

## SE Coast Cervical Screening QARC Interim Guidance for laboratories on cervical sample acceptance

### List of accepted reasons/categories for sample rejection and inadequate cytology reports in SE Coast

Version 6, January 2015

The Cancer Reform Strategy requires implementation of 14 day turnaround of cytology results, from sample to result to woman. Draft National Guidance recommends that such issues must be resolved within 48 hours of identification, or the sample must be reported as inadequate and the woman will be invited to re-attend for screening. This course of action is undesirable and every effort should be made by laboratories and primary care sample takers to address cytology sample queries and issues very promptly.

The following has been agreed by the SEC QA Team and SEC Screening & Immunisation Teams and Public Health Commissioners as interim guidance pending national guidance:

1. Samples should not be routinely rejected solely on the basis that a screening invitation letter has not been issued.
2. It is not possible for laboratories to check invitation status on Open Exeter with complete accuracy, although the likelihood of an invitation having been sent can be surmised from next test due date. As far as possible, samples should not be rejected if an invitation letter has been issued by PCSS/PCA.
3. Colposcopists should not ask PCSS/PCA to change next test due date without a valid clinical reason, and should ensure the next test due date complies with national HPV triage/test of cure protocols unless there are exceptional circumstances. The role of PCA/PCSS does not include questioning instruction given by clinicians. Colposcopists should be mindful that, if their laboratory lacks the facility to check invitation status, a sample taken too early may be rejected, even when the woman has been invited by the programme. Non-compliance to the triage & test of cure protocol causes difficulty for laboratory colleagues, variation in screening programme provision and effectiveness and may not comply with information given to the woman about her care.
4. Parameters have been set to allow for samples to be taken marginally early to allow for some flexibility. **If the laboratory has the facility to check whether a woman has been invited by PCA/PCSS, and that shows she has been invited, her sample should be screened regardless.** If she has not been invited but attends early, the requirement to accept the sample will depend on the recall interval originally set. The following has been formulated to allow some flexibility whilst being mindful that the national recall intervals are based on clinical evidence:
  - Recall period 5 years, sample accepted if taken at or after 54 months (6 months early)
  - Recall period 3 years, sample accepted if taken at or after 30 months (6 months early)
  - Recall period 12 months, sample accepted if taken at or after 10½ months (6 weeks early)
  - Recall period 6 months, sample accepted if taken at or after 5½ months (2 weeks early)

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5. Some colposcopists and gynaecologists continue to have concerns about or lack understanding of the HPV triage and test of cure protocol. As that may lead them to use old recall protocols, laboratories should not routinely accept out of scope hospital samples but should either query why the sample has been taken so that a decision may be made on the appropriateness of each one, or reject the sample.
  
6. Samples laboratories have returned samples with minor labelling errors to the sample taker by some laboratories so they have responsibility for correcting the error. This practice carries several risks so samples should not be returned to the sample taker for correction of labelling errors. Single minor errors may be accepted but notified to the sample taker with a comment on the report. Samples with more than one minor error or a major error should be rejected.
  
7. Records must be kept of all samples received, although it is not always possible to identify the source of those which are unlabelled or mislabelled. BSCC guidance recommends that unlabelled/mislabelled samples are not booked in as it is not possible to attribute the samples to an individual, booking them in will inflate inadequate rates and make comparability of inadequate rates impossible. It is preferable to record and report on them separately. If booked in, there must be a means to identify those types of inadequates so that they may be separated out on the KC61 statistics.

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### Sample Condition issues identified when specimen received

Error code	Issue	Notes	Further action/recall
E14	Sample in a container other than a ThinPrep© vial		<ul style="list-style-type: none"> <li>▪ Book in</li> <li>▪ Discard sample</li> <li>▪ Inform sender</li> </ul>
	Sample taken more than 6 weeks before receipt in laboratory		
E13	ThinPrep© vial out of date		<ul style="list-style-type: none"> <li>▪ Book in</li> <li>▪ Discard sample</li> <li>▪ Inform sender &amp; ask them to return any out of date vials to laboratory for safe disposal</li> </ul>
E10	ThinPrep© sample containing brush head		<ul style="list-style-type: none"> <li>▪ Book in</li> <li>▪ Screen</li> <li>▪ Report as inadequate if not abnormal</li> </ul>
E15	Sample taken more than 5 days & less than 6 weeks before receipt in laboratory		<ul style="list-style-type: none"> <li>▪ Book in</li> <li>▪ Screen &amp; report</li> <li>▪ Send template letter to sample taker asking them to investigate the reason for the delay and take appropriate action</li> </ul>

### Sample Documentation issues identified when specimen received

Error code	Issue	Notes	Further action/recall
	Patient Id issues:		
E1	Labelled vial arrives without request form		<ul style="list-style-type: none"> <li>▪ Contact sender and ask for form</li> <li>▪ If no form received after 3 days, discard sample</li> <li>▪ Inform sender</li> </ul>
E2	Completed request form arrives with no vial		<ul style="list-style-type: none"> <li>▪ Contact sender and check sample was taken</li> <li>▪ If no vial received after 3 days, request repeat after 3 months (identifiers on the vial must match the form)</li> </ul>
E3	Unlabelled vial arrives with or without request form		<ul style="list-style-type: none"> <li>▪ Discard sample</li> <li>▪ Inform sender</li> </ul>
E6a	Insufficient identifiers on request form	There must be at least 3 of: <ul style="list-style-type: none"> <li>▪ First name</li> <li>▪ Surname</li> <li>▪ Date of birth</li> <li>▪ NHS number</li> <li>▪ Hospital number for hospital samples</li> </ul>	
E6b	Other major labelling error, e.g. <ul style="list-style-type: none"> <li>▪ Double labelled or re-labelled with original details visible</li> <li>▪ label with identifiers that cannot be the woman's, e.g. child, man</li> <li>▪ vial label unreadable</li> <li>▪ use of initials rather than full first</li> </ul>		

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Error code	Issue	Notes	Further action/recall
	names on form & vial		
E5a	Vial & request form labels do not match	At least 3 of these identifiers must match on vial and request form: <ul style="list-style-type: none"> <li>First name</li> <li>Surname</li> <li>Date of birth</li> <li>NHS number</li> <li>Hospital number for hospital samples</li> </ul>	
E5b	More than one sample in a bag with only one request form		<ul style="list-style-type: none"> <li>Contact sender and establish if more than one sample was taken from the same woman at the same time - issue a single report based on the worse result</li> <li>If the samples are not from the same woman, discard both and inform sample taker</li> </ul>
E4a	Multiple minor labelling discrepancy between request form and vial (two or more)	Examples of a minor discrepancy are: <ul style="list-style-type: none"> <li>Minor spelling error</li> </ul>	<ul style="list-style-type: none"> <li>Discard sample</li> <li>Inform sender</li> </ul>
E4b	Single minor labelling discrepancy between request form and vial	<ul style="list-style-type: none"> <li>Use of a previous surname on form and/or vial</li> <li>Single digit error in date of birth when all other identifiers correct</li> </ul>	<ul style="list-style-type: none"> <li>Check details on Open Exeter</li> <li>Record in laboratory error log</li> <li>Inform sender of error with comment on report</li> <li>Screen &amp; report</li> </ul>
E7a	Patient details differ from 'Open Exeter' - major discrepancy or multiple minor discrepancies (two or more)	<ul style="list-style-type: none"> <li>Use of initials rather than full first names on form or vial (not both)</li> </ul>	<ul style="list-style-type: none"> <li>Check details on Open Exeter</li> <li>If unresolved: <ul style="list-style-type: none"> <li>Discard sample</li> <li>Inform sender</li> </ul> </li> </ul>
	<b>Sample out of scope:</b>		
E12	See detailed guidance in Appendix 1		<ul style="list-style-type: none"> <li>Book in</li> <li>Discard sample</li> <li>Inform sender</li> </ul>
	<b>Sample Taker id issues:</b>		
E8	Sample Taker id number absent Sample Taker id number not recognised If sample taker name legible, Sample Taker id number does not correspond with sample taker name		Contact QARC or Screening and Immunisation Team or sender to attempt to identify sample taker: <ul style="list-style-type: none"> <li>If identified as a trained LBC sample taker, establish why the sample taker id is not recognised (e.g. not on lab's list) - action that issue. Screen sample.</li> <li>If it cannot be established that the sample taker is trained, refer the matter to the Screening and Immunisation Team who administers sample taker numbers. If the Screening and Immunisation</li> </ul>

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Error code	Issue	Notes	Further action/recall
			Team confirm that the sample taker is trained and will soon have a sample taker id, screen sample as usual. If the Screening and Immunisation Team is unable to confirm training in a timely way, report as inadequate unless abnormal.
	<b>Clinical details:</b>		
E9	Request form states "cervix not seen" or other indicator of inadequate sample taking		<ul style="list-style-type: none"> <li>Book in</li> <li>Screen</li> <li>Report as inadequate if not abnormal</li> </ul>
E16	Woman recorded as having no cervix		<ul style="list-style-type: none"> <li>Query screening history with sample taker</li> <li>If woman has cervix, screen &amp; report</li> <li>If woman has no cervix, treat as a non-cervical sample</li> </ul>

### Sample Adequacy issues identified when screened

Error code	Issue	Notes	Further action/recall
E17	Heavily blood stained - insufficient cells seen		<ul style="list-style-type: none"> <li>Book in</li> <li>Screen</li> <li>Report as inadequate if not abnormal</li> </ul>
	Insufficient cells present (possibly due to contamination with lubricant or poor sample taking)		
	Mostly endocervical cells, insufficient squamous cells (not follow up of endocervical abnormality)		
	Insufficient endocervical cells (follow up of endocervical abnormality)		
	Squamous cells obscured by polymorphs/debris		

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## Appendix 1 - Out of scope samples (significant criteria highlighted)

Previous screening result	Related histology result	Treated?	Age	Invitation sent from Exeter?	Interval from last test date to this test date	Screen / Reject
Irrelevant	N/A	N/A	Under 24½	No	Irrelevant	Reject
Irrelevant	N/A	N/A	Under 24½	Yes	Irrelevant	Screen
Ceased for clinical reasons or age reasons** **(unless not been screened since age 50 or with recent abnormal tests)	N/A	N/A	Irrelevant	Irrelevant	Irrelevant	Reject
Irrelevant (not ceased for clinical reasons)	N/A	N/A	25-49	Irrelevant	Over 36 months	Screen
Irrelevant (not ceased for clinical reasons)	N/A	N/A	50-64	Irrelevant	Over 60 months	Screen
Any cytology & HPV result combination with action: 3 month recall	N/A	N/A	Irrelevant	Irrelevant	Under 89 days	Reject
Any cytology & HPV result combination with action: 3 month recall	N/A	N/A	Irrelevant	Irrelevant	89 days or over	Screen
Any cytology & HPV result combination with action: refer for colposcopy	Unsatisfactory colposcopy	N/A	Irrelevant	Irrelevant	Irrelevant	Screen
Any cytology & HPV result combination with action: refer for colposcopy	Negative / less than CIN1	No	Irrelevant	Yes	Irrelevant	Screen
Any cytology & HPV result combination with action: refer for colposcopy (CGIN follow-up)	Negative / less than CIN1	No	Irrelevant	Irrelevant	Under 5½ months	Reject
Any cytology & HPV result combination with action: refer for colposcopy (CGIN follow-up)	Negative / less than CIN1	No	Irrelevant	Irrelevant	Over 5½ months	Screen

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Previous screening result	Related histology result	Treated?	Age	Invitation sent from Exeter?	Interval from last test date to this test date	Screen / Reject
Any cytology & HPV result combination with action: refer for colposcopy (referred for failed TOC)	Negative / less than CIN1	No	Irrelevant	No / Not known	Under 30 months	Reject
Any cytology & HPV result combination with action: refer for colposcopy (referred for failed TOC)	Negative / less than CIN1	No	Irrelevant	Irrelevant	Over 30 months	Screen
Any cytology & HPV result combination with action: refer for colposcopy (not Test of Cure)	Negative / less than CIN1	No	25-49	No / Not known	Under 30 months	Reject
Any cytology & HPV result combination with action: refer for colposcopy (not Test of Cure)	Negative / less than CIN1	No	25-49	Irrelevant	Over 30 months	Screen
Any cytology & HPV result combination with action: refer for colposcopy (not Test of Cure)	Negative / less than CIN1	No	50 or over	No / Not known	Under 54 months	Reject
Any cytology & HPV result combination with action: refer for colposcopy (not Test of Cure)	Negative / less than CIN1	No	50 or over	Irrelevant	Over 54 months	Screen
Any cytology & HPV result combination with action: refer for colposcopy	CIN1	No	Irrelevant	Yes	Irrelevant	Screen
Any cytology & HPV result combination with action: refer for colposcopy	CIN1	No	Irrelevant	No / Not known	Under 10½ months	Reject
Any cytology & HPV result combination with action: refer for colposcopy	CIN1	No	Irrelevant	Irrelevant	Over 10½ months	Screen

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Previous screening result	Related histology result	Treated?	Age	Invitation sent from Exeter?	Interval from last test date to this test date	Screen / Reject
Any cytology & HPV result combination with action: refer for colposcopy	CIN1 / CIN2 / CIN3 / CGIN	Yes	Irrelevant	Yes	Irrelevant	Screen
Any cytology & HPV result combination with action: refer for colposcopy	CIN1 / CIN2 / CIN3 / CGIN	Yes	Irrelevant	No / Not known	Under 5½ months	Reject
Any cytology & HPV result combination with action: refer for colposcopy	CIN1 / CIN2 / CIN3 / CGIN	Yes	Irrelevant	Irrelevant	Over 5½ months	Screen
Any cytology & HPV result combination with action: routine recall	N/A	N/A	Irrelevant	Yes	Irrelevant	Screen
Any cytology & HPV result combination with action: routine recall (36 months)	N/A	N/A	25-49	No / Not known	Under 30 months	Reject
Any cytology & HPV result combination with action: routine recall (36 months)	N/A	N/A	25-49	Irrelevant	Over 30 months	Screen
Any cytology & HPV result combination with action: routine recall (60 months)	N/A	N/A	50-64	No / Not known	Under 54 months	Reject
Any cytology & HPV result combination with action: routine recall (60 months)	N/A	N/A	50-64	Irrelevant	Over 54 months	Screen
Any cytology & HPV result combination with action: 6 month recall	N/A	N/A	Irrelevant	Yes	Irrelevant	Screen
Any cytology & HPV result combination with action: 6 month recall	N/A	N/A	Irrelevant	No / Not known	Under 5½ months	Reject
Any cytology & HPV result combination with action: 6 month recall	N/A	N/A	Irrelevant	Irrelevant	Over 5½ months	Screen
Any cytology & HPV result combination with action: 12 month recall	N/A	N/A	Irrelevant	Yes	Irrelevant	Screen

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Previous screening result	Related histology result	Treated?	Age	Invitation sent from Exeter?	Interval from last test date to this test date	Screen / Reject
Any cytology & HPV result combination with action: 12 month recall	N/A	N/A	Irrelevant	No / Not known	Under 10½ months	Reject
Any cytology & HPV result combination with action: 12 month recall	N/A	N/A	Irrelevant	Irrelevant	Over 10½ months	Screen
Any cytology & HPV result combination with action: 3 year recall	N/A	N/A	Irrelevant	Yes	Irrelevant	Screen
Any cytology & HPV result combination with action: 3 year recall	N/A	N/A	Irrelevant	No / Not known	Under 30 months	Reject
Any cytology & HPV result combination with action: 3 year recall	N/A	N/A	Irrelevant	Irrelevant	Over 30 months	Screen

N.B Women who are HIV positive or immunocompromised due to a medical condition with associated protocol recommending annual screening should have their sample accepted if interval of at least 10½ months

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