Public Health England

NHS

NHS Cervical Screening Programme

Guidance for acceptance of cervical screening samples in laboratories and pathways, roles and responsibilities

Public Health England leads the NHS Screening Programmes

About Public Health England

Public Health England exists to protect and improve the nation's health and wellbeing, and reduce health inequalities. We do this through world-class science, knowledge and intelligence, advocacy, partnerships and the delivery of specialist public health services. We are an executive agency of the Department of Health, and are a distinct delivery organisation with operational autonomy to advise and support government, local authorities and the NHS in a professionally independent manner.

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About PHE screening

Screening identifies apparently healthy people who may be at increased risk of a disease or condition, enabling earlier treatment or better informed decisions. National population screening programmes are implemented in the NHS on the advice of the UK National Screening Committee (UK NSC), which makes independent, evidence-based recommendations to ministers in the four UK countries. The Screening Quality Assurance Service ensures programmes are safe and effective by checking that national standards are met. PHE leads the NHS Screening Programmes and hosts the UK NSC secretariat.

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1. Purpose

The purpose of this document is to improve the quality of service provided by the NHS Cervical Screening Programme (NHSCSP) by reducing the administrative and technical errors associated with cervical screening sample requests.

Implementing this guidance will reduce:

- the risk of women receiving incorrect screening
- the time taken for all women to receive their cervical screening test results

This guidance supports the recommendations of the NHSCSP guidance in conjunction with NHS Improvement (2009) for achieving the national 14 day turnaround time standard [1].

This guidance gives the minimum requirements for the processing and auditing of cervical samples that are sent to cytology laboratories. Recording, auditing and reporting errors is important to identify any problems in the local sample taking process. This reduces the risk of potential incidents and gives an opportunity for learning and quality improvement.

2. Roles and responsibilities

The NHSCSP is a complex pathway with multiple providers. It is essential to have clear roles and responsibilities to ensure that high quality screening occurs and that appropriate action is taken where this is found not to be the case.

1.1 Screening commissioner responsibilities

It is the responsibility of NHS England, via the Section 7a agreement and cervical screening service specification No. 25, to commission services across the screening pathway[2].

Best practice includes the establishments of a sample taker register in collaboration with laboratories to ensure the provision of:

- sample taker registers
- comprehensive feedback both by individual sample taker and by general practice/clinic on reporting profiles, workload, and error rates (for example incomplete patient identity details)

This will normally involve the need to define:

- unique personal identification numbers (PINs) for sample takers to facilitate sample taker databases
- local requirements for acceptable sample taker training (in line with national screening guidance) and what checks of training are required
- the process for oversight of sample taker performance, quality and safety
- a mechanism to report performance information to relevant parties
- the process for communication and escalation of any issues that arise so that action can be taken

These responsibilities may be discharged directly, by the screening and immunisation team, or by commissioning other providers. Whichever approach, or combination is determined locally, the arrangements should be documented.

1.2 Sample taking provider responsibilities

Sample taking providers are usually general practices, but may also be community clinics, sexual health services and hospitals.

It is the responsibility of the sample taking providers/employer organisations to ensure that:

- all sample takers are adequately trained as described in national screening guidance

- protocols and procedures consistent with national screening guidance are in place for the:
  - completion of the screening test and its associated documentation
  - safe transport of screening specimens to the cytology laboratory

The ‘Open Exeter’ web-based application is recommended for all administration regarding the NHSCSP. Open Exeter references data from the national call and recall system so holds the master screening history records. This gives the laboratory immediate access to relevant data when reporting a test so that an appropriate next action can be specified. This in turn minimises the likelihood of rejection of invalid test results by the call and recall system and reduces delays in issuing results to women.

1.3 Sample taker responsibilities

1.3.1 Demonstration of competence

It is the sample taker’s responsibility to ensure that they:

- have received appropriate initial training to take cervical cytology samples[3]
- understand how the programme operates and their responsibilities within it
- keep themselves updated on programme developments and policy to avoid taking inappropriate tests (this is best carried out through 3-yearly updating[3]
- audit their practice routinely and are proactive in seeking advice should they identify any issues

On demonstration of competence, sample takers should be issued with a PIN for carrying out unsupervised screening tests. This PIN will be unique and must not be used by anyone else. It will reflect the locally agreed PIN arrangements, which may use General Medical Council (GMC), Nursing and Midwifery Council (NMC) numbers or other locally agreed unique identifier. It may be necessary to use different numbers for the same person where personnel work in more than one practice/clinic so as not to skew any practice-based data.

1.3.2 Sample request forms

Sample takers should preferably use the prepopulated HMR101 cervical cytology request forms (2009 version) available via Open Exeter. Only this version has the full screening history. Use of other versions may result in either delays due to the laboratory checking the full history on Open Exeter or the risk of issuing an inappropriate management recommendation by the laboratory. Sample takers must have knowledge of the “Open Exeter” application to download the correct prepopulated HMR101 cervical

cytology request form (2009) version and be an authorised user. They should follow the guidelines for completion of the form and produce the preferred size for their laboratory (usually A5 size).

If a non-Open Exeter request form is used for a legitimate reason, for example, the patient is not yet registered or the Open Exeter system is unavailable, then this must be explained to the laboratory on the non-Open Exeter request form and recent/relevant history should be provided.

Where laboratory electronic requesting systems are in use, there must be mechanisms in place to provide the past screening history as it is on Open Exeter. This ensures sample takers do not take unnecessary samples and that laboratories are able to give correct patient management recommendations.

1.3.3 Taking the sample

The sample taker must establish that a woman is eligible for a test (invited from age 24.5 to 64 for routine tests) and that a test is now due (or overdue). Some women outside the standard screening age range can be eligible for screening if:

- they have a routine recall date allocated as a result of a previous test
- they are under surveillance or follow-up as a result of a previous abnormality
- they did not respond to their last invitation and now wish to be tested

The sample taker should be aware of when not to take a sample and what/when other investigations are appropriate for women with symptoms or abnormal bleeding [4].

The sample taker is responsible for ensuring that the sample and request submitted relate to the correct patient. It is essential that the sample taker checks with the woman that the details on the downloaded request form are hers and that her correspondence address is current. This can best be achieved by the sample taker asking the woman to check with them that the details are hers, such as full name, date of birth and address. If the address is not current then the call and recall service needs to be advised of the new details as soon as possible to prevent downloaded results from laboratories being rejected or correspondence sent to the wrong address.

It is the sample takers responsibility to ensure that the woman is contactable so that she can be advised of any further tests or investigations that may be required based on her cervical sample result.

A cervical sample should be taken in accordance with programme sample taker training guidance. The vial should be checked to ensure that it has not passed its expiry date

and that it has at least 14 days remaining as HPV testing cannot be carried out on expired vials.

The test request form and vial should be completed with relevant patient information which must comply with the guidelines outlined in the ‘Specimen requirements’ section of this document. It is important to include previous cervical cytology and cervical histology results and treatments on the sample request form so that correct management can be determined by the laboratory.

Where a sticky label is used with the woman’s details it should not obscure the expiry date or obscure the clear area between each end of the label already on the vial; this interferes with the laboratory processor’s ability to read the level of fluid in the vial.

It is essential for the laboratory receiving the request form and vial that the two can be matched to each other and that all the appropriate information is given to ensure that the test can be processed and reported.

It remains the sample taker’s responsibility to fully visualise and sample the cervix appropriately.

Sample takers should take steps to assure themselves of the process by which the samples they take, and their accompanying request forms, are stored in their practice/clinic and then passed to the sample transport provider to ensure that this is safe, prompt and that forms and vials do not become dissociated from one another.

Sample takers should ensure that there is a failsafe system in place where they can assure themselves that a cervical sample result comes back for every test they take and that appropriate action is taken when necessary.

1.3.4 Incidents

Sample takers should report and discuss any rejected samples. This should always include any sample where the laboratory has had to reject the test due to insufficient/conflicting information or where it has been taken inappropriately. Such events should be reflected on, formally recorded internally and reported as necessary according to practice/clinic clinical governance policies. Only situations that fulfil the criteria of a ‘screening incident’ should be managed in line with national screening incident guidance [5].

Sample takers should take responsibility for communicating events leading to rejection of a sample to the women concerned in an honest and sensitive manner and advise them when another sample should be taken. Repeat samples should not be taken within

3 months of a previous test to allow sufficient time for the cervical epithelium to regenerate otherwise a false result may be obtained.

1.3.5 Summary of sample takers' responsibility

Sample takers should ensure that:

- they are adequately trained in line with programme guidance to take the test[3]
- they have and use a unique PIN and do not share this number
- they have adequate and up-to-date knowledge about the test, results and management
- they are able to download a request form from Open Exeter or use any local electronic requesting system
- they have checked that the woman is eligible for a test
    - Is she 24.5 to 64 years of age?
    - Is she aged 65 or over, and under surveillance or follow-up?
    - Has she been invited for a test?
    - Is she due for a test?
    - Is the test appropriate or is referral to gynaecology or sexual health/genitourinary medicine (GUM) clinic more appropriate?
- the sample vial is in date, and has at least 14 days left before its expiry (time period left at least equivalent to the average waiting time for results)
- the patient details on the request form and vial match, are correct and that all necessary information is given (see section on 'Specimen requirements')
- the registration of the woman's address is correct
- the woman receives the appropriate follow up and management
- adverse events and incidents are recorded, discussed and investigated
- they communicate appropriately with the woman if her sample is rejected

1.4 Laboratory responsibilities

It is the responsibility of the cytology laboratory to:

- check that all cytology samples are in an adequate condition when received for processing
- prepare, screen and report samples in accordance with national guidelines
- notify the sample taker and GP or responsible clinician and the call and recall system of test results and recommendations for management
- identify any errors in form filling and vial labelling promptly and ensure sample takers notified
- maintain a suitable log of sample issues, as outlined in this document, to monitor and report trends, as agreed locally

- promptly highlight any sample request errors that could indicate that a screening incident has occurred, in accordance with national screening incident guidance

3. Specimen requirements

Cervical cytology samples must satisfy minimum requirements and any errors that compromise the safety of the patient will result in the sample being rejected. Therefore all required fields of the HMR101 must be completed correctly.

Box 1. Essential specimen data requirements.
Patient's full name ie at least first name and surname (2 identifiers) Patient's date of birth NHS number Patient address Name and address of GP Name and address of sample taker (sender) Sample taker personal ID number (PIN)

Use of Open Exeter prepopulated cytology request forms will provide the necessary patient identifiers and general practice details, including the practice code and woman's area of residence (Q code). These should therefore always be on the form used, unless exceptional circumstances render Open Exeter unavailable. If a non-Open Exeter request form is used for a legitimate reason (for example, the patient is not registered or the Open Exeter system is unavailable) then this must be explained to the laboratory on the form. The fields that then **must** be manually completed by the sample taker are listed in Box 3.

Box 2. Prepopulated HMR101/5 (2009 version) information
NHS number Patient date of birth Patient name, address, postcode Name and address of GP or practice GPs national and local codes Date of last 15 tests Result of last 15 tests (code) and action

Box 3. Specimen Information requirements for manually completed sample requests
Sample taker name and PIN Clinical data including any previous cervical biopsy results and treatments. Any other appropriate clinical details Test date Reason for the current test

1.5 Patient identifiers and clinical details

Upon receipt in the laboratory of a cervical cytology sample, both the form and sample should be checked for patient and clinical details so that the laboratory can be confident both that the form and sample can be linked together and that they can be linked with any existing record for that individual. There should be a minimum of 3 legible and correct patient identifiers to link a form and vial that arrive together. There should be a minimum of 3 legible and correct patient demographics to identify a patient and to match them with any existing record on the pathology system. Ideally the NHS number should be used.

Box 4. Minimum identifying requirement for cervical samples.
Patient's full name (first name and surname) Patient's date of birth Ideally fourth identifier: NHS number Other acceptable fourth identifier: patient address

1.5.1 Major labelling discrepancy

The absence or significant mismatch of one or more of the key patient demographics, Box1, for example, the first 3 items in the essential data list constitutes a major discrepancy. In these circumstances, the laboratory cannot be certain of the patient's identity. The sample details should be recorded on an electronic searchable database. The sample should be rejected and not processed as the patient's identity cannot be confirmed with full certainty. An electronic record of all defective/rejected samples should be kept so that lists and audits can easily be generated to inform other interested parties of the scale of these problems (see section on error logs and error reporting).

Where the patient identity differs on the form and the vial, the sample should be attributed to the individual on the form for error recording purposes.

The laboratory will inform the sender immediately advising them of the faults and reasons for rejecting sample and advising them that a repeat test should be carried out in 3 months' time (see Appendix 1). If possible, the laboratory should keep records such that it may be possible to identify if the repeat test is taken within the 3 month period and should therefore be rejected.

In the event that the sample taker is unable to confirm with confidence which woman was tested giving rise to concern that an incident may have occurred, the Screening QA Service should be informed for advice, in line with national screening incident guidance.

1.5.2 Minor labelling discrepancy

A minimal spelling difference, a specimen or form labelled with the woman's maiden or previous name while the corresponding form/specimen is labelled with her current surname, or a single digit error in date of birth with all other identifiers matching constitutes a minor discrepancy. In these circumstances, the laboratory is confident of the patient's identity despite the discrepancy.

Such samples will be booked in and reported. Details can be checked by the laboratory via the Open Exeter application. The discrepancy and remedial action taken should be recorded in the laboratory error log and the sender will be informed of the discrepancy. Any discrepancy should be explained in the report using standard codes, such as the examples in Appendix 2. These can also be used to generate error reports.

Multiple minor discrepancies constitute a major discrepancy and are dealt with accordingly.

1.5.3 Out-of-programme samples

All out-of-programme samples should be rejected by the laboratory.

Samples from women under 25 years of age, who have not been invited by the programme, will be classed as out of programme if they have been taken earlier than 6 months before the woman's 25th birthday. However, tests should be accepted from women under 25 who are:

- on routine recall after previously being tested at 20 years in Wales, Scotland, Northern Ireland

- from private healthcare who are being followed up for previous abnormal cytology
- being followed up after having had an incidental biopsy showing cervical glandular intraepithelial neoplasia (CGIN) but have had no prior cytology

Samples from women 65 years of age and over will be classed as out of programme unless:

- the woman has never had a cervical screening test and now requests one (which should be indicated by the sample taker on the request form)
- if the woman did not attend for her last invitation when aged 60 or over and now wishes to have that final test
- if the woman's last 3 tests included an abnormal result and/or she is still in surveillance or follow up following treatment for CIN

For women over 65 on normal routine recall with fewer than 3 consecutive negative tests, laboratories should check whether they have been invited by the call and recall service before rejecting the sample.

Samples taken from women on routine recall should be considered out of programme if they are taken: 1) less than 30 months since a previous test (women aged under 50); or 2) less than 54 months since a previous test (women aged 50 to 64).

Where triage and test of cure has taken place, a sample should not be taken before the recommended recall. The laboratory should reject samples from women who have had an unreliable HPV test repeated in less than 6 months for triage samples and less than 3 months for test of cure samples. The sample taker should be notified.

Samples taken within 3 months of any previous test cannot be reliably interpreted and so should be rejected. The sample taker should be notified.

Vaginal vault cytology samples from women who have had a total hysterectomy for benign conditions or for non-cervical cancers (for example, endometrial, ovarian) are classed as out of programme as vault cytology is no longer part of the screening programme. Women requiring vault cytology for follow up will normally be managed by their local colposcopy unit.

With the exception of HIV patients, there are no circumstances where routine annual screening is indicated [6]. Screening for women with HIV commences at 24.5 years in line with all other women. Tests taken outside the normal screening age range should be rejected. It is not always possible for the laboratory to know when routine annual

screening is appropriate. Sample takers should make this clear on the request form (see Appendix 6).

Screening for military personnel is part of the NHSCSP. Screening for women in the military commences at 24.5 years in line with all other women. Tests taken outside the normal screening age range or at incorrect intervals should be rejected.

1.6 Condition of sample

The condition of the sample should be checked, always ensuring that the vial data matches that on the request form.

A check that no leakage has occurred should be made and that the volume of liquid in the vial is adequate. For SurePath© samples, the broom head must be present in the vial. In the case of ThinPrep© specimens, the sampling broom head should have been removed from the vial and a check should be made that that the vial cap is screwed on hand tight.

1.6.1 Samples in incorrect container or with insufficient volume

Vials containing an insufficient volume of liquid to produce a suitable sample (SurePath© samples without a broom head present in the vial and ThinPrep© samples with the broom still in) should be processed and reported as inadequate unless abnormal cells are detected. Manufacturer's officially published guidance should be followed on what constitutes the minimum acceptable volume for routine processing. See Appendix 5 for more details on HPV testing in these circumstances. ThinPrep© samples received in the wrong container should be rejected.

1.6.2 Samples in out-of-date vial

The sample taker should have already checked the expiry date of the vial but where samples are received in an out-of-date vial they should be rejected. Details of such samples should be recorded electronically. The sample taker should be informed and advised to check for further out-of-date stock which should be returned to the laboratory for safe disposal.

1.6.3 Reporting results

In all cases where the patient's identity is not in question but a repeat sample is required because of the quality of the sample received, the sample should be booked onto the

laboratory system and an inadequate or abnormal report issued as appropriate. This allows for robust failsafe, ensures that follow-up requirements are reported in a standard manner to the sample taker and to the call and recall service, and that the result is transferred electronically so that the patient gets an appropriate result letter and is recalled at the appropriate recall interval.

1.6.4 Missing form or specimen

The following procedure should take place for specimens or forms received without the corresponding form/specimen:

- the source (general practice or clinic) should be informed of the error and that the specimen/form will be retained within the department for 2 working days in case it has become separated from the corresponding form/specimen during transit and will arrive later
- if the missing items appear within the specified 2 working days, the sender should be informed and the sample processed for reporting as usual

- if after the 2 working days the missing component has not materialised, the source (general practice or clinic) should be informed and a request made that the woman is recalled for a repeat sample to be taken in 3 months
- the details of the error should be added to the electronic laboratory error log

1.7 Sample taker details

The GP name, address and practice code must be provided for all registered women. These will be present if the prepopulated Open Exeter form is used.

If the GP details are not provided, the laboratory should seek to identify the woman's GP registration details using Open Exeter. The sample should be booked in against the GP with which the woman is shown to be registered, to ensure there are no delays in issuing her result. If there is any doubt about the woman's identity, the major discrepancy process should be used.

Details of the error should be logged and reported to the sample taker. Local commissioners may also wish to be notified.

1.7.1 Personal Identification number (PIN) absent or invalid

The sample taker's PIN should be present and valid as this confirms that the sample taker is appropriately trained and competent in cervical sample taking. The absence of a valid PIN on the sample request requires investigation before it can be reported. If the

PIN information can be confirmed, the sample can be reported. This should be done swiftly so as not to adversely affect the time the woman waits for her result.

Sample takers must **not** use a PIN belonging to someone else. Trainee sample takers should use a unique PIN that identifies them as a trainee.

If the sample taker PIN is invalid or cannot be provided, the sample should be reported as inadequate by the laboratory unless abnormal cells are identified.

If enquiries related to an absent or invalid PIN raise concerns that the sample taker may not be trained or does not meet the minimum requirements to be a sample taker, advice should be sought from the Screening QA Service, in line with national screening incident guidance.

1.8 Summary of non-acceptable cervical samples

Table1. Summary of nonacceptable cervical samples.		
Nonacceptable cervical samples	**Laboratory action**	**Error report**
Unlabelled samples	Recorded electronically but rejected and not processed, request repeat test	Record in error log
Sample with non-matching or incomplete patient details on form and vial (major labelling discrepancy) and samples taken inappropriately at any source	Recorded electronically but rejected and not processed, request repeat test	Record in error log
Samples from uninvited women under 24.5 years	Sample booked on to laboratory system (if possible)/recorded electronically but rejected and not processed	Record in error log
Samples from women over 65 (unless woman unscreened, missed last invitation or is in follow up for previous abnormal)	Sample booked on (if possible)/recorded electronically but rejected and not processed	Record in error log
Samples from women on routine recall which are taken more than 6 months ahead of schedule	Sample booked on (if possible)/recorded electronically but rejected and not processed	Record in error log
Samples which have been requested following an unreliable HPV test as part of triage but have been taken less than 6 months from the last test or repeated test of cure samples taken less than 3 months	Sample booked on (if possible)/recorded electronically but rejected and not processed	Record in error log
Samples taken at an inappropriate period after a negative HPV test or inappropriately taken at colposcopy contrary to NHSCSP HPV testing implementation guidance	Sample booked on (if possible)/recorded electronically but rejected and not processed	Record in error log
Samples taken at less than a 3 month interval following a previous inadequate or rejected test	Sample booked on (if possible)/recorded electronically but rejected and not processed	Record in error log
Vault samples from women with total hysterectomy for non-cervical malignancy or benign conditions	Sample booked on (if possible)/recorded electronically but rejected and not processed.	Record in error log
Samples in poor condition (insufficient fluid, SurePath© sample without broom head, ThinPrep© with broom)	Process sample. Report as inadequate unless abnormal cells detected. Inform sender of reason	Record in error log

Samples in out-of-date vials	Sample booked on (if possible)/recorded electronically but rejected and not processed, request repeat test	Record in error log
Samples with missing request form/specimen	Inform sender. Sample booked on/recorded electronically but rejected and not processed, request repeat test	Record in error log
Samples with invalid sample taker PIN	Process sample. Attempt to confirm PIN. Report as inadequate unless abnormal cells detected if PIN not confirmed Inform sender of reason.	Record in error log

4. Laboratory management advice for tests requiring a repeat sample

Management advice from laboratories for tests requiring a repeat sample should include the text ‘Unable to process sample. Please repeat after 3 months from initial sample. Do not repeat immediately as the cervical epithelium needs time to regenerate and the test result may be unreliable’, or similar.

The reason the sample needs to be repeated should be stated on the cytology report. This ensures the sample taker is clear how to explain the need for the repeat test to the woman.

5. Error logs and error reporting

Reports should be made available to commissioners as required locally. This should be documented, including frequency, format and process for follow-up of issues.

An electronic record rather than manual record of all defective/rejected samples should be kept so that lists and audits can easily be generated to inform commissioners, sample taker providers and sample takers of the scale of these problems.

Recorded details should include the date, patient details, clinic/sender details, error details plus error code, action, and resolution date. Ideally, all errors should be coded with a relevant error code. This will provide the laboratory with a means to audit and report problems back to sample takers, providers and commissioners.

Where samples are rejected these tests must not be included in the electronic download to the call and recall service or in the KC61 return or other laboratory workload data.

Error logs should be regularly audited, at least quarterly. The results should be reported to the appropriate organisation(s), as agreed locally, to facilitate local action. Error rates and issues should be reported at commissioner-led multidisciplinary Programme Board meetings. An example is shown in Appendix 3.

Audit reports for individual sample takers and/or sample taker providers should be produced and disseminated at locally agreed intervals, such as annually. An example of such a report is shown in Appendix 4.

Appendix 1 Example sample error letter

Date:

Laboratory name and address
Laboratory Ext:

Dear Doctor/Practice Nurse

Unfortunately we cannot accept the enclosed **cervical** screening test **request** for the reasons indicated below.

As the sample has not been processed there will be no result letter issued. It is the sample taker's responsibility to inform the woman of this situation and, if required, to arrange a repeat test in NOT LESS than 12 weeks after the last sample was taken sample should be taken on or after

Please do not repeat immediately as the cervical epithelium needs time to regenerate and the test result may be unreliable.

Yours sincerely

Head of Cytology

PRACTICE NAME
……

PATIENT'S NAME ……..
D.O.B…….

DATE RECEIVED
……

SAMPLE TAKER NAME (IF RELEVANT)…… **I.D. CODE**
…….

RETURNED TO SENDER BY: …… **DATE** ……

Reason for rejecting sample

☐	No request form received	☐	Details on form illegible
☐	No sample received	☐	Details on sample illegible
☐	Insufficient details on request form	☐	Insufficient details on sample
☐	Sample and request details do not correspond	☐	Out of date vial used
☐	Outside age range for screening	☐	Sample repeated too early outside of programme guidance

☐	No/insufficient fluid in vial	☐	Previous positive HPV test & recommendation for colposcopy. Repeat test not required. Arrange referral to colposcopy
☐	Previous negative HPV test and return to routine recall. Repeat test not required		
☐	Other……		

Appendix 2 Example error codes

Error Codes

All sample/request errors should be coded with the relevant error code. This will provide the laboratory with a means of auditing these samples.

ERROR CODE	EXPANSION	COMMENTS
E1	Vial received without form	Contact sender and ask for form. If no form, reject sample and request repeat test to be taken after 3 months
E2	Form received without vial	Contact sender and check sample was taken. If no vial request repeat test to be taken after 3 months
E3	Vial is unlabelled	Inform sender. Reject sample and request new sample to be taken after 3 months
E4	Vial only partially labelled	Follow guidance for minor/major labelling discrepancies
E5	Patient details on form and vial do not match	Significant data inconsistencies require a repeat sample. Inform sender. Reject sample and request new sample to be taken after 3 months
E6	Insufficient patient details on form	Depends on severity. Inform sender. Reject sample and request new sample to be taken after 3 months if major discrepancy
E7	Patient details differ from cytology records	Reject if major labelling discrepancy. If minor discrepancy, check Open Exeter and process but inform sender of error
E8	Valid PIN not provided	Verify PIN. If not verified report sample as inadequate unless sample is abnormal. If verified, record PIN and report sample in the usual way. Inform sender.
E9	Vial spilt in transit/ incorrect container/ brush inappropriately missing or present	Process sample and report as inadequate unless sample is abnormal. Inform sender
E10	Form/vial details illegible	Depends on severity. Inform sender. Reject sample and request new sample to be taken after 3 months
E11	Out of programme sample (age, too early repeat, inappropriate vault)	Inform sender and reject sample
E12	Out-of-date vial	Reject sample. Inform sender. Ask sender to check stock and return any out of date vials to the laboratory for safe disposal

Appendix 3 Example laboratory audit report to commissioners

	Discrepancy profile											
	From : _____ Trust Reporting period:											
	Surgery /Clinic	**Total tests sent with errors**	**Total number of errors**	**No sample received**	**Un-labelled vial**	**Specimen labelling**	**Name**	**DOB**	**NHS no**	**PIN missing/ incorrect**	**Missing clinical data**	**Other**
1		**5**	**5**				**2**		**3**			
2		**1**	**2**				**1**	**1**				
3		**1**	**1**		**1**							
4		**8**	**13**			**5**	**3**	**4**	**1**			
5		**2**	**2**							**2**		
7		**1**	**2**			**1**	**1**					
8		**6**	**9**			**1**	**2**	**2**	**2**	**2**		
9		**3**	**3**		**3**							
10		**2**	**2**	**1**		**1**						

Other errors: Details
Number of repeat samples required:
Comments:

Appendix 4 Example sample taker audit report

Laboratory name

CERVICAL SAMPLE REPORTING PROFILES

PRACTICE/CLINIC NAME and CODE:

TIME PERIOD OF REPORT:

Total number of samples submitted: 111

SAMPLE TAKER	LBC CERVICAL SAMPLES			
	Total	Negative	Abnormal	Inadequate
PIN 1	4	4	0	0
PIN 2	1	0	0	1
PIN 3	85	79	3	3
PIN 4	20	18	1	1
Total	**110**	**101**	**4**	**5**

Total Inadequate rate = 4.5%

Discrepancy data

TYPE OF DISCREPANCY	TOTALS	REPEAT SAMPLE REQUIRED
No sample received with form	0	0
Unlabelled vial	1	1
Form and vial mismatch	0	0
DOB incorrect	1	1
Name incorrect	0	0
NHS number incorrect	0	0
Missing/incorrect PIN number	1	0
Other missing data	0	0
Specimen label error	0	0
TOTALS	**3**	**2**

Appendix 5 Cervical screening sample integrity

1. Introduction

Liquid-based cytology samples are used for both cytology and HPV testing. There are 2 approved systems for use in the UK, SurePath and ThinPrep.

From time to time, samples may be received in the laboratory which have leaked. HPV test platforms have defined minimum volumes for processing. Any sample which contains insufficient volume will be reported as inadequate for HPV testing and appropriate management pathways will need to be followed.

Tests for HPV are extremely sensitive and could be vulnerable to contamination.

This document represents a consensus and advice on handling and reporting of samples from vials which have leaked but have sufficient residual volume for HPV testing.

2. Risks of contamination – HPV testing

There is considered to be no significant risk of leakage occurring into a sample vial, even if, for example, there is a small defect in the lid. Therefore a sample with such a defect can be processed with no significant risk that it will test falsely positive.

Samples which have leaked and therefore potentially have HPV positive material on the outside of the vial could cause contamination of HPV testing equipment, and this could result in other samples testing falsely positive.

The potential harm to a woman of a false positive HPV test falls into the category of Mild Harm. A woman may be required to have an additional annual screen or, if her cytology is mildly abnormal but her HPV test should have been negative, have an unneeded colposcopy referral. It should be noted that the rate of HPV positivity varies between platforms and a significant number of women who test positive with one system may have tested negative with another.

Contamination poses no risk of a false negative diagnosis or missed abnormality.

3. Risks of contamination – cytology

There is no risk of contamination involving transfer of cells. Therefore all cytology investigations are safe even in the event of significant contamination, provided there is sufficient cellular content.

4. Risk of decision not to process a sample

If a sample is inappropriately rejected, the woman will need to be offered a repeat sample. There is good evidence that many women do not take up this invitation in a timely manner, or at all. Therefore failure to process and report places a woman at risk of having undetected disease or a delay in diagnosis.

5. Routine practice

Routine virology practice requires full awareness of contamination risks, and all HPV test platforms have standard decontamination regimes.

Contamination may also arise during manual test processes, for example, uncapping and pipetting, and policies will routinely exist for management of these occurrences.

6. Quality management

As a minimum, laboratories should have the following standard operating procedures, the exact details of which will depend on the Liquid-Based Cytology and HPV platforms in use.

6.1 Identification of a potentially contaminated vial.
6.2 Criteria for reporting for cytology in a low volume vial (cytology primary screening).
6.3 Criteria for reporting for HPV in a low volume vial (cytology primary and HPV primary screening).
6.4 Planned regular cleaning and decontamination of the HPV testing equipment, in accordance with manufacturer's instructions.
6.5 Protocol for decontamination of vials believed to have surface contamination, before HPV testing.
6.6 Policy for avoiding contamination during analysis process.
6.7 Policy for internal Quality Control of HPV testing including identification of batches which may have been affected by contamination.

7. Conclusion

Cervical screening samples with contamination of the exterior of the vial should be accepted for processing for HPV testing and cytology.

If there is insufficient volume, cervical screening programme policies should be used to report as inadequate or abnormal, and appropriate recall intervals set according to national guidance.

Standard techniques for decontamination of such vials, together with regular cleaning and decontamination of HPV test platforms (according to the manufacturer's

specification) should be documented and undertaken. If this is correctly carried out, there is no significant risk of contamination to other samples from a contaminated vial.

Appendix 6 Immunosuppressant therapy

The NHSCSP in England is highly quality assured and recognised to be of a world class standard. Recommendations for annual screening for women using immunosuppressant treatment frequently originate in the USA or other countries where there is no quality national screening programme, so the circumstances are different and need to be taken into consideration.

A variety of immunosuppressant drugs used following organ transplantation or, for example, treatment of autoimmune disorders or neurological disorders that increase the risk of contracting HPV but they have no impact on the rate of progression through HPV and CIN to cervical cancer which takes many years. Therefore it is important that women should engage with cervical screening when invited but there is no need to invite more frequently. Additional testing will give no benefit and will increase anxiety to the woman.

This issue has been considered by national expert groups and this is the best clinical advice.

Women over the cervical screening age range (65 years) are generally at lower risk of acquiring HPV, assuming they have been adequately screened up to age 65.

The programme advice would be to ensure that all women on immunosuppressant's have a complete screening history, including those over 65. Women who have not attended for screening should be offered another cervical screening test and remain eligible for screening.

As for other unscheduled cervical screening tests, samples should be rejected by laboratories if they have not been taken according to the recommended screening interval.

References

1. NHS Cervical Screening Programme, Cytology improvement guide -achieving a 14 day turnaround time in cytology, November 2009
2. NHS England, NHS public health functions agreement 2016-17. Service specification No. 25 NHS Cervical Screening Programme, February 2016
3. NHS Cancer Screening Programmes, Guidance for the training of cervical sample takers November 2016
4. Kitchener HC, Sonnex C, Butler J, Firth S, Moss K, Shaf M, Walker P; Subgroup of the Advisory Committee on Cervical Screening, Clinical Practice Guidance for the Assessment of Young Women aged 20-24 with Abnormal Vaginal Bleeding, March 2010
5. NHS Screening Programmes and NHS England, Managing safety incidents in NHS screening programmes: October 2015
6. NHS Cancer Screening Programmes, Colposcopy and Programme Management, March 2016

Further Information

NHS Cervical Screening Programmes publications and guidance for professionals – see:
https://www.gov.uk/government/collections/cervical-screening-professional-guidance

NHS Cervical Screening Programme Cervical screening- programme overview –commissioning information see:
https://www.gov.uk/guidance/cervical-screening-programme-overview