Technical Report on the Global HPV LabNet DNA Genotyping Proficiency Panel 2024

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Abbreviations

AFR	African Region
AMR	Region of the Americas
EMR	Eastern Mediterranean Region
Equalis	External Quality Assessment in Laboratory Medicine in Sweden
EUR	European Region
GE	Genome Equivalent
GRL	Global Reference Laboratory
HPV	Human Papilloma Virus
HPV LabNet	HPV Laboratory Network
IU	International Unit
PAHO	Pan American Health Organization
PP	Proficiency Panel
SEAR	South East Asian Region
WHO	World Health Organization
WPR	Western Pacific Region

Global HPV DNA genotyping proficiency panel 2024

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1. Introduction

Accurate and internationally comparable HPV DNA detection and typing methodology is an essential component both for research and evaluation of HPV vaccines and in effective implementation and monitoring of HPV vaccination programmes. The WHO started a WHO Global HPV Laboratory Network (LabNet) in 2006 to support the world-wide development and implementation of HPV vaccines through improved laboratory standardization and quality assurance of HPV testing and typing methods used for research and evaluation of HPV vaccines as well as for HPV surveillance and monitoring of HPV vaccination programmes (*http://www.who.int/biologicals/vaccines/hpv/en/index.html*). A major method for achieving progress towards this goal was development, preparation and validation of proficiency panels (PP) to qualify methods and laboratories.

Call for participation in this proficiency study was sent to all laboratories that had participated in the HPV LabNet proficiency panels in previous years and advertised at HPV conferences (Eurogin and IPVC) (Annex 1, 2).

2. Aims

The aims of this panel were:

1. To assess the proficiency of HPV typing assays when routinely used in laboratories worldwide
2. To evaluate the sensitivity and type-specificity of HPV detection of the different HPV assays when routinely used in laboratories worldwide
3. Identify problems with any assays routinely used

3. Methods

3.1 Panel composition

Complete genomes of HPV cloned into plasmid vectors had been provided to the International HPV Reference Center by the respective proprietors with written approval for use in this PP. All samples were purified plasmids diluted in TE buffer (10 mM TRIS-HCl, 0.1 mM EDTA, pH 8.0) with 10 ng/µl of COT human DNA (Roche 11581074001). The HPV types included were: 6, 11, 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 68a (HPV 68 prototype) and 68b (ME-180 isolate).

Three additional samples, A, B and C were cell lines used as controls for the DNA extraction step in the testing. The composition of the panel is shown in Table 1.

Table 1: 2024 HPV PP composition by randomised sample ID

HPV types	HPV genome equivalents (GE) or international unit (IU) per 5 µl	Randomised Panel ID
16	50	10
16	5	27
18	50	33
18	5	8
6	500	37
6	50	19
11	500	22
11	50	2
31	500	38
31	50	34
33	500	20
33	50	11
35	500	28
35	50	36
39	500	7
39	50	24
45	500	39
45	50	1
51	500	15
51	50	6
52	500	35
52	50	29
56	500	12
56	50	25
58	500	16
58	50	41
59	500	21
59	50	5
68a	500	30
68a	50	17
68b	500	40
68b	50	3
6, 18, 31, 59	500	13
6, 18, 31, 59	50	9
11, 33, 45, 68b	500	23
11, 33, 45, 68b	50	31
16, 35, 51, 56	500	18
16, 35, 51, 56	50	4

39, 52, 58, 68a	500	26
39, 52, 58, 68a	50	32
TE buffer with 10 ng/µl human placenta DNA	0	14
HPV 16 positive SiHa cells	2500	B
HPV 16 positive SiHa cells	25	A
HPV- negative C33A cells	0	C

3.2 Validation of the PP

The PP was pre-tested at the International HPV Reference Laboratory in Sweden using a modified GP5+/6+ PCR followed by Luminex-based typing for HPV types 6, 11, 16, 18, 26, 30, 31, 33, 35, 39, 40, 42, 43, 45, 51, 52, 53, 54, 56, 58, 59, 61, 66, 67, 68a, 68b, 69, 70, 73, 74, 81, 82, 86, 87, 89, 90 and 91 (Söderlund-Strand et al, J. Clin Microbiol 2009 Mar;47(3):541-6).

3.3 Distribution of the PP

After pre-test validation by the International HPV Reference center in Sweden, the PP was compiled in September 2024 and distributed to laboratories throughout six WHO regions in October 2024, following the call for participation and requests received from the laboratories. The fee for participation was for commercial entities 715 Euros, whereas academic and public health entities had a fee of 300 Euros. Participants from low and lower-middle income countries could apply for waiving of the fee. As in previous years the HPV reference laboratory in Sweden prepared the materials for the 2024 HPV DNA PP, but subcontracted the administration and distribution of the PP to Equalis (External quality assessment of laboratory medicine in Sweden; https://www.equalis.se/en/ a public, non-profit company that administrates the external quality assessment for public health care laboratories in Sweden) that handled the logistics and distribution of the panel. This model has continued to work well and is a possible mode of operation of a sustainable long-term activity with global distribution of an HPV DNA typing proficiency panel.

One hundred sixty-nine datasets from 96 laboratories were obtained. The number (n) of laboratories submitting results per WHO Region is shown in Figure 1. These are EUR (n = 28), SEAR (n = 3), WPR (n = 49), AFR (n = 5), EMR (n=1) and AMR (n = 10). Sixty-six laboratories submitted a data set from one assay, eight laboratories submitted data sets from 2 different assays, two laboratories submitted data sets from 3 assays, nineteen laboratories submitted data sets from 4 different assays and one laboratory submitted data sets from 5 different assays.

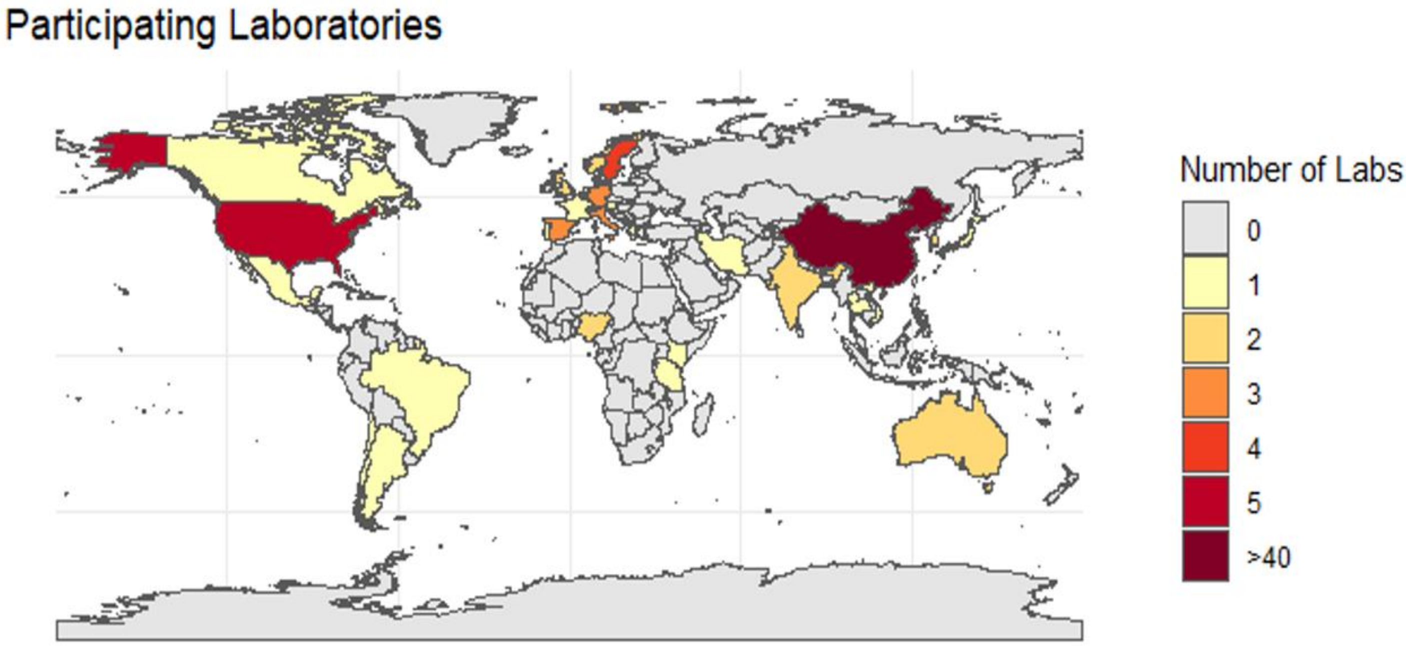

Figure 1: Global distribution of laboratories that submitted results for the 2024 HPV DNA PP.

3.4 Data analysis

Results analysed in this report include all results returned prior to the 31st of January 2025. Data was compiled by Equalis and transferred to the HPV reference laboratory in Sweden for analyses. Each data set was designated a number from 1 to 169. The data were analysed by region of the laboratory, by assay used and by HPV type.

From the data sets submitted, it was noted that participating laboratories used a range of commercial assays as well as in-house assays (Table 2). The proportion of correct HPV typing results, reported by the laboratory, was analyzed as data sets by laboratory and according to assay used.

A data set was considered proficient when it detected at least 50 international units (IU) of HPV 16 and HPV 18 in 5 µl and 500 genome equivalents (GE / IU) in 5 µl of the other HPV types, in both single and multiple infection. For proficiency, it was required that no false positive type was detected.

4. Results

Ninety-six participating laboratories submitted one hundred sixty-nine data sets. Twenty-six data sets were generated using assays that either did not discriminate specific HPV types or reported results as HPV 16, 18 and "other" High Risk HPV types (Hybribio 14 HR, Realquality, Harmonia HPV, Tellgene and OncoPredict). These data sets were only analyzed for the specific types tested for individually.

Detection of 5 IU / 5 µl of HPV16 and HPV18 and 50 GE / 5 µl of the other HPV types was not required for proficiency - these samples are intended for training and for providing information on whether the test just barely met the requirements or whether it exceeded them.

Each data set submitted by each laboratory was analyzed and a feedback letter was sent to all participating laboratories that had paid the fee in February 2025.

4.1 Results by assays used

4.1.1 Commercial assays

A total of 150 data sets were obtained using commercially available tests. The most commonly used assays were the Hybribio 37 HPV array (Hybribio) that were used in 21 laboratories, followed by Hybribio 21 HPV array (Hybribio) and 27 HPV Genotyping (Tellgen) that were used in 20 laboratories each, HPV 23 genotyping (Hybribio) and Hybribio 14 HR (Hybribio) were used by 18 laboratories each (Table 2).

4.1.2 In-house assays

Nineteen of the data sets were obtained using a variety of in-house assays (Table 2).

4.2 Results analysed by assay

4.2.1 Assay details

The assays used for testing and typing of HPV as well as the number of submitted data sets and different part of the HPV genome targeted by each assay is shown in Table 2. The distribution of assays in different WHO regions is shown in Figure 2.

Table 2: Assays used for testing and typing of HPV.

HPV assay type	Number of data sets	HPV region targeted (primers)
All assays	**169**	**L1/L2/E1/E2/E4/E5/E6/E7**
Hybribio 37 array HPV (Hybribio)	21	L1 (MY09/11)
Hybribio 21 array HPV (Hybribio)	20	L1 (MY09/11)
27 HPV Genotyping (Tellgene)	20	L1 (MY09/11)
HPV-23 Genotyping (Hybribio)	18	L1/L2/E1/E2/E4/E6/E7
Hybribio 14 HR (Hybribio)	18	E6 / E7
Allplex HPV28 (Seegene)	17	L1 / E6 / E7
In-house PCR Luminex	8	L1 / E7
Anyplex II HPV28 (Seegene)	5	L1 / E6 / E7
InnoLiPA Extra (Fujirebio)	4	L1 (SPF10)
In-house sequencing	4	L1 / E6 / E7
In-house realtime PCR	4	E6 / E7
Realquality (AB Analitica)	3	E6 / E7
In-house PGMY-CHUV/Lineblot	3	L1
Allplex HPV HR (Seegene)	2	L1 / E6 / E7
Other Commercial assays [a)]	22	L1/L2/E1/E2/E4/E6/E7

a) Other commercial assays include one laboratory using each of: Anyplex II HPV-HR, Venus HPV, LyoVenus HPV, Harmonia HPV, LyoHarmonia HPV, Liferiver Genotyping23, NeoPlex HPV 29, Tellgene 14HR 16/18, Tellgene 14HR 16/18/58/52/33, SPF10 DEIA-LiPA, HPV direct flow chip, OncoPredict QT Kit, OncoPredict HPV SCR, Sansure 13-HPV assay, Sansure HPV Genotype, MehrViru HPV, Chapter Dx, Novaplex HPV28, Prayer-AID HPV DNA Array, HPV-QUANT-21, Ampliquality HPV-type, f-HPV typing multiplex-fluorescent PCR.

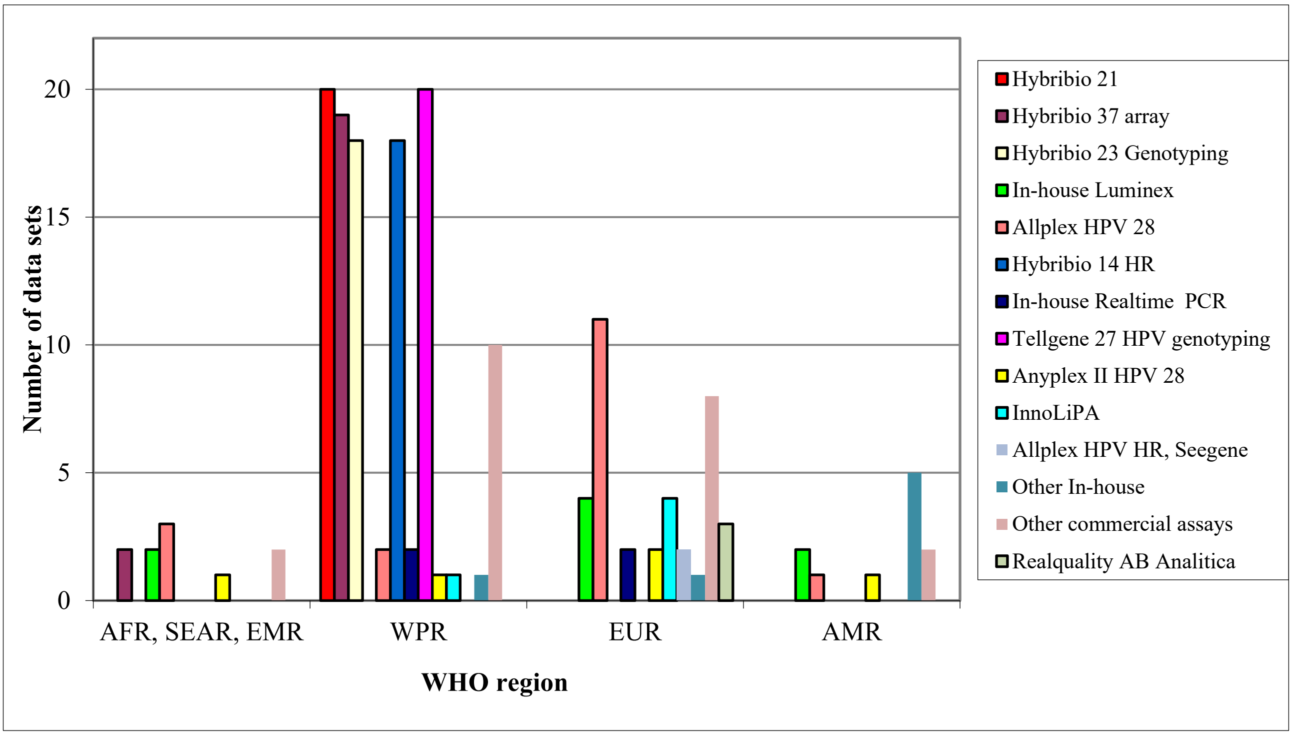

Figure 2: Type of assay in use for HPV DNA typing by WHO region. Data for AFR, SEAR and EMR region are combined.

4.2.2 Results achieved by participating laboratories

Since 2019, the criteria for proficiency includes no false positive results allowed. According to that criteria, 81 % (137/169) of the data set that typed for at least one HPV type were 100 % proficient for the types claimed to be detected by the test.

Of these, 129 data set correctly identified the content of all samples, including the samples with copy number amounts that were lower than required for proficiency. Tests that did not type for all the types in the panel could still be 100 % proficient, as the denominator was the number of types claimed to be detected by the test (not the number of types included in the panel).

The proportion of laboratory proficiency including all datasets grouped by WHO region is shown in Figure 3 and Table 3. The percent proficiency of detecting HPV types grouped by assay used for testing is shown in Table 4.

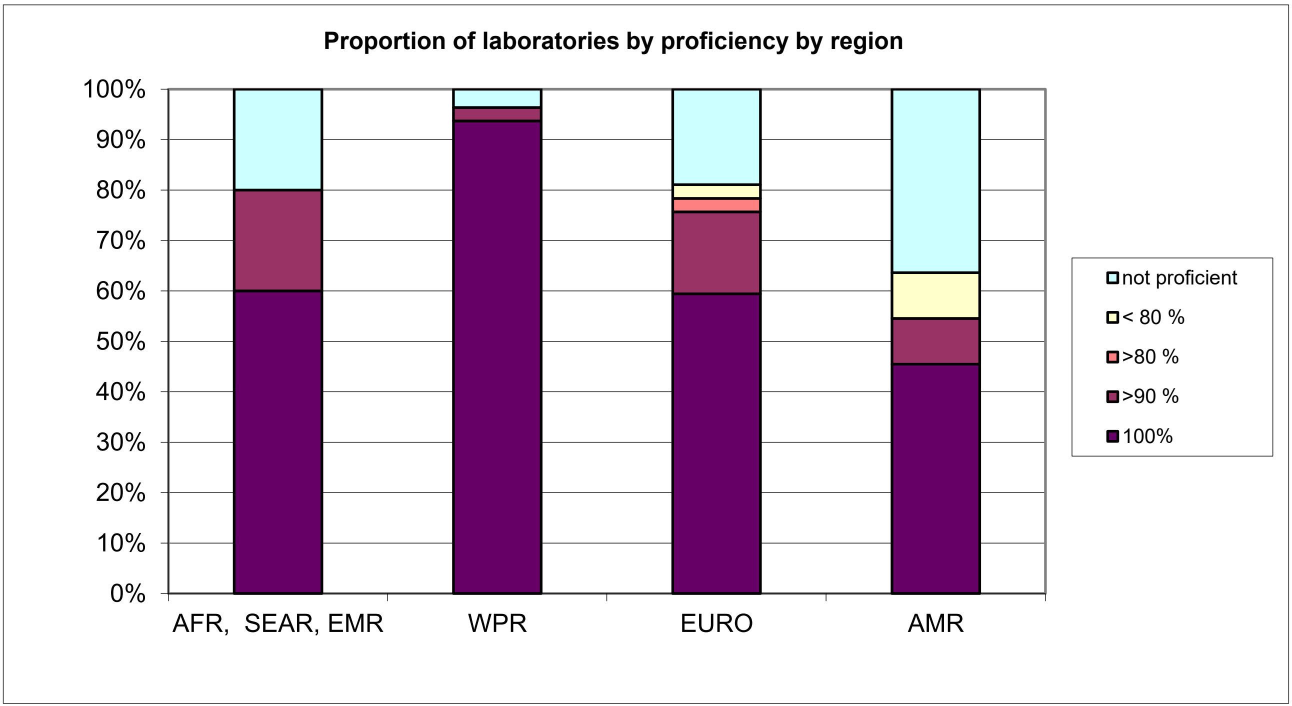

Figure 3: Proficiency for HPV DNA typing by WHO region. The figure includes all 169 data sets.

Table 3: Proportion of data sets submitted by WHO region with ≥ 90 % proficient HPV typing results.

Region (data sets)	Proportion of laboratories with 100 % correct typing	Proportion of laboratories with ≥90 % correct typing
EUR (37)	60 %	76 %
AFR, SEAR, EMR (10)	60 %	80 %
AMR (11)	45 %	55 %
WPR (111)	94 %	96 %

Table 4: Proficiency for detection of specific HPV types by assay used.

HPV assay type	Number of data sets	No. of proficient data sets				
		100 % proficient	99-90 % proficient	89-80 % proficient	<80 % proficient	Not proficient
All assays	**169**	**137**	**12**	**1**	**2**	**17**
Hybribio 37 array HPV (Hybribio)	21	21	0	0	0	0
Hybribio 21 array HPV (Hybribio)	20	20	0	0	0	0
27 HPV Genotyping (Tellgene)	20	20	0	0	0	0
HPV-23 Genotyping (Hybribio)	18	18	0	0	0	0
Hybribio 14 HR (Hybribio)	18	18	0	0	0	0
Allplex HPV28 (Seegene)	17	15	0	0	0	2
In-house PCR Luminex	8	2	3	0	1	2
Anyplex II HPV 28 (Seegene)	5	4	0	0	0	1
InnoLiPA Extra (Fujirebio)	4	2	0	0	0	2
In-house sequencing	4	1	0	0	1	2
In-house realtime PCR	4	2	1	1	0	0
Realquality (AB Analitica)	3	0	3	0	0	0
In-house PGMY-CHUV/Lineblot	3	2	0	0	0	1
Allplex HPV HR (Seegene)	2	2	0	0	0	0
Other Commercial assays [a)]	22	10	5	0	0	7

a) Other commercial assays include one laboratory using each of: Anyplex II HPV-HR, Venus HPV, LyoVenus HPV, Harmonia HPV, LyoHarmonia HPV, Liferiver Genotyping23, NeoPlex HPV 29, Tellgene 14HR 16/18, Tellgene 14HR 16/18/58/52/33, SPF10 DEIA-LiPA, HPV direct flow chip, OncoPredict QT Kit, OncoPredict HPV SCR, Sansure 13-HPV assay, Sansure HPV Genotype, MehrViru HPV, Chapter Dx, Novaplex HPV28, Prayer-AID HPV DNA Array, HPV-QUANT-21, Ampliquality HPV-type, f-HPV typing multiplex-fluorescent PCR.

4.2.3 HPV types detected

The sensitivity to detect each HPV type, as percent of laboratories detecting the different copy number (IU / GE) of the HPV types is shown in Figure 4. This data includes laboratories with multiple false positives. In Table 5 and 6 the lowest detected GE / IU grouped by assay used are shown.

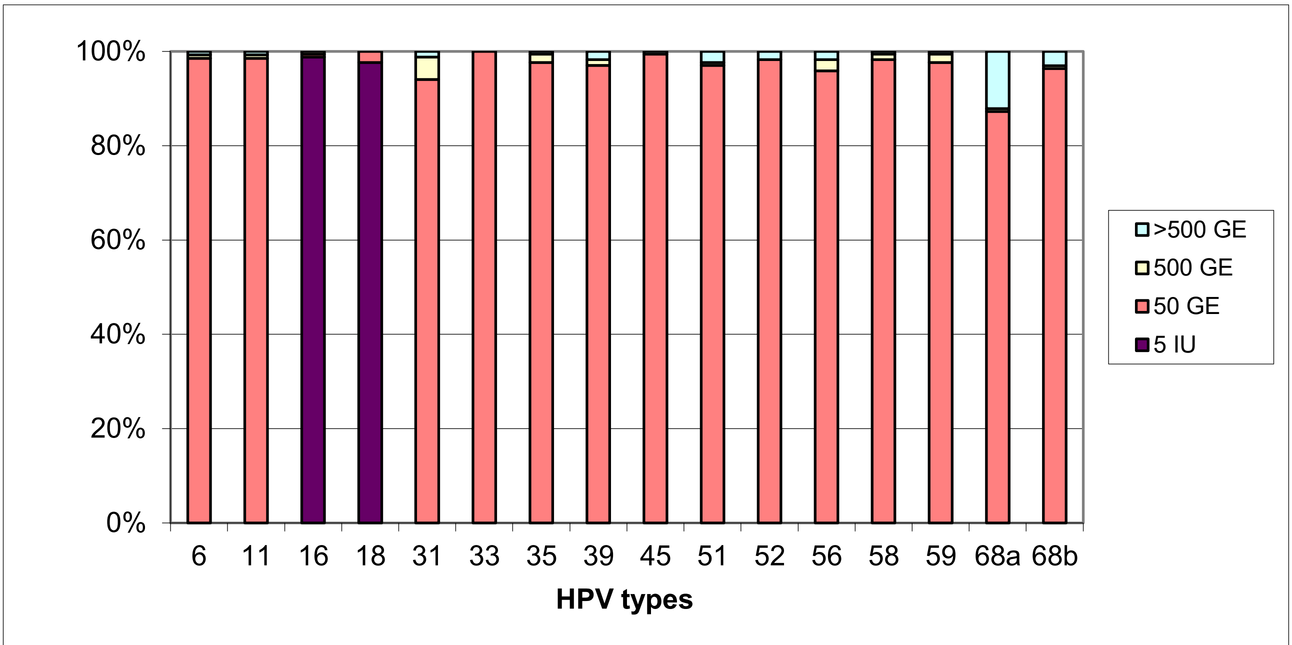

Figure 4: HPV Genome Equivalents (GE) or International Units (IU) detected per 5 µl in both single and multiple infections. Please note that only HPV16 and 18 were diluted to 5 IU (not all data sets analyze all HPV types).

Table 5: HPV GE or IU detected and typed per 5 µl in samples with both single and multiple HPV types among the most commonly used **commercial** assays. The lowest detected GE / IU are indicated.

HPV type	HPV IU /GE	All Assays (%)	Hybribio 37 array HPV	Hybribio 21 array HPV	27 HPV Genotyping (Tellgene)	HPV 23 Genotyping Hybribio	Hybribio 14	Allplex HPV 28	Anyplex II HPV 28	InnoLiPA
16	5	167 / 169 (99)	21 / 21	20 / 20	20 / 20	18 / 18	18 / 18	17 / 17	5 / 5	4 / 4
16	50	168 / 169 (99)								
16	500	169 / 169 (100)								
18	5	164 / 169 (97)	21 / 21	20 / 20	20 / 20	18 / 18	18 / 18	17 / 17	5 / 5	4 / 4
18	50	169 / 169 (100)								
18	500									
6	50	136 / 138 (99)	21 / 21	20 / 20	20 / 20	18 / 18	nt [a)]	17 / 17	5 / 5	4 / 4
6	500	137 / 138 (99)								
11	50	136 / 138 (99)	21 / 21	20 / 20	20 / 20	18 / 18	nt [a)]	17 / 17	5 / 5	3 / 4
11	500	137 / 138 (99)								4 / 4
31	50	159 / 169 (94)	21 / 21	20 / 20	20 / 20	18 / 18	18 / 18	16 / 17	5 / 5	3 / 4
31	500	167 / 169 (99)						17 / 17		4 / 4
33	50	169 / 169 (100)	21 / 21	20 / 20	20 / 20	18 / 18	18 / 18	17 / 17	5 / 5	4 / 4
33	500									
35	50	164 / 168 (98)	20 / 21	20 / 20	20 / 20	18 / 18	18 / 18	17 / 17	5 / 5	4 / 4
35	500	167 / 168 (99)	21 / 21							
39	50	164 / 169 (97)	21 / 21	20 / 20	20 / 20	18 / 18	18 / 18	17 / 17	5 / 5	4 / 4
39	500	166 / 169 (98)								
45	50	168 / 169 (99)	21 / 21	20 / 20	20 / 20	18 / 18	18 / 18	17 / 17	5 / 5	4 / 4
45	500									
51	50	164 / 169 (97)	21 / 21	20 / 20	20 / 20	18 / 18	18 / 18	17 / 17	5 / 5	4 / 4
51	500	165 / 169 (98)								
52	50	166 / 169 (98)	21 / 21	20 / 20	20 / 20	18 / 18	18 / 18	17 / 17	5 / 5	4 / 4
52	500									
56	50	162 / 169 (96)	21 / 21	20 / 20	20 / 20	18 / 18	18 / 18	17 / 17	5 / 5	3 / 4
56	500	168 / 169 (99)								4 / 4
58	50	166 / 169 (98)	21 / 21	20 / 20	20 / 20	18 / 18	18 / 18	17 / 17	5 / 5	4 / 4
58	500	168 / 169 (99)								
59	50	165 / 169 (98)	19 / 21	20 / 20	20 / 20	18 / 18	18 / 18	17 / 17	5 / 5	4 / 4
59	500	168 / 169 (99)								

68a	50	143 / 165 (87)	20 / 21	20 / 20	20 / 20	18 / 18	18 / 18	17 / 17	5 / 5	4 / 4
68a	500	145 / 165 (88)								
68b	50	160 / 166 (96)	21 / 21	20 / 20	20 / 20	18 / 18	18 / 18	17 / 17	5 / 5	4 / 4
68b	500	161 / 166 (97)								

a) Nt: Not tested

Table 6: HPV GE or IU detected and typed per 5 µl in samples with both single and multiple HPV types among in-house assays and commercial assays used by 3 and 2 laboratories, assays used by one laboratory are grouped together. The lowest detected GE / IU are indicated.

HPV type	HPV IU /GE	In-house Luminex	In-house Realtime PCR	In-house NGS	In-house PGMY-CHUV/ Lineblot	Realquality (AB Analitica)	Allplex HPV HR	Other Commercial[b)]
16	5	7 / 8	4 / 4	4 / 4	2 / 3	3 / 3	2 / 2	22 / 22
16	50	8 / 8			3 / 3			
16	500							
18	5	8 / 8	3 / 4	4 / 4	2 / 3	3 / 3	2 / 2	20 / 22
18	50		4 / 4		3 / 3			22 / 22
18	500							
6	50	6 / 7	2 / 3	4 / 4	3 / 3	3 / 3	nt [a)]	13 / 13
6	500		3 / 3					
11	50	7 / 7	3 / 3	3 / 4	3 / 3	3 / 3	nt [a)]	13 / 13
11	500							
31	50	6 / 8	4 / 4	1 / 4		3 / 3	2 / 2	22 / 22
31	500	7 / 8		3 / 4	3 / 3			
33	50	8 / 8	4 / 4	4 / 4	3 / 3	3 / 3	2 / 2	22 / 22
33	500							
35	50	6 / 7	4 / 4	3 / 4	2 / 3	3 / 3	2 / 2	22 / 22
35	500	7 / 7			3 / 3			
39	50	8 / 8	3 / 4	1 / 4	3 / 3	3 / 3	2 / 2	21 /22
39	500		4 / 4					
45	50	8 / 8	4 / 4	3 / 4	3 / 3	3 / 3	2 / 2	22 / 22
45	500							
51	50	6 / 8	4 / 4	1 / 4	3 / 3	3 / 3	2 / 2	22 / 22
51	500	7 / 8						
52	50	8 / 8	4 / 4	1 / 4	3 / 3	3 / 3	2 / 2	22 / 22

52	500							
56	50	7 / 8	4 / 4	1 / 4	2 / 3	3 / 3	2 / 2	21 / 22
56	500	8 / 8		4 / 4	3 / 3			
58	50	8 / 8	3 / 4	4 / 4	3 / 3	3 / 3	2 / 2	20 / 22
58	500		4 / 4	4 / 4				21 / 22
59	50	8 / 8	4 / 4	2 / 4	3 / 3	3 / 3	2 / 2	22 / 22
59	500			3 / 4				
68a	50	4 / 7	nt [a)]	1 / 4	1 / 2	nt [a)]	2 / 2	14 / 21
68a	500							
68b	50	6 / 7	3 / 3	1 / 4	2 / 3	3 / 3	2 / 2	20 / 21
68b	500				3 / 3			

b) nt: not tested

c) Other commercial assays include one laboratory using each of; Anyplex II HPV-HR, Venus HPV, LyoVenus HPV, Harmonia HPV, LyoHarmonia HPV, Liferiver Genotyping23, NeoPlex HPV 29, Tellgene 14HR 16/18, Tellgene 14HR 16/18/58/52/33, SPF10 DEIA-LiPA, HPV direct flow chip, OncoPredict QT Kit, OncoPredict HPV SCR, Sansure 13-HPV assay, Sansure HPV Genotype, MehrViru HPV, Chapter Dx, Novaplex HPV28, Prayer-AID HPV DNA Array, HPV-QUANT-21, Ampliquality HPV-type, f-HPV typing multiplex-fluorescent PCR.

4.3 Results by sample number

Percentage of laboratories reporting correct HPV type with **no false positive** HPV type detected are shown in table 7. The number of datasets without false positive results differs for each sample.

Table 7: Percentage of laboratories reporting correct HPV type as claimed and with **no false** positive HPV type detected, including test that type HPV 16, HPV 18 and other high risk HPV types.

HPV types	HPV genome equivalents per 5 µl	Percent correct data sets (N)
16	50	**99.4 (168 / 169)**
16	5	98.8 (167 / 169)
18	50	**100.0 (168 / 168)**
18	5	97.6 (163 / 167)
6	500	**100.0 (138 / 138)**
6	50	100.0 (136 / 136)
11	500	**100.0 (137 / 137)**
11	50	100.0 (137 / 137)
31	500	**100.0 (167 / 167)**
31	50	99.4 (166 / 167)
33	500	**100.0 (169 / 169)**

33	50	100.0 (169 / 169)
35	500	**100.0 (167 / 167)**
35	50	99.4 (167 / 168)
39	500	**100.0 (165 / 165)**
39	50	98.8 (164 / 166)
45	500	**100.0 (168 / 168)**
45	50	100.0 (169 / 169)
51	500	**100.0 (165 / 165)**
51	50	99.4 (165 / 166)
52	500	**100.0 (167 / 167)**
52	50	99.4 (167 / 168)
56	500	**99.4 (165 / 166)**
56	50	99.4 (166 / 167)
58	500	**99.4 (167 / 168)**
58	50	98.8 (165 / 167)
59	500	**100.0 (166 / 166)**
59	50	98.8 (167 / 169)
68a	500	**89.5 (145 / 162)**
68a	50	87.6 (142 / 162)
68b	500	**98.8 (161 / 163)**
68b	50	98.8 (164 / 166)
6, 18, 31, 59	500	**95.9 (162 / 169)**
6, 18, 31, 59	50	94.0 (157 / 167)
11, 33, 45, 68b	500	**97.0 (163 / 168)**
11, 33, 45, 68b	50	96.4 (162 / 168)
16, 35, 51, 56	500	**97.0 (162 / 167)**
16, 35, 51, 56	50	95.8 (160 / 167)
39, 52, 58, 68a	500	**90.5 (153 / 169)** [a]
39, 52, 58, 68a	50	90.5 (153 / 169) [a]
TE buffer with 10 ng/µl human placenta DNA	0	**99.4 (168 / 169)** (1 false positive)
HPV 16 positive SiHa cells	2500	99.4 (167 / 168) (1 false positive)
HPV 16 positive SiHa cells	25	94.6 (157 / 166) (3 false positive)
. HPV-negative C33A cells	0	98.2 (166 / 169) (3 false positive)

[a] Data sets known not to detect the HPV 68a plasmids in this panel are considered as correct when the other HPV types in the sample are detected.

4.4 Analysis of false positive results

To be considered as proficient for HPV testing no false positive result was accepted. The number of false positive samples by assay is shown in Table 8.

Table 8: Number of false positive HPV types detected per data set reported by assay used.

HPV assay type	Number of data sets	No. of false positive samples per data set				
		0 samples	1 sample	2 samples	3 samples	> 3 samples
All assays	**169**	**152**	**10**	**0**	**1**	**6**
Hybribio 37 array HPV (Hybribio)	21	21	0	0	0	0
Hybribio 21 array HPV (Hybribio)	20	20	0	0	0	0
27 HPV Genotyping (Tellgene)	20	20	0	0	0	0
HPV-23 Genotyping (Hybribio)	18	18	0	0	0	0
Hybribio 14 HR (Hybribio)	18	18	0	0	0	0
Allplex HPV28 (Seegene)	17	15	1	0	0	1
In-house PCR Luminex	8	6	2	0	0	0
Anyplex II HPV 28 (Seegene)	5	4	1	0	0	0
InnoLiPA Extra (Fujirebio)	4	2	1	0	0	1
In-house sequencing	4	2	0	0	0	2
In-house realtime PCR	4	4	0	0	0	0
Realquality (AB Analitica)	3	3	0	0	0	0
In-house PGMY-CHUV/Lineblot	3	2	0	0	0	1
Allplex HPV HR (Seegene)	2	2	0	0	0	0
Other Commercial assays [a)]	22	15	5	0	1	1

a) Other commercial assays include one laboratory using each of; Anyplex II HPV-HR, Venus HPV, LyoVenus HPV, Harmonia HPV, LyoHarmonia HPV, Liferiver Genotyping23, NeoPlex HPV 29, Tellgene 14HR 16/18, Tellgene 14HR 16/18/58/52/33, SPF10 DEIA-LiPA, HPV direct flow chip, OncoPredict QT Kit, OncoPredict HPV SCR, Sansure 13-HPV assay, Sansure HPV Genotype, MehrViru HPV, Chapter Dx, Novaplex HPV28, Prayer-AID HPV DNA Array, HPV-QUANT-21, Ampliquality HPV-type, f-HPV typing multiplex-fluorescent PCR.

We searched the data sets for patterns of consistent false positivity for any specific sample in the panel. The false positivities appeared to be essentially randomly distributed among the samples, indicating that the problem with false positives is usually not related to a property of the assays itself (e.g. cross-reactivity), but rather with the laboratory conditions of use (e.g. contamination).

4.5 Comparison of results for laboratories that participated 2024 and in the years 2008, 2010, 2011, 2013, 2014, 2017, 2019, 2021, 2022 and 2023

In total 62 laboratories that participated in 2024 also participated in the HPV LabNet PPs from at least one previous year. Ten laboratories that submitted results in 2024 had participated already in 2008 at the start of the proficiency study.

Out of these 10, seven laboratories participated in all 11 PPs (2008, 2010, 2011, 2013, 2014, 2017, 2019, 2021, 2022, 2023 and 2024). One laboratory analysed the PP 10 years, 4 laboratories 9 years, 3 laboratories 8 years, 2 laboratories 7 years, 5 laboratories 6 years, 7 laboratories 5 years, 4 laboratories 4 years, 13 laboratories analysed the panel 3 years, and 16 laboratories analysed the panel 2 years. Comparisons of these results were made for each laboratory. Some of the laboratories used the same tests during all years, whereas some laboratories had changed at least one of the tests used. Several of the assays used in the first panels are not available any longer e.g. Linear Array. Many laboratories have switched from in-house assays to commercial assays, in 2010, 45% (60/132) of the total datasets were from in-house assays, compared to 15% (19/128) in 2024. Percent proficiency, for each year is shown in Table 9a and 9b, the sensitivity for individual HPV types in Table 10 and the specificity with number of false positive samples in Table 11a and 11b.

Table 9a: Proficiency of detecting HPV types by laboratories that participated in 2024 PP, using identical assays in 2008, 2010, 2011, 2013, 2014, 2017, 2019, 2021, 2022 and 2023.

Not proficient = One or more false positive results

Proficiency	All test by laboratories that participated in 2008, 2010, 2011, 2013, 2014, 2017, 2019, 2021, 2022, 2023 and 2024 using identical assays										
	2008 (%)	**2010 (%)**	**2011 (%)**	**2013 (%)**	**2014 (%)**	**2017 (%)**	**2019 (%)**	**2021 (%)**	**2022 (%)**	**2023 (%)**	**2024 (%)**
100 % proficient	0 / 5 (0)	1 / 8 (12)	5 / 13 (38)	6 / 14 (43)	9 / 17 (53)	14 / 27 (52)	9 / 29 (31)	72 / 90 (80)	78 / 95 (82)	45 / 57 (79)	101 / 127 (80)
99-90 % proficient	1 / 5 (20)	0 / 8 (0)	1 / 13 (7.7)	0 / 14 (0)	2 / 17 (12)	1/ 27 (3.7)	9 / 29 (31)	1 / 90 (1.1)	3 / 95 (3.2)	3 / 57 (5.2)	10 / 127 (7.9)
89-80 % proficient	0 / 5 (0)	2 / 8 (25)	1 / 13 (7.7)	3 / 14 (21)	1 / 17 (5.9)	3 / 27 (11)	1 / 29 (3,4)	0 / 90 (0)	0 / 95 (0)	1 / 57 (1.8)	1 / 127 (0.8)
<80 % proficient	2 / 5 (40)	1 / 8 (12)	1 / 13 (7.7)	0 / 14 (0)	0 / 17 (0)	0 / 27 (0)	1 / 29 (3,4)	0 / 90 (0)	1 / 95 (1.1)	0 / 57 (0)	1 / 127 (0.8)

Not proficient	2 / 5 (40)	4 / 8 (50)	5 / 13 (38)	5 / 14 (36)	5 / 17 (29)	9 / 27 (33)	9 / 29 (31)	17 / 90 (19)	13 / 95 (14)	8 / 57 (14)	14 / 127 (11)

Table 9b: Proficiency of detecting HPV types by laboratories that participated in 2024 PP, with data from 2008, 2010, 2011, 2013, 2014, 2017, 2019, 2021, 2022 and 2023.

Not proficient = one or more false positive result

Proficiency	**All test by laboratories that participated in 2008, 2010, 2011, 2013, 2014, 2017, 2019, 2021, 2022, 2023 and 2024**										
	2008 (%)	**2010 (%)**	**2011 (%)**	**2013 (%)**	**2014 (%)**	**2017 (%)**	**2019 (%)**	**2021 (%)**	**2022 (%)**	**2023 (%)**	**2024 (%)**
100 % proficient	3 / 11 (27)	3 / 16 (19)	12 / 25 (48)	9 / 24 (35)	11 / 26 (42)	19 / 41 (46)	10 / 39 (26)	74 / 95 (78)	80 / 97 (82)	49 / 64 (77)	101 / 128 (79)
99-90 % proficient	1 / 11 (9.1)	1 / 16 (6.2)	1 / 25 (4.0)	2 / 24 (7.7)	2 / 26 (7.7)	4 / 41 (9.8)	10 / 39 (26)	1 / 95 (1.1)	3 / 97 (3.1)	3 / 64 (4.7)	10 / 128 (7.8)
89-80 % proficient	0 / 11 (0)	3 / 16 (19)	2 / 25 (8.0)	4 / 24 (15)	3 / 26 (12)	4 / 41 (9.8)	2 / 39 (5.1)	0 / 95 (0)	0 / 97 (0)	1 / 64 (1.6)	1 / 128 (0.8)
<80 % proficient	2 / 11 (18)	1 / 16 (6.2)	2 / 25 (8.0)	0 / 24 (0)	0 / 26 (0)	0 / 41 (0)	1 / 39 (2.6)	0 / 95 (0)	1 / 97 (1.0)	1 / 64 (1.6)	2 / 128 (1.6)
Not proficient	5 / 11 (45)	8 / 16 (50)	8 / 25 (32)	9 / 24 (42)	10 / 26 (38)	14 / 41 (34)	16 / 39 (41)	20 / 95 (21)	13 / 97 (13)	10 / 64 (16)	14 / 128 (11)

Table 10: HPV GE or IU detected and typed per 5 µl in samples with both single and multiple HPV types by laboratories participating in 2013, 2014, 2017, 2019, 2021, 2022, 2023 and 2024. Table includes samples with detection of false positive HPV types. Lowest detected GE/IU is indicated.

HPV type	HPV IU /GE	All test by laboratories participating both in 2013, 2014, 2017, 2019, 2021, 2022 and 2023							
		2013 (%)	**2014 (%)**	**2017 (%)**	**2019 (%)**	**2021 (%)**	**2022 (%)**	**2023 (%)**	**2024 (%)**
16	5	20 / 24 (83)	18 / 26 (69)	34 / 40 (85)	36 / 39 (92)	91 / 95 (96)	93 / 97 (96)	58 / 64 (91)	127 / 128 (99)
16	50	22 / 24 (92)	24 / 26 (92)	39 / 40 (98)	39 / 39 (100)	95 / 95 (100)	95 / 97 (98)	63 / 64 (98)	
16	500	24 / 24 (100)	26 / 26 (100)	40 / 40 (100)			97 / 97 (100)	64 / 64 (100)	128 / 128 (100)
18	5	20 / 24 (83)	17 / 25 (68)	29 / 41 (71)	36 / 38 (95)	89 / 95 (94)	93 / 97 (96)	58 / 64 (91)	126 / 128 (98)
18	50	22 / 24 (92)	21 / 25 (84)	38 / 41 (93)	38 / 38 (100)	95 / 95 (100)	96 / 97 (99)	60 / 64 (94)	127 / 128 (99)
18	500	24 / 24 (100)	25 / 25 (100)	41 / 41 (100)			97 / 97 (100)	64 / 64 (100)	128 / 128 (100)
6	50	14 / 20 (70)	15 / 21 (71)	25 / 31 (81)	30 / 33 (91)	70 / 74 (95)	76 / 78 (97)	44 / 50 (88)	99 / 101 (98)
6	500	17 / 20 (85)	19 / 21 (90)	30 / 31 (97)	33 / 33 (100)	72 / 74 (97)		48 / 50 (96)	100 / 101 (99)
11	50	18 / 20 (90)	19 / 21 (90)	28 / 31 (90)	32 / 33 (97)	72 / 74 (97)	77 / 78 (99)	49 / 50 (98)	99 / 101 (98)
11	500	20 / 20 (100)	21 / 21 (100)	31 / 31 (100)	33 / 33 (100)	74 / 74 (100)		50 / 50 (100)	100 / 101 (99)
31	50	15 / 24 (62)	17 / 26 (65)	31 / 41 (77)	33 / 39 (85)	91 / 95 (96)	93 / 97 (96)	59 / 64 (92)	120 / 128 (94)
31	500	19 / 24 (79)	23 / 26 (88)	37 / 41 (90)	37 / 39 (95)	93 / 95 (98)	96 / 97 (99)	62 / 64 (97)	126 / 128 (98)
33	50	21 / 24 (88)	22 / 26 (85)	36 / 41 (88)	38 / 39 (97)	94 / 95 (96)	96 / 97 (99)	63 / 64 (98)	128 / 128 (100)
33	500	24 / 24 (100)	26 / 26 (100)	41 / 41 (100)	39 / 39 (100)	95 / 95(100)	97 / 97 (100)		
35	50	19 / 23 (83)	22 / 25 (88)	37 / 40 (92)	35 / 39 (90)	91 / 95 (96)	94 / 97 (97)	61 / 64 (95)	124 / 127 (98)
35	500	23 / 23 (100)	24 / 25 (96)	38 / 40 (95)	38 / 39 (97)	94 / 95 (99)	96 / 97 (99)	64 / 64 (100)	126 / 127 (99)
39	50	19 / 23 (83)	20 / 25 (80)	36 / 40 (81)	37 / 39 (95)	91 / 95 (96)	95 / 97 (98)	59 / 64 (92)	123 / 128 (96)
39	500	23 / 23 (100)	24 / 25 (96)	39 / 40 (92)	39 / 39 (100)	92 / 95 (97)	96 / 97 (99)	63 / 64 (98)	125 / 128 (98)
45	50	19 / 24 (79)	22 / 26 (85)	38 / 41 (93)	38 / 39 (97)	94 / 95 (99)	97 / 97 (100)	60 / 64 (94)	127 / 128 (99)
45	500	22 / 24 (92)	25 / 26 (96)	40 / 41 (98)				63 / 64 (98)	
51	50	20 / 24 (83)	23 / 26 (88)	34 / 41 (83)	37 / 39 (95)	90 / 95 (95)	95 / 97 (98)	59 / 64 (92)	123 / 128 (96)
51	500	23 / 24 (96)	25 / 26 (96)	36 / 41 (88)	38 / 39 (97)	93 / 95 (98)		60 / 64 (94)	124 / 128 (97)
52	50	22 / 24 (92)	21 / 26 (81)	40 / 41 (98)	39 / 39 (100)	93 / 95 (98)	96 / 97 (99)	62 / 64 (97)	125 / 128 (98)
52	500	24 / 24 (100)	25 / 26 (96)	41 / 41 (100)		94 / 95 (99)			
56	50	20 / 23 (87)	22 / 25 (88)	32 / 40 (80)	34 / 39 (87)	90 / 94 (96)	92 / 97 (95)	56 / 64 (88)	124 / 128 (97)
56	500	22 / 23 (96)	25 / 25 (100)	36 / 40 (90)	38 / 39 (97)	92 / 94 (98)	96 / 97 (99)	61 / 64 (95)	127 / 128 (99)
58	50	19 / 23 (83)	22 / 25 (88)	30 / 40 (75)	38 / 39 (97)	91 / 95 (96)	96 / 97 (99)	60 / 64 (94)	125 / 128 (98)
58	500	22 / 23 (96)	24 / 25 (96)	38 / 40 (95)	39 / 39 (100)	94 / 95 (99)		62 / 64 (97)	127 / 128 (99)
59	50	16 / 23 (70)	19 / 25 (76)	31 / 40 (78)	31 / 39 (79)	90 / 95 (89)	95 / 97 (98)	61 / 64 (95)	124 / 128 (97)
59	500	22 / 23 (96)	24 / 25 (96)	39 / 40 (98)	37 / 39 (95)	93 / 95 (96)	96 / 97 (99)	63 / 64 (98)	127 / 128 (99)
68a	50	5 / 17 (29)	12 / 20 (60)	20 / 34 (59)	22 / 36 (61)	70 / 90 (78)	84 / 93 (90)	45 / 53 (85)	108 / 123 (88)
68a	500	7 / 17 (41)	14 / 20 (70)		25 / 36 (69)	72 / 90 (80)	85 / 93 (91)	48 / 53 (91)	109 / 123 (89)
68b	50	16 / 22 (73)	17 / 24 (71)	31 / 39 (79)	5 / 37 (13)	87 / 93 (94)	93 / 96 (97)	55 / 62 (89)	120 / 123 (98)
68b	500	22 / 22 (100)	24 / 24 (100)	34 / 39 (87)	14 / 37 (38)	89 / 93 (96)	94 / 96 (98)	58 / 62 (94)	

Table 11a: Number of samples with false positive HPV types detected per data set reported by laboratories using identical assays in 2008, 2010, 2011, 2013, 2014, 2017, 2019, 2021, 2022, 2023 and 2024 years proficiency studies.

No of false positive samples	All test by laboratories that participated in 2008, 2010, 2011, 2013, 2014, 2017, 2019, 2021, 2022, 2023 and 2024 using identical assays										
	2008 (%)	2010 (%)	2011 (%)	2013 (%)	2014 (%)	2017 (%)	2019 (%)	2021 (%)	2022 (%)	2023 (%)	2024 (%)
0 samples	3 / 5 (60)	4 / 8 (50)	8 / 13 (62)	9 / 14 (64)	12 / 17 (71)	18 / 27 (67)	20 / 29 (69)	73 / 90 (81)	82 / 95 (86)	49 / 57 (86)	113 / 127 (89)
1 sample	1 / 5 (20)	0 / 8 (0)	1 / 13 (7.7)	2 / 14 (14)	2 / 17 (12)	5 / 27 (19)	6 / 29 (21)	12 / 90 (13)	10 / 95 (11)	3 / 57 (5.3)	9 / 127 (7.1)
2 samples	0 / 5 (0)	3 / 8 (38)	3 / 13 (23)	0 / 14 (0)	0 / 17 (0)	1 / 27 (3.7)	1 / 29 (3.4)	4 / 90 (4.4)	3 / 95 (3.1)	2 / 57 (3.5)	0 / 127 (0)
3 samples	0 / 5 (0)	0 / 8 (0)	0 / 13 (0)	2 / 14 (14)	1 / 17 (5.9)	1 / 27 (3.7)	1 / 29 (3.4)	0 / 90 (0)	0 / 95 (0)	0 / 57 (0)	1 / 127 (0.8)
>3 samples	1 / 5 (20)	1 / 8 (12)	1 / 13 (7.7)	1 / 14 (7.1)	2 / 17 (12)	2 / 27 (7.4)	1 / 29 (3.4)	1 / 90 (1.1)	0 / 95 (0)	3 / 57 (5.3)	4 / 127 (3.1)

Table 11b: Number of samples with false positive HPV types detected per data set reported by laboratories participating in 2008, 2010, 2011, 2013, 2014, 2017, 2019, 2021, 2022, 2023 and 2024 years proficiency studies.

No of false positive samples	All test by laboratories that participated in 2008, 2010, 2011, 2013, 2014, 2017, 2019, 2021, 2022, 2023 and 2024										
	2008 (%)	2010 (%)	2011 (%)	2013 (%)	2014 (%)	2017 (%)	2019 (%)	2021 (%)	2022 (%)	2023 (%)	2024 (%)
0 samples	6 / 11 (55)	8 / 16 (50)	16 / 25 (64)	15 / 24 (62)	16 / 26 (62)	27 / 41 (66)	23 / 39 (59)	75 / 95 (79)	84 / 97 (87)	54 / 64 (84)	114 / 128 (89)
1 sample	2 / 11 (18)	0 / 16 (0)	4 / 25 (16)	5 / 24 (21)	3 / 26 (12)	7 / 41 (17)	9 / 39 (23)	13 / 95 (14)	10 / 97 (10)	5 / 64 (7.8)	9 / 128 (7.0)
2 samples	1 / 11 (9.1)	3 / 16 (19)	3 / 25 (12)	0 / 24 (0)	2 / 26 (7.7)	2 / 41 (4.9)	2 / 39 (5.1)	4 / 95 (4.2)	3 / 97 (3.1)	2 / 64 (3.1)	0 / 128 (0)
3 samples	1 / 11 (9.1)	3 / 16 (19)	0 / 25 (0)	2 / 24 (8.3)	2 / 26 (7.7)	1 / 41 (2.4)	1 / 39 (2.6)	0 / 95 (0)	0 / 97 (0)	0 / 64 (0)	1 / 128 (0.8)
>3 samples	1 / 11 (9.1)	2 / 16 (12)	2 / 25 (8)	2 / 24 (8.3)	3 / 26 (12)	4 / 41 (9.8)	4 / 39 (10)	3 / 95 (3.2)	0 / 97 (0)	3 / 64 (0)	4 / 128 (3.1)

5. Discussion

A total of 97 laboratories applied for participation in the 2024 proficiency study. The 2024 proficiency panels were distributed to all solicitants and a total of 169 datasets from 96 laboratories were returned before the deadline (January 2025).

Gladly, the global deterioration in HPV typing proficiency that was seen and reported in the 2019 PP has significantly reversed, with a total of 81% (137/169) datasets showing 100% proficiency in 2024. Again, this is the highest percentage of 100% proficient datasets seen in all proficiency studies. The highest percentage previously was seen in 2023 with 79% (112/141) datasets being 100% proficient. Proficiency criteria was defined as: i) detection of at least 50 international units (IU) per 5 ul of HPV 16 and HPV 18, in both single and multiple HPV infections, ii) detection of at least 500 genome equivalents (GE) in 5 ul of the other HPV types (not HPV 16 nor HPV 18) in both single and multiple HPV infections and iii) no false positivity detection. The criteria for proficiency since the 2019 PP include no false positivity (in previous years, a maximum of one false positive had been allowed for proficiency).

Not all assays tested for every HPV type included in the panel. Twenty-six data sets were generated using assays that either did not discriminate specific HPV types or reported results as HPV 16, 18 and “other” High Risk HPV types (Hybribio 14 HR, Realquality, Harmonia HPV, Tellgene and OncoPredict). These data sets were only analyzed for the specific types tested for individually.

E.g., if an assay did not include HPV 68, laboratories using such an assay were considered as not testing for HPV 68. According to these criteria, 137/169 (81%) datasets that typed for at least one HPV type were 100 % proficient for the types claimed to be detected by the test. Of these, 129/169 (76%) datasets correctly identified the content of all samples, including the samples with copy number amounts that were lower than required for proficiency. HPV 16, 18 and 45 (most prevalent ones in cervical cancer) were detected in more than 97% datasets, indicating high performance of the participating laboratories for detection of these HPV types.

Most datasets were provided using commercially available assays (150/169). The most commonly used assays were the Hybribio 37 array HPV assay that were used in 21 different laboratories, Hybribio 21 HPV array and the 27 HPV Genotyping from Tellgene were used in 20 different laboratories each.

Nineteen datasets were obtained using a variety of in-house assays. The proportion of commercial assays used in the proficiency studies has exponentially increased over time, from 57% in 2011, 80% in 2019 to >86% in the last four years (150/169 datasets using commercial assays in 2024).

The increased use of commercial assays may have allowed for greater standardization among the participating laboratories, which partially could have contributed to the remarkable proficiency improvement since 2021 (>77%-82% of datasets 100% proficient 2021-2024 vs 27%-46% 2008-2019).

There were several assays used by more than one laboratory from which all the datasets provided showed 100% proficiency (e.g. Hybribio 37 array HPV (Hybribio), HPV-23 Genotyping (Hybriobio), Hybribio 21 array HPV (Hybribio), 27 HPV Genotyping (Tellgene)). Overall, 89.3% (151/169) of datasets showed no false positivity. Twelve different assays showed no false positivity including the assays being 100% proficient and described above.

We aimed to investigate if there was any specific sample or assay where false positivity was consistently detected. Results from false positivity investigation revealed that false positivity appeared to be essentially randomly distributed among the samples, indicating that the problem with false positivity was not related to a specific sample nor an assay itself (e.g. cross-reactivity), but rather due to laboratory conditions of use (e.g. cross-contamination).

A common finding, seen also in previous studies, is that the laboratory performing the test has a big impact on the performance of the test itself, in particular for certain assays. As an example, Allplex HPV 28 (Seegene) which was used to generate 17 data sets, provided 15/17 datasets which were fully proficient and 2/17 datasets which were not proficient with 1 or more false positive result each. This is an example of the impact of the laboratory. Several of the datasets submitted in 2024 were generated using assays that were used by 4 or fewer laboratories and thus, it was difficult to draw conclusions regarding the generalizability of the performance of these assays.

A major finding with robustness was detected with the assays by Hybribio. The datasets generated with these assays were fully proficiency in all cases (77/77 datasets) from different laboratories, which constitutes 45 % of all fully proficient datasets (89%) achieved by the 2024 proficiency study. The widespread use of these assays and the 27 Genotyping assay from Tellgene in laboratories in the WPR region appears to be a major reason why the proficiency was highest in this region.

All plasmids in the panel were detected at the required concentration for proficiency (at least 50 international units (IU) per 5 ul for HPV 16 and HPV 18, and at least 500 genome equivalents (GE / IU) in 5 ul of the other HPV types) in at least 89.5% of the datasets. Plasmids in the panel contained full-length genomes, except HPV 68a that only contained L1. All datasets generated using assays targeting other parts of HPV 68a or that used the PGMY primers were considered as not testing for HPV 68a in this study. It is well reported in literature that all PGMY-based assays (directed against L1) cannot detect HPV68a, and therefore, we also added HPV 68b in the panel. HPV68b can be detected by PGMY-based primers and other common primer systems.

Three additional samples (A, B, C) in the PP were used to evaluate the DNA extraction step prior to HPV testing and typing. Two of the samples contained different amounts of the cervical cancer cell line SiHa mixed with the HPV negative cancer cell line C33A and one sample with only C33A cells served as negative control. There were at least 20 different extraction procedures used among the laboratories. The most commonly used were different extraction kits from Qiagen used to generate 31 data sets. Other utilized methods were STARMag from Seegene, Nuclisens EasyMag from BioMerieux, Hybribio extraction kits and Tellgene extraction kit. We did not observe any obvious difference in performance between different extraction methods.

In sample B containing 2500 cells / 5 ul of the cervical cancer cell line SiHa, HPV 16 was correctly identified by 99 % of the datasets with no reported false positive HPV types. In sample A containing 25 SiHa cells / 5ul, HPV 16 was detected in 95 % of the data sets with no false positive result reported. The negative control containing only C33A cells was correctly reported as negative by 98 % of the laboratories.

Overall, the low false HPV-positivity rate among the DNA-extracted true HPV-negative samples indicate good laboratory performance in the vast majority of the participating laboratories.

Participating laboratories involved public health laboratories, research laboratories and diagnostic test manufacturers. There was a charge for laboratories to participate, although participants from low and lower middle-income countries could have their fees waived. The analysis that was restricted to laboratories that had participated multiple times did find a continued improvement in performance in 2024 (from 10/39 being 100% proficient in 2019 to 74/95 in 2021, 80/97 in 2022, 49/64 in 2023, to 101/128 in 2024 from 26% to 79%), indicating that there has occurred a global improvement in the performance of HPV genotyping.

The PP is designed for the genotyping needs in HPV vaccine research and the proficiency criteria are not intended for clinical HPV screening purposes, where the requirements for analytical sensitivity may be different. Starting in 2022, we did issue a HPV screening panel (with screening-relevant concentrations of the HPV genotypes important for screening) to promote proficiency in HPV screening services as well. Several laboratories that have previously participated in testing the genotyping panel have analyzed the screening panel this year. There were 35 laboratories that analysed both the genotyping and the screening panel in 2024. The results from the screening panel 2024 are presented in a separate technical report.

6. Conclusions and recommendations

This technical report summarizes the results obtained from the 11th HPV LabNet HPV DNA proficiency study that was open for participation to all laboratories across the globe. The proficiency panel provided the possibility to evaluate the specificity and sensitivity for different HPV typing assays to correctly identify 13 oncogenic or probably oncogenic HPV types and 2 benign, vaccine-targeted HPV types. These HPV types are the most important for HPV vaccine research as well as for HPV surveillance and monitoring.

We report that the global proficiency in HPV genotyping services had increased in the 2024 proficiency study. The increased proficiency is seen both in laboratories that had participated in previous studies as well as in laboratories participating for the first time. The WPR was the region with most data sets submitted (111 datasets) from 49 different laboratories with almost 100 % proficient datasets. The 28 participating laboratories from the EURO region submitted 37 datasets.

The 2024 Global HPV LabNet HPV DNA proficiency panel further supports that it is possible to perform global studies comparing the sensitivity and specificity of different HPV typing assays, as well as the performance of participating laboratories, in a consistent manner that allows comparison of results generated by different laboratories worldwide and over time. Comparing the results from 2008, 2010, 2011, 2013, 2014, 2017, 2019, 2021, 2022, 2023 and 2024 Global HPV DNA PPs, we can see overall improvements.

Moreover, the highest overall proficiency (81% of datasets) was achieved in this proficiency study, 2024 – higher than in any previous proficiency study. We suggest that recommendations for HPV laboratory testing should continue to include a strong emphasis on the use of negative controls in the assays.

It is possible to achieve a global improvement in proficiency of HPV genotyping services. The improvement in proficiency seen since the 2021 proficiency studies suggests that continuing proficiency testing is helpful to sustain and improve accuracy and to avoid a deterioration in proficiency, as seen in the previous proficiency study in 2019. In the efforts to eliminate cervical cancer, the International HPV Reference Center will continue to issue PP yearly to promote proficiency in HPV testing services. Starting in 2022, we do also issue HPV screening panels (with screening-relevant concentrations of the HPV genotypes important for screening) to promote proficiency in HPV screening services as well.

Annex 1:

Call for participation:
Global HPV DNA Typing Proficiency Panel 2024 (456)

Accurate and internationally comparable **HPV DNA detection and typing** methodology is an essential component in research on HPV vaccines and in effective implementation and monitoring. A WHO initiative established a Global HPV LabNet to support the worldwide implementation of HPV vaccines through improved laboratory standardization and quality assurance of HPV testing and typing methods to promote international comparability of results. The major methods for achieving progress towards this goal are developing international biological standards as well as preparing and validating proficiency panels to qualify methods.

We are now seeking international participation in an international HPV DNA testing and typing proficiency study. Laboratories that are or will be involved in HPV surveillance and/or vaccine development are particularly welcome.
Participant laboratories will be asked to perform HPV typing using one or more of their usual assays on the 44 challenges in this panel. This challenge is intended to evaluate assays that type HPV and is not appropriate for assays that detect HPV in general or grouped as high risk/low risk.

Composition of sample material

- 41 samples containing purified whole genomic plasmids of **HPV 6, 11, 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 68a** and **68b** in a background of human cellular DNA. Each sample may contain either single types or a mixture of HPV types at varying concentrations.
- 3 samples containing cell suspensions to allow evaluation of DNA extraction methods.

Participation fee

Participation in the proficiency study is subject to a participation fee per panel consisting of 44 samples: 715 Euros for commercial entities and 300 Euros for academic entities. Participants from low and lower middle-income countries (World Bank classification with GNI (gross national income) per capita: <4045USD) can apply for waiving of fee. Laboratories that have outstanding payments from past Global HPV proficiency studies will need to clear their debts before their registration is accepted.

Data submission

The International HPV Reference Laboratory in Sweden is organizing this study in collaboration with the Swedish external quality assurance provider Equalis AB, who is responsible for management and distribution. Laboratories that have more than one assay are encouraged to provide results on each assay they commonly use. Data submitted will become the property of the organizers and may be analyzed for publication by the Global HPV reference laboratories either as an internal document or peer reviewed manuscript. All results will be handled in a coded anonymous fashion, with summaries grouped by method. The code linking data to originating laboratories will be kept confidential. Laboratories that provide data within the required time-frame will receive a copy of their own results and the summary data.

Scientific issues

Dr. Joakim Dillner
HPV International Reference Laboratory, Sweden
Center for Cervical Cancer Prevention

E-mail: joakim.dillner@ki.se or www.hpvcenter.se

Registration

Application forms for the 2024 panel can be found at: equalis.se

Important

- If an import permit is required to send samples to you, please send it to us by e-mail to info@equalis.se

Preliminary dates

17th of April 2024: Registration for participation opens.
20th of June 2024: Registration for participation closes.
September/October 2024: Dispatch of panels begins.
1st of December 2024: Last day for submitting results.
January/February 2025: Individual participant report compared to the expected value.
March/April 2025: Final report compiled.

Participation, management and practical issues

Equalis AB, Sweden www.equalis.se
E-mail: HPV@equalis.se

Annex 2: Global HPV DNA Typing Proficiency Panel 2024 (456)

Requested number of panels:

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I accept the participant terms and conditions, and I have read the privacy information. *
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Annex 3:

Source of panel material.

Complete genomes of HPV cloned into plasmid vectors had been provided to the Lund University by the respective proprietors with a written approval to be used in this proficiency panel: Dr Ethel-Michele de Villiers (HPV types 6, 11, 16, 18 and 45), Dr Gérard Orth (HPV types 33, 39 and 68a prototype), Dr Elisabeth Schwarz (HPV 68b), Dr Saul Silverstein (HPV type 51), Dr Attila Lörincz (HPV types 31, 35 and 56), Dr Wayne Lancaster (HPV type 52) and Dr Toshihiko Matsukura (HPV types 58 and 59).

The HPV genomes are cloned into different cloning vectors: HPV 6 in pBR322 at position 4724 in the HPV genome, HPV 11 in pGEM4Z at position 4781, HPV 16 in pBR322 at position 6152, HPV 18 in pGEM-5Zf vector in the L2 region, HPV 31 in pT713 at position 3362, HPV 33 in pBR322 at position 2797, HPV 35 are cloned in two fragments 5012-956 and 956-5012 in pT713, HPV 39 in pGEM4z at position 1714, HPV 45 in pGEM4Z at position 75, HPV 51 in pGEM4z at position 4511, HPV 52 in pUC19 at position 7559, HPV 56 in pT713 at position 5521, HPV 58 in pGEM4Z at position 1158, HPV 59 in pUC9 at position 69, HPV 68a prototype in a bluescript vector, and HPV68b (ME180) of about 7 kb containing L1, L2, E1, E2, E4, E5, E6, E7 with an incomplete E2 gene in pCR4-TOPO.

The nucleic acid sequences for each of these HPV genomes have been reported previously and are available in Gene Bank with the following accession numbers; HPV 6 nr X00203; HPV 11 nr M14119; HPV 16 nr K02718; HPV 18 nr X05015; HPV 31 nr J04353; HPV 33 nr M12732; HPV 35 nr M74117; HPV 39 nr M62849; HPV 45 nr X74479; HPV 51 nr M62877; HPV 52 nr X74481; HPV 56 nr X74483; HPV 58 nr D90400; HPV 59 nr X77858; HPV 68a nr X67161 and HPV 68b nr FR751039.

Annex 4:

List of participants in the HPV LabNet Proficiency Study of HPV DNA Typing, 2024

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