Standards for

Quality Assurance in Cervical Screening

Quality Assurance in Laboratories Providing HPV Testing, Cytology and Histopathology Services

An tSeirbhís Náisiúnta Scagthástála
National Screening Service

CervicalCheck
AN CLÁR NÁISIÚNTA SCAGTHÁSTÁLA CEIRBHEACS
THE NATIONAL CERVICAL SCREENING PROGRAMME

Quality Assurance in Laboratories Providing HPV Testing, Cytology and Histopathology Services

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Introduction

Since 2015, the high risk HPV (hrHPV) test has been performed on cervical screening samples taken in CervicalCheck that are cytologically classified as low grade abnormalities (hrHPV triage), and in colposcopy clinics for management of uncertainty (MUCH) or following treatment as a test of treatment (hrHPV ToC – test of cure).

In the primary HPV cervical screening pathway, cytology is used as a triage test in women where hrHPV is detected to determine whether immediate referral to colposcopy is required. Any abnormal cytology results lead to colposcopy referral; a query glandular neoplasia (non-cervical) result will normally be referred for a gynaecological opinion.

This document replaces chapters 4, 5, and 7 of the second edition of *Guidelines for Quality Assurance in Cervical Screening* published in 2014 in readiness for high risk human papilloma virus (hrHPV) to be introduced as the primary screening test for CervicalCheck - the National Cervical Screening Programme. The document is organised into two sections, Section A covers screening laboratory requirements and standards (Cytology and HPV) and Section B covers diagnostic testing requirements (histopathology).

Primary hrHPV testing is a major undertaking that impacts upon all elements of the cervical screening programme (CSP) and requires significant service redesign across the entire screening pathway. Many changes will occur because of primary hrHPV screening implementation, and comprehensive HPV vaccination will result in a progressive reduction in the prevalence of cervical neoplasia.

CervicalCheck has reviewed best practice guidelines[1,2,3] and adopted standards which will be referenced throughout this document. CervicalCheck has approved a number of the available hrHPV tests for use with appropriate liquid based cytology samples[4]. The document is based on the validation exercises carried out on hrHPV tests by Public Health England (PHE)[5] and provides guidance for laboratories on HPV cervical screening quality control and assurance.

This guidance was developed by the CervicalCheck Laboratory Advisory Group (LAG) and based on best evidence where available or recommended best practice. The LAG is a sub-group of the CervicalCheck Clinical Advisory Group and functions to provide clinical laboratory advice to CervicalCheck. The group contains members who are experienced professionals in the fields of HPV primary screening, cytopathology and histopathology.

Ensuring quality assurance in service delivery comprises compliance with both quality requirements and quality standards. Quality standards are those with a measurable level of performance and associated target for achievement. *Where no target is provided these are considered quality requirements that the service provider must fulfil. These requirements are identified with a "must" or "will" statement.*

Section A
Screening laboratories (primary hrHPV testing and cytology triage)

3.1 Laboratory organisation

3.1.1 Compliance and assurance framework

The Irish National Accreditation Board (INAB) is the sole national accreditation body for medical laboratories in the Republic of Ireland.

QR83. Quality requirement	Screening laboratories must have accreditation to the ISO 15189:2012 *Medical laboratories - requirements for quality and competence*[6]. Laboratories providing services for CervicalCheck that are outside of the European Union must have accreditation to the appropriate standards within the country of origin of the contracted laboratory. The scope of the laboratory accreditation must include HPV / cytology testing as applicable.

3.1.2 Quality management system

QR84. Quality requirement	The laboratory will have a quality management system (QMS) in place as required by the appropriate, local accreditation standards.
QR85. Quality requirement	The laboratory will have a designated person responsible for quality management who will liaise with CervicalCheck to resolve any quality issues that may arise.
QR86. Quality requirement	Any quality issues raised through the QMS in relation to the cervical screening laboratory service must be notified to CervicalCheck.

3.1.3 Health and safety compliance

QR87. Quality requirement	The laboratory shall be compliant with all national legal and statutory health and safety requirements. *Note: The Clinical and Laboratory Standards Institute (CLSI) document 'MM3-A2-Molecular Diagnostics Methods for Infectious Diseases; Approved Guideline-Current Edition[7]' is the reference document recommended for HPV testing.*

3.1.4 Data protection

QR88. Quality requirement	In relation to the provision of services to the National Screening Service (NSS), all data protection requirements (storage, access, security, confidentiality and data transfer) will be compliant with the General Data Protection Regulation. Laboratories will comply with all requests for data or reports by Irish health agencies and authorities, subject to the conditions imposed by GDPR, or the appropriate data protection agency operational in the country of origin of the laboratory concerned.
QR89. Quality requirement	A Virtual Private Network (VPN) must be installed between the laboratory and the programme operations office for the secure exchange of electronic data. Where services are provided in two separate laboratory organisations, a VPN must be installed between the two laboratories for the secure exchange of electronic data.

3.1.5 Laboratory information management system

QR90. Quality requirement	A validated and verified laboratory information management system (LIMS) will be operated in the laboratory.
QR91. Quality requirement	The LIMS will be in a secure facility with the provision for adequate back-up arrangements.
QR92. Quality requirement	Access to the LIMS will be by secure privilege level access control.
QR93. Quality requirement	The LIMS will be capable of generating periodic quality metrics and audit returns to CervicalCheck and to CervicalCheck requirements.

QR94. Quality requirement	The LIMS will be capable of recording the minimum dataset from the CervicalCheck laboratory request form.

It is desirable that laboratories are capable of receiving orders electronically and issuing results electronically to and from ordering doctors or clinics, according to a specified messaging standard. Electronic laboratory order format is HL-7 based and conforms to the Laboratory order message specifications of the Health Information and Quality Authority (HIQA) current GP Messaging Standard. HL-7 based orders and results use Healthlink's Message Broker System. The physical form for electronic orders includes a barcode, which laboratories shall be able to scan and extract the included details for automatic import into their data entry system.

QR95. Quality requirement	The LIMS will be capable of recording test results including a primary HPV screening test result in combination with a secondary triage test result(s) where applicable and generating a single management recommendation for the combined result(s). In the case of laboratories on different sites it will be the responsibility of the cytology service to authorise the final report.
QR96. Quality requirement	The LIMS will be capable of recording the identity of the reporting screeners, pathologist(s) and the authorising virology technologist.
QR97. Quality requirement	In addition the LIMS will: • Link multiple test results for the same patient. • Provide easy access to details about previous cervical screening history for the patient. • Provide a mechanism for ascertaining and recording clinical outcome after screening tests and diagnostic/ treatment procedures. • Provide the data necessary for evaluation of the CervicalCheck programme.
QR98. Quality requirement	The LIMS will be capable of extracting and transferring necessary data to the programme in the required format as per CervicalCheck specifications (notification and result files). The laboratory will also receive information from the programme in specified formats and transfer it to its information systems (error and history/ eligibility files).
QR99. Quality requirement	The laboratory will have the capability to exchange electronic communications between staff members and programme staff through secure protocols (e.g. secure email).

3.1.6 Telephone support

QR100. Quality requirement	Laboratories must provide Freephone telephone access (for calls made from Ireland) to laboratory staff during normal business hours (GMT) for registered sample takers and NSS staff for queries and follow-up.

3.1.7 Other laboratories

QR101. Quality requirement	Laboratory(ies) will make relevant clinical information and follow-up data available to other laboratories providing services to CervicalCheck.

3.1.8 Segregation, identification and traceability of programme samples

QR102. Quality requirement	All work carried out in relation to the provision of laboratory services to the NSS will be clearly distinguishable from the work carried out for other clients of the laboratory, beginning with receipt of samples, throughout the screening and resulting processes, to reporting, later investigations and reviews, as well as storage and archiving.

3.1.9 Health agencies and authorities

QR103. Quality requirement	Laboratories engaged by CervicalCheck will comply with all requests for data or reports by Irish health agencies and authorities, including the Department of Health and the National Cancer Registry Ireland (NCRI). All requests for data from other health agencies and authorities must come to and be processed through CervicalCheck.

3.1.10 Changes to service capacity, capability or conformance to quality assurance standards

QR104. Quality requirement	Any changes that impact on or could have an impact on any aspect of laboratory services, including laboratory accreditation status, processes, system procedures, analysis and reporting, must be agreed with CervicalCheck. Any changes will be advised in advance in writing and must be approved before implementation by CervicalCheck.

3.2 Clinical governance

The Health Service Executive (HSE) is accountable for continuously improving the quality of its service to safeguard high standards of care by creating an environment in which clinical excellence will flourish.

Clinical governance encompasses quality assurance, quality improvement and risk and incident management which are core functions of a laboratory screening service.

Clinical governance for CervicalCheck screening samples is the responsibility of the cytopathology service under the lead pathologist.

QR105. Quality requirement	Networked laboratory solutions in the context of cervical screening services must be supported by closely aligned QMS, LIMS and document management systems. *Note: All screening should take place at the minimum number of laboratory sites possible.*
QR106. Quality requirement	A medically qualified consultant pathologist must take responsibility for the issue of all cervical screening test results. • At least 2 medically qualified consultant pathologists who actively practice in cervical cytology must be involved in the provision of a CervicalCheck cervical screening service. • The consultant pathologists must practise in cervical cytology within the laboratory network where screening of cervical cytology samples is undertaken. • One consultant pathologist is always available to provide direction to staff. • The consultants must be fully integrated into the working of the department(s) and be available during normal laboratory opening hours for staff to consult with or vice versa.

3.2.1 Contracting arrangements between NSS and screening laboratory(ies)

QR107. Quality requirement	Laboratories must adhere to the terms of any contract/Service Level Agreement (SLA) or Memorandum of Understanding (MOU) between the NSS and the laboratory.

3.2.2 Service level agreement/ Memorandum of Understanding / Contract for virology services

QR108. Quality requirement	Cervical cytology laboratories must have an SLA(s)/ MOU/ contract in place for virology services if provided by a third party to specify the services required.
QR109. Quality requirement	Molecular HPV testing services must be provided by a legally recognised organisation as must the cervical cytology service, although not necessarily within the same department or the same organisation. The cytology and virology leads must set clearly defined parameters for collaborative working and agree processes and interactions to demonstrate regular engagement for the duration of the contract/ agreement.

3.2.3 Service level agreement/ Memorandum of Understanding / Contract for virology support within the cytology department

QR110. Quality requirement

A cytology service undertaking hrHPV testing must have appropriate consultant virologist support, documented in an SLA/MOU, as appropriate. The SLA/MOU should make sure that virology support is available to the cytology service when required.

As a minimum, the SLA/MOU must specify the following:

- The organisations or departments the agreement is between.
- The tenure for the service.
- The expected level of activity.
- The arrangements for modifications to the agreement.
- The service being provided.
- The cost of the service.
- The payment terms.
- The legal issues, for example, penalty clauses for underperforming.
- The requirement for the laboratory to be accredited to the appropriate standards e.g. College of American Pathologists (CAP), ISO 15189.
- The requirement to notify the partner service of any change to its accreditation status.
- The hrHPV testing platform that will be used.
- The arrangements for transport of samples to virology.
- How samples will be tested including a fully integrated electronic LIMS to CervicalCheck link and GDPR.

- That internal quality control (IQC) and quality assurance must be carried out in accordance with national guidance.
- How final results will be authorised and provided to cytology.
- The expected turnaround time of samples for hrHPV testing to make sure there is compliance with the overall CervicalCheck turnaround standard.
- Steps involved in the specimen pathway and areas of responsibility for cytology and virology.
- The business continuity planning for the hrHPV testing service.
- The arrangements for patient confidentiality training.
- The arrangements for health and safety.
- The compliance with staff training and competency assessments.
- The requirements to provide performance data to the CervicalCheck programme.
- The requirements to attend meetings to discuss performance or any service issues or changes.

3.2.4 Contract for service advisors

QR111. Quality requirement

A consultant virologist or lead scientist appointed to provide external advisory services to a cytology laboratory must hold a contract with the host provider.

As a minimum the contract must state:

- The contracting organisation as a legal entity.
- The professional registration requirements.
- The duties of the contracted appointee.
- The reporting and accountability arrangements.
- The arrangements for appraisal and performance development.
- The arrangements for any performance requirements.

3.2.5 Outsourcing laboratory services

QR112. Quality requirement

Laboratory services must not be outsourced without full and comprehensive discussion, planning and written approval from CervicalCheck.

3.3 Laboratory personnel (roles and responsibilities and staff qualifications)

3.3.1 Service leads and staff roles and responsibilities

Service leads have specific responsibility for clinical governance and are directly accountable for the quality of their own work and that of their departmental teams. The entire screening pathway, including associated follow up services, must be functional and safe.

The team must incorporate personnel with molecular biology training and skills, knowledge of the instrumentation and software in use, knowledge of the screening programme, capacity to organise the work with large numbers of samples, problem solving ability and also the skills to enable interaction with external individuals which serve the screening programme.

QR113. Quality requirement	Scientific, medical and non-medical staff must be qualified for the positions they hold according to national requirements to practice. Staff must be registered with the appropriate regulatory board according to national requirements to practice (eg. CORU in Ireland).
QR114. Quality requirement	Laboratories must have an organisation chart that identifies the individual(s) within the department who is/are responsible for each element. There must be agreement on processes and interactions which set clear expectations for effective working.

3.3.2 The role of the lead pathologist for cervical cytology triage

QR115. Quality requirement

The lead pathologist for cervical cytology triage must:

- Be a consultant cellular pathologist registered with the appropriate national professional and regulatory body.
- Have a nominated deputy medical pathologist.
- Be employed in a laboratory or laboratory network which provides the cervical cytology service.
- Report cervical cytology and satisfy CervicalCheck standards in relation to cervical screening.
- Have a job description which takes account of this role and its time commitment.
- Have satisfactory and appropriate participation in an appropriate Continuing Professional Development (CPD) scheme (for example, RCPath).
- Participate satisfactorily in an accredited External Quality Assessment (EQA) Scheme for Gynaecological Cytopathology.

- Be available to the department/network on a daily basis as far as practically possible (or, if not, the nominated deputy must be).
- Support assessing the overall quality of the laboratory screening service. Take overall responsibility for the quality of reports including HPV results issued for CervicalCheck.
- Ensure, along with the lead scientist, that all laboratory staff are qualified for their roles.
- Ensure, with the lead medical scientist and cellular cytology laboratory manager, that the laboratory follows all national guidance related to cervical screening.
- Advise on the implementation of new guidance or monitoring of new standards as communicated by CervicalCheck.
- Attend cervical screening Multi-Disciplinary Team (MDT) meetings, or make sure that a laboratory representative (other consultant or consultant biomedical scientist (BMS)) is present, to discuss appropriate cases.
- Ensure that 100% of MDT meetings are attended by a suitably qualified person.
- Be responsible for making sure the necessary pathology input is made for cervical cancer reviews.
- Advise and participate in audit for the cervical screening programme.
- Attend internal and external cervical screening meetings - or make sure that a deputy is present where the performance of the service will be monitored and local issues discussed.
- Sign off screening statistical reports and other data returns and audits as required.
- Be the primary medical contact within the department for cervical cytology triage matters.

3.3.3 The role of the consultant cytopathologist

QR116. Quality requirement

The consultant pathologist for cervical cytology triage must:

- Be a consultant cellular pathologist registered with the appropriate national professional and regulatory body.
- Be employed in a laboratory or laboratory network which provides the cervical cytology service.
- Report cervical cytology and satisfy CervicalCheck standards in relation to cervical screening.
- Have a job description which takes account of this role and its time commitment.
- Have satisfactory and appropriate participation in an appropriate CPD scheme (e.g. RCPath).
- Participate satisfactorily in an accredited EQA Scheme for Gynaecological Cytopathology.
- Be available to the department/network on a daily basis as far as practically possible (or, if not, the nominated alternate must be).
- Support assessing the overall quality of the laboratory screening service. Take overall responsibility for the quality of reports issued on behalf of CervicalCheck.
- Advise on the implementation of new guidance or monitoring of new standards as communicated by CervicalCheck.
- Attend cervical screening MDT meetings, or make sure that a laboratory representative (other consultant or consultant BMS) is present, to discuss appropriate cases.
- Advise and participate in audit for the cervical screening programme.

Note: Pathologists - if there is an absence from work for a period exceeding six months then the individual must undertake a short period of retraining consisting of double screening a minimum of 150 cases with 95 per cent sensitivity for HSIL and have successfully participated in the most recent round of EQA slides/proficiency testing.

3.3.4 The role of the consultant biomedical scientist (currently only applicable to referral laboratories based in the UK)

The consultant BMS is a non-medical individual who is qualified to Diplomate of the RCPath or equivalent (diploma of advanced practice- cervical cytology, Institute of Biomedical Sciences (IBMS)/ RCPath conjoint examination board) or recognised equivalent.

QR117. Quality requirement

The consultant BMS for cervical cytology triage must:

- Be a consultant BMS registered with the appropriate national professional and regulatory body.
- Be employed in a laboratory or laboratory network which provides a cervical cytology service.
- Report cervical cytology and satisfy CervicalCheck standards in relation to cervical screening.
- Have a job description which takes account of this role and its time commitment.
- Have satisfactory and appropriate participation in an appropriate CPD scheme (e.g. IBMS/RCPath).
- Participate satisfactorily in an accredited EQA Scheme for gynaecological cytopathology.
- Be available to the department/network on a daily basis as far as practically possible (or, if not, the nominated responsible person must be available).
- Support quality assessment and improvement of the laboratory screening service.
- Ensure, with the lead medical scientist and cellular cytology laboratory manager, that the laboratory follows all national guidance related to cervical screening.
- Advise on the implementation of new guidance or monitoring of new standards as communicated by CervicalCheck.
- Attend cervical screening MDT meetings - or make sure that a laboratory representative (other consultant or consultant BMS) is present, to discuss appropriate cases.
- Advise and participate in audit for the cervical screening programme.
- Attend internal and external cervical screening meetings as required - or make sure that a alternate is present where the performance of the service will be monitored and local issues discussed.

3.3.5 The role of the lead medical scientist /laboratory manager for cervical cytology triage

QR118. Quality requirement

The lead scientist for cervical cytology triage must:

- Be employed in a cytology laboratory which provides a cervical screening service to CervicalCheck.
- Be appropriately qualified and competent to carry out the role. Where the role involves cervical cytology, only report negative or inadequate cytology samples that are positive for hrHPV and that have undergone an initial and quality assurance screen.
- Be registered with the appropriate regulatory body, if applicable.
- Have a nominated deputy.
- Work collaboratively with the medical/non-medical consultants and laboratory managers to monitor and maintain a high quality laboratory cervical screening service.
- Have experience of leading a clinical laboratory service.
- Oversee the development and review of laboratory policies and procedures.
- Ensure that the cervical screening laboratory services are in line with appropriate laboratory accreditation standards such as CAP, ISO 15189.
- Ensure the cytology lab has detailed standard operating procedures (SOPs) (in conjunction with the molecular laboratory) to record the end to end cervical screening test protocols to CervicalCheck standards or recommendations.
- Ensure that the laboratory follows CervicalCheck guidance in relation to all aspects of cervical screening.
- Support the implementation of new guidance or monitoring of new standards as published by CervicalCheck or other relevant bodies as appropriate.
- Ensure that all scientific and laboratory support staff have the appropriate qualifications, training and registration where appropriate.
- Ensure that the competence of all laboratory staff is monitored, maintained and evidenced.
- Notify CervicalCheck of any instance where there are issues with staff competence and remove the staff member from CervicalCheck workload until the issue is satisfactorily resolved.
- Have satisfactory participation in the CPD scheme appropriate to their professional practice.

Note: If there is an absence from cervical screening work for a period exceeding three months then the individual must undertake a formal period of retraining. If absent for more than six months, then, external training may be required.

3.3.6 The role of the cervical cytotechnologist/medical scientist

A cervical cytotechnologist is a trained individual employed to undertake the cytological examination of cervical cytology samples.

QR119. Quality requirement

The cervical cytotechnologist/ medical scientist for cervical cytology triage must:

- Be employed in a cytology laboratory which provides a cervical screening service to CervicalCheck.
- Be appropriately qualified and competent to carry out the role.
- Be registered with the appropriate regulatory body, if applicable.
- Have successfully completed an approved training programme.
- Only sign out and report negative or inadequate cytology samples that are positive for hrHPV and that have undergone an initial and quality assurance screen.
- Participate in the primary, double and rapid screening of cervical samples.
- Maintain their competence through participation in proficiency testing schemes, recognised cervical cytopathology EQA schemes and in-house training, as appropriate.
- Have satisfactory participation in the CPD appropriate to their professional practice.

Note: If there is an absence from work for a period exceeding three months then the individual should undertake a formal period of retraining. If absent for more than six months, then, external training may be required.

3.3.7 Proficiency and competency of cytology staff

QR120. Quality requirement

Those undertaking screening should NOT be employed on a less than half time basis.

QR121. Quality requirement

Update training must be provided on a minimum 2 yearly basis.

QR122. Quality requirement	Screeners identified as persistently not detecting abnormal cytology must be removed from CervicalCheck cytology screening. Following suspension from screening, return to normal, unsupervised screening should only be where update reskilling training has been successfully completed in the last 2 years and after an agreed period of double screening (at least 200 cases, followed by 50% double screening for next 100 slides) and careful monitoring[8]. If any high grade cases are undetected during this supervised period then a period of further re-education monitoring must be instigated. Any suspension from screening must be recorded in writing in the screener's training file.
QR123. Quality requirement	There will be protocols and practices in operation to demonstrate a system of both internal and external continuing education for scientific and medical staff reporting CervicalCheck cases. *Note: Internal continuing education may comprise some or all of the following:* • *Discussion of difficult/review cases between cytotechnologists, medical scientists and/or cytopathologists. Laboratories should have a multi-headed microscope for this purpose.* • *Provision of up-to-date cytology textbooks and/or electronic material for consultation in the cytopathology laboratory.* • *Access to one or more of the cytology journals.* *External continuing education may comprise some or all of the following:* • *Attending workshops and symposia.* • *Attendance at regular update courses.* • *Regional inter-laboratory slide review sessions.* • *Participation in proficiency testing.* • *Teaching cytotechnology students and pathology trainees.* • *Independent study contributions to laboratory handbooks or work in committees of the relevant medical and/or professional societies.*

3.3.8 The role of the lead virologist for hrHPV testing

QR124. Quality requirement

The lead virologist must:

- Be a consultant virologist (medical or clinical scientist), registered with the appropriate national professional and regulatory body.
- Have a nominated deputy virologist.
- Be employed in or have a contract with a laboratory which provides an accredited hrHPV testing service. This laboratory must have an SLA or MOU if appropriate with the laboratory providing cytology services to the programme.
- Ensure the molecular lab has detailed SOPS (in conjunction with the cytology laboratory) to record the end to end cervical screening test protocols to CervicalCheck standards or recommendations.
- Have a job description which takes account of this role and its time commitment.
- Have satisfactory participation in the CPD scheme for their professional body.
- Work with the lead pathologist to assure the overall quality of the hrHPV testing service.
- Ensure, along with the lead scientist, that all laboratory staff are qualified for their roles.
- Advise on the implementation of new guidance or monitoring of new standards as communicated by CervicalCheck.
- Sign off screening statistical reports and other data returns and audits as required that relate to hrHPV testing.
- Advise the lead scientist for hrHPV on participation in a national EQA scheme for hrHPV testing, internal quality control monitoring and internal quality assurance (IQA) procedures.
- Advise on compliance with CervicalCheck criteria for the assessment and implementation of new or modified techniques relevant to the hrHPV service.
- Be available for advice on a daily basis, or make sure there is support from the nominated deputy.
- Advise on the implementation of new guidance or monitoring of new standards as published by CervicalCheck, RCPath or other relevant bodies.
- Attend cervical screening MDT meetings where appropriate, or ensure that a deputy provides cover.
- Advise on audit for the local cervical screening programme relevant to the role in the programme.
- Receive minutes of CervicalCheck meetings, as appropriate, where the performance of the service is monitored and programme issues discussed.
- Contribute where necessary to any quality reports given to the CervicalCheck programme, local cervical screening business or governance meeting and contribute to any annual reports relating to the service.
- Be the primary contact within the laboratory service for hrHPV clinical matters.
- Ensure all authorised reports transfer successfully to the cytology LIMS.

3.3.9 The role of the lead scientist/medical scientist for hrHPV testing

QR125. Quality requirement

The lead scientist/ medical scientist must:

- Be employed in or have a contract with a laboratory which provides an accredited hrHPV testing service to CervicalCheck.
- Be appropriately qualified and competent to carry out the role.
- Be registered with the appropriate national and regulatory body, if applicable.
- Work collaboratively with the medical consultants, and laboratory managers to monitor and maintain a high quality laboratory cervical screening service.
- Support all aspects of delivery of the hrHPV service.
- Have experience of leading and troubleshooting a high-throughput molecular diagnostic service.
- Provide an hrHPV testing service in line with the appropriate accreditation standards e.g. CAP, ISO 15189.
- Oversee the development and review of laboratory policies and procedures.
- Ensure that the laboratory follows CervicalCheck guidance in relation to all aspects of cervical screening.
- Support the implementation of new guidance or monitoring of new standards as published by CervicalCheck or other relevant bodies as appropriate.
- Ensure that all scientific and laboratory support staff have the appropriate qualifications, training and registration where appropriate.
- Make sure there is compliance with CervicalCheck criteria for the assessment and implementation of new or modified techniques relevant to the HPV service.
- Provide molecular diagnostics training and support.
- Ensure that the competence of all laboratory staff is monitored, maintained and evidenced. Notify CervicalCheck of any instance where there are issues with staff competence and remove the staff member from CervicalCheck workload until the issue is satisfactorily resolved.
- Have satisfactory participation in the CPD scheme appropriate for their professional body.

3.3.10 The role of the virology scientist/ medical scientist for hrHPV testing

QR126. Quality requirement

The virology scientist/ medical scientist for hrHPV testing must:

- Be employed in or have a contract with a laboratory which provides an accredited hrHPV testing service to CervicalCheck.
- Be appropriately qualified and competent to carry out the role.
- Be registered with the appropriate national and regulatory body, if applicable.
- Work collaboratively with the medical consultants and laboratory managers to maintain a high quality laboratory cervical screening service.
- Support all aspects of delivery of the hrHPV service.
- Be capable of troubleshooting a high-throughput molecular diagnostic service.
- Provide an hrHPV testing service in line with the appropriate accreditation standards e.g. CAP, ISO 15189.
- Follow CervicalCheck guidance in relation to all aspects of cervical screening.
- Support the implementation of new guidance or monitoring of new standards as published by CervicalCheck or other relevant bodies as appropriate.
- Follow CervicalCheck criteria for the assessment and implementation of new or modified techniques relevant to the HPV service.
- Provide molecular diagnostics training and support.
- Have satisfactory participation in the CPD scheme appropriate for their professional body.

3.3.11 Proficiency and competency of virology staff

QR127. Quality requirement

There will be protocols and practices in operation to demonstrate a system of both internal and external continuing education for scientific and medical staff reporting CervicalCheck cases.

Note: Internal continuing education may comprise some or all of the following:

- *Discussion of difficult cases.*
- *Provision of up-to-date textbooks and/or electronic material for consultation in the virology laboratory.*
- *Access to one or more of the virology journals.*

External continuing education may comprise some or all of the following:

- *Attending workshops and symposia.*
- *Attendance at courses.*
- *Regional inter-laboratory QA sessions.*
- *Teaching.*
- *Independent study contributions to laboratory handbooks or work in committees of the relevant medical and/or professional societies.*

3.3.12 Locum staff

QR128. Quality requirement	Locum staff must: • Be appropriately qualified and competent to carry out the role. • Be registered with appropriate national regulatory bodies. • Meet the requirements and standards of the CervicalCheck cervical screening programme. • Meet the training and update requirements of the CervicalCheck cervical screening programme. • Routinely participate in an appropriate and validated/ accredited EQA scheme. *Note: The service provider is responsible for making sure these requirements are included in any contract.*

3.4 Sample acceptance, reception and data entry

The cytology laboratory has overall responsibility for acceptance and reception of CervicalCheck screening samples.

3.4.1 Sample acceptance

QR129. Quality requirement	SOPs must be in place for handling CervicalCheck samples. Sample acceptance must adhere to the *HPV Primary Screening Eligibility Framework/Reference Guide for GPs and Clinics* (see Appendix 4).
QR130. Quality requirement	Laboratories will accept orders via postal delivery and via electronic laboratory orders where applicable (followed by the receipt of the physical sample and form). For electronic orders the laboratory will be capable of extracting bar-coded information.
QR131. Quality requirement	The laboratory must only accept programme samples from doctors or clinics that are notified to the laboratory by CervicalCheck.
QR132. Quality requirement	Only those samples accompanied by a current, approved version of the CervicalCheck cervical screening form will be accepted.
QR133. Quality requirement	Only those samples inclusive of informed consent will be accepted.

3.4.2 Specimen reception

QR134. Quality requirement	All forms must be date-stamped upon receipt and date of receipt must be captured on the LIMS.
QR135. Quality requirement	Sample vials will be checked for leaks and damage and matched to the accompanying forms prior to labelling. To ensure a robust 'chain of custody' within the laboratory, cross-checking of a minimum of three patient identifiers must be performed. *Note: If the testing procedure requires pre-aliquoting from the LBC vial then a second person verification should be in place to ensure a robust 'chain of custody'. For an automated aliquoting process a single step verification is required.*
QR136. Quality requirement	A documented discrepancy handling and resolution process must be in place to manage all discrepancies for CervicalCheck samples received. Discrepancies will be recorded and the log will be made available to CervicalCheck specification. *Note: The CervicalCheck guidance document "Discrepancy Handling and Resolution Guidance for Laboratories participating in the CervicalCheck Screening Programme[9]" is available for laboratories contracted to the programme and must be adhered to.* *Samples returned to ordering sample takers or clinics must be traceable.*
QR137. Quality requirement	Samples notified as ineligible by the Programme for screening will not be tested.
QR138. Quality requirement	Where samples are unsuitable for testing a report may be generated. Unsuitable specimens will be tracked using the laboratories non-conformance log.
QR139. Quality requirement	Following acceptance of the sample and form for processing, both will be labelled with a unique identification number (laboratory accession number). The unique laboratory accession number for the sample must remain the same regardless of test.

3.4.3 Data entry

QR140. Quality requirement	Data entry of the details recorded on CervicalCheck forms accompanying submitted sample vials must conform to CervicalCheck data capture requirements. All data relevant to cervical screening recorded on the Cervical Screening Form by the sample taker will be entered onto the LIMS.	
QR141. Quality requirement	A second person verification of all relevant data entered from the form on to the computer system will be carried out and deemed to be correct before the sample is authorised for further processing.	
QR142. Quality requirement	Samples must be assigned to the correct clinically responsible doctor or clinic as per the received form.	
QR143. Quality requirement	CervicalCheck must have access to HPV cervical screening request/order forms received by the laboratory in electronic format and indexed by laboratory accession number.	
Standard 3-1	Cervical screening samples must be notified promptly to CervicalCheck once they are accessioned on the LIMS.	**Target** 95% within 48 hours, minimum 80% by 17:00 GMT next working day.

3.5 Sample processing and analysis

3.5.1 Molecular hrHPV testing

QR144. Quality requirement	HPV testing services will be provided in a dedicated laboratory area or facility. All areas will be clean, well-lit, temperature monitored and well-ventilated.
QR145. Quality requirement	Laboratories must use those hrHPV assays approved by CervicalCheck. Modifications to existing assays must be notified in writing and CervicalCheck approval sought prior to implementation by the laboratory.
QR146. Quality requirement	Processors used in either the molecular HPV testing or cytology preparation area must be maintained only by laboratory staff who have been trained by the manufacturer or individuals designated by the manufacturer.
QR147. Quality requirement	Handling procedures will ensure a robust "chain of custody" across all phases of the laboratory process, including specimen receipt, HPV detection (pre-analytics and analytics), documentation and storage. An audit trail will be in place for sample processing.
QR148. Quality requirement	Laboratories will verify each new reagent batch and/or new reagent lot number prior to use, using a defined and documented procedure. There must be sufficient documentation explaining the criteria for acceptance. This ensures consistency of performance between batches and that the change in reagent has had no impact on the quality of the examination.
QR149. Quality requirement	Processing of samples will be carried out according to instrument user manuals and assay specific package inserts. User ID should be traceable for all activities performed on the platform and for each step of the HPV testing process. *Note: For comprehensive guidance regarding request form/vial discrepancy handling, please refer to the SOP on discrepancy handling*[9]*.*

3.5.1 Molecular hrHPV testing

IQA must be carried out to monitor all specimen processing activities through the laboratory, starting from reception and ending in the dispatch of the final report. IQA measures must also assess the reproducibility of the laboratory sample processing and HPV testing techniques.

QR150. Quality requirement	Laboratories must carry out IQA and document the findings.

3.5.1.2 Laboratory internal quality control (assay) of molecular primary HPV testing

Laboratories performing hrHPV testing for the CervicalCheck cervical screening programme should refer to the National Health Service Cervical Screening Programme (NHS CSP) document *Laboratory Quality and Assurance for human papillomavirus testing*[10]. It provides guidance on IQC and IQA procedures and their monitoring, plus EQA.

The guidance was commissioned by PHE and CervicalCheck recognise that although the guidance refers continually to ISO 15189:2012 standards, it is imperative that laboratories must operate to the NHS CSP document as a minimum, along with any further quality standards dictated by the external accrediting body appropriate to that laboratory such as CAP, CLIA etc.

QR151. Quality requirement	In-house validation and verification of assays must be carried out prior to the introduction of any CervicalCheck approved HPV assay.

The laboratory must use the appropriate control and monitoring procedures to manage assay run "drift" in addition to the manufacturer kit controls.

QR152. Quality requirement	Manufacturers' controls must conform to product kit insert for the assay concerned.
QR153. Quality requirement	IQC must be performed at sufficient intervals to assure result integrity and reduce the risk of retesting in the event of a failure. Evidence of same must be available. If internal quality controls are prepared by the lab, internal documentation relating to their preparation must be in place. Any change to a new control should be planned and cotested with the existing control to facilitate validation prior to introduction.
QR154. Quality requirement	To monitor for long term deviations, a control chart, registering each value obtained in each batch, is mandatory. This allows easy identification of trends in quality control data, and identification of both systematic and random errors. A procedure outlining rejection rules and immediate flagging of rejection events must be in place. Associated corrective actions should also be clearly documented.

Other aspects important for quality monitoring include the assessment of positivity rates and quantification of the number of samples with values close to the cut off, and those that require repeat for technical reasons. Checks on the internal reproducibility of the assay can provide insight into the longitudinal performance.

QR155. Quality requirement	Laboratories must monitor and document invalid (indeterminate) sample rates, by reason appropriate to the HPV assay platform. An increase in rates above expected should trigger further lab investigation and corrective action taken as appropriate.
QR156. Quality requirement	Laboratories must undertake yearly verification of HPV assays. Reports for verification should incorporate a review of IQC and EQA performance as well as a summary of any operational or manufacture issues that have arisen in the time period concerned. Laboratories must clearly state the method of verification and criteria for acceptable performance.

3.5.1.3 EQA of molecular primary HPV testing

QR157. Quality requirement	All laboratories providing HPV testing must participate, and show adequate performance, in an approved EQA scheme. Ideally, the laboratory should also participate in a regular programme of inter-laboratory comparison (ILC).
QR158. Quality requirement	EQA samples will be analysed as part of the routine laboratory assay run, by personnel who routinely test patient samples. The EQA samples should be subject to the same primary methods as for patient samples to mimic routine laboratory testing conditions as far as possible.
QR159. Quality requirement	EQA performance will be evaluated on an ongoing basis, with prompt corrective action taken for unacceptable results. The EQA performance and any corrective action(s) undertaken will be fully documented and recorded in the laboratory annual management review.
QR160. Quality requirement	No more than two repeat tests will be performed on failed samples including those where clots are detected before reporting as hrHPV indeterminate.

3.5.2 Cytology triage

QR161. Quality requirement	Liquid-based cytology (LBC) is mandatory. Liquid-based specimens must be processed according to the manufacturer's instructions.
QR162. Quality requirement	Slides will be stained using the Papanicolaou stain (original or modified). The samples should have a cover slip that covers all the cellular material.
QR163. Quality requirement	Slide labels should include patient surname and forename or first initial of forename in addition to the accession number. Where the laboratory uses automated processors which read and transfer the unique laboratory accession number (via barcode) onto the slide, it may not be possible to include all three identifiers on the sample slide.

3.5.2.1 Staining

QR164. Quality requirement	The laboratory must participate in an appropriate EQA scheme for staining known as “Technical EQA”.
QR165. Quality requirement	Internal technical quality assurance checks must be carried out routinely including quality of staining and quality of preparation. The results of these checks should be available for review and should specify individual processors if multiple processors are used.

3.5.2.2 Microscopy

The cytological examination is a full manual screen of a cervical cytology sample following a positive hrHPV test. The ThinPrep Imaging System (TIS) has not been evaluated[11] for use in a setting where the primary screening test is a hrHPV test and is not currently approved for use in clinical practice by CervicalCheck.

QR166. Quality requirement	Equipment (microscopes, multi-headed microscopes, digital imaging systems) must be available and configured to the ergonomic standards for microscopy work.
QR167. Quality requirement	Only approved protocols will be used, approval must be sought prior to implementation. *Note: TIS may be used for IQC screening in a HPV primary cytology triage programme.*
QR168. Quality requirement	Prior to the assessment of the sample, the patient’s screening history will be retrieved from the local laboratory files and/or the CervicalCheck screening database and be made available to the scientific staff screening the sample. *Note: Within 48 hours of receipt of sample notification, CervicalCheck will transmit an electronic file or record containing all previous screening history for the woman known to the programme for samples that are to be processed by the laboratory.*
QR169. Quality requirement	Screeners and pathologists must register with CervicalCheck and submit their assigned numbers to CervicalCheck in the results file.
QR170. Quality requirement	Everyone who expresses an opinion on a slide must have their opinion recorded in a retrievable manner. Screeners will record their results independently on the LIMS.

QR171. Quality requirement	Cytology reporting must be controlled and monitored carefully to manage any overcall/ bias due to a positive HPV primary screen.	
QR172. Quality requirement	Screeners must overlap fields by at least 30 per cent. *Note: Screening should be carried out using a x10 objective, but in particularly crowded or difficult samples, it may be safer to slow down considerably or screen using a x20 objective.*	
Standard 3-2	Lead medical scientist, cytology manager, supervisory scientific staff: if the role involves cervical screening then a minimum number (1,000) of cases will be screened.	
Standard 3-3	In order to maintain proficiency, a minimum number (1,000) of cytology screens per year must be screened per screener.	**Target** Cytology screening should be limited to 6 hours within a 24 hour period.
Standard 3-4	In order to maintain quality, accuracy and safety in the screening process, the maximum time spent on full manual screening of LBC slides must not be exceeded.	**Target** No individual to rapid screen more than 50 cases in the allocated screening time.
QR173. Quality requirement	There must be a break from continuous screening of at least 30 minutes' duration in the screening day (ideally should be taken away from the screening room). Regular micro-breaks of several seconds must be taken every 10 to 15 minutes. *Note: The other duties required of cervical cytotechnologists may serve as breaks from microscopy.*	
Standard 3-5	Weekly workload must not exceed 6 consecutive days in a 7 day period.	
Standard 3-6	Pathologist proficiency: To maintain a medical consultant's diagnostic skill in cervical cytopathology, a minimum number (750) of cases will be reviewed.	
Standard 3-7	Multi-Disciplinary Meetings: A lead cytopathologist reporting CervicalCheck workload will participate in regular MDT meetings.	**Target** 50% minimum, 90% achievable.

3.5.2.3 Laboratory internal quality assurance of cytology triage

QR174. Quality requirement	Accuracy of screening must be monitored and managed with approved protocols and procedures for defining and dealing with poor performance.
QR175. Quality requirement	IQA of cytology screening must be monitored by: • Re-screening of slides initially judged during primary screening as negative or inadequate to detect false positives/negatives and to determine sensitivity and specificity rates. • Monitoring screening detection and reporting rates by measuring the percentages of the main types of cytological findings (high grade, low grade, inadequate, negative) detected by individual screeners and cytopathologists, and in comparison with the laboratory as a whole, the programme and national standards. • Performance evaluations to identify those with deficiencies in knowledge and skills who would benefit from a more directed educational programme. • Correlation of cytology with clinical/histological outcomes. • Correlation of cytology with HPV testing for sample tests reported as ASCUS. • Monitoring and analysis of quality metrics as requested by CervicalCheck. *Note: Internal laboratory quality assurance may be undertaken by the use of full re-screen, rapid review or rapid preview re-screening of cytology samples.*

3.5.2.3.1 Rapid review / preview

Rapid review[12] is one of the approved methods for routine quality control of cervical cytology. Rapid review is a swift re-examination of all cervical cytology samples identified as negative or inadequate at the initial cytological examination, as part of the quality control process. The cytology samples are not fully screened. Rapid preview[12] is an alternative approved method for routine quality control in cervical cytology. Rapid preview is performed microscopically in exactly the same way as rapid review and is undertaken prior to the initial full cytological examination of the slide. All cytology slides are subject to rapid preview not just those classified as negative or inadequate. The cytology samples are not fully screened.

A second full screen can also be employed as a method for routine quality control in cervical cytology. A full screen involves the full review of all material on the slide.

QR176. Quality requirement

Rapid review/ preview must:

- Only be carried out by qualified members of staff who are meeting competency standards.
- The rapid reviewer must be a different individual from the person undertaking the full screen.
- Individuals must undergo training in rapid review/ preview prior to undertaking this activity and show competency in this technique.
- A rapid review/ preview must take at least 60 seconds.
- If a discrepancy is identified during rapid review/ following rapid preview then this must be recorded and passed to a staff member responsible for checking.
- Rapid review/ preview data must be recorded to allow for individual screening numbers and sensitivities to be calculated.
- The method of rapid review/ preview must be regularly audited within the laboratory to validate its effectiveness.

3.5.2.4 Checking of abnormal cases

"Checkers" are experienced staff with varied roles and responsibilities within the cervical screening laboratory. As well as undertaking initial cytological examination of slides, an experienced cytotechnologist can, depending on requirements, perform a second examination of a slide initially deemed potentially abnormal (checking) of abnormal cytology samples.

QR177. Quality requirement

- "Checkers" must have a minimum of five years' experience in cervical screening and meet the appropriate competency standards.
- Where the checker has already undertaken primary or rapid screening in that working day a suitable break MUST be taken before proceeding to checking of slides.
- In cases where the primary screener has indicated that they suspect the sample is demonstrating high grade dyskaryosis or glandular neoplasia and the checker considers the test to be negative or inadequate the slide must be passed to a second checker/ consultant to spot review the slide before allowing it to be reported.
- Individual checker referral rates must be calculated and compared to the overall laboratory average.
- The percentage of slides referred as abnormal, but finally reported as negative should be monitored and compared across individual checkers to identify inconsistencies in abnormal referral rates.

3.5.3 Audit

QR178. Quality requirement

Laboratories will carry out additional audits in accordance with departmental annual plans.

3.5.4 Amended result following discussion at multi-disciplinary meeting

QR179. Quality requirement

Where a screening report is changed following review at a MDT meeting the treating clinician and NSS must be notified of this change.

3.5.5 External quality assessment

QR180. Quality requirement	Laboratories must participate in the relevant accredited interpretive and technical national EQA schemes.
QR181. Quality requirement	All individuals reporting cervical cytology must participate in and demonstrate acceptable performance in the interpretive EQA scheme.
QR182. Quality requirement	The laboratory should also participate in an approved EQA scheme for the preparation and staining of cervical LBC samples.
QR183. Quality requirement	EQA results must be evaluated by the laboratory on an ongoing basis, with prompt and documented corrective action taken for unacceptable results.

3.6 Reporting and classification of cervical screening samples

HPV results may be batch authorised within the virology laboratory to forward to cytology for triage of HPV detected results and application of management recommendation prior to final authorisation.

3.6.1 HPV results

QR184. Quality requirement	HPV test results must adhere to CervicalCheck test results and management recommendation protocols (see Appendices 1 and 2).

3.6.2 Cytology classification and reporting codes

QR185. Quality requirement	The reporting classification for CervicalCheck samples is the Bethesda system[13] and this must be incorporated into laboratory SOPs. *Note: Appendix 1 details the cytology classification and cytology reporting codes which are used in routine reporting practice on hrHPV positive samples.*

3.6.2.1 Adequacy of cervical cytology samples

QR186. Quality requirement	Laboratories must follow Bethesda and NHS guidance on adequacy of 5,000 well preserved cells[13,14] Where cell counting is performed, the method for counting must be incorporated into laboratory SOPs.

3.6.2.2 Reporting multiple diagnoses

QR187. Quality requirement	Where cervical abnormalities co-exist with non-cervical glandular neoplasia the cervical lesion must be reported to the screening programme. The report to the clinician must contain both results. *Note: Where there is uncertainty in reporting cervical pathology the most severe interpretation should be captured and reported on.*

3.6.2.3 Women with 2 cervices

Multiple reports can also be possible in a case where a woman has 2 cervices. The laboratory should receive separate samples labelled to identify which cervix they have come from.

QR188. Quality requirement	The laboratory must have a system to maintain the identification of both cervical samples by accession numbers. The sample report must identify which cervix it relates to.

3.7 Management of women

Note: refer to Appendix 1: Cervical screening results and recommendations table; Appendix 2: Management recommendation table and Appendix 3: HPV primary screening algorithm.

3.7.1 Reporting of cervical screening samples

QR189. Quality requirement	The CervicalCheck HPV result file will be reported in the format specified by CervicalCheck. Generally, the details required include: HPV test methodology, HPV test result, subtypes tested and reference range. *Note: All women with a negative hrHPV result will not have cytology performed. Samples from women testing positive for hrHPV must undergo cytology triage.*
QR190. Quality requirement	The CervicalCheck cytology result file will be reported with the detail and in the format specified by CervicalCheck.
QR191. Quality requirement	The screening history of the woman provided by the sample taker via the cervical screening form and from the CSR (where such history is available) must be referred to and taken into account during the results process.
QR192. Quality requirement	An independent check of the case result and management code will be in place, prior to report authorisation.
QR193. Quality requirement	Every result will be appropriately authorised before release. The responsible authoriser will be identifiable. Abnormal cytology results will only be reported by a pathologist.
QR194. Quality requirement	Results, once authorised and released, will be issued in the agreed summary format as soon as possible by electronic means to CervicalCheck.
QR195. Quality requirement	The contents of the results report to ordering doctors and clinics must be in accordance with the guidelines outlined in CervicalCheck Programme guidelines.
QR196. Quality requirement	Results, once authorised and released, must be issued promptly to the ordering doctor or clinic.

QR197. Quality requirement	Results reports will be issued to the correct ordering doctor or clinic. Documented processes are required to ensure that results are sent to the correct doctor. For every sample received there will be a report transmitted. *Note: It is desirable that where possible all results reports be issued to ordering doctors or clinics and CervicalCheck in full electronic format via a nominated telecommunications pathway. The electronic format for results is HL-7 based and conforms to the laboratory result message specifications of HIQA's GP Messaging Standard.*	
QR198. Quality requirement	Laboratories will have procedures in place to manage and respond to requests for amending management recommendations, and provide replacement reports to doctors/clinics where necessary. Amended results, once authorised and released, must adhere to the same standards and targets as the original report. This also applies to rescreening requests.	
Standard 3-8	Cervical screening results must be authorised, released and transmitted to CervicalCheck within the target turnaround time from sample validation by the programme.	**Target** 95% within 10 working days.

3.8 Storage and archiving

QR199. Quality requirement	Secure archiving of Cervical Screening Forms, samples, slides and written and/or computerised reports is required for specific retention periods as outlined in the RCPath guidelines on specimen retention[15]. Vials must be stored until samples are finally authorised.
QR200. Quality requirement	Laboratories are required to provide CervicalCheck access to materials including logs and records, on request.

3.9 Protocol for multi-disciplinary team meetings

Laboratories will provide facilities, participation and support for MDT meetings held in programme colposcopy services.

Laboratories are encouraged to incorporate MDT meetings into the internal continuing education of scientific staff.

Cytology laboratories will retrieve slides or digital images for cases notified for review at MDT meetings on request, and provide them within 10 working days.

3.10 Quality metrics and performance monitoring

The laboratories must provide a service satisfying the requirements of the national programme standards. While these standards aim to ensure a safe and effective programme, they do not guarantee satisfactory performance.

The standards assess the screening process and allow for continuous improvement. Performance outside the indicated range must be examined and corrected where necessary.

Note: The expected reported ranges are calculated from the 5th to the 95th percentile from the previous year's NHS CSP statistical KC61 returns. For high grade results ASC-H is included in the overall rate but atypical glandular cells are excluded.

QR201. Quality requirement	A complete and accurate report containing prescribed quality metrics must be provided at defined intervals (combined HPV and cytology return) as specified by CervicalCheck to allow comparisons against national standards and other quality indicators. The identifier assigned to each individual screener and cytopathologist will be the same for different metrics of the report and over successive reporting periods. *Note: Laboratories must have the ability to separate CervicalCheck workload from other workloads for statistical and monitoring purposes.*
QR202. Quality requirement	Performance measures must be continuously monitored by the laboratory. Failure to meet them must always trigger further investigation and result in appropriate documented action taken when necessary.
QR203. Quality requirement	Laboratories must have systems in place where performance data is regularly reviewed at departmental and laboratory/hospital governance meetings.
QR204. Quality requirement	Where performance falls outside the indicated ranges this must be discussed at CervicalCheck operational management meetings. In conjunction with the CervicalCheck Laboratory Coordination team, the laboratory will cooperate in investigating the issue and provide evidence to support the explanation for this performance. This explanation might not necessarily be related to reporting practice, however, if a root cause is identified, preventative and reporting practices must be addressed immediately. Persistent outliers against performance standards will be investigated within the CervicalCheck governance and quality structures.

3.11 Quality assurance visits

QR205. Quality requirement	Laboratories will accommodate on-site visits by NSS-designated personnel for quality monitoring, audit and assurance purposes, providing access to personnel, resources, processes, documentation and results.

3.12 Audit of invasive cervical cancers

QR206. Quality requirement	Placeholder standard: To be updated once the Expert Reference Group on Clinical Audit of Interval Cancer in the Screening Population publishes its report and recommendations.

3.13 Risk and incident management

Errors can, and will, happen. Some errors will be relatively minor but others can be serious.

QR207. Quality requirement	National guidance for managing safety concerns, safety incidents and serious incidents in the HSE must be adhered to for services that may be involved in identifying or managing a screening incident.

3.14 Business planning and service continuity

QR208. Quality requirement	The laboratory service must have a contingency plan in place to make sure there is resilience and continuity of service when faced with disruptive events such as equipment failure and down time, prolonged loss of power or IT systems or flood/ fire damage to the laboratory.
QR209. Quality requirement	There must be a formal record which identifies the main risks, how they would be mitigated and how the laboratory would recover from a major incident or fault.
QR210. Quality requirement	Individuals with service critical skillsets must also be identified and systems put in place to make sure there is continuity of service in event of their prolonged absence.
QR211. Quality requirement	All agreements with external agencies to maintain service resilience must be clearly documented in a formal document such as a SLA or MOU. Formal agreements must clearly identify individual responsibilities. All agreements must meet the CAP/ ISO 15189 standards or the accreditation standards appropriate to the country of origin of the laboratory.

Section B

Histopathology

3.15 CervicalCheck requirements for histopathology

HrHPV testing and cervical cytology triage currently represents the primary screening method. Colposcopy locates the most abnormal areas of the cervix. Histopathology provides the final diagnosis of cervical neoplasia, forming the basis for which treatment is planned. Histopathology diagnoses include the presence or absence of high or low grade non-invasive squamous lesions, high grade glandular abnormalities (high grade cervical glandular intraepithelial neoplasia (CGIN)/adenocarcinoma-in-situ) as well as details of any invasive cancer present.

Histopathology is the source of diagnostic data stored at the NCRI and used for the evaluation of screening programmes. It serves as the 'gold standard' for quality control of cytology and colposcopy albeit that it is subject to similar issues of reproducibility and subjectivity as cytologic and colposcopic analyses.

As in cytopathology, the sample pathway for histopathology can be subdivided into three key stages:

1. Pre-analytical - sample taking, sample transport and receipt of sample in the laboratory

Accurate histopathological diagnosis of tissue specimens depends on adequate quality samples, obtained by colposcopically directed punch biopsies (with endocervical curettage, if necessary, Large Loop Excision of the Transformation Zone (LLETZ) or knife cone excision).

2. Analytical - sample processing and interpretation

Accurate histopathological diagnosis further depends on appropriate macroscopic description, technical processing, microscopic interpretation and quality management correlating cytological and histopathological diagnoses.

3. Post-analytical - report generation

It is important to recognise that the interpretative reports provided in histopathology and cytopathology are the opinion of the reporting pathologists. There is therefore a subjective element in the content of any report. Some diagnoses require the combined input of a colposcopist, cytologist and histopathologist. There are a variety of reasons why clinical appearances, cytology, biopsy and excision results may appear discrepant. MDT meetings can often resolve such discrepancies. If a colposcopist is unsure of the significance or meaning of a report or feels that a report is incorrect, they should contact the issuing laboratory or reporting pathologist.

QR212. Quality requirement	Histopathologists must remain abreast of current and emerging interpretation guidelines.

3.15.1 Quality requirements and standards

Ensuring quality assurance in service delivery comprises compliance with both quality requirements and quality standards.

3.15.1.1 Accreditation

The INAB is the sole national accreditation body for medical laboratories in the Republic of Ireland. Irish laboratories must have or be registered for accreditation to the ISO 15189:2012 *Medical laboratories - requirements for quality and competence*[6].

QR213. Quality requirement	Laboratories providing services for CervicalCheck that are outside of the European Union must have or be registered for accreditation to the appropriate standards within the country of origin of the contracted laboratory.

3.15.1.2 Changes to service capacity, capability or conformance to quality assurance standards

QR214. Quality requirement	Any changes that have or could have an impact on any aspect of the laboratory services, including standards and guidelines, laboratory accreditation status, processes, system procedures, analysis, and reporting should be immediately advised to CervicalCheck.

3.15.2 Organisational requirements

3.15.2.1 Health agencies and authorities

Laboratories will comply with all requests for data or reports by Irish health agencies and authorities, subject to the conditions imposed by GDPR, or the appropriate data protection agency operational in the country of origin of the laboratory concerned.

3.15.2.2 Laboratory facilities

All laboratories will provide appropriate facilities. These will include appropriate areas for sample reception, specimen dissection, processing, reporting, typing and authorisation.

3.15.3 Specimen reception

SOPs will be in place for handling CervicalCheck samples. For the purposes of data capture, samples originating from CervicalCheck colposcopy services must be segregated from samples from other sources. This may be via the programme's Cervical Histology Form (where applicable) or by an accredited laboratory form where the origin of a sample is clearly identifiable. The woman's consent should be incorporated into the processes for sample data capture and data exchange.

QR215. Quality requirement	All cervical histology samples will be processed in the manner appropriate for an externally assessed and accredited histopathology laboratory.
QR216. Quality requirement	A discrepancy handling and resolution process will be in place to manage all discrepancies with CervicalCheck samples received.

3.15.3.1 Data entry and notification to CervicalCheck

Relevant clinical details recorded on the Cervical Histology Form will be recorded on the LIMS. Notification and result files should be sent to CervicalCheck in a defined format at specified intervals. A periodic reconciliation of files sent and received should be in place between CervicalCheck and the laboratory.

QR217. Quality requirement	A standard SNOMED[16] biopsy and result code dictionary approved by CervicalCheck must be used and applied by either coding only for the worst degree of dysplasia or coding multiple pathologies separately.

3.15.4 Specimen dissection and assessment

Specimen description and sampling will be done in such a way as to facilitate microscopic reporting and pathological staging.

3.15.4.1 Sample 'chain of custody'

Handling procedures will ensure a robust 'chain of custody' throughout the specimen pathway. The appropriate professional standards and guidance (e.g. RCPath and NHS CSP) must be adhered to.

3.15.5 Proficiency and competency of staff

3.15.5.1 Staff qualifications and competencies

QR218. Quality requirement	Scientific, medical and non-medical staff will be qualified for the positions they hold according to national requirements to practice.

QR219. Quality requirement	The histopathology laboratory will be led by a medically qualified consultant who works in that discipline on a regular basis. All samples will be reported by a medically qualified consultant or appropriately qualified and experienced consultant BMS in the UK.

There will be a lead medical scientist who is responsible for the day-to-day management of the department and who has responsibility for supervision of non-medical staff.

3.15.5.2 All staff

All staff will be competent to carry out their roles. Competency will be maintained by regular training and education. Training and competency records should be retained and available for review.

3.15.5.3 Continuing education

Continuing education will be facilitated with evidence of internal and external educational activities.

3.15.5.4 Pathologists

All pathologists will participate in continuing medical education (CME) as required by Part 11 of the *Medical Practitioners (Amendment) Act 2017 – Maintenance of Professional Competence.* Consultant Biomedical Scientists will participate in an approved CPD scheme.

3.15.5.5 Lead medical scientist, manager and supervisory scientific staff

The lead medical scientist will be responsible for maintaining a high quality service. Sufficient supervisory scientific staff will be available to provide satisfactory supervision for the training, service development and quality control of staff output.

3.15.6 Microscopy and reporting of results

Pathologists must have access to relevant resources to facilitate accurate diagnosis including the appropriate immunohistochemistry.

The relevant RCPath Dataset (currently *Histological Reporting of Cervical Neoplasia (3rd edition), 2011*[17]) can be used as a reporting guide. Diagnostic terminology should include terms used in the current *World Health Organisation (WHO) Classification of Tumours of the Female Reproductive Organs*[18].

QR220. Quality requirement	All histopathology reports must be authorised by a consultant pathologist/ consultant biomedical scientist where applicable (electronic and/or manual).

All histopathological results must be entered onto a LIMS to allow quality assessment. Amended reports and supplementary reports will be auditable.

The microscopic diagnosis will record all grades of squamous and/or glandular intra-epithelial neoplasia, and invasive lesions. The description of a lesion will note if an orientated specimen has been submitted. Any invasive lesions are classified and graded according to national protocols and guidelines.

Where an excision procedure has been undertaken, where possible the microscopic report will indicate whether or not the squamous or glandular lesion has been completely excised.

When a biopsy fails to reveal the source of the abnormal cells in an LBC slide, it is important to differentiate between a biopsy that is technically adequate but fails to identify a lesion, and a biopsy that is technically inadequate.

All reports will be coded (using approved SNOMED nomenclature[16]) to allow data collection.

3.15.6.1 Authorisation of results

Every result will be appropriately authorised before release. Every report should be checked for inconsistencies before authorisation.

3.15.6.2 Recording of results

Results details will include at least:

- Patient identification data.
- Name and address of the laboratory.
- Name of requesting physician.
- Laboratory ID number.
- Date of specimen procurement (specimen date).
- Date of arrival of the specimen in the laboratory.
- Sample type.
- Anatomical site of origin.
- Relevant clinical details.

Standard 3-9	The results of the laboratory examination will be presented in accordance with the current standard classification system and data format, including a judgment of the quality and adequacy of the histopathological slide (if necessary), date of authorisation of the final report and name of pathologist who has evaluated the sample.

3.15.6.3 Turnaround time

This is defined as the time taken between the reporting of histology results relating to the specimen and the date of arrival of the specimen into the laboratory.

Standard 3-10	> 90% of samples will be reported within 4 weeks of the woman's attendance *Note: Biopsies are regarded as small specimens (<3 blocks). LLETZ, cone, trachelectomy, hysterectomy are deemed to be large specimens.*	**Target** Small specimen: minimum 80% within 10 days. Large specimen: minimum 80% within 14 days.

3.15.6.4 Results reporting

Standard 3-11	Laboratory management will ensure that histology results, once authorised and released, must be issued promptly to the ordering doctor or clinic.	**Target** 100% to be received within 5 days of report being authorised.

3.15.6.5 Delivery of results reports to ordering doctors or clinics

Results reports will be issued to the correct ordering doctor or clinic. The laboratory will ensure that an appropriate delivery mechanism is in place for these reports.

3.15.6.6 Review requests and amended reports

Laboratories will have procedures in place to manage and respond to requests for second opinions and to issue amended or addendum reports as necessary. Additional or amended reports, once authorised and released, must adhere to the same standards and targets.

3.15.7 Storage and archiving

Standard 3-12	Administration, archiving and disposal procedures will comply with accreditation standards and national and regional legislation, including that relating to confidentiality and data security of personal health information and disposal of hazardous medical waste or chemicals.

Secure archiving of cervical histology forms, blocks, slides and written and/or computerised reports is required for specific retention periods as defined in the latest Storage and Retention of samples guidance of the Royal College of Pathologists of the United Kingdom[15].

Note 1: Cervical histology forms may be in paper format or in their electronic equivalent, as per local accredited practice.

Note 2: All slides/blocks will be stored in conditions adequate for preservation.

Note 3: Records will be stored to allow prompt retrieval if required.

3.15.7.1 Retention and disposal of specimens

Logs of specimens retained or disposed of will be maintained. Samples will not be disposed of prior to final report authorisation by the pathologist. Retention of specimens will comply with relevant legislation[15].

3.15.7.2 Access to materials

Laboratories are required to provide CervicalCheck access to materials including slides and records on request.

3.15.8 Multi-disciplinary team meetings

There are a wide variety of reasons for cases to be included in MDT meetings. Cases discussed must include reported discrepancies between cytology, histology and clinical appearances.

3.15.8.1 Participation in multi-disciplinary meetings

Histopathologists are integral participants in MDT meetings. MDT meetings are convened by and organised by programme colposcopy services. The locations, timing and frequency of MDT meetings may vary from time to time but reasonable notice will be provided by the colposcopy service to the laboratory. While clinical teams are primarily responsible for case selection, laboratories are encouraged to submit cases for discussion. MDT meetings and cases require preparation.

3.15.8.2 Protocol for MDT meetings

Participation, including a signed record of personnel attending and operational decisions, will be recorded by a person nominated by the programme. Participants must be subject to confidentiality and data protection requirements. Laboratories are encouraged to incorporate MDT meetings into the internal continuing education of scientific staff within the laboratory.

3.15.9 Audit of invasive cervical cancers

QR221. Quality requirement	Placeholder standard: To be updated once the Expert Reference Group on Clinical Audit of Interval Cancer in the Screening Population publishes its report and recommendations.

3.15.9.1 Review of histology slides

The processes around the review of histology slides are being reconsidered for updating at the current time and will be documented subsequent to the approval of the revised process.

3.15.9.2 Independent third-party review

Laboratories will provide all case material where requested for cases identified as warranting independent third-party review by the process for cervical cancer review.

3.15.10 Quality assurance and continuous improvement

3.15.10.1 External quality assurance

QR222. Quality requirement	Laboratories will participate, and show adequate performance, in accredited EQA schemes for histopathology and for technical quality.

3.15.10.2 Internal quality control

IQC of microscopic diagnosis should be an integral part of histopathology reporting practices. This can be achieved by a variety of activities, including:

- Monitoring histopathology detection and reporting rates.
- Correlation of cytology with clinical/histological outcome.
- Participation in regular MDT meetings including slide review.

3.15.10.3 Quality metrics

A complete and accurate report (Histo 1) containing prescribed quality metrics will be provided at regular intervals to CervicalCheck. Complete data at least quarterly, to be received by CervicalCheck within one month of quarter-end.

The quality metrics required are detailed in the current version of the CervicalCheck 'Histo 1 Report'. They include measures which should be readily available from the laboratory's internal quality control processes and are based on quality assurance metrics specified by the appropriate professional bodies concerned. Quality metrics include, amongst others, details of:

- Workload.
- Cytological/histological correlation and follow-up (where available).
- Retrospective review.
- MDT meetings.
- EQA.
- Turnaround times.

QR223. Quality requirement	Laboratories must have the ability to separate CervicalCheck workload from other workload(s) for statistical and monitoring purposes.

The identifier assigned to an individual pathologist will be the same for different sections of the report and over successive reporting periods.

3.15.10.4 Quality metrics improvement

Laboratories will undertake appropriate and timely measures to address performance issues that impact on quality metrics and resulting values outside of laboratory, national and/or international norms.

Sub-optimal performance identified by the provider laboratory in the Histo1 return will require addressing in line with the officially approved guidance of the appropriate professional body. Such performance issues should be notified immediately to the NSS and evidence of corrective action including retraining, if applicable, will be sought by the NSS.

3.15.10.5 Quality assurance visits

QR224. Quality requirement	Laboratories will accommodate on-site visits by NSS-designated personnel for quality monitoring, audit and assurance purposes and provide access to personnel, resources, processes, documentation and results.

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Cervical Screening results and recommendations table

CervicalCheck
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THE NATIONAL CERVICAL SCREENING PROGRAMME

HPV Test Result	Cytology Pattern (where applicable)	Code	Management Recommendation	Rationale/ Recommendation
Not Detected/ Negative	**N/A**	**R1**	Screening completed	Woman is aged 61 or over at date of test OR post hysterectomy and no requirement for increased surveillance
		R3	I year recall	if HIV+. Or as per colposcopy discharge if recommended increased surveillance (increased surveillance = more than one annual test required post colposcopy discharge & discharge date is after HPV primary screening implementation date)
		R2a	3 year recall	If aged between 25 and 29 years (includes women discharged for one test in 12 months post discharge).
		R2b	5 year recall	If aged 30 - 60 years at test date.
Indeterminate HPV result	**N/A**	**R6**	3 month repeat	First or second indeterminate screening test result
		R7	Refer to colposcopy	3 consecutive indeterminate screening test results
				Any 3 screening test results that are not normal in previous 10 years & woman has not had colposcopy
Test not Processed	**N/A**	**R6**	3 month repeat	Repeat 3 months
Detected/ Positive	**P1 (Unsatisfactory)**	**R6**	3 month repeat	Repeat 3 months
	P2 (No abnormality detected)	**R3**	1 year re-call	First HPV positive and cytology NAD, repeat screening test in 1 year
		R7	Refer to colposcopy	Second consecutive HPV positive and cytology NAD (disregard intervening indeterminate or unsatisfactory results), refer to colposcopy Any HPV positive test for woman with HIV, refer to colposcopy Any HPV positive and increased surveillance (increased surveillance = more than one annual test required post colposcopy discharge & discharge date is after HPV primary screening implementation date)
	P3a+ (ASCUS or worse)	**R7**	Refer to colposcopy	Any HPV positive result with abnormal cytology, refer to colposcopy

NOTE:

Where cervix is suspicious for invasive disease, refer for urgent colposcopy, do not take screening test.

When current clinical details record Post Coital Bleeding (PCB)/intermenstrual bleeding(IMB)/ Post-Menopausal (PMB) Bleeding it is recommended to refer for gynaecological assessment.

Where there is a cytology result: If there are endometrial cells present out of cycle for a woman over 40 years it is recommended to refer for gynaecological assessment.

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Appendix 2
Management recommendation table

It is important to note that for women post-colposcopy, the HPV result supersedes the original discharge recommendation from colposcopy.

Result	Recommendation	
HPV Not Detected	R1	Woman is aged 61 or older at date of test, no further screening required
	R1	No further screening post hysterectomy unless recommended by colposcopy or oncology
	R2a	If the woman is between 25 and 29 years – repeat in 3 years (includes women discharged for 1 test in 12 months post discharge) from colposcopy
	R2b	If the woman is 30 – 60 years (at date of test) – repeat in 5 years
	R3	Patients who are HIV positive
	R3	If recommended increased surveillance post colposcopy (>1 test required post discharge & discharge date is after HPV primary screening implementation date)
HPV Detected	R7	If cytology triage result is ASCUS or worse- refer to colposcopy – any test
	R6	First screening test with cytology triage test result of unsatisfactory – repeat in three months
	R3	First screening test with cytology triage test result of No abnormality detected – repeat test in 12 months
	R7	Second consecutive screening test with cytology triage test result of No abnormality detected (disregard intervening indeterminate or unsatisfactory results) – refer to colposcopy
	R7	If HIV +ve- refer to colposcopy
	R7	If discharged for increased surveillance (>1 test required post discharge) – refer to colposcopy
HPV indeterminate result	R6	If this is the first or second indeterminate screening test result – repeat no earlier than 3 months
	R7	If this is the third consecutive indeterminate screening test result – refer to colposcopy
	R7	If the woman has had any three screening test results that are not normal in the previous 10 years and has not had a colposcopy – refer to colposcopy
Test not processed	R6	Repeat no earlier than three months

Where a cytology result is present:

Endometrial cells in a woman over 40 (out of cycle)	Refer for gynaecological assessment.
Clinical details of abnormal bleeding (PCB/IMB/ PMB)	Refer for gynaecological assessment.

Note: where the cervix is suspicious for the presence of cancer a screening test should not be taken, instead an urgent referral should be made to the colposcopy service. A detailed description of the cervix should be provided on the referral form.

Appendix 3

HPV primary screening algorithm

HPV Primary Screening Algorithm

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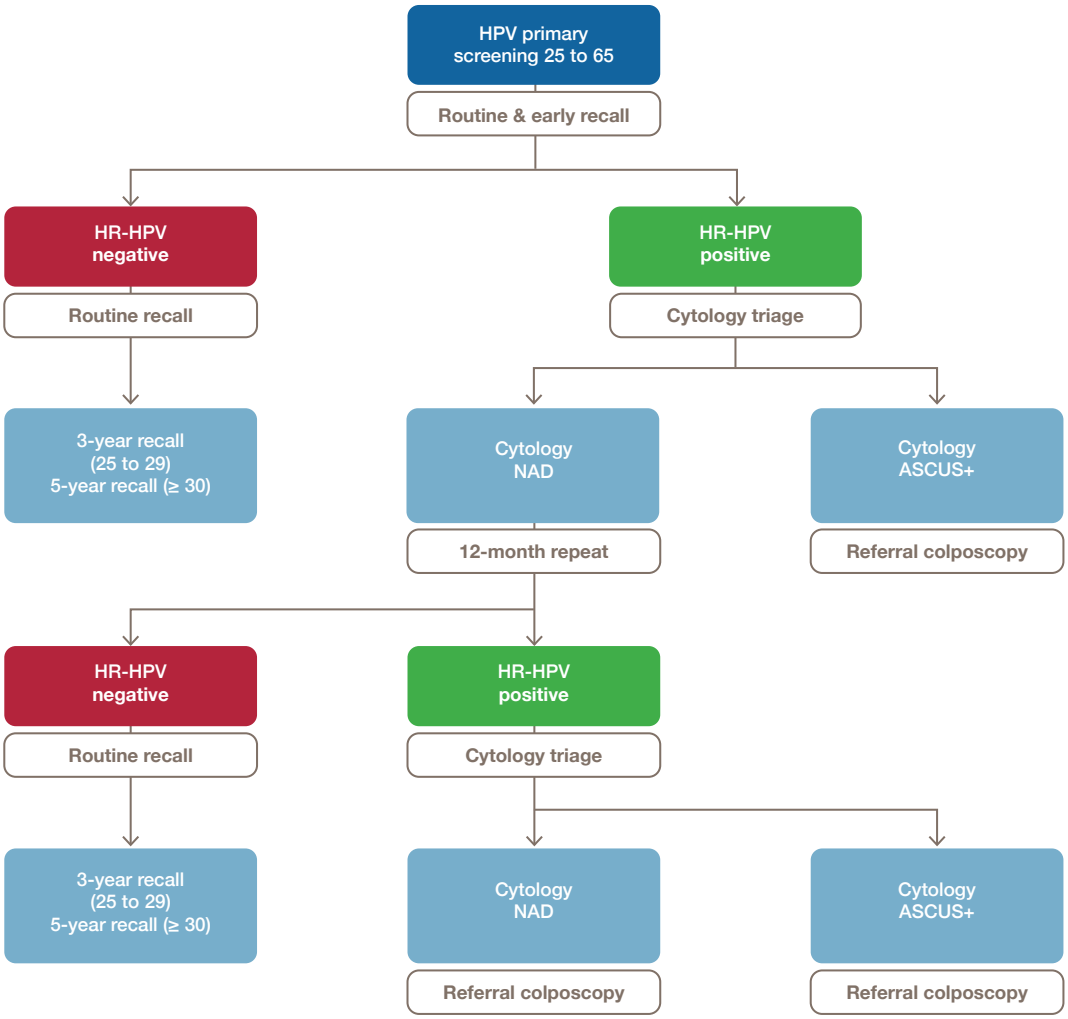
THE NATIONAL CERVICAL SCREENING PROGRAMME



The agreed HPV Primary Screening algorithm comprises the following key steps:

- Active invite and recall for all women resident in Ireland within the age range of 25-65
- Women who test negative for HPV are returned to routine recall
- 3 year recall for women ages 25-29
- 5 year recall for women aged >=30
- At first test: Women who test positive for any of the 14 oncogenic HPV variants and who are cytology negative, will be tested again in 12 months time.
- At first test: Women who test positive for any of the 14 oncogenic HPV variants and who are cytology ASCUS+ will be referred to colposcopy.
- On repeat testing after 12 months, all women who test positive for any of the 14 oncogenic HPV variants will be referred to colposcopy; regardless of cytology.
- HR-HPV positive refers to HPV positivity for any of the 14 high-risk./oncogenic HPV sub-types = 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66 and 68.

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Appendix 4
HPV primary screening: eligibility framework

HPV Primary Screening: Eligibility Framework / Reference Guide for GPs and Clinics

Please note, throughout this document, where we refer to 'women', we mean 'women, or people with a cervix'.

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THE NATIONAL CERVICAL SCREENING PROGRAMME

A. Women – standard eligible population i.e. women aged 25 to 65 years who have a cervical screening requirement			GP / Clinic Payment
Women aged 25 to 29 years:	Routine Screening:	Every 3 years for women with negative HPV test results.	Yes if interval observed
Women aged 30 years or older:	Routine Screening:	Every 5 years for women with negative HPV test results.	
Women aged 25 years or older:	12 month repeat:	1-year repeat following positive HPV test with triage negative (NAD cytology).	
	3 month repeat:	Unsatisfactory result or expired sample / vial	
Women aged over 65	Screening completed:	No further programme screening following 1 (one) negative HPV test result.	

B. Women – special circumstances		GP / Clinic Payment
Women: • post-colposcopy screening tests	• First screening test as per colposcopy discharge recommendation, thereafter as per screening test recommendation.	Yes if interval and criteria observed
Women: • post-total hysterectomy	• Women with no CIN at hysterectomy: no further screening is required. • Women with completely excised CIN at hysterectomy: follow up is undertaken by the treating clinician in line with colposcopy management protocols • If histology is unknown: No further programme screening following 1 (one) negative HPV test result.	
Women: • with HIV infection (coded 'CD4i')	• Women are eligible for programme screening from the time of their HIV diagnosis. • Cervical screening should be performed within one year of HIV diagnosis. • Annual screening for women with negative HPV test results. • After first positive HPV result, women will be referred to colposcopy.	If woman is under 25 or over 65 years GP/Clinic must seek payment from CervicalCheck 061 406500 admin@cervicalcheck.ie
Women: • with renal failure requiring dialysis • about to undergo renal transplant • post organ transplant • undergoing pre-organ transplant workup	• Screening test required at or shortly after diagnosis of renal failure. • Women about to undergo organ transplantation should have had a cervical screening test performed within 1 year. • Further management of these cohorts is governed by the standard HPV screening algorithm.	
Women: • Post pelvic radiotherapy for cervical, bladder, rectal and other pelvic cancers • Congenital absence of the cervix	• Cervical screening not recommended.	Not Applicable

Eligibility check **Check woman's next test due date** **www.cervicalcheck.ie**

Notes		GP / Clinic Payment
1.	Women aged less than 25 years who have never had a cervical screening test or have had a previous negative test result.	Not eligible. No payment
2.	Women not yet due a routine or surveillance screening test.	Not eligible. No payment
3.	Women aged 65 years or older (with no requirement for increased surveillance)	Not eligible. No payment
4.	Women aged under 25 years with previous (non-CervicalCheck) screening test result that is not normal requiring a repeat test.	Not eligible. No payment
5.	Women over 25 with previous CervicalCheck normal result and subsequent non-CervicalCheck test requiring a repeat test.	Not eligible. No payment
6.	Women over 25 to 65 years receiving long-term immuno-suppressant medication or attending DES clinic.	Standard HPV screening algorithm applies.

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