Lenco
DIAGNOSTIC LABRATORY
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Date: August 14, 2018

Laboratory Update:

Onclarity™ HPV - Surepath

HIGHLIGHTS

- *Multiplexed FDA-approved PCR assay for detection of 14 high risk HPV genotypes.*
- *Utilizing E6/E7 target*

"Committed to Excellence"

Lenco Laboratory is pleased to announce we now offer Onclarity™ HPV. Performed from SurePath™ this multi-genotype FDA-approved HPV assay that will eclipse legacy diagnostic assays.

BACKGROUND

Human Papillomavirus (HPV) can cause certain cancers and diseases in both males and females. HPV often has no signs or symptoms, thus many people who have the virus don't know they are infected. There are over 100 types of HPV with at least 40 of them that can infect the genital area. Of those, 14 cause the majority of HPV-related cancers and diseases. [1]

USING EPI PROCOLON IN YOUR CLINICAL PRACTICE

Onclarity™ HPV allows clinicians to receive more actionable information, faster with separate on-demand reporting of high risk genotypes 16, 18 and 45 without any additional lab testing required.[2] It is a multiplexed real-time PCR assay for the qualitative detection of the 14 high risk HPV genotypes. It utilizes the E6/E7 target and each patient test incorporates a human beta globin internal control for the highest confidence when reporting negative test results. [2]

Onclarity™ HPV is the companion assay to the SurePath™ Pap test. Many clinicians insist on running both tests (co-testing) as best practice for their cervical cancer screening needs. Guidelines also permit ASCUS reflex testing where the Pap test is run first, and HPV subsequently ordered in the instances where cellular abnormalities are present and indicate the need for further investigation.

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If you have any questions about this important change, or any other provider information, please don't hesitate to contact your representative or our Client Service Department at 718-232-1515, Ext 9. Once again, we thank you for your friendship, and your trust.

Best Regards,

Dr. Elena Agranovsky
Medical Director

TEST NAME:	BD Viper LT HPV Test
TEST NUMBER:	5009
COLLECTION:	Pap sample collected with a cytobroom, cytobrush, or spatula; Cytobroom, cytobrush, or spatula tip submitted in a SurePath collection vial.
CONTAINER:	SurePath vial
TRANSPORT/STABILITY:	Refrigerated up to 30 days
REJECTION:	Expired specimen; Improper specimen collection
DAYS SET UP:	Thursday, Friday
EXPECTED TAT:	7 days
METHOD:	Real-time PCR
CPT CODE(S):	87621

References:

1. BD Onclarity HPV Assay Package Insert US label no. 8089894
2. HPV.com (Merck 2018)
3. https://www.cancer.gov/types/cervical/pap-hpv-testing-fact-sheet#q5 (Aug 2018)