



Women's Health

Professional Relationships, Personalized Services

Molecular Pathology Laboratory Network, Inc. (MPLN) delivers a comprehensive menu of molecular diagnostic tests and cytogenetic services for women's health. In addition, our pathologists and laboratory directors are readily available to offer diagnostic consultations and provide appropriate reflex testing options.

Liquid Cytology Testing

Test from a single liquid cytology specimen (ThinPrep® PAP solution or SurePath™ Test Pack) for:

- Cystic fibrosis (CF)
Detects 32 mutations, including the 23 core mutations recommended by the American College of Medical Genetics.
- Human papillomavirus (HPV) and HPV genotyping (HPV G)
- *Chlamydia trachomatis* (CT)
- *Neisseria gonorrhoeae* (NG)
- Herpes simplex virus (HSV)

ThromboFLEX Profile

Analyze a complete profile of factors simultaneously to detect risk for venous thrombosis and/or arterial thrombosis.

- Factor V Leiden (FVLEI)
- Factor II Prothrombin (F2PRO)
- Methylenetetrahydrofolate Reductase (MTHFR)
- Plasminogen Activator Inhibitor gene mutations (PAI)

Prenatal Cytogenetics

- Monitors the health of the unborn fetus
- Detects presence of congenital abnormalities or genetic disorders
- Provides information regarding risks for future pregnancies
- Predicts potential high-risk deliveries or impending fetal demise

Adjunct studies are also performed in addition to chromosomal analysis, including alpha fetoprotein and maternal serum quad screening.

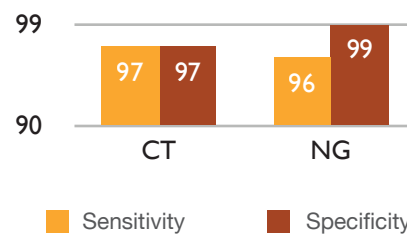
Complete Clinical Menu

MPLN's partner laboratory, Ascendant Medical Laboratory, can help clients provide a complete menu of clinical women's health testing to OB/GYN practices. Please call MPLN at 800.932.2943 for details.

CTNG Aptima Combo 2® Assay - Gen-Probe

Higher sensitivity, Greater specificity

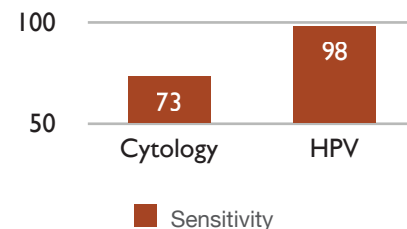
- FDA-cleared to detect CT and NG
- Second generation test eliminates inhibition and cross reactivity problems and minimizes equivocal results
- Three technologies: Target capture, transcription-mediated amplification, and dual kinetic assay



Rapid Capture® II for HPV HR - Qiagen

Primary adjunctive screen - ASC-US Triage

- FDA-cleared for HPV screening as a primary adjunctive screen for women 30 and older with a Pap test
- For ASC-US triage to colposcopy
- High negative predictive value for CIN 2/3 of 99-100%



HPV 16/18 Genotyping - Cervista

- Increases early detection of women at greatest risk for development of CIN3+ cervical cancer
- Cytology negative HPV HR positive women 30 years and older with HPV 16/18 can be referred to colposcopy sooner.



Test Name	Methodology	Specimen Requirements	CPT Codes
CT NG	APTIMA COMBO 2® Assay Gen-Probe	1mL liquid cytology media transferred to APTIMA specimen transfer (green) tube 3mL ThinPrep PAP or SurePath Test Pack One cervical or urethral swab (APTIMA Unisex Collection (white) tube kit) 2mL urine transferred to APTIMA Urine Collection (yellow) tube kit	87491, 87591
HPV HR	Rapid Capture® System Qiagen	4mL ThinPrep PAP or 2mL SurePath Test Pack 5mm ³ biopsy in Digene collection tube at -20°C Cervical or vaginal swab	87621
CT NG and HPV HR	See individual assays	7mL ThinPrep PAP or 8mL SurePath Test Pack	See individuals
HPV Genotype	Cervista HPV 16/18 by INVADER technology	2mL ThinPrep or SurePath Test Pack	83891, 83892 x4, 83896 x6, 83903 x2, 83908x2, 83912
HPV HR and HPV Genotype	See individual assays	6mL ThinPrep PAP or 4mL SurePath Test Pack	See individuals
CT NG and HPV HR and HPV Genotype	See individual assays	9mL ThinPrep PAP or 7mL SurePath Test Pack	See individuals
HSV I/II	Polymerase Chain Reaction (PCR)	2mL ThinPrep PAP or SurePath Test Pack 2mL CSF 4°C 2mL EDTA whole blood 4°C 5mm ³ fresh or frozen -20°C tissue Swab from any site 4°C	87529 x2
Cystic Fibrosis	PCR/Oligonucleotide Ligation Assay	2mL ThinPrep PAP or SurePath Test Pack 5mL EDTA (ACD) peripheral blood Two swabs - buccal 10-30mL amniotic fluid	83901, 83914, 83891, 83900, 83909, 83912

References

- Chernesky M et al. (2006). High Analytical Sensitivity and Low Rates of Inhibition May Contribute to Detection of Chlamydia trachomatis in Significantly More Women by the APTIMA Combo 2 Assay. J Clin Microbiol. 44(2):400-405.
- Chernesky et al. (2007). Abilities of APTIMA, AMPLICOR, and ProbeTec Assays to Detect Chlamydia trachomatis and Neisseria gonorrhoeae in PreservCyt ThinPrep Liquid based Pap samples. J Clin Microbiol. 45(8): 2355-2358.
- Khan MJ et al. (2005). The elevated 10-year risk of cervical precancer and cancer in women with human papillomavirus (HPV) type 16 or 18 and the possible utility of type-specific HPV testing in clinical practice. JNCI. 97:1072-1079.
- Welch D.F. (2007). Screening for Chlamydial and Gonorrheal Infections; Current Laboratory Approaches. Infections in Medicine.24(6): 266-270
- Wright et al. (2004). HPV Testing as adjunct to cytology. Obstet Gynecol. 103:2, 304-309.
- Wright TC et al. (2007). 2006 consensus guidelines for the management of women with abnormal cervical cancer screening tests. Am. J. Obstet. Gynecol. 197:346-355.6

Regulatory status

These tests are cleared by the FDA for IVD use with the following specimen types:

CTNG Aptima Combo 2 assay by Gen-Probe¹: endocervical, vaginal and urethral swabs, urine and specimens collected in Cytoc ThinPrep Pap Test PreservCyt® Solution.

HPV HR assay by Qiagen¹: hc2 DNA Collection Device, broom type collection device and placed in Cytoc ThinPrep Pap Test PreservCyt Solution and biopsies in Specimen Transport Medium™ (STM).

HPV 16/18 genotyping by Cervista¹: ThinPrep Pap Test PreservCyt Solution, Broom-type device or Endocervical Brush/Spatula. Cervista HPV 16/18 results are cleared for IVD use when interpreted in conjunction with the Cervista™ HPV HR test and cervical cytology test results.

Notes

- Cervical Specimens collected in SurePath Test Pack and tested for CTNG, HPV HR and HPV 16/18 have been validated by MPLN as an off-label laboratory determined test (LDT) under MPLN's high complexity CLIA license.

Trademarks

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Rapid Capture is a trademark of Qiagen Corporation. APTIMA Combo 2 is a trademark of Gen-Probe, Inc.