Global HPV Reference LabNet Meeting – Minutes

Date: 17 April 2026

Location: Virtual (Microsoft Teams)

32 participants from 15 NRLs

MSF, Netherlands, Denmark and WHO representatives attending

Name	NRL/Country
Dolores Fellner	Argentina
Mariel Correa	Argentina
María Alejandra Picconi	Argentina
Marc Arbyn	Belgium
Sharon Dhillon	Belgium
Marcelo A. Soares	Brazil
Vanessa Schulz	Canada
Aida Sivro	Canada
Jesper Hansen Bonde	Denmark
Jean-Luc Pretet	France
Steffi Silling	Germany
Ulrike Wieland	Germany
Francesca Carocci	Italy
Clementina Cocuzza	Italy
Marianna Martinelli	Italy
Iwao Kukimoto	Japan
Noé Escobar	Mexico
Federica Inturrisi	MSF
Dieneke Hoeve-Bakker	Netherlands
Lesly Solis	Peru
Kate Cuschieri	Scotland
Mario Poljak	Slovenia
Anja Oštrbenk	Slovenia
Camilla Lagheden	Sweden
Sadaf Sakina Hassan	Sweden
Emel Yilmaz	Sweden
Joakim Dillner	Sweden
Sara Arroyo	Sweden
Nannan Jiang	USA
Anian Wu	USA
Nguyen Van Trang	Vietnam
Maribel Almonte	WHO

Agenda

13:00 - 13:10 Introduction (Joakim Dillner)

13:10 – 13:20 Introduction of new members (Canada and Vietnam)

13:20 – 13:30 Eurogin LabNet session: Summary (Sara Arroyo)

13:30 - 13:50 International Collaborative Study on Limit of Detection of HPV virus types and discussion on evaluation of new HPV tests (Joakim Dillner)

13:50 – 14:45 Working groups (5- 10 min each)

- International collaboration on HPV prevalences (Argentina, France, Nethrlands. Peru and Sweden on board so far).
- Sample adequacy (Mario & Clementina)
- HPV negative tumors (Sara Arroyo: Norway, Denmark, Australia, Germany, Slovenia on board)
- HPV Lab Manual and elearning resources (Sara Arroyo. Chapters ongoing)
- International Task Force (Kate Cuschieri. Twinning.)

14:45 Questions and concluding remarks

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1. Introduction

Joakim opened the meeting, introduced the agenda, and emphasized the increasing importance of working groups as LabNet continues to expand.

He highlighted the core areas of activity:

- The current funding focus: Development of inexpensive and internationally standardized strategies for evaluation of HPV assays.
- Other core activities:
    - Genotyping and screening proficiency panels remain central.
    - Networking for mutually beneficial collaboration continues to be a key component.

Proficiency Panel Results

- 2025 Proficiency screening study: 195 datasets from multiple laboratories (global distribution expanding).
- While initial participation was mainly from Europe and North America, there is an increasing participation from:
    - Latin America (notably Argentina and Peru organizing QA schemes)
    - Africa (growing representation, positive for global coverage)
- Performance results**:**
    - HPV 16/18 detection: 96% detected mandatory 10 IU
    - Medium oncogenic types (1000 IU): 99–100% detection
    - Overall assay performance: 177/195 datasets achieved 100% proficiency
    - Dominant platforms: Cobas 4800 and Abbott Alinity m

LabNet Expansion

- Current composition: 19 laboratories. Italy has 2 regional laboratories (Lombardy and Tuscany)
- Potential new National Reference Laboratories (NRLs):
    - Ethiopia, Netherlands, Ghana, Denmark (ongoing discussions)

2. Introduction of new members: Canada and Vietnam

Ppts are attached at the end of the pdf.

3. Eurogin LabNet Session & WHO Collaboration.

- Summary of Eurogin was presented by Sara Arroyo.
- The ppts from all speakers are available at https://www.hpvcenter.se/wp-content/uploads/LabNet_Eurogin_2026.pdf

4. International Collaborative Study on Limit of Detection of HPV virus types and discussion on evaluation of new HPV tests

A total of 300 clinical specimens (100 CIN2+ and 200 population-based controls without disease) were distributed and quantified for HPV across 10 NRLs. The study is now in press in *Journal of Medical Virology*.

Proposed thresholds for HPV detection (for CIN2+) are:

- HPV16/18: 3 IU/µl
- Other vaccine types and HPV 35: 25 IU (HPV31, 33, 35, 45, 52 and 58)
- HPV 39, 51, 56, 59: 100 GE (low contribution to cancer)

Key considerations:

- Thresholds optimized for high sensitivity without loss of specificity
- 1 IU/µl desirable for HPV16/18 but technically challenging → 3 IU adopted

Validation:

- Swedish registry-linked dataset (~120,000 samples) confirmed thresholds
- Self-sampling dataset (~175,000 samples) yielded similar thresholds

Suggested Next Steps

- Encourage NRLs with PCR databases linked to cancer registries to replicate analyses
- Move toward international consensus on HPV assay validation criteria

Proposed framework for HPV assay validation:

- Use international standards (plasmids). Next HPVLabNet screening proficiency panel will use the published thresholds.
- Include clinical samples: Controls and CIN2/3 cases weighted by HPV type importance
- Prepare NRLs for national assay evaluation demands
- Additional requirement: Include sample adequacy control in assays

Technical Discussion Outcomes

Need to circulate/develop a standardized procedure on how to convert Ct values to International Units (IU)/ul.

5. WORKING GROUPS

5. 1. HPV Prevalence Studies – Concerns & Proposal

Over 20,000 publications on HPV prevalence:

- Many lack quality-assured assays
- Study design often unclear
- Vaccination data frequently missing

Implication: Key data on vaccination effectiveness and screening design may become unpublishable.

Observations from Sweden:

- HPV16/18 prevalence declining sharply
- >83% vaccination coverage in school-based programs
- Non-vaccine HPV types remain more common
- Indirect protection observed beyond vaccinated cohorts (herd immunity)

Proposal: Guideline paper on requirements for HPV prevalence studies. Requirements:

- Use LabNet-proficient laboratories and validated assays
- Clearly defined sampling strategy (population-based, calendar year)
- Include vaccination coverage data

Interested countries: Netherlands, Argentina, France, Italy, Peru, Slovenia, Sweden

5. 2. Sample Adequacy Activities

Eurogin 2026 session:

- *"Sample cellularity as an obligatory component of QA in HPV-based screening"*
- Emphasis on the need to integrate sample adequacy assessment into QA frameworks

Ongoing work:

- Compilation of internal control (IC) Ct thresholds from manufacturers
- Evaluation of IC use across validated HPV assays

- Creation of a database of IC targets and Ct cut-offs
- Development of “challenging” sample panels (Mario & Anja)

Key considerations:

- Current IC cut-offs are manufacturer-defined and not independently validated
- Sample cellularity impacts HPV Ct values and test performance
- Lack of standardized criteria for defining sample adequacy in HPV testing

Future directions:

- Collect IC Ct data from national screening programs
- Evaluate HPV positivity across IC Ct intervals
- Assess sample adequacy in:
    - Cytology-inadequate samples
    - HPV-negative cancer cases

Presentation from Clementina included at the end of the slides

5. 3. HPV negative tumors

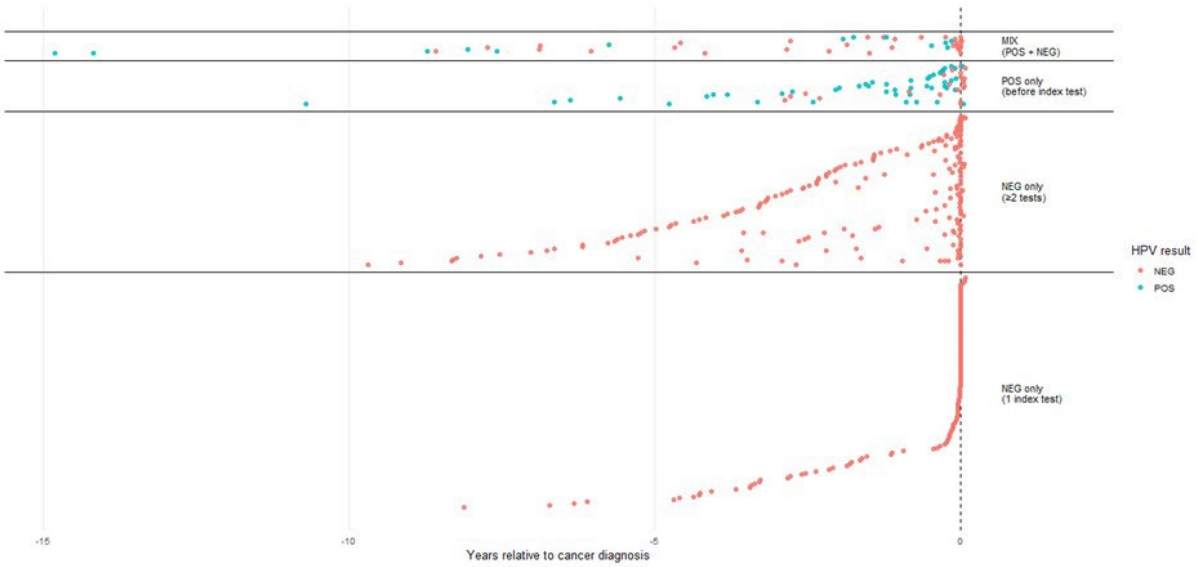
Lead: Sara Arroyo

Biomarkers for HPV negative tumors

Focus on HPV negative tumors, building on quality-assured confirmatory testing of HSIL+ HPV-negative cases

Key findings (Registry data)

- Women with HPV-negative tests prior to cancer diagnosis tend to be older, are diagnosed at more advanced stages and often have limited or no prior screening history
- Testing patterns:
    - Majority had only HPV-negative results
    - A small proportion had transient HPV positivity that cleared
    - HPV fluctuating positivity is very rare (~1/3000 cases)



(Invasive cervical cancers after an HPV-negative test: insights from screening histories | medRxiv)

Next steps:

- Expand international collaboration to increase sample size: Australia, Denmark, Denmark, Slovenia, Norway and Germany involved.
- Harmonize case definitions and inclusion criteria.
- Develop joint analytical strategy

5.4 HPV Lab Manual & e-learning

Status:

- Chapters currently under development
    - Laboratory setup
    - HPV assay validation
    - Proficiency panels
    - WHO target product profile for HPV screening tests
    - Registry and quality assurance (QA)

Educational strategy:

- Emphasis on decision support rather than traditional education
- Need to develop practical, accessible resources:
    - Short laboratory guides (2-page format)
    - Decision trees

    - Micro-learning resources

Next steps:

- Develop complementary materials:
    - Podcasts linked to key publications
    - Chatbot support integrated into the HPV Center website
- Transition towards:
    - Decision-support tools. Example: IHRC guidance on expected HPV test performance (included in supporting materials)

5.5 . Capacity Building & Collaboration

Lead: Kate Cuschieri

Context: The HPV Lab Manual provides general guidance, but:

- Laboratories operate in diverse settings with specific challenges
- Additional tailored support is often required
- Direct mentorship (remote or in-person) remains difficult to replace

Proposed mentorship models

- Model 1: Skill-based mentorship register
    - Labs register as mentors for specific activities (e.g., QA, assay verification, sample extraction)
- Model 2: Ad hoc partnerships
    - Based on existing collaborations or strategic links. LabNet maintains a list of partnerships
- Model 3: Partner organization–driven approach
    - Collaboration with organizations such as World Health Organization or other partners
    - Identification of priority settings requiring support
    - LabNet assigns mentorship on a case-by-case basis

Key considerations

- Resources required to support mentorship (especially on-site work)

- Institutional support from mentor laboratories
- Alignment with LabNet mandate and responsibilities
- Need for: Training materials, SOP templates, QC databases and verification tools

Discussion points and planned actions

- Preferred mentorship model(s) for LabNet (survey to NRLs be sent)
- Identification and validation of core training materials
- Engagement with external partner organizations

Presentation from Kate Cuschieri is shared at the end of the pdf.

6. Closing

Open discussion and questions

Emphasis on:

- Strengthening global collaboration
- Standardization of methods
- Development of inexpensive and internationally standardized strategies for evaluation of HPV assays
- Supporting laboratories worldwide (IHRC can support travel for lab twinning initiatives)

NRL Canada

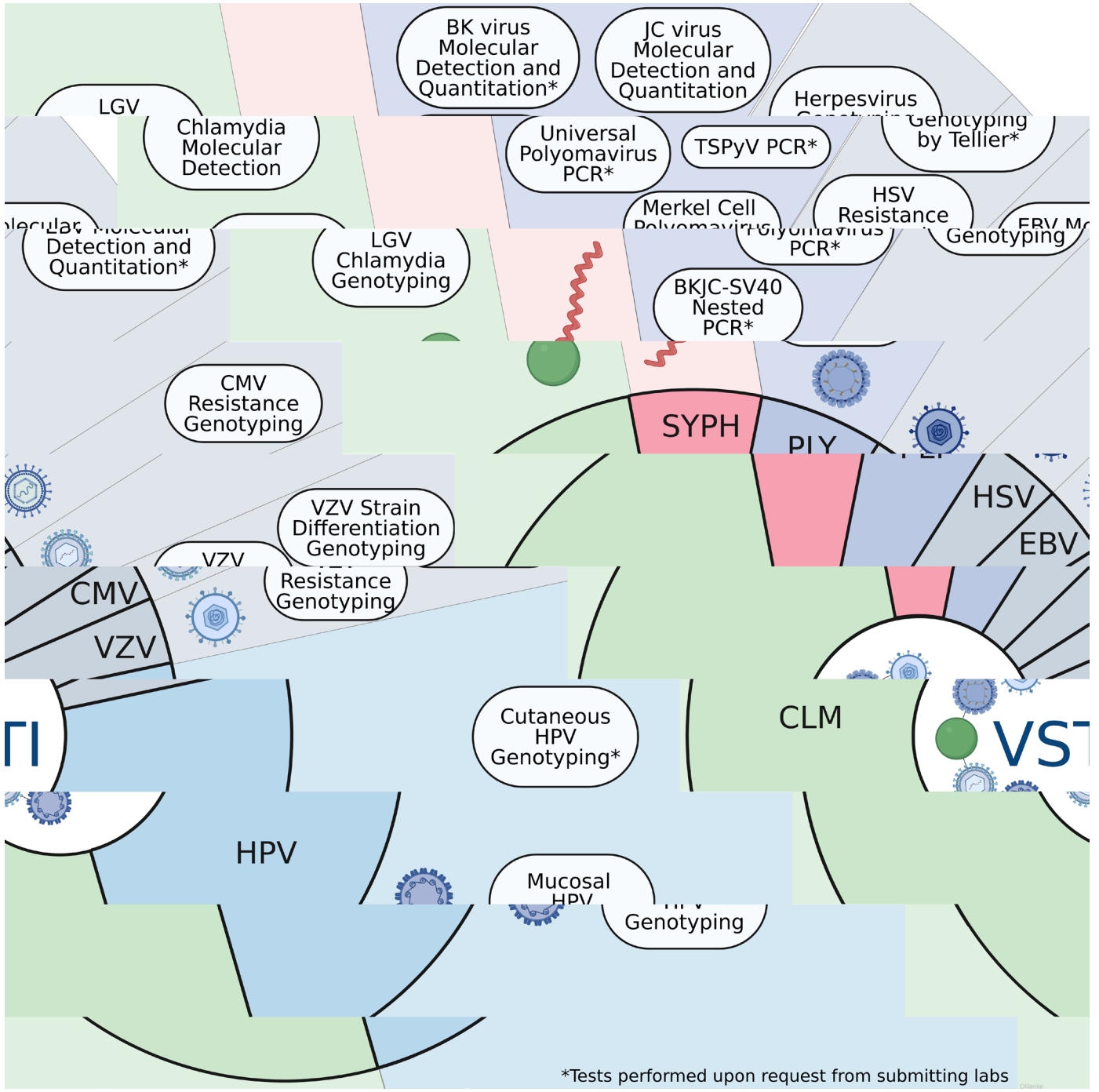
Public Health Agency of Canada (PHAC)

National Microbiology Laboratory (NML)

Public Health Agency of Canada

Agence de la santé publique du Canada

SEXUALY TRANSMITTED AND OPPORTUNISTIC PATHOGENS (STOP) SECTION



Guide to services

Viral Sexually Transmitted Infections - Guide to Services – CNPHI (Section undergoing name change from VSTI to STOP)

HPV testing is undergoing revamp – addition of secondary assays targeting E6/E7 and HPV Deep Sequencing for cutaneous HPV testing and HPV negative samples

In house developed assay (L1 DNA)

- Assay can genotype 46 HPV types
- High risk: 16,18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68
- Possibly high risk: 26, 53, 69, 70, 73,
- Low risk: 6,11, 40, 42, 54, 61, 62, 71, 81
- Others: 13, 30, 32, 43, 44, 67, 72, 74, 82, 83, 84, 85, 86, 87, 89, 90, 91, 97)

Novel Microsphere-Based Method for Detection and Typing of 46 Mucosal Human Papillomavirus Types

Vanessa Zubach,[a] Gerry Smart,[b] Samuel Ratnam,[a,c] and Alberto Severini[a,d]

National Microbiology Laboratory, Public Health Agency of Canada, Winnipeg, Manitoba,[a] Cadham Provincial Laboratory, Winnipeg, Manitoba,[b] Faculty of Medicine, Memorial University, St. John's, Newfoundland and Labrador,[c] and Department of Medical Microbiology and Infectious Diseases, University of Manitoba, Winnipeg, Manitoba,[d] Canada

HPV Studies -> national

Deborah Money (UBC) **National NOVA study**	A Study of Reduced Dosing of the Nonavalent HPV Vaccine in Women Living with HIV Improving HPV vaccination strategies
Jennifer Brown Broderick (Saskatchewan Cancer agency) and Jessica Minion (Saskatchewan Health Authority	HPV Self-Sampling for Primary Cervical Cancer Screening in Underserved Saskatchewan Women
Sarah Kean (Cancer Care Manitoba)	CERVICAL CANCER IN MANITOBA: ARE WE MOVING TOWARDS ELIMINATION?

HPV Studies -> international

 **Chemtai Mungo** (University of North Carolina)	Factors driving HPV-cancer development in rural Kenya
 **Keith Fowke/ Joshua Kimani/Lyle McKinnon** (University of Manitoba)	HPV therapeutic vaccine – immunological drivers of HPV clearance
 **Souleymane Diabate** (University of Laval)	Cervical Cancer Prevention in Côte d'Ivoire, West Africa: Evaluation of Quadrivalent Vaccine Efficacy for human papillomavirus in a pilot project for girls aged 9 to 13 years

Additional HPV research interests: Alternative sample collection methods

| Clinical Microbiology | Research Article | 2 April 2026

Development and evaluation of dried urine strip for genital chlamydia and gonorrhea testing

Authors: Suzanne Gibbons, Clarissa Klenke, Felicia Roy, Vanessa Schulz, Kimberly Ta, Sharon Simon, Jennifer Beirnes, SHOW ALL (21 AUTHORS) , Aida Sivro | AUTHORS INFO & AFFILIATIONS

https://doi.org/10.1128/jcm.01618-25 • Check for updates

Evaluation of DUS for HPV testing is being evaluated as a way to increase screening rates in remote areas.

STOP Students

Clarissa Klenke (PhD)

Chlamydia and gonorrhea prevalence, incidence and molecular characteristics among sex works in Nairobi, Kenya.

Harrison Deng (MSc)

Development of whole genome sequencing methods for *Chlamydia trachomatis* directly from clinical specimens

Quinton Murdock (MSc)

HPV viral load quantification and viral characterisation in cervical samples from women with cytological abnormalities.

Contacts

Section head:

Aida Sivro (aida.sivro@phac-aspc.gc.ca, sivroaida@gmail.com)

HPV unit technical lead:

Vanessa Schulz (vanessa.schulz@phac-aspc.gc.ca)

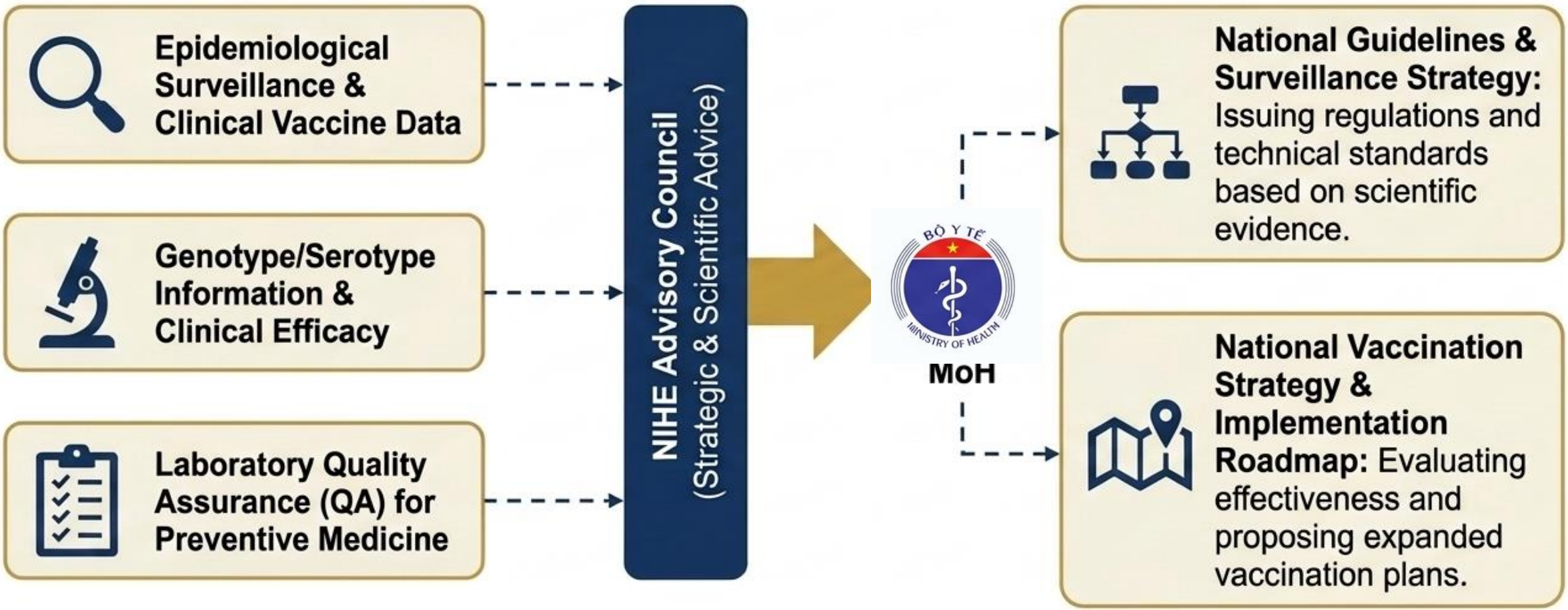
General lab email: nml.stop-lnm.psto@phac-aspc.gc.ca

NRL Vietnam

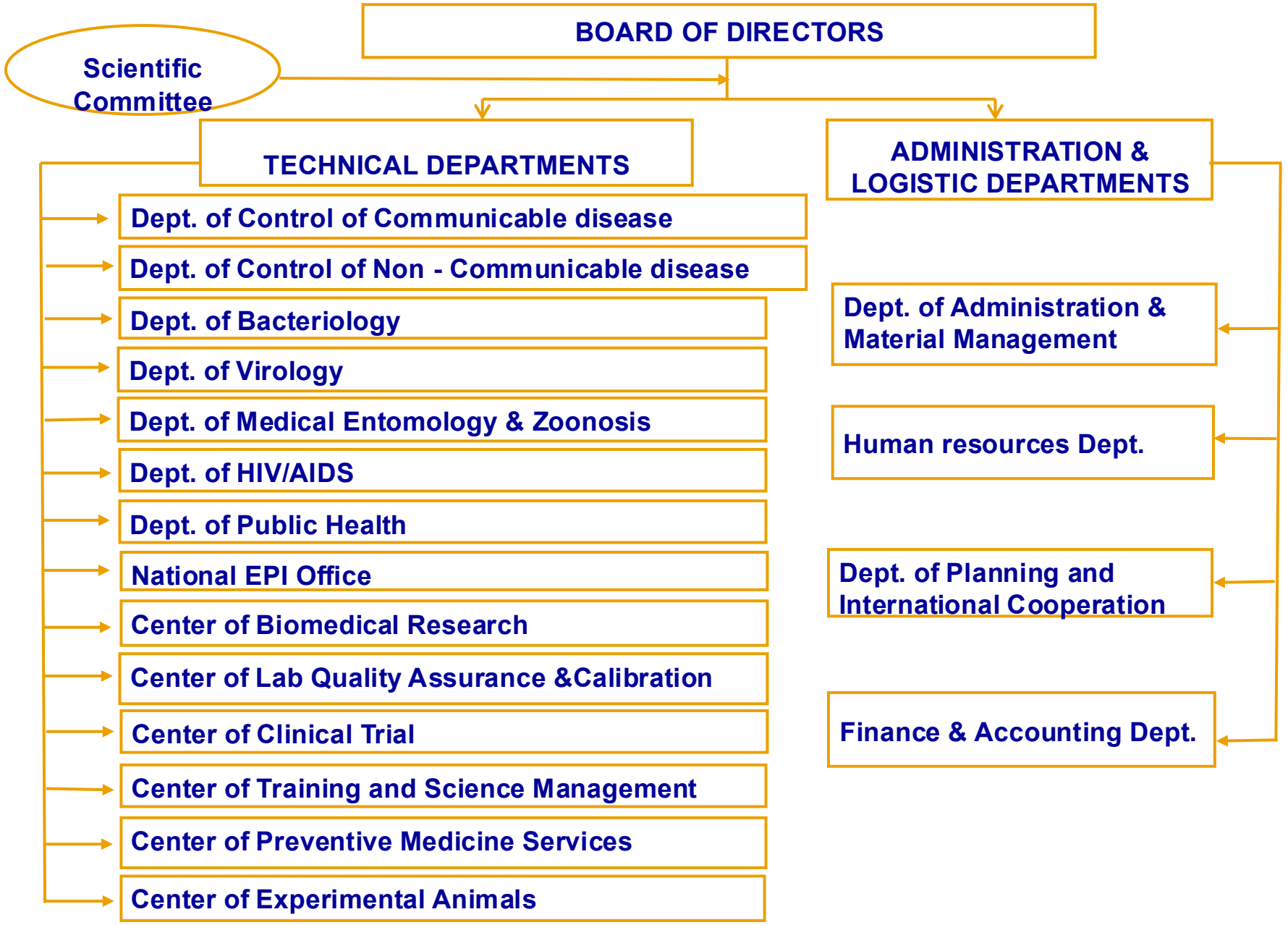
HPV research activities at the National Institute of Hygiene and Epidemiology, Vietnam

Nguyen Van Trang , PhD
Biomedical Research Center
Hanoi 17 April 2026

NIHE's Role in the National Strategy for Vaccination and Surveillance



NIHE's Organizational Structure



VIETNAM'S NATIONAL STRATERGY FOR HPV SCREENING AND VACCINATION

Updated Screening Guidelines

Decision 3792/QĐ-BYT

Primary Screening
High-performance HPV DNA/mRNA testing established as the frontline standard.

Risk Triage
Advanced dual-stain cytology (p16/Ki-67) to identify high-risk lesions.

Screen-and-Treat
Streamlined clinical pathways for rapid management of precancer.

Vaccine Integration Roadmap

Resolution 104/NQ-CP

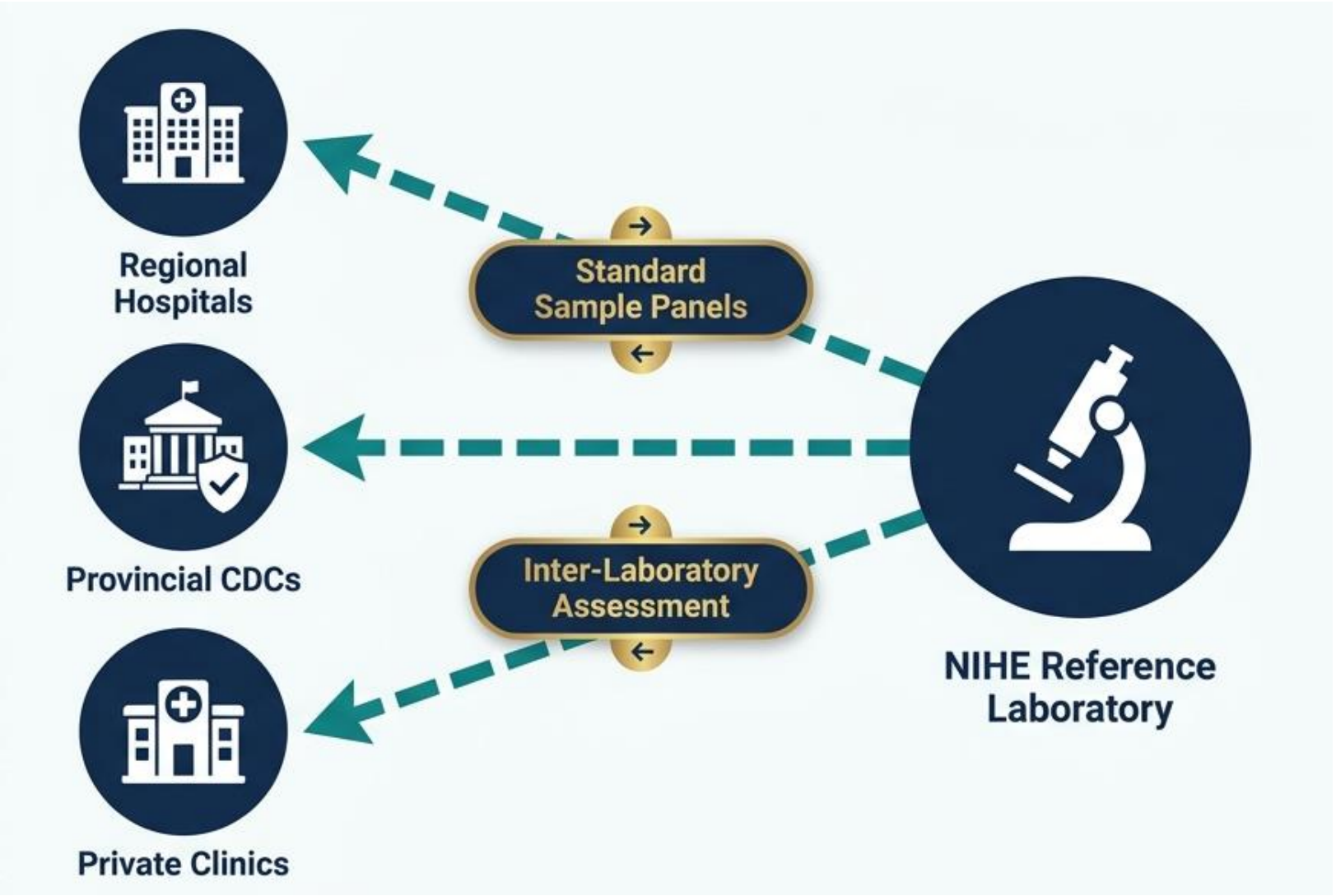
Official mandate to integrate the HPV vaccine into the National Expanded Immunization Program by 2026.

2026

WHO Global Strategy Targets

- **90%** of girls vaccinated by age 15
- **70%** of women screened by 35 & 45
- **90%** of women with disease treated

NIHE'S REFERENCE LABORATORIES



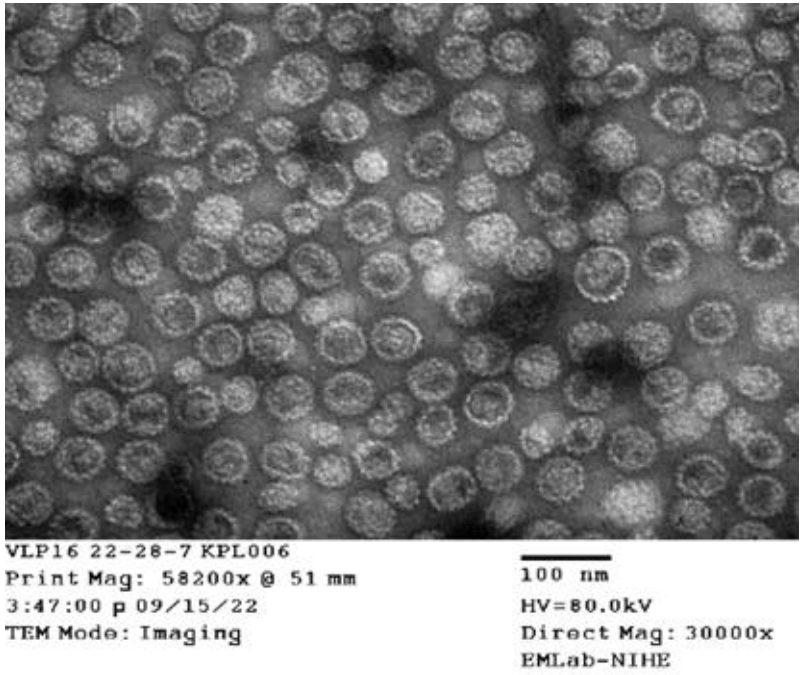
-Standard Panels: Designing, validating, distributing reference panels to clinical lab nationwide, followed ISO 17043,
-HIV, HCV Dengue, enteric bacteria panels: in production and distribution
HPV panels: preparation for circulation

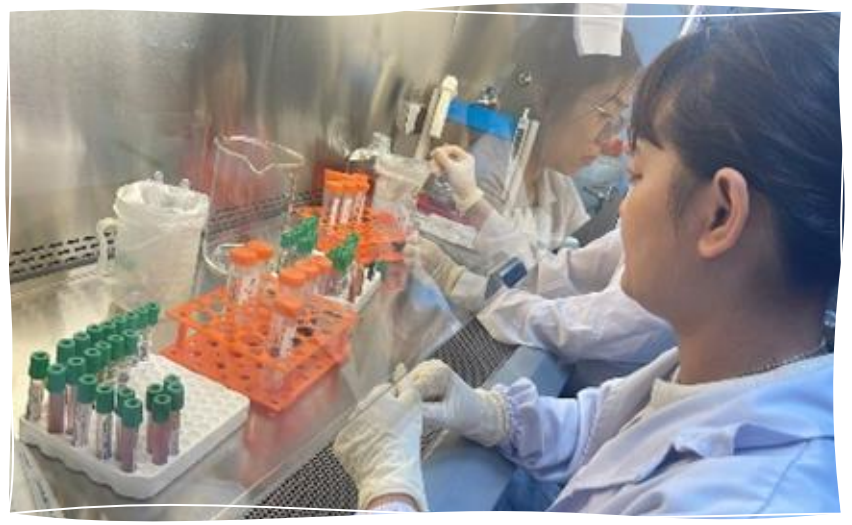
-Interlab assesment: various pathogens, followed ISO 15189: 2022

-Deployment of cutting edge virological, immunological and molecular techniques.

NIHE’s HPV lab capacity

- HPV dx capacity: Executing **targeted molecular surveillance** of HPV genotypes across diverse high-risk and sentinel populations to bridge data gaps in the absence of a national registry.
  - Use of commercial kits and in-house HPV genotyping method (14hrHPV, HPV 6 and 11)
  - Participating in PT (Inter. HPV Ref center) since 2024 (2 rounds)
- Immunogenicity assessment capacity: optimize own-VLP-based ELISA and **pseudovirus-neutralization assays (PBNA) (Technical supported by MCRI)**.”
- Advanced **genomic capacity:** Sanger sequencing and **Next-Generation Sequencing (NGS)** for viral evolution studies and lineage identification.
- Quality Control : Implementation of **digital PCR (dPCR)** for absolute genome copy quantitation and the development of **plasmid-based standard panels** to ensure **inter-laboratory comparability** and EQA compliance."





Epidemiological surveillance across key demographics

Female Sex Workers (FSW)

- **Overall HPV prevalence:** 26.3% across all participants.
- **HrHPV prevalence:** 17.6%
- Most common HPV types: 52, 58

WPSAR 13,4(2022) doi 10.5365

University Students

- **Overall HPV prevalence:** Only **4.2%** of the female students were infected with any type of HPV.
- **HrHPV prevalence: 3.4%**
- Most common HPV type: 52, 39

In Vivo **2022**; 36:241-50.

Men who Have Sex with Men

- **Overall HPV prevalence: 32.3%** of MSM infected with any type of HPV.
- **HrHPV prevalence: 24.5%**
- Most common HPV types: 52, 39

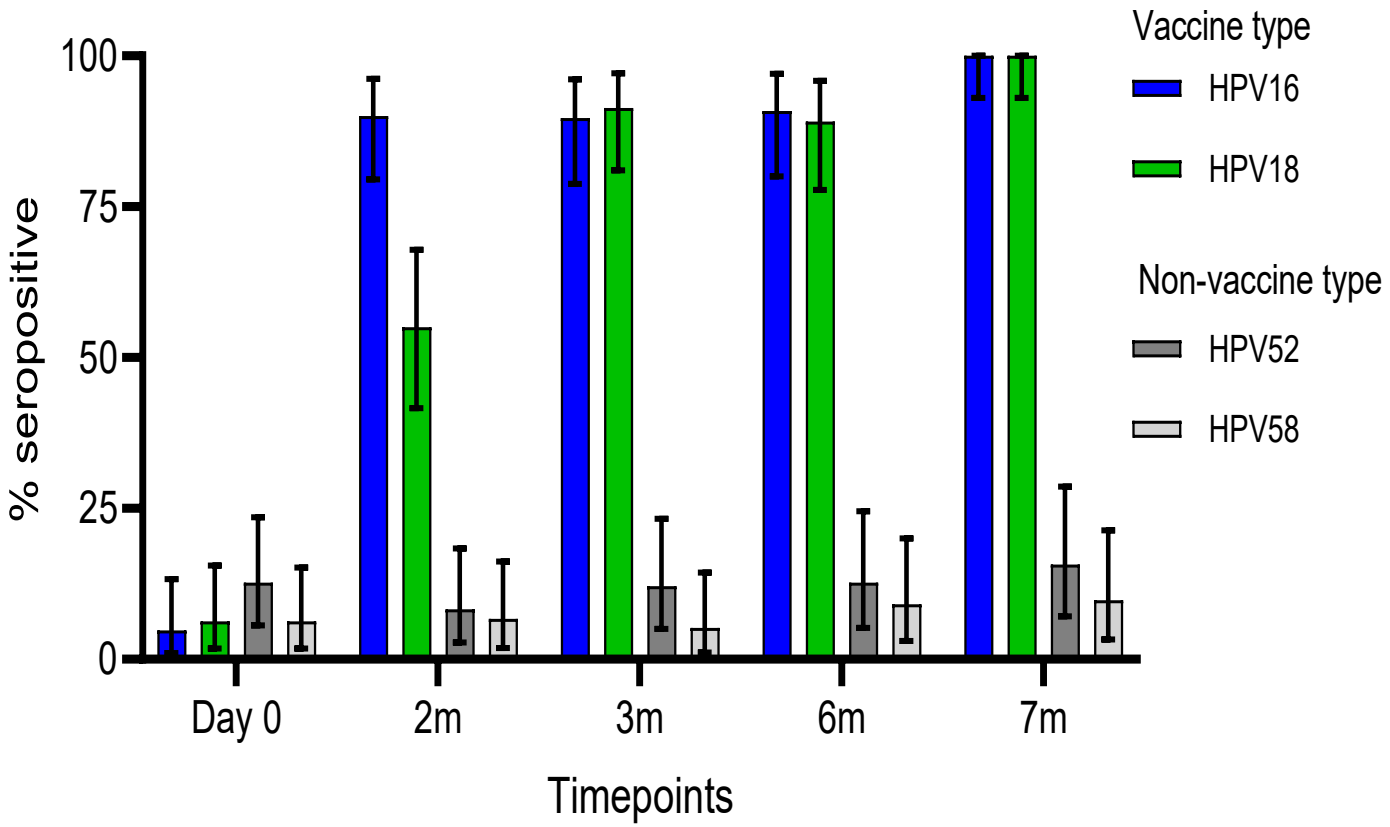
IJID 112 (2021) 136-143

Married Women

- The prevalence of HPV infection in Southern Vietnam is 10%, in the Northern provinces/cities and Central region is 6-9%.
- Most common HPV types:16, 18, 58 and 52

BMC Womens Health 2015; 15:16

Clinical Insight: Vaccine Responses in FSWs



- **After 1 Dose (at Month 2): 90%** of the participants seroconverted for HPV16, only **55%** seroconverted for HPV18.
- **After 2, 3 Doses (at Month 3,7): ~ 90%-100%** of the participants were seropositive for both HPV16 and HPV18.
- **Comparison to the General Population:** the FSWs in this cohort elicited only about half the level of antibodies for HPV16, though their HPV18 antibody levels were comparable.

- **Implications for Single-Dose Schedules:** While a single dose of 4vHPV is highly immunogenic for HPV16 in FSWs, it is significantly lower for HPV18, suggesting that protection conferred by a single dose may vary depending on the genotype

J Infect Dis. 2026 Mar 1:jiag112. doi: 10.1093/infdis/jiag112.

Thank you for having us in HPV Labnet!

Contact: nvt@nihe.org.vn

Sample adequacy (Italy and Slovenia)

Sample adequacy Working Group Activities

Activities

1. EUROGIN 2026 Session: «Sample Cellularity – an obligatory part of the Quality Assurance in HPV-based Cervical Cancer Screening Programs».

2. Evaluation from the IFU or from contacts with manufacturers of validated HPV assays regarding the *Internal Controls* used in the different assays & relative Ct cut-offs in order to build on a database.

1. Mario and Anja are working on generating a first set of “complicated” samples - such samples will soon be available for sharing

.

EUROGIN 2026 SESSION:

AN OBLIGATORY PART OF THE QUALITY ASSURANCE PROGRAMS IN HPV-BASED CERVICAL CANCER SCREENING

In line with international guidelines, many countries have or are in the process of transitioning from cytology to HPV-based cervical cancer screening, offering improved sensitivity and longer screening intervals. WHO's recommendations for the elimination of cervical cancer have also recently included the implementation of cost-effective

HPV testing on self-collected samples, improving screening coverage and access to treatment, although relying on non-professional sample collection.

Sample cellularity can significantly reflect test accuracy in cervical cancer prevention programs; however, unlike cytology-based screening, no consensus guidelines presently exist for sample quality assessment in HPV DNA molecular testing of both clinician and self-collected samples.

This session aims to address potential challenges in evaluating sample cellularity by HPV molecular assays and encourage discussion on the need to introduce appropriate sample adequacy assessment as part of the quality assurance of HPV-based screening programs.

EUROGIN 2026 SESSION:

AN OBLIGATORY PART OF THE QUALITY ASSURANCE PROGRAMS IN HPV-BASED CERVICAL CANCER SCREENING

SS 24-1 • Introduction **Arbyn M.** (Belgium) **Cocuzza C.** (Italy)

SS 24-2 • Challenges and potential solutions in defining sample cellularity **Doorbar J.** (UK)

SS 24-3 • Sample adequacy assessment: Experience from the VALHUDES validation studies **Cocuzza C.** (Italy)

SS 24-4 • Effect of sample cellularity on HPV test results: Real-life experience from The Netherlands **Schuurman R.** (Netherlands)

SS 24-5 • Review of major external quality control panels for HPV testing **Cuschieri K.** (UK)

SS 24-6 • Challenging samples signaling problems with sample cellularity and inhibition should be included in the External Quality Control Panels **Oštrbenk A.** (Slovenia)

SS 24-7 • Cellularity, clinical significance, and validation aspects **Arbyn M.** (Belgium)

«Internal Control»

- Endogenous human cell gene target – **not cell type-specific**

- Sample cellularity (human DNA /reaction)
  - Qualitative cellularity assessment
  - Dependant on the preanalytical & analytical workflow
  - **IC assays' cut-offs** – *defined by manufacturers and not independently evaluated as part of HPV assay's validation*.

  - What should be the criteria for defining IC cut-off?
  - Should IC cut-offs be assessed as part of the clinical validation of HPV assays?

How is Sample Adequacy presently assessed in Validated HPV-assays?

HPV Ct cut-offs will also be influenced by sample cellularity

Internal control in HPV validated assays

Table 1

List of validated HPV nucleic acid tests that can be used in cervical cancer screening on cervical clinician-collected specimens (as of April 2024)

ASSAY	MANUFACTURER	GENOTYPING CAPACITY	NUMBER OF TYPES	GENOTYPING DETAIL‡	HUMAN GENE¥	STORAGE MEDIA
A. Standard comparator hrHPV DNA tests (validated in population-based randomised trials), used as comparator in validation studies:						
A1. Hybrid Capture 2 HPV DNA Test	Qiagen, Gaithersburg, MD, USA	None	13	16/18/31/33/35/39/45/51/52/56/58/59/68	No	PC,SP
A2. GP5+/6+ PCR-EIA	Diassay, Rijkswijk, the Netherlands	None	14	16/18/31/33/35/39/45/51/52/56/58/59/66/68	No	PC,SP
B. hrHPV DNA tests validated consistently in multiple studies against standard comparator tests:						
B1. Alinity m HR HPV Assay	Abbott, Wiesbaden, Germany	Extended	14	16,18,45,31/33/52/58,35/39/51/56/59/66/68	Yes	PC
B2. Anyplex II HPV HR Detection	Seegene, Seoul, South Korea	Full	14	16,18,31,33,35,39,45,51,52,56,58,59,66,68	Yes	PC
B3. Cobas 4800 HPV Test	Roche Molecular System, Pleasanton, CF, USA	Limited	14	16,18,31/33/35/39/45/51/52/56/58/59/66/68	Yes	PC,SP
B4. HPV-Risk Assay	Self-Screen BV, Amsterdam, The Netherlands	Limited	15	16,18,31/33/35/39/45/51/52/56/58/59/66/67/68	Yes	PC,SP
B5. NeuMoDX HPV assay	Qiagen, Ann Arbor, MI, USA	Limited	15	16,18,31/33/35/39/45/51/52/56/58/59/66/68	Yes	PC
B6. Onclarity HPV Assay	BD Diagnostics, Sparks, MD, USA	Extended	14	16,18,31,45,51,52,33/58,35/39/68,56/59/66	Yes	PC,SP
B7.PapilloCheck HPV-Screening Test	Greiner Bio-One, Frickenhausen, Germany	Full	24	06,11,16,18,31,33,35,39,40,42,43,45,44/55,51,52,53,56,58,59,66,68,70,73,82	Yes	PC
B8. RealTime High Risk HPV Test	Abbott, Wiesbaden, Germany	Limited	14	16,18,31/33/35/39/45/51/52/56/58/59/66/68	Yes	PC
B9. Xpert HPV	Cepheid, Sunnyvale, CA, USA	Extended	14	16,18/45,31/33/35/52/58,51/59,39/56/66/68	Yes	PC
C. hrHPV DNA test validated consistently in multiple studies against alternative comparator test:						
C1. Cobas 6800 HPV Test	Roche Molecular System, Pleasanton, CF, USA	Limited	14	16,18,31/33/35/39/45/51/52/56/58/59/66/68	Yes	PC
D. hrHPV DNA tests evaluated in only one study against standard comparator tests:						
D1. CLART HPV4S	GENOMICA SAU, Madrid, Spain	Full	16	06,11,16,18,31,33,35,39,45,51,52,56,58,59,66,68	Yes	PC,SP
D2. OncoPredict HPV Screening	Hiantis Srl, Milan, Italy	Limited	13	16,18,31/33/35/39/45/51/52/56/58/59/68	Yes	PC
D3. REALQUALITY RQ-HPV Screen	AB ANALITICA, Padua, Italy	Limited	14	16,18,31/33/35/39/45/51/52/56/58/59/66/68	Yes	PC
E. hrHPV mRNA test:						
E1. APTIMA HPV Assay	Hologic, Bedford, MA, USA	None*	14	16/18/31/33/35/39/45/51/52/56/58/59/66/68	No	PC
F. Added since the last international publication of the list of clinically validated HPV tests						
F1. OncoPredict HPV QT	Hiantis Srl, Milan, Italy	Full	12	16,18,31,33,35,39,45,51,52,56,58,59	Yes	PC
F2. RIATOL HPV genotyping qPCR assay	AML, Antwerp, Belgium	Full	17	06,11,16,18,31,33,35,39,45,51,52,53,56,58,59,66,68	Yes	PC
F3. Allplex HPV HR Detection assay	Seegene, Seoul, South Korea	Full	14	16,18,31,33,35,39,45,51,52,56,58,59,66,68	Yes	PC
F4. Vitro HPV Screening Assay	Vitro S. A., Sevilla, Spain	Limited**	14	16,18,31/33/35/39/45/51/52/56/58/59/66/68	Yes	PC

Human gene IC Cutoff

-
-

Beta-globin 32 Ct
Beta-globin +
Beta-globin 40 Ct
Beta-globin 33 Ct

Beta-globin POS/NEG
Beta-globin 34.2 Ct

ADAT-1 gene ??
Beta-globin 35 Ct
HMBS gene ??

Beta-globin ? 40 Ct

CFTR gene ??
CCR5 <400 cells/reaction
Beta-globin 34 Ct

-

CCR5 <400 cells/reaction
Beta-globin <0.12 ng/ul
Beta-globin 43 Ct
Beta-globin <10 ng/ul

M Arbyn et al. (July 2024). Validated HPV tests usable in cervical cancer screening on clinician-collected cervical specimens. www.HPVWorld.com, 270

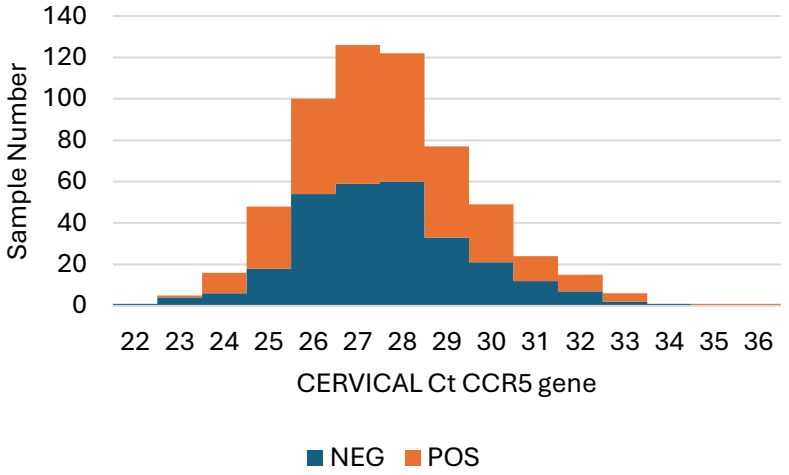
European VALHUDES results:
OncoPredict HPV® Sample Cellularity Assessment

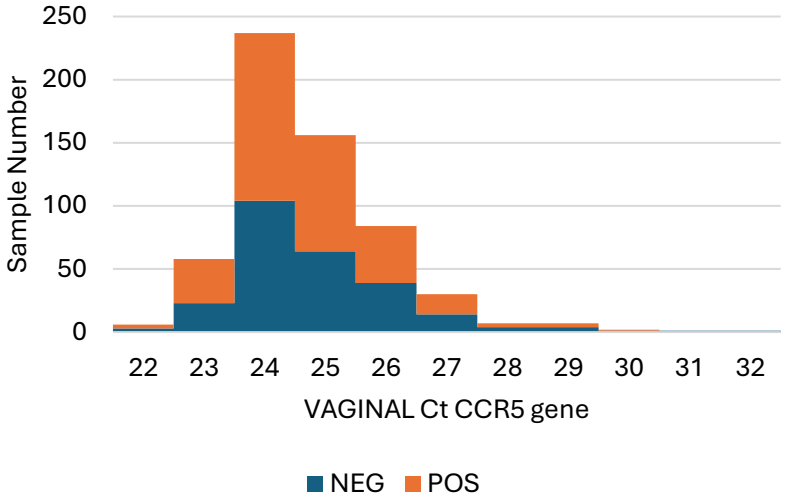
Cervical	Ct	**Cervical**	Cellularity
Mean	27.7	Mean	7748
Min	22.5	Min	5
Max	35.7	Max	170761

Vaginal	Ct	**Vaginal**	Cellularity
Mean	24.8	Mean	41572
Min	21.6	Min	0
Max	32.0	Max	331400

	n	**Cervical Median Ct [IQR]**	**Vaginal Median Ct [IQR]**	**p-value**
CCR-5 gene	449[b]	27.3 [26.3- 28.6]	24.3 [23.8-24.9]	0.000
		Median N cells	Median N cells	
Cellularity	449[b]	3875 [1469- 8956]	42049 [25823- 59300]	0.000

[b]Number of matched valid samples





Int. J. Cancer: **119,** 1102–1107 (2006)

Determination of viral load thresholds in cervical scrapings to rule out CIN 3 in HPV 16, 18, 31 and 33-positive women with normal cytology

Peter J.F. Snijders[1], Cornelis J.A. Hogewoning[2], Albertus T. Hesselink[1], Johannes Berkhof[3], Feja J. Voorhorst[3], Maaike C.G. Bleeker[1] and Chris J.L.M. Meijer[1]*

when considering only women with CIN 3 who were infected with one of these types, sensitivities of 100% (with 95% CI 59.0–100% for HPV 18 and 95% CI 75.3–100% for both HPV 31 and 33) were obtained in case the thresholds of up to the 33rd percentiles were used, similar as what was found for HPV 16. The 33rd thresholds were 0.30 c/c, 1.03 c/c and 5.13 c/c for HPV 18, 31 and 33, respectively.

Overall, when combining the data of all 4 HPV types, the sensitivity for ≥CIN 2 was 96.8% (95% CI 92.0–99.1%) when the type-specific thresholds were set at the 25th percentile, 95.2% (95% CI 89.9–98.2%) at the 33rd percentile and 87.2% (95% CI 80.0–92.5%) at the 50th percentile. Restricting the analyses to women with CIN 3, these figures reached a sensitivity of 100% (95% CI 93.9–100%) for all 4 HPV types at both the 25th and 33rd percentiles thresholds and 89.8% (95% CI 75.0–94.0%) at the 50th percentile threshold (Table III). There was no significant age differ-

women with normal cytology as reference group and considered these women as having no underlying ≥CIN 2 lesion. Still, this group may include a small proportion of women with prevalent high-grade CIN lesions missed by cytology. Since we anticipate that such cases would display increased viral copy numbers that fall in the higher viral load percentiles,[19] we consider the sensitivity of the 33rd percentile thresholds set in this study not over represented. It is also noteworthy that total DNA can be derived from many types of cells from the cervix, including inflammatory cells that are not HPV host cells. This may affect the relationship of HPV to cell number in a variable manner. Nevertheless, this apparently does not influence the outcome for sensitivity of ≥CIN 2 when the 33rd percentile thresholds are used. Therefore, we have the impression that the influence of DNA of the non-HPV host cells on viral load levels in general practice is limited.

Remarkably, median viral load values differed considerably be-

Sample cellularity assessment by molecular methods - not able to distinguish cell types which are clinically relevant for the detection of HPV – does it have different implications when applied to vaginal samples?

DATA BASE:

Internal Controls used in the different HPV validated assays
&
Ct cut-offs

Assay	HPV Viral cutoffs	Human Genes Cut-offs	
Hybrid Capture 2 HPV DNA Test	RLU≥1	-	
GP5+,6+ PCR-EIA	Not defined	-	
RealTime High Risk HPV	CN≤32.0 for HPV16, HPV18, and the aggregate of 12 other hrHPV types	CN≤32.0 for β-globin	
Anyplex II HPV HR Detection	0, +, ++, +++	≥ ++, +++	
Cobas 4800 HPV Test	Ct≤40.5 for HPV16	Ct≤40.0 for β-globin	
	Ct≤40.0 for HPV18 and the aggregate of 12 other hrHPV types		
BD Onclarity ™ HPV Assay	Ct≤38.3 for HPV16	Ct≤34.2 for β-globin	
	Ct≤34.2 for all other HPV types or type groups		
Cobas HPV Test	Ct≤38.5 for HPV16	Ct≤34.5 for β-globin	
run on Cobas on 5800, 6800 or 8800 platforms		Ct≤38.0 for HPV18	
	Ct≤34.5 for the aggregate of 12 other hrHPV types		
Allplex HPV HR Detection assay	Ct≤40.0 for HPV16 and HPV18	Ct≤43.0 for β-globin	
	Ct≤37.0 for for HPV31, HPV33, HPV45, HPV52, HPV58		
	Ct≤35.0 for HPV39, HPV35, HPV51, HPV56, HPV59, HPV66, HPV68		
Alinity m HR HPV Assay	confidential for HPV	not defined for β-globin	
HPV-Risk Assay	Ct≤36 for HPV16, HPV18 and for the aggregate of 13 other hrHPV types	Ct≤36 for β-globin	
NeuMoDX HPV assay	Ct≤33 for HPV16, HPV18 and Ct≤30 for the aggregate of 13 other hrHPV types	Ct≤33 for β-globin	
PapilloCheck HPV-Screening Test	No Ct value threshold described in IFU - method PCR followed by hybridization	Cut-offs not defined for ADAT-1 gene	
Xpert HPV v2	No Ct value threshold described in IFU	Cut-offs not defined for HMBS gene	
CLART	No Ct value threshold described in IFU - method PCR followed by hybridization	Cut-offs not defined for CFTR gene	
OncoPredict HPV Screening	Ct≤40.0 for HPV16, HPV18 and for the aggregated of 11 other hrHPV types	<400 cells/reaction	
REALQUALITY RQ-HPV Screen	Ct≤40 for HPV16, HPV18 and for the aggregate of 12 other hrHPV types	Ct≤40 for β-globin	
OncoPredict HPV QT	Ct≤40.0 for all 12 carcinogenic HPV genotypes (IARC group 1)	<400 cells/reaction	
RIATOL HPV genotyping qPCR assay	$\log_{10}$ (copies / ul) ≥6.493 for all HPV types	Concentration β-globin <0.12mg/ml	
Vitro HPV Screening Assay	Ct≤40 for HPV16, HPV18 and the aggregate of 12 other hrHPV types	<10 ng/reaction	
PapilloPlex (version 1)	Ct≤36 for all HPV types	Ct≤38 for ARHGEF11	
APTIMA HPV Assay	No information in IFU on cut-off values	-	

Future Possible Activities of Sample Adequacy Working Group

- Collect data on Ct values of IC of different validated HPV assays used in national screening programs: to evaluate HPV positivity rates at different IC Ct intervals.
- LBC samples from biobanks of reference laboratories that have resulted in inadequate cytology: to be test with different validated HPV assays to check for HPV positivity and IC Ct values
- LBC samples from "HPV-negative" cervical cancer cases for quantitative sample cellularity assesment.

Advisory task Force - Scotland

National Services Division
Commissioning for Scotland's Health

NHS National Services Scotland

NHS Lothian

THE UNIVERSITY OF EDINBURGH

Advisory Task Force – HPV LabNet

Royal Infirmary of Edinburgh, NHS Lothian

Kate Cuschieri, 17th April 2026

Scottish HPV Reference Laboratory

Royal Infirmary of Edinburgh [1]

HPV Research Group University of Edinburgh[2]

1:https://www.edinburghlabmed.co.uk/Specialities/reflab/hpv/Pages/default.aspx
2: https://www.ed.ac.uk/centre-reproductive-health/staff/associates/kate-cuschieri-crh

International support

- We hope the lab manual provides valuable information
- Each lab/setting **may have specific needs/challenges**; how to support this optimally?
- Hard to substitute/replace specific/“face to face” (online or in 3D) support
- **Mentor/mentee lab set up?**

Models

1: Each existing lab in the LabNet registers interest in becoming a mentor lab for a specific activit(ies) (eg), creation of a “skill register”

- Quality Assurance
- Assay verification
- Sample extraction etc etc – these can be finessed, and a lab can have more than one activity

Pros? Shares the load, resilience?

Cons? Require a certain level of coordination when applications for support come in– who does that ?

2: Ad-hoc arrangements according to historic or strategic ties between a more established and a less established lab. LabNet to keep a “list” of these

Pros? One-on-one commitment can ensure lasting, evolving partnerships. Easier to resource?

Cons? Ad-hoc… is the expertise provided to those that need it the most? Are the learnings shared amount the LabNet community?

Models

3: LabNet works with partner organisation (?WHO, ?European Cancer Organisation, ?IPVS) who identify settings/contexts where lab expertise & mentorship is required. Generation of “priority list” and review on case by case basis by LabNet as to who can provide support)

Pros? Comprehensive approach?

Cons? Will this work –?stable enough connections with partner organisations. Who manages the process?

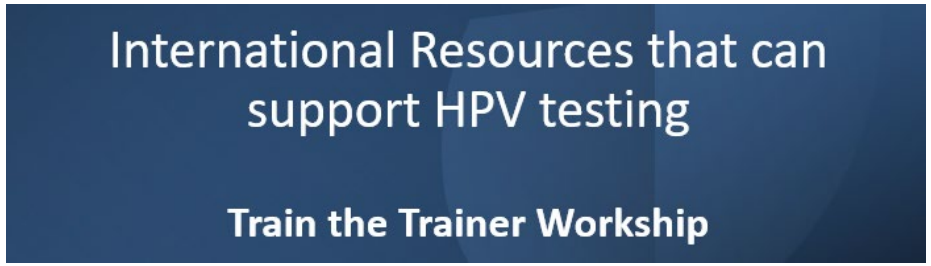
Other considerations for Mentor/Mentee labs

- Resource to support partnerships (particularly if onsite work required)…some models will be easier to resource than others
- Is there support of mentor “parent” organization to act in this capacity. Is it in the general remit of most ref labs in LabNet. Do potential mentor labs need to seek permission to act in this capacity? What can we refer to from the “charter” of LabNet

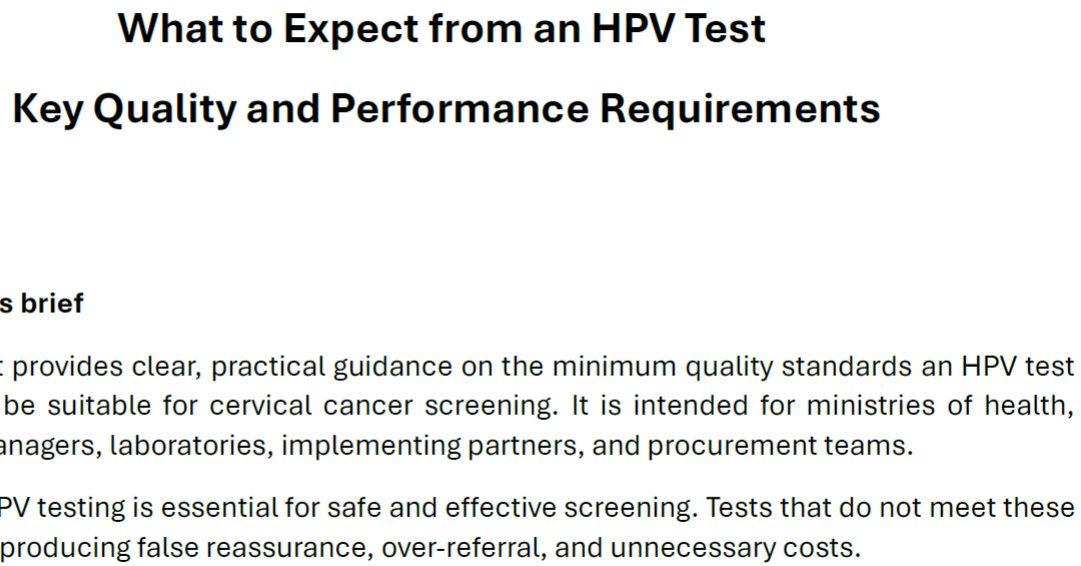
- Training materials…

Training materials

- Concise “primer” materials beyond the manual
- Verification templates?
- SOP templates?
- QC database template/trending



Example from Scottish Ref Lab – Used for Uzbek project


What to Expect from an HPV Test

Key Quality and Performance Requirements

Purpose of this brief

This document provides clear, practical guidance on the minimum quality standards an HPV test must meet to be suitable for cervical cancer screening. It is intended for ministries of health, programme managers, laboratories, implementing partners, and procurement teams.

High-quality HPV testing is essential for safe and effective screening. Tests that do not meet these standards risk producing false reassurance, over-referral, and unnecessary costs.

Example from Swedish Ref Lab – Used for Ukraine project

Discussion – candid comments welcome!

1: What model do LabNet think might work of those proposed, or do we need further alternatives?

2: Register of labs willing to act as mentor labs

3: Define “skill” categories for skill register

4: Identification of primer/core documents that could sit alongside the lab manual which would have value – **who ratifies**?

5: Which other partner organisations should we be speaking to ?