyskaryosis	3/M	4K2J
High-grade dyskaryosis (moderate)	7	4K2K
High-grade dyskaryosis (severe)	4	4K2L
High-grade dyskaryosis? Invasive squamous carcinoma	5	4K2M
? Glandular neoplasia of endocervical type	6	4K2N
? Glandular neoplasia (non-cervical)	0/G	4K2P
High-risk Human Papillomavirus (HR-HPV) not detected	X	4K3E

**Appendix B Sample acceptance policy – rejection categories**

<b>Error code</b>	<b>Reason for rejection</b>
E1	Vial, no form
E2	Form, no vial
E3	Unlabelled vial
E4	Partially labelled vial
E5	Discrepant details on vial & form
E6	Insufficient patient ID on form
E7	Patient details differ from cytology/Exeter
E8	Invalid sample taker PIN
E9A	Vial leaked, no fluid
E9B	Incorrect sample container used
E10	Illegible patient details on form or vial
E11	Out of programme sample due to: A- Under 24 ½ years B- Over 65 years C- Early repeat D- Vault sample taken in primary care E- Post-radiotherapy treatment
E12	Out of date vial