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

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.3

A negative cobas® HPV Test provides the confidence that ≥CIN3 will not develop within 3 years vs a negative Pap.4
Not all HPV positive women have the same risk

Risk of developing ≥CIN3 within 3 years\(^4\)

- **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.\(^4\)**

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**The HPV Primary Screening Algorithm**

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

- **cobas® HPV Test**
- **HPV-**: Routine Screening → Follow up
- **HPV16+/18+**: Colposcopy
- **12 other hrHPV+**: Triage → Positive → Colposcopy

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

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3 tests in 1 for confident risk stratification

- **16** (HPV16)
- **18** (HPV18)
- **31 33 35 39 45 51 52 56 58 59 66 68** (12 pooled hrHPV)
- **β-globin** (internal control)

*The cobas® 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)®

Cervical Cancer Incidence per 100,000

Age group
0 2 4 6 8 10 12 14 16

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®

≥CIN3 cases per 10,000 women

Age
25-29 30-39 40-49 50+
0 30 60 90

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.

For more information, visit www.hpv16and18.com

References:

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