

Take the guess work  
out of cervical  
cancer screening.™



**FHACT**®

FISH-based HPV-Associated Cancer Test



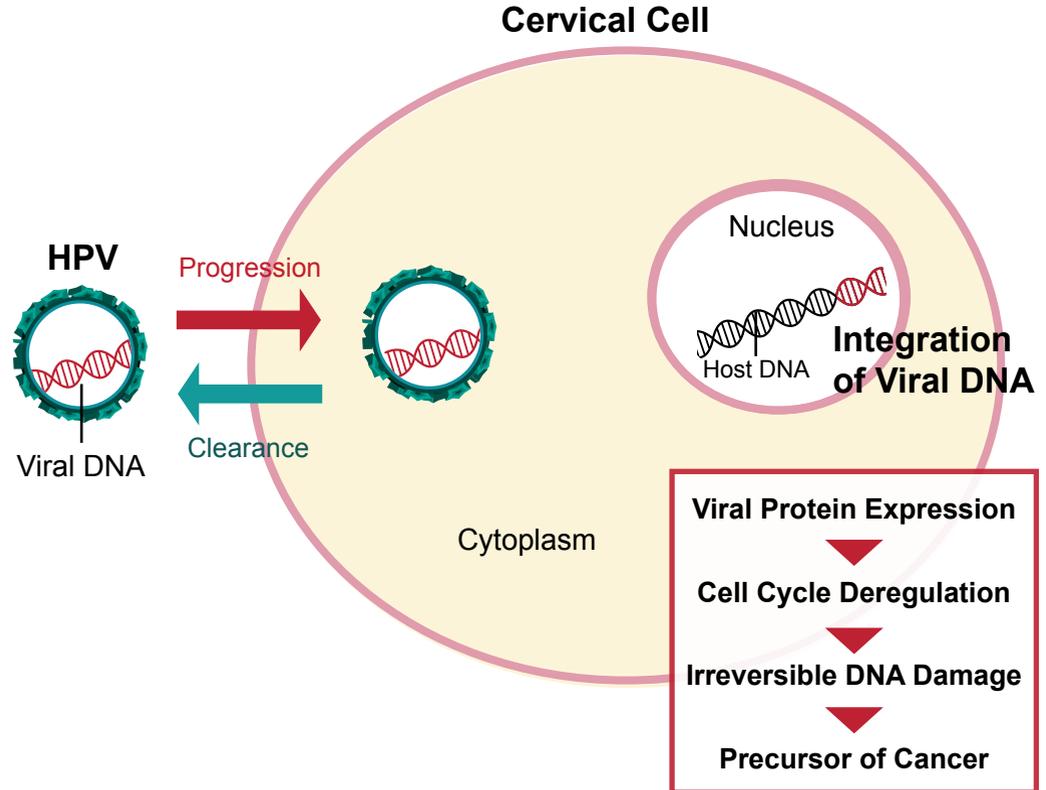
# HPV Infection and the Progression to Cervical Disease

Infection with high-risk HPV is necessary but not sufficient for the initiation of cervical oncogenesis.

Additional genetic events in the host's cells are essential for precancerous lesions to progress to malignancy.

Genomic changes are the hallmark of cellular transformation.

FHACT® looks for these genomic changes in the woman's DNA.



# The Need for Additional Biomarkers in Cervical Cancer Screening

## Liquid cytology testing has imperfect sensitivity.

- ▶ Pap smears lead to too many false negatives (poor sensitivity).
- ▶ Results can be uncertain, especially for specimens with mild cellular abnormalities.
- ▶ Cytology cannot predict disease progression.

## HPV typing doesn't distinguish transient vs. persistent infection.

- ▶ HPV typing leads to too many "false positives" (poor specificity).
- ▶ Most infections will clear on their own within 2 years.
- ▶ HPV typing detects only the most common high-risk HPV strains.

## Current screening protocol may lead to over treatment.

- ▶ Most LSIL patients are reflexed to colposcopy (70-90% are HPV+) whereas only ~20% LSILs present CIN2+ (medically actionable) by histology.<sup>1</sup>
- ▶ ~40% of ASC-US, LSIL specimens that are referred to colposcopy come back with a normal colposcopy result.<sup>2</sup>

# FHACT® Aids in the Triage of LSIL/ASCUS Lesions

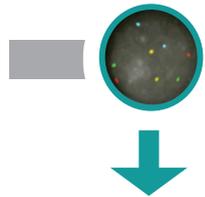
Today, these women are all referred for colposcopy:



HPV + women with abnormal or unclear liquid-based cytology

**~90%**  
**REGRESS**  
within 2 years  
of the infection

**~10%**  
**PROGRESS**  
to higher grade  
cervical disease



**No colposcopy  
required now**

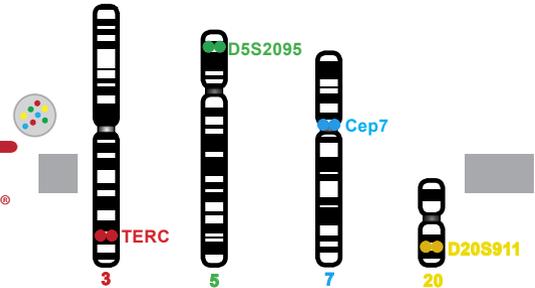


**Referred for  
colposcopy**

**FHACT** identifies women with low grade or undetermined lesions who are likely to progress to more advanced cervical disease.

**FHACT**

FISH-based HPV-Associated Cancer Test



# Reduce Overtreatment, Improve Women's Health

**FHACT**  is the only test with four biomarkers that detects genomic alterations associated with progression of cervical lesions.

**Include FHACT® as additional triage before referral for colposcopy.**

- ▶ Performed on remnant liquid cytology sample - no resampling necessary.
- ▶ Fewer women referred for colposcopy.
- ▶ Reduced healthcare costs.
- ▶ Reduced patient anxiety.
- ▶ May help prevent complications associated with overtreatment.

**FISH-based HPV-Associated Cancer Test (FHACT®)**

- ▶ FHACT® assesses non-random genomic alterations associated with progression of lesions.<sup>3</sup>
- ▶ Gain at one or more of the FHACT® loci is detected in up to 89.5% of all cervical cancers.<sup>1</sup>
- ▶ FHACT® provides the highest sensitivity for a test in its category.



## References

1. The Cancer Genome Atlas (TCGA) (<http://cancergenome.nih.gov>).
2. Leusley & Downey, Journal of Lower Genital Tract Disease, Nov 2009
3. Luhn P, et al. (2013) Chromosomal gains measured in cytology samples from women with abnormal cervical cancer screening results. Gynecol Oncol, 130, 595-600.

# Help identify women most at risk for cervical cancer.

FHACT<sup>®</sup> is a new aid in the triage of ASCUS and LSIL/HPV+ women.

**FHACT<sup>®</sup>**

FISH-based HPV-Associated Cancer Test

**Cervical Cancer**



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**CANCER GENETICS<sup>®</sup>**

Empowering Personalized Cancer Treatment