

Section 3: Managing participants with invalid HPV test results and/or unsatisfactory cytology samples

Very occasionally, HPV test results will be reported as invalid because of issues with technical processing. Other HPV samples may be reported as unsuitable for analysis because of LBC vial or HPV collection tube leakage. For cytology, a small number of samples will be unsatisfactory for evaluation.

Invalid HPV tests

HPV tests can be invalid because of the effects of inhibitory substances (abundant blood or inflammation) or because there is insufficient cellular material present (usually none) due to difficulties with sampling technique. If this occurs, then the test will be reported as invalid with a recommendation for a repeat sample.

If the HPV test is invalid on an LBC sample, cytology will be reported where possible. This may facilitate the repeat HPV test to be a vaginal swab sample, as repeat cytology will not be required. Invalid HPV tests may be repeated without any time delay and should be repeated within 4 weeks.

Table 1. Management of invalid HPV tests

Test result combination	Recommended Management
HPV invalid and ASC-H or higher grade cytology	Refer to colposcopy
HPV invalid and ASC-US or LSIL cytology	Repeat HPV test – can be a self-test If repeat HPV test is invalid refer to colposcopy
HPV invalid cervical sample and negative cytology	Repeat HPV test – consider a clinician assisted vaginal swab If repeat HPV test is invalid – recommend clinician taken vaginal swab or cervical sample If the third test is invalid refer to colposcopy
HPV invalid vaginal swab no cytology	Repeat HPV test – consider a clinician assisted vaginal swab

	<p>If repeat HPV test is invalid – recommend clinician taken vaginal swab or cervical sample</p> <p>If the third test is invalid refer to colposcopy</p>
HPV invalid and unsatisfactory cytology*	<p>Repeat cervical sample so an HPV test and cytology can be repeated*</p> <p>If either repeat test is invalid or unsatisfactory refer to colposcopy</p>

*A short course of vaginal estrogen therapy is recommended in post-menopausal women. It may also be useful for participants with vaginal atrophy associated with progestogen only contraception or people using testosterone therapy.

Unsuitable for analysis HPV tests

LBC vials and HPV collection tubes that have leaked on receipt in the laboratory will not be processed for an HPV test. The HPV test will be reported as unsuitable for analysis because of LBC vial or HPV collection tube leakage. If the HPV test is not performed because of LBC vial leakage and there is a sufficient volume of fluid remaining in the LBC vial, the cytology will be reported. This may facilitate the repeat HPV test to be a swab sample, as repeat cytology will not be required.

Invalid and unsuitable for analysis HPV tests may be repeated without any time delay and this should occur within 4 weeks.

Unsatisfactory cytology

An LBC cytology preparation can be unsatisfactory for evaluation for a range of reasons, only some of which are a result of sampling technique. If the sample is unsatisfactory, the laboratory will report the reason why, and recommend a repeat sample. A repeat cervical sample for cytology should be taken in 6-12 weeks after the first sample to reduce the risk of missed lesions. Referral to colposcopy after two unsatisfactory cytology reports is indicated as there is a small a risk of missed lesions. Refer to Table 2 for management of unsatisfactory cytology.

Table 2: Management of unsatisfactory cytology

Test result combination	Recommended Management
HPV 16 or 18 and unsatisfactory cytology	Refer to colposcopy
HPV detected Other and unsatisfactory cytology	Repeat cytology * unless referral to colposcopy is already indicated, based on the HPV Other result If repeat cytology is unsatisfactory refer to colposcopy
HPV not detected and unsatisfactory cytology	Repeat cytology * If repeat cytology is unsatisfactory refer to colposcopy
HPV invalid and unsatisfactory cytology	Take a cervical sample so that the HPV test and cytology* can both be repeated. If either test is invalid or unsatisfactory on repeat testing refer to colposcopy

*A short course of vaginal estrogen therapy is recommended in post-menopausal participants. It may also be useful for participants with vaginal atrophy associated with progestogen only contraception, or people using testosterone therapy.

Reporting invalid or unsuitable for analysis HPV tests and unsatisfactory cytology in combined results reports

When both HPV and cytology are reported on the same LBC sample, the results will be reported in one report with one recommendation based on both results. This will still occur if the HPV test result is invalid or unsuitable for analysis if cytology has been performed, and will also occur for samples where an HPV result is available but the cytology result is unsatisfactory.

RECOMMENDATIONS – INVALID OR UNSUITABLE FOR ANALYSIS HPV TESTS AND/OR UNSATISFACTORY CYTOLOGY RESULTS

<p>R3.01 Management of an invalid or unsuitable for analysis HPV test result</p>	<p>Practice point If the HPV test result is invalid or unsuitable for analysis, the HPV test may be repeated without any time delay and should be repeated within 4 weeks. Where possible, cytology should be reported on any LBC sample where the HPV result is invalid or unsuitable for analysis to allow the repeat HPV sample to be a vaginal swab sample. Participants with an invalid HPV test result and a cytology report of ASC-H or worse should be referred to colposcopy,</p>
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	<p>Participants with negative, ASC-US or LSIL cytology and two consecutive invalid HPV results should be referred for colposcopy.</p> <p>Participants with an invalid HPV result on a vaginal swab, it is important to work with the participant to determine the cause. A repeat HPV test should be performed, and screen takers can consider taking a clinician assisted vaginal swab. If the repeat HPV test is invalid, screen takers should consider cause and consider clinician taken vaginal swab or cervical sample. If there is a third invalid test after a clinician assisted test referral to colposcopy should occur.</p>
<p>R3.02 Management of an unsatisfactory cytology sample result</p>	<p>Practice point</p> <p>If the cytology test is unsatisfactory, then the cytology test should be repeated no sooner than six weeks' and no later than three months' time.</p> <p>If the reason for the unsatisfactory sample has been identified, then the problem should be corrected, if possible, before the repeat sample is collected.</p> <p>Participants with a test result of HPV 16 or 18 must be referred to colposcopy, regardless of whether or not they have an unsatisfactory cytology result.</p> <p>Participants with HPV detected Other with two consecutive unsatisfactory cytology results should be referred for colposcopy.</p> <p>Participants with HPV not detected and two consecutive unsatisfactory cytology results should be referred for colposcopy.</p>
<p>R3.03 Use of vaginal estrogen for postmenopausal participants before a cervical sample is taken</p>	<p>Practice point</p> <p>A short course of vaginal estrogen therapy is recommended in post-menopausal women. It may also be useful for participants with vaginal atrophy associated with progestogen contraception or people using testosterone therapy.</p> <p>The recommended course of vaginal estrogen treatment is nightly for 3 weeks and should be stopped 2 nights prior to a cervical sample being taken.</p> <p>The reason for the use of vaginal estrogen should be explained to participants. (to reduce discomfort from the speculum and improve the diagnostic accuracy of cytology).</p>
<p>R3.04 Notifying participants and whānau about requiring a repeat sample</p>	<p>Practice point</p> <p>Participants and whānau should be informed and reassured that unsatisfactory screening samples occur and that it is not their fault.</p>

It is important to encourage participants to return for follow up screening where required and this may include offering referral to Support to Screening Services.

Consider transport, cultural support and, where appropriate, offer referral to Support to Screening Services.
