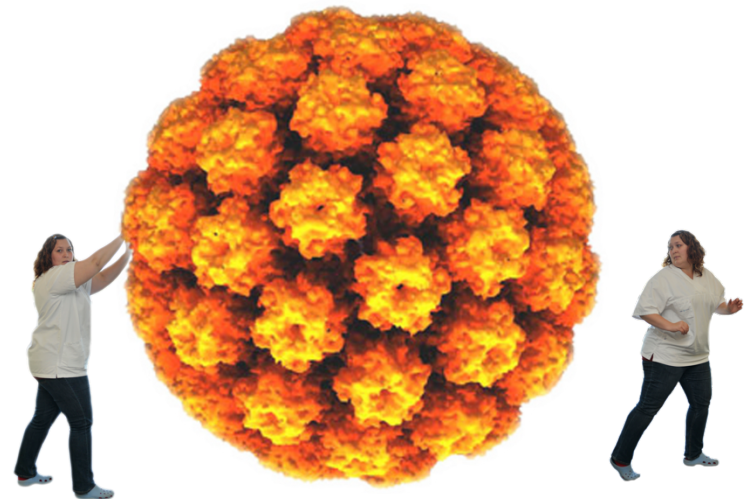


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Agenda

- HPV-testing
- Tilgjengelige HPV-tester
- Tanker for fremtiden



Tilgjengelige HPV-tester



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Review

Nucleic Acid Tests for the Detection of Alpha Human Papillomavirus

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ARTICLE INFO

Testing for high-risk types of alpha human papillomaviruses (HPV) is an invaluable part of clinical guidelines for cervical carcinoma screening, management and treatment. In this comprehensive inventory of commercial tests for detection of alpha-HPV, we identified at least 125 distinct HPV tests and at least 84 variants of the original tests. However, only a small subset of HPV tests has documented clinical performance for any of the standard HPV testing indications. For more than 75% of HPV tests currently on the market, no single publication in peer-reviewed literature can be identified. HPV tests that have not been validated and lack proof of reliability, reproducibility and accuracy should not be used in clinical management. Once incorporated in the lab, it is essential that the whole procedure of HPV testing is subject to continuous and rigorous quality assurance to avoid sub-optimal, potentially harmful practices. Manufacturers of HPV tests are urged to put more effort into evaluating their current and future products analytically, using international standards, and for clinical applications, using clinically validated endpoints. To assist with analytical validation, the World Health Organization is developing international standards for HPV types other than HPV16 and HPV18 and is planning development of external quality control panels specifically designed to be used for performance evaluation of current and future HPV tests. There is a need for more competitively priced HPV tests, especially for resource-poor countries, and uniform test validation criteria based on international standards should enable issuing more competitive and fair tender notices for purchasing. Automation systems allowing large-scale testing, as well as further increases in clinical performance, are the main needs in the further improvement of HPV tests. This article forms part of a special supplement entitled "Comprehensive Control of HPV Infections and Related Diseases" Vaccine Volume 30, Supplement 5, 2012.

Screening
Cervical cancer

Table 1

Short list of the most widely used commercial HPV tests (status April 2012); for an extended list of HPV tests see Table S1.

hrHPV DNA tests	Current status
→ Hybrid Capture® 2 (HC2) HPV DNA Test (QIAGEN Inc., Gaithersburg, MD; USA (previously Digene Corp.)) EIA kit HPV GP HR (Diassay, Rijswijk, The Netherlands) Cervista® HPV HR Test (Hologic, Madison, WI) CareHPV™ Test (QIAGEN Inc., Gaithersburg, MD; USA)	US FDA-approved (2003) ^a clinically validated ^a US FDA-approved (2009) clinically validated
hrHPV DNA tests with concurrent or reflex partial genotyping for the main hrHPV types	
<i>Tests with concurrent partial genotyping for the main hrHPV types</i>	
→ cobas® 4800 HPV Test (Roche Molecular Systems Inc., Alameda, CA, USA)	US FDA-approved (2011) ^a
→ RealTime High Risk HPV test (Abbott Molecular, Des Plaines, IL)	clinically validated ^a
<i>Tests with reflex partial genotyping for the main hrHPV types</i>	
Cervista HPV 16/18 Test (Hologic, Madison, WI)	US FDA-approved (2009)
digene® HPV Genotyping PS Test, RUO (Qiagen, Hilden, Germany)	
HPV DNA full genotyping tests	
<i>Strip, filter or microtiter-well hybridization based full genotyping tests</i>	
→ Linear Array® HPV Genotyping Test (Roche Molecular Systems Inc., Alameda, CA, USA)	widely used test
→ INNO-LiPA HPV Genotyping Extra (Innogenetics NV, Gent, Belgium)	widely used test
HPV SPF10 LiPA25 _{version 1} (Labo Bio-Medical Products, Ev Rijswijk, The Netherlands)	widely used test
digene HPV Genotyping RH Test (Qiagen, Hilden, Germany)	widely used test
<i>Medium or low density microarray-based full genotyping tests</i>	
→ PapilloCheck® HPV-Screening Test/High-risk Test (Greiner Bio-One, Frickenhausen, Germany)	clinically validated ^b
→ Clart® HPV 2 - Papillomavirus Clinical Arrays (Genomica, Coslada, Spain)	widely used test
<i>Microsphere beads based full genotyping tests</i>	
<i>Gel electrophoresis based full genotyping tests</i>	
<i>Capillary electrophoresis based full genotyping tests</i>	
<i>Real time PCR based full genotyping tests</i>	
<i>PCR combined with matrix-assisted laser desorption/ionization time-of-flight mass spectrometry</i>	
HPV DNA type- or group-specific genotyping tests	
<i>Real-time PCR based tests</i>	
<i>Gel electrophoresis based test</i>	
hrHPV E6/E7 mRNA tests	
APTIMA® HPV Test (Gen-Probe Inc., San Diego, CA)	US FDA-approved (2011)
→ PreTect HPV-Proofer (NorChip, Klokkearstua, Norway)/NucliSENS EasyQ® HPV (Biomerieux, Marcy l'Etoile, France)	widely used test
In situ based hybridization HPV tests	

^afully or ^bpartially clinically validated according to the international Guidelines for HPV DNA test requirements for primary cervical cancer screening in women 30 years and older [16].

HPV: Human papillomavirus; hrHPV: High-risk human papillomavirus; PCR: Polymerase chain reaction.

hr-HPV DNA tests

- Hybrid Capture 2 (HC2) HPV DNA Test (QIAGEN Inc., Gaithersburg, MD, USA (previously Digene Corp.))
- EIA kit HPV GP HR (Diassay, Rijswijk, The Netherlands)
- Cervista® HPV HR Test (Hologic, Madison, WI)
- CareHPV™ Test (QIAGEN Inc., Gaithersburg, MD, USA)
- Amplior HPV Test (Roche Molecular Systems Inc., Alameda, CA, USA)
- HPV4A ACE Screening CE (Seegene, Seoul, Korea)
- HPV/STD4 ACE Screening CE (Seegene, Seoul, Korea)
- 13 High-risk HPV Real Time PCR (HybriBio, Beijing, China)
- Biorad Dx HR-HPV Test (Bio-Rad)
- Urine-Based HPV (High and Low Risk) PCR Detection Kit (Norgen, Thorold, Canada)
- Absolute HPV HR Test (BioSewoom, Seoul, Korea)
- HPV High Risk Screen (Sacace, Como, Italy)
- HPV High Risk Screen FEP (Sacace, Como, Italy)
- HPV High Risk Screen Real-TM Quant (Sacace, Como, Italy)
- HPV High Risk Screen Real-TM Quant 2 x (Sacace, Como, Italy)
- STD kit (Autoimmun Diagnostika GmbH, Strassberg, Germany)
- Human (HPV) 12 Multiplex Real-time PCR Kit (USBio, Swampscott, MS)
- Biovue's Sharpvue HPV detection kit (Biovue Technology Ltd, Shanghai, China)
- AmpliSens® HPV HCR screen-Eph PCR kit (Federal State Institution of Science, Moscow, Russia; Ecoli, Bratislava, Slovak Republic)
- AmpliSens® HPV HCR screen-titre-FRT PCR kit (2x-4x) (Federal State Institution of Science, Moscow, Russia; Ecoli, Bratislava, Slovak Republic)
- AmpliSens® HPV HCR screen-FEP PCR kit (3x) (Federal State Institution of Science, Moscow, Russia; Ecoli, Bratislava, Slovak Republic)
- HPV-DNA Assay Kit (Tofema, Seoul, Korea)
- HPV Total & High Risk (Clonit, Milano, Italy)

HPV hr-HPV DNA tests with concurrent or reflex partial genotyping

- Tests with concurrent partial genotyping for the main hr-HPV
- cobas® 4800 HPV Test (Roche Molecular Systems Inc., Alameda, CA, USA)
 - RealTime High Risk HPV test (Abbott Molecular, Des Plaines, IL)
 - BD Viper HPV test/BD HPV-GT Assay (BD Diagnostics, Sparks, MD)
 - 14 High-risk HPV with 16/18 Genotyping Real-time PCR Kit (HybriBio, Beijing, China)
 - RealQuality RQ-HPV HR (AB Analitica, Padova, Italy)
 - GenoFlow HPV-HR Screening Test (DiagCor Bioscience, Hong Kong)
 - AID HPV screening kit (Autoimmun Diagnostika GmbH, Strassberg, Germany)
 - AdvanSure HPV Screening real-time PCR (LGLS Diagnostics, Seoul, Korea)
 - GenoID Real-time HPV test (GenoID, Budapest, Hungary)
 - AmpliSens® HPV HCR screen-FEP PCR kit (Federal State Institution of Science, Moscow, Russia; Ecoli, Bratislava, Slovak Republic)
 - RealLine HPV High Risk, Genotype (Str-format); (Fla-format) (Bioron Diagnostics GmbH, Ludwigschafen, Germany)
 - RealLine HPV High Risk, Genotype quantitative (Str-format) (Bioron Diagnostics GmbH, Ludwigschafen, Germany)

Tests with reflex partial genotyping for the main hr-HPV

- Cervista® HPV 16/18 Test (Hologic, Madison, WI)
- digene® HPV Genotyping PS Test, RUO (Qiagen Gaithersburg, Inc., MD, USA (previously Digene Corp.))
- HPV 16/18 Real-TM Quant (Sacace, Como, Italy)
- Human papillomavirus 16/18 (Sacace, Como, Italy)
- HPV 16/18 FEP (Sacace, Como, Italy)
- HPV-TS-16 and HPV-TS-18 PCR-DEIA (Labo Bio-medical Products, Ev Rijswijk, The Netherlands)
- HPV-TS-31 and HPV TS-45 PCR-DEIA (Labo Bio-medical Products, Ev Rijswijk, The Netherlands)
- AmpliSens® HPV 16/18-FRT PCR kit (Federal State Institution of Science, Moscow, Russia; Ecoli s.r.o., Bratislava, Slovak Republic)
- AmpliSens® HPV 16/18-Eph PCR kit (Federal State Institution of Science, Moscow, Russia; Ecoli s.r.o., Bratislava, Slovak Republic)
- AmpliSens® HPV 16/18-FEP PCR kit (Federal State Institution of Science, Moscow, Russia; Ecoli s.r.o., Bratislava, Slovak Republic)

HPV DNA full genotyping tests

- Strip, filter or microtiter-well hybridization based full genotyping tests
- Linear Array® HPV Genotyping Test (Roche Molecular Systems Inc)
 - HPV SPF10 LIPAZ25_{medium} (Labo Bio-Medical Products, Ev Rijswijk, The Netherlands)
 - HPV PCR-DEIA (SPF10) (Labo Bio-Medical Products, Ev Rijswijk, The Netherlands) + HPV SPF10 LIPAZ25_{version 1}
 - INNO-LIPA HPV Genotyping Extra (Innogenetics NV, Gent, Belgium)
 - digene® HPV Genotyping RH Test (Qiagen Gaithersburg, Inc., MD, USA (previously Digene Corp.))
 - EasyChip® HPV Blot Kit (King Car, Taiwan)
 - REBA HPV-ID (Catch by Gene, Gangwon-do, Korea)
 - PGMY-CHUV low cost Test (World Health Organisation)
 - AmpliQuality HPV-type (AB Analitica, Padova, Italy)
 - AmpliQuality HPV-type HR (AB Analitica, Padova, Italy)
 - AmpliQuality HPV-type HS (AB Analitica, Padova, Italy)
 - GenoFlow HPV Array Test (DiagCor Bioscience, Hong Kong, China)
 - HPV Direct-Flow Chip (Master Diagnostica, Granada, Spain; Hospitex Diagnostics, Firenze, Italy)
 - AID HPV typing kit (Autoimmun Diagnostika GmbH, Strassberg, Germany)
 - Full Spectrum Genital Human Papillomavirus PCR Amplification and Genotyping Kit (GenoID, Budapest, Hungary)
 - PapillomaStrip High Risk (Operon, Zaragoza, Spain)
 - PapillomaStrip Low Risk (Operon, Zaragoza, Spain)

Medium or low density microarray based full genotyping tests

- PapilloCheck® HPV-Screening Test (Greiner Bio-One, Frickenhausen, Germany)
- PapilloCheck® High-risk Test (Greiner Bio-One, Frickenhausen, Germany)
- Clart® HPV 2 - Papillomavirus Clinical Arrays (Genomica, Coslada, Spain)
- 21 HPV GenoArray Test Kit (HybriBio Limited, Hong Kong)
- GeneTrack HPV DNA Chip (Genomic Tree, Daejeon, South Korea)
- GeneSQUARE HPV Microarray (Kurabo Industries, Osaka, Japan)
- InfiniIt® HPV Genotyping Test (AutoGenomics, Carlsbad, CA)
- InfiniIt® HPV-HR Quad Test (AutoGenomics, Carlsbad, CA)
- InfiniIt® HPV-Quad Test (AutoGenomics, Carlsbad, CA)
- PANArray™ HPV Genotyping Chip (PANAGEN, Daejeon, Korea)
- HPVNDChip (Biomedlab, Seoul, South Korea)
- GG HPVCHIP (GoodGene, Seoul, Korea)
- BMT HPV 9G DNA Kit™ (Biometric Technology, Chuncheon, Korea)
- BMT HPV Genotyping 9G Membrane Kit (Biometric Technology, Chuncheon, Korea)
- ProDect® Chip HPV Typing kit (Bcs Biotech, Cagliari, Italy)
- HPV type 3.5 LCD-Array Kit (Chipiron, Berlin, Germany)
- Decipher HPV23^{genotyping DNA chip} (Yaneng Bioscience, Shenzhen, China)

Microsphere beads based full genotyping tests

- Multiplex HPV Genotyping Kit (Progen/Multimetrix, Heidelberg, Germany)
- digene® HPV Genotyping LQ Test (Qiagen Gaithersburg, Inc., MD, USA (previously Digene Corp.))
- PapType HR HPV detection and genotyping (Genera Biosystems, Melbourne, Australia)
- GENOSEARCH-HPV31 (Medical & Biological Laboratories, Nagoya, Japan)
- Tellegenplex™ High-risk HPV Genotyping Panel (Tellegen, Shanghai, China)
- Tellegenplex™ 26 HPV Genotyping Panel (Tellegen, Shanghai, China)
- HPV genotyping kit (PlexBio, Taipei, Taiwan)
- HPV Liquid Beads Microarray Genotype PCR Kit (Innomedtech, Seoul, Korea)
- HPV Liquid Beads Microarray Genotype Kit (Innomedtech, Seoul, Korea)

Gel electrophoresis based full genotyping tests

- BIOTYPAP Kit (Biotools, Madrid, Spain)
- PCR Human Papillomavirus Typing Set (Takara Bio Inc, Shiga, Japan)
- Human papilloma virus genotyping (Genekam Biotechnology, Duisburg, Germany)

Capillary electrophoresis based full genotyping tests

- f-HPV typing™ (Genomed Diagnostics, Wollerau, Switzerland; Molgentix, Barcelona, Spain)

Real time PCR based full genotyping tests

- HPV High Risk Typing (Sacace, Como, Italy)
- HPV High Risk Screen Real-TM (Sacace, Como, Italy)
- AmpliSens® HPV HCR genotyping-FRT PCR kit (Federal State Institution of Science, Moscow, Russia; Ecoli, Bratislava, Slovak Republic)
- Uterine Cervix Cancer of High-risk HPV Genotype Related Real Time PCR Kit (Liferiver, Shanghai, China)
- High-risk HPV 13 Genotypes Related Real-time PCR Kit (Liferiver, Shanghai, China)
- SuperFast HPV 12 Multiplex Real-time PCR Kit (Kogenebiotech, Seoul, Korea)
- HPV MassArray (Sequenom, San Diego, CA)

HPV DNA type- or group-specific genotyping tests

Real-time PCR based tests

- AdvanSure HPV 16/18 real-time PCR (LGLS Diagnostics, Seoul, Korea)
- Human papilloma virus, HPV (16, 18) (DNA-Technology LLC, Moscow, Russia)
- HPV 16 & 18 Real Time PCR Kit (Liferiver, Shanghai, China)
- HPV 6 & 11 Real Time PCR Kit (Liferiver, Shanghai, China)
- Quantification of Human Papillomavirus 6; 11; 16; 18; 33; 52; 58 (PrimerDesign, Southampton, UK)
- AmpliSens® HPV 6/11-FRT PCR kit (Federal State Institution of Science, Moscow, Russia; Ecoli, Bratislava, Slovak Republic)
- AmpliSens® HPV 6/11-FEP PCR kit (Federal State Institution of Science, Moscow, Russia; Ecoli, Bratislava, Slovak Republic)
- AccuPower® HPV16 & 18 Real-Time PCR Kit (Bioneer, Daejeon, Korea)
- Human Papilloma Virus (HPV-16) (high risk profile) (Genekam Biotechnology, Duisburg, Germany)
- Human Papilloma Virus (HPV-18) (high risk profile) (Genekam Biotechnology, Duisburg, Germany)
- Human papillomavirus high-oncogenic risk HPV (16, 31, 35), (33, 52, 58), (18, 39, 45, 59) (DNA-Technology LLC, Moscow, Russia)
- SuperFast HPV 16, 6, 11 Multiplex Real-time PCR Kit (Kogenebiotech, Seoul, Korea)
- SuperFast HPV 16, 18 Multiplex Real-time PCR Kit (Kogenebiotech, Seoul, Korea)
- SuperFast HPV 5 Low risk Multiplex Real-time PCR Kit (Kogenebiotech, Seoul, Korea)
- Human Papilloma Virus (HPV) (Types 16 and 18) PCR Kit (Daan Diagnostics, Burnaby, Canada)
- Human Papilloma Virus (HPV) (Types 6 and 11) PCR Kit (Daan Diagnostics, Burnaby, Canada)
- High-risk Human Papilloma Virus (HR-HPV) PCR Kit (Daan Diagnostics, Burnaby, Canada)
- RealLine HPV 16/18; 52/56; 51/58; 35/45; 31/33; 6/11 (Str-format) (Bioron Diagnostics GmbH, Ludwigschafen, Germany)
- RealLine HPV 16/18; 52/56; 51/58; 35/45; 31/33; 6/11 (Fla-format) (Bioron Diagnostics GmbH, Ludwigschafen, Germany)

Gel electrophoresis based tests

- Human papilloma virus, HPV (16, 31, 33, 35, 35H, 58, 52, 67) (DNA-Technology LLC, Moscow, Russia)
- Human papilloma virus, HPV (18, 45, 39, 59) (DNA-Technology LLC, Moscow, Russia)
- Human papilloma virus, HPV (16, 18) (DNA-Technology LLC, Moscow, Russia)
- Human papilloma virus, HPV (51, 26) (DNA-Technology LLC, Moscow, Russia)
- Human papilloma virus, HPV (6, 11) (DNA-Technology LLC, Moscow, Russia)
- HPV, Mixed Type, L1 Genes Primer Set (Maxim Biotech, Rockville, MD)
- HPV-1; HPV-6; HPV-11; HPV-16, HPV-18; HPV-31; HPV-33; E6 Gene Primer Set (Maxim Biotech, Rockville, MD)
- MPCR Kit for Human Papillomavirus (Maxim Biotech, Rockville, MD)

- AmpliSens® HPV 31/33-Eph PCR kit (Federal State Institution of Science, Moscow, Russia; Ecoli, Bratislava, Slovak Republic)
- AmpliSens® HPV 35/45-Eph PCR kit (Federal State Institution of Science, Moscow, Russia; Ecoli, Bratislava, Slovak Republic)
- AmpliSens® HPV 6/11-Eph PCR kit (Federal State Institution of Science, Moscow, Russia; Ecoli, Bratislava, Slovak Republic)
- HPV-2; HPV-4; HPV-7 (Genekam Biotechnology, Duisburg, Germany)
- HPV-6; HPV-6/11; HPV-11 (Genekam Biotechnology, Duisburg, Germany)
- HPV-42; HPV-43; HPV-44; HPV-45 (Genekam Biotechnology, Duisburg, Germany)
- HPV-16; HPV-16/18; HPV-18; HPV-31; HPV-33; HPV-35; HPV-39 (Genekam Biotechnology, Duisburg, Germany)
- HPV-51; HPV-56; HPV-58; HPV-59; HPV-66; HPV-68 (Genekam Biotechnology, Duisburg, Germany)

hr-HPV E6/E7 mRNA tests

- APTIMA® HPV Test (Gen-Probe Inc., San Diego, CA)
- PreTect HPV-Proofer (NorChip, Klokstarut, Norway)
- NucliSens EasyQ® HPV (Biomerieux, Marcy l'Etoile, France)
- Quantivirus™ HPV E6/E7 RNA 3.0 Assay (bDNA) (DiaCarta LLC, Hayward, CA)

In situ hybridization based HPV tests

- INFORM HPV II Family 6 Probe (B) (Ventana, Tucson, AZ)
- INFORM HPV II Family 16 Probe (B) (Ventana, Tucson, AZ)
- GenPoint™ HPV Biotinylated DNA probe (Types 16/18/31/33/35/39/45/51/52/56/58/59/68) (Dako, Glostrup, Denmark)
- Wide Spectrum HPV Biotinylated DNA Probe (Types 6/11/16/18/31/33/35/39/45/51/52) (Dako, Glostrup, Denmark)
- HPV Types 6/11; 16/18; 31/33 Biotinylated DNA Probes (Dako, Glostrup, Denmark)
- ZytoFast HPV type 6/11; 16/18; 31/33 Probes (ZytoVision, Bremerhaven, Germany)
- ZytoFast HPV type 16/18/31/33/35 Probe (ZytoVision, Bremerhaven, Germany)
- ZytoFast HPV type 16/18/31/33/35/45/51/52 Probe (ZytoVision, Bremerhaven, Germany)
- ZytoFast HPV type 6/11/16/18/31/33/35 Screening Probe (ZytoVision, Bremerhaven, Germany)
- ZytoFast HPV type 6/11/16/18/31/33/35/45/51/52 Screening Probe (ZytoVision, Bremerhaven, Germany)
- HPV Screening (HPV6/11/16/18/31/33) (PanPath, Amsterdam, The Netherlands)
- HPV typing: HPV 6; 11; 16; 18; 31; 33; 6/11; 16/18; 31/33 DNA probe (PanPath, Amsterdam, The Netherlands)
- HPV In Situ Hybridization/Detection Kit (Types 6/11/16/18/31/33) (Maxim Biotech, Rockville, MD)
- HPV In Situ Hybridization/Detection Kit (Types 6/11) (Maxim Biotech, Rockville, MD)
- HPV In Situ Hybridization/Detection Kit (Types 16/18) (Maxim Biotech, Rockville, MD)
- HPV In Situ Hybridization/Detection Kit (Types 31/33) (Maxim Biotech, Rockville, MD)

Ahus

- HPV Pretect Proofer
- HPV Amplicor
- HPV Linear Array
- Sanger-sekvensering
- Ion Torrent
- MiSeq
- Real-time PCR med typespesifikke primere
- Gelelektroforese
- Luminex HPV
- Hybrid Capture 2
- Clart HPV
- Seegene Anyplex II HPV28
- Cobas 4800
- Papillocheck
- MicroArray
- Lasermikrodisseksjon
- Immunhistokjemi
- FISH

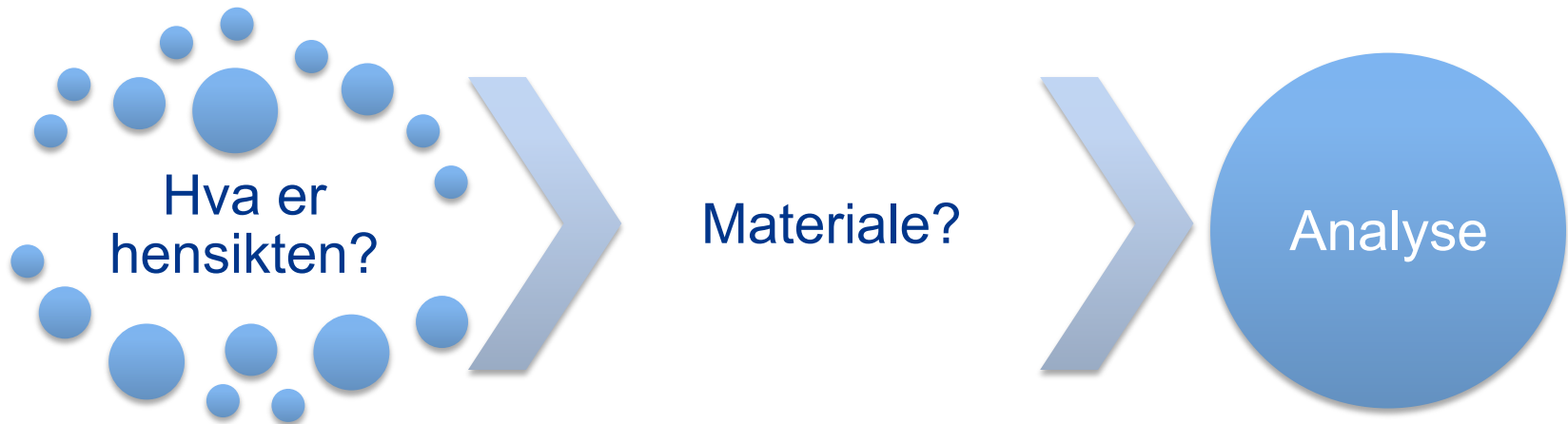
Valgets kvaler



HPV-testing - når?

- Som sekundærscreening til masseundersøkelsen
 - Ved lavgradige eller usikre funn i cytologi (LSIL / ASC-US)
- Forskning
 - HPV-assosierte cancere
 - Genotyping
- Vaksineovervåkning

HPV-testing



Hva er viktig i screening?

- Reproduserbarhet
- Hensiktsmessige resultater
- God prøveflyt ved høyt prøvevolum
- Plattformen som er enkle å håndtere
 - Opplæring, daglig bruk, kvalitet
- Stabilitet
 - Lite nedetid, rask service



- Automatiserte plattformer
 - Mindre ressurser
 - Risiko for kontaminering minimeres
 - Risiko for prøveforbytting minimeres
 - Prøvene blir likt behandlet

Tanker for fremtiden

Screening

- Plattformer med mulighet for høyt prøvevolum
- Enkle i bruk
- Kompatible med LBC

Forskning

- Relevant informasjon
- Reproduserbarhet
- Fleksibilitet

Takk for oppmerksomheten!

