Primary screening with the cobas® HPV Test

Evidence behind the new paradigm
Up to 1/3 of cervical cancers occurred in women with a negative Pap

Normal Pap does not mean cancer-free.

Kaiser Permanente and 2 other healthcare plans (N=833)

Swedish healthcare system (N=1230)

Other causes of cervical cancer included no recent screen and failure of follow-up on abnormal Pap

A new paradigm in cervical cancer prevention

Primary screening with the cobas® HPV Test - data from ATHENA trial

Increase the sensitivity of your initial screening test

Increase your confidence in negative results

The cobas® HPV Test is significantly more sensitive in detecting cases of ≥CIN3 than Pap.

A negative cobas® HPV Test provides the confidence that ≥CIN3 will not develop within 3 years vs a negative Pap.
Not all HPV positive women have the same risk

Risk of developing ≥CIN3 within 3 years\textsuperscript{4}

- HPV16+ 1 in 4 developed ≥CIN3
- HPV18+ 1 in 9 developed ≥CIN3
- 12 other hrHPV+ 1 in 19 developed ≥CIN3

HPV16 and HPV18 genotyping allows clinicians to stratify patients into risk groups for appropriate management.\textsuperscript{4}

The HPV Primary Screening Algorithm

Balances sensitivity of disease detection with number of follow-up procedures

- HPV-\textsuperset{\rightarrow}\text{Routine Screening}\textsuperset{\rightarrow}\text{Follow up}
- HPV16+/18+\textsuperset{\rightarrow}\text{Colposcopy}
- 12 other hrHPV+\textsuperset{\rightarrow}\text{Triage}

The algorithm that utilizes 16/18 genotyping and triage to help protect women from cervical cancer and overtreatment

3 tests in 1 for confident risk stratification

\textbf{16} 18 31 \textbf{33} \textbf{35} \textbf{39} \textbf{45} \textbf{51} 52 \textbf{56} 58 59 66 68

\texttt{\textbf{β}-globin (internal control)}}

The cobas\textsuperscript{®} HPV Test is the only clinically validated, FDA-approved and CE-IVD marked assay for first-line, primary screening of cervical cancer
Evidence that can’t be ignored
Screening women starting at 25 years with the **cobas® HPV Test** will help reduce the incidence of cervical cancer

SEER Tumor Registry (1975-2010)\(^5\)

![Cervical Cancer Incidence per 100,000 by Age Group](chart)

Sharp rise in incidence of invasive cervical cancer in women 25 to 34 years of age.

ATHENA rate of ≥CIN3 by age group within 3 years\(^4\)

![Graph](chart)

Significantly higher disease burden of ≥CIN3 in ages 25-29 vs 40+.

Pap was false negative in 56.3% of ≥CIN3 cases in women 25-29 yrs of age.

The **cobas® HPV Test** was clinically validated in the ATHENA trial. ATHENA, the largest US prospective registrational clinical study of its kind, evaluated the performance of the **cobas® HPV Test** in primary screening, ASC-US triage and co-testing in women with normal cytology.

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For more information, visit [www.hpv16and18.com](http://www.hpv16and18.com)

References:

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