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.

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

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

Increase your confidence in negative results

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**

- **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.

The HPV Primary Screening Algorithm

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

**cobas® HPV Test**

- HPV- → **Routine Screening** → Negative → **Follow up**
- 12 other hrHPV+ → **Triage**
- HPV16+/18+ → **Colposcopy** → Positive → **Colposcopy**

*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

- **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)\(^5\)

<table>
<thead>
<tr>
<th>Age group</th>
<th>Cervical Cancer Incidence per 100,000</th>
</tr>
</thead>
<tbody>
<tr>
<td>15-19</td>
<td>0</td>
</tr>
<tr>
<td>20-24</td>
<td>4</td>
</tr>
<tr>
<td>25-29</td>
<td>6</td>
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<tr>
<td>30-34</td>
<td>4</td>
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<tr>
<td>35-39</td>
<td>8</td>
</tr>
<tr>
<td>40-44</td>
<td>12</td>
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<tr>
<td>45-49</td>
<td>16</td>
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<tr>
<td>50-54</td>
<td>12</td>
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<tr>
<td>55-59</td>
<td>8</td>
</tr>
<tr>
<td>60-64</td>
<td>4</td>
</tr>
</tbody>
</table>

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

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

<table>
<thead>
<tr>
<th>Age</th>
<th>$\geq$CIN3 cases per 10,000 women</th>
</tr>
</thead>
<tbody>
<tr>
<td>25-29</td>
<td>180</td>
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<tr>
<td>30-39</td>
<td>120</td>
</tr>
<tr>
<td>40-49</td>
<td>60</td>
</tr>
<tr>
<td>50+</td>
<td>30</td>
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</tbody>
</table>

56.3% missed by Pap

Significantly higher disease burden of $\geq$CIN3 in ages 25-29 vs 40+.

Pap was false negative in 56.3% of $\geq$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: