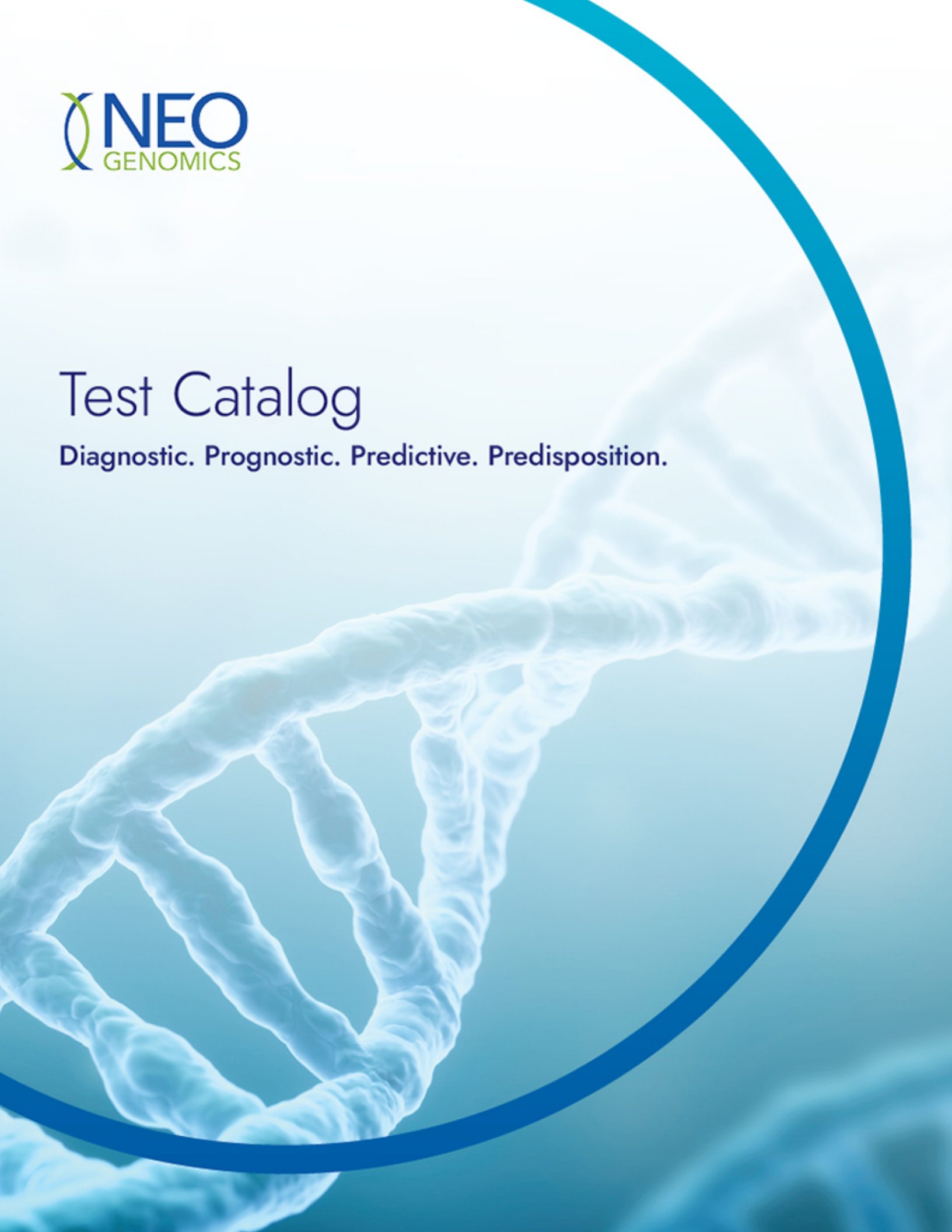
NEO GENOMICS

# Test Catalog

**Diagnostic. Prognostic. Predictive. Predisposition.**



# HPV RNA ISH

## Alternative Name
HPV RNA ISH 16/18, HPV RNA ISH High Risk Cocktail, HPV RNA ISH Low Risk Cocktail

## Methodology
In Situ Hybridization (ISH)

## Test Description
In situ hybridization on FFPE tissues for qualitative detection of E6/E7 mRNA in up to 28 HPV subtypes with the complete panel: low risk (10 subtypes: 6, 11, 40, 43, 44, 54, 69, 70, 71, 74) plus high risk (18 subtypes: 16, 18, 26, 31, 33, 35, 39, 45, 51, 52, 53, 56, 58, 59, 66, 68, 73, 82). Testing with the complete panel is recommended, but orders for partial panels are accepted. Orderable components are (1) 16/18 High Risk; (2) High Risk Cocktail with all of the previously-named high risk subtypes; and (3) Low Risk Cocktail with all previously-named low risk subtypes. Reports will identify which component or cocktail is positive, but will not identify specific subtypes as positive. Testing is performed only on a global or consult basis at this time.

## Clinical Significance
This test provides detection of human papilloma virus E6/E7 mRNA, histological localization of HPV within the tissue, and differentiation of low-risk vs. high-risk subtypes in formalin-fixed paraffin-embedded tissues. Positive results in this assay provide evidence of transcriptional activation of viral E6/E7 oncogenes and support the diagnosis of active infection. Studies have shown RNA ISH to have greater sensitivity and specificity than DNA ISH for HPV detection. RNA ISH may be useful in resolving cases with p16 overexpression that tested negative for HPV DNA by other methods. Testing is commonly performed on tissues of the uterine cervix, anus, and head and neck, particularly the oropharynx. HPV ISH may help resolve cervical cases with morphology discrepant from HPV status as determined from cytology specimens. Positive HPV status is associated with improved overall survival in oropharyngeal squamous cell carcinoma.

## Specimen Requirements
- **Cut Slides:** Block is preferred over cut slides. Send 9-11 cut slides (minimum is 9) plus one H&E slide. Sections must be wrinkle and artifact-free. No additives in the water bath. Cut sections at 4-5 microns, and place tissue at the center bottom of a positively-charged slide.
- **Paraffin block:** Formalin-fixed paraffin-embedded tissue. Block should be sent with a cold pack. Block identifiers should be clearly written and match exactly with the specimen ID and the block labeling as noted on the requisition.
- **Note:** This test is not available on samples in ThinPrep® or SurePath™ Pap vials.

## Storage & Transportation
Use cold pack for transport, making sure cold pack is not in direct contact with specimen.

## CPT Code(s)*
Complete panel (16/18, high risk cocktail, and low risk cocktail): 88365x1, 88364x2. Partial panel: 88365x1 for first component/cocktail, 88364x1 for second component/cocktail.

## New York Approved

Yes

## Level of Service

Global

## Turnaround Time

5 days

*The CPT codes provided with our test descriptions are based on AMA guidelines and are for informational purposes only. Correct CPT coding is the sole responsibility of the billing party.

Please direct any questions regarding coding to the payor being billed.

NeoGenomics Laboratories is a specialized oncology reference laboratory providing the latest technologies, testing partnership opportunities, and interactive education to the oncology and pathology communities. We offer the complete spectrum of diagnostic services in molecular testing, FISH, cytogenetics, flow cytometry, and immunohistochemistry through our nation-wide network of CAP-accredited, CLIA-certified laboratories.

Committed to research as the means to improve patient care, we provide Pharma Services for pharmaceutical companies, in vitro diagnostic manufacturers, and academic scientist-clinicians. We promote joint publications with our client physicians. NeoGenomics welcomes your inquiries for collaborations. Please contact us for more information.

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