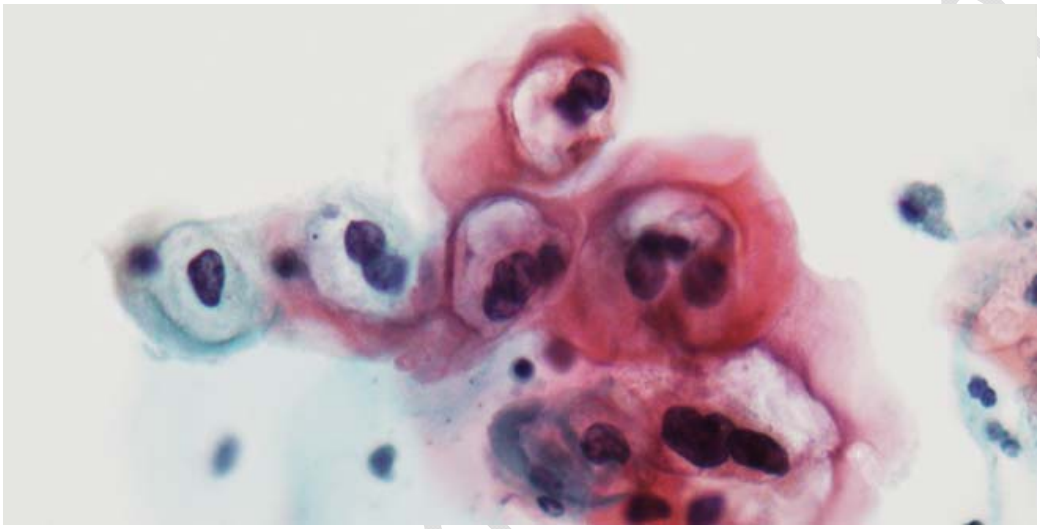
Manchester University
NHS Foundation Trust

Manchester Cytology Centre

NHS Cervical Screening Programme



INFORMATION PACK

FOR CERVICAL SAMPLE TAKERS

JULY 2019

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

Accreditation No. 8648

SUMMARY OF CHANGES

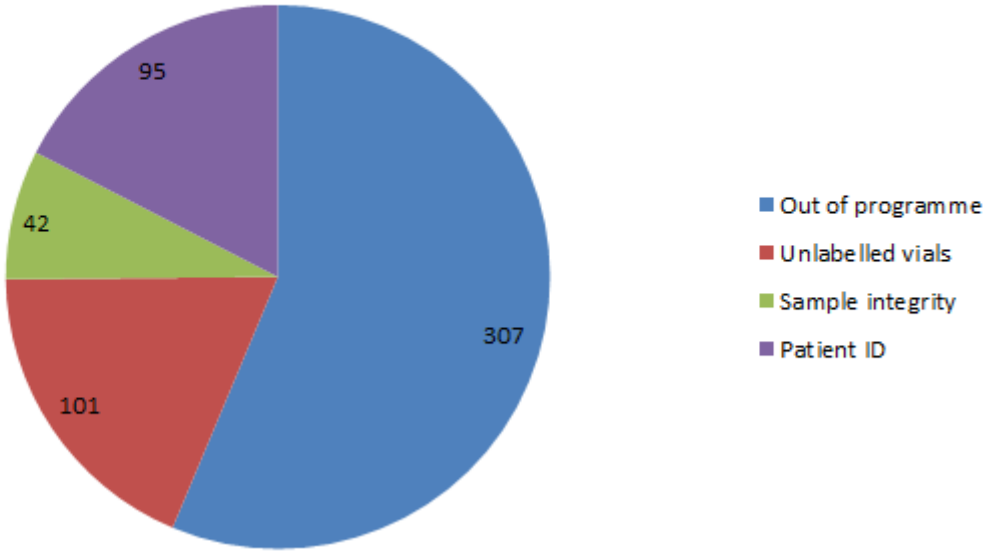
- The laboratory no longer reports samples from the private sector
- The roll out of electronic requesting continues with a small number of practices continuing to use paper copy request forms.
- The laboratory fully converted to HPV primary screening using ThinPrep liquid based cytology on 8th July 2019
- Rejection of early repeat samples was implemented during 2018. Samples taken more than 6 months before the next test due date, for women on routine recall are rejected by the laboratory in line with national guidance
- National office have given confirmation of the Read codes that should be used for recording cervical screening test results on GP clinical systems. **Appendix A**

SAMPLE ACCEPTANCE POLICY:

A recent audit has shown that the most common reason for the laboratory to reject a sample is 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

Total rejected samples in Q1 2019/2020



CONTENT

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	Tel: 0161 276 5111 Fax: 0161 276 3258
General email enquiries	cyto.pathology@mft.nhs.uk
Patient-related email enquiries	mft.mcc@nhs.net

Opening Hours

The department is open from 8.00 am – 5.00 pm, Monday to Friday (except bank holidays) and will shortly operate a Saturday sample reception service

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 scientist (BMS) **Adanna Ehirim** or the technical lead BMS **Richard Lambert**

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
Janet A Parker	Consultant biomedical scientist Cervical Screening Provider Lead (CSPL)	0161 701 0228
Steve Burrows	Consultant biomedical scientist Deputy CSPL	0161 701 0228
Paul Hermansen	Consultant biomedical scientist	0161 276 5103
Peter Heptinstall	Consultant biomedical scientist	0161 276 5118
Dr David Nuttall	Consultant biomedical scientist	0161 701 1443
Nadira Narine	Consultant biomedical scientist	0161 701 1443
Dr Andrew Turner	Consultant Medical Virologist	0161 276 8853
Dr Alex Sargent	Clinical scientist & HPV lead	0161 701 4774

1.2 Senior Management Team

Sally Wood	Cellular pathology manager	0161 276 6138
Vicky Edwards	Deputy cellular pathology manager	0161 276 6138
Ann Taylor	Cervical cytology manager	0161 276 5111
Adanna Ehirim	Lead biomedical scientist	0161 276 5119
Richard Lambert	Technical lead biomedical scientist	0161 276 5119
Wendy Mitchell	Failsafe & Office manager	0161 276 5123
Joanne Ward	Deputy failsafe manager	0161 701 0209

1.3 Medical Secretariat

Bernie Carden-Flynn	Manager, medical secretaries	0161 276 5115
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
	Fax number	0161 276 5113

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. Sample that are primary screened for HR-HPV are processed by the Virology department who participate in the UK National EQA and QCMD 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 cellular pathology manager.

Gynaecological queries

A consultant cytopathologist or a consultant biomedical scientist is available to answer any 'gynaecological queries' and discuss any aspect of the cytology report as well as give advice on patient management – 0161 276 5111

2.1 TRANSPORT AND LBC KITS

Specimen collection and transport

The laboratory will deliver a supply of LBC sample kits to each practice/clinic. If there are any issues relating to the provision of LBC kits, please contact the lead biomedical scientists 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 laboratory 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

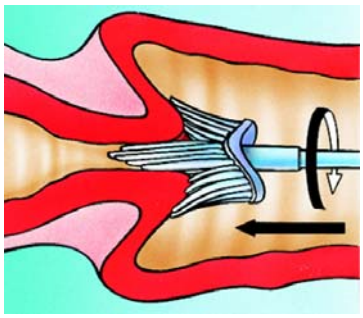
3

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

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.

4.1 Electronic requesting: the laboratory is actively encouraging the use of electronic request forms. 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

Cervical Screening Request Form — Central Manchester University Hospitals NHS Foundation Trust

NHS Number: NHS Number	GP	Order Number: Order number

Patient Details:	*Requester Details:*
Surname:	Sample Taker:
Forename:	Contact No:
DOB:	GP/Clinician:
Sex:	Location:
Address:	Copy to GP:

Request Details:	
Date and Time of request:	Site:
LMP:	Condition:
Previous test date:	Appearance:
Reason for request:	Haemorrhage:
Sampler:	

Clinical Details:
Signature:.....

Laboratory use only:	Initials	Details or comments
Error code:		
Broom check: 2nd check – HPV 1°		
Request allocated by:		
Exeter history check:		
Primary screener:		
Checker 1:		
Checker 2:		

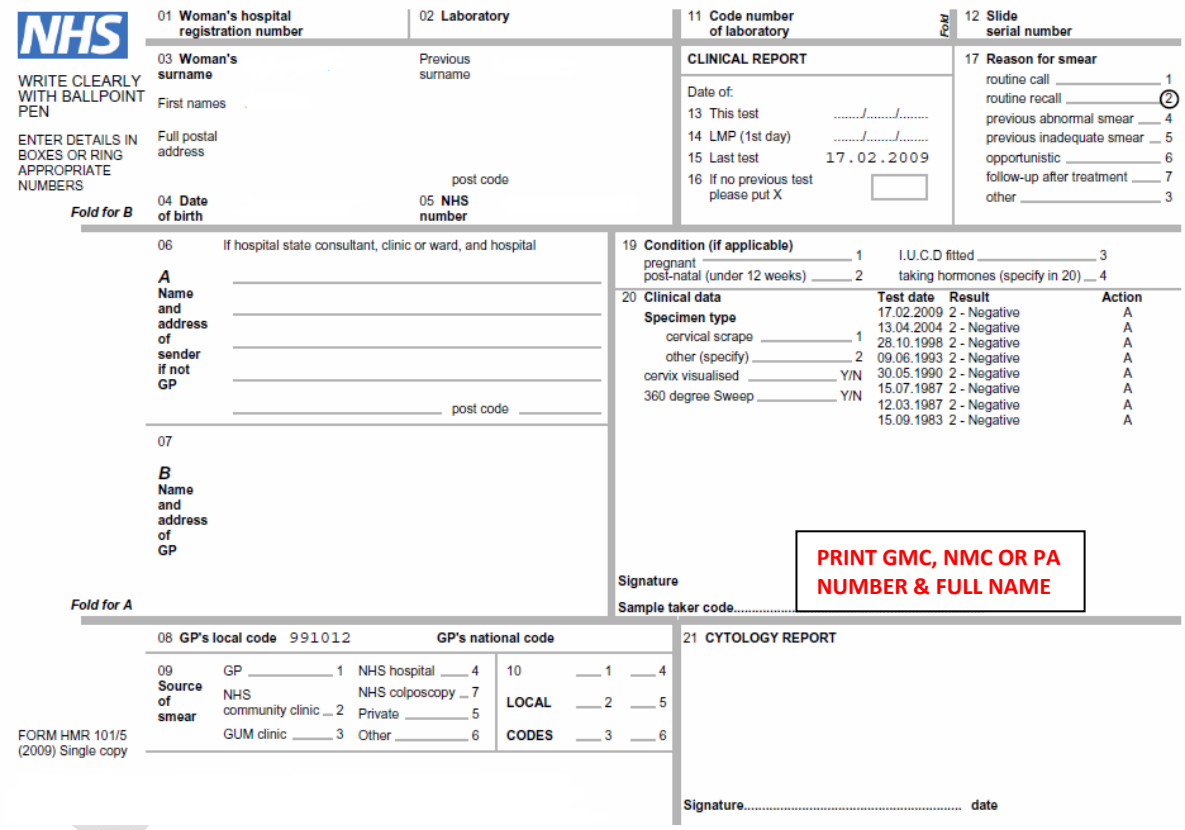
4.2 Open Exeter request form: until you are set up for electronic requesting, the Open Exeter HMR101 form can be downloaded from the Exeter system. Please complete the form, paying particular attention to the provision of relevant clinical history. **Also print your full name and your NMC, GMC or PA number**

The version to use is HMR101 form A5 PDF (2009). This document will be pre-populated with the forename, surname, date of birth and NHS number, as well as the date of the previous test. Also printed on the form is the cervical cytology history for the woman.

If you require any support in accessing the request form on Open Exeter, please contact

Tel: PCSE Customer Support Centre on 0333 014 2884

Email: Preston office: pcse.screening-preston@nhs.net


NHS

WRITE CLEARLY WITH BALLPOINT PEN

ENTER DETAILS IN BOXES OR RING APPROPRIATE NUMBERS

Fold for B

01 Woman's hospital registration number

02 Laboratory

11 Code number of laboratory

Fold

12 Slide serial number

03 Woman's surname

Previous surname

First names

Full postal address

post code

04 Date of birth

05 NHS number

CLINICAL REPORT

Date of:

13 This test ...../...../.....

14 LMP (1st day) ...../...../.....

15 Last test 17.02.2009

16 If no previous test please put X

17 Reason for smear

routine call 1

routine recall 2

previous abnormal smear 4

previous inadequate smear 5

opportunistic 6

follow-up after treatment 7

other 3

06 If hospital state consultant, clinic or ward, and hospital

A Name and address of sender if not GP

post code

07

B Name and address of GP

19 Condition (if applicable)

pregnant 1

post-natal (under 12 weeks) 2

I.U.C.D fitted 3

taking hormones (specify in 20) 4

20 Clinical data

Specimen type

cervical scrape 1

other (specify) 2

cervix visualised Y/N

360 degree Sweep Y/N

Test date	Result	Action
17.02.2009	2 - Negative	A
13.04.2004	2 - Negative	A
28.10.1998	2 - Negative	A
09.06.1993	2 - Negative	A
30.05.1990	2 - Negative	A
15.07.1987	2 - Negative	A
12.03.1987	2 - Negative	A
15.09.1983	2 - Negative	A

PRINT GMC, NMC OR PA NUMBER & FULL NAME

Signature

Sample taker code.....

Fold for A

08 GP's local code 991012

GP's national code

09 Source of smear

GP 1

NHS community clinic 2

GUM clinic 3

NHS hospital 4

NHS colposcopy 7

Private 5

Other 6

10 LOCAL CODES

21 CYTOLOGY REPORT

Signature..... date

FORM HMR 101/5 (2009) Single copy

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

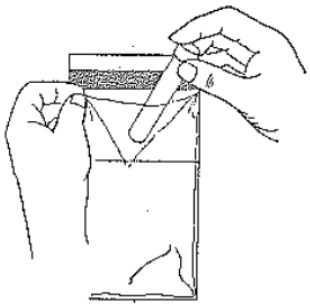
Whichever request form is used, the provision of information relating to previous biopsies (punch, LLETZ/loop, cone etc) with histology grade and date of biopsy, as well as details of any treatment are ESSENTIAL to ensure correct patient management is given.

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.

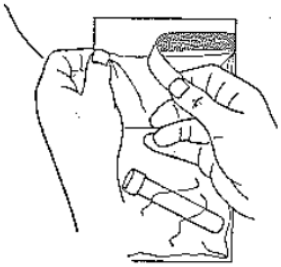
PIN codes: The GMC, NMC or Physician Associate (PA) number is the unique sample taker identifier, or PIN code. This information MUST be provided on all request forms. The sample taker name should also be printed clearly. If a PIN code is not given, is illegible or the sample taker is not registered on 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.

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 as indicated below and the request form securely attached using the second adhesive strip.

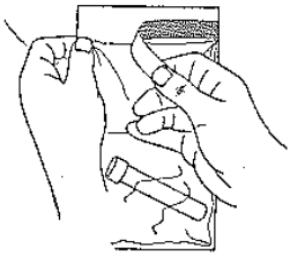


Place labelled specimen container in bag

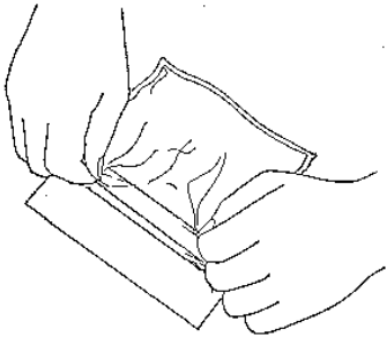


Remove protective strip above the bag

Fold onto the bag and press firmly to seal



Remove second protective strip on the reverse



Secure specimen bag to the request form by affixing the adhesive strip to the form.

6 Reporting cervical screening results

The laboratory provides cervical screening results to over 1500 locations. All primary care locations receive their results electronically. The result is sent to a nominated destination within the practice to ensure all reports are seen and actioned.

Primary Care Support Services (the call/recall agency) receive an electronic copy of the report to update the cervical screening history on the Exeter system.

7 PATIENT MANAGEMENT PROTOCOLS

7.1 INDEPENDENT SECTOR CERVICAL SCREENING SAMPLES

Primary care colleagues have raised concerns regarding cervical cytology testing at independent facilities i.e. "private smear tests". Cervical cytology samples undertaken in the Independent Sector are not part of the national screening programme. Colleagues felt it would be helpful if GPs/practices were made aware of the issue.

All eligible women (aged from 25-64) will automatically receive their invitation letter from the Primary Care Support England (PCSE) 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 cytology done privately. The GP/practice should then advise the woman that her private cervical cytology 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 PCSE

7.2.1 Abnormal looking cervix

If there is a clinical suspicion of cervical disease, cytology 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 [2]

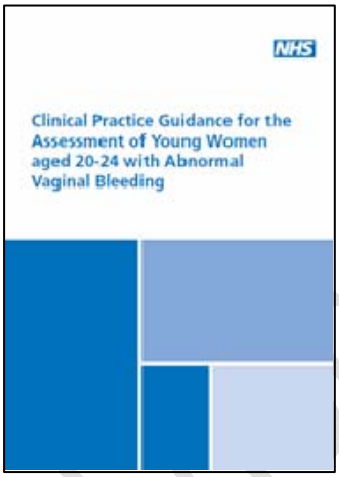
1 The first invitation letter is sent at 24 years, 6 months.

2 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 cytology 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



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
- In women with genital warts
- In women with a vaginal discharge
- In women with pelvic infection
- In women who have had multiple sexual partners
- In women who are heavy cigarette smokers

7.2.4 Symptomatic women

Women with symptoms of cervical cancer should be referred for gynaecological examination. Cervical cytology 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 e.g. colposcopy 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 the NHSCSP guidelines, Colposcopy & Programme Management Publication No.20, Third Edition, March 2016

https://www.bsccp.org.uk/assets/file/uploads/resources/NHS_Cervical_Screeing_Programme._Publication_Number_20_-_Third_Edition.pdf

8 CERVICAL SAMPLE TAKER DATABASE (CSTD)

NHS
Manchester

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 REFERRAL TO COLPOSCOPY

The laboratory has well-established systems of direct referral to all the colposcopy units in Greater Manchester, Cumbria and Lancashire and will be rolling out the protocol to Cheshire and Merseyside. It provides details of the test result to allow efficient allocation of appointments based on the cytology grade 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 NHSCSP In August 2018

https://www.gov.uk/government/publications/cervical-screening-cytology-reporting-failsafe/cervical-screening-failsafe-guidance

Laboratory failsafe for colposcopy referrals

All colposcopy referrals are included in laboratory failsafe procedures and an enquiry is generated in the event that 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.

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.

CERVICAL SCREENING
AUDIT PROFORMA FOR NON-CERVICAL GLANDULAR NEOPLASIA REFERRALS

Patient name: _____

Cytology number: _____

Date of test: _____

Name of person at GP surgery _____ Fax: No: _____

Name of person @ MCC making the phone call _____

Date/time of phone call _____

Advise of the following:
- ⚐ sample taker is responsible for referral ⚐
- ⚐ 2-week rule applies ⚐
- ⚐ Receipt of the faxed report MUST be acknowledged ⚐

Ask which hospital woman will be referred to _____

[Office use]

Report faxed **Yes/No** [ ] Receipt of fax acknowledged **Yes/No** [ ]

Details entered into diary for failsafe _____ (date in diary) [ ]

(initial in brackets [ ]

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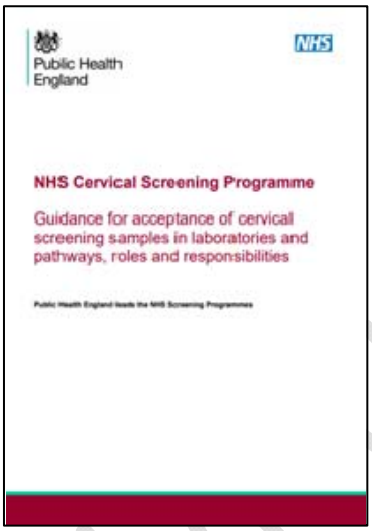
11 SAMPLE ACCEPTANCE

The national sample acceptance policy was published in early 2017 and implemented from 1st 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

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 digits 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

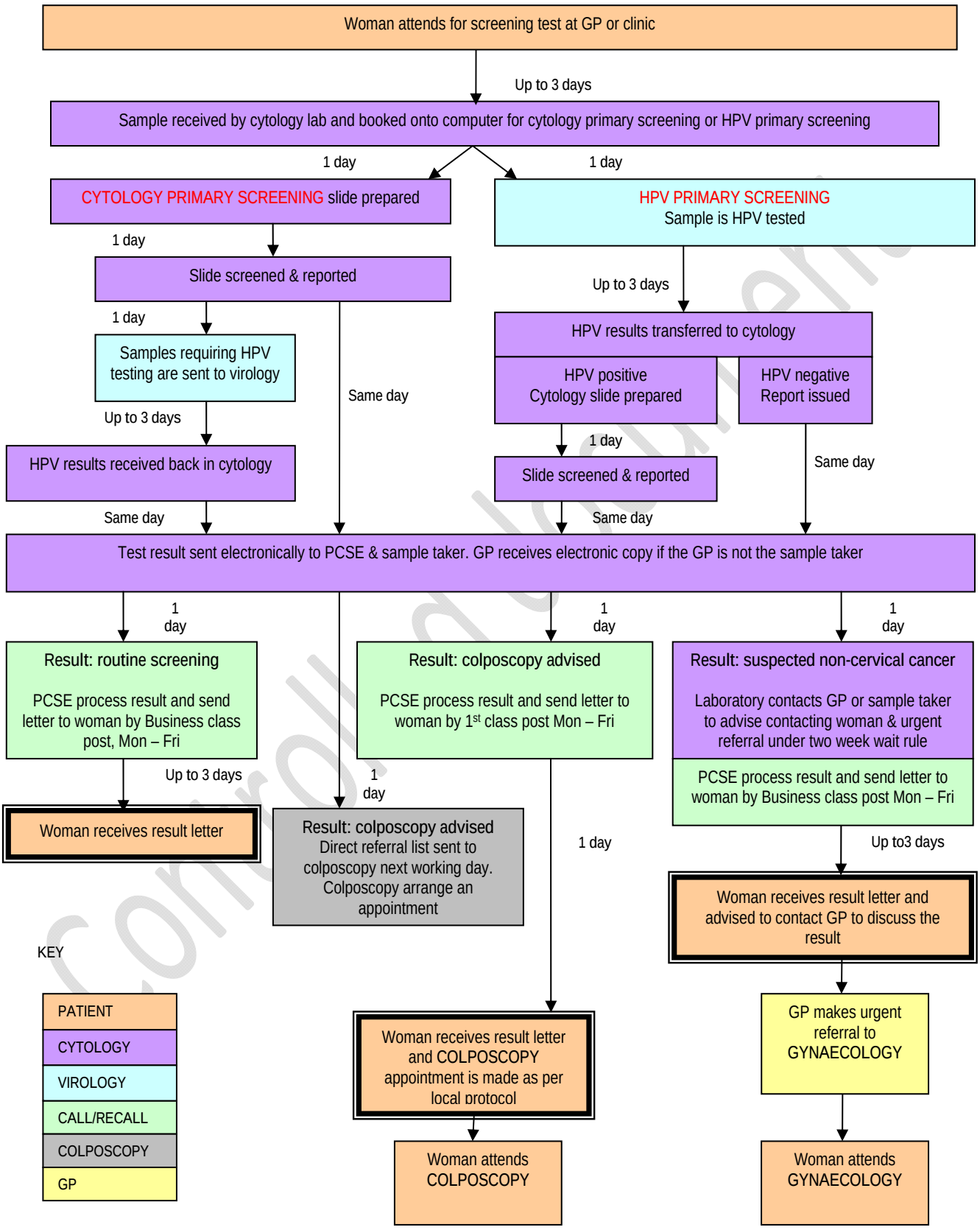
Major discrepancies

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

12 PATIENT PATHWAY THROUGH CERVICAL SCREENING



Appendix A Cytology result codes and associated Read codes

Cervical screening report terminology	Result code on Exeter	Read code
Inadequate	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
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