Test Definition: HPVHR
HPV High-Risk ONLY DNA ISH

Overview

Useful For
Detection of human papillomavirus DNA from high-risk genotypes (16, 18, 31, 33, and 51)

Testing Algorithm
Human papillomavirus (HPV) High Risk E6/E7 RNA ISH could be performed and reported at the discretion of the Mayo pathologist if clinically indicated but will not be billed separately.

Method Name
In Situ Hybridization

NY State Available
Yes

Specimen

Specimen Type
Special

Additional Testing Requirements
If additional interpretation or analysis is needed, request PATHC / Pathology Consultation along with this test.

The probe set used in this human papillomavirus (HPV) DNA in situ hybridization (ISH) test cannot detect all potential HPV serotypes that are associated with oropharyngeal squamous cell carcinoma. If this test is negative, a more sensitive test, Human Papillomavirus (HPV) High Risk E6/E7 RNA In Situ Hybridization, could be performed and reported if clinically indicated but will not be billed separately.

Shipping Instructions
Attach the green pathology address label included in the kit to the outside of the transport container.

Necessary Information
A pathology/diagnostic report and a brief history are required.

Specimen Required

Supplies: Pathology Packaging Kit (T554)

Specimen Type: Formalin-fixed, paraffin-embedded tissue block

Specimen Volume: Entire block

Specimen Type: Slides

Slides: 5 unstained glass, positively charged slides with 5 (+ or - 1)-microns formalin-fixed, paraffin-embedded tissue

Forms
If not ordering electronically, complete, print, and send 1 of the following forms with the specimen:
Test Definition: HPVHR
HPV High-Risk ONLY DNA ISH

-Oncology Test Request (T729)

-Immunohistochemical (IHC)/In Situ Hybridization (ISH) Stains Request (T763)

Reject Due To

<table>
<thead>
<tr>
<th>Tissue/Other</th>
<th>Wet/frozen tissue</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Cytology smears</td>
</tr>
<tr>
<td></td>
<td>Nonformalin fixed tissue</td>
</tr>
<tr>
<td></td>
<td>Nonparaffin embedded tissue</td>
</tr>
<tr>
<td></td>
<td>Noncharged slides</td>
</tr>
<tr>
<td></td>
<td>ProbeOn slides</td>
</tr>
</tbody>
</table>

Specimen Stability Information

<table>
<thead>
<tr>
<th>Specimen Type</th>
<th>Temperature</th>
<th>Time</th>
<th>Special Container</th>
</tr>
</thead>
<tbody>
<tr>
<td>Special</td>
<td>Ambient (preferred)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Refrigerated</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Clinical and Interpretive

Clinical Information
Persistent infections with high-risk human papillomavirus (HPV) genotypes (16, 18, 31, 33, and 51) are associated with cervical, vaginal, vulvar, and head and neck malignancies. Patients with HPV-related oropharyngeal squamous cell carcinoma (OPSCC) have shown better disease-specific survival and overall survival when compared to HPV-negative cases of OPSCC.

Interpretation
This test, when not accompanied by a pathology consultation request, will be answered as either positive or negative. If additional interpretation or analysis is needed, request PATHC / Pathology Consultation along with this test.

Cautions
No significant cautionary statements

Clinical Reference


Performance
Method Description
In situ hybridization on sections of paraffin-embedded tissue. (Unpublished Mayo method)

PDF Report
No

Day(s) and Time(s) Test Performed
Monday through Friday

Analytic Time
5 days

Maximum Laboratory Time
7 days

Specimen Retention Time
Until staining is complete.

Performing Laboratory Location
Rochester

Fees and Codes

Fees
- Authorized users can sign in to Test Prices for detailed fee information.
- Clients without access to Test Prices can contact Customer Service 24 hours a day, seven days a week.
- Prospective clients should contact their Regional Manager. For assistance, contact Customer Service.

Test Classification
This test was developed and its performance characteristics determined by Mayo Clinic in a manner consistent with CLIA requirements. This test has not been cleared or approved by the U.S. Food and Drug Administration.

CPT Code Information
88365-Primary

88364-If additional ISH

LOINC® Information

<table>
<thead>
<tr>
<th>Test ID</th>
<th>Test Order Name</th>
<th>Order LOINC Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>HPVHR</td>
<td>HPV High-Risk ONLY DNA ISH</td>
<td>49896-4</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Result ID</th>
<th>Test Result Name</th>
<th>Result LOINC Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>71194</td>
<td>Interpretation</td>
<td>50595-8</td>
</tr>
<tr>
<td>71195</td>
<td>Participated in the Interpretation</td>
<td>No LOINC Needed</td>
</tr>
<tr>
<td>71196</td>
<td>Report electronically signed by</td>
<td>19139-5</td>
</tr>
<tr>
<td>71198</td>
<td>Material Received</td>
<td>81178-6</td>
</tr>
<tr>
<td>Result ID</td>
<td>Test Result Name</td>
<td>Result LOINC Value</td>
</tr>
<tr>
<td>-----------</td>
<td>------------------</td>
<td>--------------------</td>
</tr>
<tr>
<td>71593</td>
<td>Disclaimer</td>
<td>62364-5</td>
</tr>
<tr>
<td>72111</td>
<td>Case Number</td>
<td>80398-1</td>
</tr>
</tbody>
</table>