The *digene* HPV Test

Cervical cancer prevention — which test should I choose

QIAGEN®

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In selecting a molecular diagnostic test to use for testing of women 30 years and older for HPV infection and for HPV adjunctive screening, there are a number of factors that both the physician and laboratory should consider.

Factor	Considerations	PCR-based tests
Clinical validity	The test should be clinically validated. In-house analytical testing or marketing claims are not sufficient. The clinical utility should be established in large-scale prospective trials.	No prospective supporting clinical studies in target population.
Regulatory approval/ clinical acceptance	The test should be CE marked, approved by the FDA and recommended by other medical groups such as ACOG, ASCCP, ACS, CDC, and NPWH. The test should be appropriate for the clinically intended use and follow best-practice guidelines for patient intervention.	Not CE-marked if in-house tests, not FDA-approved, or recommended by major medical organizations for any intended clinical use.
Test performance	The test should be independently tested in a number of different laboratories and its performance evaluated and documented in independent peer-reviewed journals.	Clinical performance not established.
Proficiency of use	The company or laboratory offering the test must have demonstrated proficiency in performing the test on large sample sizes and should have the required technical support infrastructure to support it.	Intra- and inter-lab reproducibility not yet established.
Throughput	The assay should be scaleable and have equally high performance during high volume use.	Depends on method — generally lower.
Risk management	The test should reduce the risk of patients proceeding to cancer when administered with a Pap test, and adhere to professional medical guidelines.	Underestimate the incidence of HPV-positive cancers due to deletion of the DNA sequences required for detection in some severe lesions and tumors.

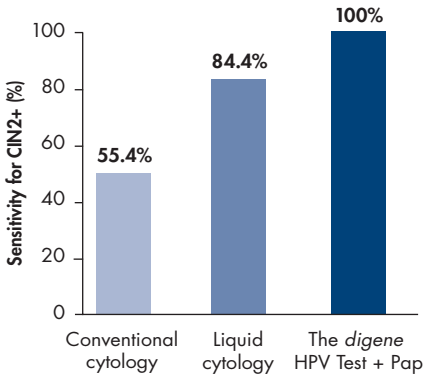
HPV testing — the choice is clear

The *digene* HPV Test
Extensive clinical validation involving almost one million patients worldwide.
The first CE-marked and FDA-approved HPV test. Recommended by medical organizations in US and Europe.
Extensive clinical validation revealed a clinical sensitivity of up to 100% when combined with a Pap test.
10 million tests per annum worldwide – published track record of reproducible performance for more than 10 years.
Fully scalable, 352 tests in 6.5 hours.
Broadest genome coverage available. Detects full length of HPV DNA. False negative results can be prevented.

When it comes to cervical cancer prevention, make the informed choice — for you and your patients.

Are you trusting a Pap alone to detect cervical cancer?

Used alone, the Pap test (conventional or liquid based) may miss cervical disease and cancer. But a Pap test in combination with the *digene* HPV Test detects the cause of high-grade cervical disease and cancer (CIN2+) — with sensitivity as high as 100% (1).



HPV testing sensitivity. Data from multi-center randomized controls trials of 10,154 women aged 30–69 years (2) and 16,706 women aged 35–60 years (3).

The Pap test

Tells whether the cervical cells have any ab-normalities. However, due to its lower sensitivity, the Pap test may miss abnormal cells when used as a standalone test.

The *digene* HPV Test

Tells whether the patient has the virus that can cause abnormal cells to develop. If high-risk HPV types are detected, the patient can be monitored more closely, if needed.

References

1. Clavel, C. et al. (2001) Human papillomavirus testing in primary cervical screening for the detection of high-grade cervical lesions: a study of 7932 women. Br. J. Cancer **84**, 1616.
2. Mayrand, M.H. et al. (2007) Human papillomavirus DNA versus Papanicolaou screening tests for cervical cancer. N. Engl. J. Med. **357**, 1579.
3. Ronco, G. et al. (2006) Human papillomavirus testing and liquid-based cytology: results at recruitment from the new technologies for cervical cancer randomized controlled trial. J. Natl. Cancer Inst. **98**, 765.

Ordering Information

Product	Contents	Cat. no.
digene HPV HC2 DNA Test	For 40 cervical samples – high risk and low risk (96 tests)	5196-1330
digene High-Risk HPV HC2 DNA Test	For 88 cervical samples (96 tests)*	5197-1330
digene Cervical Sampler	A cervical brush and Specimen Transport Medium	5122-1220

* Includes probe diluent, high-risk HPV probe, quality controls, calibrator, capture microplate, reagents, and buffers.

The *digene* HPV HC2 DNA Test and *digene* High-Risk HPV HC2 DNA Test are intended for in-vitro diagnostic use.

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