IMPROVED PROTECTION AGAINST CERVICAL CANCER



PreTect<sup>®</sup> SEE

Supports Cytology to increase women's safety!

Be confident! Focus on the infection that matters!

HPV mRNA E6/E7 16, 18, 45

## CLINICAL BENEFITS OF PreTect<sup>®</sup> SEE

- Qualitative detection of E6/E7 mRNA expression from HPV 16, 18, 45
- Intrinsic sample control ensuring sample adequacy
- High specificity, minimizing unnecessary interventions
- High PPV for CIN2+
- Enhanced identification of cervical adenocarcinoma
- Low positivity rate in general population
- CE-IVD kit

# **PreTect**<sup>®</sup> **SEE**

## Background

- Cervical cancer is caused by the continuous overexpression of the E6/E7 oncogenes from high-risk HPV types<sup>1)</sup>
- 10-30% of women < 40 years have an HPV infection,<sup>2)</sup> but the majority of these infections are harmless and resolve spontaneously<sup>3)</sup>
- HPV 16, 18 and 45 are aggressive types associated with rapid progression, accounting for > 90% of all cervical cancer worldwide in young women<sup>4)</sup>
- Despite well-established screening programs, the incidence of cervical cancer is increasing in young women<sup>5), 6)</sup>
- 50% of women diagnosed with high-grade precancerous lesions are aged >35 years <sup>7</sup>)
- Cervical adenocarcinoma has increasing prevalence in recent decades and is clearly linked to HPV 16, 18, 45<sup>5),8)</sup>



#### References:

1) Zur Hausen H (2002) Nat Rev Cancer 2(5):342-350. Review
2) Preisler S et al (2013) PLOS ONE 8(3):e59765
3) Elfgren et al (2000) Am J Obstet Gynecol 183(3):561-567
4) Munoz N et al (2004) Int J Cancer 111(2):278-285
5) www.kreftegisteret.no/globalassets/publikasjoner-ograpporter/livmorhalskreft
/arsrapport/arsrapport-livmorhalsprogrammet-2015.pdf
6) NORDCAN; Cancer stat fact sheets; Norway-Cervix uteri: http://wwwdep.iarc.fr/NORDCAN/english/StatsFact.asp?cancer=212&country=578
7) Tjalma W et al (2013) Int J Cancer 132 (4):854-867
8) Van der Horst J et al (2017) Cancer Med 6 (2):416-423

#### **TEST INFORMATION**

Individual HPV genotyping	E6/E7 mRNA HPV 16, 18 and 45
Intrinsic Sample Control (ISC)	Targeted mRNA from housekeeping gene
Sample type	Cervical samples
Storage media	PreTect TM (PreTect AS) PreservCyt/ThinPrep (Hologic) SurePath (BD Diagnostics)
Input material	Isolated Nucleic Acid (DNA/RNA)*
Technology	Real-time NASBA isothermal amplification (41°C) with four specific molecular beacon probes
Format	96-well PCR plate pre-filled with reagents n=94
Assay time	~ 150 minutes
Instrumentation:	Fluorescence reader / RT-PCR (CFX-96/QuantStudio5)

\* DNA/RNA isolation reagents not included.

## Key facts

- PreTect SEE: a qualitative CE-IVD kit identifying women with carcinogenic expression of high-risk HPV types, at risk for cervical cancer
- Co-testing with Pap smear improves the sensitivity of existing screening programs without excessive follow up burden
- High clinical specificity; low positive rate in the general population
- Ideal as a standalone test in low-income countries
- High capacity and low cost

DNA	mRNA
Double stranded	Single stranded
Stores genetic information	Decodes DNA info to produce proteins
Indicates presence of virus	Indicates gene activity

#### Contact us for further information!

#### PreTect AS

Ustadhagan 8 | N-3490 Klokkarstua | Norway Tel: +47 32 79 88 00 | www.pretect.no E-mail: pretect@pretect.no

