SCIENTIFIC SESSIONS

Hall N1 **12.00 • 13.30**

SS 03 • GLOBAL HPV LABORATORY NETWORK: STRENGTHENING HPV LABORATORY CAPACITY FOR CERVICAL CANCER ELIMINATION

CHAIR: Arroyo Mühr L. S. (Sweden) • Padalko E. (Belgium)

This session brings together leading experts to present recent advances and strategic developments in global HPV laboratory networks. The focus will be on the evolving needs from WHO, innovations in assay evaluation and sample adequacy, and the implementation of laboratory support and training in new regions.

SS 03-1 • Introduction	**Arroyo Mühr L. S.** (Sweden)
SS 03-2 • Needs from WHO and possibilities for LabNet	**Almonte M.** (Switzerland)
SS 03-3 • Proficiency studies 2.0: Evaluation of novel HPV assays	**Yilmaz E.** (Sweden)
SS 03-4 • Sample adequacy revisited: Lessons from large-scale self-sampling programs	**Cocuzza C.** (Italy)
SS 03-5 • Advisory task force for HPV testing in new countries: Lab manual, training and rollout	**Cuschieri K.** (UK)
SS 03-6 • International collaboration for HPV prevalence studies	**Dillner J.** (Sweden)
SS 03-7 • Updates from NRL countries: France	**Lepiller Q.** (France)
SS 03-8 • Updates from NRL countries: Belgium	**Padalko E.** (Belgium)
SS 03-9 • Updates from NRL countries: Brazil	**Soares M.** (Brazil)
SS 03-10 • Updates from NRL countries: Norway	**Soreng K.** (Norway)
SS 03-11 • Updates from NRL countries: Scotland	**Cuschieri K.** (UK)
SS 03-12 • Updates from NRL countries: Slovenia	**Oštrbenk A.** (Slovenia)
SS 03-13 • Updates from NRL countries: Sweden	**Eklund C.** (Sweden)
Discussion and Q&A	

Global HPV Laboratory Network (LabNet): Strengthening HPV Laboratory Capacity for Cervical Cancer Elimination

Laila Sara Arroyo Mühr, Associate Professor

International HPV Reference Center

Karolinska Institutet

Center for Cervical Cancer Elimination

CCCE

Karolinska Institutet

KAROLINSKA UNIVERSITY HOSPITAL

What is LabNet

- International network of reference laboratories and experts in HPV diagnostics
- Established by WHO in 2005 and coordinated by IHRC
- Supports standardization, quality assurance, and capacity building
- Work towards elimination of cervical cancer

Why is it needed

- HPV testing recommended by WHO as primary screening
- Reliable performance essential
- Ensures global comparability
- Many countries require technical support

What does LabNet do

- Proficiency testing and assay evaluation
- Guidance for implementation and validation
- Training and support for labs
- Global collaboration and data sharing

Argentina
Australia
Belgium
Brazil
Canada
France
Gabón
Germany
Italy
Japan
Mexico
Norway
Perú
Rwanda
Scotland, UK
Slovenia
Sweden
USA
Vietnam

Recent work

A) Distribution of proficiency panels developed for cervical screening assays,

B) Publication of an interactive and up to date HPV Laboratory manual

https://www.hpvcenter.se/hpv-laboratory-manual/

C) Guidance for quality assurance in HPV testing for primary cervical screening,

D) Guidance for confirmatory testing (re-analysis of “HPV-negative” high grade lesions or worse

E) Establishment of an e-learning platform aiming to provide e-resources for HPV researchers and laboratory users.

› J Med Virol. 2024 Oct;96(10):e70022. doi: 10.1002/jmv.70022.

Continuous Global Improvement of Human Papillomavirus (HPV) Genotyping Services: The 2022 and 2023 HPV LabNet International Proficiency Studies

Laila Sara Arroyo Mühr [1], Carina Eklund [1], Camilla Lagheden [1], Emel Yilmaz [1], Ola Forslund [2], Marina Lilja [3], Joakim Dillner [1]

Affiliations + expand

PMID: 39439211 DOI: 10.1002/jmv.70022

Review › Int J Gynecol Cancer. 2023 May 1;33(5):802-811. doi: 10.1136/ijgc-2022-004197.

Quality assurance in human papillomavirus testing for primary cervical screening

Kate Cuschieri [1], María Dolores Fellner [2], Laila Sara Arroyo Mühr [3] [4], Elizaveta Padalko [5], Rita Mariel Correa [2], Joakim Dillner [6] [4], Murat Gultekin [7], Maria Alejandra Picconi [2]

Affiliations + expand

PMID: 36914171 PMCID: PMC10176393 DOI: 10.1136/ijgc-2022-004197

› J Clin Virol. 2024 Apr:171:105657. doi: 10.1016/j.jcv.2024.105657. Epub 2024 Feb 20.

Human papillomavirus negative high grade cervical lesions and cancers: Suggested guidance for HPV testing quality assurance

Jean Luc Prétet [1], Laila Sara Arroyo Mühr [2], Kate Cuschieri [3], María Dolores Fellner [4], Rita Mariel Correa [4], María Alejandra Picconi [4], Suzanne M Garland [5], Gerald L Murray [5], Monica Molano [6], Michael Peeters [7], Steven Van Gucht [7], Charlotte Lambrecht [8], Davy Vanden Broeck [8], Elizaveta Padalko [9], Marc Arbyn [10], Quentin Lepiller [1], Alice Brunier [1], Steffi Silling [11], Kristiane Søreng [12], Irene Kraus Christiansen [12], Mario Poljak [13], Camilla Lagheden [2], Emel Yilmaz [2], Carina Eklund [2], Hem R Thapa [14], Troy D Querec [14], Elizabeth R Unger [14], Joakim Dillner [15]

Affiliations + expand

PMID: 38401369 PMCID: PMC11863830 (available on 2025-04-01) DOI: 10.1016/j.jcv.2024.105657

Join us

Requirements:

- Appointed by the national government
- Proficient in HPV testing

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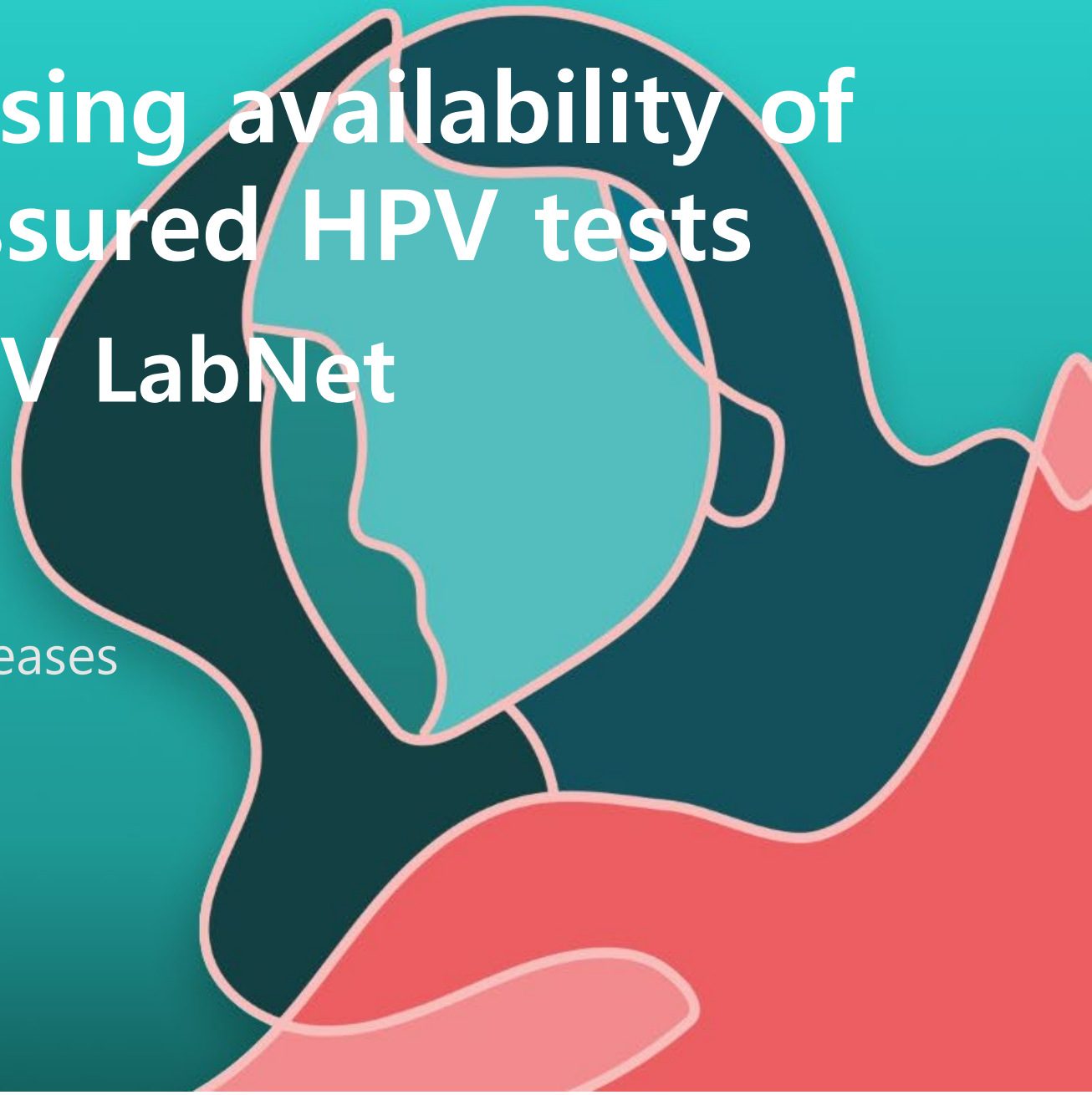
WHO asks for increasing availability of affordable quality-assured HPV tests

Possibilities for the HPV LabNet

Maribel Almonte
Department of Non-Communicable Diseases
and Mental Health

World Health Organization



70%

of women are screened with a **high-performance test** by 35 and 45 years of age

CCEI Pillar 2 Strategic Actions

- Ensure affordable supply of quality assured, high-performance screening tests & treatment devices
- Integrate screening and treatment services into primary care to increase coverage
- Understand barriers, create enabling environment
- Promote screen-and-treat to increase retention and programmes' efficiency
- Strengthen laboratory capacity

World Health Organization

Promote simple screening algorithms to increase retention and improve programmes' efficiency

Guidelines

WHO guideline for screening and treatment of cervical pre-cancer lesions for cervical cancer prevention

Use of human papillomavirus (HPV) DNA genotyping

April 2026

Evaluation considering:

1) screening programmes follow-up capacity (the more visits to complete the screening process, the more lost to follow-up)
2) Reduction in cervical cancer cases and deaths
3) Cost-effectiveness

No recommendations for women living with HIV

Recommendations:

1) Multiple options stratified by follow-up capacity, including HPV DNA limited and extended genotyping
2) Treating all HPV positives most effective and cost-effective
3) HPV DNA extended genotyping in scenarios with high follow-up capacity allowing reduction of overtreatment

What actions should we take to:

Ensure affordable supply of quality assured high-performance screening tests & treatment devices

REGULATORY agencies and clinical validation criteria for HPV in-vitro Dx

1. WHO PQ, WLA, and National Regulatory Agencies (China, India, South Africa, Brazil)
2. Meijer criteria https://pubmed.ncbi.nlm.nih.gov/18973271/
3. VALGENT protocol https://pubmed.ncbi.nlm.nih.gov/26522865/ ; VALGENT studies: https://pubmed.ncbi.nlm.nih.gov/36541733/; https://pubmed.ncbi.nlm.nih.gov/31569008/; etc; VALGENT recent list of validated tests: https://www.hpvworld.com/articles/validated-hpv-screening-tests:-the-importance-of-validation/

PRIVATE SECTOR DIALOGUES:

✓ main global platforms = > Global access pricing

WHO pre-qualified HPV tests since started

HPV Test	Manufacturer	Year PQ
Xpert HPV	Cephied AB	2017
careHPV Test	Qiagen GmbH	2018
Abbott RealTime High Risk HPV	Abbott GmbH	2019
Cobas HPV	Roche Molecular Systems, Inc.	2023
Cobas 4800 HPV	Roche Molecular Systems, Inc.	2024
Alinity m HR HPV	Abbott Molecular Inc.	2025
Aptima 16 18/45 Genotype Assay	Hologic, Inc	2025
Aptima HPV Assay	Hologic, Inc	2025
BD Onclarity HPV Assay for the BD COR System	Becton, Dickinson and Company, BD Biosciences - MD Site	2025
BD Onclarity HPV Assay for the BD Viper LT System	Becton, Dickinson and Company, BD Biosciences - MD Site	2025

WHO pre-qualified HPV tests since started

WHO's announcement on PQ performance evaluations for HPV assays

NEWS 1 October, 2025 - 12:27 (CEST) ANNOUNCEMENT

IVD

WHO adopting the fulfilment of Meijer's 2009 criteria in independent evaluations as WHO's prequalification independent performance evaluation component for HPV nucleic acid tests.

R		◆	F	S
information requested from manufacturer	in process	stage complete	follow-up amendments	scheduled; date confirmed

Please note: these tables are updated regularly; while every attempt is made to provide current data, the most recent information might not be reflected. This table is intended only as an update on progress and does not reflect a final decision on prequalification. This table should not be used to inform procurement.Information may not yet be reflected here.
Last update: 25 November 2025
https://extranet.who.int/pqweb/vitro-diagnostics/products-under-assessment
The product was prequalified and a change request was submitted and accepted to add an intended use claim.

HPV Nucleic Acid Tests progress of the active applications in the prequalification of IVDs assessment pipeline

Product name	Product code(s)	Manufacturer name	Dossier review	Product performance evaluation	Labelling review	Application number
				Compliance with Meijer's criteria under consideration		PQDx 12643-13346-00
				Compliance with Meijer's criteria under consideration		PQDx 11588-10152-00

HPV tests validated under VALGENT up to 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

Arbyn et al,
HPV World 2024

HPV tests validated under VALGENT up to April 2024

ASSAY	MANUFACTURER	GENOTYPING CAPACITY	NUMBER OF TYPES	GENOTYPING DETAIL‡	HUMAN GENE¥	STORAGE MEDIA
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

* Another mRNA assay (APTIMA HPV16, 18/45, Hologic) can identify HPV16 and HPV18/45

** HPV Direct Flow Chip (Vitro S.A): provides full genotyping if Vitro HPV Screening shows other hrHPV (not HPV16/18)

‡ A slash "/" means that HPV types are identified as an aggregate; a comma "," means that HPV types or groups of types are identified separately

A HPV genotype in green does not belong to the IARC group I "carcinogenic types" or to group IIA "probably carcinogenic types" (Bouvard Lancet Oncol 2009[9])

¥ Amplification of human gene, which is an internal quality indicator that the specimen contains human cells

PC PreservCyt (Hologic, Bedford, MA, USA)

SP SurePath (BD Diagnostics, Sparks, MD, USA)

Recently validated, first Brazilian test: Biomol HPV Alto Riesgo

Arbyn et al,
HPV World 2024

What actions should we take to:

Ensure affordable supply of quality assured high-performance screening tests & treatment devices

2024 HPV TPPs Guidance for manufacturing of future tests, alignment to facilitate future validation

Companies aligning new products with TPPs, e.g. POC

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1. Update and harmonised validation criteria
2. Develop protocol for rapid evaluation of tests in use in countries: non-validated HPV tests using open platforms, novel POC tests, etc, to mitigate harms!

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Companies aligning new products with TPPs, e.g. POC

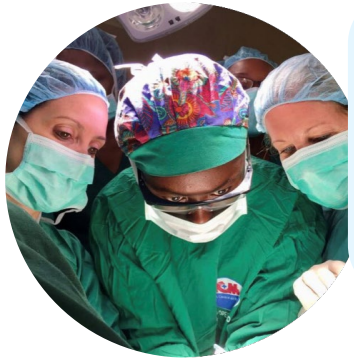
HPV LabNet contribution to WHO listing of high-quality HPV tests

1. Quality assurance of HPV testing: implementation and monitoring
2. Building capacity to perform validations: research and biobanking

Thanks to all that contribute to progress to cervical cancer elimination

Governments

- Commit to 90-70-90 **national CCEI policies**
- **Invest resources** linked to policy commitments
- Leverage **multi-sectoral engagements**, linked to **integrated programmes**



Donors

- Agile **funding** for national programmes
- Strengthen **pricing approaches** through **coordinated procurement**
- Commit to **national coordination**, support MoHs

Academia and Private Sector

- Make reliable stream of **affordable vaccine supplies**
- **Increase availability** of QA HPV tests and treatment devices
- **Innovate in line with community needs**

World Health Organization

Proficiency studies 2.0: Evaluation of novel HPV assays

Emel YILMAZ, MSc

Center for Cervical Cancer Elimination, Karolinska University Hospital & Karolinska Institutet, Stockholm, Sweden

International HPV Reference Center, Karolinska University Hospital, Stockholm, Sweden

- I have no conflict of interest to declare

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- Two panels:
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- IHRC has organized an **international collaborative study (Study I)** to determine the thresholds that would result in optimal sensitivity and specificity of HPV screening assays.
- Establishment of such thresholds will enable simple, yet internationally standardized evaluation of the performance of novel HPV assays for screening.

METHODS

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- Cycle threshold (Ct) values from serially diluted standards, were utilized to generate standard curves for HPV types
- And used for estimation of virus amounts in the cervical samples

STUDY I

*Preprint: https:/ / www.medrxiv.org/ content/ 10.64898/ 2026.02.03.26345438v1

STUDY I

- International Collaborative Study on Human Papillomavirus Analytical Thresholds for Sensitivity and Specificity in Cervical Screening*
- Participating laboratories from **AUSTRALIA, BELGIUM, FRANCE, GERMANY, ITALY, SCOTLAND, SLOVENIA, SWEDEN, TÜRKİYE, and USA**

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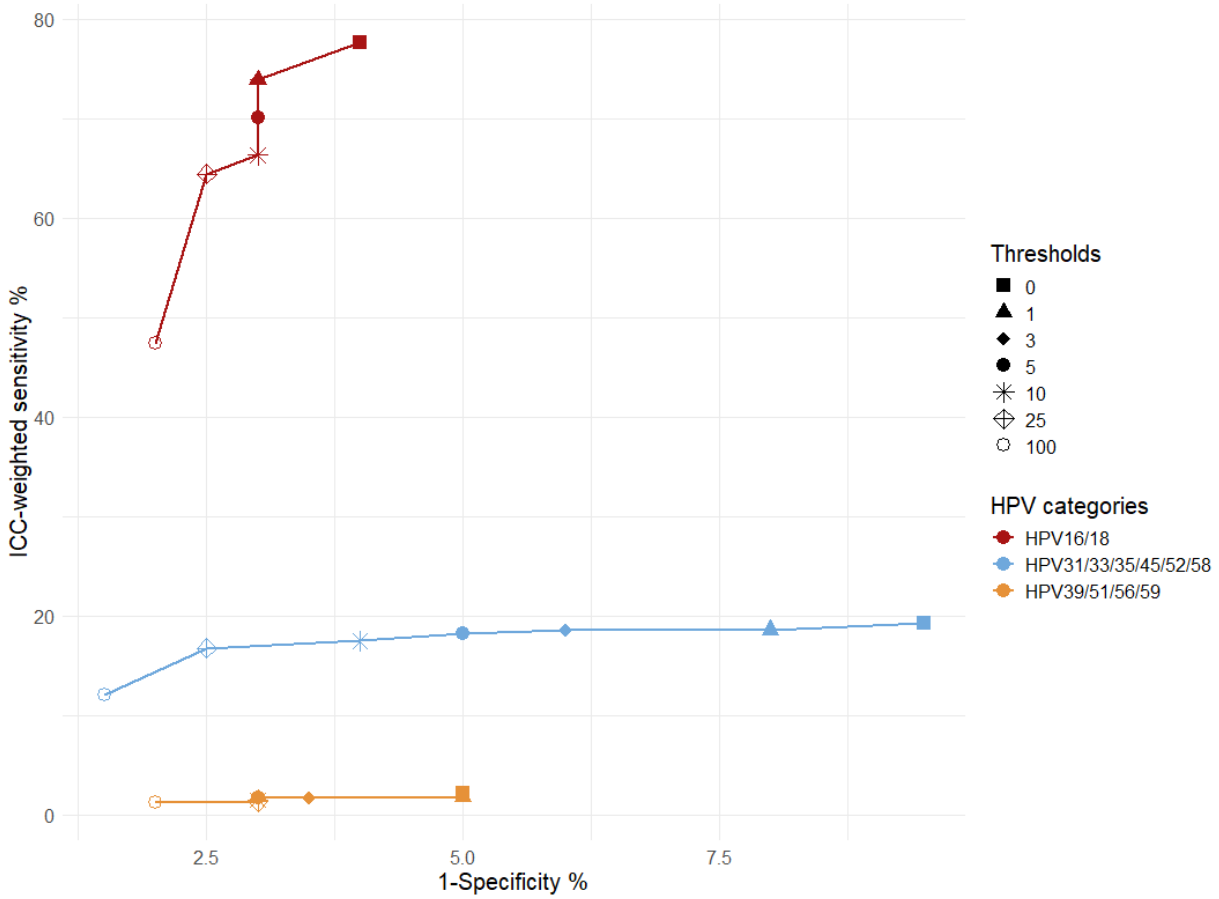
- ICC-weighted sensitivity using IARC attributable fractions for invasive cervical cancer** and 1-specificity of CIN2+ by HPV types



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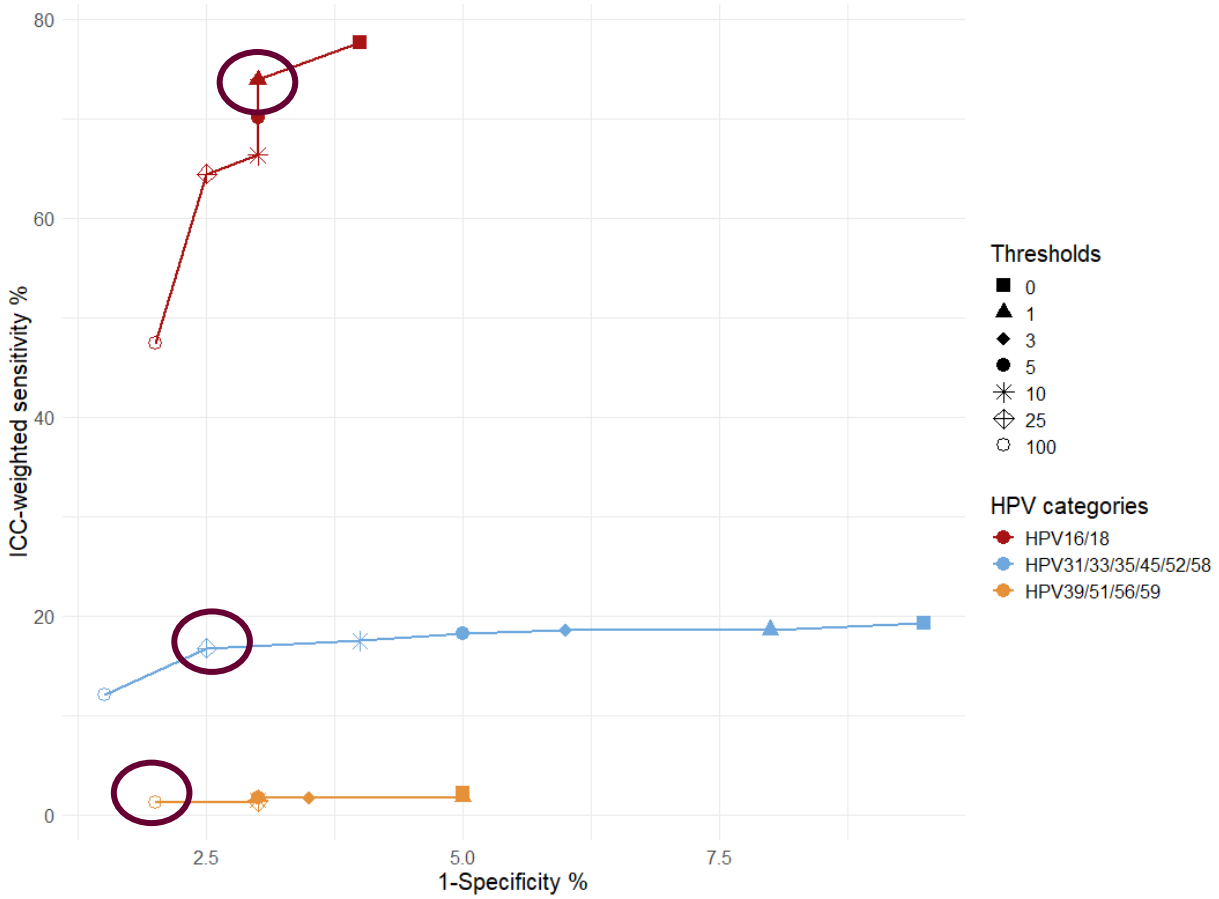
  - **3 IU/ µl** for HPV16 and 18
  - **25 IU/ µl** for HPV31, 33, 45, 52 and 58 and **25 GE/ µl** for HPV35
  - **100 GE/ µl** for HPV39, 51, 56 and 59.



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  - HPV analysis results from 2022 April to 2025 June
    - including Ct values of HPV16, 18, 31, 45, 51, 52, (33/58), (56/59/66), (35/39/68)

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  - HPV analysis results from 2022 April to 2025 June
    - including Ct values of HPV16, 18, 31, 45, 51, 52, (33/58), (56/59/66), (35/39/68)
- HPV data linked to Swedish National Gynecological Cancer Register (from 2022 to 2024)

STUDY II – prel. data

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SELF COLLECTED SAMPLES

175 280 index self collected samples

STUDY II – prel. data

SELF COLLECTED SAMPLES

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44 cancer diagnosis at the same date or after HPV results of index self collected samples

STUDY II – prel. data

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44 cancer diagnosis at the same date or after HPV results of index self collected samples

175 236 - no matched cancer diagnosis or cancer diagnosis before index HPV analysis

STUDY II – prel. data

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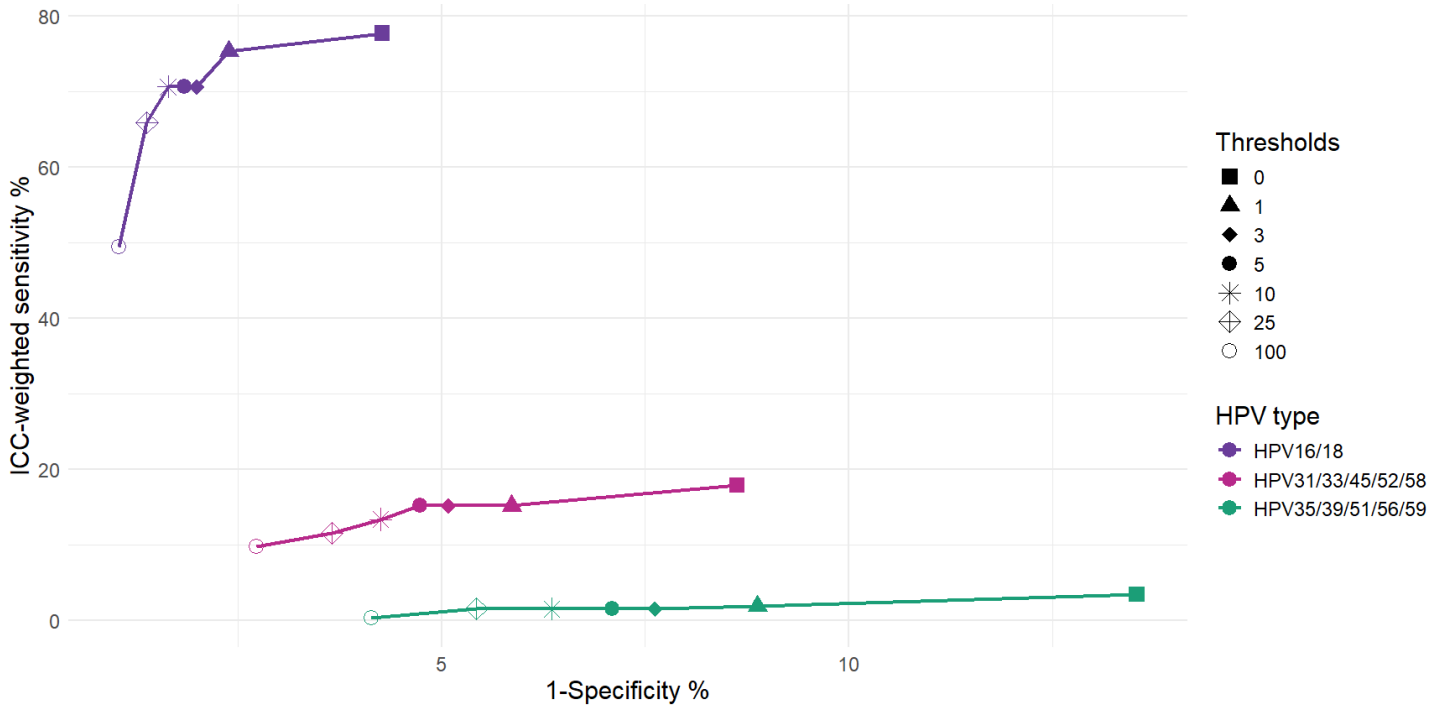
- ICC-weighted sensitivity using IARC attributable fractions for invasive cervical cancer** and 1-specificity of invasive cervical cancer by HPV types



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STUDY II – prel. data

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- *Analytical thresholds from Study I*

- **3 IU/ µl** for HPV16 and 18
- **25 IU/ µl** for HPV31, 33, 45, 52 and 58 and
- **100 GE/ µl** for HPV35, 39, 51, 56 and 59.

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STUDY II – prel. data

CLINICIAN TAKEN SAMPLES

STUDY II – prel. data

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117 771 index clinician taken samples

STUDY II – prel. data

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92 cancer diagnosis at the same date or after HPV results of index clinician taken samples

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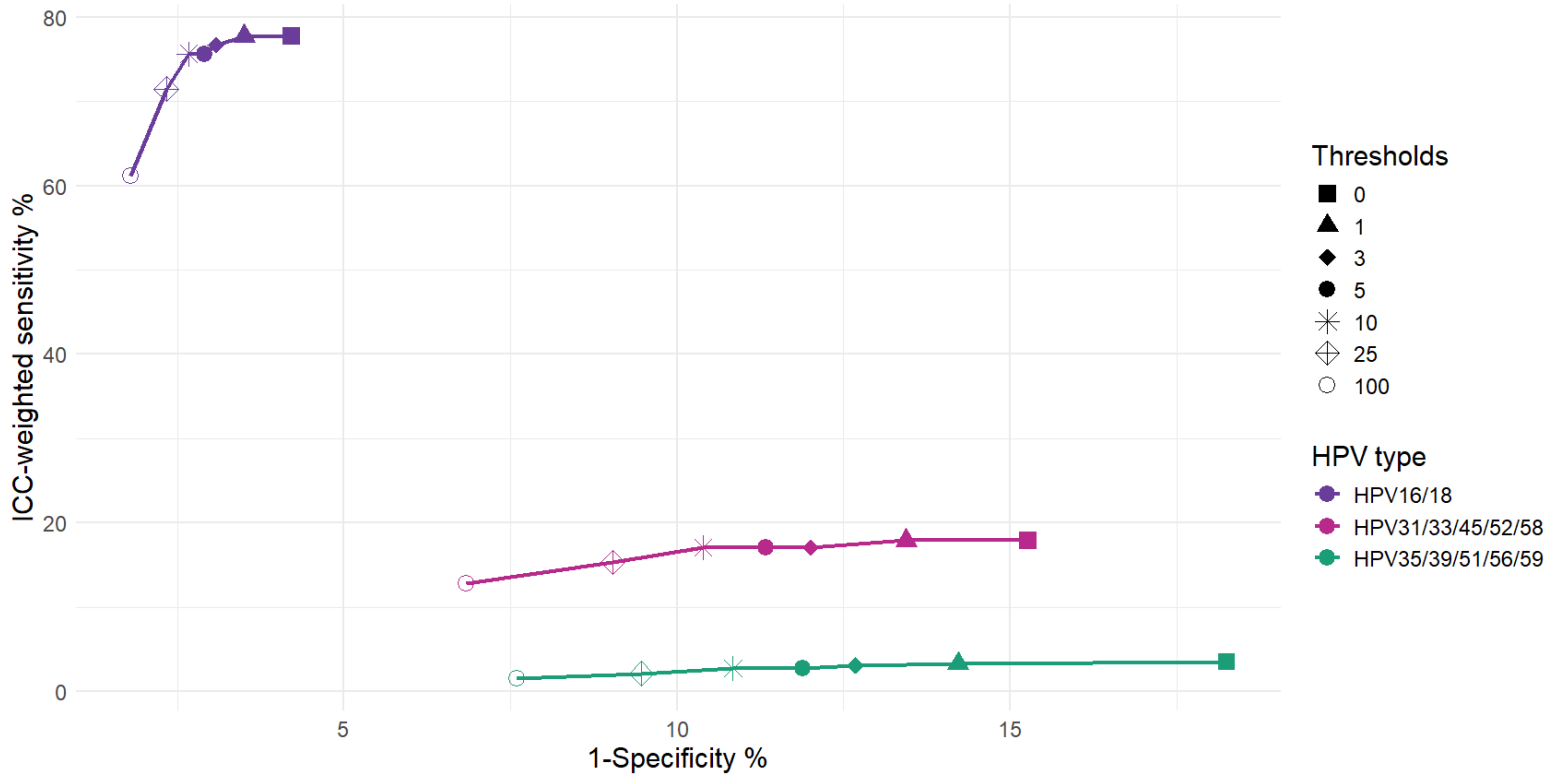


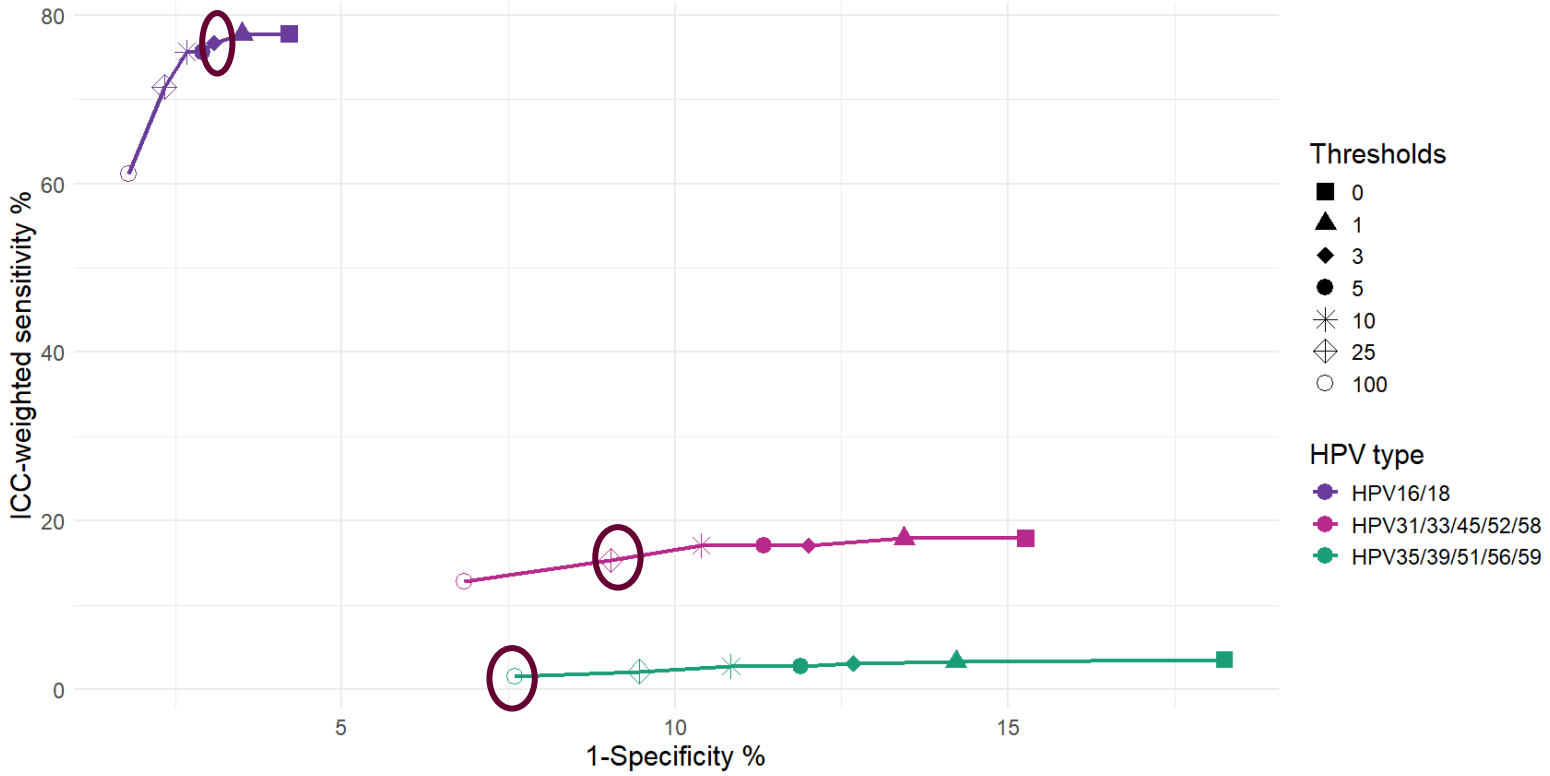
**IARC (2022). Cervical cancer screening. IARC Handb Cancer Prev. 18:1–456. Available from: https://publications.iarc.fr/604

STUDY II – prel. data

CLINICIAN TAKEN SAMPLES

- ICC-weighted sensitivity using IARC attributable fractions for invasive cervical cancer** and 1-specificity of invasive cervical cancer by HPV types
- *Analytical thresholds from Study I*

- **3 IU/ µl** for HPV16 and 18
- **25 IU/ µl** for HPV31, 33, 45, 52 and 58 and
- **100 GE/ µl** for HPV35, 39, 51, 56 and 59.



**IARC (2022). Cervical cancer screening. IARC Handb Cancer Prev. 18:1–456. Available from: https://publications.iarc.fr/604

SUMMARY

- We present a structured internationally standardized evaluation framework for novel HPV testing methods based on simple serial dilutions of IS
- Robust, internationally standardized validation approach would facilitate validation at minimal cost

Acknowledgement

- All employees at Center for Cervical Cancer Elimination (CCCE)
- HPV LabNet
- International Human Papillomavirus Reference Center

FUNDING

- Bill & Melinda Gates Foundation
- The Swedish Cancer Society
- The Swedish Research Council

Thank you!

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EUROGIN
INTERNATIONAL MULTIDISCIPLINARY HPV CONGRESS

MARCH 18-21, 2026
VIENNA-AUSTRIA

Sample Adequacy Revisited:
Lessons from Large-Scale Self-Sampling Programs

Clementina Cocuzza
University of Milano-Bicocca

DISCLOSURES

Research funding and /or Free Consumables provided in the last two years by Elitech, Becton Dickinson, Copan, Seegene, VITRO S.A.

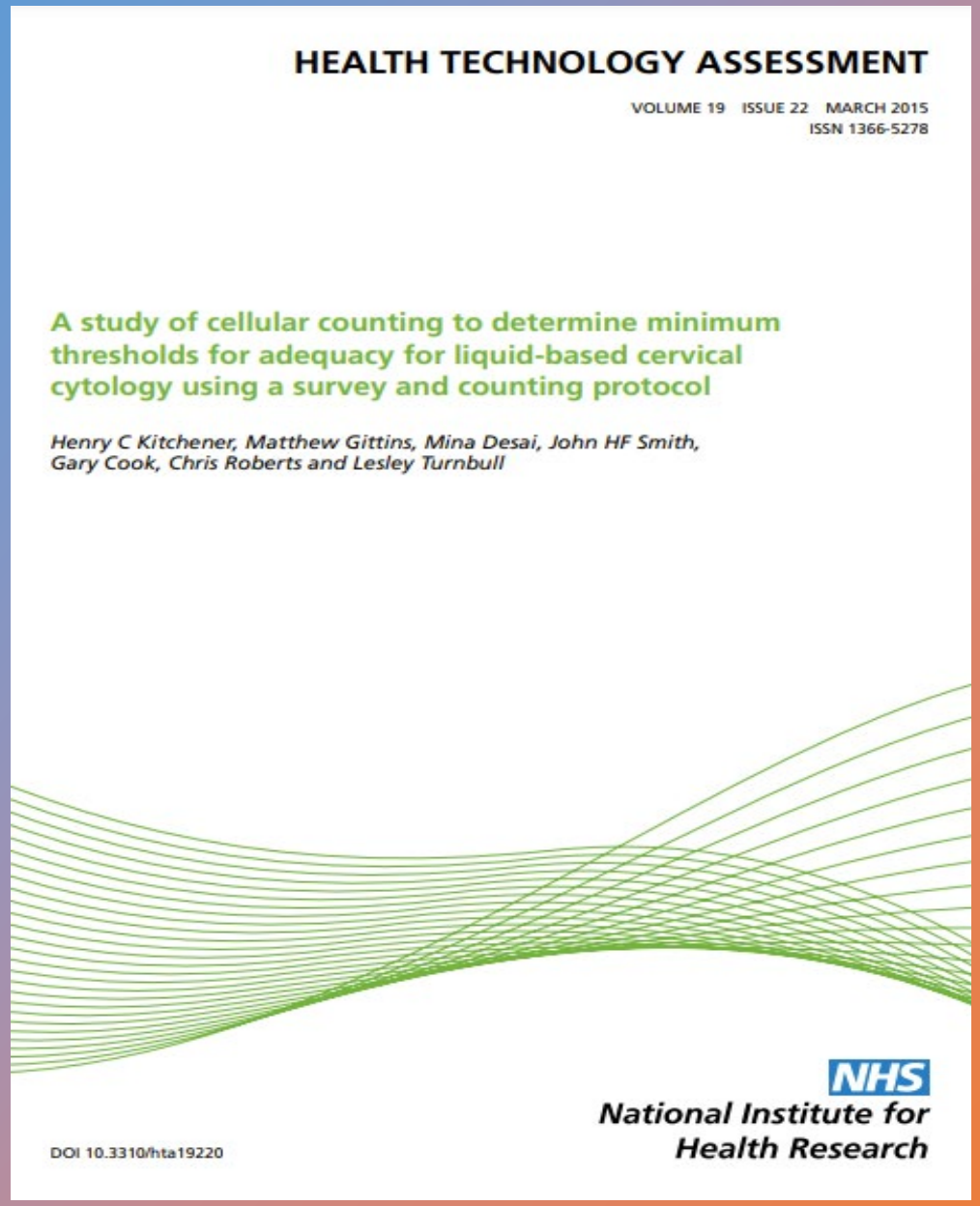
Cofounder of Hiantis Srl

SAMPLE ADEQUACY ASSESSMENT: in Cervical Cancer Screening Programs

- **Cytology and HPV tests are based on the collection of samples from a body surface with a potential variability in sample cellularity.**

- **Sample cellularity affected by**
  - Operator performing collection (professional vs self-collection)
  - Sample-Collection Device & Procedure of collection
  - Resuspension medium & volume
  - Sample transport & stability (ie time, temperatures…) prior to testing
  - Woman's age, etc.

- **Requirement for Quality Assurance in Cervical Cancer Screening:**
  - *Accurate risk assessment*
  - *Avoids potentially «false negative»* results



Sample Adequacy Assessment for Cytology-based Screening on Cervical Samples

The Bethesda System indicates a **minimum acceptable cell count of 5000 squamous cells on the slide** for a preparation to be regarded as adequate.

Nayar R, Wilbur DC (eds): The Bethesda System for Reporting Cervical Cytology, ed 3 Definitions, Criteria, and Explanatory Notes. New York, Springer, 2015.

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

«Internal Control»

- «Endogenous» human cell gene target
  - **Usually only providing a qualitative assessment**
  - **Not cell type-specific**

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

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

Internal control 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 GENEV	STORAGE MEDIA	Human gene IC Cutoff
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	Beta-globin 32 Ct
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	Beta-globin +
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	Beta-globin 40 Ct
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	Beta-globin 33 Ct
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	Beta-globin POS/NEG
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	Beta-globin 34.2 Ct
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	ADAT-1 gene ??
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	Beta-globin 35 Ct
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	HMBS gene ??
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	Beta-globin ? 40 Ct
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	CFTR gene ??
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	CCR5 <400 cells/reaction
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	Beta-globin 34 Ct
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	CCR5 <400 cells/reaction
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	Beta-globin <0.12 ng/ul
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	Beta-globin 43 Ct
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	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

Criteria for second generation comparator tests in validation of novel HPV DNA tests for use in cervical cancer screening

TABLE 2 Characteristics of candidates for second generation comparator HPV tests that could be used for validation of emerging HPV tests for use in cervical cancer screening. The last two columns contain the pooled relative sensitivity and specificity of second versus first generation comparator HPV tests to detect CIN2+.

Assay	Nb of validation studies: Accuracy[f]	Nb of validation studies: Reproducibility[g]	Group I carcinogenic HPV types targeted[h]	Group II carcinogenic HPV types targeted[i]	Collection and storage media[j]	Pooled relative clinical sensitivity (90% CI)[k]	Pooled relative clinical specificity (90% CI)[k]
Anyplex[a]	3	2	all 12	66, 68	PC, HP	1.007 (0.979-1.037)	1.004 (0.991-1.018)
Cobas 4800[b]	5	2	all 12	66, 68	UCM, PC, SP	1.002 (0.979-1.025)	1.003 (0.992-1.013)
HPV-risk[c]	3	1	all 12	66, 67, 68	PC, SP	0.993 (0.962-1.024)	1.018 (1.002-1.035)
Onclarity[d]	4	2	all 12	66, 68	PC, SP	1.001 (0.974-1.029)	0.998 (0.981-1.014)
RealTime[e]	6	3	all 12	66, 68	STM, PC	0.992 (0.971-1.014)	1.015 (1.009-1.022)

Beta-globin Human gene IC

+/- No Ct value

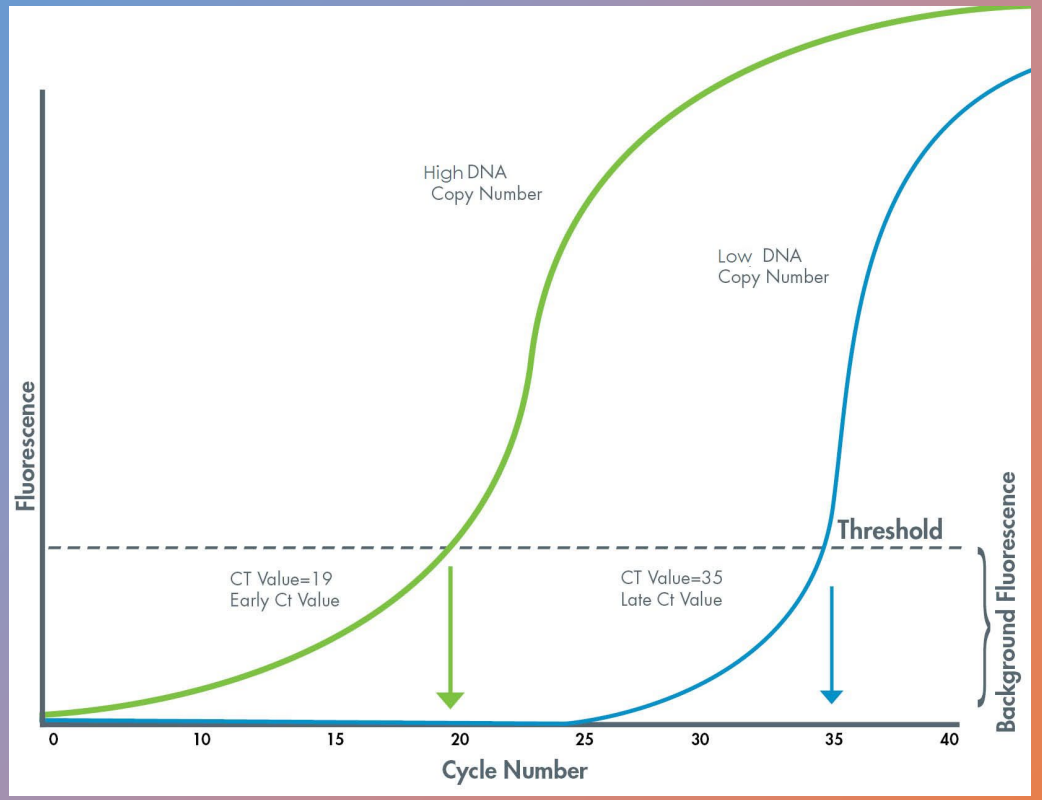
40 Ct

(33 Ct)

34.2 Ct

35 Ct

Arbyn M, Cuschieri K, Bonde J, Schuurman R, Cocuzza C, Broeck DV, Zhao FH, Rezhake R, Gultekin M, de Sanjosé S, Canfell K, Hawkes D, Saville M, Hillemanns P, Dillner J, Berkhof J, Prétet JL, Gheit T, Clifford G, Basu P, Almonte M, Wentzensen N, Poljak M. Criteria for second generation comparator tests in validation of novel HPV DNA tests for use in cervical cancer screening. J Med Virol. 2024 Sep;96(9):e29881. doi: 10.1002/jmv.29881.



What informations do Ct values provide?

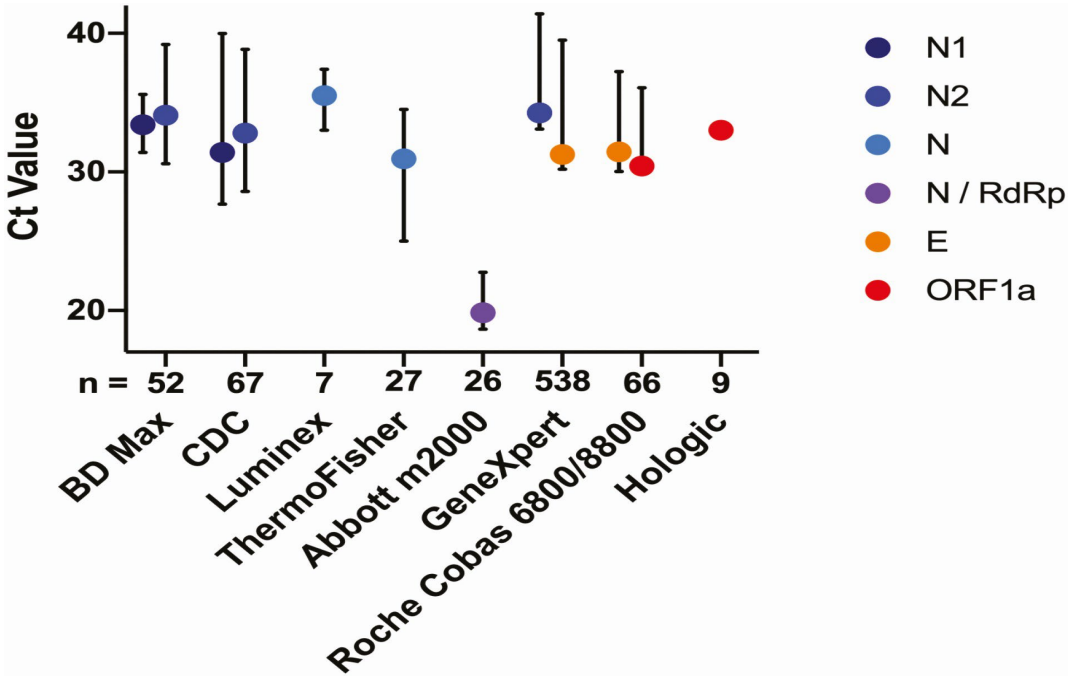
- Cycle threshold (Ct) values refer to the number of PCR cycles required to amplify the targeted nucleic acid sequence to a detectable level
- Real-time PCR tests or experiments are usually programmed to run 40 cycles and Ct values for most HPV assays provide a qualitative / semi-quantitative assessment:
- Ct values beween different qualitative assays **cannot** be compared as they use different:
  - sequences of gene targets
  - preanalytical & analytical workflows

Clinical Infectious Diseases

CORRESPONDENCE

College of American Pathologists (CAP) Microbiology Committee Perspective: Caution Must Be Used in Interpreting the Cycle Threshold (Ct) Value

Ct values for gene targets and manufacturers for the same batch of testing material. Median Ct values



Clin Infect Dis, Volume 72, Issue 10, 15 May 2021, Pages e685–e686, https://doi.org/10.1093/cid/ciaa1199

Quality Assurance in Cervical Cancer Screening: Evaluation of Sample Adequacy in HPV DNA Testing

M. d'Avenia[1,2] | F. Dell'Anno[3] | M. Martinelli[1] | L. Santomauro[2] | R. C. Njoku[1] | L.S. Arroyo Mühr[4] | M. Iacobellis[2] | C. E. Cocuzza[1]

[1]School of Medicine and Surgery, University of Milano-Bicocca, Milan, Italy | [2]UOSVD Cytopathology and Screening Laboratory, ASL BARI, Bari, Italy | [3]National Reference Center of Veterinary and Comparative Oncology (CEROVEC), Istituto Zooprofilattico Sperimentale del Piemonte, Liguria e Valle d'Aosta, Genoa, Italy | [4]Department of Clinical Science, Intervention and Technology (CLINTEC), Karolinska Institutet, Center for Cervical Cancer Elimination, Stockholm, Sweden

HPV test results sorted by β-globin Ct-value.
Numbers and percentages of positive and negative HPV cases for each Ct group of β-globin amplification.

	β-globin (Ct values)					
HPV	**β-globin ≤ 28** N (%)	**28 < β-globin ≤ 32** N (%)	**32 < β-globin ≤ 34** N (%)	**34 < β-globin ≤ 40** N (%)	**Total** N (%)	**Chi squared χ^2** (p-value)
Negative	16,981	16.7	839	211	34,701	
	90.3	94.2	96.1	98.6	92.3	219.9
Positive	1,820	1,034	34	3	2,891	<0.001
	9.7	**5.8**	**3.9**	**1.4**	**7.7**	
Total	18,801	17,704	873	214	37,592	
	100	100	100	100	100	

37,592 LBC samples from screening

Overall 7.7% HPV-Positivity Rate
using Cobas®4800

*Cobas 4800 β-globin Cut-off ≤ Ct 40

d'Avenia M et al. Quality Assurance in Cervical Cancer Screening: Evaluation of Sample Adequacy in HPV DNA Testing. J Med Virol. 2025 Jul;97(7):e70482.

Quality Assurance in Cervical Cancer Screening: Evaluation of Sample Adequacy in HPV DNA Testing

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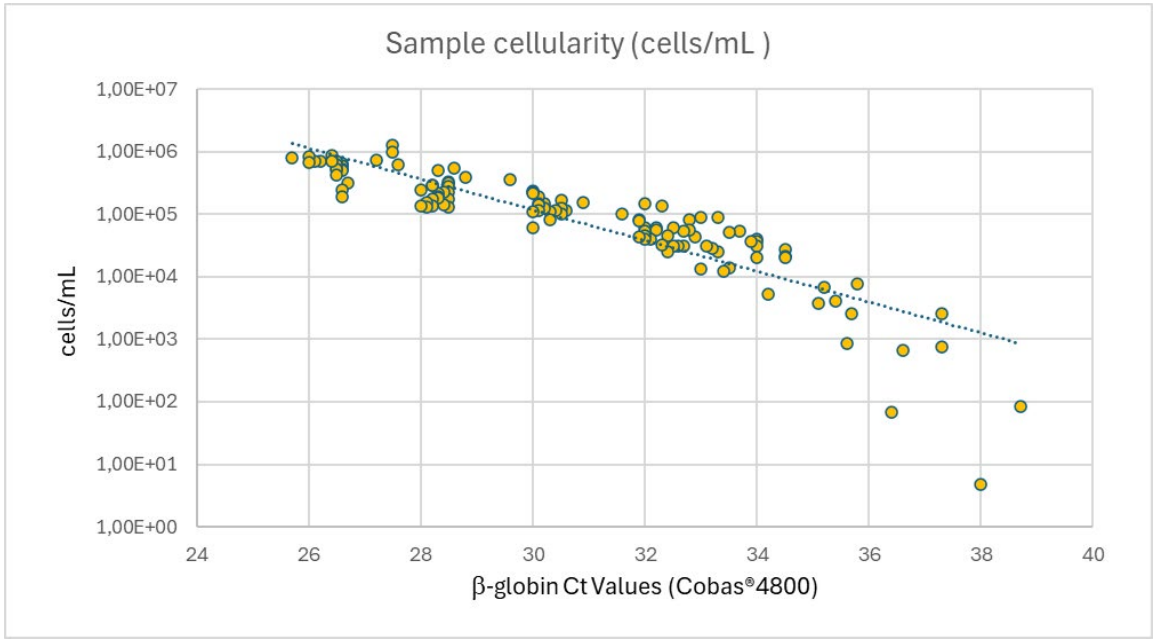
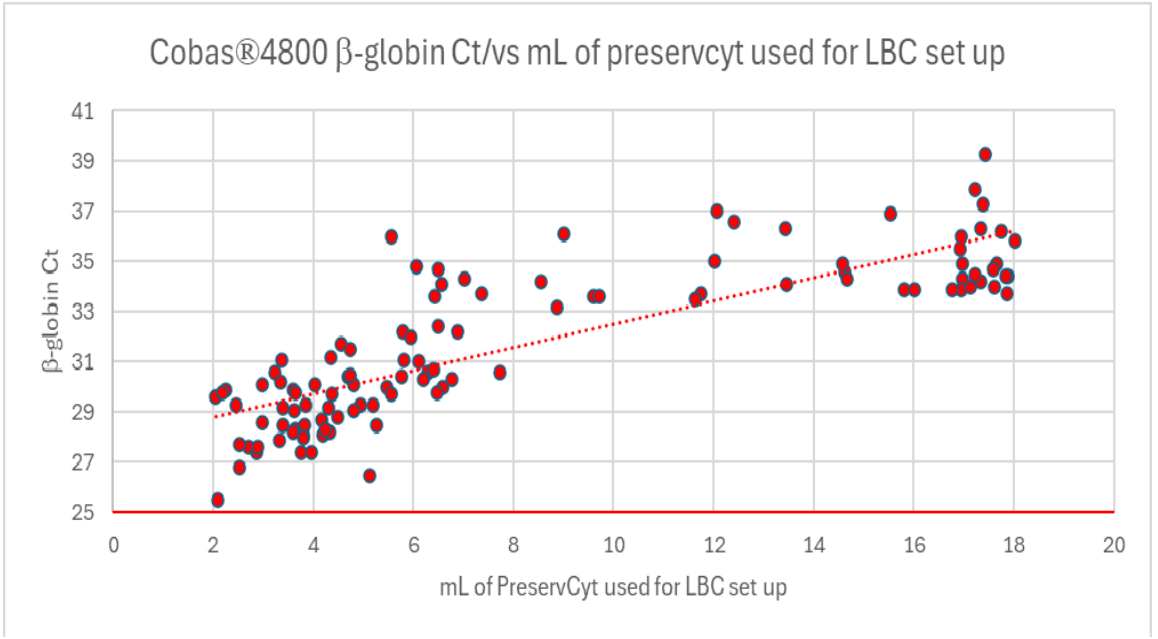
Sample cellularity evaluated in 195 HPV-negative samples using Cobas®4800 (Roche) qualitative β-globin IC and OncoPredict HPV (Hiantis) quantitative cellularity assessment.





*Cobas 4800 β-globin Cut-off ≤ Ct 40

d'Avenia M et al. Quality Assurance in Cervical Cancer Screening: Evaluation of Sample Adequacy in HPV DNA Testing. J Med Virol. 2025 Jul;97(7):e70482.

WHY DOES SAMPLE ADEQUACY ASSESSMENT NEED REVISITING FOR HPV ASSAYS USED ON SELF-SAMPLES?

RESEARCH Open Access

Evaluation of the applicability of internal controls on self-collected samples for high-risk human papillomavirus is needed

Bo Verberckmoes[1,6*], Tamara De Vos[2], Karel Maelegheer[3], Catherine Ali-Risasi[4], Yolande Sturtewagen[2], Marleen Praet[2], Davy Vanden Broeck[1,5] and Elizaveta Padalko[2]

Abstract

Background Self-collection of cervical samples to detect high-risk human papillomavirus (hr-HPV) is a trending topic in primary cervical cancer screening. This study evaluates the applicability of a self-sampling device to routine molecular procedures for hr-HPV detection.

Methods In a primary health care facility in Kinshasa, Congo, 187 self-collected samples (Evalyn Brush) were gathered and sent to Ghent University Hospital (UZ Ghent) and Algemeen Medisch Labo (AML) in Belgium where routine tests for hr-HPV were applied (Abbott RealTime hr-HPV and qPCR (E6/E7), respectively). Sample type effect was evaluated by comparing the internal control (IC) between the self-collected samples and routine, clinician-taken samples randomly selected from the UZ Ghent archive.

Results In UZ Ghent an error was encountered in 9.1% (17/187) of self-collected samples due to a lack of IC signal. The hr-HPV prevalence in the remaining 170 samples was 18,8%. Comparing IC results between the self-collected and clinician-collected groups, a significant difference ($p < 0{,}001$) was found, with higher IC signals in the clinician-collected group. In AML, an error was encountered in 17.6% (33/187) of samples, including 16/17 of the UZ Ghent. The remaining sample with IC error gave a negative result in AML. Among the 154 samples without IC error at AML, a correlation of 90% was seen between both laboratories with a 77% negativity rate.

Conclusion Testing the self-collected specimens by 2 routine hr-HPV tests gave a high IC error rate (9.1–17.6%). A possible solution would be to differentiate cut-offs for IC values depending on sample type, as currently used cut-offs are set for clinician-taken samples.

Keywords Human papillomavirus, Self-sampling, Internal control, HPV assay

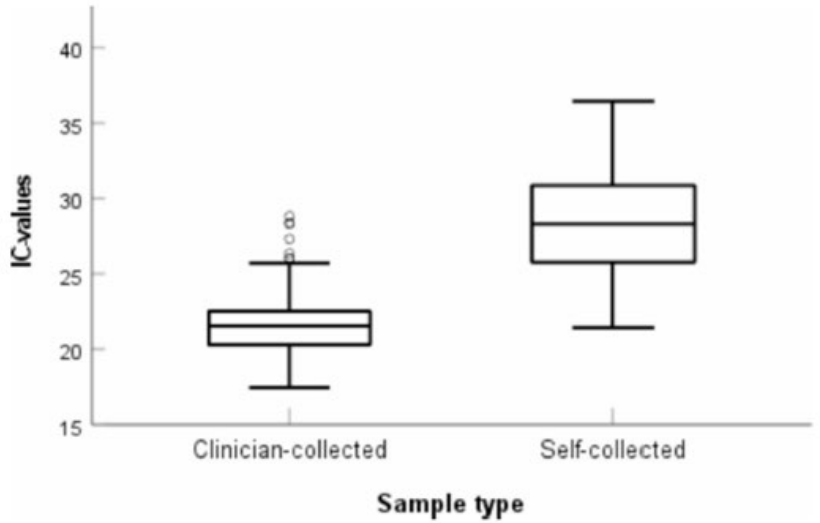


Fig. 2 Comparison of CN values of IC signals between the self-collected and clinician-collected samples

Different IC cut-offs values based on sample type, rather than currently used cut-offs set for clinician-taken samples

Europe PMC Funders Group
Author Manuscript
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doi:10.1158/1055-9965.EPI-20-1226.

A randomised comparison of different vaginal self-sampling devices and urine for human papillomavirus testing – Predictors 5.1

Louise Cadman[1,†], **Caroline Reuter**[1], **Mark Jitlal**[1], **Michelle Kleeman**[1,3], **Janet Austin**[1], **Tony Hollingworth**[1], **Anna L. Parberry**[2], **Lesley Ashdown-Barr**[1], **Deepali Patel**[1,3], **Belinda Nedjai**[1], **Attila T. Lorincz**[1], **Jack Cuzick**[1]

[1]Centre for Cancer Prevention, Wolfson Institute of Preventive Medicine, Queen Mary University of London, Charterhouse Square, London

[2]Colposcopy Department, Royal London Hospital, London

[3]NIHR Biomedical Research Centre, Guy's and St Thomas' NHS Foundation Trust and King's College, London

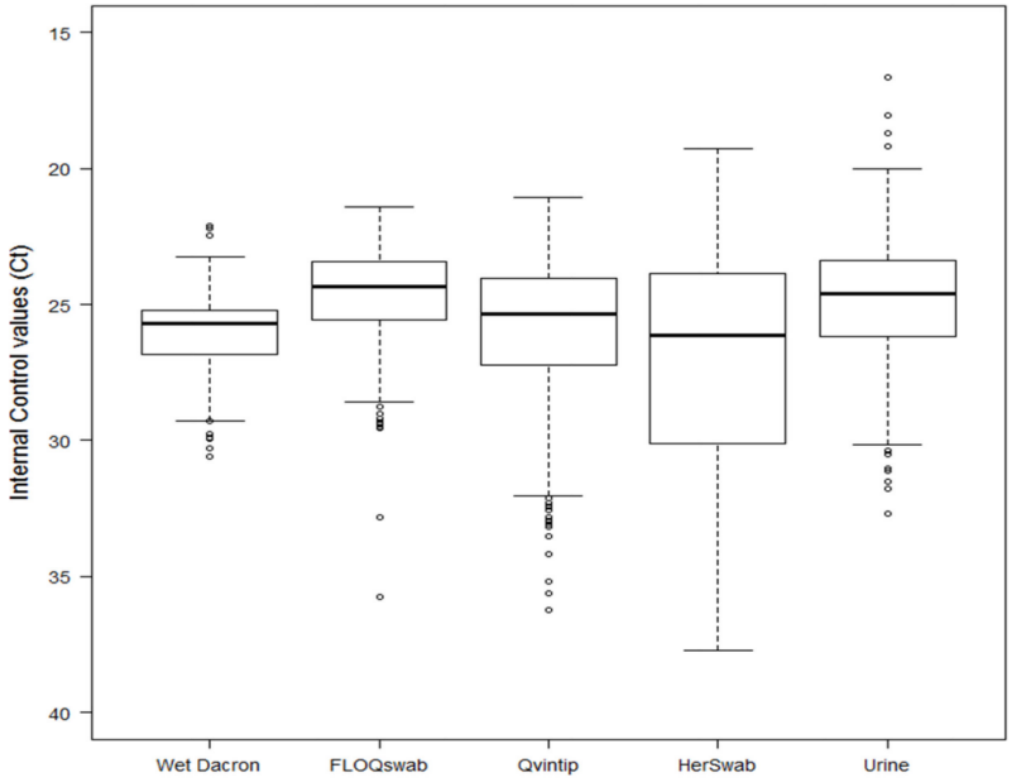


Figure 2.
Cellularity of samples by device type. The cellularity is represented by the Ct values of the internal control (β-globin). A low Ct value indicates a higher cellularity and the vertical scale is ordered by decreasing Ct values.

Cadman et al. A randomised comparison of different vaginal self-sampling devices and urine for human papillomavirus testing – Predictors 5.1 Cancer Epidemiol Biomarkers Prev. 2021 April 01; 30(4): 661–668.

HPV-based Cervical Cancer Screening on Self-samples in the Netherlands: Challenges to Reach Women and Test Performance Questions

Marc Arbyn[1,2], Stefanie Costa[1], Ardashel Latsuzbaia[1], Eliane Kellen[3], Paolo Girogi Rossi[4], Clementina E. Cocuzza[5], Partha Basu[6], and Philip E. Castle[7]

Table 2. Parameters that may influence the accuracy of hrHPV testing on vaginal self-samples.

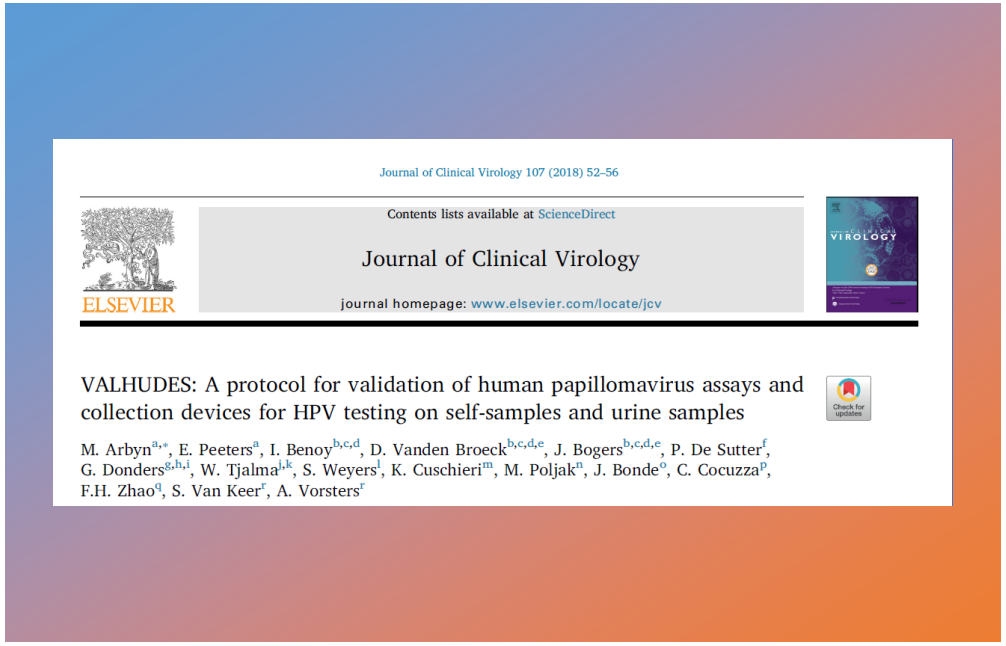
Vaginal self-sample collection procedure:
- Collection device
- Recommended depth of device insertion during collection/device shaft length
- Procedure for self-collection (i.e., number of vaginal rotations during collection)
- Usage of vaginal products (creams, gels, etc.) preceding sample collection (these may result in PCR inhibition)

Self-sample transport:
- Sample resuspended immediately following collection or transported dry to the laboratory
- Sample stability and storage conditions (temperature and time from collection to laboratory processing)
- Transport medium
- Volume of transport medium used for vaginal sample resuspension
- Sample vortexing (intensity and duration) prior to processing

Preanalytical workflow following vaginal sample resuspension:
- Sample starting volume selected for further processing
- Sample centrifugation with resuspension of cellular pellet versus sample starting volume to be used for nucleic acid extraction
- Nucleic acid extraction method: rapid extraction (i.e., rapid heat extraction) versus standard extraction protocols
- Elution volume—volume used for eluting extracted nucleic acids present in the sample starting volume following standard extraction methods

Analytic procedure—HPV testing using PCR-based methods
- Volume of extracted nucleic acids used in PCR mix
- Positivity criterion in terms of C_t value, viral concentration using standard curve analysis, normalized viral load (viral concentrations adjusted for number of cells per sample)
- Sample's endogenous control to evaluate sample adequacy and/or "internal" control to check for PCR inhibition, or other metrics.

Arbyn M et al. HPV-based Cervical Cancer Screening on Self-samples in the Netherlands: Challenges to Reach Women and Test Performance Questions. Cancer Epidemiol Biomarkers Prev. 2023 Feb 6;32(2):159-163.



Journal of Clinical Virology 107 (2018) 52–56

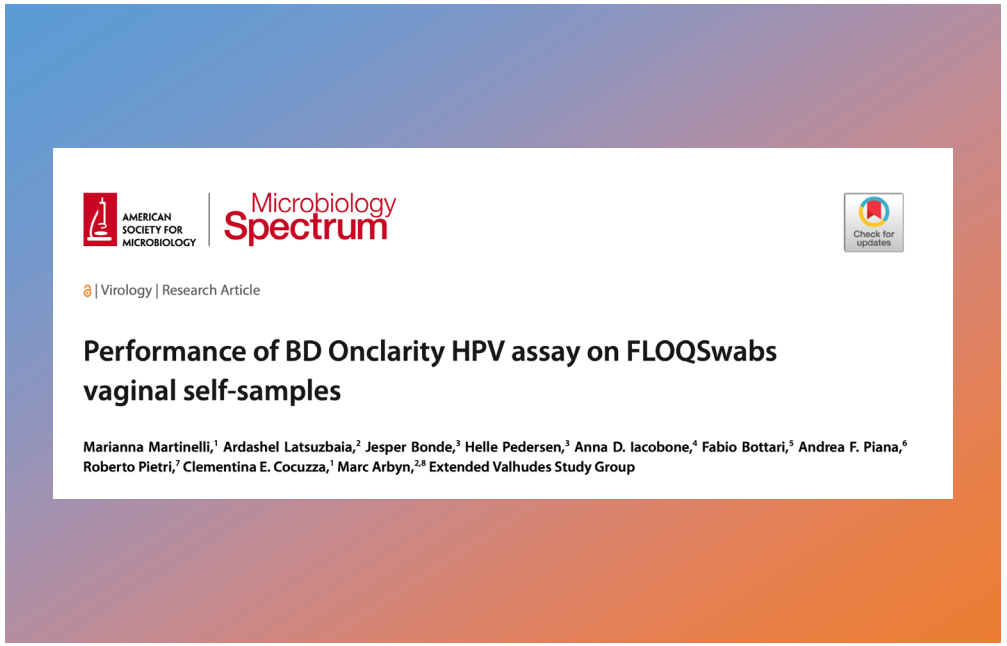
Contents lists available at ScienceDirect

Journal of Clinical Virology

journal homepage: www.elsevier.com/locate/jcv

VALHUDES: A protocol for validation of human papillomavirus assays and collection devices for HPV testing on self-samples and urine samples

M. Arbyn[a,*], E. Peeters[a], I. Benoy[b,c,d], D. Vanden Broeck[b,c,d,e], J. Bogers[b,c,d,e], P. De Sutter[f], G. Donders[g,h,i], W. Tjalma[j,k], S. Weyers[l], K. Cuschieri[m], M. Poljak[n], J. Bonde[o], C. Cocuzza[p], F.H. Zhao[q], S. Van Keer[r], A. Vorsters[r]



Microbiology Spectrum

Virology | Research Article

Performance of BD Onclarity HPV assay on FLOQSwabs vaginal self-samples

Marianna Martinelli,[1] Ardashel Latsuzbaia,[2] Jesper Bonde,[3] Helle Pedersen,[3] Anna D. Iacobone,[4] Fabio Bottari,[5] Andrea F. Piana,[6] Roberto Pietri,[7] Clementina E. Cocuzza,[1] Marc Arbyn,[2,8] Extended Valhudes Study Group

Clinical Validation of HPV assays for their use on self-collected samples

Martinelli M et al. Performance of BD Onclarity HPV assay on FLOQSwabs vaginal self-samples. Microbiol Spectr. 2024;12(3)

Arbyn M et al.VALHUDES: A protocol for validation of human papillomavirus assays and collection devices for HPV testing on self-samples and urine samples. J Clin Virol. 2018 Oct;107:52-56.

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Journal of Clinical Virology

journal homepage: www.elsevier.com/locate/jcv

Assessing sample adequacy and clinical performance of self-collected and clinician-collected HPV specimens using internal control Ct values

Marianna Martinelli [a,1], Sadaf Sakina Hassan [b,1], Emel Yilmaz [b], Camilla Lagheden [b], Sara Nordqvist Kleppe [b], Clementina Cocuzza [a], Laila Sara Arroyo Mühr [b,*]

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ARTICLE INFO

Keywords:
Sample adequacy
Ct
HPV testing
Cervical screening

ABSTRACT

Background: Human papillomavirus (HPV) testing is the primary method for cervical cancer screening, but reliable detection depends on adequate sample cellularity. Cycle threshold (Ct) values for the assay's internal control (IC), such as β-globin, are commonly used as proxies for adequacy, yet standardized Ct cut-offs are lacking. We aimed to contribute evidence-based thresholds for sample adequacy using real-world data.
Methods: We analyzed 237,853 clinician-collected and self-collected samples tested with the BD Onclarity™ HPV Assay between 2022 and 2024. β-globin Ct values were assessed by HPV status to evaluate adequacy. Histologically confirmed CIN2+ outcomes were linked via the National Cervical Screening Registry to assess clinical performance.
Results: Among 110,482 clinician-taken samples, 73.63 % (81,350) were HPV negative; 74.32 % (60,457) of these had β-globin Ct ≤28, and only 1.28 % exceeded Ct 32.1. In 127,390 self-collected samples, 83.47 % (106,329) were HPV negative; 99.66 % (105,967) had Ct ≤28 and only 0.06 % exceeded Ct 32.1. HPV positivity declined gradually beyond Ct 26 and more markedly above Ct 28. CIN2+ cases (n = 5546) were rarely HPV negative (n = 73), and these showed low β-globin Ct values, indicating adequate cellularity. Self-collected samples had significantly lower Ct values than clinician-taken ones (median 21.5 vs. 26.5; p < 2.2e-16), likely due to lower resuspension volume.
Conclusions: Both clinician- and self-collected samples showed adequate cellularity, with potentially false negative HPV results from low cellular content appearing rare. Observed patterns suggest Ct <26 as optimal and Ct <28 as a minimum for program-level quality assurance with the BD Onclarity™ HPV Assay.

Martinelli M et al . Assessing sample adequacy and clinical performance of self-collected and clinician-collected HPV specimens using internal control Ct values. J Clin Virol. 2025 Dec;181:105869.

SAMPLE ADEQUACY FROM LARGE-SCALE SELF-SAMPLING PROGRAMS

Journal of Clinical Virology 181 (2025) 105869

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Assessing sample adequacy and clinical performance of self-collected and clinician-collected HPV specimens using internal control Ct values

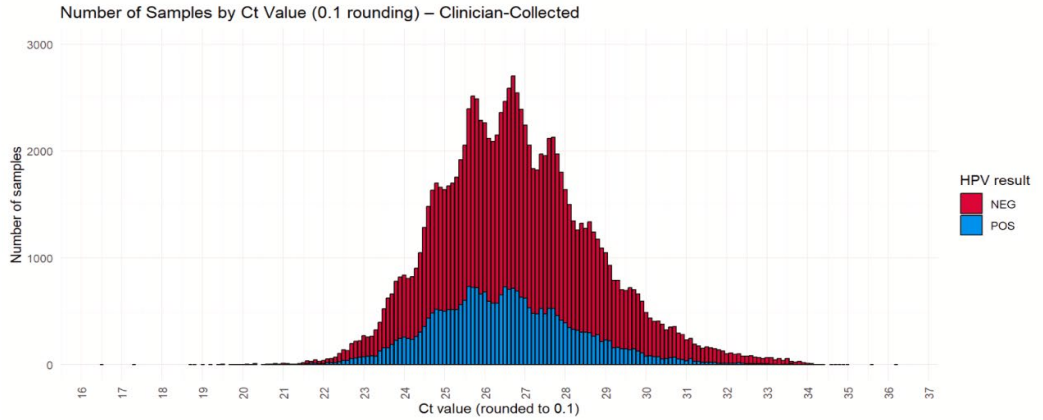
Marianna Martinelli [a,1], Sadaf Sakina Hassan [b,1], Emel Yilmaz [b], Camilla Lagheden [b], Sara Nordqvist Kleppe [b], Clementina Cocuzza [a], Laila Sara Arroyo Mühr [b,*]

[a] School of Medicine and Surgery, University of Milano-Bicocca, Milan 20126, Italy
[b] International HPV Reference Center, Center for Cervical Cancer Elimination, F56, Karolinska Institutet, Stockholm 14186, Sweden

- 237,853 Clinician-collected and Self-collected samples tested with the BD Onclarity™ HPV Assay
- Self-collected samples had significantly lower Ct values compare to clinician-taken samples
  - median Ct 21.5 vs. 26.5

β-globin evaluated in 3 separate reactions - Cut-off ≤ Ct 34.2

A) Total number of samples per Ct value (β-globin), illustrating the distribution of sample adequacy in clinician-collected samples.



B) Total number of samples per Ct value (β-globin), illustrating the distribution of sample adequacy in self-collected samples.

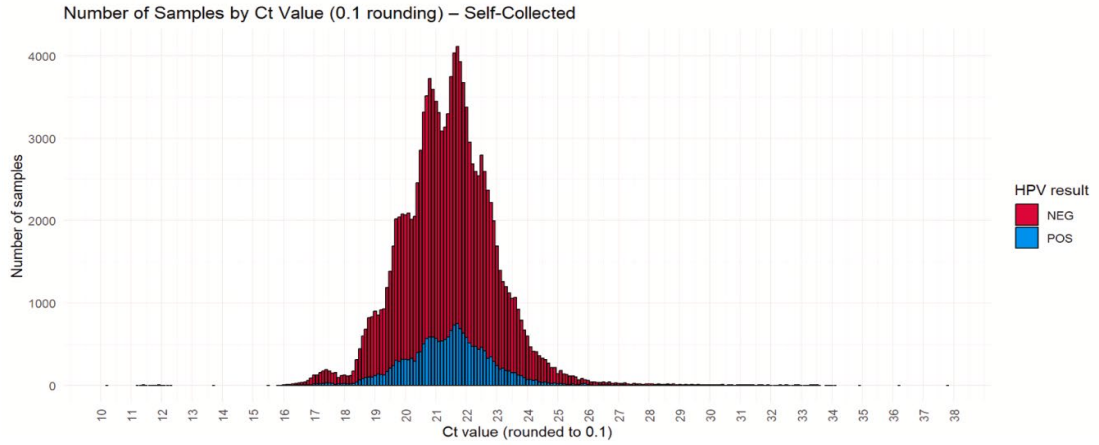


Fig. 1. Distribution of samples by β-globin Ct value.

Martinelli M et al . Assessing sample adequacy and clinical performance of self-collected and clinician-collected HPV specimens using internal control Ct values. J Clin Virol. 2025 Dec;181:105869

SAMPLE ADEQUACY FROM LARGE-SCALE SELF-SAMPLING PROGRAMS

Internal control Ct Values (β-globin) among histologically confirmed CIN2+ cases by HPV status and sample type.

HPV status	Sample type	Ct metric	HBB1_CtScore	HBB2_CtScore	HBB3_CtScore
HPV Negative	Self-sampling	Median	21.3	21.3	21.1
(n = 73)	(n = 14)	Min	18.9	18.8	19
		Max	26.9	26.8	26.4
	Clinician Taken	Median	26.4	26.5	26.3
	(n = 59)	Min	23.6	23.7	23.8
		Max	33.3	33.2	32.9
HPV Positive	Self-sampling	Median	21.1	21.2	21.1
(n = 5473)	(n = 413)	Min	16.3	16.6	16.5
		Max	30.3	30.8	30.1
	Clinician Taken	Median	26.3	26.4	26.3
	(n = 5060)	Min	21	21.1	20.9
		Max	34.8	34.5	35.7

Cycle threshold (Ct) values for β-globin (HBB1, HBB2, HBB3) are shown for both HPV positive and HPV negative samples, stratified by sample type (self-collected vs. clinician-collected). Ct values reflect DNA quantity, with lower Ct indicating higher DNA content. HPV testing was conducted within one year prior to CIN2+ diagnosis. HPV tests were performed within one year before CIN2+ diagnosis. Ct, cycle threshold; HBB, human beta-globin; HPV, human papillomavirus.

Martinelli M et al . Assessing sample adequacy and clinical performance of self-collected and clinician-collected HPV specimens using internal control Ct values. J Clin Virol. 2025 Dec;181:105869.

What are the challenges in defining sample adequacy that still need to be addressed?

- **Standardized criteria for sample adequacy in HPV-based screening are still lacking**
- DNA molecular tests **do not discriminate between different cell types.**
- Increased variability in **self-collected samples due to preanalytical factors.**
- **Should sample adequacy assessment be part of the clinical validation of HPV assays in the future?**

Marianna Martinelli
Chiara Giubbi
Ruth Chinyere Njoku
Giulio Mannarà
Federica Perdoni
Rosario Musumeci

Thank you for your attention!

Please attend the session on Friday!

SCIENTIFIC SESSIONS

Hall N1 **14.30 • 16.00**

SS 24 • ASSESSMENT OF THE SAMPLE CELLULARITY SHOULD BE AN OBLIGATORY PART OF THE QUALITY ASSURANCE PROGRAMS IN HPV–BASED CERVICAL CANCER SCREENING

CHAIR: Arbyn M. (Belgium) • Cocuzza C. (Italy)

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.

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)

Discussion and Q&A

National Services Division
Commissioning for Scotland's Health

NHS National Services Scotland

NHS Lothian

THE UNIVERSITY OF EDINBURGH

HPV testing in new countries: Lab manual, training and roll-out

Royal Infirmary of Edinburgh, NHS Lothian

Dr Kate Cuschieri

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

HPV LabNet

- "…the LabNet's mission includes developing laboratory expertise and infrastructure for HPV testing used in cervical cancer screening"

- LabNet is currently supported by the Bill and Melinda Gates Foundation and is composed of 18 national reference laboratories distributed in 5 WHO Regions worldwide with the International HPV Reference Center (IHRC) coordinated the network

HPV Laboratory Manual

The most recent version of the manual should be useful for

- Those involved in the development and implementation of HPV vaccines particularly laboratories generating or using HPV laboratory data
- *Laboratories performing cervical screening (HPV testing)*
- ..and other HPV researchers.

"This manual is a **living document** that will be amended in the light of future advances made in the area, and future global experience of HPV screening, HPV laboratory surveillance and vaccination monitoring"

HPV Laboratory Manual – online

CHAPTER	
1	Introduction
2	HPV Taxonomy
3	Laboratory Quality Assurance
4	Collection and handling of specimens for HPV testing
5	Nucleic Acid Extraction
6	HPV detection and typing
7	HPV serology
8	HPV International Standards
9	Data Management
10	International and National HPV Reference Centres
11	*Setting up an HPV Laboratory*

Red chapters arguably more suitable for labs considering screening/service work

Ideally need ***quality assurance resources tools and a system*** as an initial commitment

https://www.hpvcenter.se/hpv-laboratory-manual/

** Work in progress*

Quality Assurance Chapter

- **Includes perspectives on**
  - **Assay validation and verification**
  - **Instruments**
  - **External Quality Assurance**
  - **Audits**

Chapter 3 - Laboratory Quality Assurance

Maria Alejandra Picconi[1], Nazlı Songur[2], Maria Dolores Fellner[1],
Rita Mariel Correa[1], Murat Gultekin[2], Kate Cuschieri[3]

[1] Oncogenic Viruses Service, HPV National and Regional Reference Laboratory, National Institute of Infectious Diseases-ANLIS "Dr. Malbrán", C1282AFF Buenos Aires, Argentina.

[2] Hacettepe University Faculty of Medicine, Department of Obstetrics and Gynecology, Division of Gynaecological Oncology, Ankara, Turkey.

[3] Scottish HPV Reference Laboratory, Department of Laboratory Medicine, Royal Infirmary of Edinburgh, EH16 4SA & HPV Research Group, Centre for Reproductive Health, University of Edinburgh.

https://www.hpvcenter.se/wp-content/uploads/Chapter-3-Laboratory-Quality-Assurance.pdf

Not interactive but associated course/module under construction, like the phylogeny chapter. Does not contain significant content on how to set up a general quality management system

Home / Publications / Overview / Laboratory quality management system: handbook

Laboratory quality management system: handbook

WHO materials

1 January 2011 | Technical document

Download (5.9 MB)

Overview

This Laboratory quality management system handbook is intended to provide a comprehensive reference on Laboratory quality management system for all stakeholders in health laboratory processes, from management, to administration, to bench-work laboratorians. This handbook covers topics that are essential for quality management of a public health or clinical laboratory. They are based on both ISO 15189 and CLSI GP26-A3 documents. The handbook is linked to the training toolkit on laboratory quality management system

The handbook is linked to the training toolkit on laboratory quality management system

- Laboratory Quality Management System Training Toolkit
- Quality manual template
- Please see also the web site for Laboratory quality management

WHO TEAM

Public Health Laboratory Strengthening (PHL), WHO Headquarters (HQ)

EDITORS

World Health Organization

NUMBER OF PAGES

REFERENCE NUMBERS

ISBN: 9789241548274

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Français | Русский | Español

Can be downloaded, publication date **2011**

Training toolkit developed through collaboration with WHO, CDC and the Clinical and Laboratory Standards Institute

Intended to provide materials to support training workshops for stakeholders in labs (management, administration, bench work)

Trainers can select and customise materials to design and set up workshops

WHO Laboratory Quality Management System Training Toolkit – offered modules

Update due ??

International support beyond written guidance

- Establishment of a quality management system/infrastructure is important
- HPV specific lab manuals/guidance are important

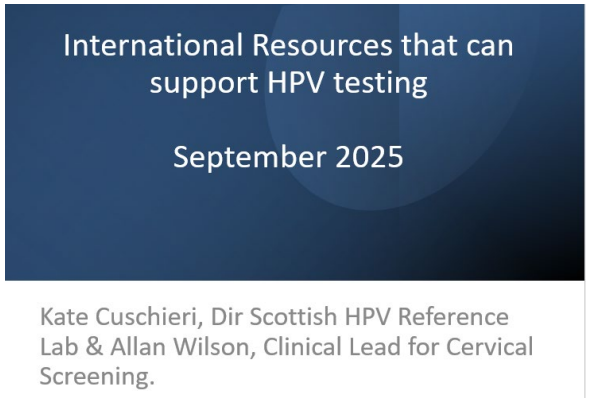
BUT

- Each lab/setting may have specific needs/challenges; how to support this optimally
- Hard to substitute/replace specific/“face to face” (online or actual) support

- **Mentor/mentee lab set up?**
- Working with WHO country-specific offices to perform training events? Work with onsite training “schools” to support sustainability

Working with WHO country-specific offices to support in training events (example)

- Scotland (Ref Lab and Clinical Lead for Cervical Screening) part of delegation to support roll out of HPV based screening in Uzbekistan
- Presentations included those on selecting HPV tests, Cytology, Quality Assurance, Accessible International Resources, included interactive aspects, knowledge assessment exercises
- Those that attended represented policy, lab & clinical disciplines



Tashkent Uzbekistan Sept. 2025

Support for HPV testing (self sampling) in Ukraine (**Swedish Reference Lab**)

1000 Women → HC → Self-sampling kit → HPV testing Laboratory → Follow up if required

Preparation & capacity building – ethics, SOPs, training of local staff
Digital platform – HPV testing, risk-stratification, women´s feedback
Implementation – self-sampling pilot in Zaporizhzhia region
Laboratory testing – centralized HPV testing and quality assurance
Follow-up system – referral to gynecological care (HPV 16, 18)
Monitoring & Process adaptation evaluation

International work..

- How easy is it to access the key learnings and materials from international collaborations? Should LabNet support a shared repository for additional training materials beyond the manual?

- International collaborations often performed, ad hoc in good faith & on the basis of “local” opportunities. Do we need to be more strategic?

- Measuring “impact” of collaborations/materials on roll out of HPV based testing important. Set this up from the start? Invite implementation scientists to have a more formal role in LabNet?

Other considerations

- Implications of more point of care testing – how can LabNet support?

- Implications and optimal use of Artificial Intelligence
  - Training
  - Trending and interpretation of data (including quality data)
  - Advice and troubleshooting
  - Et cetera et cetera!

Perspectives – what do we need

- To inform development of future outputs/training – feedback from international community
- Lab manual chapters to be transcribed into interactive courses
- Update of existing training “toolkits” on (general) laboratory quality management systems
- Consolidation of HPV-specific training materials used to support past or existing international partnerships
- Establishment of lab “partnerships” (more established lab with new lab)

International collaboration for HPV prevalence studies

Joakim Dillner

Center for Cervical Cancer Elimination

Karolinska University Hospital & Karolinska Institutet, Stockholm, Sweden

Center for Cervical Cancer Elimination

Cancer Prevention Europe

Karolinska Institutet

KAROLINSKA UNIVERSITY HOSPITAL

HPV vaccines prevent HPV infection. In countries with adequate vaccination strategies, HPV prevalences are dropping fast.

HPV infection is the most relevant endpoint to measure on whether vaccination strategies are effective.

Type-specific HPV prevalences are fundamental for design of HPV screening strategies.

Very large number of reports on HPV prevalences (>20,000 reports in MedLine)

Concern:

-Too many papers with either i) not quality assured HPV tests ii) unclear study designs (not population-based) and iii) no associated vaccination coverage data.

-Key data on vaccination effectiveness and basis for design of screening programs may become unpublishable.

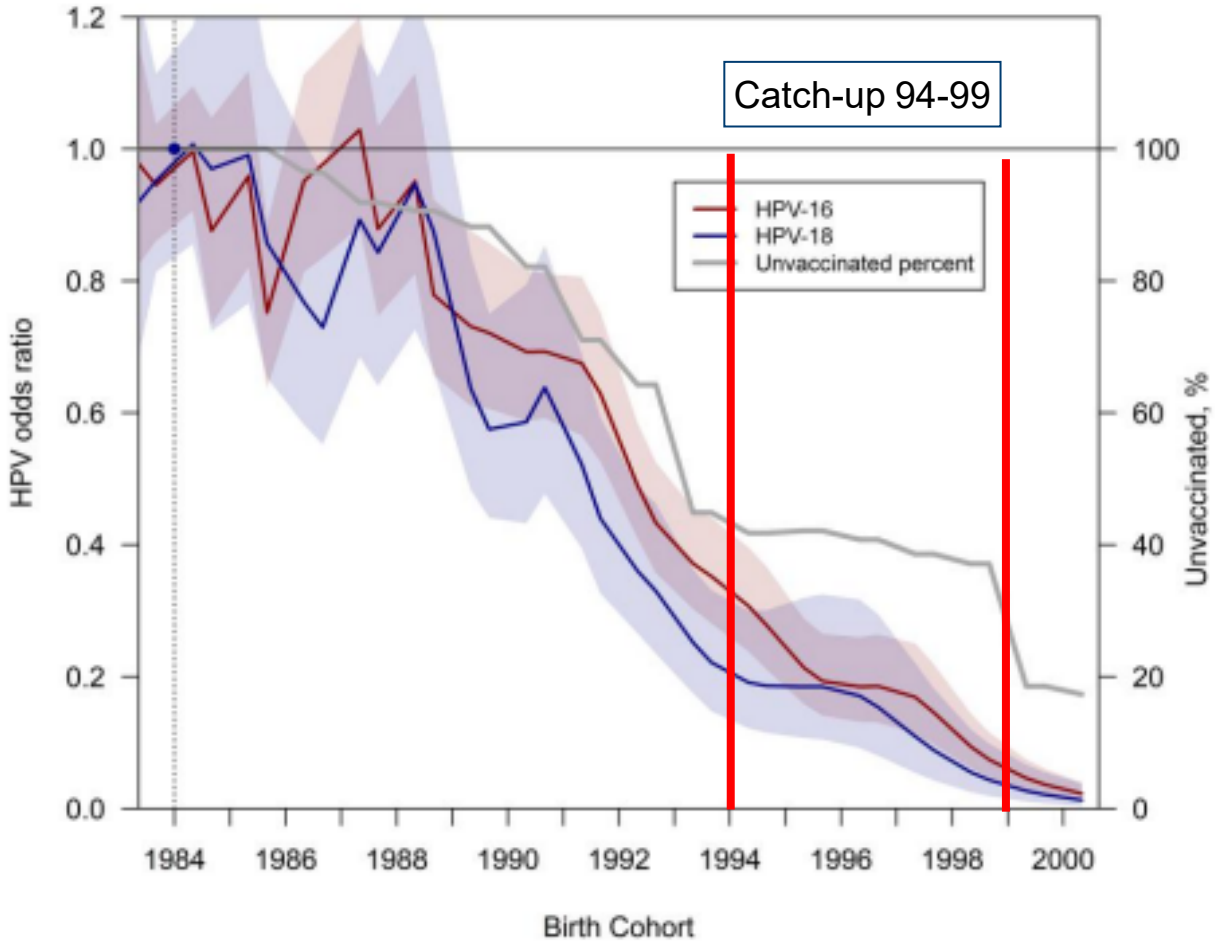


Figure 3. Estimated odds ratios (95% confidence intervals [CIs]) comparing the odds of human papillomavirus (HPV) type 16 and 18 positivity among birth cohorts relative to the 1984 birth cohort (the reference cohort where HPV vaccination coverage was negligible), as estimated via the age-period-cohort model plotted against the HPV-unvaccinated percentage (1 minus the HPV vaccination coverage) of women in Sweden. The shaded area around the line represents the 95% CIs.

HPV16/18 almost eliminated among women born 1999 and later

Among women vaccinated in school compared to unvaccinated birth cohorts:

- **98% decline of** HPV 16
- **99% decline of** HPV 18

Data from the population-based cervical screening program (that uses HPV testing with extended genotypimg)

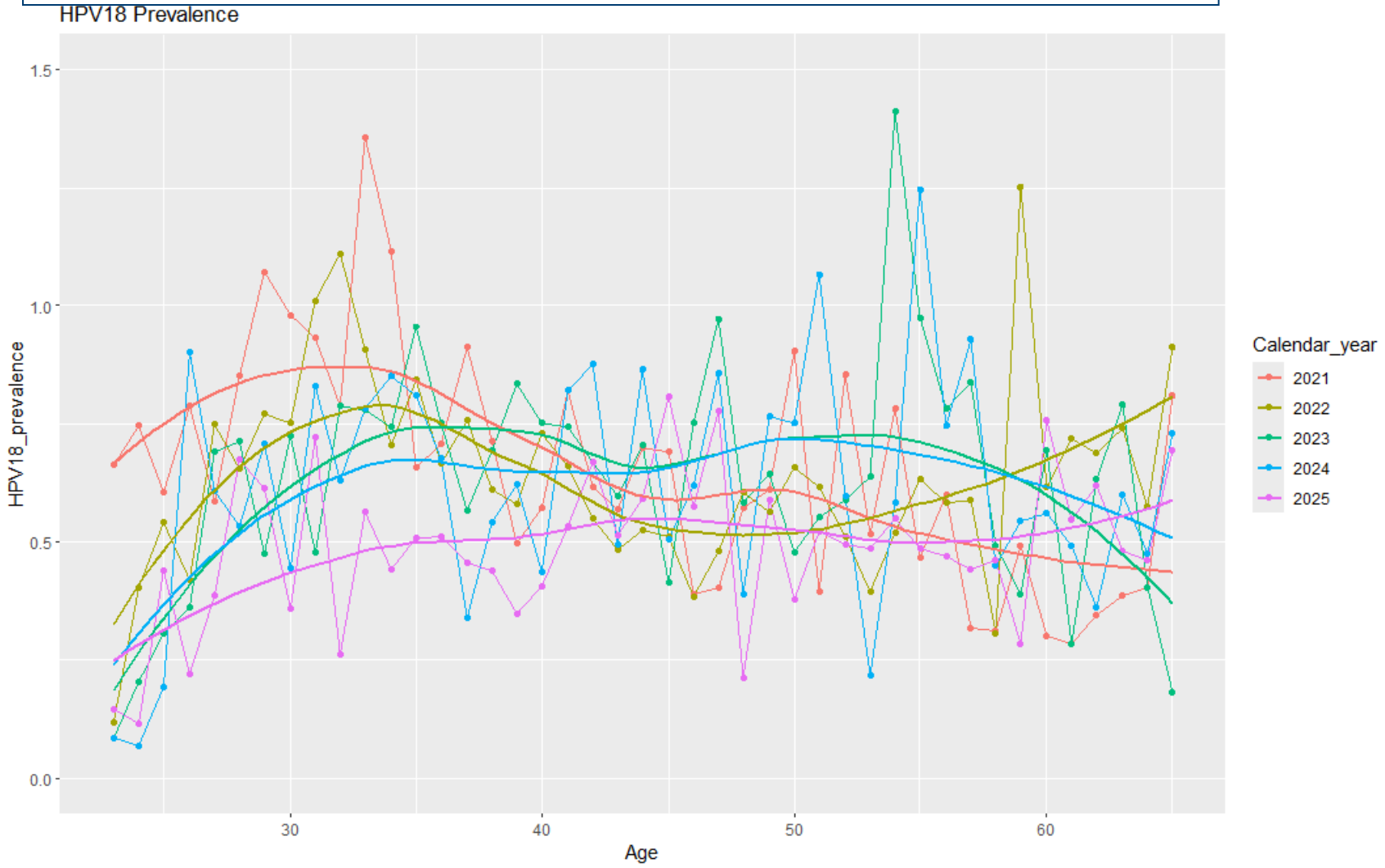
Gray et al., JID 2025

Among girls who have received Gardasil4 at school: Medium and low oncogenicity viruses (not in Gardasil4) are very common.
Screening should focus on the high oncogenicity types HPV16/18

Prevalence “other” HPV types in 2023

		Type specific HPV Prevalence (%) in 2023 among women attending cervical screening in Stockholm region								
		Vaccine targeted		Cross-protected	Non-vaccine types					
	Age (years)	HPV16	HPV18	HPV31	HPV45	HPV51	HPV52	HPV33/58	HPV35/39/68	HPV56/59/66
School-based vaccination	***24***	0.73	0.20	1.62	2.07	3.02	5.09	4.46	6.23	7.83
	23	0.54	0.09	1.28	2.02	3.19	5.55	4.93	6.89	8.15

HPV18 in the Swedish HPV screening program (whole country)



HPV18 is declining fast – and when the core group (women <30) is immune, herd immunity starts spreading also to older (unvaccinated) age groups

Proposal:

1) A guideline paper with requirements for HPV prevalence studies that they should:

i) Use only assays and labs that are proficient in the the global HPV LabNet proficiency studies.

ii) Clearly describe that the samples used are population-based

iii) Report the population-based HPV vaccination coverage in the same birth cohorts.

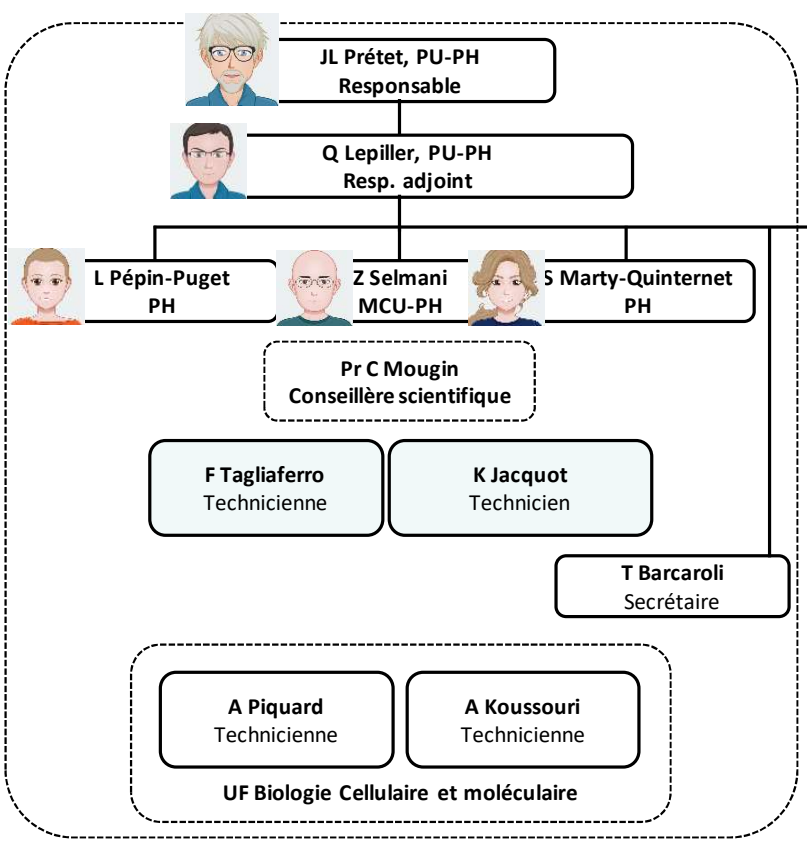
2) Joint HPV LabNet papers that reports results from several countries that fulfil the criteria i, ii and iii above.

Interested? Please send a mail with your interest to joakim.dillner@ki.se

NRL country updates: France

EUROGIN, March 2026
Lepiller Quentin, Jean-Luc Prétet
CNR Papillomavirus, CHU Besançon
q1lepiller@chu-besancon.fr

The French team



French NRL activities in 2025

- Evaluation of commercial kits
- National and international projects
  - **IMPACT** study (HPV distribution in HSIL in vaccinated women)
  - **PrevIST** (prevalence STIs in France)
  - **i-Predict** (HPV prevalence in women 18-24 years)
  - HPV in **waste waters**
  - **EDITHG** (HPV in CIN2+ lesions in French Guiana)
  - **Papillor** (Concordance genital / oral HPV)

Lenoir P, *J Gynecol Obstet Hum reprod*, 2025; Chung PYJ, *J Med Virol*, 2025 ; Guillet J, *in preparation*

Local projects in 2025

- Prevalence and distribution of HPV in **vaccinated** women
- Prevalence and distribution of hrHPV during **CCS**
- HPV anal infections during **PrEP** (ANAPreP-HPV)
- **School nurses'** perceptions of HPV vaccination
- **Interlaboratory comparison panel** (ICP) for French labs

Poy M, *Virologie*, 2026; Yacoub N, *in revision;* Gross S, *submitted*; Magnenet L, submitted; Poy M, *in preparation*

Local projects in 2025

- Prevalence and distribution of HPV in **vaccinated** women
- Prevalence and distribution of hrHPV during **CCS**
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Poy M, *Virologie*, 2026; Yacoub N, *in revision;* Gross S, *submitted*; Magnenet L, submitted; Poy M, *in preparation*

Preparation of the interlaboratory comparison panel (ICP)

Composition of the panel

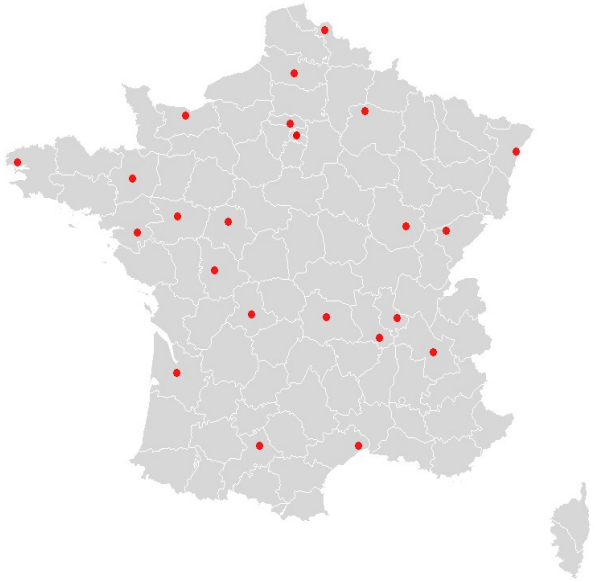
DNA copies/mL						
	HPV16	HPV18	HPV33	HPV39	HPV52	HPV56
	SiHa cells	HeLa cells	Plasmids (+ C-33A HPV$^-$ cells)			
Sample-1	2.10^4	-	-	-	-	-
Sample-2	-	4.10^5	-	-	-	-
Sample-3	10^4	2.10^4	-	-	-	-
Sample-4	-	-	-	-	-	-
Sample-5	10^4	-	-	-	9.10^3	-
Sample-6	-	2.10^5	8.10^3	-	-	-
Sample-7	-	-	-	9.10^3	-	9.10^3

Validation of the panel

Alinity m (Abbott), INNO-LiPA (Fujirebio), ddPCR HPV16/18, in-house qPCR (HPV16/18/33/39/52/56)

Sending to the participants

25 French laboratories



Annual number of samples

Type of test used (HPV screening / genotyping tests)

Qualitative HPV test results (mandatory)

Quantitative HPV test results (optional)

Genotyping results (optional)

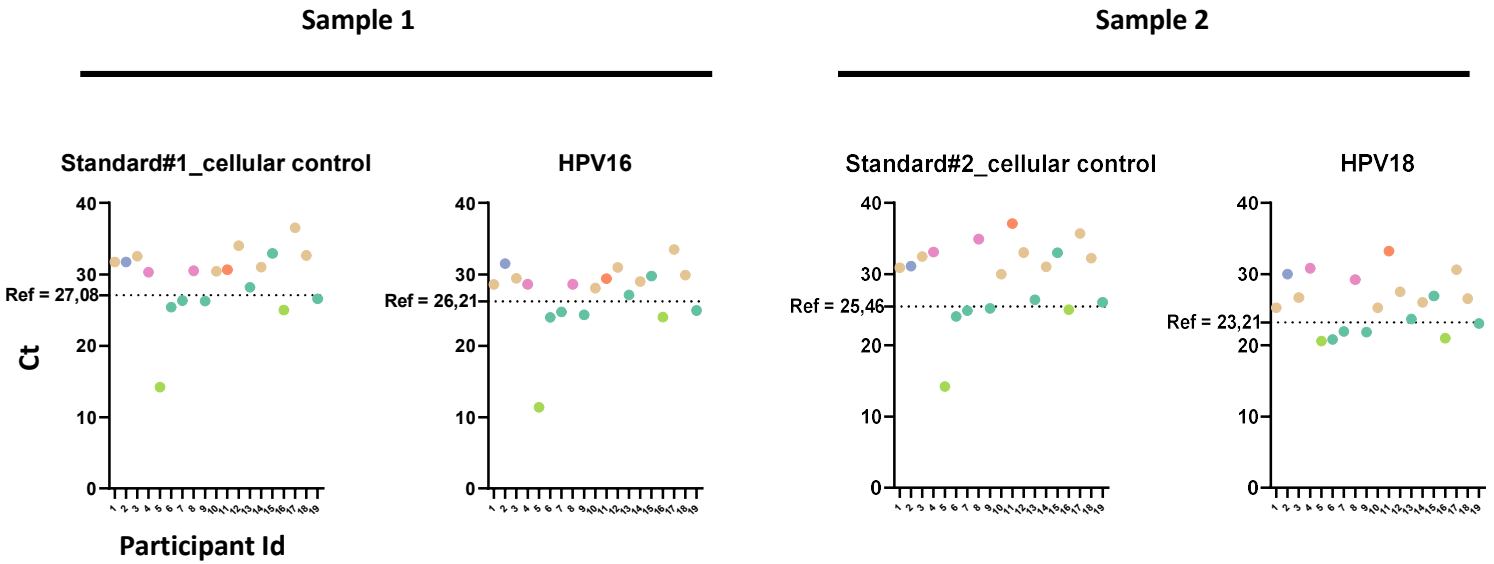
HPV screening tests : qualitative results

By HPV screening test

	Xpert (Cepheid ; n=2)	Alinity m (Abbott ; n=6)	Aptima (Hologic ; n=3)	Cobas (Roche ; n=8)	Allplex / Anyplex (Seegene ; n=3)	BD Onclarity (n=1)
HPV16	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
HPV18	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
HPV33	100.0%	66.7%	66.7%	75.0%	100.0%	0.0%
HPV52	100.0%	50.0%	66.7%	87.5%	33.3%	0.0%
HPV56	100.0%	83.3%	66.7%	37.5%	100.0%	0.0%
HPV39	100.0%	83.3%	66.7%	37.5%	0.0%	0.0%
Mean percentage of detection	**100.0%**	**80.6%**	**77.8%**	**72.9%**	**72.2%**	**33.3%**

Various detection percentages according to the techniques

HPV screening tests : quantitative results

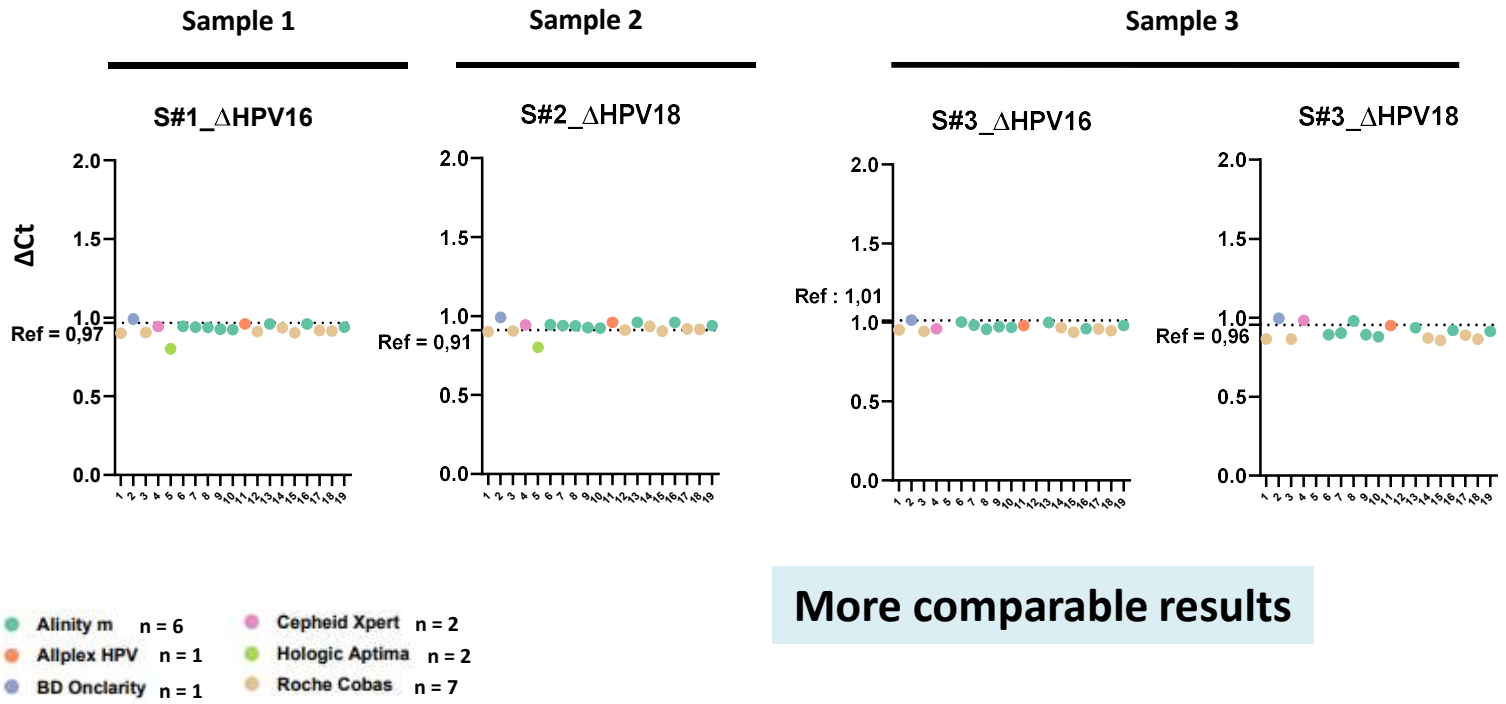


Ct values vary according to the techniques used

- Alinity m n = 6
- Allplex HPV n = 1
- BD Onclarity n = 1
- Cepheid Xpert n = 2
- Hologic Aptima n = 2
- Roche Cobas n = 7

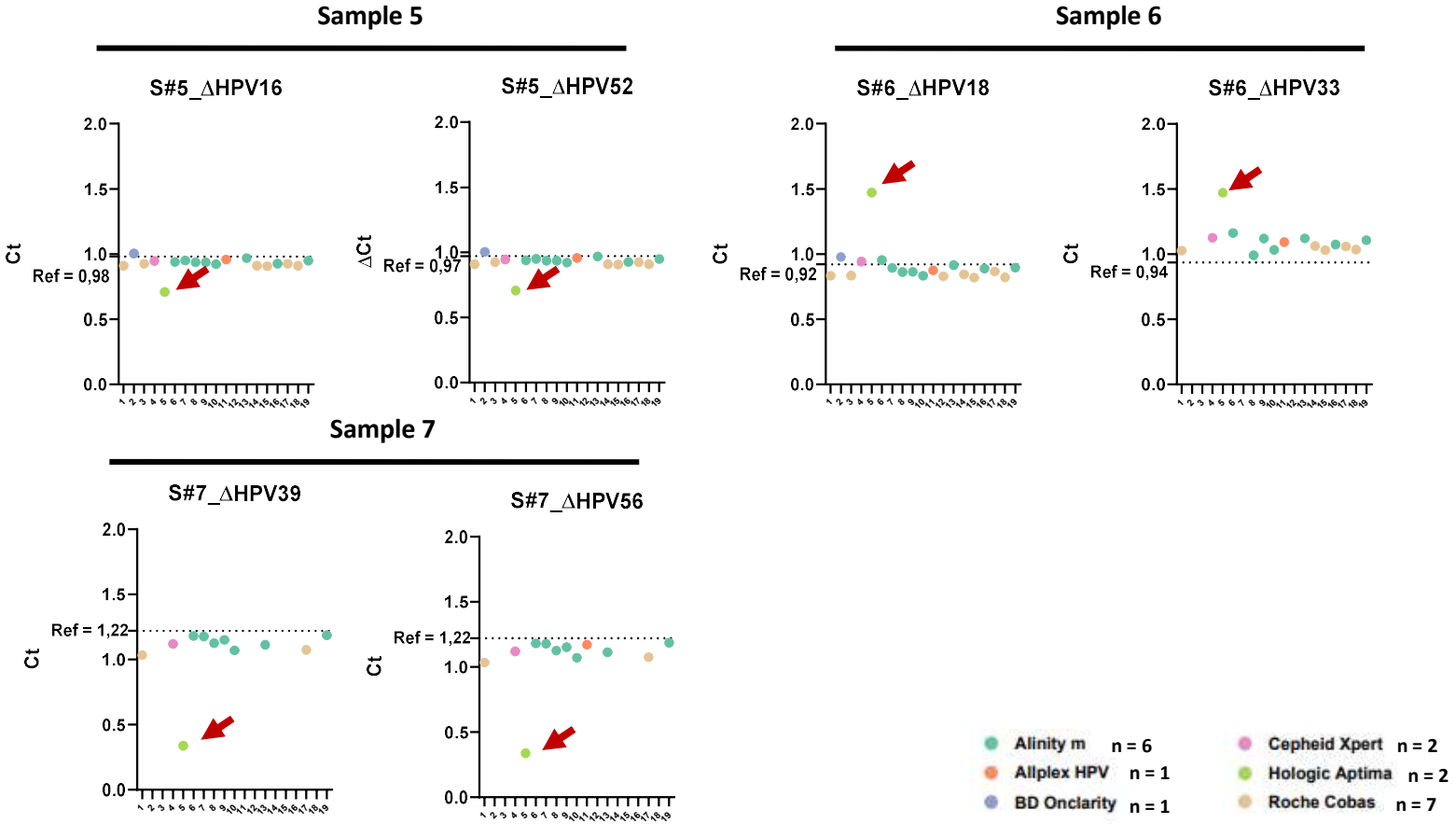
HPV screening tests : quantitative results

Normalisation : Ct HPV gene / Ct cellular gene



More comparable results

HPV screening tests : quantitative results



Acknowledgments

CNR Papillomavirus

Pr. Jean-Luc Prétet

Pr. Christiane Mougin

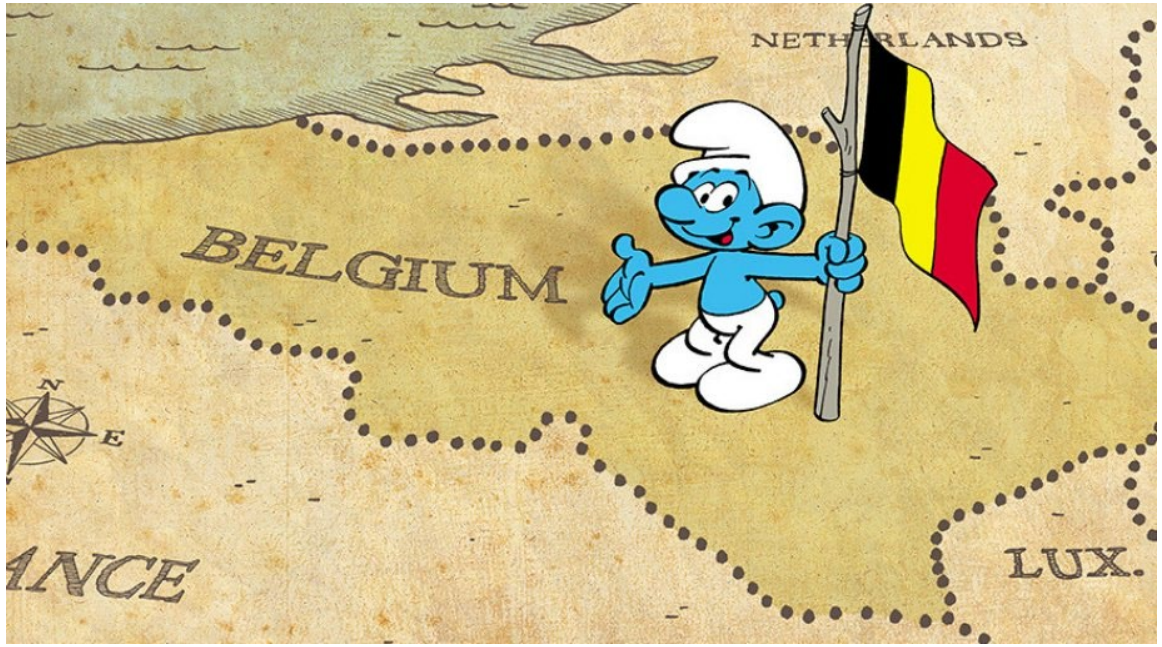
Dr. Line Puget

Marty POY

Clémentine PRIMUS

Thank you for your attention

NRL country update: Belgium



Elizaveta Padalko, MD, PhD

Laboratory of Medical Microbiology, Ghent University and University Hospital

Ghent, Belgium

EUROGIN 2026 Vienna, Austria

18th of March 2026

Conflict of interest statement: E.Padalko (EP)'s institution has received consumables to support research from Seegene and Copan in the last 3 years

NRL Belgium: structure

- Embedded in the network of National Reference Centres (NRC's) in Human Microbiology under coordination of the Scientific Institute of Public Health, Sciensano
- One of the 41 NRC's

National Reference Centers (NRC) in Human Microbiology | sciensano.be
http://www.sciensano.be/en/national-reference-centers-human-microbiology

NRL Belgium: structure

UZ GENT

AML

sciensano

Virale ziekten

Liza Padalko

Team: T Vermassen (H&N), H Hamerlinck (WGS)

Main tasks:

HPV detection (WGS), HPV surveillance

Davy Vanden Broeck

Team: L Tavernier (studies), S Cortoos (ring test, surveillance), V Thierens (Cytologie)

Main tasks:

HPV detection, cytologie

HPV proficiency panels, HPV surveillance

Jade Pattyn

Team: I Rouckaerts (back-up, NRC MMR, hep), former NRC coordinator: V Hutse, M Peeters

Main tasks: **Coordination**

National Reference Center (NRC) for Human Papillomavirus| sciensano.be

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

Cortesy of Jade Pattyn

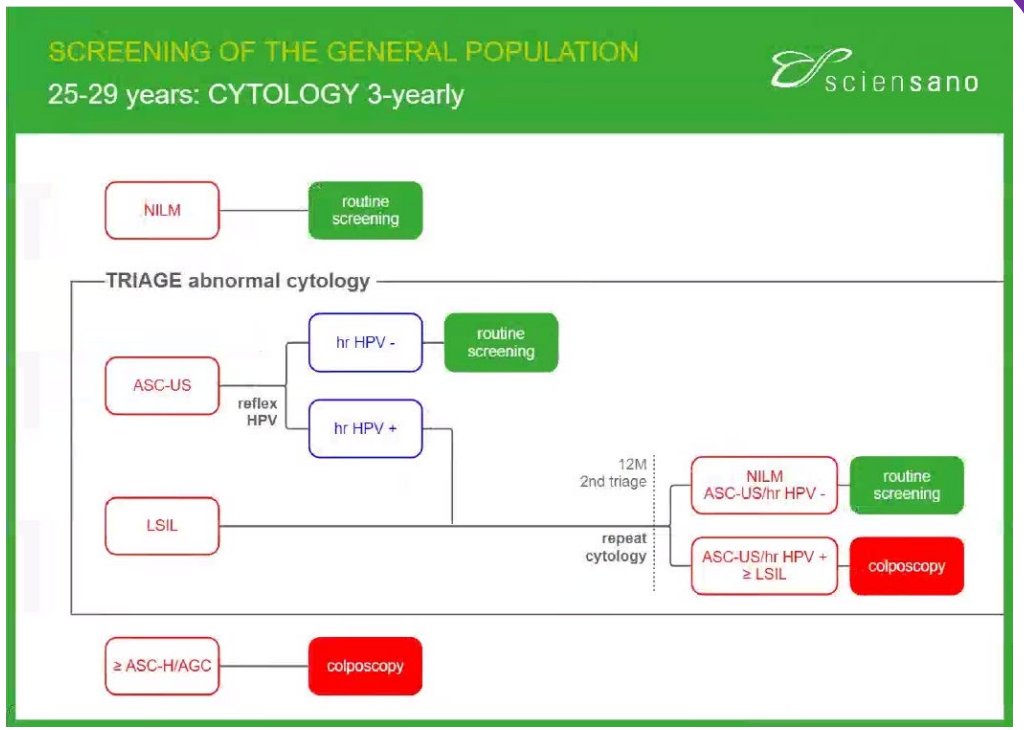
Belgium: update of national cervical cancer screening protocol

01/01/2025: Switch from cytology-based to HPV-based primary screening

Belgium: update of national cervical cancer screening protocol

Adapted

01/01/2025: Switch from cytology-based to HPV-based primary screening

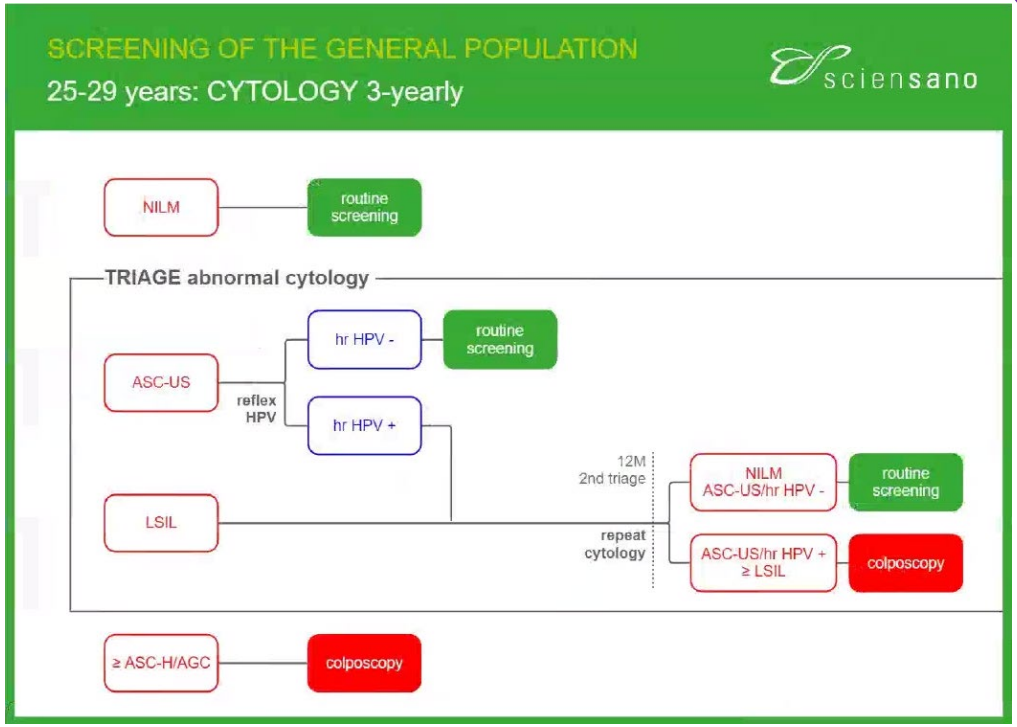


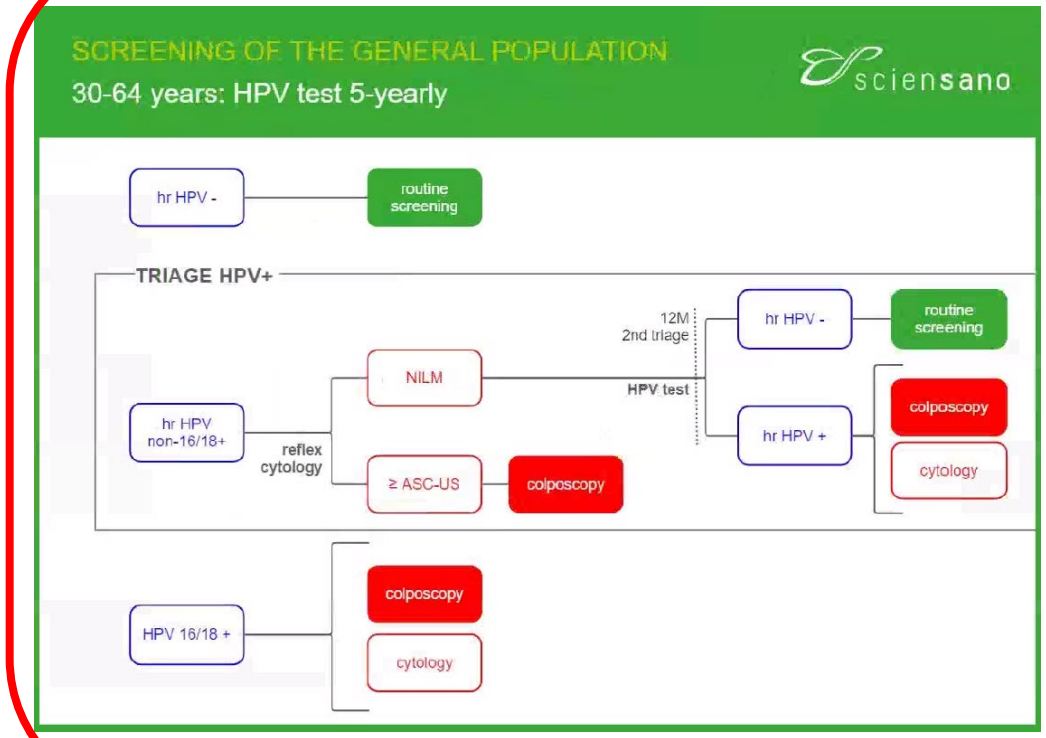
https://www.sciensano.be/en/cervical-cancer-screening

Belgium: update of national cervical cancer screening protocol

Adapted

01/01/2025: Switch from cytology-based to HPV-based primary screening





https://www.sciensano.be/en/cervical-cancer-screening

NRL Belgium: HPV surveillance: past & present (2016-2025)

- Objective: **estimate the prevalence of cervical HPV infection in young women (15-30y) having a Pap smear taken in Belgium**
- Design: population-based, repeat cross-sectional study
- Each year (**2016-2025**): 4 labs collected 300 samples (N=10472)
- All samples tested with clinically validated Riatol Assay.

- Expected results:
- **Estimate (vaccine-targeted) HPV prevalence by year / age / between 2 time periods 2016-2019 vs 2021-2025**
- **Look at regional differences** (Flanders, Brussels, Wallonia)
- **Look at differences between vaccination cohorts**
    - 1990 and older (no program) – expect no vaccination coverage
    - 1991-1997 (reimbursed) // 1993-1991 → vaccinated at 15 years or older
    - 1998 and younger (school-based)

Cortesy of Jade Pattyn

NRL Belgium: HPV surveillance: present & future (2026-2027)

In light of the changes to the screening program → HPV DNA genotyping data are now available via Belgian Cancer Registry (BCR).

- **2026:** Shift year → surveillance study in 2026 on AML database with focus on **evaluation of school-based vaccinated cohort** → possible adjustments to screening programme needed?

→ **Change methodological framework of NRC HPV surveillance to men // other HPV related diseases**

- **2027:** HPV surveillance in study investigating MSM using prep (anal and oral prevalence) – participate in HPV Assessment and scReening in MSM population Focus on anal and head & neck cancer (CHARM) study funded by Stichting tegen kanker

Cortesy of Jade Pattyn

Potential HPV projects to improve HPV cancer prevention in Belgium and beyond

Progress achieved in Belgium		Next steps / projects
 **Oropharyngeal cancer prevention, screening and treatment**	Current lack of oropharyngeal cancer screening in Belgium	**Assess concordance of HPV genotyping (feasibility)** ***Comparison*** *oropharyngeal swab versus mouth and deep gargle collection* **Determination of oropharyngeal HPV prevalence in Belgium** ***Region-wide assessment*** *oropharyngeal HPV prevalence* **Evaluation of people at risk** ***Establishment*** *of risk prediction nomograms* • *Focus on specific risk groups in the population (e.g. HIV and PrEP patients)* • *Determination additional biomarkers next to HPV prevalence (triage technique) that enable accurate risk prediction for development of HPV-related head and neck cancer (HPV seropositivity, DNA methylation, etc.)* • *Subsequent development of region-wide or nation-wide screenings programs* • *Determine other co-factors (e.g. oral microbiome) contributing to increased acquirement of oropharyngeal HPV infections* **Treatment of HPV⁺ head and neck cancer** ***De-escalation studies*** *for patients with HPV⁺ head and neck cancer* *Patients with HPV⁺ head and neck cancer have an improved survival outcome. Further research is needed to determine if patients will benefit from reduced treatment regimens (similar outcome with less treatment-related toxicity)* **Role of HPV vaccination in patients with HPV⁺ head and neck cancer** *Determine effectiveness and potential survival improvement of* ***HPV vaccination*** *in patients receiving definite treatment for an HPV⁺ head and neck cancer* **Align recommendations / screening program with latest evidence/ best practices** *Provide guidelines* ***screening and repeat vaccination of HPV vaccinated populations*** *(age start/stop, interval, triaging)*

Cortesy of Tijl Vermassen

NRL Belgium: support of laboratories

National Reference Center (NRC) for Human papillomavirus

Important information

Assays for the detection of high-risk human papillomaviruses in the context of Belgian cervical cancer primary screening.

The table below presents a list of molecular assays for the detection high-risk Human Papillomaviruses (hrHPV). These assays are clinically validated according to international criteria (Arbyn M. *et al.*, Clin Microbiol Infect 2021[1]; Arbyn M *et al.*, ESGO Textbook of Gynaecological Oncology 2023[2]; Dhillon *et al.*, J Med 2023[3]; Arbyn et al., Clin Microbiol Infect 2023[4]). The table below is updated at least twice a year, as new scientific evidence becomes available.

Responsible laboratories

Coordinator

- Sciensano

Associated

- Algemeen medisch laboratorium (AML) Sonic Healthcare
- UZGent

- Individual laboratories are free to choose the assay from a limited list available on NRC website of recommended molecular assays validated according to international criteria (Meyer + VALGENT)
- ISO 15189 accreditation is mandatory for HPV testing

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

NRL Belgium: support of laboratories

Frequently asked questions

Important message for **Allplex HPV HR Detection Assay, Seegene, users**: The same cut-offs, called clinical cut-offs by Accuramed, should be used for all HPV indications on cervicovaginal takings (primary screening, reflex testing, follow-up, ...) and also for the quality control done annually by Sciensano. - 15.01.2025

Important message for **Allplex HPV HR Detection Assay and Anyplex II HPV HR Detection Assay, both Seegene, CLART HPV4S, GENOMICA SAU, and RIATOL HPV genotyping qPCR in-house test, AML, users**: given according to the latest International Agency for Research on Cancer (IARC) update, HPV66 belongs to group 2B, potentially carcinogenic, isolated HPV66 positivity should be reported as a negative result for high-risk HPV and should also be followed up as such. - 16.01.2025

In the context of follow-up co-test: What if HPV66 is isolated positive, but cytologically an ASCUS/LSIL/ HSIL result is also obtained. Does this then still fall under isolated HPV66 positive? Isolated HPV66 should also be considered negative for high-risk HPV within follow-up or co-test. In case of isolated HPV66-positive HSIL, please forward such a sample to NRC-HPV for monitoring causes of hrHPV-negative HSILs (Human papillomavirus negative high grade cervical lesions and cancers: Suggested guidance for HPV testing quality assurance — PubMed) - 06.05.2025

Important notice to users of Aptima HPV Assay, Hologic, and Xpert HPV, Cepheid: Since both assays are technically unable to distinguish between HPV18, HPV45 or the presence of both types, it is not possible to correctly follow up women aged 30 to 64/ 65+ with an HPV18/45-positive result within the national screening algorithm. Therefore, positive samples with an HPV18/45 result can be sent to one of the clinical laboratories of the NRC HPV consortium (AML or UZ Gent). After analysis, the NRC laboratory will send the result (HPV18, HPV45 or HPV18 and HPV45) to the referring laboratory. That laboratory is responsible for reporting the full result to both the applicant and the Belgian Cancer Registry (BCR). The application form is available via the hyperlink on the right-hand side of the screen. - 17.12.2025

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

NRL Belgium: HPV proficiency testing

- **Why:**
  - To evaluate ability of laboratories to correctly detect high-risk HPV
- **When:**
  - Each year, 1st regular year = 2024 (before: 3 x pilot studies)
- **What:**
  - Samples prepared by mixing clinical ThinPrep's
  - Some educational samples (low viral load) included
- **How:**
  - Panel sent to ~ 50 Belgian diagnostic laboratories
  - General and individual reporting sent to participating laboratories

https://www.sciensano.be/nl/kwaliteit-van-laboratoria/eke-moleculaire-biologie-microbiologie

NRL Belgium: thanks for fruitfull collaboration and thank you for your attention!

EUROGIN INTERNATIONAL MULTIDISCIPLINARY HPV CONGRESS
MARCH 18 21 2026
Austria Center Vienna • Austria

Global HPV National Laboratory Network: Updates from NRL Countries: Brazil

Marcelo A. Soares

Head, Brazilian HPV National Reference Laboratory
Head, Tumor Genetics and Virology Program
Head, Division of Translational Research
Instituto Nacional de Câncer
Rio de Janeiro, RJ, Brazil

Current Activies

- HPV Public Healthcare
- HPV Research
- HPV Awareness

Public Healthcare related to HPV

- Project with Instituto de Biologia Molecular do Paraná (IBMP) with funding from the Brazilian Ministry of Health (Program for Local Development and Innovation – PDIL)
  - To automate the IBMP HPV molecular test
    - “From collection tube to Final Result”

Public Healthcare related to HPV

- HPV molecular and reflex cytology screening laboratory certification of proficiency
  - Program developed with the Secretary of Health Specialized Care (SAES) of the Brazilian Ministry of Health
  - Certification based on the E-QUALIS Program of the HP LabNet developed by the International HPV Reference Centre (KI)

EQUALIS

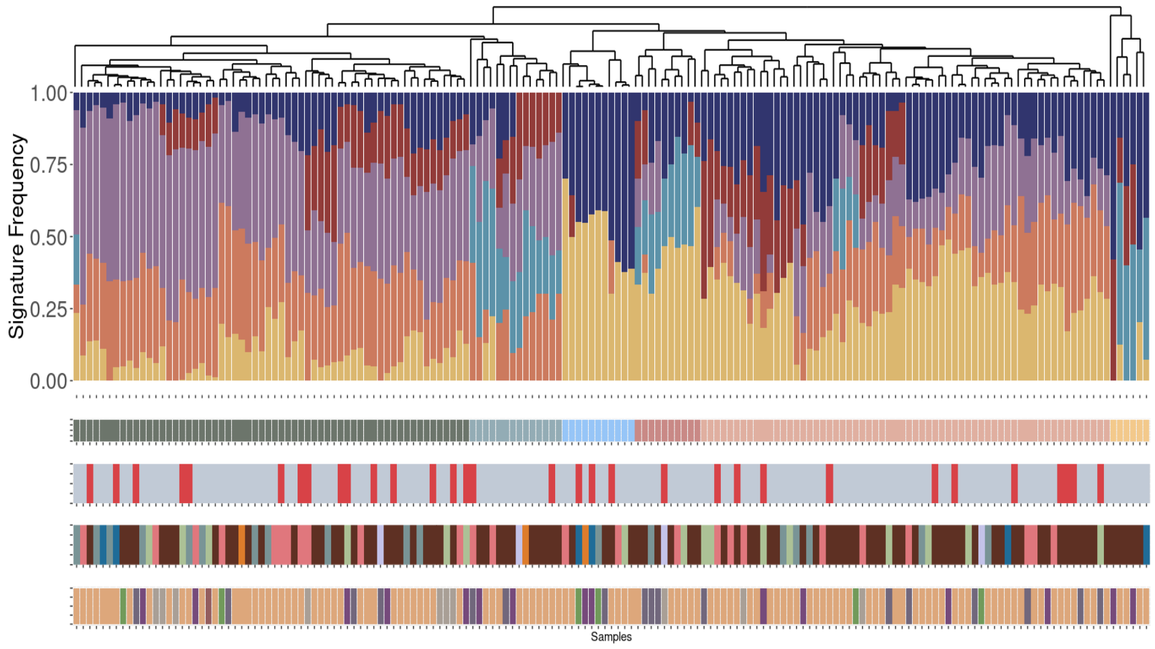
INCA

HPV Research

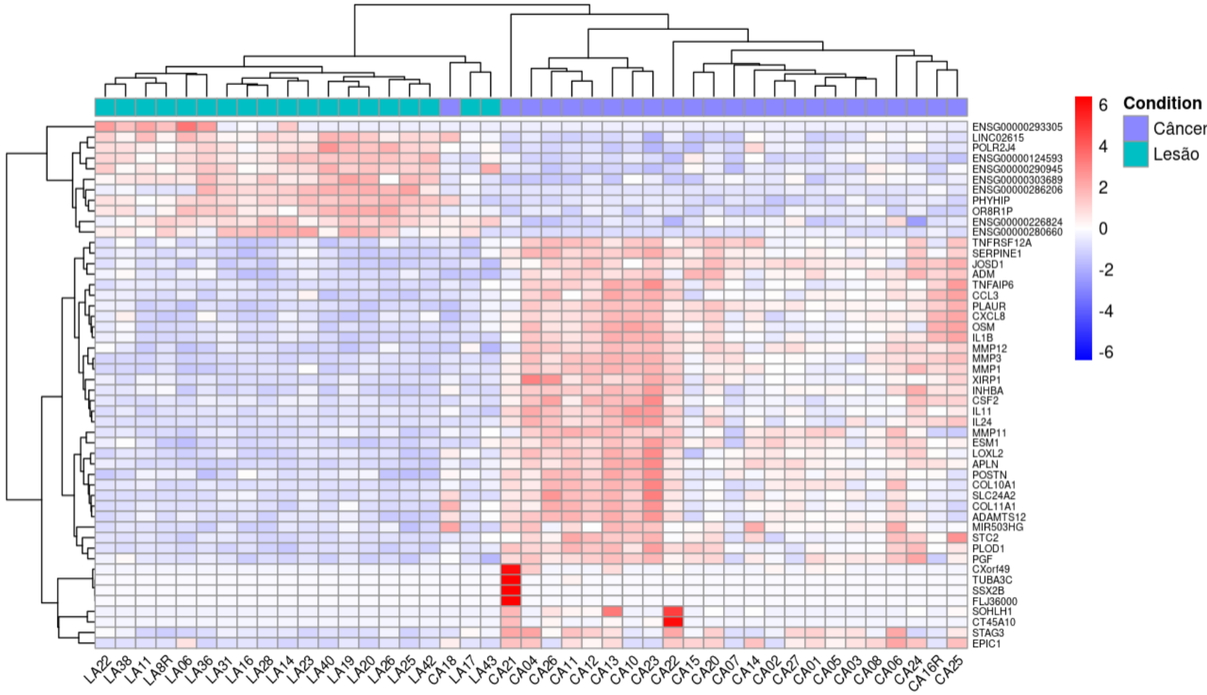
GENOMAS BRASIL

Genomas Brasil Câncer: Multiomic Integration of HPV-related cancers (cervical, anal, penile) for biomarker discovery in disease progression and recurrence

Cervical cancer: Multiomic integration analysis (WGS, RNAseq, Methylome and Microbiome)



HPV-related anal cancer: Differential expression analysis between cancer and premalignant lesions



HPV Awareness

- We have recently joined the HPV Awareness Group of the International Papillomavirus Society (IPVS):
  - São Paulo State Cancer Institute (ICESP), São Paulo
  - Brazilian National Cancer Institute (INCA), Rio de Janeiro

- Awareness activities expected in October 2026 (Pink October in Brazil) and in March 2029 (International HPV Awareness Day)

Acknowledgements

Oncovirology Group at INCA

Juliana Siqueira
Livia Goes
Caroline Carvalho
Élida Mendes
Julia Botto
Esther Jaccoud
Laura Moura
Maria Clara Oliveira
Poliana Araujo
Ornella Botelho
Fernanda Fernandes
Raisa Raulino
Evellyn Moreira
Natalia Santiago
Andressa Oliveira

International HPV Reference Centre

Joakim Dillner

Carina Eklund

Sara Arroyo Mühr

International Papillomavirus Society

Global Awareness Committe

Lara Termini (ICESP)

masoares@inca.gov.br

AKERSHUS UNIVERSITY HOSPITAL

Updates from

The Norwegian HPV Reference Laboratory

Milan Stosic
(on behalv of Kristiane Søreng)

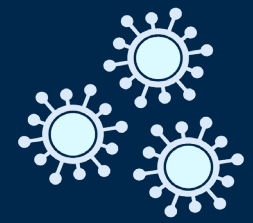
Department of Microbiology and Infection control,
Akershus University Hospital,
Norway

SS03 – Global HPV laboratory network

Eurogin 2026

Akershus University Hospital

Norwegian HPV Reference Laboratory – *Main responsibilities*



Norwegian HPV Reference Laboratory since 2007

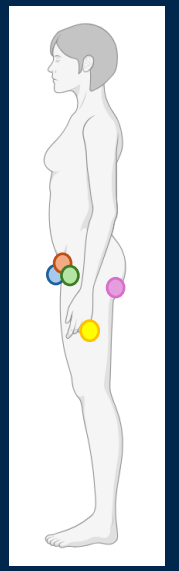
- Reference diagnostics
- Scientific advice and support
- Collaboration and research
- Method development
- Vaccine surveillance

- National cervical screening programme:
  - ✓ Implementation of self sampling
  - ✓ Quality assurance – HPV negative cancers
- HPV vaccine surveillance:
  - ✓ HPV genotyping of precancerous/cancerous lesions
- Research projects:
  - ✓ HPV whole genome sequencing (TaME-seq)
    - ✓ TaME-seq repertoire: HPV16, 18, 31, 33, 45, 51, 52, 58 and 59
  - ✓ New HPV research biobank

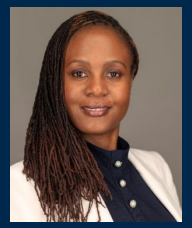
HPV-variation in pre-malignant and malignant lesions of HIV-positive women in Zimbabwe

Cervical cancer is the most prevalent cancer type among women in Zimbabwe: 61,7 per 100 000 *(2024)*

- ✓ Unequal access to screening
- ✓ Delayed diagnosis
- ✓ Co-infection with HIV:
  - → Increased risk of cervical cancer
  - → Risk of new HPV-related cancers (multi-site)



Vulva
Vagina
Cervix
Anus
Skin



Newlands Clinic

Racheal Dube Mandishora,
MOFFIT Cancer Center, USA
Newlands Clinic, Zimbabwe

Analysis of multi-site lesions from HIV positive women

- ✓ HPV genotyping
- ✓ HPV whole genome sequencing (TaME-seq)
  - *HPV genotype distribution*
  - *HPV variant analysis*

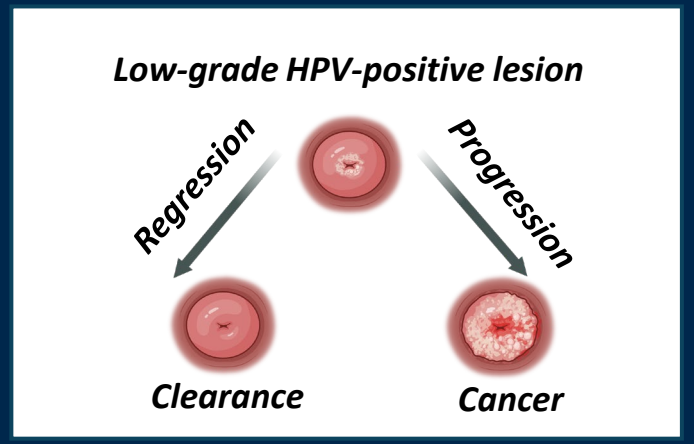
ARCHaM- Assessing Risk of Cervical disease via HPV and Microbiome

Can viral and microbiome signals at the first HPV-positive low-grade lesion predict progression to high-grade lesions or cervical cancer?

Sara Arroyo Muhr
Senior Research Specialist | Docent
Center for Cervical Cancer Elimination, Karolinska institutet

HPV whole genome sequencing (TaME-seq)
- *Intrahost Variation*

16s Microbiome profiling



Acknowledgements

- *The national HPV reference laboratory*
- *Department of Pathology*
- *Division of Gynaecology and Obstetrics*

- *HPV-seq group:*
  Cancer Registry, University of Oslo,
  Oslo Metropolitan University

- *National Cervical Screening program*

- *Norwegian Institute of Public Health*
- *Norwegian Norwegian Surveillance System for Communicable Diseases (MSIS)*

- *Global HPV reference laboratory network - LabNet*

Norwegian HPV reference laboratory

✓ "Variant calling: Accuracy, Filtering and Interpretation"

Friday 20.03 – SS22 (NGS and bioinformatics)
Milan Stosic

National Services Division
Commissioning for Scotland's Health

Update from Scottish HPV Reference Lab

Royal Infirmary of Edinburgh, NHS Lothian

Dr Kate Cuschieri

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

Edinburgh and Lothians Laboratory Medicine / Specialities / Scottish Microbiology Reference Laboratories, Edinburgh / Scottish Human Papillomavirus Reference Laboratory

- Blood Science
- Cell Science

Scottish Human Papillomavirus Reference Laboratory

Scottish HPV Reference Laboratory (SHPVRL)

- Established in 2008 to provide a specialist testing and advisory service to NHS Scotland.

- Workstreams
  - Clinical genotyping (including for head and neck cases)
  - Evaluation of HPV immunisation programme
  - Support for quality monitoring
  - Sample biobanking
  - Support for national developments in screening
  - Research and Development (in partnership with HPV Research Group at University of Edinburgh

[Scottish Human Papillomavirus Reference Laboratory | Edinburgh and Lothians Laboratory Medicine]

Clinical genotyping (including for head and neck cases)

SATURDAY **MARCH 21**

SCIENTIFIC SESSIONS

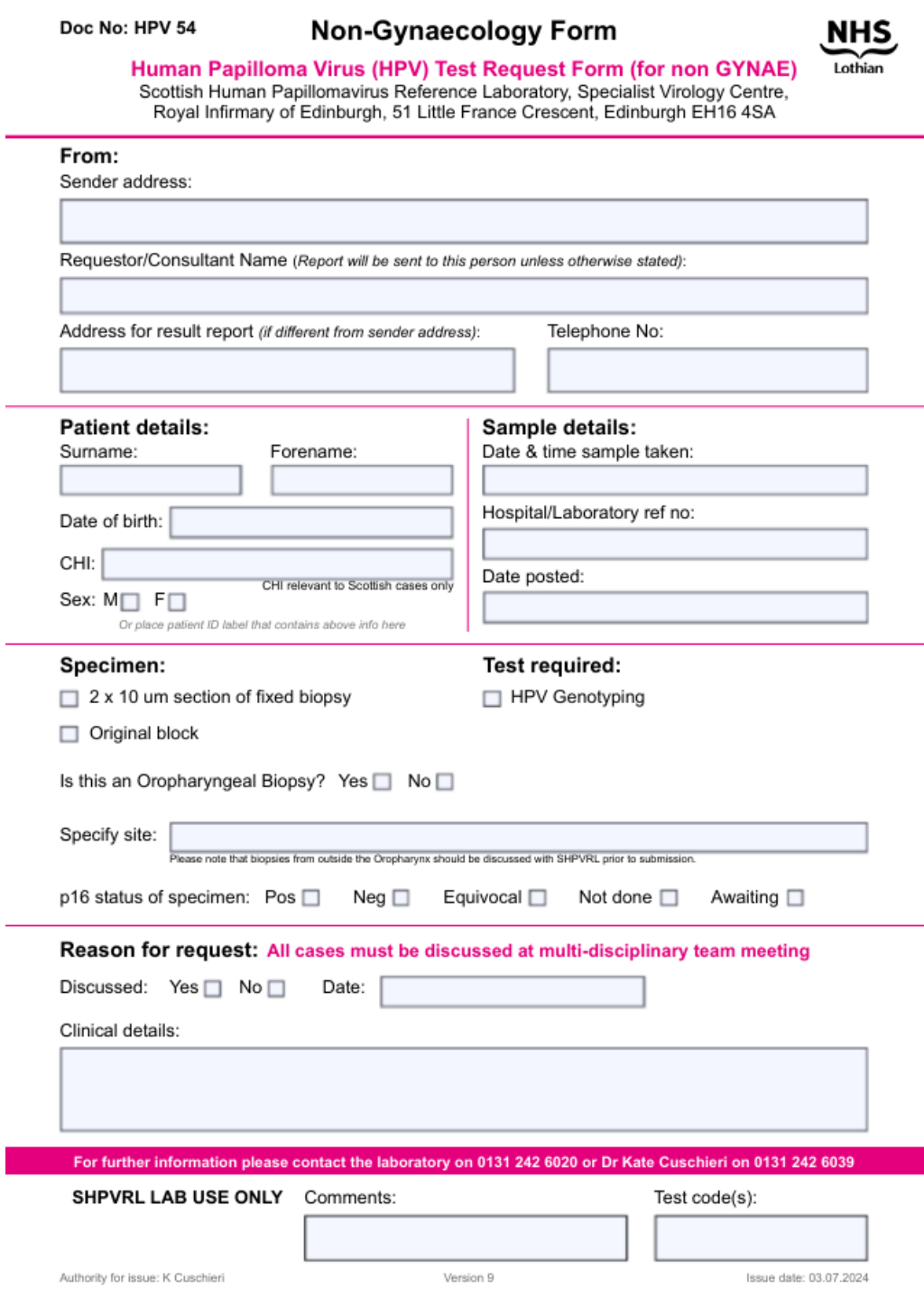
Hall N1 **8.00 • 9.30**

SS 28 • CHALLENGES IN THE LABORATORY METHODS FOR THE SCREENING, DIAGNOSIS AND MANAGEMENT OF HPV-ASSOCIATED OROPHARYNGEAL CANCER

CHAIR: Arbyn M. (Belgium) • Cocuzza C. (Italy)

SS 28-4 • Optimal molecular annotation of oropharyngeal cancer Connor L. (UK)

Audit of clinical service (annotation of oropharyngeal cancers for HPV status, including concordance of HPV&p16), implications of assay.



Doc No: HPV 54

Non-Gynaecology Form

NHS Lothian

Human Papilloma Virus (HPV) Test Request Form (for non GYNAE)

Scottish Human Papillomavirus Reference Laboratory, Specialist Virology Centre, Royal Infirmary of Edinburgh, 51 Little France Crescent, Edinburgh EH16 4SA

From:

Sender address:

Requestor/Consultant Name *(Report will be sent to this person unless otherwise stated)*:

Address for result report *(if different from sender address)*: Telephone No:

Patient details: Surname: Forename:

Date of birth:

CHI: CHI relevant to Scottish cases only

Sex: M ☐ F ☐

Or place patient ID label that contains above info here

Sample details: Date & time sample taken:

Hospital/Laboratory ref no:

Date posted:

Specimen:

☐ 2 x 10 um section of fixed biopsy

☐ Original block

Test required:

☐ HPV Genotyping

Is this an Oropharyngeal Biopsy? Yes ☐ No ☐

Specify site:

Please note that biopsies from outside the Oropharynx should be discussed with SHPVRL prior to submission.

p16 status of specimen: Pos ☐ Neg ☐ Equivocal ☐ Not done ☐ Awaiting ☐

Reason for request: **All cases must be discussed at multi-disciplinary team meeting**

Discussed: Yes ☐ No ☐ Date:

Clinical details:

For further information please contact the laboratory on 0131 242 6020 or Dr Kate Cuschieri on 0131 242 6039

SHPVRL LAB USE ONLY Comments: Test code(s):

Authority for issue: K Cuschieri Version 9 Issue date: 03.07.2024

Evaluation of HPV immunisation programme (1)

FRIDAY MARCH 20

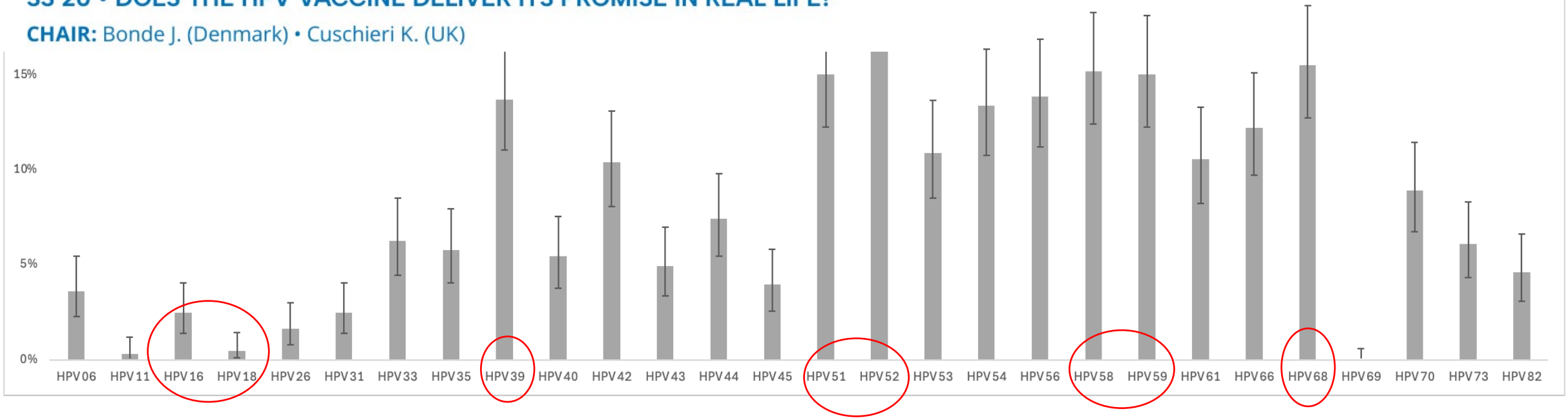
SCIENTIFIC SESSIONS

SS 20-3 • The Scottish experience Palmer T. J. (UK)

Hall N1 10.00 • 11.30

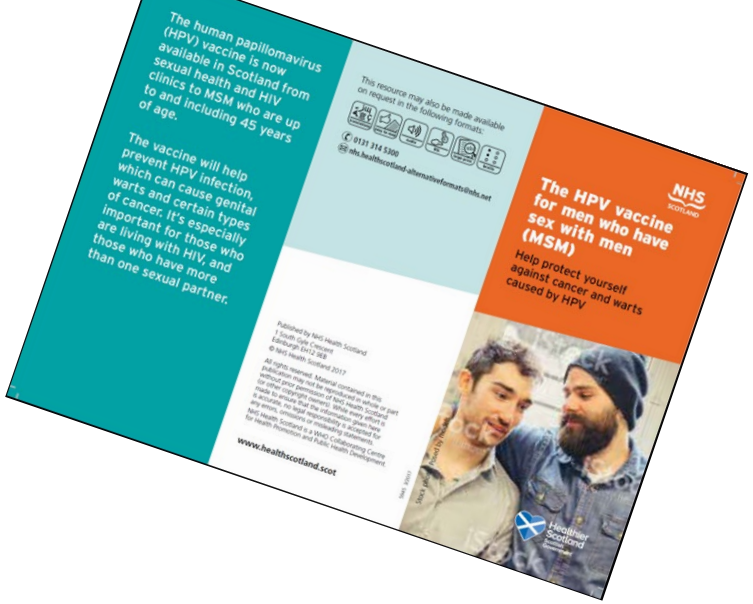
SS 20 • DOES THE HPV VACCINE DELIVER ITS PROMISE IN REAL LIFE?

CHAIR: Bonde J. (Denmark) • Cuschieri K. (UK)



Unpublished - ddistribution of type specific HPV in 600 “hr-HPV” initially APTIMA positive women at first screen (aged 25) birth cohort(s) ~ 1999. Each infection counted including If part of a multiple infection

Evaluation of Immunisation Programme (2): HPV type prevalence in gay, bisexual and other men who have sex with men following HPV vaccination programme: a repeated cross-sectional study



Year	9v vaccine type HPV positive		4v vaccine type HPV positive		HPV 16/18 positive		HPV 6/11 positive	
	Prevalence ratio (95% CI)	p-value	Prevalence ratio (95% CI)	p-value	Prevalence ratio (95% CI)	p-value	Prevalence ratio (95% CI)	p-value
Pre-vaccine samples (2016/17)	Reference	-	Reference	-	Reference	-	Reference	-
Post-vaccine sample one (2018/19)	1.05 (0.98-1.12)	0.174	1.06 (0.97-1.16)	0.208	1.02 (0.89-1.17)	0.753	1.14 (1.01-1.3)	0.038
Post-vaccine sample two (2019/20)	1.42 (1.35-1.51)	<0.001	1.62 (1.51-1.75)	<0.001	1.26 (1.11-1.43)	<0.001	2.19 (1.97-2.43)	<0.001
Post-vaccine sample three (2021)	0.91 (0.84-0.98)	0.010	0.77 (0.7-0.86)	<0.001	0.76 (0.66-0.88)	<0.001	0.75 (0.64-0.86)	<0.001

Submitted for publication BMJ STI - Jan 2026 – Cameron et al

Support for national developments in screening

- Scotland to “go live” with self sampling in 2026
- Reference lab support
  - Materials for Verification
  - Biobanking
  - Quality aspects
  - Advice
    - Patient-facing materials
    - Laboratory processes
  - Support for companion research

Assay Developments

- Next Generation Sequencing – validation phase
  - Not accredited or EQA'd…yet! Sequencing rigs at laboratory, bioinformatics supported by national public health agency (Public Health Scotland).
- HPV type specific digital PCR

SATURDAY **MARCH 21**

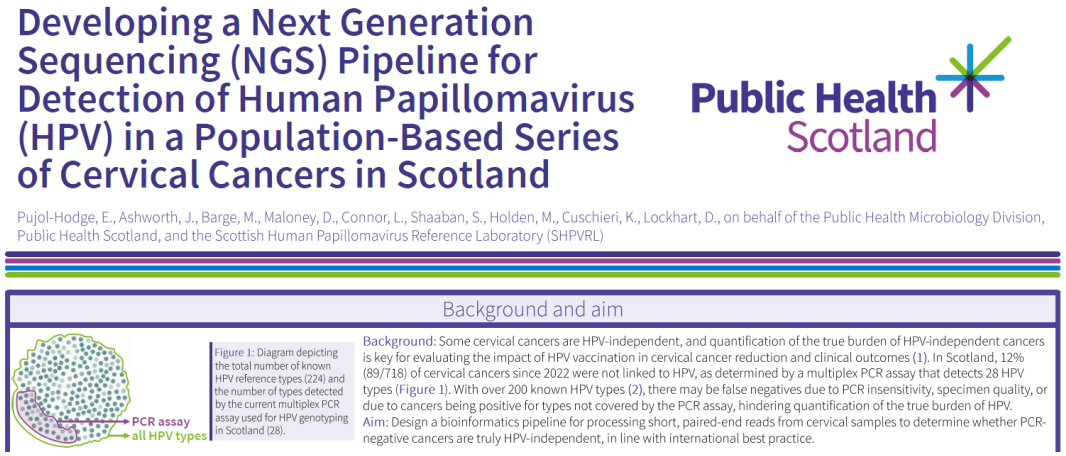
FREE COMMUNICATIONS

Hall N1 **11.00 • 12.30**

FC 27 • HPV TESTING

CHAIR: Lepiller Q. (France) • Yilmaz E. (Sweden)

FC 27-6 • Development of a partitioning digital PCR assay for the detection and quantification of type-specific human papillomavirus McMahon H. (UK)



Developing a Next Generation Sequencing (NGS) Pipeline for Detection of Human Papillomavirus (HPV) in a Population-Based Series of Cervical Cancers in Scotland

Public Health Scotland

Pujol-Hodge, E., Ashworth, J., Barge, M., Maloney, D., Connor, L., Shaaban, S., Holden, M., Cuschieri, K., Lockhart, D., on behalf of the Public Health Microbiology Division, Public Health Scotland, and the Scottish Human Papillomavirus Reference Laboratory (SHPVRL)

Background and aim

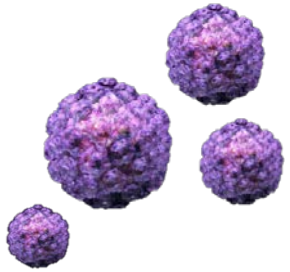
PCR assay
all HPV types

Figure 1: Diagram depicting the total number of known HPV reference types (224) and the number of types detected by the current multiplex PCR assay used for HPV genotyping in Scotland (28).

Background: Some cervical cancers are HPV-independent, and quantification of the true burden of HPV-independent cancers is key for evaluating the impact of HPV vaccination in cervical cancer reduction and clinical outcomes (1). In Scotland, 12% (89/718) of cervical cancers since 2022 were not linked to HPV, as determined by a multiplex PCR assay that detects 28 HPV types (Figure 1). With over 200 known HPV types (2), there may be false negatives due to PCR insensitivity, specimen quality, or due to cancers being positive for types not covered by the PCR assay, hindering quantification of the true burden of HPV.
Aim: Design a bioinformatics pipeline for processing short, paired-end reads from cervical samples to determine whether PCR-negative cancers are truly HPV-independent, in line with international best practice.

Scottish HPV Ref Lab Get in touch!

loth.hpv@nhs.scot



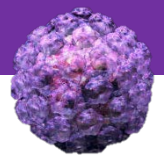
National HPV Reference Laboratories
NRL country updates: Slovenia

Anja Oštrbenk, Mario Poljak

Institute of Microbiology and Immunology
Faculty of Medicine, University of Ljubljana
Slovenia

University of Ljubljana | Faculty of Medicine

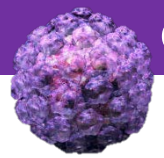
INSTITUTE OF MICROBIOLOGY AND IMMUNOLOGY



Conflict of interest

I have received travel grants and/or speaker fees from Seegene, Abbott, and Qiagen during the last 5 years.

My institution has received research funding, free-of-charge reagents, and consumables to support research from the following commercial entities in the last three years: Qiagen, Self-screen, Seegene, Abbott, Liferiver, and Roche, all paid to their employer.



In primary cervical cancer screening, it is crucial to use only HPV assays that are clinically validated!

2010

Poljak M, Kocjan BJ. Commercially available assays for multiplex detection of alpha human papillomaviruses.
Exp Rev Anti Infect Ther 2010; 8: 1139-62.

2012

Poljak M, Cuzick J, Kocjan BJ, Iftner T, Dillner J, Arbyn M. Nucleic acid tests for the detection of alpha human papillomaviruses.
Vaccine 2012; Suppl 30: F100-6.

2015

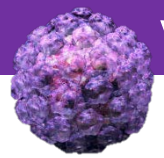
Poljak M, Kocjan BJ, Oštrbenk A, Seme K. Commercially available molecular tests for human papillomaviruses (HPV): 2015 update.
J Clin Virol 2016; 76: (Suppl 1): S3-S13.

2020

Poljak M, Oštrbenk Valenčak A, Gimpelj Domjanič G, Xu, L, Arbyn M. Commercially available molecular tests for human papillomaviruses: a global overview.
Clin Microbiol Infect 2020; 26: 1144-50.

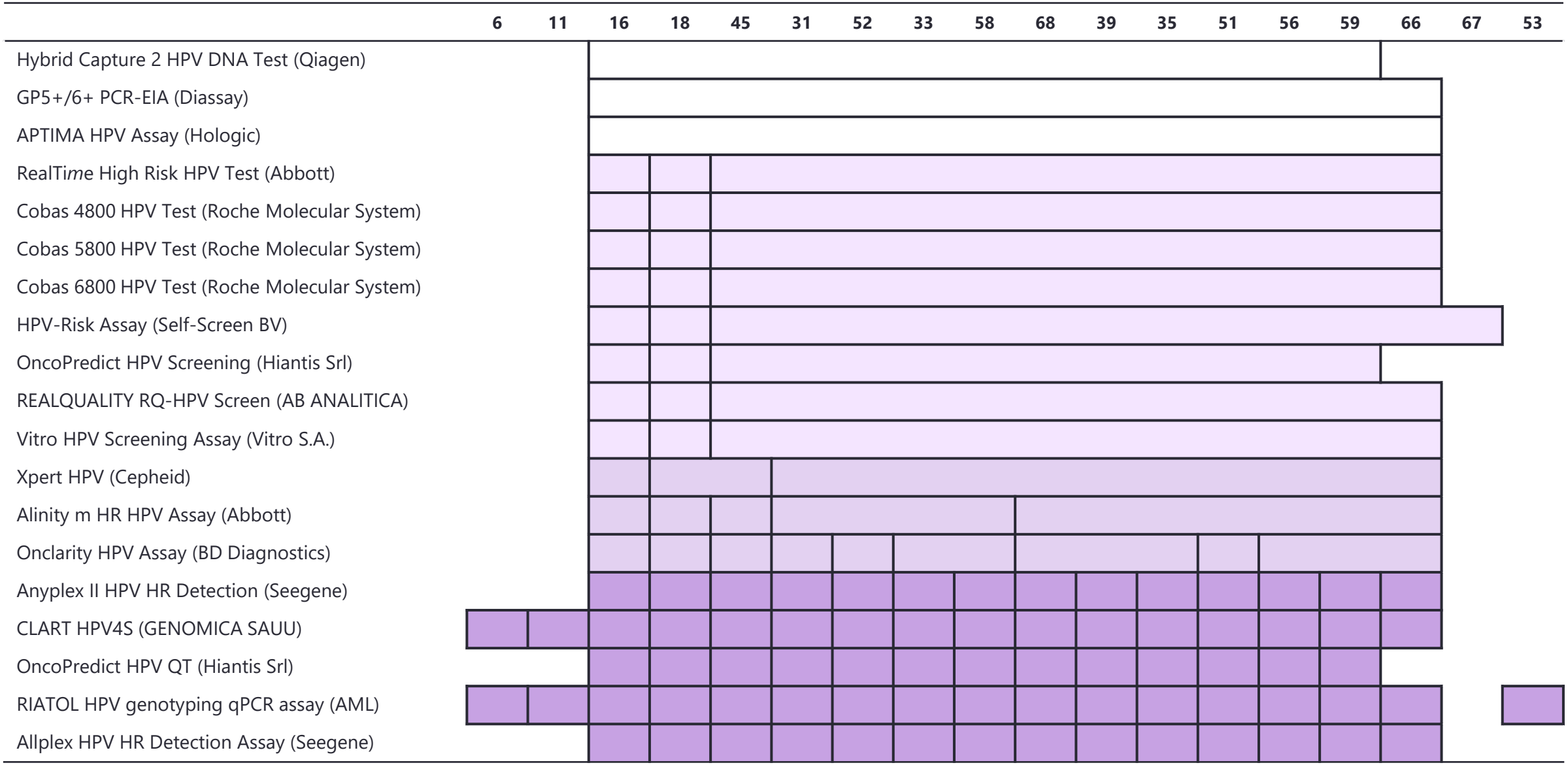
2023

Poljak M, Oštrbenk Valenčak A, Cuschieri K, Bohinc KB, Arbyn M. 2023 global inventory of commercial molecular tests for human papillomaviruses (HPV).
J Clin Virol 2024; 172: 105671.



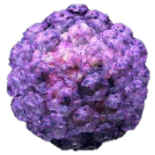
VALIDATION FOLLOWING INTERNATIONAL VALIDATION CRITERIA (Meijer, 2009) OR VALGENT

Clinically validated HPV nucleic acid tests currently available on the market that can be used in cervical cancer screening on cervical clinician-collected specimens (March 2025) according to their genotyping capacity



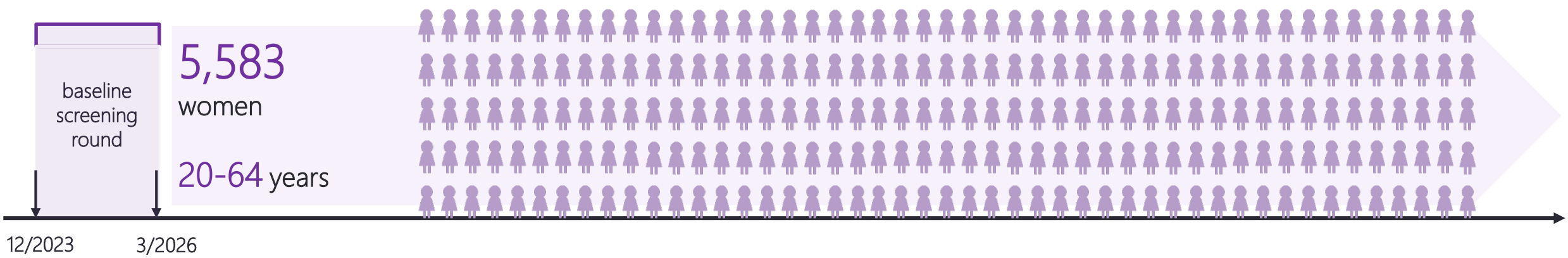
Arbyn & Dhillon & Poljak. HPV World 2024; 270: 1-5.

SLOVENIAN NATIONAL POST-VACCINATION HPV PREVALENCE STUDY



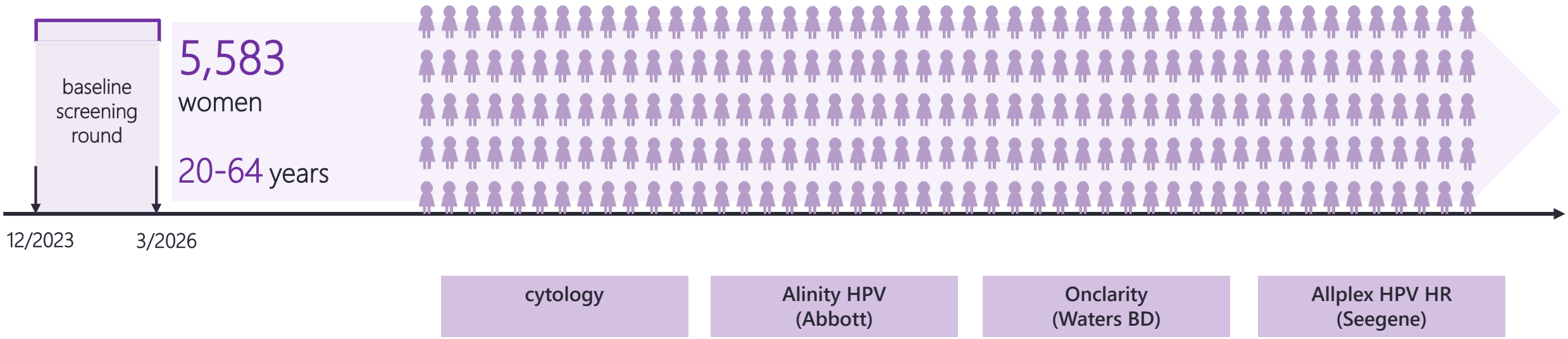
Sep 2023 – ongoing

SLOVENIAN NATIONAL HPV PREVALENCE STUDY - TIMELINE



- women aged 20-64 years, who attended routine PAP screening with local gynecologists
- representative Slovenian population-based screening cohort
- cervical sample collected in ThinPrep medium, aliquoted and stored -80°C
- conventional cytology, certified cytologists blinded to HPV results (standard of care)
- colposcopy and biopsy (if necessary) performed based study protocol

SLOVENIAN NATIONAL HPV PREVALENCE STUDY - TIMELINE



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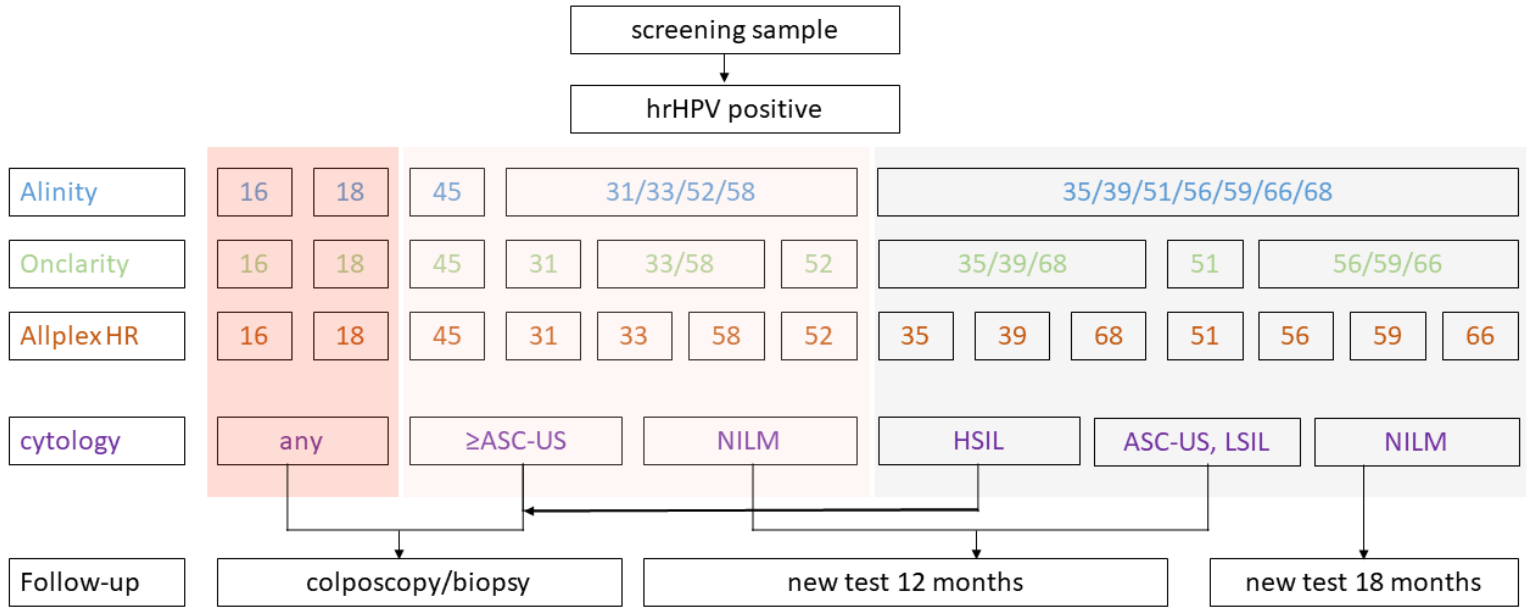
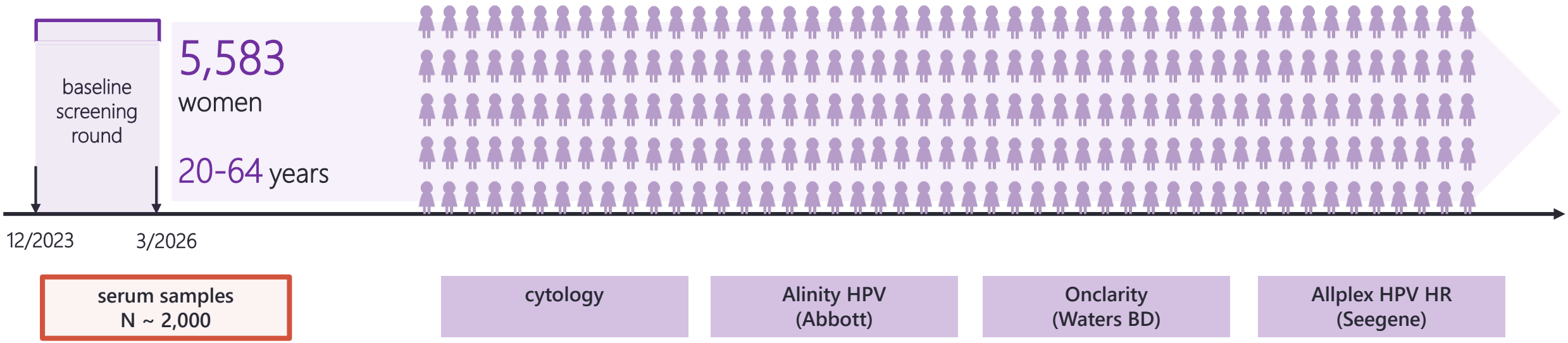
SLOVENIAN NATIONAL HPV PREVALENCE STUDY - TIMELINE

cytology	Alinity HPV (Abbott)	Onclarity (Waters BD)	Allplex HPV HR (Seegene)



SLOVENIAN NATIONAL HPV PREVALENCE STUDY - TIMELINE



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29] 05023-05043 /2

28] 05001-05022 /2

27] 04, 07, 08

26] 04001-04765/2

31] 05431-05457 /2

32] 05411-05433 /2

33] 05087-05110 /2

34] 05067-05086 /2

35] 05228-05250 /2

36] 05180-05202 /2

37] 05203-05227 /2

44] 06071-06132 /2

43] 06095-06115 /2

42] 06044-06094 /2

41] 06046-06070 /2

45] 06230-06252 /2

HPV ABBOTT 2

46] 06208-06229 /2

47] 06185-06204 /2

48] 06164-06184 /2

80] 11001-11024 /2

79] 10, 11

78] 10094-11113 /2

77] 11072-11093 /2

85] 11132-11167 /2

84] 11105-11136 /2

83] 11073-11104 /2

82] 11050-11072 /2

90] 15001-15021 /2

89] 12037-13003 /2

88] 12001-12036 /2

87] 11201-11235 /2

95] 15117-15142 /2

94] 15036-15116 /2

93] 15071-15095 /2

92] 15046-15072 /2

96] 15237-15263 /2

97] 15211-15236 /2

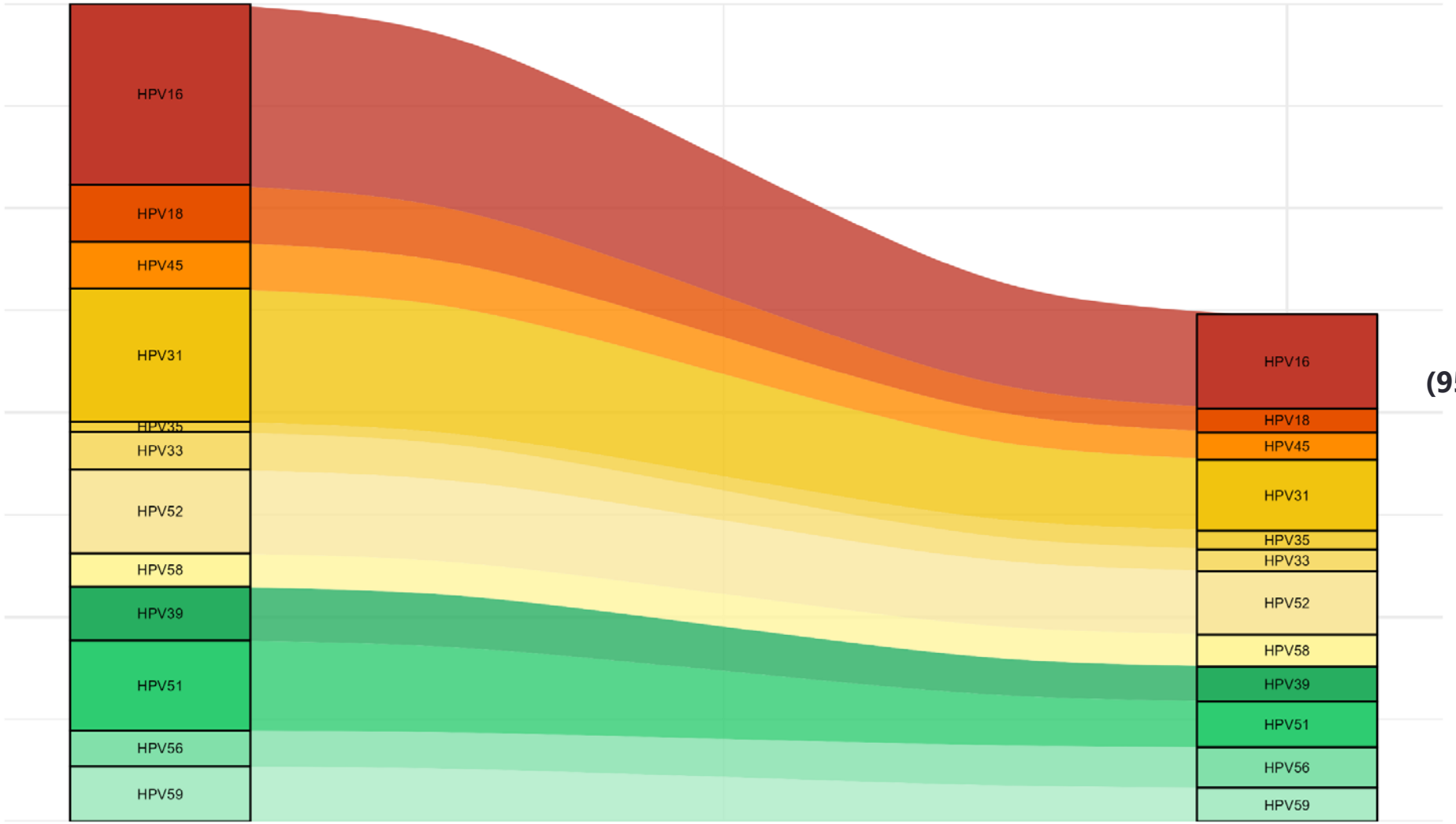
98] 15179-15209 /2

99] 15166-15188 /2

Type-specific prevalence of 12 IARC hrHPV types among Slovenian women aged 20 to 64 years old before (2009) and 14 years after (2025) the implementation of the national HPV vaccination program

Overall hrHPV prevalence:

13.1%
(95% CI: 12.1-14.1%)

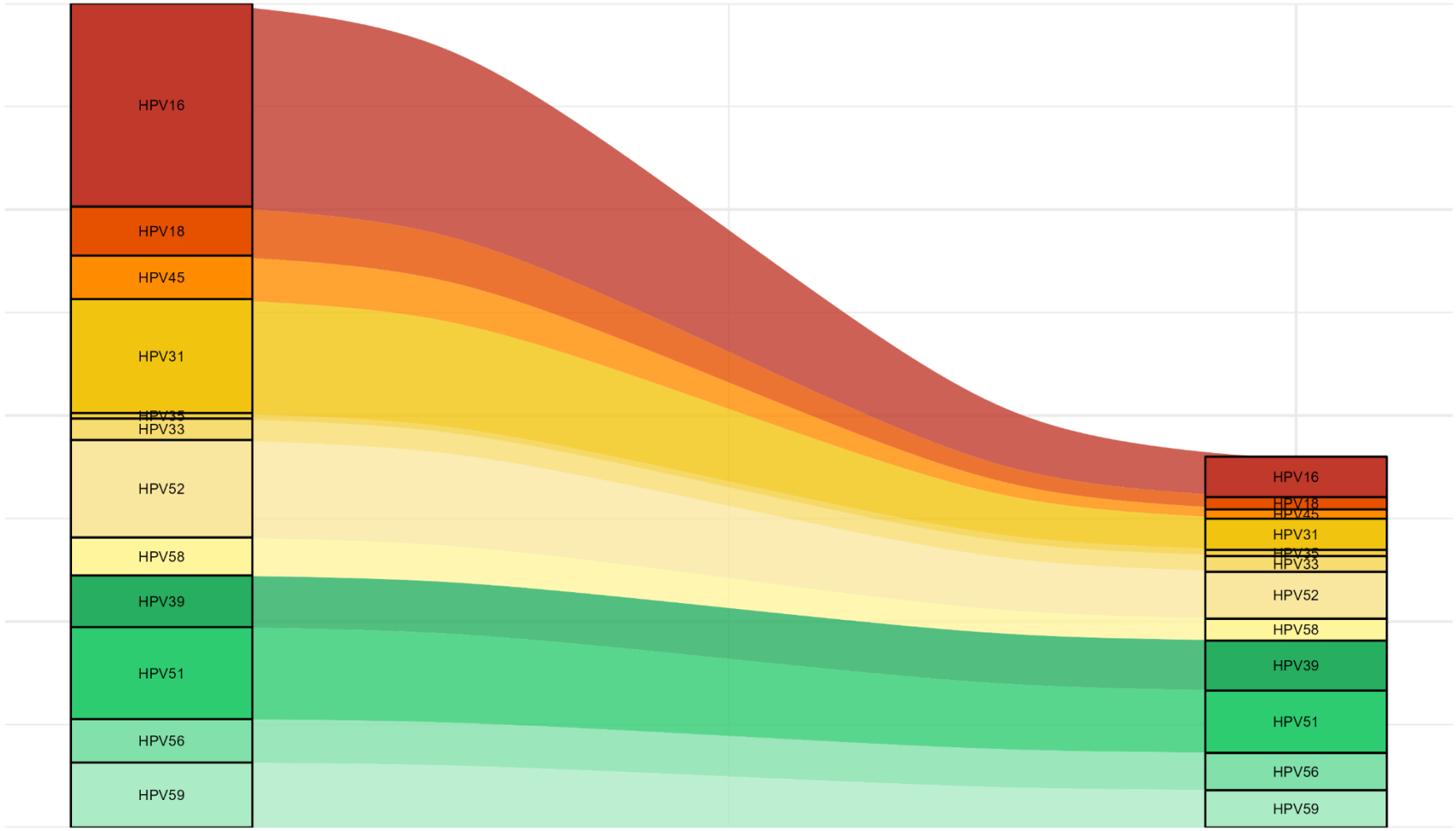


8.1%
(95% CI: 7.3-8.9%)

Type-specific prevalence of 12 IARC hrHPV types among Slovenian women aged 20 to 26 years old before (2009) and 14 years after (2025) the implementation of the national HPV vaccination program

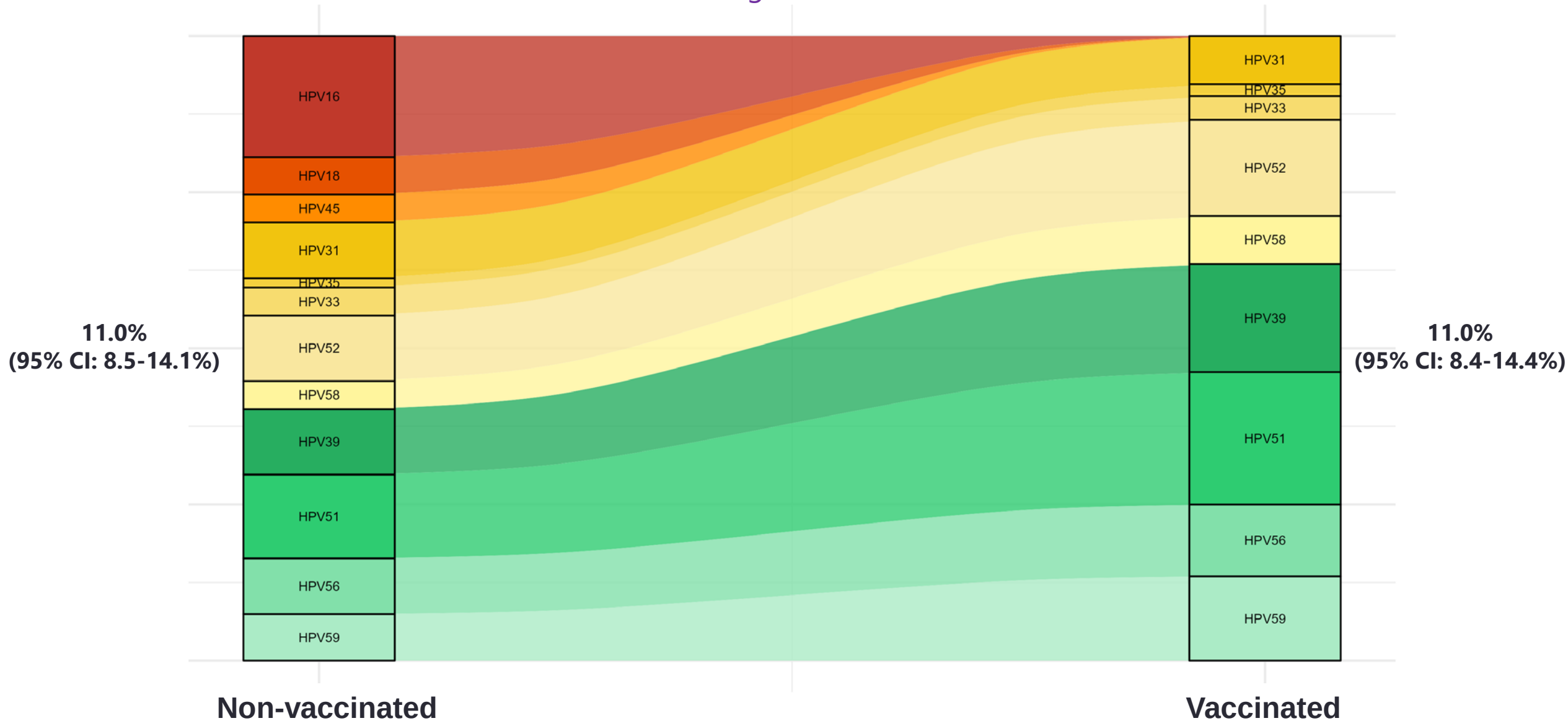
Overall hrHPV prevalence:

24.3%
(95% CI: 21.5-27.3%)



11.0%
(95% CI: 9.1-13.2%)

Type-specific prevalence of hrHPV types among Slovenian women aged 20 to 26 years old stratified according to vaccine status in 2025



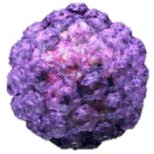
11.0%
(95% CI: 8.5-14.1%)

11.0%
(95% CI: 8.4-14.4%)

Non-vaccinated

Vaccinated

THANK YOU FOR YOUR ATTENTION



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NRL Sweden
HPV Screening studies

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Karolinska Institutet

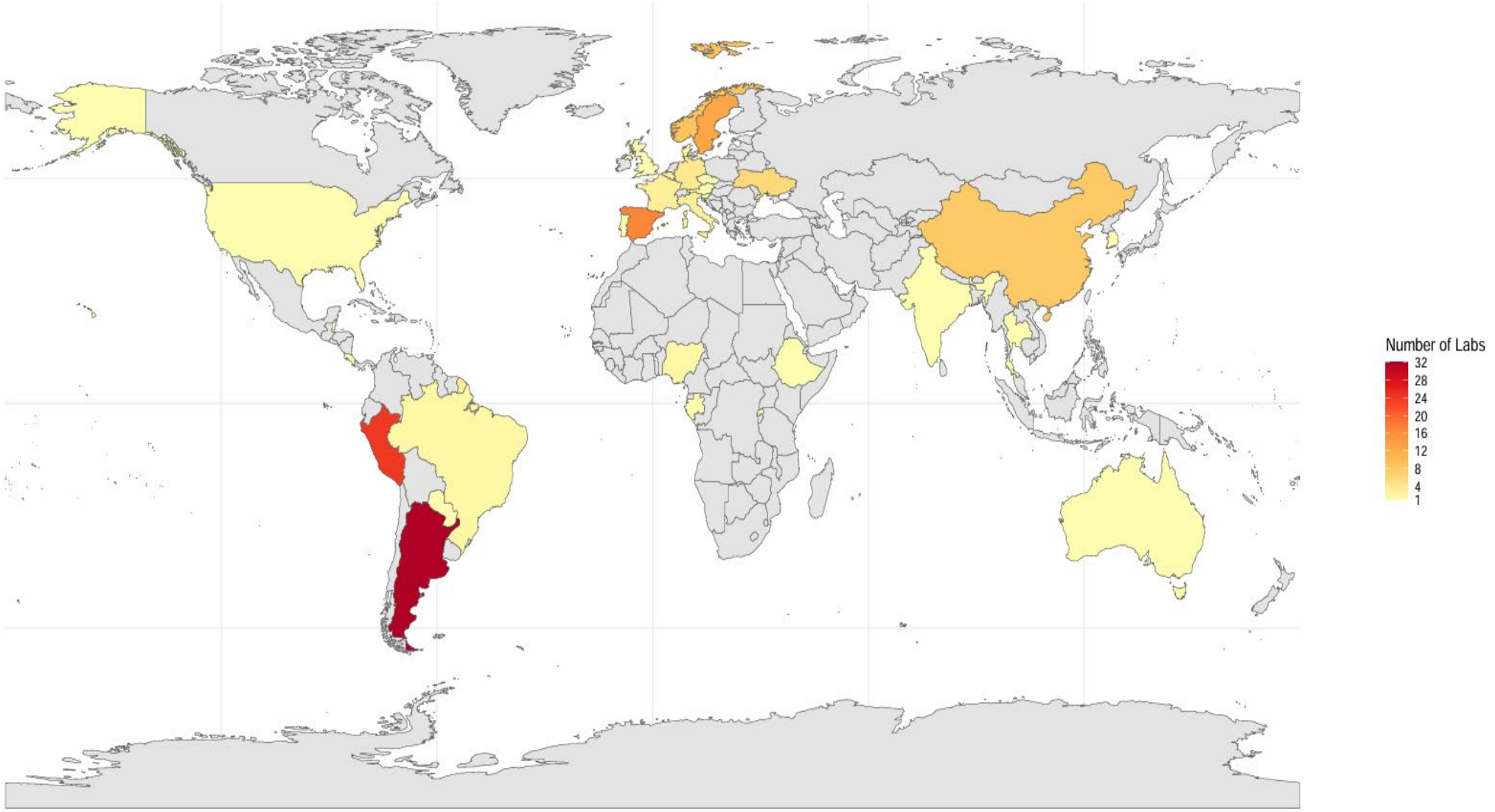
KAROLINSKA
UNIVERSITY HOSPITAL

No conflicts of interest

Global HPV Labnet Proficiency panels

- Traceable to international standard preparation of DNA with defined amount (International Unit) to allow reproducibility of panels over time - necessary to compare quality over time.
- Tests detection of multiple infections
- High capacity to detect typing error
- Possible to use with all known HPV DNA tests
- **Screening panel:**
- HPV types: The 7 most oncogenic HPV types and the additional 5 types that are classified as oncogenic
- 12 samples with plasmids, one negative control
- NRLs offered the proficiency screening panels in bulk if they want to arrange national QC programs: Launched in Norway, Peru and Argentina
- **Participation 2026:**
- The **screening panel; 146** laboratories in five WHO regions;
  - America (64 labs); Europe (65 labs); South East Asia (2 labs); Western Pacific region (10 labs); Africa (5 labs);
- Submitted results from **195** analyses (datasets)

Participation screeningpanel 2025



Screening panel results

Expected results HPV type	copies/ul/type	Correct HPV detected 195 datasets submitted % adequat datasets	Not detected Number of datasets	False positive Number of datasets
16	10	96 %	4	4
18	10	96 %	4	3
31	1000	99 %	-	1
33	1000	98 %	1	2
35	1000	100 %	-	-
45	1000	99 %	-	2
52	1000	100 %	-	-
58	1000	99 %	1	1
neg	0	99 %	-	1
16	1	94 %	10	3
18	1	85 %	29	1
31, 33, 35, 45, 52, 58	100	96 %	4[a]	3
39, 51, 56, 59, 68	100	96 %	5[a]	3

a) Not all types detected

Acknowledgment

- **Center for Cervical Cancer Elimination;** Joakim Dillner, Sara Arroyo Muhr, Camilla Lagheden, Emel Yilmaz
- **EQUALIS;** Karin Dahlin Robertsson, Moa Skarin
- **Lund University;** Ola Forslund

- **Funding** by Bill and Melinda Gates Foundation

Percent proficient results of HPV screening, as claimed to be detected by test

HPV assay	Number of data sets	No. of proficient data sets				
		100 % proficient	99-90 % proficient	89-80 % proficient	<80 % proficient	Not proficient
All assays	**195**	**177**	**0**	**3**	**2**	**13**
Cobas 4800 (Roche)	45	39	0	2	0	**4**
Abbott Alinity m (Abbott)	17	16	0	0	0	**1**
Vitro HPV Screening Kit (Vitro S.A)	15	15	0	0	0	**0**
Onclarity/COR (BD)	12	12	0	0	0	**0**
Allplex HPV HR (Seegene)	11	11	0	0	0	**0**
Abbott m2000 HPV	10	10	0	0	0	**0**

Full technical report for all assays will be posted at hpvcenter.se