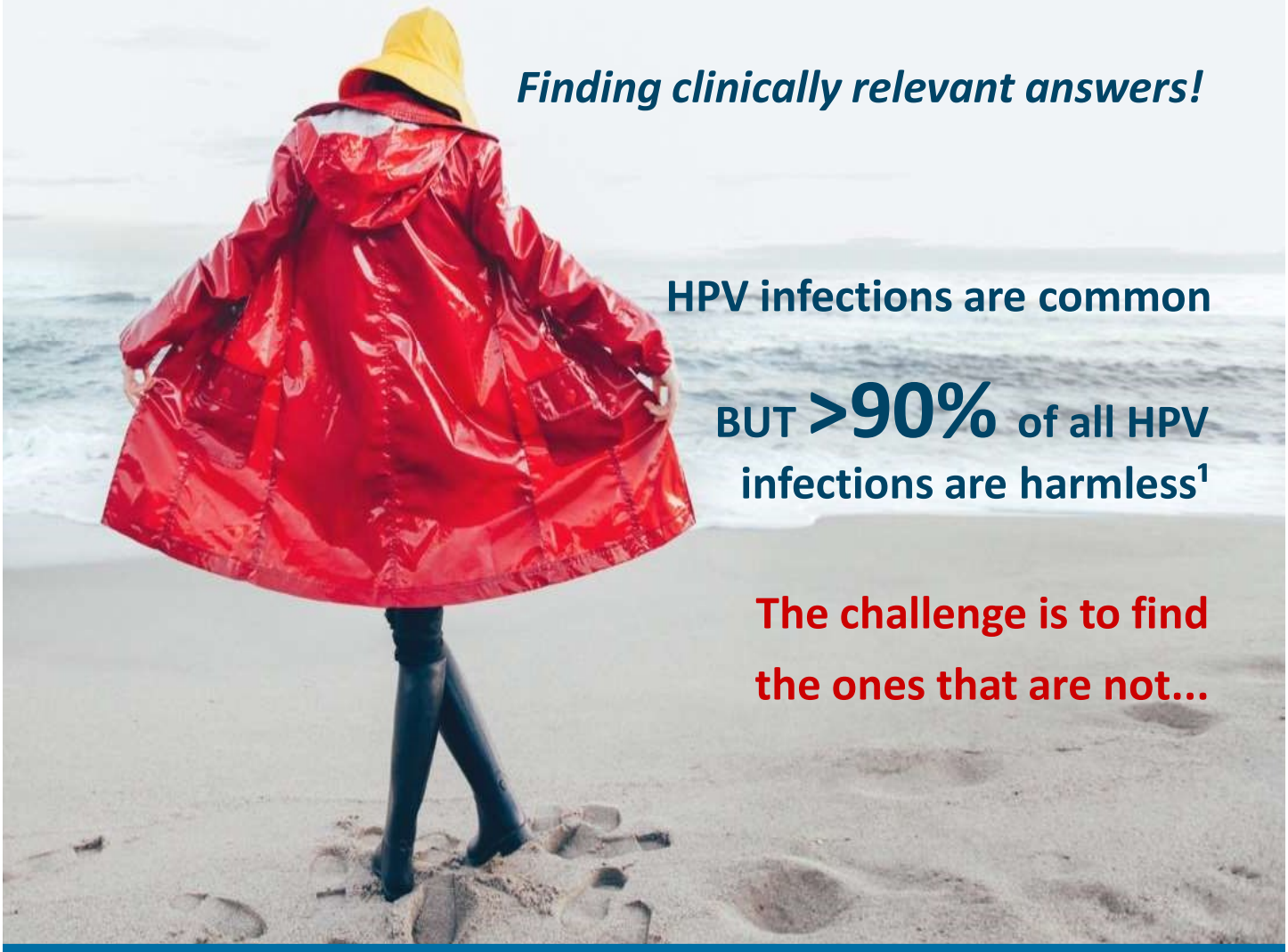
Advances in Cervical Cancer Prevention

PreTect®
HPV-Proofer`7



Finding clinically relevant answers!

HPV infections are common

BUT >90% of all HPV infections are harmless[1]

The challenge is to find the ones that are not...

Clinical benefits of using PreTect HPV-Proofer`7

- Risk stratification and direct genotyping
- E6/E7 mRNA expression from HPV 16, 18, 31, 33, 45, 52 and 58
- Identifies cervical precursors most likely to progress to invasive cancers
- Accurate patient management; Triaging HPV DNA positive women/Cytology
- Enhances identification of cervical adenocarcinoma
- Minimize unnecessary referral and over-treatment
- Suitable even in young women
- Covers the carcinogenic HPV's in the nine-valent vaccine

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Background

Cervical cancer is caused by the continuous over-expression of the E6/E7 oncogenes from high-risk HPV viruses. [2)]

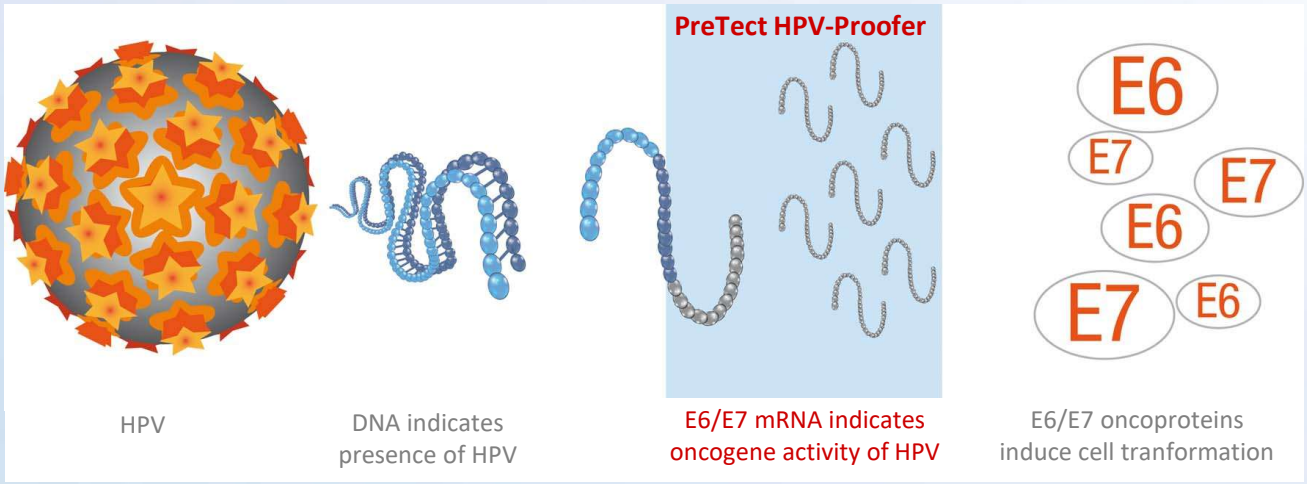
Almost 80% of women get infected with HPV during their lifetime. However, most infections are harmless and will clear spontaneously.

More than 100 HPV types are known but only a few are dominating severe pre-stages and cervical cancer.

Optimal screening strategy requires high specificity and more accurate patient management to minimize potential harm caused by unnecessary follow-up of false positives.

Test Information	
Individual HPV genotyping	E6/E7 mRNA HPV 16, 18, 31, 33, 45, 52 and 58
Intrinsic Sample Control (ISC):	Targeting mRNA from housekeeping gene
Sample type:	Cervical samples
Preservatives:	PreTect TM (PreTect AS); PreservCyt; SurePath
Input-material:	Isolated Nucleic Acid (DNA/RNA)*
Technology:	Real time NASBA Isothermal amplification (41°C) Eight specific molecular beacons
Format:	96-well PCR plate/strips Pre-filled with reagents
Assay time:	~ 150 minutes
Instrumentation:	Fluorescence reader / RT-PCR (CFX-96/QuantStudio5)

* DNA/RNA isolation reagents not included.



HPV

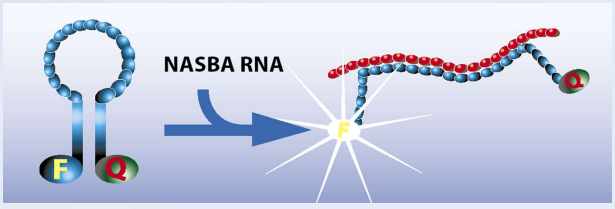
DNA indicates presence of HPV

E6/E7 mRNA indicates oncogene activity of HPV

E6/E7 oncoproteins induce cell tranformation

Key Facts

- Qualitative CE-IVD kit identifying the few women at highest risk of cervical disease
- Amplifies mRNA selectively; identifying carcinogenic activity, not viral presence
- HPV mRNA positives have elevated 10-years risk of CIN3+ [3)]
- HPV mRNA negatives have low 10-years risk of CIN3+ [3)]
- Unique risk stratification and genotyping



References

1) Elfgren et al (2000) *Am J Obstet Gynecol* **183**(3):561-567

2) Zur Hausen H (2002*) Nat Rev Cancer* **2**(5):342-350. Review

3) Norwegian data presented at XIII International Workshop on Lower Genital Tract Pathology (Rome, April 12-13 2018)

For further information please contact us!

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