

Mia Comprehensive Cervical Cancer Test



The most comprehensive, comfortable and convenient test for Cervical Cancer

The Mia Comprehensive Cervical Cancer Test is the only HPV test that identifies both high-risk HPV strains associated with cervical cancer and automatically detects whether the HPV infection is active and capable of causing the disease. This is achieved without requiring a second sample collection.



Problem: Cervical cancer kills although it is 100% preventable

Cervical cancer can be prevented if an active high-risk HPV infection is identified early through testing for both high-risk HPV DNA and E6/E7 mRNA overexpression, which indicates oncogenic activity.



Solution: Mia Comprehensive Cervical Cancer Test can determine not only if a high-risk HPV infection is present, but active, indicating carcinogenic activity and aiding in the prevention or early identification of cervical cancer.

Comfortable and Convenient Collection

Mia is a comfortable device enabling self-collection without use of a speculum – as easy as using a tampon

- More patients will return for routine screening.

Dual testing for hrHPV genotypes and E6/E7 gene activity is more predictive of developing cervical cancer than one test alone

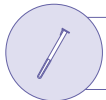
- Reduces unnecessary follow ups, procedures and referrals.

Clear actionable results clarify follow up decisions

- Treat preventable cervical cancer lesions early while at the same time, avoid unnecessary colposcopies.

Aligned with clinical guidelines – Mia supports extended screening intervals

- Builds patient trust and demonstrates best-in-class preventative care standards.



1

Collect Sample

Collect the specimen during a routine visit.



2

Ship Sample

Place the sample in the provided transport tube and send it to our CLIA/CAP certified lab.



3

HPV DNA Test

Initial molecular assay detects 14 high-risk HPV genotypes.



4

HPV mRNA Test

If high-risk HPV DNA is present, Mia detects E6/E7 mRNA without requiring an additional sample.



5

Clear Results

Comprehensive results are easy to interpret.

127,000+

Validated cases in women world wide

2x

Higher predictive accuracy

>50%

Fewer unnecessary colposcopies



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MEL-MONT MEDICAL, Inc.

Product Specifications



Mia by XytoTest® Sample Collection Kit

Intended Purpose

Self-collecting vaginal sample device for cervical cancer screening and HPV risk assessment in a medical setting.



Kit Contents

- Self-sampling device
- Transport tube with 5 mL of transport media
- Shipping label and return envelope
- Biohazard bag
- Instructions for Use
- Important Product Information
- Test Requisition Form

Store kit at room temperature prior to use.

cobas® HPV DNA Test

Intended Use

cobas® HPV for use on the cobas 5800/6800/8800 Systems (cobas HPV) is an automated qualitative in vitro test for the detection of human papillomavirus (HPV) DNA in patient specimens. The test utilizes amplification of target DNA by the Polymerase Chain Reaction (PCR) and nucleic acid hybridization for the detection of 14 high-risk (HR) HPV types in a single analysis. The test specifically identifies HPV16 and HPV18 while concurrently detecting the other high-risk types (31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68) at clinically relevant infection levels.

For in vitro diagnostic use.

Proofer 7 HPV mRNA E6/E7 Biomarker Test

Intended Purpose

The Proofer-7 test is a Laboratory Developed Test (LDT) for the qualitative detection of the presence of HPV E6 and E7 oncogenes from carcinogenic high-risk HPV types 16, 18, 31, 33, 45, 52 and 58. The test is based on real-time NASBA technology.

Specimens are processed at Global Diagnostics Labs, a wholly owned subsidiary of Mel-Mont Medical, Inc. Results are expected within 12 days of sample collection and shipping.



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