Reaching Every Woman – the careHPV® Test

Now WHO prequalified for HPV testing in cervical cancer screening
Portable and robust HPV testing

The global burden of cervical cancer is well documented. It is the second most common cancer in the world, and the majority of those who die from cervical cancer are underprivileged women in developing countries with a poor healthcare system lacking in infrastructure, funding, access, and skilled personnel. Cervical cancer is preventable through proper screening, key to which is human papillomavirus (HPV) testing. Providing women access to HPV testing improves early detection and outcomes for patients most at risk.

The QIAGEN careHPV Test was developed to address the unmet need of HPV testing in low resource areas. Through global cooperation and partnerships, careHPV is now changing the story of cervical cancer diagnosis and treatment around the world. The careHPV Test is now a WHO prequalified IVD solution for developing countries, offering practical and affordable testing for high-risk HPV in limited resource settings. The careHPV Test is to be used for primary, stand-alone screening in women 30 years and older to determine high-risk HPV infection, which is a risk factor for developing cervical intraepithelial neoplasia (CIN) 2 or more severe.

Accurate and effective test for the detection of high-risk HPV

The careHPV Test is a nucleic acid hybridization assay with signal amplification that uses microplate chemiluminescence for the qualitative detection of 14 high-risk types of HPV DNA in cervical and vaginal specimens. The HPV types detected by the assay are the high-risk HPV DNA types 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68. Individual HPV types cannot be determined using this test. The careHPV Test is CE-marked for use as an in vitro diagnostic test.

Adaptable, robust assay

The careHPV Test allows users to run HPV tests in limited-resource settings. The test may be run by a healthcare worker with basic training—no formal laboratory skills are required. Cervical cells are collected by a healthcare worker and vaginal cells can be self-collected. The test may be run on main electricity or using a battery with an inverter, making it portable and adaptable. The test can be run in a flexible temperature range, from 15°C to 40°C.

The careHPV Test offers:

- Detection of 14 high-risk HPV types
- Convenient test results in 2.5 hours (excluding sample prep) for possible same-day follow up
- Accurate, robust, and accessible primary screening
- High clinical sensitivity and specificity

Reduce cervical cancer risk in developing countries

The careHPV Test can identify women at risk of developing cervical cancer. As a primary screening tool with test results in 2.5 hours, it will potentially reduce the waiting time for follow-up (cytology) in patients for whom the results indicate a high-risk HPV result. The careHPV Test offers a new option for developing countries—a practical and affordable test that can be used in limited-resource settings.
Ordering Information

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<th>Product</th>
<th>Contents</th>
<th>Cat. no.</th>
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<tr>
<td>careHPV Test Kit</td>
<td>For 90 cervical or vaginal samples; includes: 1 positive calibrator, 1 negative calibrator, 96-well microplate, reagents, reconstitution diluents</td>
<td>614015</td>
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<tr>
<td><strong>Accessories</strong></td>
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<tr>
<td>careBrush</td>
<td>50 prescored cervical brushes</td>
<td>619024</td>
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<tr>
<td>careHPV Collection Medium</td>
<td>50 tubes (1 ml careHPV Collection Medium per tube)</td>
<td>619025</td>
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<tr>
<td>careHPV Test System</td>
<td>careHPV instruments; includes: careHPV Test Controller (9001775), careHPV Test Luminometer (9001773), careHPV Test Shaker (9001774), and careHPV Test Magnetic Plate Holder</td>
<td>9001772</td>
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Contact QIAGEN today to find out more about the careHPV Test.

Reference:


The careBrush, careHPV Collection Medium, and the careHPV Test are CE-marked for in vitro diagnostic use. Not available in all countries.

For up-to-date licensing information and product-specific disclaimers, see the respective QIAGEN® kit handbook or user manual. QIAGEN kit handbooks and user manuals are available at [www.qiagen.com](http://www.qiagen.com) or can be requested from QIAGEN Technical Services or your local distributor.