Chapter 10 - International and National HPV Reference Centers

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Contents

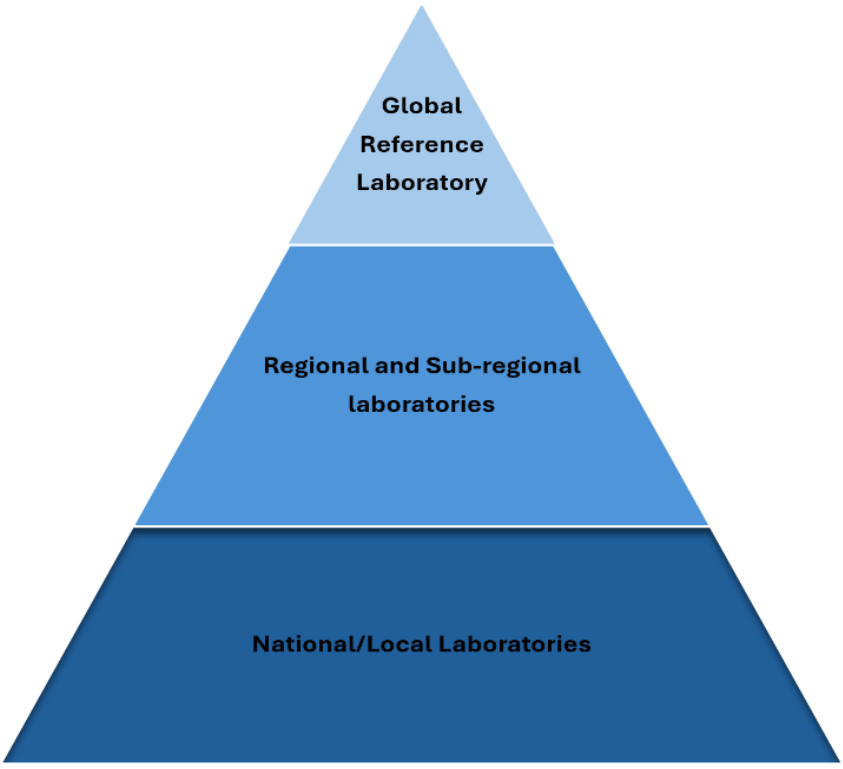
10.1 LEGACY OF WHO GLOBAL HPV LABORATORY NETWORK (HPV LABNET)

The world health organization (WHO) successfully established a global human papillomavirus (HPV) laboratory network (LabNet) in 2005, to support the introduction of HPV vaccines, and surveillance of disease and infection.[1] Back then, the terms of reference were established as the following:

Terms of reference

The proposed mission for the global HPV laboratory network is to contribute to improving quality of laboratory services for effective surveillance and HPV vaccination impact monitoring, through enhanced, state-of-the-art laboratory support. Expert laboratories will be identified to support HPV-laboratory work and will facilitate public health strategies for HPV-vaccination. The network structure comprises laboratories at three levels of involvement: reference, regional and subregional (**Figure 10-1**)

Figure 10-1 Network structure



Laboratories are expected to assume national, regional and/or international responsibilities, and to be instrumental in developing and supporting HPV laboratory work in their respective geographical areas. In its respective capacity, each laboratory would be expected to be active in the following four areas:

a) Scientific and technical advice

– Provide scientific advice to the HPV laboratory network in its region, in virological and serological surveillance of HPV infections (reference and regional levels).

– Collaborate with local and regional public health and research institutions, as well as with WHO and other international agencies, on monitoring HPV vaccination (all levels).

– Disseminate knowledge on, and the use of, HPV international standard reagents to improve accuracy of genotyping, and serological measurements and derived information (all levels).

b) Quality assurance

– Participate in developing guidelines and standard operation procedures (SOPs) for establishing a regional laboratory-based quality control programme (reference and regional levels).

– Serve as a resource for storage and distribution of standardized reagents, proficiency panels and cell lines to other laboratories as required (reference and regional levels).

– Ensure that all HPV assays perform at acceptable levels of sensitivity, specificity and reproducibility (all levels). Critical test reagents used in WHO studies should be validated by the relevant WHO reference laboratory prior to utilization.

– Participate in on-site visits to other countries/provinces as part of the WHO evaluation team, if requested (all levels).

– Perform confirmatory testing on samples from other laboratories in the project area, if necessary (reference level).

c) Training

– Contribute to developing training materials for HPV laboratory research and surveillance within its respective region, as required (all levels).

– Coordinate and participate in laboratory training workshops for staff within the laboratory network.

– Assure that sufficiently trained and qualified personnel are available to fulfill the tasks related to HPV detection and serology (all levels).

– Provide training on the appropriate collection of clinical samples for HPV typing (all levels).

It was agreed that for a functioning network the laboratories should have involvement in public health and should preferably be able to provide evidence of efforts in improving it. Reference laboratories would offer training courses (theoretical and practical) for staff members of regional laboratories. Laboratories should have experts in virology, be internationally recognized, and

should have produced publications in the relevant area. Preferably, laboratories should also have had both HPV DNA as well as specific antibody experience. Diagnostic routine work must be a separate function, and can be allowed, provided other laboratory obligations are fulfilled. Testing performed as part of network activities should not be used for clinical diagnosis.

d) Communication

– Promote and participate in the exchange of information between national, regional and reference laboratories, and the HPV laboratory network (all levels)

– In consultation with the WHO laboratory focal point, raise funds for specific activities related to the network (all levels).

– Within determined timelines, provide information to WHO on laboratory activities, and an annual compilation of virological and serological surveillance (all levels).

The HPV laboratory network will ensure the availability of competent laboratory services worldwide. Its structure will be based on three responsibility levels which will be assumed voluntarily by institutions included in the network, namely: global reference laboratories; regional and sub-regional laboratories; and national/local laboratories. Initially at least one HPV regional laboratory for each continent/WHO region would be established, namely African, Americas, South-East Asia, European, Eastern Mediterranean, and Western Pacific.

10.2 RESULTS OF GLOBAL HPV LABORATORY NETWORK

International collaborative studies indicated that in order to produce HPV data that could be compared and interpreted worldwide, international standards and standardized procedures for HPV test performance were required.[2,3,4] Therefore, initial work of the HPV LabNet focused in two major areas:

1) development and implementation of IS for HPV DNA and serology.

2) harmonization and standardization of HPV assays for use in surveillance and vaccine evaluation.

By having internationally comparable assays based on international standards available to evaluate vaccine quality and efficacy, and consistency and impact, initiatives in developing countries to formulate new HPV vaccines at reduced cost would be greatly facilitated; inter-laboratory comparability of epidemiological, clinical, and vaccine-related data gathered in various studies throughout the world would also be assured. The first HPV Laboratory manual was produced.

10.3 CURRENT GLOBAL HPV LABNET

Today, the global HPV LabNet is supported by the Bill and Melinda Gates Foundation and is composed of 15 national reference laboratories (NRL) distributed in 5 WHO Regions worldwide,

and the International Human Papillomavirus Reference Center (IHRC) which coordinates the network.

As of January 10th, 2025 these are the NRLs comprising the LabNet:

- Argentina
- Australia
- Belgium
- Brazil
- France
- Germany
- Japan
- Mexico
- Norway
- Perú
- Rwanda
- Scotland (UK)
- Slovenia
- Sweden
- USA

The current global HPV LabNet encompasses the mission of the first LabNet but has expanded in recognition of WHO's Global Strategy for cervical cancer elimination adopted in 2018.[5] WHO calls for 90% of girls to be vaccinated by age 15, 70% of women screened using a high-performance test (like HPV primary screen) by the age of 35 and again at age 45, and 90% of women with cervical cancer and precancer by 2030.[5] Therefore, the LabNet's mission also includes developing laboratory expertise and infrastructure for HPV testing used in cervical cancer screening.

The recent work performed by the global HPV LabNet includes a) distribution of proficiency panels developed for cervical screening assays,[6] b) publication of an interactive and up to date HPV Laboratory manual, c) guidance for quality assurance in HPV testing for primary cervical screening,[7] d) guidance for confirmatory testing (re-analysis of "HPV-negative" high grade lesions or worse and,[8] e) establishment of an e-learning platform aiming to provide e-resources for HPV researchers and laboratory users (available at https://www.hpvcenter.se/e-learning-resources).

10.3.1 The International Human Papillomavirus Reference Center (IHRC)

The IHRC was originally established at the German Cancer Research Center in Heidelberg in 1985 and was under the leadership of Dr. Ethel-Michele deVilliers until 2012.[9,10] In 2012, the IHRC was transferred to the Karolinska Institutet (Stockholm, Sweden), under the leadership of Dr. Joakim Dillner.

The IHRC coordinates the global HPV LabNet. also It is responsible for confirming DNA sequences of novel HPV types after the whole genomes have been cloned, assigning HPV type numbers, depositing and maintaining the reference clones.[11] The IHRC also distributes samples of the

reference material for research use (following MTAs with the clone owners) (https://www.hpvcenter.se/services/).

Furthermore, the IHRC has, since the outset, coordinated global HPV DNA typing proficiency studies to a) assess the proficiency of HPV typing assays routinely used in laboratories worldwide, b) evaluate the sensitivity and type-specificity of HPV detection of these HPV assays and, c) identify problems with any assays routinely used.[4,12-18] Each HPV DNA typing proficiency panel includes 41 specimens (+3 extraction controls) designed for HPV typing assays used in monitoring HPV vaccine impact (vaccinology). Accurate and internationally comparable human papillomavirus (HPV) DNA typing is essential for HPV vaccine research and for HPV surveillance. Evaluation of the HPV testing assays, as actually performed in different laboratories, is essential to ensure the quality, reliability, and accuracy of HPV-based typing services. In addition, the existence of WHO-established International Standards (IS) enables a globally uniform definition of the amounts of virus detected by different assays in different laboratories.

Since 2008, the typing proficiency assessment has been repeated annually. The success of the program demonstrates that it is possible to perform continuous global studies based on plasmid DNA with unitage traceable to international standards. Each annual assessment provides an overview of the status of HPV detection and typing methodologies worldwide. Annual results showed continued improvement in proficiency except for the study performed in 2019, where a worldwide deterioration in comparability and reliability of HPV testing was found.[16] However, studies from 2021, 2022 and 2023 revealed a reverse trend and an overall increase in proficiency, suggesting that continuing proficiency testing is helpful to sustain accuracy and to avoid a deterioration in proficiency.[17,18]

Proficiency criteria for clinical HPV assays differ as the requirement is not for analytical sensitivity but for clinical sensitivity. The analytic threshold for clinical sensitivity differs by HPV type. For HPV screening, it is important to detect the most carcinogenic viruses (HPV16 and 18) at high sensitivity, but for less carcinogenic viruses a lower analytic sensitivity is more appropriate. In addition, only 14 types are included in clinical assays, and most do not specify the type(s) detected.

As the traditional HPV proficiency panel (typing panel) contains 44 challenge samples, many laboratories have asked for a smaller proficiency panel tailored to what is important for assessing the quality of HPV screening services. Testing for oncogenic HPV in cervical cancer screening is a globally recommended health policy and therefore, since 2022 the International HPV Reference Center has been conducting a parallel proficiency test for cervical cancer screening assays, the HPV screening proficiency panel.[6,20] The first round had a total of 84 laboratories submitting 158 datasets (laboratories could submit datasets from >1 HPV testing platform). Of those, 122 (77%) were 100% proficient.[6] In 2023, 95 laboratories participated submitting 152 datasets and proficiency increased up to 91%.[20]

IHRC: Where to find us:

Center for Cervical Cancer Elimination
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10.3.2 National HPV Reference Centers (NRLs)

As of January 2025, a total of 15 NRLs distributed in 5 WHO Regions are members. Each member laboratory has responsibilities in the areas of 1) scientific and technical advice, 2) quality assurance, 3) training and, 4) communication (https://www.hpvcenter.se/hpv-labnet/). Specific tasks are defined for each reference laboratory based on its expertise and capacity.

Tasks of national/local laboratories are to:

- provide assistance as required in transferring laboratory technology, methodology and protocols on HPV DNA and antibody detection to other laboratories within their country
- provide information on the use of international standard reagents for HPV DNA and antibody detection
- participate in quality assurance programme
- comply with biosafety guidelines
- refer selected HPV isolates to reference laboratories for sequencing
- coordinate with national authorities on all laboratory-based information relating to HPV diseases
- report results in a timely manner.

As already described before, countries with member NRLs are as follows: Argentina, Australia, Belgium, Brazil, France, Germany, Japan, Mexico, Norway, Perú, Rwanda, Scotland (UK), Slovenia, Sweden, Turkey and USA. Additional NRLS are always welcome to the LabNet, with the requirement of being actively working with HPV (screening and research) and being appointed as NRL by the corresponding national authority.

A summary of their activities and contact information is presented in chronological order.

10.3.2.1 ARGENTINA NRL

Where to find us:

National Institute of Infectious Diseases-ANLIS "Dr. Malbran"

Oncogenic Viruses Laboratory, Virology Department

HPV National and PAHO Regional Reference Laboratory

Av. Velez Sarsfield 563, C1282AFF- Buenos Aires, ARGENTINA

Competence

The HPV Reference Laboratory of Argentina (Ministry of Health) has been working on this virus for decades, implementing and updating molecular techniques for typing, leading research mainly related to HPV molecular epidemiology, pathogenesis, cervical cancer screening using HPV testing (ESTAMPA study) and HPV vaccine impact evaluation. Likewise, it has been actively training laboratory personnel and supporting the prevention of cervical cancer through permanent interaction with the National Programs for Cervical Cancer Prevention (screening) and Immunopreventable Diseases (HPV vaccination).

Since 2008, it acts as the Pan-American Health Organization (PAHO) HPV Regional Reference Laboratory for Latin America (in the framework of the former WHO HPV LabNet, created in 2006). It maintains an active interaction with the current HPV LabNet, contributing to the vaccine monitoring and implementation of HPV testing for screening, with special focus on quality assurance.

Members

- María Dolores Fellner, PhD. Senior Researcher, Head
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- María Alejandra Picconi, PhD. Senior Researcher-Scientific Advisor
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- Rita Mariel Correa, PhD. Deputy Head, Senior Researcher
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- Jorge Basiletti, MSc. Researcher
- Maria Celeste Colucci, BSc. Researcher
- Florencia Torrá, Biochemist. Researcher
- Karina Durand. Senior laboratory analyst
- Valeria Padin. Senior laboratory analyst
- Martin Rogé. Junior laboratory analyst
- Cristian Proruk. Administrative assistant

10.3.2.2 AUSTRALIA NRL

Where to find us:

The Royal Women's Hospital

Grattan Street, Parkville,

Melbourne, Victoria, 3052

Australia

Competence

The laboratory has a multidisciplinary team with backgrounds in sexual health, clinical microbiology, molecular biology, bioinformatics, and epidemiology. The laboratory research interests span both cervical and anal cancer, including the development and evaluation of diagnostic methods, and the characterization of biomarkers of disease. The laboratory has coordinated the Australian National HPV Monitoring Program since 2014, with the objective of monitoring the impact of the Australian National HPV Vaccination Program. Additionally, the laboratory provides support for international projects on HPV including quality assurance for projects in South Africa, Ethiopia, Vietnam and Fiji. Our laboratory regularly prepares material for the Royal College of Pathologists of Australasia Quality Assurance Survey.

Members

Prof Suzanne Garland: Clinical microbiologist and group leader

Dr Gerald Murray: Senior scientist

Dr Dorothy Machalek: Epidemiologist

Dr Monica Molano: Postdoctoral Researcher

Dr Jennifer Danielewski: Postdoctoral Researcher

Ms Prisha Balgovind: Research Assistant

Ms Yanping Huang: PhD student

10.3.2.3 BELGIUM NRL

Where to find us:

Sciensano

Infectious Diseases in Humans, Viral Diseases

Rue Juliette Wytsman 14

1050 Brussels, Belgium

https://www.sciensano.be/en/nrc-nrl/national-reference-center-nrc-human-papillomavirus

Competence

The Belgian National HPV Reference Center is a multidisciplinary group, comprising clinicians, epidemiologists and virologists with competencies in HPV virology, prevention and treatment of HPV-related disease. Sciensano acts as coordinator of the NRL, whereas HPV molecular diagnosis and typing is performed at the AML laboratory and whole genome sequencing at Ghent University Hospital. The Belgian NRL oversees the national HPV surveillance program and the organization of a proficiency test. The NRC is also involved in HPV research activities.

Members

Marc Arbyn
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10.3.2.4 BRAZIL NRL

Where to find us:
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Competence

The Brazilian National HPV Reference Center, located at the Tumor Genetics and Virology Program at INCA, is one of the two groups within the Program that develops a wide range of studies at the basic, clinical, R&D and implementation levels concerning the human papillomavirus and associated malignancies. We are part of the Governing Council of the Brazilian Ministry of Health that is responsible for the approval and implementation of HPV molecular testing in the Brazilian Public Health System (SUS), in accordance to the national program towards cervical cancer elimination in Brazil. We are also responsible for testing and validating domestic solutions for HPV molecular testing to be used in Brazil and eventually in other Latin American and also in African countries.

At the basic investigational level, we develop protocols to study HPV prevalence and molecular characterization, as well as associated determinants (microbiome, sociodemographic factors, etc.), in the general population and also in particular settings (e.g., cancer patients, people living with HIV, transgender subjects, quilombolas and indigenous peoples). To achieve that, the laboratory is highly well equipped with state-of-the-art technologies, such as next-generation sequencing (NovaSeq X Plus, NextSeq 1000, MiSeq), cell culture facilities (including one BSL- 3 laboratory for small animal research), and robust bioinformatics resources.

Tumor Virology Members

Marcelo A. Soares,
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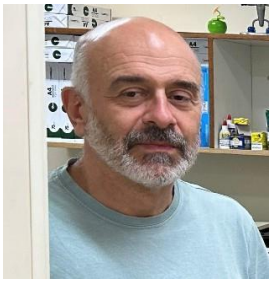

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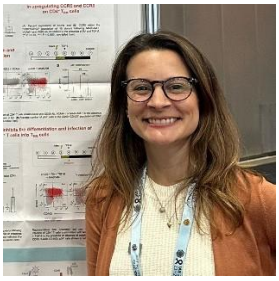

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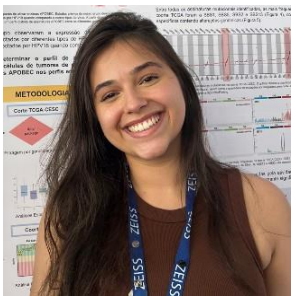

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10.3.2.5 FRANCE NRL

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Centre National de Référence Papillomavirus

Competence

The French National HPV Reference Laboratory is a unit within the "Oncobiology, Genetics and Bioinformatics" department of the Besançon University Hospital. In addition to the processing of hospital samples for cervical cancer screening, the team provides expertise and counselling on HPV infection and associated diseases and participates in epidemiological surveillance studies of HPV infection. The medical members are cell biologists and virologists involved in the HPV NRL on a part-time basis, alongside their respective hospital and university activities. The NRL also benefits from the expertise of the research team "HPV-associated carcinogenesis: predictive and prognostic factors" from University of France-Comté, involved for over twenty years in basic and translational research into HPV infection and associated lesions.

Members (0.8 and 2.6 FTE medical and paramedical personnel respectively)

Pr Jean-Luc Prétet, PhD, Head of the French NRL: jean_luc.pretet@univ-fcomte.fr
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10.3.2.6 GERMANY NRL

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Competence

The German National HPV Reference Center is located at the Institute of Virology of the University Hospital of Cologne. It was nominated by the German Federal Ministry of Health in 2009 and is re-evaluated every three years. Concerning HPV, our focus is on improvement and quality management of HPV diagnostics, laboratory-developed tests, as well as clinical and epidemiological studies.

Members

Prof. Dr. Ulrike Wieland, Head of the NRC ulrike.wieland@uk-koeln.de
Dr. Steffi Silling, Deputy Head, Senior laboratory analyst steffi.silling@uk-koeln.de
Univ.-Prof. Dr. Baki Akgül, HPV research group leader baki.akguel@uk-koeln.de

10.3.2.7 JAPAN NRL

Where to find us:

Pathogen Genomics Center

National Institute of Infectious Diseases

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Tokyo 208-0011, Japan

Email address: ikuki@niid.go.jp

Competence

1. Perform HPV surveillance to monitor the impact of HPV vaccines in Japan
2. Provide quality-assured HPV genotyping and serology assays
3. Perform quality control of HPV vaccines

Members

Iwao Kukimoto: Head of Laboratory, ikuki@niid.go.jp

10.3.2.8 MEXICO NRL

Where to find us:

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Web site**:** https://www.gob .mx/salud/acciones-y-programas/instituto-de-diagnostico-y-referencia-epidemiologicos-indre

Competence

The Molecular Methods Transfer Laboratory at InDRE is a technological development area for the desing and evaluate molecular techniques for diagnosis and characterization of infectious agents with importance in public health. Since 2016, it has collaborated with the National Cervical Cancer Prevention Program to design external quality control strategies to monitor the performance of laboratories that are part of the program's support network. It also carries out research projects focused on the genetic and genomic characterization of high-risk HPV genotypes that are prevalent in the Mexican population.

Team members

- Alejandra Armengol Alonso, MD. Director of Cervical Cancer Prevention Program
- Kathia Carolina Vázquez Guzmán. Cervical Cancer Prevention Program Direction
- Lucía Hernández Rivas, MSc. Director of Services and Technical Support
- Imelda Eréndira Molina Gómez, MSc. Department of Molecular Biology
- Judith Estevez Ramírez, MSc. Sample Control and Services Department
- Ludwig Erick González Mena, MD. Pathology Coordination head
- Elizabeth Andrade Montiel, QBP. Molecular Methods Transfer Laboratory analyst
- María del Carmen Esteban Valencia, Biol. Molecular Methods Transfer Laboratory analyst
- Diana Rangel Medrano, QBP. Cervical Cancer Prevention Program analyst
- Claudia Rubicela González Contreras, EBC. Cervical Cancer Prevention Program analyst
- Miguel Aarón Moreno Jiménez, MSc. Cervical Cancer Prevention Program analyst
- David Esaú Fragoso-Fonseca, MSc. Molecular Methods Transfer Laboratory analyst
- Noé Escobar-Escamilla, PhD: Molecular Methods Transfer Laboratory head
- Laboratory Network supporting the Cervical Cancer Prevention Program

10.3.2.9 NORWAY NRL

Where to find us:

Akershus University Hospital,

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Email address: hpvreflab@ahus.no

Competence:

The responsibilities of the Norwegian HPV Reference Laboratory include reference diagnostics, HPV vaccine surveillance and research. In addition, the laboratory provides advice and support to laboratories and authorities for improved diagnostics, quality assurance and regulations.

The laboratory works closely with the Cancer Registry of Norway managing the cervical cancer screening programme, and with the Norwegian Institute of Public Health being responsible for the Norwegian vaccine surveillance programme. To study changes in HPV type distribution as part of the vaccination programme, the laboratory is responsible for HPV typing of tissue samples obtained from all pathology departments in Norway. This work comprises biobanking of DNA and reporting the HPV-data to the Norwegian Surveillance System for Communicable Diseases.

In collaboration with Oslo Metropolitan University and The Cancer Registry of Norway, our research projects focus on new developments using next generation sequencing and bioinformatics, including HPV whole genome sequencing investigating HPV genomic variability, chromosomal integration and cancer risk stratification.

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Irene Kraus Christiansen: PhD, Head of laboratory. irene.christiansen@ahus.no

10.3.2.10 PERÚ NRL

Where to find us

National Institute of Health,

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National Reference Laboratory for Sexually Transmitted Viruses (NRL STV)

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Email adress: vts.cnsp@ins.gob.pe

Website: https://www.gob.pe/ins

Competence

The Peruvian HPV Reference Laboratory has a multidisciplinary team with experience in public health and molecular biology. The laboratory's research interests focus on cervical cancer and the evaluation of diagnostic methods.

The laboratory interacts continuously with the National Cancer Control Programme of the Ministry of Health through the interoperability of information systems, the preparation of technical reports, as well as in the supervision, training, and development of regulations for the improvement and management of the quality of HPV diagnostics in first-level care laboratories that conduct cervical cancer screening using molecular HPV tests.

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10.3.2.11 RWANDA NRL

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Competence:

The National Reference Laboratory (NRL) was established in 2002 under the auspices of the Ministry of Health with the primary objective of enhancing diagnostic capabilities across Rwanda by providing training and technical support to the laboratory network, performing specialized tests, establishing quality assurance, conducting disease surveillance and supporting research. We are committed to supporting healthcare providers, policymakers, and various stakeholders in their efforts to combat diseases and improve the overall health outcomes of the Rwandan population and citizens of other countries residing and temporarily staying in Rwanda.

The NRL is composed of six units namely: Microbiology (Bacteriology, Mycobacteriology, and Parasitology), Immuno-virology (Molecular Virology, Immunology, Serology), Clinical Pathology (Biochemistry and Hematology), Laboratory Services Coordination and Quality Assurance, Molecular Genomics, and Medical Entomology.

The National Reference Laboratory (NRL) oversees the screening of Human Papilloma Virus (HPV) in Rwanda. We have a target to screen over 20,000 women throughout the country. The HPV testing includes both the Polymerase Chain Reaction (PCR) and sequencing. The NRL provides technical assistance to the HPV testing laboratories through staff training and development of testing documents.

Members:

Dr. Noel Gahamanyi, PhD
Ag. Division Manager, NRL
Unit

Emmanuel Kabalisa
Director of Immuno-Virology Unit

Kayigi Etienne
Director of Clinical Pathology Unit

Esperence Umumararungu
Director of Molecular Genomics

10.3.2.12 SCOTLAND NRL AND ASSOCIATED HPV RESEARCH GROUP

Where to find us:

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EH16 4SA

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Competence

The Scottish HPV Reference Laboratory (SHPVRL) is commissioned by National Services Division and Public Health Scotland and hosted by NHS Lothian. It provides an analytical and advisory service to NHS Boards and Public Health Scotland in relation to identification, testing and typing of HPV, and supplies detailed epidemiological information for health protection purposes. SHPVRL is accredited to ISO 15189 standards and is a prequalification laboratory for the WHO.

SHPVRL also provide advice and materials to support quality assurance related to HPV testing including for the Scottish Cervical Screening Programme. The team at SHPVRL are involved in an active portfolio of research and development in the context of both anogenital and head and neck disease and work very closely with the HPV Research Group (HPVRG) at the Centre for Reproductive Health, University of Edinburgh, where the Scottish HPV Archive, a biobank to support HPV research, is also based.

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10.3.2.13 SLOVENIA NRL

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Competence

The Slovenian National HPV Reference Center is a multidisciplinary research group comprising both clinical and basic science researchers. Research activities are wide and include several HPV-related topics: all diagnostic aspects of HPV, development of novel HPV tests, evaluation of various commercial HPV tests, periodic global inventory of commercial HPV tests, detection of HPV in archival clinical specimens, genomic diversity of selected HPV types, identification and characterization of novel HPV types, as well as etiopathogenesis and natural history of HPV-related anogenital and extragenital benign and malignant tumors. The center provided samples and coordinated validation of HPV genotyping tests (VALGENT-3), the largest head-to-head comparison of HPV assays performed from the original clinical sample. The center has always been open to observers, trainees, and young researchers, and more than 90 colleagues from across the world have visited our center. In the last 15 years the center positioned itself as a leading advocate for implementing primary (HPV vaccination) and secondary (HPV-based screening) cervical cancer prevention in central and eastern Europe. The center is performing routine HPV testing for five clinical indications as part of the national organized cervical cancer cytology-based screening program with the coverage over 70% (approximately 12,000 HPV tests annually).

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10.3.2.14 SWEDEN NRL

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Competence

The Swedish National HPV Reference Center is a multidisciplinary group including a wide range of competencies and backgrounds conducting both clinical and research studies. The clinical group is responsible for screening all HPV samples from the organized screening program at Stockholm Region and biobanking all these specimens. The main task for the National HPV reference center is confirmatory testing, where all cervical high-grade lesions (HSIL) or worse that are tested as HPV negative by any laboratory in Sweden, are sent to the NRL for re-analysis.

The research group conducts related research including next generation sequencing, bioinformatics as well as e-learning resources. The International HPV Reference Center, responsible for quality and standardization of HPV testing, works in close collaboration with the National reference Laboratory.

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10.3.2.15 USA, US Centers for Disease Control and Prevention, HPV Laboratory

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Competency

The HPV Laboratory in the US Centers for Disease Control and Prevention was established in 1997. The initial focus was to establish the natural history of HPV, investigate HPV molecular biology and establish HPV as the prime risk factor for cervical and anogenital cancer. The lab's focus has shifted to high throughput testing and methods development to address public health questions. The laboratory served as one of two Global Reference Laboratories for the WHO HPV Laboratory Network (2007-2011).

The laboratory monitors HPV impact in the US through several ongoing surveillance initiatives, including the general population [National Health and Nutritional Evaluation Survey (NHANES)], at risk populations [anogenital HPV in MSM and women living with HIV], and type-specific prevalence in cancers. The laboratory supports vaccine implementation through data on serologic response to altered and reduced dosing strategies, evaluating novel administration routes, and supporting development of biosimilar HPV vaccines. The laboratory has been active in preparing and validating HPV standards for DNA and antibodies and has prepared a unique set of HPV plasmids with all reading frames intact that are applicable as reference reagents for all HPV DNA assays. In addition, the laboratory is involved in training and laboratory infrastructure support for HPV testing globally. CDC's laboratory developed M9ELISA and enriched whole genome sequening assay (eWGS) are notable contributions to the field.

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10.4 REFERENCES

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