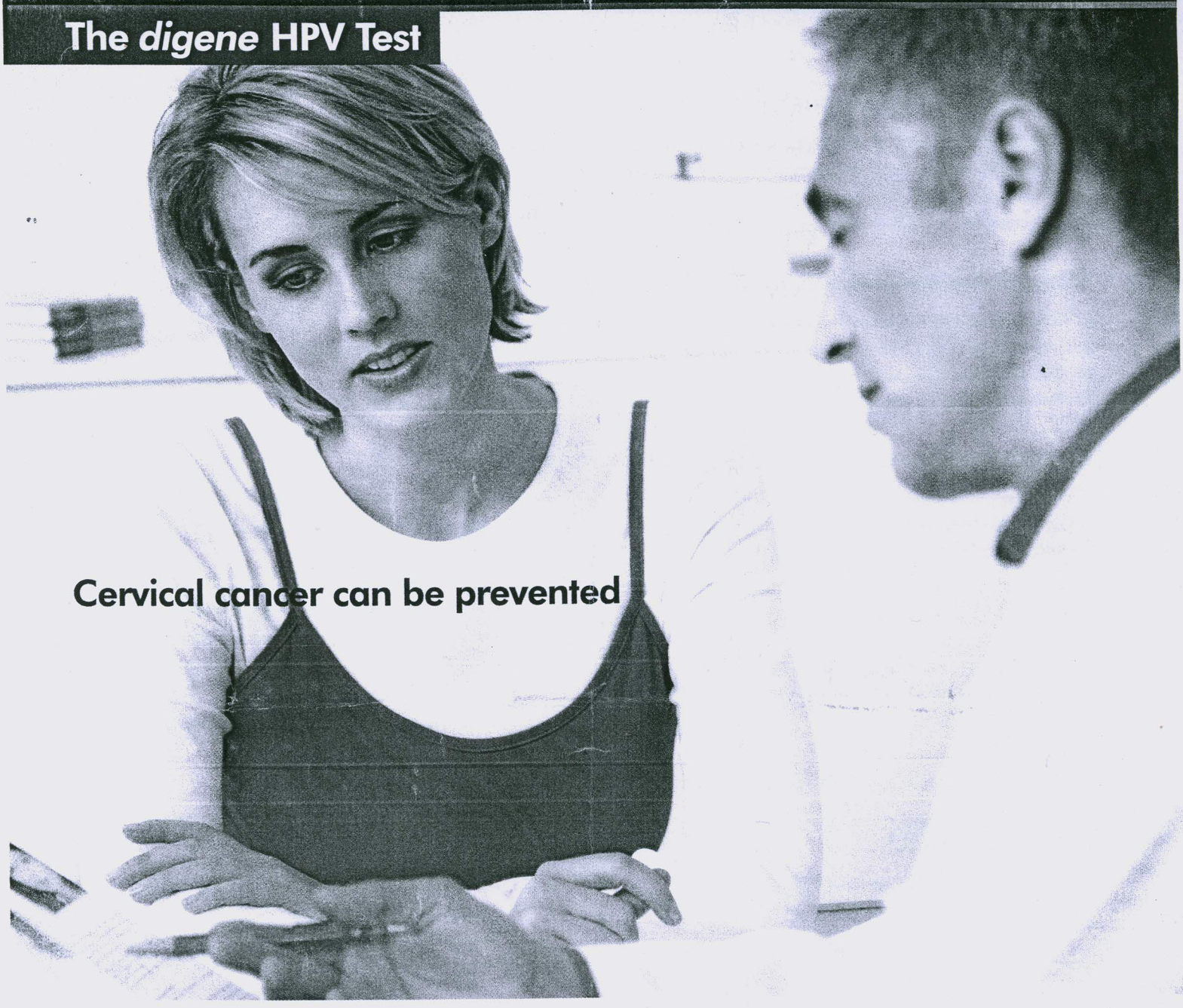
# The gold standard in cervical cancer screening

## The *digene* HPV Test



**Cervical cancer can be prevented**

**Early detection of the disease, caused by high-risk types of the human papillomavirus (HPV) (1), saves lives.**

**The *digene* HPV Test, targeting HPV DNA, offers significant benefits such as:**

- Early detection of cervical disease (precancer)
- Significantly increased sensitivity over cytology; 98% for CIN 2+ and 100 % for CIN 3+ (2-4)
- Technology advantages that deliver objective, accurate results
- Essentially eliminates risk of missed disease in screening
- Recommended by leading gynecologists, oncologists, and epidemiologists in the field of cervical cancer

QIAGEN®

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# The gold standard in cervical cancer screening

### Screening with the *digene* HPV DNA Test

- Clinical validation against histological end points of CIN 2+
- Clearly differentiates between infection and disease allowing for better risk assessment
- Detection of 13 HPV oncogenic types
- FDA-approved and CE-marked

### Expert recommendations for cervical cancer screening

- Screening with HPV DNA test for exquisite sensitivity and early detection of serious disease
- Triage with cytology, colposcopy, or visual inspection with acetic acid (VIA) for those patients testing HPV (+)
- Genotype only those patients who are HPV (+) at baseline (5)
- Follow-up at 12 months for those women who are diagnosed HPV (+) and Pap (–) at baseline (5)

## Unequivocal results and outstanding performance

**The *digene* HPV Test — HC2 HPV Test**
**Gold standard in cervical cancer screening**

- ☐ US FDA-approved and in Europe CE-marked
- ☐ Over 300 publications for HC2 HPV DNA test
- ☐ Multiple clinical trials involving over 800,000 women
- ☐ Clinically validated against CIN 2+
- ☐ Sensitivity of 98% for CIN 2+ and 100% for CIN 3+

**The *digene* HPV Test — HC2 HPV Test**
**Multiple applications**

- ☐ Primary screening for women >age 30
- ☐ Doubtful Pap/ASCUS (US FDA-approved)
- ☐ Past history of CIN 2+ (US FDA-approved)
- ☐ Post-vaccine screening of women >age 30
- ☐ Test of cure for regressed cancers

## What does an HC2 HPV DNA test result mean?

**Negative HC2 result**

- ☐ Negligible risk of cancer with a 99.7% certainty
- ☐ Reduce screening interval to once every 3 years

**Positive HC2 result**

- ☐ Increased risk of progression due to high risk HPV
- ☐ Immediate follow-up is essential
- ☐ Repeat test in 12 months


**References:**

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2. Mayrand, M.H., et al. (2007) Human papillomavirus DNA versus Papanicolaou screening tests for cervical cancer. N. Engl. J. Med. **18; 357(16)**, 1579.
3. Clavel C. et al. (2001) Human papillomavirus testing in primary screening for the detection of high-grade cervical lesions: a study of 7932 women. Br. J. Cancer. **15; 84(12)**, 1616.
4. Salmeron, J. et al. (2003) Comparison of HPV-based assays with Papanicolaou smears for cervical cancer screening in Morelos State, Mexico. Cancer Causes Control. 14(6), 505.
5. (2009) ACOG Practice Bulletin, Obstet. Gynecol. 114.


## Take the test, not the risk!


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