

11. Setting up an HPV laboratory

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11.1 PREPARATORY CONSIDERATIONS

Setting up a laboratory for human papillomavirus (HPV) testing requires careful planning, as the laboratory may operate within a broader network of clinical care, public health, screening, vaccination, surveillance and/or research activities.¹⁻⁵ The first step is to define the intended scope and function of the laboratory. This includes whether the laboratory will provide clinical testing services=(for example as part of cervical cancer screening), support epidemiological surveillance, contribute to research activities or combine several of these functions. The general requirements of a laboratory described in **Section 11.4** should therefore be adapted to the specific type of activities planned or ongoing.

Depending on said activities, the laboratory must comply with relevant national and international regulations, including biosafety requirements, data protection rules and (where applicable) accreditation or quality standards, such as ISO 15189:2013⁶ for medical laboratories. In many settings, the laboratory's role and responsibilities may be reflected in an agreement with a commissioner, funder or national authority, which should be periodically reviewed. Adequate financial planning is essential to ensure that infrastructure, equipment, reagents, personnel, information systems and long-term sustainability are properly covered (**Figure 11-1**).

Although no two laboratories are identical, all HPV laboratories share the same overarching objective: to provide a robust, reliable and high-quality testing service appropriate to their function. This requires attention to pre-analytical, analytical and post-analytical processes within a quality assurance and biosafety framework. Governance and oversight mechanisms should also be established, including clear lines of accountability, reporting responsibilities and decision-making processes. This chapter provides practical guidance for establishing an HPV laboratory and outlines the core technical, operational and regulatory elements needed to support different HPV laboratory functions.

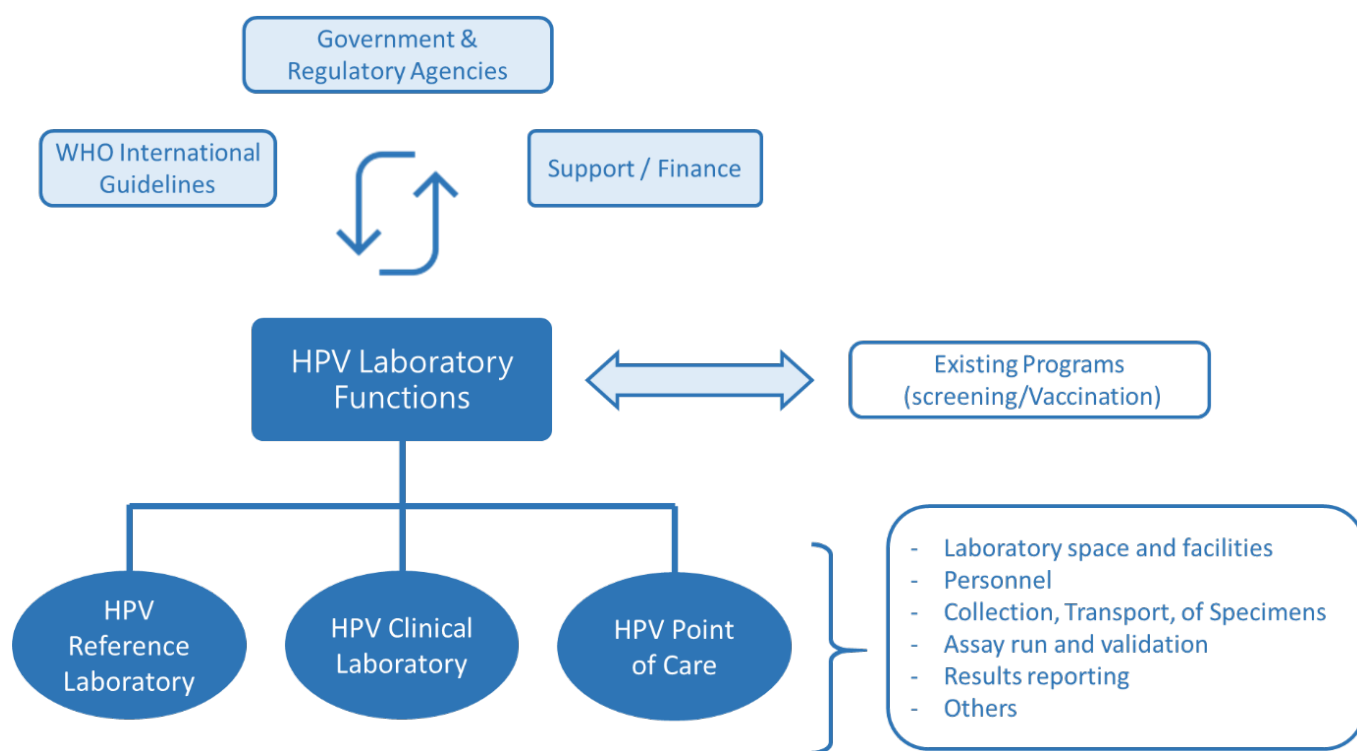
11.2 COMPLIANCE

As outlined above, HPV laboratories must comply with applicable national and local regulations, including requirements for clinical laboratory testing, biosafety, data protection, quality assurance and information governance. Before implementation, laboratories should ensure that all necessary permits, licenses or institutional approvals are in place, particularly when the laboratory provides clinical results for patient care or screening programmes.

Laboratories should also consider relevant guidance from national, regional and international authorities. These may include regulatory and public health bodies such as the Food and Drug Administration (FDA, United States), European Medicines Agency (EMA, Europe), National Medical Products Administration (NMPA, China), African Medicines Agency (AMA, Africa), World Health Organization (WHO),

Compliance should include appropriate handling of personal and clinical data, in line with applicable data protection regulations, such as the General Data Protection Regulation (GDPR) in Europe or the Health Insurance Portability and Accountability Act (HIPAA) in the United States. Secure systems for sample tracking, result reporting, data storage and data transfer should be established.

Figure 11-1. Framework for HPV laboratory functions within screening and vaccination programmes



This figure illustrates how HPV laboratory functions are positioned within a broader system of regulatory oversight, international guidance, financing and existing screening and vaccination programmes. Depending on local infrastructure and programme needs, HPV testing may be delivered through reference laboratories, clinical laboratories or point-of-care models. Each model requires core operational elements, including appropriate facilities, trained personnel, specimen collection and transport systems, validated assays, quality assurance procedures, result reporting pathways and secure data management.

As described laboratories providing clinical services should operate within a suitable quality management framework, such as ISO 15189:2022 for medical laboratories. Even when laboratories do not provide a clinical diagnostic service, these principles remain useful for ensuring quality, traceability and accountability. Research laboratories should apply the principles of Good Laboratory Practice (GLP, [Good laboratory practice compliance | European Medicines Agency \(EMA\)](#)), where relevant, to ensure that studies are planned, performed, monitored, recorded, reported and archived according to recognized quality standards. Laboratories involved in clinical research should also follow Good Clinical Practice (GCP, [ICH E6 Good clinical practice - Scientific guideline | European Medicines Agency \(EMA\)](#)), the international ethical and scientific quality standard for conducting research involving human participants.

11.3 FINANCIAL ASPECTS

The financial viability of an HPV laboratory depends on securing sustainable funding sources and effectively managing both initial and recurrent operational costs. Financial planning should be adapted to the country context, the intended laboratory function, expected sample throughput, level of automation, quality requirements and long-term service needs. Key financial considerations include:

A. Potential funding sources

- Government agencies and national public health programmes
- Non-governmental organizations (NGOs)
- International organizations, associations and grants, such as WHO, UICC or Gavi
- Public–private partnerships
- Academic, hospital or institutional funding mechanisms

B. Cost components

- Infrastructure, including laboratory space, utilities, storage facilities, biosafety containment, general administration and staff facilities
- Equipment and consumables, such as PCR platforms, sequencing platforms, extraction systems, reagents, assay kits and general laboratory consumables
- Personnel and training, including management, scientific, technical and support staff, continuous education and competency assessment
- Quality assurance, including internal quality control, external quality assessment, assay validation or verification, and accreditation-related costs
- Sample logistics, including collection materials, transport, storage and waste management
- Data management and IT infrastructure, including LIMS, secure data storage, cybersecurity and reporting systems
- Equipment maintenance, service contracts and contingency planning

C. Long-term sustainability models

- Integration of HPV testing into national cervical cancer screening programmes
- Centralized or regionalized testing models to optimize sample throughput and reduce costs
- Cost-effectiveness analyses to guide procurement, test selection and resource allocation
- Long-term procurement agreements for reagents, consumables and equipment maintenance
- Partnerships with public health services, academic institutions, private laboratories or industry
- Planning for recurrent costs to avoid interruptions in testing, reporting and follow-up

11.4 PRE-IMPLEMENTATION CONSIDERATIONS

The function and purpose of the HPV laboratory will determine the specific pre-implementation requirements, including facility design, equipment, test selection, staffing and quality assurance. The infrastructure and staffing required will also depend on whether the HPV laboratory is established within an existing laboratory structure or as a stand-alone facility. The following key aspects should be considered.

11.4.1 Laboratory space and facilities

Before implementation, a risk assessment and needs assessment should be performed to determine how laboratory activities can be conducted safely, efficiently and in compliance with regulatory and quality requirements. These assessments should consider the intended testing volume, workflow, sample types, equipment, biosafety requirements and available infrastructure.

Key considerations include:

- Biosafety and biosecurity requirements for handling human clinical samples
- Quality assurance measures, including contamination prevention, workflow optimization and implementation of a quality management system (See [Chapter-3-Laboratory-Quality-Assurance.pdf](#))
- Facility design based on workflow, including separation of pre-analytical, analytical and post-analytical areas where required
- Ventilation, contamination control and clean areas, where appropriate
- Accessibility, ergonomics and safe working conditions for laboratory personnel

The facility layout should minimize cross-contamination risks and support efficient sample processing. Although the final design will depend on the equipment and systems required for the laboratory procedures, biosafety, biosecurity and quality assurance should be considered from the planning stage.^{2,4,5}

HPV testing laboratories generally require Biosafety Level 2 (BSL-2) precautions, as they handle human samples that may contain infectious agents such as HPV, HIV, HBV or HCV. The following biosafety measures should be implemented:

- A health and safety policy and manual should be established, functional and accessible to all staff
- Dedicated laboratory areas should be defined, with clear demarcated separation/areas for sample reception, nucleic acid extraction, PCR set-up and amplification. Also where possible, a unidirectional workflow should be established. Such processes can help minimize contamination. Where this level of separation is not possible having a minimum of two areas to support pre-amplification and amplification/post amplification tasks is recommended. For selected manual steps of non-automated HPV assays, dedicated workstations may be considered to further reduce the risk of cross-contamination.
- Personal protective equipment (PPE) should be used according to the level of risk associated with the sample type, procedure and local setting. At a minimum, laboratory coats and gloves should be worn when handling clinical samples, with additional protection such as eye protection, face shields or masks used when there is a risk of splashes, aerosols or exposure to bloodborne pathogens.
- Class II biosafety cabinets should be available for handling and processing liquid clinical samples to minimize aerosol exposure
- Aerosol-generating procedures should be minimized; closed-system processing methods should be used where possible, and open pipetting, vortexing or splashing should be avoided
- A waste disposal policy should be in place and comply with relevant biohazard regulations
- Laboratory benches and equipment should be regularly decontaminated using appropriate virucidal agents and, where needed, products suitable for reducing nucleic acid contamination, such as bleach or equivalent agents. Equipment-specific decontamination instructions should be followed and records maintained
- A dedicated separated handwashing sink should be available
- Staff should receive training in biosafety practices and emergency procedures; access to post-exposure prophylaxis should be considered, particularly in settings with high HIV prevalence

Laboratory staff should be offered hepatitis B vaccination and other relevant vaccinations according to national recommendations. In settings with high HIV prevalence or increased risk of exposure to bloodborne infections, enhanced BSL-2 measures may be considered, including stricter aerosol control, enhanced PPE and HIV post-exposure prophylaxis availability. BSL-3 containment is not required for standard HPV diagnostic work.

11.4.2 Equipment and Supplies

The choice of equipment and supplies depends on the function of the laboratory, expected sample throughput, level of automation, sample types and HPV test(s) to be implemented.

Essential considerations include:

Sample throughput and automation

- Estimate the expected number of samples to be processed daily, weekly and annually.
- Determine whether manual, semi-automated or fully automated workflows are appropriate.
- Automated systems for sample preparation, nucleic acid extraction, amplification and result interpretation can increase efficiency, reduce hands-on time and minimize human error although they generally require higher testing volumes, centralized laboratory services and greater maintenance requirements to be efficient and cost-effective.
- Backup/contingency arrangements should be created in view of pressures that may significantly affect (or stop) activity including but not confined to equipment failure, contamination issues, manpower shortages, reagent issues or unexpected increases in sample volume. These arrangements may take the form of a reciprocal arrangement with another laboratory to ensure continuity of HPV testing, particularly in the event of a contamination incident.

Equipment inventory and maintenance

- Maintain an accurate and up-to-date inventory of all laboratory equipment and consumables.
- Keep records of installation, validation or verification, calibration, maintenance, service visits, downtime and decontamination.

- Ensure that critical equipment has maintenance contracts, access to technical support and, where possible, backup options.

Storage conditions and space allocation

- Ensure sufficient and separate storage areas for biological samples and reagents/kits
- Biological samples should be stored under appropriate conditions, such as room temperature, 2–8°C, -20°C or -80°C, depending on the sample type, collection medium and intended use.
- Reagent aliquots should be stored in a way that minimize cross-contamination and support accurate inventory management and sample retrieval.
- Chemicals, reagents and assay kits should be stored according to manufacturer instructions, including required temperature, light protection and expiry date monitoring.

Storage capacity should be planned according to expected throughput, procurement schedules and contingency needs.

Basic Space requirements

- Appropriate ventilation
- Clear, secure entry and exits(s)
- Handwashing sink(s)
- Electric sockets
- Benches (fixed or modular) which can bear the load/requirements of relevant equipment

Basic laboratory equipment

Depending on the laboratory function and test platform, equipment may include:

- Centrifuges, vortexers and heating blocks
- Calibrated pipettes and multi-channel pipettes
- Biosafety cabinets, usually Class II for handling liquid clinical samples
- Nucleic acid extraction systems
- PCR, RT-PCR or qPCR platforms
- Automated liquid handling systems, where appropriate

- Sequencing platforms, where relevant to the laboratory remit
- Refrigerators and freezers for reagent and sample storage
- Autoclaves or access to validated waste decontamination systems
- Biobank capacity, where long-term storage of national or research sample collections is part of the laboratory remit

Biosafety and decontamination supplies

- PPE should reflect the level of risk associated with the sample type, procedure and local setting. Laboratory coats and gloves should be used when handling clinical samples, with eye protection, face shields or masks added when splashes, aerosols or exposure to bloodborne pathogens may occur.
- Appropriate disinfectants should be available for both biological decontamination and reduction of nucleic acid contamination. The choice of product should reflect the intended purpose, for example virucidal activity versus removal of DNA contamination.
- Decontamination stations and clearly defined cleaning procedures should be available for work surfaces, equipment and spills.
- Waste containers and disposal systems should comply with local biosafety and biohazard regulations.

Laboratory information management system

A secure laboratory information management system (LIMS), or equivalent data management system, is essential for tracking samples, recording patient or study information, managing results and supporting quality monitoring. The system should be able to:

- Track samples from receipt to analysis, reporting and storage or disposal
- Store and manage test results and relevant metadata
- Support review, approval and audit of results
- Maintain secure data management in compliance with local regulations
- Enable data extraction for quality monitoring, surveillance or reporting, where appropriate
- Include backup procedures and access control

11.4.3 Choice of HPV test

The choice of HPV test should clearly be guided by the intended laboratory function, target population and purpose of testing^{7,8}. For cervical cancer screening, assays should be clinically validated for screening use and appropriate for the sample type, including clinician-collected or self-collected samples where relevant. Additional considerations include expected sample throughput, degree of automation, need for partial or extended genotyping, regulatory status, quality assurance requirements, data reporting needs and compatibility with existing laboratory infrastructure.

Where testing is performed for surveillance or research additional assay characteristics may be required, such as type-specific detection, sequencing capacity, viral load estimation or detection of HPV types not included in routine screening assays. Point-of-care HPV tests may be considered in settings where rapid results and same-day clinical management are priorities, provided that the assay has adequate performance for the intended use and that appropriate quality assurance and reporting systems are in place.

Detailed technical descriptions of HPV detection and typing methods are provided in [Chapter 6](#).

11.4.4 Quality assurance (QA)

All laboratories performing HPV testing should operate within a Quality Management System (QMS) that promotes accuracy, reliability, reproducibility, patient safety, and continuous improvement. Laboratories providing clinical services should aspire to accreditation according to internationally recognized standards, such as ISO 15189:2022, where feasible. Detailed guidance on quality management systems, accreditation, quality control, assay validation, personnel competency, and audits is provided in [Chapter 3: Laboratory Quality Assurance](#).

Key quality assurance elements include:

- **Internal Quality Control (IQC):** Routine monitoring of assay performance through the use of appropriate controls and validation of reagents and equipment.
- **External Quality Assessment (EQA):** Participation in proficiency testing schemes to benchmark performance against national or international standards.
- **Standard Operating Procedures (SOPs):** Documented procedures covering sample collection, processing, testing, reporting, and quality management activities.

- **Personnel competency:** Initial training, documented competency assessment, regular appraisal, and continued professional development (CPD) to ensure staff maintain the knowledge and skills required for HPV testing.
- **Validation and verification:** Appropriate validation or verification of assays, instruments, reagents, and any modifications to established testing procedures before implementation and during routine use.
- **Audits and continuous improvement:** Regular internal review and corrective and preventive actions (CAPA) to support ongoing quality improvement.

Further details on these requirements are provided in [Chapter 3](#).

11.5 FUNCTION OF THE LABORATORY

Different types of laboratories may contribute to HPV testing in different ways, depending on their mandate, governance, technical capacity, and role within the health system.^{9,10} This section describes three broad laboratory functions: 1) national or reference laboratories, 2) clinical laboratories performing HPV testing in routine care, and 3) point-of-care testing settings. These categories are not fixed, and responsibilities may overlap or vary between countries.

11.5.1 National or reference laboratories

HPV reference laboratories generally provide national or regional expert support for HPV testing, surveillance, quality assurance, training, and policy development. An HPV reference laboratory is not necessarily “implemented” according to a single model. Rather, an existing laboratory may be formally designated or nominated by national authorities to undertake defined reference functions according to national needs, resources, and public health priorities.

The explicit remit of a reference laboratory varies internationally. Some reference laboratories may provide HPV testing for screening or diagnostic purposes, while others may focus primarily on surveillance, quality assurance, training, research, or technical advice. Therefore, the following should be considered desired characteristics rather than mandatory requirements.

Key functions may include:

- providing expert scientific and technical advice to national health authorities on HPV testing and prevention of HPV-associated disease;
- supporting clinical and laboratory professionals with specialist advice on HPV-related diagnostics and interpretation;
- advising on the evaluation and introduction of new HPV testing technologies;
- supporting laboratories that deliver HPV testing through training, troubleshooting, quality assurance guidance, and technical assistance;
- contributing to surveillance of HPV prevalence, genotype distribution, vaccine impact, and disease burden;
- supporting or coordinating quality assurance activities, including external quality assessment or proficiency testing where appropriate;
- acting as a research or research-facilitation hub to generate evidence for service development and policy;
- supporting the development and maintenance of nationally representative sample collections or biobanks, where appropriate;
- participating in international networks, such as the Global HPV LabNet, to promote harmonization, peer collaboration, and alignment with international standards.

Further details on the role of national and international HPV reference centres are provided in [Chapter-10-International-and-National-HPV-Reference-Centers.pdf](#). **Annex I** provides examples of current reference laboratory models, including their governance, resourcing, functions, and activities.

The desired characteristics for the designation and function of an HPV reference laboratory are described in **Table 11-1**.

Table 11-1. Desired characteristics of an HPV reference laboratory

CHARACTERISTIC	DESIRED CHARACTERISTICS
Laboratory space and facilities	Facilities should be suitable for molecular biology procedures, with appropriate separation of pre-amplification and post-amplification areas where relevant. A unidirectional workflow should be considered to reduce contamination risk. Ventilation, air pressure, and ultraviolet irradiation may also be considered according to the procedures performed and local biosafety requirements.

Equipment and supplies	The laboratory should define the equipment and supplies required for its designated functions, which may include HPV detection, screening, genotyping, serology, sequencing, or other specialist activities. Equipment placement should support a unidirectional workflow where relevant. Sufficient storage capacity, including refrigerators and freezers, should be available for clinical samples, reagents, and reference materials.
Procedure Manual and Standard Operating Procedures (SOPs)	The laboratory should maintain an up-to-date procedure manual and controlled SOPs for all relevant procedures, including testing, quality control, sample handling, reporting, equipment use, and safety.
Personnel	The laboratory should have appropriately trained personnel according to its scope of work. This may include HPV or molecular laboratory specialists, technical staff, quality professionals, managers, data/IT staff, administrative personnel, and logistics or support staff. Training and competency documentation should be in place
Laboratory safety	Laboratory safety policies and procedures should comply with national and local regulations. These should include procedures for handling clinical samples, use of personal protective equipment, chemical safety, waste management, and exposure control. Personnel performing laboratory work should be appropriately trained in biosafety procedures.
Collection and transport of Specimens	SOPs should describe the collection, labelling, transport, and receipt of each specimen type to be analysed. Clinical samples may be collected within the same institution, received from other healthcare centres, or self-collected, depending on the laboratory's remit and national programme design. (see Chapter-4-Collection-and-Handling-of-Specimens-for-HPV-Testing.pdf)
Registry and Preparation of Specimens	SOPs should describe specimen registration, acceptance criteria, preparation, aliquoting, processing, and traceability for each specimen type. (see Chapter-4-Collection-and-Handling-of-Specimens-for-HPV-Testing.pdf).
Storage of Specimens	SOPs should describe storage conditions, retention periods, access control, sample retrieval, and disposal for each specimen type, in accordance with national and local regulations. (see Chapter-4-Collection-and-Handling-of-Specimens-for-HPV-Testing.pdf)
Reagents	Reagents should be stored, handled, and monitored according to the manufacturer's instructions or documented laboratory procedures. Lot numbers, expiry dates, storage conditions, and acceptance checks should be recorded.
Assay run and validation	Assays should be validated or verified before routine implementation and when significant changes occur. Each assay run should be performed according to SOPs and include appropriate controls. Quality assurance procedures should be in place, as described in Chapter-3-Laboratory-Quality-Assurance.pdf .
Results reporting	The laboratory should have a documented system for reporting results to the appropriate recipient, which may include clinicians, patients, laboratories, screening programmes, researchers, or

	public health authorities. Reporting should follow national requirements and protect confidentiality and data security.
Records and data management	Laboratory records, quality records, test results, and sample data should be stored securely and retained for the required period according to national and local regulations. Appropriate IT systems, data security procedures, and laboratory information systems should be in place where relevant. (see Chapter-9-Data-management.pdf)

11.5.2 Clinical laboratory

Clinical laboratories perform HPV testing to support patient care, including cervical cancer screening, diagnosis, triage, and follow-up according to national guidelines. These laboratories are typically integrated within healthcare services, such as hospital, pathology, microbiology, or diagnostic laboratory settings.

The primary role of a clinical laboratory is to provide accurate, timely, and reliable HPV test results to support clinical decision-making. In the context of HPV, this most commonly refers to HPV detection for cervical cancer screening, although some clinical laboratories may also provide additional services, such as HPV genotyping or testing of tissue samples associated with cervical or non-cervical HPV-related disease.¹¹

Clinical laboratories vary in size, infrastructure, testing platforms, and workload. Testing may be centralized in high-throughput laboratories or performed in smaller regional facilities, depending on the organization of the health system. Test selection should therefore reflect the intended clinical use, expected sample volume, available infrastructure, regulatory status, and assay performance. For cervical cancer screening, clinically validated HPV assays should be used.

The general operational characteristics described in Table 11-1 are also relevant to clinical laboratories performing HPV testing, particularly regarding facilities, equipment, SOPs, personnel competency, biosafety, specimen management, reagent handling, assay validation or verification, quality assurance, reporting, and records.

Clinical laboratories should operate within an appropriate quality management system covering personnel competency, quality control and assessment, assay validation or verification, biosafety, reporting and record retention. Detailed guidance is provided in [Chapter 3 – Laboratory Quality Assurance.pdf](#).

In some settings, the distinction between clinical and reference laboratory functions may not be clear-cut, and a single institution may perform both.

11.5.3 Point-of-care

Point-of-care testing (POCT) refers to diagnostic testing performed at or near the location where care is provided, rather than in a centralized laboratory.¹²⁻¹⁴ For HPV testing, POCT has the potential to expand access to screening in settings where laboratory infrastructure is limited, including remote, rural, outreach, and low-resource settings. POCT may also support more efficient clinical pathways by reducing the time between sample collection, testing, and clinical decision-making.

An important advantage of HPV POCT is the potential to provide results during the same clinical encounter or within a short period after testing. This may facilitate timely referral, triage, or treatment and reduce loss to follow-up, particularly in settings where patients face barriers to repeated healthcare visits.

Although HPV POCT technologies continue to evolve and remain less established than laboratory-based HPV testing, they represent a promising approach for increasing screening coverage and supporting cervical cancer elimination efforts. The selection and implementation of HPV POCT should be based on demonstrated clinical performance, fitness for purpose, local infrastructure, and integration within existing healthcare pathways.

Where possible, HPV POCT services should be linked to a clinical or reference laboratory to support quality assurance activities, staff training, competency assessment, supervision, troubleshooting, data management, and referral pathways. Such support can help ensure the reliability and consistency of testing and facilitate integration into national screening programmes.

The desired characteristics of HPV point-of-care testing settings are described in **Table 11-2**.

Table 11-2. Desired characteristics of an HPV point-of-care testing setting

CHARACTERISTIC	DESIRED CHARACTERISTICS
Space and facilities	POCT may be performed outside a conventional laboratory, including in outpatient clinics, outreach settings, mobile units, or low-resource settings. The testing area should be clean, safe, and allow privacy for sample collection. Requirements for electricity, clean water, refrigeration, ventilation, and waste disposal should be assessed according to the test used and the local setting.

Equipment and supplies	The test may be instrument-free or performed using a small portable device. Required equipment and consumables should be defined in advance and may include sample collection kits, cartridges, heating blocks, timers, mobile phones or tablets for result read-out and data capture, and materials for safe waste disposal.
Standard Operating Procedures (SOPs)	SOPs or simplified job aids should be adapted to the POCT setting and should cover sample collection, labelling, test operation, result interpretation, recording, reporting, referral, troubleshooting, cleaning, and waste disposal.
Personnel	Testing may be performed by trained healthcare workers, laboratory personnel, or lay workers, depending on the test and programme design. ¹⁰ All operators should receive documented training and competency assessment, with supervision and refresher training where appropriate. ¹⁰
Safety and waste disposal	National and local requirements for biosafety and medical waste disposal should be followed. Even when POCT systems are closed or self-contained, procedures should address safe sample handling, use of personal protective equipment, spills, sharps where relevant, and disposal of used test materials.
Specimen collection and transport	Vaginal samples may be self-collected or collected by a healthcare worker and do not require visualization of the cervix. Cervical samples require speculum examination and collection by a trained healthcare worker. Where testing is performed immediately on site, transport may not be required; if samples are transported, procedures should define transport conditions and time limits. (see Chapter-4-Collection-and-Handling-of-Specimens-for-HPV-Testing.pdf)
Specimen registration and preparation	Procedures should ensure correct participant identification, specimen labelling, traceability, and acceptance criteria. Sample preparation should be simple and preferably integrated into the test system or performed using ready-to-use reagents. (see Chapter-4-Collection-and-Handling-of-Specimens-for-HPV-Testing.pdf)
Specimen storage	Storage requirements should follow the manufacturer's instructions. Preference should be given to collection and testing systems that tolerate a broad temperature range for storage given cold storage can be limiting. (see Chapter-4-Collection-and-Handling-of-Specimens-for-HPV-Testing.pdf)
Reagents	Reagents should be ready to use and included in the kit where possible, including reagents for sample preparation, nucleic acid extraction if applicable, amplification, and detection. Storage conditions, expiry dates, and stock control should be monitored.
Test run validation and quality control	Each test or run should be interpreted according to the manufacturer's instructions and internal kit controls. POCT programmes should include quality control procedures, supervision, troubleshooting, and, where possible, support from a clinical or reference laboratory. (see Chapter-3-Laboratory-Quality-Assurance.pdf)
Results reporting	Results should ideally be available during the same clinical encounter or on the same day as sample collection and testing. Reporting procedures should define how results are communicated

	to patients, healthcare providers, and screening programmes, and how positive results are linked to triage, referral, or treatment.
Records and data management	Results and quality records should be documented securely. Where possible, POCT devices should be connected or interfaced with electronic medical records, laboratory information systems, or screening registries, while maintaining confidentiality and data security. (see Chapter-9-Data-management.pdf)

11.6 FINAL REMARKS

The establishment or designation of an HPV laboratory, tailored to the needs and resources of each setting, is an important step toward strengthening public health initiatives for the prevention and control of HPV, cervical cancer, and other HPV-associated diseases. This does not always require the creation of a new laboratory or major initial investment. In many settings, existing laboratory infrastructure, molecular diagnostic platforms, sequencing capacity, quality systems, and trained personnel can be adapted or expanded to support HPV testing or reference laboratory functions, provided there is institutional and public health commitment.

Developing HPV laboratory capacity should therefore be viewed as a stepwise process. Strategic planning is needed to define the laboratory's purpose, expected functions, infrastructure, training needs, quality requirements, referral pathways, and sustainability. By providing reliable, accurate, and timely HPV testing, laboratories play a key role in screening, diagnosis, triage, follow-up, surveillance, and prevention of HPV-related disease.

Beyond diagnostic testing, HPV laboratories, particularly reference laboratories, can contribute to research, molecular epidemiology, surveillance, and evaluation of new technologies. Studies that improve understanding of HPV biology, genotype distribution, vaccine impact, and disease associations provide evidence to inform future vaccination, screening, and treatment strategies.

As HPV screening and prevention continue to evolve, laboratories will remain central to cervical cancer elimination efforts, particularly through the integration of self-sampling, point-of-care testing, molecular diagnostics, sequencing, and data systems. The Global HPV LabNet provides an important international platform for expert advice, peer collaboration, best-practice sharing, and support for the development and implementation of high-quality HPV testing programmes worldwide. Further information on national and international HPV reference centres is provided in [Chapter 10 and through the International HPV Reference Center: "HPV LABNET – International Human Papillomavirus Reference Center"](#).

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ANNEX I. EXAMPLES OF NATIONAL HPV REFERENCE LABORATORY MODELS

National HPV reference laboratories have evolved in different ways according to local public health priorities, available resources, healthcare structures, and historical expertise. There is therefore no single model for establishing or designating a reference laboratory. The examples presented below illustrate four HPV reference laboratory models from different countries and healthcare systems. They highlight the diversity of governance structures, funding mechanisms, responsibilities, accreditation status, and integration within wider laboratory infrastructures. While their specific mandates vary, common elements include provision of expert advice, support for quality assurance, contribution to surveillance activities, promotion of research, and collaboration with national and international stakeholders.

NOTE: These examples are intended to provide practical illustrations rather than prescriptive models.

Brazilian HPV Reference Laboratory

When were you established	2024
Who commissions/funds the service	The Brazilian Ministry of Health
Are service/activity levels described in a formal agreement which is reviewed periodically	Not yet, but an agreement is under elaboration.
What were the drivers for your establishment?	Implementation of a national HPV-based screening program
Prior to ratification of the reference laboratory, was there existing local knowledge and expertise on HPV	Yes. HPV testing had been developed and delivered for applied research projects for which grant funding had been sought and secured. However core funding allowed resilience and continuity.
Overview of core service	Provide support to guide clinical management of individual patients with HPV-related cancers (cervical, anal, vaginal, oropharyngeal) Maintains an archive of samples that contributes to surveillance, research, quality assurance and teaching. Development of advanced HPV research using multi-omic technologies Diverse HPV detection methods
Who do you routinely provide advice to	The Brazilian Public Health System (SUS); Public and private teams involved in the delivery of cervical screening; clinicians accessing the service
Additional work associated with reference laboratory	Research (requires separate, additional funding).
What accreditation is relevant for you (note this may not be relevant for labs that do not have a clinical remit)	-----
Are you located within a wider laboratory infrastructure	Yes
Links for further information	https://www.gov.br/inca/en?set_language=en https://www.gov.br/inca/pt-br/assuntos/pesquisa/pesquisa-translacional-e-aplicacao-diagnostics

French HPV Reference Laboratory

When were you established	2017
Who commissions/funds the service	Ministry of Health through "Santé publique France"
Are service/activity levels described in a formal agreement which is reviewed periodically	Yes
What were the drivers for your establishment?	Implementation of a national HPV immunisation programme (2008) and expectation of HPV based cervical screening.
Prior to ratification of the reference laboratory, was there existing local knowledge and expertise on HPV	Yes. Another laboratory held the papillomavirus NRL since 2008.
Overview of core service	Provide microbiological expertise on HPV infection, associated diseases and detection. Provide counselling to medical professionals, health authorities and patients. Provide up-dated data on HPV epidemiology in the French population. Alert the health authorities in case of any abnormal signals.
Who do you routinely provide advice to	French Public Health Agency (Santé publique France) National Cancer Institute (Institut du Cancer) High Health Authority (Haute Autorité de Santé) Technical Committee for Vaccinations (Commission technique des vaccinations)
Additional work associated with reference laboratory	Research as part of the Research Unit Chrono-Environnement, University Marie and Louis Pasteur (requires separate, additional funding).
What accreditation is relevant for you (note this may not be relevant for labs that do not have a clinical remit)	ISO15189
Are you located within a wider laboratory infrastructure	Yes
Links for further information	Centre National de Référence Papillomavirus - CHRU de Besançon Centres nationaux de référence pour la lutte contre les maladies transmissibles

Norwegian HPV Reference Laboratory

When were you established	2007
Who commissions/funds the service	Akershus University Hospital
Are service/activity levels described in a formal agreement which is reviewed periodically	The service/activity of the HPV Reference Laboratory is regulated in Circular I-5/2013 from the Norwegian Ministry of Health and Care Services. We report annually to the Norwegian Directorate of Health who evaluates our activity.
What were the drivers for your establishment?	The establishment of the HPV Reference Laboratory was driven by the need for increased competence linked to the implementation of HPV testing in the national cervical screening program as well as the HPV-vaccine introduction.
Prior to ratification of the reference laboratory, was there existing local knowledge and expertise on HPV	Akershus University Hospital had a strong scientific environment and interdisciplinary collaboration between the Department of Pathology, Microbiology and Infection Control, and the Division of Gynaecology and Obstetrics. The hospital had already secured ethical approval and funding to establish a new research biobank for cervical samples and was committed to moving forward with the initiative.
Overview of core service	The requirements and responsibilities of national reference laboratories in medical microbiology vary by agent but are all based on definitions from the ECDC report " <i>Core functions of microbiology reference laboratories for communicable diseases</i> ": • Reference diagnostics • Reference material resources • Scientific advice • Collaboration and research • Monitoring, alert and response
Who do you routinely provide advice to	We provide support to the National bodies involved in cervical screening, including the Norwegian Cancer Registry and the Norwegian cervical Screening Programme, the National Institute of Public Health and the Norwegian Directorate of Health. We also provide advice and support to clinicians and HPV screening laboratories.
Additional work associated with reference laboratory	Obtaining external research funding.
What accreditation is relevant for you (note this may not be relevant for labs that do not have a clinical remit)	The HPV reference laboratory operates in accordance with the requirements of ISO 15189, although the laboratory is not currently accredited under this standard. The principles of this standard are actively used for quality assurance through internal audits. The primary HPV screening is performed at the hospital's pathology department and is accredited according to ISO 15189.
Are you located within a wider laboratory infrastructure	The HPV reference laboratory is located within the Department of Microbiology and Infection Control, with access to a well-established, high-quality laboratory facility.
Links for further information	http://www.ahus.no/hpv-reflab

Scottish HPV Reference Laboratory

When were you established	2008
Who commissions/funds the service	National Health Service (National Services Division/Public Health Microbiology)
Are service/activity levels described in a formal agreement which is reviewed periodically	Yes
What were the drivers for your establishment?	Implementation of a national HPV immunisation programme (2008) and expectation of HPV based cervical screening.
Prior to ratification of the reference laboratory, was there existing local knowledge and expertise on HPV	Yes. HPV testing had been developed and delivered for applied research projects for which grant funding had been sought and secured. However core funding allowed resilience and continuity.
Overview of core service	Provide specialist advice and testing services to guide the clinical management of patients. Contribute to the generation of epidemiological data (including vaccine surveillance data) that is collected by national agencies Maintains an archive of samples that contributes to: • surveillance • research • quality assurance • audit • teaching
Who do you routinely provide advice to	Public Health Scotland including Immunisation teams; National teams involved in the delivery of Cervical Screening; Clinicians accessing the service (withing and outside the gynae context)
Additional work associated with reference laboratory	Research (requires separate, additional funding). Support for providers of external quality assurance scheme (separately funded)
What accreditation is relevant for you (note this may not be relevant for labs that do not have a clinical remit)	ISO15189-2022
Are you located within a wider laboratory infrastructure	Yes, situated within a department of Laboratory Medicine
Links for further information	Reference laboratories - Overview of public health microbiology in Scotland - Public health microbiology - Health protection - Population health - Public Health Scotland Microbiology reference and specialist laboratories National Services Scotland