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 Cervaigeach
The National Cervical Screening Programme

Contents

1 Introduction

The previous standards were revised to reflect the introduction of HPV primary screening. This revision considers the changes to date following this introduction.

In the primary HPV cervical screening pathway, cytology is used as a triage test in women where high-risk human papillomavirus (hrHPV) is detected to determine whether immediate referral to colposcopy is required. Any abnormal cytology results lead to colposcopy referral. Section A covers screening laboratory requirements and standards (Cytology and HPV), and Section B covers diagnostic testing requirements (histopathology).

CervicalCheck continues to review best practice guidelines 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. The document is based on the validation exercises carried out on hrHPV tests by Public Health England (PHE) and provides guidance for laboratories on HPV cervical screening quality control and assurance.

This guidance was developed in conjunction with 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 and cytopathology. Histopathology experience was sought from consultant histopathologists actively practicing in this field.

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.

Quality requirements are monitored on a continuous basis by laboratories and are assessed at formal quality assurance visits by the NSS.

Section A: Screening Laboratories (Primary hrHPV testing and Cytology triage)

2 Laboratory Organisation

2.1 Compliance and assurance framework

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

QR 4.01 Quality requirement	Irish screening laboratories must have accreditation to the ISO 15189:2012 *Standards for the Medical Laboratory.* Laboratories providing services for CervicalCheck that are outside 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.

2.2 Quality management system

QR 4.02 Quality requirement	The laboratory will have a quality management system (QMS) in place as required by its accreditation standards and to the standards as required by CervicalCheck.
QR 4.03 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.
QR 4.04 Quality requirement	Any quality issues in relation to the cervical screening laboratory service raised through the QMS must be notified to CervicalCheck.

2.3 Health and safety compliance

QR 4.05 Quality requirement	The laboratory shall be compliant with all national legal and statutory health and safety requirements.

2.4 Data protection

QR 4.06 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.
QR 4.07 Quality requirement	A secure file transfer protocol (SFTP) must be in place between the laboratory and the programme operations office for the secure exchange of electronic data. Where services are provided in two separate laboratory organisations, there must be a secure method of file transfer in place between the two laboratories for the secure exchange of electronic data.

2.5 Laboratory information management system

QR 4.08 Quality requirement	A validated and verified laboratory information management system (LIMS) will be operated in the laboratory.
QR 4.09 Quality requirement	The LIMS will be in a secure facility with the provision for adequate back-up arrangements.
QR 4.10 Quality requirement	Access to the LIMS will be by secure privilege level access control.
QR 4.11 Quality requirement	The LIMS will be capable of generating periodic quality metrics and audit returns to CervicalCheck and to CervicalCheck requirements.

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 order includes a barcode, which laboratories shall be able to scan and extract the included details for automatic import into their data entry system.

QR 4.12 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 generation of 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.
QR 4.13 Quality requirement	The LIMS will be capable of recording the identity of the reporting screeners, pathologist(s) and the authorising virology scientist/ technologist.
QR 4.14 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 as specified by the CervicalCheck programme. • Contain clear audit trails to show original report, amended report, explanation why result was amended and name of individual who authorised the amended report
QR 4.15 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).
QR 4.16 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).

2.6 Telephone support

QR 4.17 Quality requirement	Laboratories must provide telephone access (as agreed in MOU or contract) to laboratory staff during normal business hours (GMT) for registered sampletakers and NSS staff for queries and follow-up.

2.7 Other laboratories

QR 4.18 Quality requirement	Laboratory(ies) will make relevant clinical information and follow-up data available to other laboratories providing services to CervicalCheck.

2.8 Segregation, identification and traceability of programme samples

QR 4.19 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.

2.9 Health agencies and authorities

QR 4.20 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.

2.10 Service capacity, capability and conformance to CervicalCheck quality assurance standards

QR 4.21 Quality requirement	A laboratory must have the staffing establishment necessary to maintain a resilient service. To allow for routine absences, the laboratory will require a minimum of two consultant cytopathologists and sufficient screening staff to meet CervicalCheck performance standards including contracted turnaround times. Any changes in staffing including prolonged leave or poor performance must be notified to CervicalCheck. 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 by CervicalCheck before implementation.

3 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. All laboratories commissioned to provide services to the NSS will have a current contract/service level agreement (SLA)/Memorandum of Understanding (MOU) as appropriate that outlines their contractor status and service provision adherent to CervicalCheck QA standards.

CervicalCheck screening work must be screened and reported in a CervicalCheck approved laboratory setting.

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

QR 4.22 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.*

3.1 Contracting Arrangements between NSS and screening laboratory(ies)

QR 4.23 Quality requirement	A medically qualified consultant pathologist must take responsibility for the issue of all cervical screening test results. A minimum of two medically qualified consultant pathologists actively practicing in cervical cytology must be involved in the provision of a CervicalCheck cervical screening service. The laboratory staffing establishment must ensure that the number of qualified cytopathologists available can enable the following requirements to be met: • The consultant pathologists must practice 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.
QR 4.24 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 Service level agreement / Memorandum of Understanding / Contract for virology services

QR 4.25 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.
QR 4.26 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. *Note: The Clinical and Laboratory Standards Institute (CLSI) document 'MM3-A2-Molecular Diagnostics Methods for Infectious Diseases; Approved Guideline-Current Edition' is the reference document recommended for HPV testing.*

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

QR 4.27 Quality requirement	A cytology service undertaking hrHPV testing must have appropriate consultant virologist support, documented in an SLA/MOU, as appropriate. Laboratory services must not be outsourced without full and comprehensive discussion, planning and written approval from CervicalCheck.

3.4 Contract for service advisers

QR 4.28 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

3.5 Outsourcing laboratory services

QR 4.29 Quality requirement	Laboratory services must not be outsourced without full and comprehensive discussion, planning and written approval from CervicalCheck.

4 Laboratory Personnel (Roles and Responsibilities and Staff Qualifications)

4.1 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 staff which serve the screening programme.

QR 4.30 Quality requirement

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

Prior to independent screening / sign out and reporting, new cytology employees are required to demonstrate:

- High grade cytology sensitivity figures for the previous two years where available
- Gynae-proficiency testing/ EQA for the most recent round where available
- A baseline proficiency assessment completed, including but not limited to at least 200 cytology assessment slides to robustly calculate sensitivity for HSIL + at >= 95%
- Training and knowledge of the latest CervicalCheck guidelines and work instructions
- Successful completion of baseline proficiency assessment will be authorised and communicated to CervicalCheck using form CS/F/Lab-21 Cytologist and Cytopathologist eligibility record for new and retrained individuals.

Individuals who have undertaken re training including return to work/ remedial training are required to demonstrate:

- Gynae-proficiency testing/ EQA for the most recent round where available
- A baseline proficiency assessment completed, including but not limited to at least 150 slides that are either of known outcome, or are double screened and demonstrate a HSIL+ sensitivity of >=95%. (More than 150 slides may need to be included to ensure that a sufficient number of all interpretive categories including high grade abnormal slides were reviewed to adequately measure the HSE sensitivity targeted thresholds). If any high-grade cases are undetected during this supervised period, then a period of further re- education monitoring must be instigated.
- Training and knowledge of the latest CervicalCheck guidelines and work instructions.
- Successful completion of baseline proficiency assessment will be authorised and communicated to CervicalCheck using form CS/F/Lab-21 Cytologist and Cytopathologist eligibility record for new and retrained individuals.

Note 1: Consultant staff must complete retraining if there is an absence from work for a period exceeding six months

Note 2: Screening staff (medical scientist or cytoscreener/ cytotechnologist grades) must complete retraining if there is an absence from work for a period exceeding three months. Where absent for more than six months completion of an approved externally provided training course is required.

QR 4.31 Quality requirement

Laboratories must have an organisation chart that identifies the individual(s) within the department who is responsible for each element. There must be agreement on processes and interactions which set clear expectations for effective working.

4.2 The role of the lead pathologist for cervical cytology triage

QR 4.32 Quality requirement

The lead pathologist for the service is appointed by the employing authority, they should be experienced and operate at a senior level.

The lead pathologist for cervical cytology triage must:

- Be a consultant cellular pathologist registered with the appropriate national professional and regulatory body
- Have overall responsibility for laboratory performance
- Have a nominated deputy medical pathologist that is clinically competent and fully compliant with current CervicalCheck standards.
- 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 and perform 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, ensure the nominated deputy will 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
- The lead pathologist will ensure that all medical and non-medical consultant cytology staff are clinically competent and fully compliant with current CervicalCheck standards
- Ensure that, along with the lead scientist, that all laboratory staff are qualified for their roles
- Ensure that, 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 meetings (MDTs), or make sure that a laboratory representative (other consultant or consultant biomedical scientist (BMS)) is present, to discuss appropriate cases
- Ensure that 100% of MDTs are attended by a suitably qualified person
- Be responsible for making sure the necessary pathology input is made for cervical cancer reviews as required
- Advise and participate in audit for the cervical screening programme
- Attend internal and external cervical screening meetings - or ensure 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

4.3 The role of the consultant cytopathologist

QR 4.33 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 take clinical responsibility for their own cervical cytology cases 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 and perform 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, ensure the nominated alternate will be available)
- 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 MDTs, or make sure that a laboratory representative (other consultant or consultant BMS) is present, to discuss appropriate cases
- Ensure feedback from consultants on discrepant slides is provided to checkers and screeners on a regular basis
- Advise and participate in audit for the cervical screening programme.

4.4 The role of the consultant biomedical scientist

The consultant biomedical scientist (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.

QR 4.34 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 or have a contract/SLA/MOU with the Programme commissioned laboratory if their services are provided via a third party provider
- Report cervical cytology and satisfies 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 and perform 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 that, 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 MDTs - or make sure that a laboratory representative (other medical consultant or consultant BMS) is present, to discuss appropriate cases
- Ensure feedback from consultants on discrepant slides is provided to checkers and primary screeners on a regular basis
- Advise and participate in audit for the cervical screening programme
- Attend internal and external cervical screening meetings as required - or make sure that an alternate is present where the performance of the service will be monitored and local issues discussed.

4.5 The role of the Chief medical scientist /Lead Scientist/ laboratory manager for cervical cytology triage

QR 4.35 Quality requirement

The Chief medical scientist /Lead Scientist/ laboratory manager 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.
- If participating in cytology screening they need to comply with requirements for cervical cytotechnologist/medical scientist (Sections 3.3.6 and 3.3.7)
- 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
- Provide leadership for the 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 (College of American Pathologists) CAP, ISO15189 standards
- 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

4.6 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.

QR 4.36 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
- Refer abnormal cytology samples to checker/cytopathologist
- 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

4.7 Proficiency and competency of cytology staff

QR 4.37 Quality requirement	Those undertaking primary cytology screening must NOT be employed on a less than half time basis.
QR 4.38 Quality requirement	Continuing education to maintain staff competence must be provided.
QR 4.39 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 occur where the laboratory can demonstrate that the screener has successfully completed their required ongoing competency training (eg. Formal update training or proficiency testing) and after an agreed period of double screening (where a sufficient number of all interpretive categories including high grade abnormal slides were reviewed to adequately measure the HSE sensitivity targeted thresholds). 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.
QR 4.40 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 must have a multi-headed microscope for this purpose* • *Participation in MDT meetings* • *Provision of up-to-date cytology textbooks and/or electronic material including legislation and guidelines 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.*

4.8 The role of the lead virologist for hrHPV testing

QR 4.41 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 that, 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
- Ensure participation in a national External Quality Assessment (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 relevant to hrHPV service as published by CervicalCheck, RCPath or other relevant bodies
- Attend cervical screening MDTs where appropriate, or ensure that a deputy provides cover
- Advise on audit for the local cervical screening programme relevant to the relevant to hrHPV service in the programme
- Receive minutes of the multidisciplinary programme board meetings, where the performance of the hrHPV 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.

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

QR 4.42 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
- Provide leadership, and 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, chief medical scientists 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 in relation to hrHPV service is monitored, maintained and evidenced. Notify CervicalCheck of any instance where there are issues with staff competence and remove the staff member from Irish workload until the issue is satisfactorily resolved.
- Have satisfactory participation in the CPD scheme appropriate for their professional body
- Ensure lab participation in EQA scheme and monitor performance.

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

QR 4.43 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.

4.11 Proficiency and competency of virology staff

QR 4.44 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*
- *Participation in MDT meetings*
- *Provision of up-to-date textbooks and/or electronic material including legislation and guidelines 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.*

4.12 Locum staff

QR 4.45 Quality requirement	Locum staff must: • Complete training requirements as outlined in QR4.30. Successful completion will be communicated to CervicalCheck using form CS/F/Lab-21 Cytologist and Cytopathologist eligibility record for new and retrained individuals • 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 including workload requirements. • Meet the training and update requirements of the CervicalCheck cervical screening programme • Routinely participate and perform satisfactorily in an appropriate and validated/ accredited EQA scheme *Note: The service provider is responsible for making sure these requirements are included in any contract.*

5 Sample Acceptance, Reception and Data Entry

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

5.1 Sample acceptance

QR 4.46 Quality requirement	SOPs must be in place for handling CervicalCheck samples. Sample acceptance must adhere to Samples Receipt – Discrepancy Handling and Resolution Guidance for Laboratories Participating in the CervicalCheck Screening Programme (CS/PUB/LAB-7).
QR 4.47 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.
QR 4.48 Quality requirement	The laboratory must only accept programme samples from doctors or clinics that are notified to the laboratory by CervicalCheck.
QR 4.49 Quality requirement	Only those samples accompanied by a current, approved version of the CervicalCheck Cervical Screening form will be accepted.
QR 4.50 Quality requirement	Only those samples inclusive of informed consent will be accepted.

5.2 Specimen reception

QR 4.51 Quality requirement	All forms must be date-stamped upon receipt and date of receipt must be captured on the LIMS.
QR 4.52 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.*
QR 4.53 Quality requirement	A documented discrepancy handling and resolution process must be in place to manage all discrepancies with CervicalCheck samples received. Discrepancies with received samples will be recorded and the log will be made available to CervicalCheck specification. Samples returned to ordering sampletakers or clinics must be traceable. *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.*
QR 4.54 Quality requirement	Categories of samples notified as ineligible for screening will not be tested.
QR 4.55 Quality requirement	Where samples are unsuitable for testing an appropriate report may be generated. There will be a process in place to record and track unsuitable specimens.
QR 4.56 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.

5.3 Data entry

QR 4.57 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 sampletaker will be entered onto the LIMS.
QR 4.58 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.
QR 4.59 Quality requirement	Samples must be assigned to the correct clinically responsible doctor or clinic as per the received form.
QR 4.60 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.

6 Sample Processing and Analysis – Molecular hrHPV testing

QR 4.61 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.
QR 4.62 Quality requirement	Laboratories must only use hrHPV assays approved by CervicalCheck. Modifications to existing assays must be notified in writing and CervicalCheck approval sought prior to implementation by the laboratory.
QR 4.63 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 that manufacturer.
QR 4.64 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.
QR 4.65 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.
QR 4.66 Quality requirement	Processing of samples will be carried out according to instrument user manuals and assay specific package inserts. User ID must 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].*

7 Laboratory internal quality assurance of molecular primary HPV testing

Internal quality assurance (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.

QR 4.67 Quality requirement	Laboratories must carry out IQA and document the findings.

7.1 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 Control and Assurance for human papillomavirus testing.* 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, laboratories should refer to the NHS CSP document as appropriate, along with any further quality standards dictated by the external accrediting body appropriate to that laboratory such as CAP, CLIA etc.

QR 4.68 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.

QR 4.69 Quality requirement	Manufacturers’ controls must conform to product kit insert for the assay concerned. In addition to manufacturers controls, third party control material may be included.
QR 4.70 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 its preparation must be in place. Any change to a new control must be planned and co-tested with the existing control to facilitate validation prior to introduction.
QR 4.71 Quality requirement	To monitor for long term deviations, a control chart, registering each value is obtained, and documented. 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 must 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.

QR 4.72 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 must trigger further investigation and corrective action taken as appropriate.
QR 4.73 Quality requirement	Laboratories must undertake yearly verification of HPV assays. Reports for verification must 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.

8 EQA of molecular primary HPV testing

QR 4.74 Quality requirement	All laboratories providing HPV testing must participate, and show satisfactory performance, in an approved External Quality Assessment (EQA) scheme. Ideally, the laboratory should also participate in a regular programme of inter-laboratory comparison (ILC).
QR 4.75 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.
QR 4.76 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.
QR 4.77 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.

9 Sample Processing and Analysis – Cytology triage

Cytology triage is only performed on hrHPV positive LBC programme samples

QR 4.78 Quality requirement	Liquid-based cytology (LBC) is mandatory. Liquid-based specimens must be processed according to the manufacturer's instructions.
QR 4.79 Quality requirement	Slides will be stained using the Papanicolaou stain (original or modified). The samples must have a cover slip that covers all the cellular material.
QR 4.80 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. In this case, it is acceptable that the accession number and surname is present.

9.1 Staining

QR 4.81 Quality requirement	All laboratories providing cytology, must participate, and demonstrate satisfactory performance, in an approved EQA scheme for staining known as 'Technical EQA'. 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.
QR 4.82 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 must be available for review and must specify individual processors if multiple processors are used.
QR 4.83 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.

9.2 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 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.

QR 4.84 Quality requirement	Equipment (microscopes, multi-headed microscopes, digital imaging systems) must be available and configured to the ergonomic standards (for further details see NHS document 17 Ergonomic working standards for personnel engaged in the preparation, scanning and reporting of cervical screening slides for microscopy work.
QR 4.85 Quality requirement	Only approved protocols will be used, approval must be sought prior to implementation. *Note: TIS may be used for IQC screening in an HPV primary cytology triage programme.*
QR 4.86 Quality requirement	Prior to the assessment of the sample, the patient's screening history will be retrieved 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.*
QR 4.87 Quality requirement	Screeners and pathologists must register with CervicalCheck and submit their assigned numbers to CervicalCheck in the results file. CervicalCheck monitoring of individual metrics can only be accomplished on CervicalCheck work
QR 4.88 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.
QR 4.89 Quality requirement	Cytology reporting must be controlled and monitored carefully to manage any overcall/ bias due to a positive HPV primary screen.
QR 4.90 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 4-1	Lead medical scientist, cytology manager, supervisory scientific staff: if the role involves cervical screening then a minimum number (1,000) of CervicalCheck cases will be reviewed.
Standard 4-2	In order to maintain proficiency, a minimum number (1,000) of CervicalCheck cytology screens per year must be screened per screener.

Standard 4-3	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** Cytology screening must be limited to 6 hours within a 24-hour period. No individual to screen more than 50 routine Internal Quality Control cases in the allocated screening time (rapid review/ preview/full screen).
QR 4.91 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 4-4	Weekly workload must not exceed 6 consecutive days in a 7 day period	
Standard 4-5	Pathologist proficiency: To maintain a medical consultant's diagnostic skill in cervical cytopathology, a minimum number (750) of CervicalCheck cases per year will be reviewed. This is to ensure that the programme has full oversight of an individual consultants reporting profiles. *Note: This number can include negative cases as well as abnormal ones and whilst the work performed can also include "slides reviewed for audit and correlation" it is vital that such work is comprehensively documented for laboratory QA audit purposes so that an individual consultant's workload can be accurately estimated over time.*	
Standard 4-6	Multi-Disciplinary Meetings: Except in exceptional circumstances at least one Cytopathologist or CBMS reporting CervicalCheck workload will participate in scheduled MDTs While this does not have to be same person for each MDT those reporting CervicalCheck workload will participate in scheduled MDT s	**Target** 50% minimum, 90% achievable

10 Laboratory internal quality assurance of cytology triage

QR 4.92 Quality requirement	Accuracy of screening must be monitored and managed with approved protocols and procedures for defining and dealing with poor performance.
QR 4.93 Quality requirement	IQA of cytology screening must be monitored by: • Re-screening (rapid rescreen/ pre-screen) 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, undetermined, negative) detected by individual screeners and cytopathologists, and in comparison, with the laboratory as a whole, the programme and national standards • Feedback from consultants on discrepant slides should be given to checkers and primary screeners on a regular basis • 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 using full re- screen, rapid review, rapid preview re-screening or imager (TIS) rescreen of cytology samples.*

10.1 Routine Internal Quality Control

Rapid review 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 is an alternative approved method for routine quality control in cervical cytology. Rapid preview is performed microscopically in 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. For imager (TIS) review 22 fields of view as a minimum are examined as a QC check

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.

QR 4.94 Quality requirement

Rapid review/ preview/ imager / full screen review- IQC must:

- Only be carried out by qualified members of staff who are meeting competency standards.
- Be performed by 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

10.2 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. This is a further quality assurance step that allows a second opinion prior to pathologist review

QR 4.95 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
- 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 must be monitored and compared across individual checkers to identify inconsistencies in abnormal referral rates

10.3 Audit

QR 4.96 Quality requirement

Laboratories will carry out audits of outcome and processes in accordance with departmental annual plans, accreditation requirements and the quality management system.

11 External quality assessment of cytology triage

QR 4.97 Quality requirement	Laboratories must participate in the relevant accredited interpretive national EQA schemes.
QR 4.98 Quality requirement	All individuals reporting cervical cytology must participate in and demonstrate acceptable performance in the interpretive EQA scheme.
QR 4.99 Quality requirement	EQA results must be evaluated by the laboratory on an ongoing basis, with prompt and documented corrective action taken for unacceptable results.

12 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.

12.1 HPV results

QR 4.100 Quality requirement	HPV test results must adhere to Cervical Screening Management Recommendation Protocol (see Appendix 2).

12.2 Cytology classification and reporting codes

QR 4.101 Quality requirement	The reporting classification for CervicalCheck samples is the Bethesda system 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.*

12.3 Adequacy of cervical cytology samples

QR 4.102 Quality requirement	Laboratories must follow Bethesda and NHS guidance on adequacy of 5,000 well preserved cells. Where cell counting is performed, the method for counting must be incorporated into laboratory SOPs. Where any abnormal cells are detected, the slide must not be classified as inadequate.

12.4 Reporting multiple diagnoses

QR 4.103 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.*

12.5 Women with 2 cervices

Multiple diagnoses 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.

QR 4.104 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.

13 Management of Results

Note: refer to Appendix 1: Cervical screening results and recommendations table and Appendix 2: HPV Primary Screening Algorithm.

13.1 Reporting of cervical screening samples

QR 4.105 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.*
QR 4.106 Quality requirement	The CervicalCheck CR result file will be reported with the detail and the format specified by CervicalCheck.
QR 4.107 Quality requirement	The screening history of the woman provided by the CSR (where such history is available) must be referred to and taken into account during the results process.

QR 4.108 Quality requirement	In cases where the primary screener has indicated that they suspect the sample is demonstrating high grade dyskaryosis or glandular neoplasia and the checker or pathologist/CBMS 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 Cases referred to a consultant as HSIL+ or AGC+ but considered to be negative by the checker or consultant must be referred for further opinion by another consultant(s) before consensus reporting. It is good practice that all cases of borderline changes in endocervical cells are double reported by consultant pathologists or CBMS to try and minimise the overcalling of reactive or benign changes.
QR 4.109 Quality	An independent check of the case result and management code will be in place, prior to report authorisation.
QR 4.110 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 or consultant biomedical scientist.
QR 4.111 Quality requirement	Results, once authorised and released, will be issued in the agreed summary format as soon as possible by electronic means to CervicalCheck.
QR 4.112 Quality requirement	The contents of the results report to ordering doctors and clinics must be in accordance with laboratory accreditation and CervicalCheck requirements
QR 4.113 Quality requirement	Results, once authorised and released, must be issued promptly to the ordering doctor or clinic.
QR 4.114 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.*

Standard 4-7	Laboratories will have procedures in place to manage and respond to requests for second opinions and to issue amended, corrected or supplementary reports as necessary. Additional or amended reports, once authorised and released, must adhere to the same standards and targets and be captured on the LIMS. Laboratories must monitor the number of results that require amendment or correction and implement corrective action as required should targets be breached. *Note: 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. This also applies to rescreening requests.*	**Target** % Amended results. Cytology cases ≤1% % Corrected results. Cytology cases ≤2% % Supplementary Reports Cytology cases ≤10%
Standard 4-8	Cervical screening results must be authorised, released and transmitted to CervicalCheck within the target turnaround time from sample receipt in the laboratory or collection point.	**Target** 95% within 10 working days

14 Storage and Archiving

QR 4.115 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 HSE record retention policy and the current RCPath guidelines on specimen retention. Cytology slides must be stored for 15 years. Vials must be stored until samples are finally authorised. Laboratories must have a SOP to describe records and materials to be retained, their storage location, how long they should be retained for and the source of the retention advice. *Note: Laboratories must be capable of tracking slides that are removed from storage.*
QR 4.116 Quality requirement	Laboratories are required to provide CervicalCheck access to materials including slides, samples, logs, and records, on request.

15 Protocol for Multi-Disciplinary Meetings (MDT)

QR 4.117 Quality requirement	Laboratories will provide facilities, participation and support for MDTs held in programme colposcopy services. Laboratories are encouraged to incorporate MDTs into the internal continuing education of scientific staff.
QR 4.118 Quality requirement	Cytology laboratories will retrieve and provide slides or digital images for cases notified for review at MDTs on request, within 10 working days.

15.1 Amended result following discussion at multi-disciplinary meeting

QR 4.119 Quality requirement	Where an MDT review outcome is deemed to affect current patient care following review at an MDT the treating clinician and NSS must be notified of this change. This will require release of an amended report via the LIMS and reference to the previous report should be made to allow retrieval if required e.g., for audit purposes.

16 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 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 result monitoring ASC-H and atypical glandular cells are included in the overall rate, however for calculation of PPV ASCH is excluded for benchmarking purposes.

QR 4.120 Quality requirement	A complete and accurate report containing prescribed quality metrics must be provided at defined intervals (combined HPV and cytology return is currently returned on a quarterly basis) including relevant individual performance data 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.*
QR 4.121 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.
QR 4.122 Quality requirement	Laboratories must have systems in place where performance data is regularly reviewed at departmental and laboratory/hospital governance meetings.
QR 4.123 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.

17 Quality Assurance Visits

QR 4.124 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.

18 Audit of Invasive Cervical Cancers

QR 4.125 Quality requirement	Placeholder standard: To be updated when an implementation plan for the recommendations of the Expert Reference Group on Clinical Audit of Interval Cancer in the Screening Population is agreed.

19 Risk and Incident Management

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

QR 4.126 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. There should be a clear procedure for staff to escalate concerns on any elements of the laboratory service including the option of confidentially contacting the appropriate external Quality Assurance (QA) group

20 Business Planning and Service Continuity

QR 4.127 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.
QR 4.128 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.
QR 4.129 Quality requirement	All agreements with external agencies to maintain service resilience must be clearly documented in a formal document such as an 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

Introduction

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. MDMs 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.

Revision of these standards considers recommendations from the National Health Service England Improvement (NHSEI) review of histology standards which are recorded in the Public Health England publication *Cervical screening; histopathology handbook*.

Additional requirements include:

- defining the adequacy of cervical biopsies and when they must be called inadequate
- monitoring reporting profiles for cervical biopsies and loop excisions
- the use of p16 staining
- the use of minimum data sets to standardise report content
- the introduction of minimum workload figures for pathologists who report programme generated histopathology samples

- histopathology input to the colposcopy multidisciplinary team (MDT) meetings
- required professional updating in cervical histopathology
- clarification of the lead pathologist's role for cervical histopathology
- audit as an integral part of a pathologist's work
- outsourcing and the use of locums
- monitoring turnaround times (TATs) for cervical histopathology

21 Histology Laboratory Organisation

Requirements for Quality Management System (QMS), Health & Safety and Data Protection are the same as for cytopathology and molecular laboratories. Requirements for Laboratory Information Management System (LIMS) data capture are detailed under reporting sections.

21.1 Compliance and assurance framework – histology

INAB is the sole national accreditation body for the Republic of Ireland.

QR 4.130 Quality requirement	Laboratories providing services for CervicalCheck should have accreditation to the appropriate standards within the country of origin of the contracted laboratory. As part of the formal schedule of CervicalCheck quality assurance audits to histology laboratories, where accreditation is not in place then the quality assurance audits will assess compliance to CervicalCheck standards

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 must be immediately advised to CervicalCheck.

QR 4.131 Quality requirement	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.

22 Clinical Governance – Histology

22.1 The role of the lead histopathologist

The lead histopathologist for cervical screening histology is a consultant cellular pathologist.

QR 4.132 Quality requirement

The lead histopathologist:

- must be a consultant cellular pathologist registered on the Irish Medical Council (IMC) specialist register
- should have a job plan which takes account of this role and its time commitment
- has satisfactory and appropriate participation in an appropriate continuing professional development (CPD) scheme or activity
- meets programme standards for reporting cervical histology
- participates in relevant histopathology EQA schemes
- has a nominated deputy
- works with the cervical screening provider lead and lead biomedical scientist to make sure the laboratory follows all national guidance related to cervical screening histology
- advises on the implementation of new guidance or monitoring of new standards as published by the programme or RCPath when appropriate
- attends cervical screening MDT meetings (or where another pathologist attends, makes sure they meet programme standards in cervical histology reporting)
- is responsible for making sure the necessary pathology input is made for cases in the national audit of invasive cervical cancer
- advises and participates in audits for the local programme relevant to their role
- attends National Screening Service Lead Histopathologist Group meetings and business meetings (or ensures that a deputy is present) where the performance of the local service will be monitored, and business issues are discussed
- contributes as necessary to any quality reports
- contributes to any annual reports relating to the local service
- signs off the cervical histology data returns
- is the primary medical contact within the department for cervical screening histology matters
- makes sure that an appropriately experienced histopathologist undertakes a review of histological biopsies that are included in MDT meetings and invasive cancer audit.

22.2 Outsourcing and locums

QR 4.133 Quality requirement

Laboratories using external referral services must inform CervicalCheck prior to referral of work.

QR 4.134 Quality requirement

Outsourcing histology samples

The contracted histopathology service provider must make sure that:

- CervicalCheck is notified of any plan to outsource histology services in advance
- Laboratories and pathologists undertaking cervical histopathology for CervicalCheck meet the required standards of the cervical screening programme
- the requirement is included in a contract or service level agreement.

QR 4.135 Quality requirement

Locums

The histopathology service provider is responsible for enabling locums to:

- meet the requirements and standards of the cervical screening programme
- meet training and update requirements of the cervical screening programme as identified in this document.

The histopathology service provider is responsible for making sure these requirements are included in a contract or service level agreement.

The lead histopathologist is responsible for making sure that locums meet training and update requirements of the cervical screening programme as identified in this document.

Locums must provide evidence of relevant and current CPD to the lead histopathologist for the service.

22.3 The role of non-consultant grade medical staff

Staff in non-consultant grades can be involved in reporting cervical histology.

- This includes specialist trainees under the direct supervision of a pathologist who meets the requirements of the cervical screening programme.
- Staff in non-consultant grades can be involved in the MDT meeting.

22.4 Chief medical scientist and supervisory scientific staff

QR 4.136 Quality requirement

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.

23 Proficiency and competency of staff

23.1 Staff qualifications and competencies

QR 4.137 Quality requirement	Scientific, medical, and non-medical staff will be qualified for the positions they hold according to national requirements to practice.
QR 4.138 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.
QR 4.139 Quality requirement	There will be a chief medical scientist who is responsible for the day-to-day management of the department and who has responsibility for supervision of non-medical staff.
QR 4.140 Quality requirement	Histopathologists reporting programme generated histology samples must remain abreast of current and emerging interpretation guidelines, guidelines, and CervicalCheck QA Standards

23.2 All staff

QR 4.141 Quality requirement	All staff will be competent to carry out their roles. Competency will be maintained by regular training and education. Training and competency records must be retained and available for review.

23.3 Maintenance of clinical skill

Standard 4-9	All pathologists reporting cervical screening histology must report a minimum of 150 histopathology specimens per year (biopsies and or loops originating in the cervical screening programme). We recommend this figure as a minimum to maintain clinical competence and allow statistical comparisons of reporting profiles.

23.4 Continuing education

QR 4.142 Quality requirement	Continuing education will be facilitated with evidence of internal and external educational activities.

23.5 Pathologists

QR 4.143 Quality requirement	All pathologists will participate in continuing medical education (CME) as required by Part 11 of the Medical Practitioners Act 2007 – Maintenance of Professional Competence. Consultant Biomedical Scientists, where appropriate will participate in an approved CPD scheme.

23.6 Maintaining professional performance through audit

The Irish Medical Council requires its members to monitor and improve the quality of their work.

QR 4.144 Quality requirement	Evidence of the review of practice and quality improvement activity is required for internal appraisal. Pathologists can demonstrate review of practice and quality improvement by performing audits of their reports against RCPath minimum data sets for cervical neoplasia and tissue pathways. It is recommended that audits submitted for evaluation comply with relevant guidance, e.g., RCPath guidance.

24 Laboratory facilities

QR 4.145 Quality requirement	All laboratories will provide appropriate facilities. These will include appropriate areas for sample reception, specimen dissection, processing, reporting, typing and authorisation.

24.1 Specimen reception

QR 4.146 Quality requirement	SOPs will be in place for handling CervicalCheck samples. For the purposes of data capture, samples originating from CervicalCheck colposcopy services must be easily identifiable. 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 issue of consent by the woman should be incorporated into the processes for sample data capture and data exchange.
QR 4.147 Quality requirement	All cervical histology samples will be processed in the manner appropriate for an externally assessed and accredited histopathology laboratory.
QR 4.148 Quality requirement	A discrepancy handling and resolution process will be in place to manage all discrepancies with CervicalCheck samples received.

24.2 Sample ‘chain of custody’

QR 4.149 Quality requirement	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.
QR 4.150 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.
QR 4.151 Quality requirement	All equipment used for histological examination should have documented validation prior to use. Continuous preventative maintenance and service history must be maintained

25 Data entry and notification to CervicalCheck

QR 4.152 Quality requirement	Relevant clinical details recorded on the Cervical Histology Form or accredited lab form will be recorded on the LIMS. Notification and result files must be sent to CervicalCheck in a defined format at specified intervals. A periodic reconciliation of files sent and received must be in place between CervicalCheck and the laboratory.

26 Specimen dissection and assessment

Specimen description and sampling will be done in such a way as to facilitate microscopic reporting and pathological staging. The following guidance is set out to ensure a consistent examination process equitable with a national screening programme commissioning multiple service laboratories.

The handling and preparation of specimens sent for histological examination is described below.

26.1 Cervical punch or wedge biopsies

To confirm or exclude the presence of cervical pathology. The biopsies received are:

- Usually fixed in formalin
- Typically 4mm to 7mm in their greatest dimension
- 2mm to 4 mm thick.

The macroscopic description of cervical biopsies should record the number of tissue fragments, and their size (in three dimensions) should be recorded. All tissue should be processed. Most biopsies do not need further sectioning and are embedded intact, however if specimens are bisected this should be recorded Wedge biopsies can be serially sectioned at 2-3 mm intervals perpendicular to the mucosal surface.

All biopsies are stained with haematoxylin and eosin (H&E) and three levels are initially examined. Further levels can be examined if there is a discrepancy between clinical or cytological evidence of a high-grade lesion, and histological appearances on the initial levels.

26.2 Cone biopsy and large loop excision of the transformation zone (LLETZ)

Cone and LLETZ (loop) biopsies from women with abnormal cytology samples or following an abnormality on punch biopsy can be diagnostic or therapeutic.

Record:

- measurements of the intact central loop or cone biopsy in 3 dimensions (2 side-to-side, and the greatest depth perpendicular to the ectocervical surface must be recorded *)
- measurements of flat or opened loop biopsy in 3 dimensions (noting which dimension is being measured)
- number of pieces for multiple loop biopsies, with the smallest and largest measured in the maximum dimension where the sample is small, or in 3 dimensions where it is larger
- presence of any surface lesions

**Note: The depth of the biopsy is important as the goal of excision is to remove all the abnormal epithelium, in accordance with the type of the transformation zone*

Type I cervical transformation zone

For treating ectocervical lesions, excisional techniques should remove tissue to a depth of more than 7mm in ≥95% of cases, though the aim should be to remove <10mm in individuals of reproductive age

Type II cervical transformation zone

Excisional techniques should remove tissue to a depth of 10 to 15mm in ≥95% of cases, depending on the position of the squamocolumnar junction within the endocervical canal.

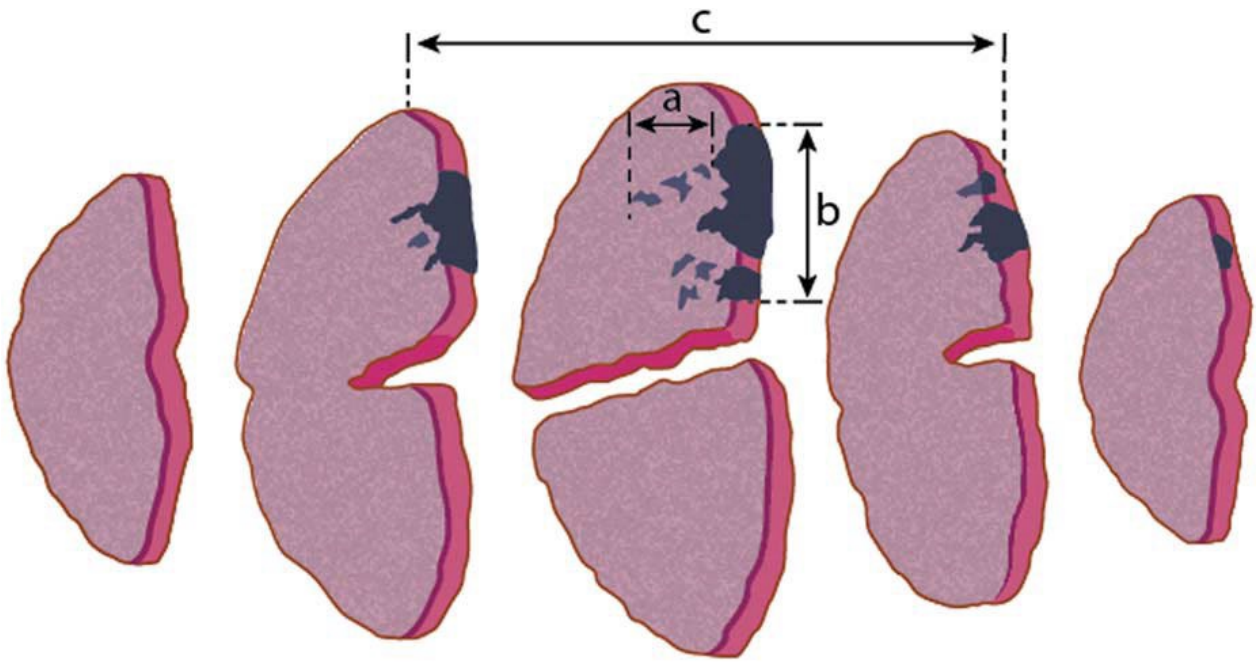
Type III cervical transformation zone

Excisional techniques should remove tissue to a depth of 15 to 25 mm in ≥95% of cases, depending on the position of the squamocolumnar junction within the endocervical canal.

When blocking a loop biopsy, LLETZ or cone biopsy one must:

- block all slices sequentially perpendicular to the transverse axis at 2-3 mm intervals
- consider whether inking the specimen will be helpful diagnostically
- Submit the entire specimen
- note that opening or probing an intact loop or cone biopsy may damage the surface epithelium.

The dataset for Histological reporting for cervical neoplasia 2021 suggests that LLETZ biopsies should be sliced serially perpendicular to the transverse axis of the external OS at 2mm to 3mm intervals when slicing intact central loop or cone biopsies. This is often referred to as ‘bookending’. Slice from one edge to the other. This allows assessment of tumour volume in small lesions and avoids the problems of interpretation that may arise when a loop or cone specimen is sectioned radially, resulting in blocks of variable thickness.



Measurement of cervical tumours in three dimensions

Process fragments for example, superficial, deep or 'top-hat', or marginal, in designated sequential cassettes (record which block relates to which fragment)

The procedure for blocking a loop (bookending) is as follows:

1. Place the surface to be cut face down in the tissue cassette, the outer (curved) surface of the first and last (edge) slices of the loop can be embedded on cut surface or on outer edge as detailed in the laboratory standard operating procedure (SOP).
2. Place each subsequent slice in a sequential cassette, with cut faces orientated similarly.
3. Place each slice of tissue in a tissue cassette. Never put more than 2 pieces of tissue in 1 cassette.

27 Embedding

It is necessary to have well orientated cervical punch biopsies for an accurate assessment of the presence and grade of cervical intraepithelial neoplasia (CIN) in cervical samples. Optimal embedding procedures should in place to ensure the specimen description and number of pieces correlate with dissection information, and robust non-conformance protocols in place where required. Additionally, samples must be embedded so orientation preserves the squamocolumnar junction and maintain intact surface of epithelium. This may include mounting the specimen on paper before fixation to provide optimal orientation. Non-conformances and competency of staff performing embedding must be monitored and actioned to ensure optimal quality.

QR 4.153 Quality requirement	Optimal embedding procedures and internal quality control (IQC) should be in place to ensure the specimen description and number of pieces correlate with dissection information, and robust non-conformance protocols followed if required

28 Microtomy & Staining

1. A single full-face H&E-stained section is initially examined on each block.
2. If the surface epithelium or squamocolumnar junction is missing, or there is a discrepancy between the histological and cytological findings, a single further level is recommended and usually adequate.

Spare sections may be required for e.g., Histochemistry and immunohistochemistry (IHC) testing.

QR 4.154 Quality requirement	Laboratories must: Have IQC protocols in place to monitor section and staining quality prior to histopathology evaluation and reporting. Participate in accredited tissue diagnostic EQA schemes for both the paraffin wax embedded tissue block and its corresponding haematoxylin and eosin (H&E) stained slides, both of which play a critical role in tissue-based diagnosis.

29 Microscopy and reporting of results

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

QR 4.155 Quality requirement	A standard SNOMED 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.

29.1 Terminology

QR 4.156 Quality requirement	For intraepithelial lesions, laboratories shall use: Existing cervical intraepithelial neoplasia (CIN) terminology for the histological reporting of squamous intraepithelial neoplasia or the lower anogenital squamous terminology (LAST) classification Cervical glandular intraepithelial neoplasia (CGIN) for the histological reporting of glandular intraepithelial neoplasia. Stratified mucin-producing intraepithelial lesion (SMILE) for the histological reporting of intra-epithelial neoplasia showing stratified epithelium with atypical cells containing mucin vacuoles in all layers of the epithelium *Note: this is in line with colposcopy standards.*

29.2 Coding of histopathology reports

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, 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.

QR 4.157 Quality requirement	Laboratories shall: • Assign SNOMED topography and morphology codes to all histopathology reports • Histopathology reporting proformas such as those based on RCPath datasets are highly recommended to provide standard and equitable data to colposcopy clinics. • Classify all cervical carcinomas according to the WHO classification of cervical neoplasms • The laboratory should assess the completeness and accuracy of the coding through periodic audits

29.3 Tumour node metastasis (TNM) and International Federation of Gynaecology and Obstetrics (FIGO) staging of cervical tumours

QR 4.158 Quality requirement	Laboratories shall: Stage all cervical carcinomas from the available material according to the FIGO system and UICC/AJCC system. The use of RCPath reporting datasets is highly recommended.

Diagnostic terminology should include terms used in the most current *World Health Organisation (WHO) Classification of Tumours of the Female Genital Tract.*

29.4 Report content

QR 4.159 Quality requirement	All histopathology reports must be authorised by a consultant pathologist/ consultant biomedical scientist where applicable (electronic and/or manual).

All reports must include the relevant data set items for loop excisions and cervical biopsies (Table 1).

Table 1. Data set items for loops and cervical biopsies

Data set items to be included	In loop excision reports	In cervical biopsy reports
	Macro	**Macro**
Specimen type	Yes	Yes
Number of pieces	Yes	Yes
Dimensions of pieces in 3 planes (height, width, depth)	Yes	Yes (1 dimension only)
Presence and completeness of cervical os	Yes	-
Description of any lesion seen naked eye	Yes	-
Method of trimming/inking, for example serially sliced in blocks	Yes	-
Other histological features if present, for example tuboendometrioid metaplasia, endometriosis, microglandular hyperplasia	Yes	Yes
Correlation with cytology (less than 1 grade difference where information is available)	Yes	Yes
Comment if case recommended for discussion at MDT	Yes	Yes
Diagnosis	Yes	Yes
SNOMED CT/SNOMED code	Yes	Yes
	Micro	**Micro**
Number of slices examined	Yes	Number of additional levels examined
Presence or absence of TZ	Yes	Yes
Presence or absence of HPV-related changes	Yes	Yes
Presence or absence of CIN	Yes	Yes
Grades of CIN when present	Yes	Yes
Presence or absence of crypt involvement by CIN	Yes	Yes
Presence or absence of CGIN	Yes	Yes
Presence or absence of SMILE	Yes	Yes
Completeness of excision at ectocervical margin	Yes	-
Completeness of excision at endocervical margin	Yes	-
Completeness of excision at deep lateral margin	Yes	-
Presence or absence of invasion	Yes. If invasion present then use RCPath data set for cervical neoplasia in loop excisions	Yes
Results of p16 or other immunohistochemistry performed	Yes	Yes

29.5 Report text

In loop excisions or punch biopsies, the microscopy report must specify whether there are any features that impair histological assessment or interpretation – for example fragmentation, crush or diathermy artefact, or epithelial loss.

There must be a clear distinction between a specimen that fails to identify the source of the abnormal cells in the cervical cytology sample because it is technically unsatisfactory or damaged, and a biopsy that is technically adequate but does not include or identify the lesion.

Include in the report all pathological lesions and non-neoplastic histological features that may be associated with cytological changes.

In a small biopsy, the text must indicate the worst grade of CIN present, as well as all other grades present.

You must not use non-specific text terms such as ‘CIN 1 to 2’ and ‘CIN 2 to 3’.

29.6 Reporting cervical biopsies

Adequate

Consider as adequate any biopsy which shows an abnormality irrespective of its size. Do not consider smaller biopsies as necessarily adequate for diagnosis. An adequate biopsy for histology reporting should:

- contain cervical epithelium
- be intact and not so fragmented or crushed as to interfere with reliable interpretation
- lack crush / diathermy artefact
- be adequately fixed and processed
- be well oriented
- be well stained.

Inadequate

In this context, the term ‘inadequate’ means that there is insufficient representative material present to allow for pathological reporting. To achieve consistency within histopathology reporting, it is recommended that:

- a cervical biopsy must not be classified as inadequate if it shows an abnormality
- a cervical biopsy taken as a result of cytology showing squamous dyskaryosis must be called inadequate if it does not contain squamous epithelium (you must state this in the report)
- a cervical biopsy taken as a result of cytology query showing a borderline endocervical abnormality or query glandular neoplasia (endocervical) must be called inadequate if it does not contain any endocervical tissue and shows no abnormality (you must state this in the report)

Not representative

Do not call inadequate a cervical biopsy which does not contain transformation zone (TZ) tissue if the sampletaker has indicated it is from the ectocervix. If not indicated, then describe it as 'may not be representative'. TZ tissue will have surface squamous epithelium with either surface columnar tissue or stromal gland crypt, or both.

No abnormality seen

If TZ sampling is present and no abnormality is seen to account for the reason for the biopsy (whether cytologically or clinically indicated) then repeat biopsy and or further investigation may be indicated, the reporting histopathologist may wish to list such a case for discussion at MDT.

Non-correlation of biopsy or loop excision with referral cervical sample

Non-correlation is defined as more than 1 grade difference between the histological diagnosis and cytological diagnosis.

Initially, 3 levels for cervical biopsies should be taken. For those cases where this does not identify features that correlate with the referral cervical cytology, a further 3 levels are advocated. For loop excisions a single full-face section initially should be performed and further levels only when required.

If the reason for referral was clinical (for example, post-coital bleeding, suspicious cervix) no more than 3 levels are necessary unless there is a suggestion of an abnormality on initial levels.

If the reason for referral was ASCUS or LSIL with hrHPV+ve, 3 further levels are only necessary if there is a suggestion of an abnormality appearing in initial levels.

If the reason for referral was not stated, follow local policy.

Ancillary tests

Further levels or use of ancillary tests such as p16 may be indicated in some cases. If the biopsy still does not correlate with the referral cervical sample or clinical impression then discussion should take place at an MDT meeting.

Review the material and the reason for referral or biopsy.

For a high grade cervical cytology sample and negative or low grade biopsy, consider:

- examining more levels
- p16 testing
- MDT discussion

29.7 Interpretation of p16 immunohistochemistry (IHC) in cervical histopathology reporting

p16INK4A (from this point referred to as p16 IHC) is a good surrogate test for the presence of a potentially transforming or hrHPV infection in premalignant and malignant lesions of the cervix; its use improves diagnostic agreement in cervical biopsy interpretation.

QR 4.160 Quality requirement	Laboratories must: Participate in relevant accredited Immunocytochemistry (ICC) EQA schemes.

P16 reporting terminology

CervicalCheck does not recommend use of the word 'positive' for reporting p16 staining. Report as 'abnormal (diffuse/block positive expression) vs negative/normal expression'.

Abnormal expression

Abnormal expression in glandular epithelial lesions is strong and diffuse positive staining in glandular epithelial cells; staining may be nuclear or more commonly nuclear and cytoplasmic.

p16 staining is not a surrogate for grade; up to 50% of cases of low grade squamous intraepithelial lesion (LSIL) (HPV/CIN 1) are p16 positive. Base the grading of squamous intraepithelial lesion (SIL) (cervical intraepithelial neoplasia - CIN) on morphological criteria and not on p16 staining.

Whilst block positive staining is (almost always) seen in high grade CIN, there may be complete absence of staining in some cases. For example, inactivation of the p16 gene through gene deletion or epigenetic silencing. These are rare cases and in such instances it is reasonable to seek the opinion of an experienced colleague.

The interpretation of p16 staining is context dependent. p16 overexpression may be occasionally seen in non-HPV related cervical gastric type adenocarcinomas, as well as occasional (2 to 3 percent) HPV-independent vulval squamous cell carcinomas.

Current evidence does not support any combination of markers to improve performance when compared with the use of p16 alone therefore do not routinely add Ki-67 to p16 IHC.

Research indicates use of p16 in the following situations.

When the H&E morphological differential diagnosis is between pre-cancer (high grade CIN; CIN 2 or CIN 3) and a mimic of this, for example, processes known to be not related to neoplastic risk such as immature squamous metaplasia, atrophy, reparative epithelial changes, tangential cutting).

When considering a H&E morphological interpretation of CIN 2 or above, use p16 IHC to help clarify the situation. Base grading on morphological features and the value of p16 is in exclusion of a high grade lesion in the presence of a negative stain.

As an adjudication tool for cases in which there is a professional disagreement in histological specimen interpretation, with the caveat that the differential diagnosis includes high grade CIN.

As an adjunct to morphological assessment for biopsy specimens interpreted as CIN 1 or lower that are at high risk for missed high grade disease, which is defined as a prior cytological interpretation of HSIL, ASCUS with hrHPV+ve or Atypical glandular cells. This is only when there is a suspicion of, or difficulty in excluding, a high-grade lesion morphologically.

p16 IHC as a routine adjunctive technique in the histological assessment of biopsy specimens is not recommended.

29.8 Authorisation of results

QR 4.161 Quality requirement	Every result will be appropriately authorised before release. Every report must be checked for inconsistencies before authorisation.
QR 4.162 Quality requirement	The results of the laboratory examination will be presented in accordance with the agreed current standard classification system(s), and standard reporting proformas, 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.

29.9 Turnaround time

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

Standard 4-10	Samples must be reported within agreed turnaround times *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 of receipt of sample. Large specimen: minimum 80% within 14 days.

29.10 Results reporting

QR 4.163 Quality requirement	Laboratory management will ensure that histology results, once authorised and released, must be issued promptly to the ordering doctor or clinic and electronically to CervicalCheck.

29.11 Delivery of results reports to ordering doctors or clinics

QR 4.164 Quality requirement	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.

29.12 Review requests and amended reports

QR 4.165 Quality requirement	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 and be captured on the LIMS.

30 Storage and archiving

Standard 4-11	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.
QR 4.166 Quality requirement	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 *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.* *Note 4: Laboratories must be capable of tracking slides or blocks that are removed from storage*

30.1 Retention and disposal of specimens

QR 4.167 Quality requirement	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.

30.2 Access to materials

QR 4.168 Quality requirement	Laboratories are required to provide CervicalCheck access to materials including slides and records on request.

31 Multi-disciplinary meetings

Effective communication between units is an essential component of high quality integrated patient care.

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

31.1 Participation in multi-disciplinary team meetings

Histopathologists are integral participants in MDTs. MDTs are convened by and organised by programme colposcopy services. The locations, timing and frequency of MDTs 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. MDTs and cases require preparation.

31.2 Protocol for multi-disciplinary team 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 MDTs into the internal continuing education of scientific staff within the laboratory.

QR 4.169 Quality requirement	Laboratories must log all cases discussed on the LIMS. Document the results of reviews of samples for MDT purposes along with the details of who carried out the review. Record any revisions to histology results and issue a supplementary report. Feedback any revisions to the original reporting pathologist. There must be an SOP in place which supports this process. *Note: Detailed guidance on MDT requirements can be found in the publication CS/PUB/CLP-21 MDT Guide* *Note: Trainees may contribute to the meetings and should be encouraged to attend for their educational benefit.*

Standard 4-12	**Required minimum attendance at MDT** Multi-Disciplinary Meetings: Except in exceptional circumstances at least one histopathologist or CBMS reporting CervicalCheck workload will participate in scheduled MDTs While this does not have to be same person for each MDT those reporting CervicalCheck workload will participate in scheduled MDTs	**Target:** 50% minimum, 90% achievable
Standard 4-13	**Frequency of attendance** All histologists reporting cervical histology must attend a minimum of 3 colposcopy MDT meetings each year. It is considered best practice to support their full integration into the service and to make sure they understand the function and management decisions taken at the MDTs.	
Standard 4-14	**MDT Agreement** MDT review opinions must be recorded and compared to the original result, the level of concordance must be recorded and made available to CervicalCheck	

32 Audit

QR 4.170 Quality requirement	**Audit of histopathology reports** Audit is an integral part of a pathologist's work. Pathologists must participate in the departmental annual audit programme. Select cases at random. The proportion of cases will depend on departmental workload and existing review practices. Audit histopathology reports against the minimum data set items to check for compliance.	**Target:**
	Intradepartmental Consultation (IDC) Histology	>3% minimum, >5% achievable,
	Retrospective Real Time Review: % Agreement - Histology	≥95%

33 Audit of invasive cervical cancers

QR 4.171 Quality requirement	Placeholder standard: To be updated when an implementation plan for the recommendations of the Expert Reference Group on Clinical Audit of Interval Cancer in the Screening Population is agreed.

33.1 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.

33.2 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.

34 Quality assurance and continuous improvement

34.1 Performance monitoring

CervicalCheck audit laboratories on their compliance with CervicalCheck QA guidance.

QR 4.172 Quality requirement	All pathologists who report cervical histology referred by the screening programme must monitor their performance in this work. Suitable exercises/ processes may include EQA (where available); inter-laboratory discussion of cases of serious discrepancy e.g., for MDT meetings: participation in MDT meetings.

Data items collected for an individual are:

- Overall number of cervical histopathology samples from cervical screening programme referral.
- Specimen type (biopsy and or LLETZ) and numbers reported by type.
- Time from cervical histology sample taken to report authorisation.
- classification or grade of abnormality as numbers and percentages of total cases reported
- Analysis is by department and by individual.

34.2 Histopathology and cytology correlation

The cervical biopsy (punch or loop) should explain the cytological findings. Correlate the histology and cytology in every case. The referral cytology should be recorded on the CervicalCheck histology request form.

Always regard the cervical cytology findings as the lowest grade of abnormality expected in a biopsy. Include a comment on correlation in every histology report. It is sufficient to state that the histopathology does or does not correlate with the cytology. Systems must be in place to make sure the cytology result is available at the time of biopsy reporting.

34.3 Histological findings higher than expected from the cytology result

This is a normal and recognised feature of cervical screening and may be due to:

- undergrading of cytological changes in cervical samples
- overgrading of histology changes
- unrepresentative cytology

A one-grade difference in CIN is an acceptable variation.

34.4 Histological findings lower than expected from the cytology result

This may be due to:

- poor quality biopsy: loss of surface epithelium or electrothermal artefact may impair histological assessment; deeper levels should be cut in these cases but may be of limited value
- unrepresentative biopsy material: the colposcopist may not have selected the most appropriate site to biopsy; not all CIN lesions produce a colposcopic abnormality
- overgrading in cytology
- undergrading in histopathology
- removal during sampling of all of the abnormal cells (in the case of a small pre-invasive lesion) resulting in a genuine negative biopsy
- natural disease regression

A one-grade difference in CIN is an acceptable variation (assuming appropriate levels have been examined).

The cytology service must carry out a cytology review if there is a discrepancy of more than 1 grade. Review of both the cytology and histology may be necessary to either confirm the original diagnosis or determine an explanation for the findings. Feedback to the MDT meeting if a technically satisfactory biopsy does not confirm a significant cytological finding.

34.5 Histological discrepancies and suspected CGIN

The limitations of punch biopsies in diagnosing CGIN are recognised and should not be taken routinely for a glandular abnormality on cytology. Do not misinterpret a cytological prediction of glandular neoplasia, followed by a negative punch biopsy alone, as a cytology overcall.

Always consider the possibility that abnormal cells found on cytology originate from elsewhere in the female genital tract, and investigate if clinically appropriate.

34.6 External quality assurance

QR 4.173 Quality requirement	Laboratories will participate, and show adequate performance, in accredited EQA schemes for histopathology and for technical quality.

34.7 Internal quality control

QR 4.174 Quality requirement	IQC of microscopic diagnosis should be an integral part of histopathology reporting practices. This can be achieved by a variety of activities, including: • Correlation of cytology with clinical/histological outcome • participation in regular MDTs including slide review

34.8 Quality metrics

A complete and accurate report containing prescribed quality metrics will be provided at regular intervals to CervicalCheck.

QR 4.175 Quality requirement	A complete and accurate report containing prescribed quality metrics must be provided as specified by CervicalCheck to allow comparisons against national standards and other quality indicators.
QR 4.176 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, including notification to CervicalCheck.
QR 4.177 Quality requirement	Laboratories must have systems in place where performance data is regularly reviewed at departmental and laboratory/hospital governance meetings. *Note: The identifier assigned to an individual pathologist will be the same for different sections of the report and over successive reporting periods.*

QR 4.178 Quality requirement	Where an issue with performance has been identified, 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.
QR 4.179 Quality requirement	Laboratories must have the ability to separate CervicalCheck workload from other workload(s) for statistical and monitoring purposes.

34.9 Quality metrics improvement

QR 4.180 Quality requirement	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 will require actioning in line with the officially approved guidance of the appropriate professional body. Such performance issues must be notified immediately to the NSS and evidence of corrective action including retraining, if applicable, will be sought by the NSS.

34.10 Quality assurance visits

QR 4.181 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.

35 Bibliography

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Appendix 1: Cervical screening results and recommendations table

Cervical Screening results and recommendations table

CervicalCheck
AN CLÁR NÁISIÚNTA SCAGTHÁSTÁLA CEIRBHEACS
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 • Discharged from colposcopy with a recommendation of no further screening • Woman is aged 64 or over at date of test and has been on annual surveillance for reason of renal dialysis / post-transplant or HIV positive.
		R3	1 year recall	• Renal dialysis • Pre / post-transplant • If HIV+ • If increased surveillance is indicated as per colposcopy discharge (see note 1 below)
		R2a	3 year recall	• If aged between 25 and 29 years with no requirement for, or completed increased surveillance • First test at completion of increased surveillance post colposcopy - Any age
		R2b	5 year recall	• If aged between 30 - 60 years at test date with no requirement for increased surveillance (women must attend for one test at 3 year interval before moving to 5 year recall on completion of increased surveillance post colposcopy).
Detected/ Positive	P1 (Unsatisfactory)	R6	3 month repeat	Repeat 3 months
		R7	Refer to colposcopy	• 3 consecutive unsatisfactory screening test results • Any 3 screening test results that are not normal in previous 10 years & woman has not had colposcopy.
	P2 (No abnormality detected)	R3	1 year recall	First HPV positive and cytology NAD, repeat screening test in 1 year (includes women on post colposcopy surveillance)
		R7	Refer to colposcopy	• Second consecutive HPV positive and cytology NAD taken in non-colposcopy setting. See note 2 below • If HIV+ • Renal dialysis • Pre / post-transplant
	P3a+ (ASCUS or worse)	R7	Refer to colposcopy	Any HPV positive result with abnormal cytology
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

NOTES:

1. Women discharged from colposcopy pre March 2020 for cytology screening who receive a HPV negative result do not require continued annual surveillance unless there is a history of invasive cervical cancer/CGIN/AIS/SMILE. Women discharged after March 2020 should attend for their recommended number of post colposcopy HPV tests.
2. Disregard intervening cytology only, indeterminate, unsatisfactory result.
3. Where cervix is suspicious for invasive disease, refer for urgent colposcopy, do not take screening test.
4. When current clinical details record Post Coital Bleeding (PCB) / Intermenstrual Bleeding (IMB) / Post-Menopausal Bleeding (PMB) it is recommended to refer for gynaecological assessment.
5. **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.
6. **Where there is a cytology result and a previous history of treatment for glandular abnormality:** Report as UNSAT if TZ cells are not present.

An tSeirbhís Náisiúnta Scagthástála
National Screening Service

CS/PUB/LAB-2 Rev. 12

Appendix 2: HPV Primary Screening Algorithm

HPV Primary Screening Algorithm

CervicalCheck
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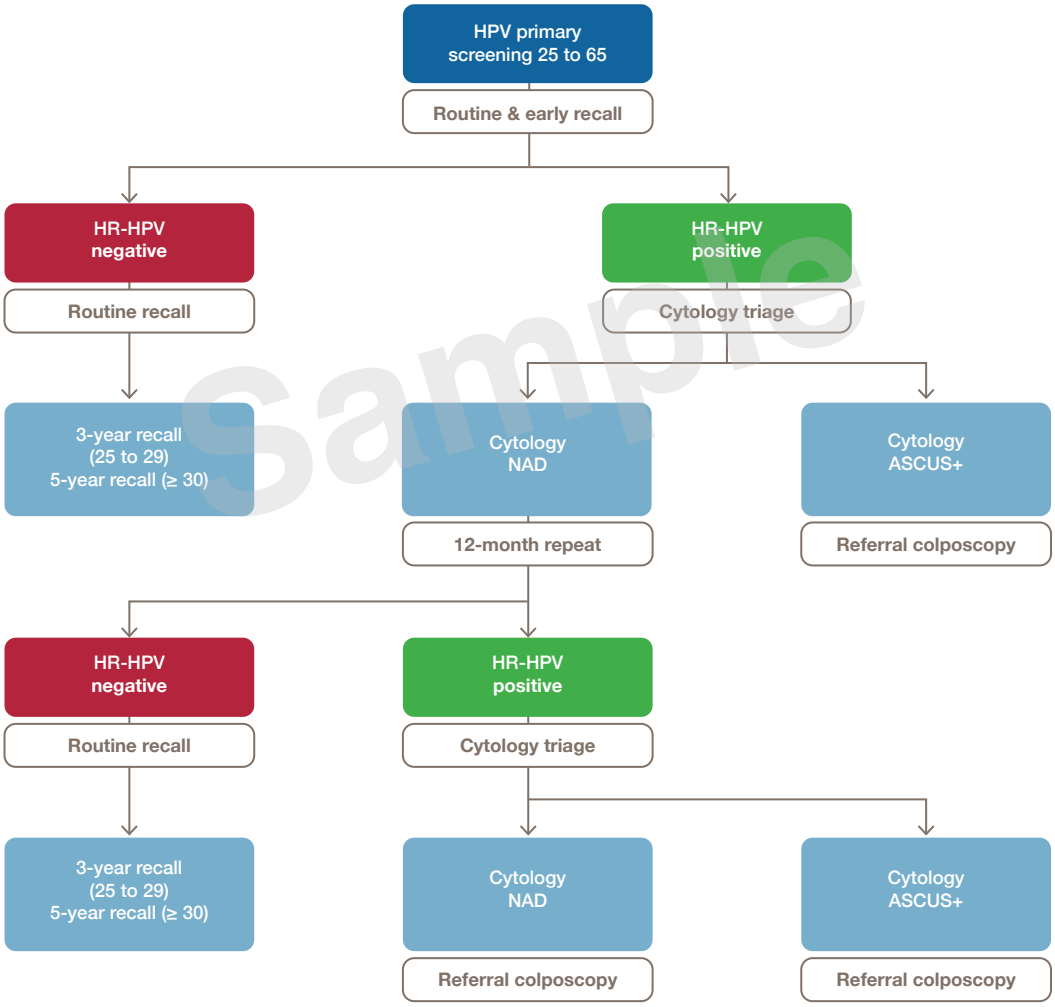
THE NATIONAL CERVICAL SCREENING PROGRAMME



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.

CS/PUB/PM-14 Rev 1

Appendix 3: Patient Eligibility Framework

HPV Primary Screening: Eligibility Framework

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

CervicalCheck
AN CLÁR NÁISIÚNTA SCAGTHÁSTÁLA CEIRBHEACS
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 to 65 years:	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	

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. • Annual screening for women with negative HPV test results. • After first positive HPV result, women will be referred to colposcopy.	
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.

CS/SPP/PM-9 Rev 9