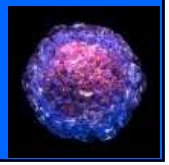
Human Papillomavirus EQA Programme 2014
(QCMD HPVDNA14)

Ed Schuuring

Pathology, UMCG, Groningen, NL
Scientific expert and advisor for QCMD HPV Program

Presentatie SKML-deelnemersvergadering
16 juni 2015



Potential conflicts of interest (2011-2015):

member of NVVP-CMDP-HPV-taakgroep

Scientific expert and advisor for QCMD HPV Program (2009-today)

Head of HPV-testing lab UMCG/Winschoten/Friesland (cobas HPV test)

Receipt of grants/research support: Hologic, QCMD, CTMM, MDXHealth/OncoMethylome

Receipt of honoraria or consultation fees: Hologic, Roche

Speaker's fee: Hologic, Roche

Travel reimbursements: Hologic, QCMD, Abbott

The early detection of cervical cancer in scraping population-based screening programs **worldwide**

1) cytomorphology only

The classical approach

2) primary cytomorphology and HPV reflex testing

Presently used commonly (eg Dutch guidelines)

3) cytomorphology /HPV co-testing

Guideline in USA (Saslow 2012)

4) primary HPV testing and reflex cytomorphology

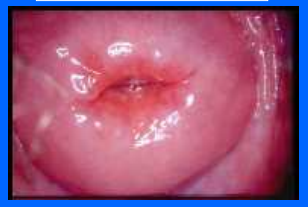
New guideline in NL starting in July 2016; interim guideline in USA 2015

5) primary HPV testing and reflex CINTEC, methylation, hrHPV-typing and others

Presentlv validated

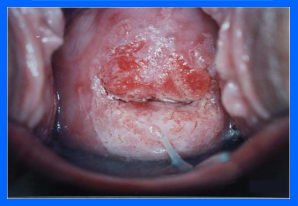
HPV in scrapings of (pre)malignant cervical lesions

~4% high-risk HPV-positive



Normal cervix

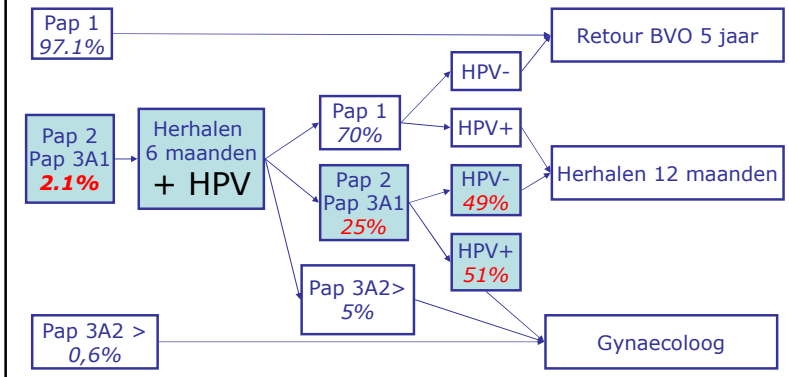
~85% high-risk HPV-positive



CIN III

100% high-risk HPV-positive

Praktijkrichtlijn BVO cervixcytologie: indicatie HPV-onderzoek bij Pap2/3A1



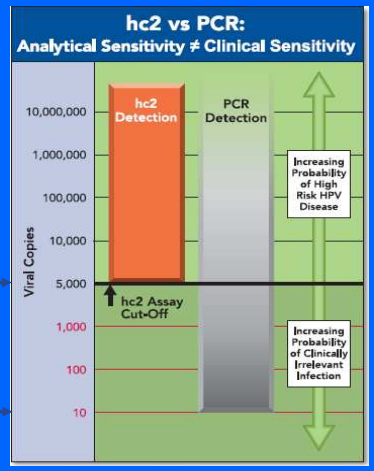
Bulkmans, the Lancet, 2007
Bais, Int J Cancer, 2005
Rebolj, Int J Cancer, 2007

J Eijsink

Analytical and clinical sensitivity of HPV-detection assays

Clinical sensitivity of HC2 is 5000 HPV copies

Analytical sensitivity of PCR-based methods detecting <10 HPV copies



Adapted from Snijders et al. Journal of Pathology 2003; 201:1-6

Clinical validated HPV-tests (in the Netherlands)

Digene HC2 HPV test (Qiagen)

GP5+/GP6+ PCR EIA (Vumc/Qiagen)

Cobas 4800 HPV test (Roche)

Cervista hrHPV test (Hologic)

GenProbe-Aptima hrHPV assay (Hologic)

Abbott realtime HR HPV assay (Abbott)

Kwantitatieve multiplex RT HPV test (PON)

FDA-approved clinical HPV tests

Digene HC2 HPV test (Qiagen)
Cervista HPV HR test (Hologic) > internal control
Cervista HPV 16/18 test (Hologic) > internal control
GenProbe-Aptima hrHPV assay (Hologic) > based on RNA
Cobas 4800 HPV test (Roche) > HPV16/18 separate and internal control

Commercial HPV tests

- Hybrid Capture 2 Qiagen
- Digene HPV genotyping RH kit Qiagen
- Digene HPV genotyping LX kit, Qiagen
- Roche Amplicor HPV Test
- Roche Linear array HPV Genotyping test
- Innogenetics INNO-LiPA HPV Genotyping test
- NucliSens EasyQ HPV Biomerieux
- Aptima Gen-Probe
- Human Papilloma Virus reagents Third Wave
- BIOPAP QTS HPV Kit Loxo
- Reveal HPV Real-Time HPV Detection Kit GenoID
- AID STD assay GenID
- AID HPV screening kit GenID
- AID HPV typing kit GenID
- Linear ArrayExtra HPV Genotyping Kit Innogenetics
- PCR Human Papillomavirus Detection Set Takara Mirus Bio
- HPV DNA Chip Biomedlab
- Array Papillomavirus Genomica
- ProDect Chip HPV typing Bcs Biotech S.P.A
- PapType Genera Biosystems
- LCD Array HPV 3.5 Chipron
- Seeplex HPV Genotyping Seegene
- Viroactiv Virofem
- HPV OncoTest Invirion Diagnostics
- Genpoint Tm HPV test Dako-Oxoid
- Abbott RealTime High Risk HPV Abbott
- Luminex HPV Genotyping, Multimetrix/Progen
- Greiner PapilloCheck HPV Screening
- PreTect HPV Proofer Norchip
- .....

Andere toepassingen voor HPV testen:

- Follow-up patienten behandeld voor CIN3
- Profylactische vaccinatie
- Therapeutische vaccinitie
- Diagnose RRP (recurrent respiratory papillomatosis)
- Klonale verwantschap
- … …

available HPV EQA platforms

1) QCMD HPVDNA:
- using established cell lines in LBC (~4 HPV types)

2) WHO HPV panel:
- Plasmid DNA spiked into cell line DNA (>30-45 types)

3) NEQAS UK:
- Patient samples (~4 samples) Fagan, JClinVirol2010

Human Papillomavirus

2014 EQA Programme Report

QAV094130 (HPVDNA14)

Prof. Ed Schuuring
Scientific Expert on behalf of QCMD
Report authorised by the QCMD Executive in November 2014

A UKAS accredited proficiency testing provider (no. 4385)

6th QCMD HPVDNA EQA

ISO17043:2010 accreditated

QCMD
Quality Control for Molecular Diagnostics

QCMD 2014 Human Papillomavirus DNA EQA Programme (HPVDNA14)
aims

Primary goals:

- To assess the proficiency of laboratories in the detection of different high risk Human Papillomavirus (HPV) types
- To provide laboratories with an analytical performance based on the consensus qualitative results of all participants
- To provide feedback on the number and percentage of datasets reporting typing result

Secondary goal:

- To provide laboratories with information on clinical reporting based on the consensus qualitative results of all participants

QCMD 2014 Human Papillomavirus DNA EQA Programme (HPVDNA14)
composition EQA panel

- Door simulatie van klinische samples mbv "established" BMKH-cellijnen in dunne-laag-cytologie
- Core samples: voor proficiency testing (rapportage performance)
- Educational samples: lastige, uitdagende monster ter lering

Human Papillomavirus 2014 EQA Programme
QCMD – QAV094130 – HPVDNA14

Internationale rondzending:

UMCG: Ed Schuuring (Scientific Advisory Board)
UMCG: Lorian Slagter-Menkema (preparation/validation)
UMCG: MD-cytology lab (cobas-HPV testing)
Reference-labs: UMCG and 3 others (?)

QCMD: Paul Wallace, Catherina di Lorenze
QCMD = Quality Control for Molecular Diagnostics (Scotland)

UMCG = CCKL(ISO15189) accreditated

QCMD 2014 Human Papillomavirus DNA EQA Programme (HPVDNA14)
composition EQA panel

Sample code	Sample matrix	Sample content	Sample status	Sample type	For information only*	
					Ct Value	RLU
HPV14-02	PreservCyt	HPV16 (Caski)	Positive	Core	30.9	6.55
HPV14-06	PreservCyt	HPV18 (Hela)	Positive	Core	28.9	5.29
HPV14-01	PreservCyt	HPV45 (CC10b)	Positive	Core	28.4	6.39
HPV14-09	PreservCyt	HPV16/18 (Caski/Hela)	Positive	Core	32/30.2	6.15
HPV14-10	PreservCyt	Low Viral Load HPV16 (SiHa)	Positive	Educational	-	0.48
HPV14-08	PreservCyt	HPV51&52 (clinical sample)	Positive	Educational	36.3	11.75
HPV14-04	PreservCyt	HPV52&56 (clinical sample)	Positive	Educational	33.4	7.38
HPV14-07	PreservCyt	HPV54&56 (clinical sample)	Positive	Educational	37.4	22.88
HPV14-03	PreservCyt	HPV Negative (BSM)	Negative	Core	-	0.44
HPV14-05	PreservCyt	HPV Negative (BSM)	Negative	Core	-	0.67

QCMD 2014 Human Papillomavirus DNA EQA Programme (HPVDNA14)
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- 10 samples in PreservCyt
- 4 core samples containing HPV16, 18, 45 or mix 16/18 in BSM using established cell lines
- 2 core samples with BSM only as HPV-negative controls
- viral load determined by both cobas and HC2 DNA testing

- 1 education sample with low viral HPV16 load ("clinical HPV-negative")
- 3 education samples with other HPV genotypes (determined by LIPA) (provided by PON)

- all samples pre-tested and confirmed in reference-labs by HC2 (2x) and cobas (2x)

QCMD 2014 Human Papillomavirus DNA EQA Programme (HPVDNA14)
aims

Primary goals using core samples:

•To assess the proficiency of laboratories in the detection of different high risk Human Papillomavirus (HPV) types

•To provide laboratories with an analytical performance based on the consensus **qualitative results** of all participants

•To provide feedback on the number and percentage of datasets reporting **typing result**

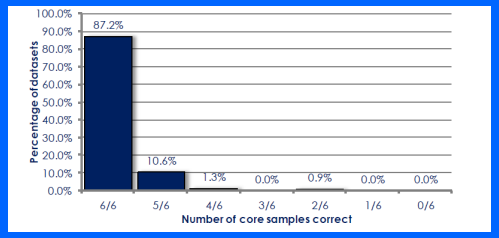
Secondary goal using educational samples:
•To provide laboratories with information on **clinical reporting** based on the consensus qualitative results of all participants

QCMD 2009/10/11/12/13/14 Human Papillomavirus DNA EQA Programme
participation

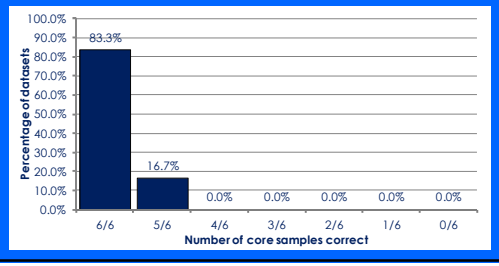
	HPVDNA09	HPVDNA10	HPVDNA11	HPVDNA12	HPVDNA13	HPVDNA14
Participants	108	155	167	171	194	228
Responders	98	136	149	153	176	203
Countries	26	26	27	31	34	37
Deelnemers in NL	14	21	27	26	31	30
Datasets:						
- Analytical	113	44	88	91	194	226
- Clinical	113	77	133	144	137	157
- Genotyping	66	84	114	115	136	151

Qualitive performance of all versus Dutch participants
QCMD-HPVDNA2014 (core samples only)

Performance of all participants



Performance of Dutch participants



Qualitive performance of all versus Dutch participants
QCMD-HPVDNA2014

Performance of all participants

Sample code	Sample content	Ct Value	RLU	Total datasets n=226 n	%
HPV14-02	HPV16 (Caski)	30.9	6.55	222	98.2
HPV14-06	HPV18 (Hela)	28.85	5.29	222	98.2
HPV14-01	HPV45 (CC10b)	28.4	6.39	209	92.5
HPV14-09	HPV16/18 (Caski/Hela)	32/30.2	6.15	221	97.8
HPV14-03	HPV Negative (BSM)	-	0.44	222	98.2
HPV14-05	HPV Negative (BSM)	-	0.67	222	98.2

Performance of Dutch participants

Sample code	Sample content	Ct Value	RLU	Total datasets n=36 n	%
HPV14-02	HPV16 (Caski)	30.9	6.55	34	94.4
HPV14-06	HPV18 (Hela)	28.85	5.29	36	100.0
HPV14-01	HPV45 (CC10b)	28.4	6.39	35	97.2
HPV14-09	HPV16/18 (Caski/Hela)	32/30.2	6.15	33	91.7
HPV14-03	HPV Negative (BSM)	-	0.44	36	100.0
HPV14-05	HPV Negative (BSM)	-	0.67	36	100.0

Qualitive performance of all versus Dutch participants
QCMD-HPVDNA2014

Performance of all participants

Sample code	Sample content	Ct Value	RLU	Total datasets n=224		PCR								Hybrid[a] capture		DNA[f] array		LiPA[g]		Other[h]	
						Conventional				Real time											
						Commercial[e] n=56		In-house[b] n=22		Commercial[c] n=57		In-house[d] n=9		n=25		n=14		n=29		n=14	
				n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
HPV14-02	HPV16 (Caski)	30.9	6.55	222	98.2	56	100.0	22	100.0	56	98.2	9	100.0	23	92	14	100.0	29	100.0	13	92.9
HPV14-06	HPV18 (Hela)	28.85	5.29	222	98.2	56	100.0	21	95.5	56	98.2	9	100.0	24	96	13	92.9	29	100.0	14	100.0
HPV14-01	HPV45 (CC10b)	28.4	6.39	209	92.5	54	96.4	21	95.5	55	96.5	7	77.8	24	96	5	35.7	29	100.0	14	100.0
HPV14-09	HPV16/18 (Caski/Hela)	32/30.2	6.15	221	97.8	54	96.4	22	100.0	55	96.5	9	100.0	24	96	14	100.0	29	100.0	14	100.0
HPV14-03	HPV Negative (BSM)	-	0.44	222	98.2	54	96.4	22	100.0	57	100.0	9	100.0	25	100	14	100.0	27	93.1	14	100.0
HPV14-05	HPV Negative (BSM)	-	0.67	222	98.2	55	98.2	21	95.5	57	100.0	9	100.0	24	96	14	100.0	28	96.6	14	100.0

Performance of Dutch participants

Sample code	Sample content	Ct Value	RLU	Total datasets n=36		PCR								Hybrid[a] capture		DNA[f] array		LiPA[g]		Other[h]	
						Conventional				Real time											
						Commercial[e] n=13		In-house[b] n=1		Commercial[c] n=3		In-house[d] n=1		n=8		n=1		n=4		n=5	
				n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
HPV14-02	HPV16 (Caski)	30.9	6.55	34	94.4	13	100.0	1	100.0	3	100.0	1	100.0	7	87.5	1	100.0	4	100.0	4	80.0
HPV14-06	HPV18 (Hela)	28.85	5.29	36	100.0	13	100.0	1	100.0	3	100.0	1	100.0	8	100	1	100.0	4	100.0	5	100.0
HPV14-01	HPV45 (CC10b)	28.4	6.39	35	97.2	13	100.0	1	100.0	3	100.0	1	100.0	8	100	0	0.0	4	100.0	5	100.0
HPV14-09	HPV16/18 (Caski/Hela)	32/30.2	6.15	33	91.7	11	84.6	1	100.0	2	66.7	1	100.0	8	100	1	100.0	4	100.0	5	100.0
HPV14-03	HPV Negative (BSM)	-	0.44	36	100.0	13	100.0	1	100.0	3	100.0	1	100.0	8	100	1	100.0	4	100.0	5	100.0
HPV14-05	HPV Negative (BSM)	-	0.67	36	100.0	13	100.0	1	100.0	3	100.0	1	100.0	8	100	1	100.0	4	100.0	5	100.0

Qualitive performance of all versus Dutch participants
QCMD-HPVDNA2014

Performance of all participants

Performance of Dutch participants

Qualitive performance of Dutch participants
QCMD-HPVDNA2014

Performance of Dutch participants

Sample code	Sample content	Ct Value	RLU	Total datasets n=36		PCR								Hybrid[a] capture		DNA[f] array		LiPA[g]		Other[h]	
						Conventional				Real time											
						Commercial[e] n=13		In-house[b] n=1		Commercial[c] n=3		In-house[d] n=1		n=8		n=1		n=4		n=5	
				n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
HPV14-02	HPV16 (Caski)	30.9	6.55	34	94.4	13	100.0	1	100.0	3	100.0	1	100.0	7	87.5	1	100.0	4	100.0	4	80.0
HPV14-06	HPV18 (Hela)	28.85	5.29	36	100.0	13	100.0	1	100.0	3	100.0	1	100.0	8	100	1	100.0	4	100.0	5	100.0
HPV14-01	HPV45 (CC10b)	28.4	6.39	35	97.2	13	100.0	1	100.0	3	100.0	1	100.0	8	100	0	0.0	4	100.0	5	100.0
HPV14-09	HPV16/18 (Caski/Hela)	32/30.2	6.15	33	91.7	11	84.6	1	100.0	2	66.7	1	100.0	8	100	1	100.0	4	100.0	5	100.0
HPV14-03	HPV Negative (BSM)	-	0.44	36	100.0	13	100.0	1	100.0	3	100.0	1	100.0	8	100	1	100.0	4	100.0	5	100.0
HPV14-05	HPV Negative (BSM)	-	0.67	36	100.0	13	100.0	1	100.0	3	100.0	1	100.0	8	100	1	100.0	4	100.0	5	100.0

a: DDL diagnostic laboratory DNA ELISA kit HPV SPF10 version 1, RHA kit HPV SPF10-LIPA25, version 1 (n=1), DIASSAY EIA KIT HPV GP HR (n=4), Diassay LMNX Genotyping Kit HPV GP (n=1), Roche cobas 4800 HPV Test (n=7).
b: Details not presented.
c: Abbott RealTime High Risk HPV (n=2), Self-screen HPV-Risk Assay (n=1).
d: Details not presented.
e: QIAGEN Digene High Risk HPV HC2 DNA test (n=7), QIAGEN Digene HPV HC2 DNA test (n=1).
f: Greiner bio-one PapilloCheck (n=1).
g: Innogenetics INNO-LIPA HPV Genotyping Extra (n=3), LBP RHA Kit HPV SPF10-LIPA25 (n=1).
h: Hologic Cervista HPV HR (n=5).

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aims

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- To provide feedback on the number and percentage of datasets reporting **typing result**

Secondary goal using educational samples:
- To provide laboratories with information on **clinical reporting** based on the consensus qualitative results of all participants

QCMD 2014 Human Papillomavirus DNA EQA Programme (HPVDNA14)

composition EQA panel – educational cases

Sample code	Sample matrix	Sample content	Sample status	Sample type	For information only*	
					Ct Value	RLU
HPV14-02	PreservCyt	HPV16 (Caski)	Positive	Core	30.9	6.55
HPV14-06	PreservCyt	HPV18 (Hela)	Positive	Core	28.9	5.29
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HPV14-08	PreservCyt	HPV51&52 (clinical sample)	Positive	Educational	36.3	11.75
HPV14-04	PreservCyt	HPV52&56 (clinical sample)	Positive	Educational	33.4	7.38
HPV14-07	PreservCyt	HPV54&56 (clinical sample)	Positive	Educational	37.4	22.88
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HPV14-05	PreservCyt	HPV Negative (BSM)	Negative	Core	-	0.67

*

Performance of all participants

Sample code	Sample content	Ct Value	RLU	Total datasets n=226		PCR: Conventional: Commercial [a] n=86		PCR: Conventional: In-house [b] n=22		PCR: Real time: Commercial [c] n=57		PCR: Real time: In-house [d] n=9		Hybrid® capture n=25		DNA[f] array n=14		LiPA[g] n=29		Other[h] n=14	
				n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
HPV14-02	HPV16 (Caski)	30.9	6.55	222	98.2	56	100.0	22	100.0	56	98.2	9	100.0	23	92	14	100.0	29	100.0	13	92.9
HPV14-06	HPV18 (Hela)	28.85	5.29	222	98.2	56	100.0	21	95.5	56	98.2	9	100.0	24	96	13	92.9	29	100.0	14	100.0
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HPV14-10	Low Viral Load HPV16 (SiHa)	-	0.48	23	10.2	7	12.5	4	18.2	8	14.0	1	11.1	0	0	2	14.3	15	51.7	7	50.0
HPV14-08	HPV51&52 (clinical sample)	36.25	11.75	196	86.7	53	94.6	17	77.3	55	96.5	6	66.7	22	88	12	85.7	27	93.1	4	28.6
HPV14-04	HPV52&56 (clinical sample)	33.4	7.38	205	90.7	56	100.0	19	86.4	55	96.5	9	100.0	25	100	10	71.4	27	93.1	4	28.6
HPV14-07	HPV54&56 (clinical sample)	37.35	22.88	198	87.6	53	94.6	19	86.4	52	91.2	8	88.9	24	96	10	71.4	28	96.6	4	28.6
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QCMD 2014 Human Papillomavirus DNA EQA Programme (HPVDNA14)

composition EQA panel (clinical reporting)

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HPV14-06	PreservCyt	HPV18 (Hela)	Positive	Core	28.9	5.29
HPV14-01	PreservCyt	HPV45 (CC10b)	Positive	Core	28.4	6.39
HPV14-09	PreservCyt	HPV16/18 (Caski/Hela)	Positive	Core	32/30.2	6.15
HPV14-10	PreservCyt	Low Viral Load HPV16 (SiHa)	Positive	Educational	-	0.48
HPV14-08	PreservCyt	HPV51&52 (clinical sample)	Positive	Educational	36.3	11.75
HPV14-04	PreservCyt	HPV52&56 (clinical sample)	Positive	Educational	33.4	7.38
HPV14-07	PreservCyt	HPV54&56 (clinical sample)	Positive	Educational	37.4	22.88
HPV14-03	PreservCyt	HPV Negative (BSM)	Negative	Core	-	0.44
HPV14-05	PreservCyt	HPV Negative (BSM)	Negative	Core	-	0.67

*

In 2014 clinical performance is NOT reported individually:

- QCMD-report provides clinical reporting data separately
- Samples HPV14-10 is considered **clinically HPV-negative**
- For own interpretation only (educational case)
- Sample does NOT represent determination of real clinical outcome
- "Impossible" to prepare a clinical relevant sample (HPV-low-copy)

Clinical reporting of all versus Dutch participants

QCMD-HPVDNA2014

Performance of all participants

Sample code	Sample content	HC2 status	Ct Value	RLU	Total datasets n=157		PCR: Conventional: Commercial [a] n=50		PCR: Conventional: In-house [b] n=7		PCR: Real time: Commercial [c] n=40		PCR: Real time: In-house [d] n=4		Hybrid® capture n=24		DNA[f] array n=8		LiPA[g] n=13		Other[h] n=11	
					% positive	% negative	% positive	% negative	% positive	% negative	% positive	% negative	% positive	% negative	% positive	% negative	% positive	% negative	% positive	% negative	% positive	% negative
HPV14-02	HPV16 (Caski)	Positive	30.9	6.55	97.5	1.9	98.0	2.0	100.0	0.0	100.0	0.0	100.0	0.0	91.7	4.2	100.0	0.0	100.0	0.0	90.9	9.1
HPV14-06	HPV18 (Hela)	Positive	28.85	5.29	97.5	1.9	98.0	2.0	85.7	14.3	100.0	0.0	100.0	0.0	95.8	0.0	87.5	12.5	100.0	0.0	100.0	0.0
HPV14-01	HPV45 (CC10b)	Positive	28.4	6.39	94.9	3.8	100.0	0.0	85.7	14.3	97.5	2.5	100.0	0.0	95.8	0.0	37.5	50.0	100.0	0.0	100.0	0.0
HPV14-09	HPV16/18 (Caski/Hela)	Positive	32/30.2	6.15	98.1	1.9	96.0	4.0	100.0	0.0	100.0	0.0	100.0	0.0	95.8	0.0	100.0	0.0	100.0	0.0	100.0	0.0
HPV14-10	Low Viral Load HPV16 (SiHa)	Negative	-	0.48	16.6	81.5	12.0	84.0	0.0	85.7	10.0	90.0	0.0	100.0	0.0	100.0	12.5	87.5	76.9	23.1	45.5	54.5
HPV14-08	HPV51&52 (clinical sample)	Positive	36.25	11.75	94.6	3.8	94.0	6.0	42.9	42.9	97.5	2.5	75.0	25.0	87.5	12.5	75.0	25.0	100.0	0.0	27.3	72.7
HPV14-04	HPV52&56 (clinical sample)	Positive	33.4	7.38	89.8	9.6	100.0	0.0	42.9	42.9	97.5	2.5	100.0	0.0	100.0	0.0	62.5	37.5	92.3	7.7	36.4	63.6
HPV14-07	HPV54&56 (clinical sample)	Positive	37.35	22.88	85.4	14.0	94.0	6.0	57.1	42.9	92.5	7.5	75.0	25.0	95.8	4.2	62.5	25.0	92.3	7.7	27.3	72.7
HPV14-03	HPV Negative (BSM)	Negative	-	0.44	0.0	96.8	0.0	98.0	0.0	85.7	0.0	100.0	0.0	100.0	0.0	100.0	0.0	87.5	0.0	84.6	0.0	100.0
HPV14-05	HPV Negative (BSM)	Negative	-	0.67	0.0	96.8	0.0	98.0	0.0	85.7	0.0	100.0	0.0	100.0	0.0	95.8	0.0	100.0	0.0	84.6	0.0	100.0

Performance of Dutch participants

Sample code	Sample content	HC2 status	Ct Value	RLU	Total datasets n=28		PCR: Conventional: Commercial [a] n=11		PCR: Conventional: In-house [b] n=1		PCR: Real time: Commercial [c] n=2		PCR: Real time: In-house [d] n=1		Hybrid® capture n=7		DNA[f] array n=1		LiPA[g] n=1		Other[h] n=4	
					% positive	% negative	% positive	% negative	% positive	% negative	% positive	% negative	% positive	% negative	% positive	% negative	% positive	% negative	% positive	% negative	% positive	% negative
HPV14-02	HPV16 (Caski)	Positive	30.9	6.55	92.9	7.1	100.0	-	100.0	-	100.0	-	100.0	-	85.7	14.3	100.0	-	100.0	-	75.0	25.0
HPV14-06	HPV18 (Hela)	Positive	28.85	5.29	100.0	-	100.0	-	100.0	-	100.0	-	100.0	-	100.0	-	100.0	-	100.0	-	100.0	-
HPV14-01	HPV45 (CC10b)	Positive	28.4	6.39	96.4	3.6	100.0	-	100.0	-	100.0	-	100.0	-	100.0	-	-	100.0	100.0	-	100.0	-
HPV14-09	HPV16/18 (Caski/Hela)	Positive	32/30.2	6.15	96.4	3.6	90.9	9.1	100.0	-	100.0	-	100.0	-	100.0	-	100.0	-	100.0	-	100.0	-
HPV14-10	Low Viral Load HPV16 (SiHa)	Negative	-	0.48	14.3	85.7	27.3	72.7	-	100.0	-	100.0	-	100.0	-	100.0	-	100.0	100.0	-	-	100.0
HPV14-08	HPV51&52 (clinical sample)	Positive	36.25	11.75	78.6	21.4	72.7	27.3	-	100.0	100.0	-	-	100.0	100.0	-	100.0	-	100.0	-	75.0	25.0
HPV14-04	HPV52&56 (clinical sample)	Positive	33.4	7.38	96.4	3.6	100.0	-	-	100.0	100.0	-	100.0	-	100.0	-	100.0	-	100.0	-	100.0	-
HPV14-07	HPV54&56 (clinical sample)	Positive	37.35	22.88	78.6	21.4	72.7	27.3	100.0	-	100.0	-	-	100.0	85.7	14.3	100.0	-	100.0	-	75.0	25.0
HPV14-03	HPV Negative (BSM)	Negative	-	0.44	-	96.4	-	100.0	-	100.0	-	100.0	-	100.0	-	100.0	-	100.0	-	-	-	100.0
HPV14-05	HPV Negative (BSM)	Negative	-	0.67	-	96.4	-	100.0	-	100.0	-	100.0	-	100.0	-	100.0	-	100.0	-	-	-	100.0

Rapportage van lab dat clinical testing uitvoert

performance-score gebaseerd op core samples

Sample	Sample Content	Qualitative: Sample Status	Qualitative: Sample Type	Qualitative: Your qualitative result	Qualitative: Your qualitative score
HPV14-02	HPV16 (Caski)	Positive	Core	positive	0
HPV14-06	HPV18 (Hela)	Positive	Core	positive	0
HPV14-01	HPV45 (CC10b)	Positive	Core	positive	0
HPV14-09	HPV16/18 (Caski/Hela)	Positive	Core	positive	0
HPV14-10	Low Viral Load HPV16 (SiHa)	Positive	Educational	negative	1
HPV14-08	HPV51&52 (clinical sample)	Positive	Educational	positive	0
HPV14-04	HPV52&56 (clinical sample)	Positive	Educational	positive	0
HPV14-07	HPV54&56 (clinical sample)	Positive	Educational	positive	0
HPV14-03	HPV Negative (BSM)	Negative	Core	negative	0
HPV14-05	HPV Negative (BSM)	Negative	Core	negative	0
Sum Qualitative Panel Score					1

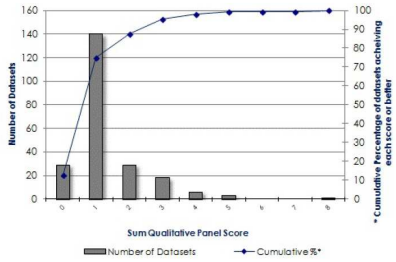
The core proficiency samples in this EQA programme were:
HPV14-01, HPV14-02, HPV14-03, HPV14-05, HPV14-06, HPV14-09
You reported 6/6 (100.0 %) of the core samples correctly.
Of the total datasets reported by all participants in this EQA programme, 87.2% reported correct results for all core proficiency samples.

Rapportage van lab dat clinical testing uitvoert
performance-score

Notes on Qualitative Panel Scoring for this EQA programme

Scores were awarded for all panel members based on qualitative sample status.
Scores provided on panel members HPV14-04, -07, -08 and -10 are for educational purposes only.

Sum Qualitative Panel Scores for all participants



The number of Qualitative datasets analysed	226
The sum of the Qualitative Panel Score for your dataset is	1
This score (or better) was achieved by	74.8 % of all datasets

QCMD 2014 Human Papillomavirus DNA EQA Programme (HPVDNA14)
composition EQA panel (clinical reporting)

Sample code	Sample matrix	Sample content	Sample status	Sample type	For information only*	
					Ct Value	RLU
HPV14-02	PreservCyt	HPV16 (Caski)	Positive	Core	30.9	6.55
HPV14-06	PreservCyt	HPV18 (Hela)	Positive	Core	28.9	5.29
HPV14-01	PreservCyt	HPV45 (CC10b)	Positive	Core	28.4	6.39
HPV14-09	PreservCyt	HPV16/18 (Caski/Hela)	Positive	Core	32/30.2	6.15
HPV14-10	PreservCyt	Low Viral Load HPV16 (SiHa)	Positive	Educational	-	0.48
HPV14-08	PreservCyt	HPV51&52 (clinical sample)	Positive	Educational	36.3	11.75
HPV14-04	PreservCyt	HPV52&56 (clinical sample)	Positive	Educational	33.4	7.38
HPV14-07	PreservCyt	HPV54&56 (clinical sample)	Positive	Educational	37.4	22.88
HPV14-03	PreservCyt	HPV Negative (BSM)	Negative	Core	-	0.44
HPV14-05	PreservCyt	HPV Negative (BSM)	Negative	Core	-	0.67

*

Sample code	Sample content	HC2 status	Ct Value	RLU	Total datasets n=157	
					% positive	% negative
HPV14-02	HPV16 (Caski)	Positive	30.9	6.55	97.5	1.9
HPV14-06	HPV18 (Hela)	Positive	28.85	5.29	97.5	1.9
HPV14-01	HPV45 (CC10b)	Positive	28.4	6.39	94.9	3.8
HPV14-09	HPV16/18 (Caski/Hela)	Positive	32/30.2	6.15	98.1	1.3
HPV14-10	Low Viral Load HPV16 (SiHa)	Negative	-	0.48	16.6	81.5
HPV14-08	HPV51&52 (clinical sample)	Positive	36.25	11.75	84.9	13.4
HPV14-04	HPV52&56 (clinical sample)	Positive	33.4	7.38	89.8	9.6
HPV14-07	HPV54&56 (clinical sample)	Positive	37.35	22.88	85.4	14.0
HPV14-03	HPV Negative (BSM)	Negative	-	0.44	0.0	96.8
HPV14-05	HPV Negative (BSM)	Negative	-	0.67	0.0	96.8

QCMD 2014 EQA Programme report Nov 2014 QAV094130

Pre-test threshold van klinisch-relevante HPV assays

Clinical HPV-tests:

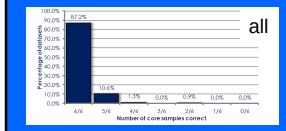
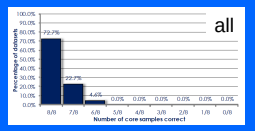
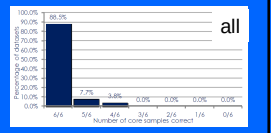
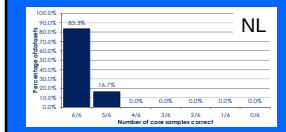
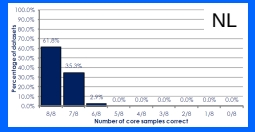
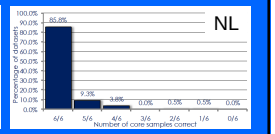
HC2: 1 pg/ml = ~5000 kopieën

Abbott: = ~5000 kopieën

Cobas = ~300 kopieën (afhankelijk van HPV-type)

Dus eigenlijk kunnen we geen panel definiëren met een klinische threshold omdat HC2 niet meer de standaard is

Qualitive performance of all versus Dutch participants
QCMD-HPVDNA2014 (core samples only)

2014	2013	2012
 all	 all	 all
 NL	 NL	 NL

QCMD HPV testen vanaf 2015 (planning)

Vanaf 2013 alleen toetsing performance van analytische interpretatie

Educatief samples alleen als aparte reportage (eigen interpretatie op basis van performance van andere met vergelijkbare testen)

Vanaf 2015 tabel bij individual reporting cores en educational samples apart

Kleinere panels en meer rondzendingen/jaar (>2016)

Andere matrices (nu een pilot SurePath)

Ontwikkelen van referentie/calibratie-sets (pilot 2015)

Dank voor uw aandacht

Vragen ?

e.schuuring@umcg.nl

UMCG