

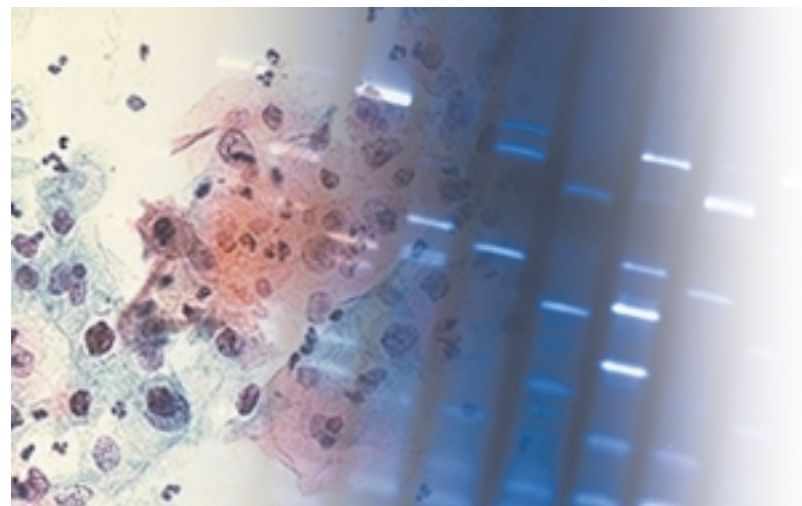
HUMAN PAPILLOMAVIRUS DETECTION AND GENOTYPING

HPVDetx[®]

HPVDetx[®] is a comprehensive service for the identification of HPV as a key risk factor in the development of cervical cancer. 2001 Guidelines from the American Society for Colposcopy and Cervical Pathology (ASCCP) recommend HPV DNA testing for the management of ASC-US pap results¹. Emerging guidelines additionally suggest the use of HPV DNA testing as a general screen performed in conjunction with routine Paps.

HIGH SCIENCE

- *Gold standard PCR methodology provides superior specificity and sensitivity^{2,3}*
- *Proven reduction in false positives common to other methods^{2,4}*
- *Specific identification for all known genital tract HPV genotypes:*
 - 30 High and High-Intermediate risk types⁵
 - 23 Low and Unknown risk types⁵
- *Addition or reclassification of HPV genotypes as new guidelines emerge*
- *Use of purified DNA ensures less than 1% failure rate from liquid cytology*
- *Internal control ensures presence of DNA in every sample, eliminating a common cause of false negatives*



ASC-H cytology slide pictured with PAGE Gel

SUPERIOR CUSTOMER SERVICE

- *Expertise in performing HPV testing on wide variety of specimen types including liquid cytology, traditional Pap, cytobrush, fresh or paraffin biopsy, dacron swab, and anal/urethral swabs*
- *Board Certified Molecular Geneticist and Pathologist available for consultation*
- *Rapid result turnaround time*
- *Single page, interpretive report*
- *Multiple billing options*

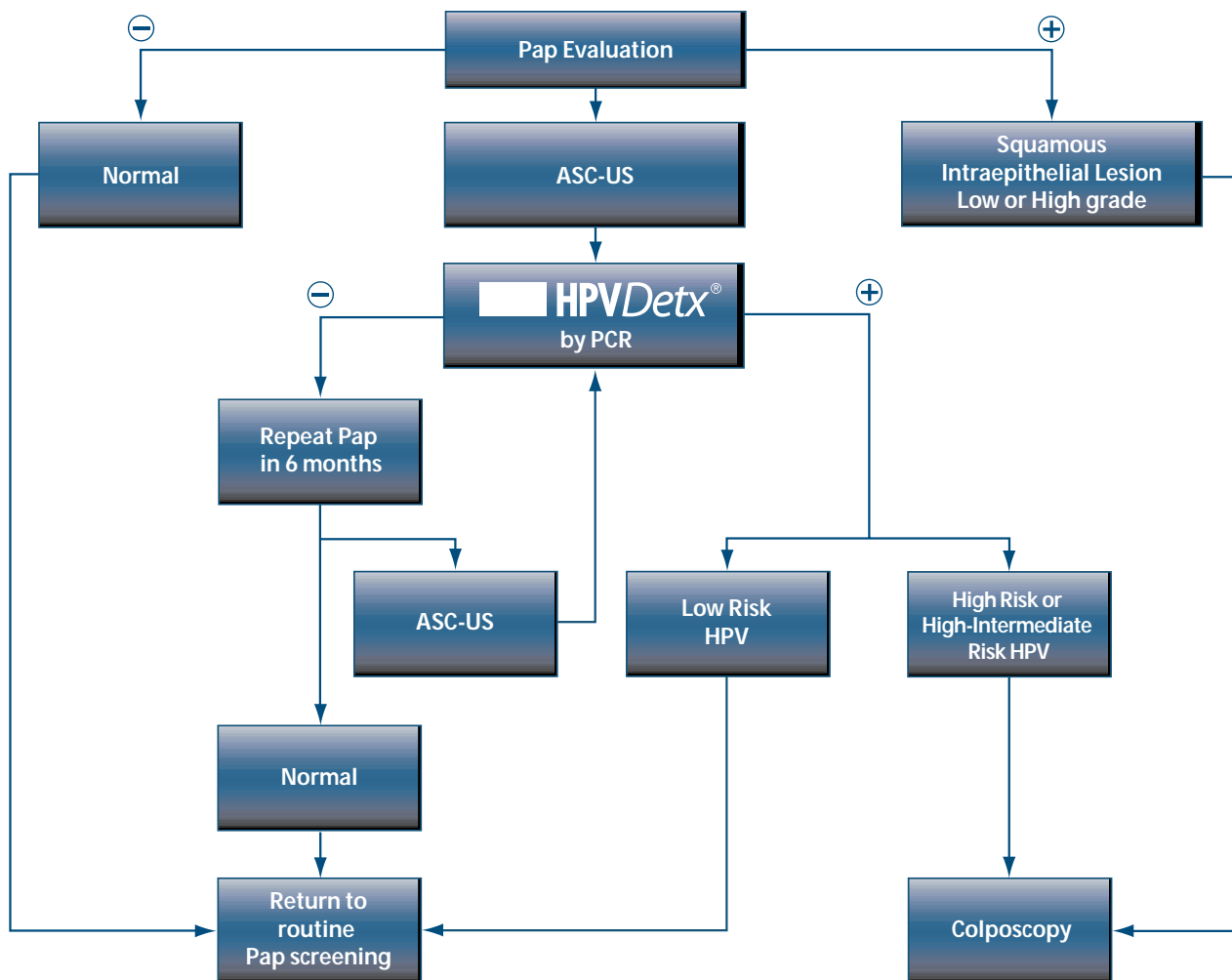
INNOVATION

- *High Risk only assessment option*
- *HPV and GC/CT testing from a single specimen*
- *Male sample testing*
- *HealthHorizons[™] – Patient information reports*
- *Medtrax[®] – Internet ordering and reporting*

HPV DNA TESTING RECOMMENDATIONS

In 2001, the American Society for Colposcopy and Cervical Pathology (ASCCP) updated the Bethesda System Terminology for cervical cytology to include HPV DNA testing as “the preferred approach” for the management of Paps with Atypical Squamous Cells of Undetermined Significance (ASC-US)¹. The American College of Obstetricians and Gynecologists (ACOG) made further recommendations in 2003 to include HPV DNA testing as a general screen performed in conjunction with cytology for women age 30 and older. Both of these new testing guidelines reflect a better understanding in recent years of HPV as a risk factor for the development of cervical cancer.

HPV DNA TESTING ALGORITHM
(based on ASCCP guidelines)



Test Code	128400
Test Name	HPVDetx® by PCR (comprehensive detection and genotyping for all human papillomavirus risk levels) Note: HPV positive samples will reflex for genotyping adding additional CPT codes
CPT Codes	Detection 83912, 83898, 83890, 83894 Positive Reflex (additional codes) 83892 x 3, 83894 x 3, 83903, 83912
Specimen Requirement	Conventional or liquid Pap smear sample, Cyto brush/cervical swab in sterile media (including saline or M4), or one (1) paraffin-embedded block of tissue. Store and ship with cool pack. Fresh tissue (0.5-1g) may also be submitted using transport media or dry ice.
Methodology	PCR-RFLP
Assay Time / Schedule	M-F / Cyto brush and liquid Pap solution: 4 - 7 days Traditional Pap, fresh or fixed tissue: 6 - 9 days

RELATED PAP REFLEX TESTING

TEST CODE	TEST NAME
128450	HPVDetx® High Risk Assesment by PCR
128402	HPVTritect™ by PCR (HPVDetx®, GC/CT)
128452	HPVTritect™ High Risk Assesment by PCR (HPVDetx® High Risk, GC/CT)
128403	GC/CTDetx™ by PCR
128404	Chlamydia trachomatis (CT) DNA by PCR
128405	GC DNA by PCR (Neisseria gonorrhoeae)

***For more information or to obtain a supply kit,
please call 800.444.9111 or visit www.esoterix.com.***

REFERENCE/ENDNOTES:

1. Wright T, Cox T, Massad L, Twigg L, Wilkinson E. 2001 Consensus Guidelines for the Management of Women With Cervical Cytological Abnormalities, JAMA, April 24th, 2002 – Vol 287, No. 16.
2. Castle PE, Schiffman M, Gravitt PE, et al. Comparisons of HPV DNA detection by MY09/11 PCR methods. Journal of Medical Virology. 2002; 68:417-23.
3. Johnson T, Bryder K, Corbet S, Fomsgaard A. Routine genotyping of human papillomavirus samples in Denmark. Apmis 2003;111(3):398-404.
4. Digene Corp. Digene HPV DNA Test Hybrid Capture 2 Package Insert, 2002.
5. A comprehensive list of references is available for all HPV genotypes upon request.
6. Crum CP. Type-specific testing for human papillomavirus. [comment]. New England Journal of Medicine 2003;349(6):614-5.
7. McGlennen R. Human papillomavirus oncogenesis. Clin Lab Med. 2000; 20:383-406
8. Munoz N, Bosch FX, de Sanjose S, Herrero R, Castellsague X, Shah KV, Snijders PJ, Meijer CJ; International Agency for Research on Cancer Multicenter Cervical Cancer Study Group. Epidemiologic classification of human papillomavirus types associated with cervical cancer. N Engl J Med. 2003 Feb 6;348(6):518-27.

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