Manchester University
NHS Foundation Trust

Manchester Cytology Centre

NHS Cervical Screening Programme

INFORMATION PACK

FOR CERVICAL SAMPLE TAKERS

January 2023

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

Accreditation No. 8648

Q Pulse Identifier: CYQUALPRO22 Edition 14

SUMMARY OF CHANGES

- The laboratory 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:

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. There must be greater than 14 days validity on vials or more than the current turnaround time – whichever is greater to ensure sufficient time for transport and processing. The laboratory turnaround times can be viewed on the CSTD homepage.

CONTENT

1 INTRODUCTION

The Manchester Cytology Centre was selected in 2019 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
Patient-related email enquiries	mft.mcc@nhs.net

Opening Hours

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

Clinical Advice

A Consultant Cytopathologist or Consultant Biomedical Scientist (CBMS) 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 CBMS team 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 welcome requests from 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 David Shelton	Consultant cytopathologist	0161 276 5109
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
Steve Burrows	Consultant biomedical scientist	0161 701 0228
Chris Evans	Consultant biomedical scientist	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
Sarah Ferris	Consultant biomedical scientist	0161 701 4708

1.2 Senior Management Team

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

1.4 Failsafe/CSTD/Logistics

Joanne Ward	Failsafe/CSTD/Logistics Manager	0161 701 0209
Gloria Lander	Failsafe/CSTD/Logistics Coordinator	0161 276 5172
Paula Flanagan	Failsafe/CSTD/Logistics Coordinator	0161 701 0174
Sandra Perry	Failsafe/CSTD/Logistics Coordinator	0161 276 5123
Natalie Mathews	Failsafe/CSTD/Logistics Coordinator	0161 701 0174
Ella Haywood	Failsafe/CSTD/Logistics Coordinator	0161 276 5112

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 in accordance with 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.

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 sent out/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 vials or more than the current turnaround time – whichever is greater to ensure sufficient time for transport and processing. The current turnaround times can be viewed on the CSTD homepage. LBC vials should be stored between 15 and 30 ^{o}C . If samples are to be stored prior to collection for any length of time, this should be done at room temperature and they **must** not be stored in a fridge.

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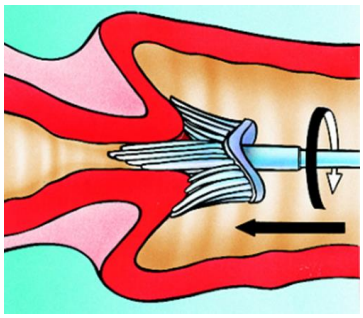
PREPARING A THINPREP LBC SAMPLE

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 Edition 14

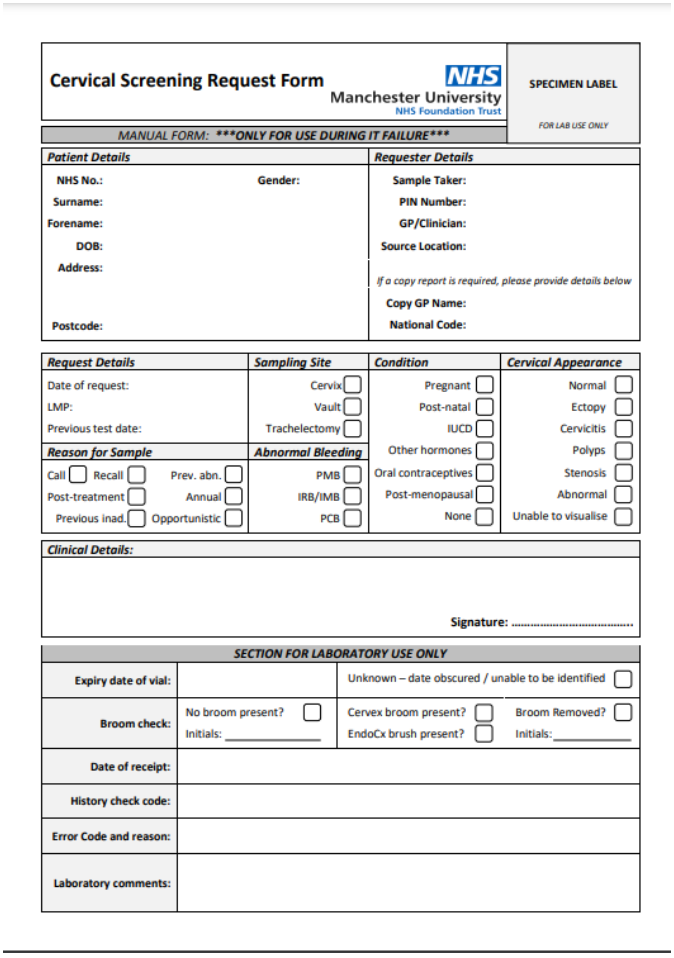
4 REQUEST FORMS

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

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 — NHS Manchester University NHS Foundation Trust — SPECIMEN LABEL — FOR LAB USE ONLY

*MANUAL FORM: ***ONLY FOR USE DURING IT FAILURE****

Patient Details	*Requester Details*
NHS No.: Gender:	Sample Taker:
Surname:	PIN Number:
Forename:	GP/Clinician:
DOB:	Source Location:
Address:	*If a copy report is required, please provide details below*
	Copy GP Name:
Postcode:	National Code:

Request Details	*Sampling Site*	*Condition*	*Cervical Appearance*
Date of request:	Cervix ☐	Pregnant ☐	Normal ☐
LMP:	Vault ☐	Post-natal ☐	Ectopy ☐
Previous test date:	Trachelectomy ☐	IUCD ☐	Cervicitis ☐
Reason for Sample	*Abnormal Bleeding*	Other hormones ☐	Polyps ☐
Call ☐ Recall ☐ Prev. abn. ☐	PMB ☐	Oral contraceptives ☐	Stenosis ☐
Post-treatment ☐ Annual ☐	IRB/IMB ☐	Post-menopausal ☐	Abnormal ☐
Previous inad. ☐ Opportunistic ☐	PCB ☐	None ☐	Unable to visualise ☐

Clinical Details:

Signature: .....

SECTION FOR LABORATORY USE ONLY

Expiry date of vial:		Unknown – date obscured / unable to be identified ☐	
Broom check:	No broom present? ☐ Initials: _____	Cervex broom present? ☐ EndoCx brush present? ☐	Broom Removed? ☐ Initials: _____
Date of receipt:			
History check code:			
Error Code and reason:			
Laboratory comments:			

Paper request forms: These are being actively phased out by the laboratory and should only be used when electronic requesting and the above manual 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.

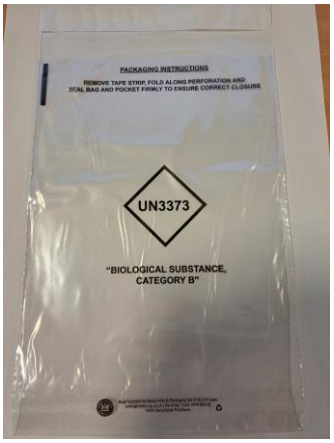
NHS number: The NHS number **MUST** be used whenever it is available as this is the unique patient identifier. In addition, the full forename, surname and date of birth MUST be given.

PIN codes: The GMC, NMC or Physician Associate (MVR) 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.

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 1200 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 [(1)]
- 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 lest 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 ? is this correct AE to check

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.

Cervical cancer is rare in the UK. Many regular sample takers will never see a single case. Signs of malignancy include:

- An enlarged cervix where the surface is irregular and friable, crumbling to the touch
- Large blood vessels which bleed freely when rubbed by the end of the speculum
- An offensive, watery discharge may also be present

If the cervix bleeds with clinical suspicion of malignancy and a clinician considers the cervical appearance is suspicious of malignancy, the woman must be urgently referred to a gynecologist

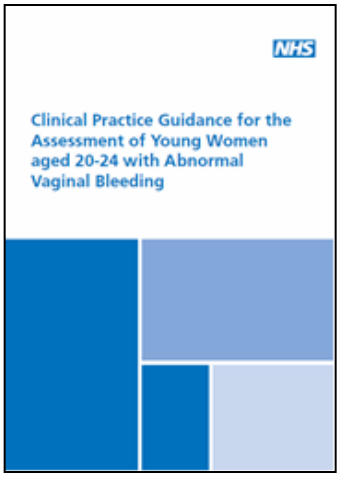
through the cancer wait times (CWT) 'two week wait' pathway. A sample should not be taken. Cervical screening is screening test, not a diagnostic tool.

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.

The guidance states that women experiencing vaginal bleeding after sex and in-between periods require a pelvic examination. Vaginal bleeding is extremely common and can be caused by a range of different problems, including cervical ectropion, hormonal changes due to the contraceptive pill or benign cervical polyps or sexually transmitted infections such as chlamydia. The guidance explains the types of questions that practice nurses and GPs need to ask in order to establish if symptoms could be related to cervical cancer. A trained nurse, doctor or registered physician associate may perform a speculum examination. A trained GP can perform a pelvic exam.

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' (Last updated 28th September 2021)

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

8 CERVICAL SAMPLE TAKER DATABASE (CSTD)

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The CSTD was launched in April 2017. Staff in the laboratory has 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 is 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 NHSE 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 Clinical support for CSPL.

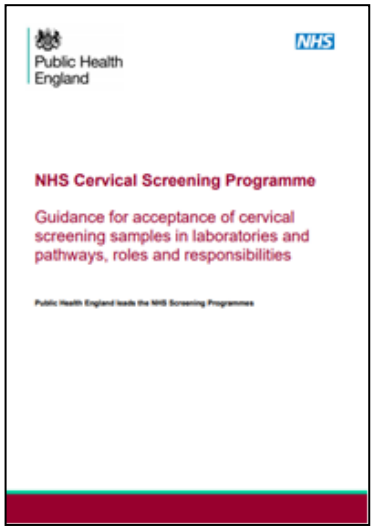
10.2 Suspected non-cervical glandular neoplasia

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 1st September 2017. (Last updated 26th October 2022)

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

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:
• Full forename or initial • Full surname • Date of birth • NHS number	• Full forename • Full surname • Date of birth • NHS number Request form must also contain the patient address

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

Cervical screening report terminology	Result code on Exeter	Read code
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

Error code	Reason for rejection
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