Overview

Useful For
Aids in the identification of human papilloma virus infection

Reflex Tests

<table>
<thead>
<tr>
<th>Test ID</th>
<th>Reporting Name</th>
<th>Available Separately</th>
<th>Always Performed</th>
</tr>
</thead>
<tbody>
<tr>
<td>IHTOI</td>
<td>IHC Initial, Tech Only</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>IHTOA</td>
<td>IHC Additional, Tech Only</td>
<td>No</td>
<td>No</td>
</tr>
</tbody>
</table>

Testing Algorithm
For the initial technical component only immunohistochemical (IHC) stain performed, the appropriate bill-only test ID will be reflexed and charged (IHTOI). For each additional technical component only IHC stain performed, an additional bill-only test ID will be reflexed and charged (IHTOA).

Method Name
Immunohistochemistry

NY State Available
Yes

Specimen

Specimen Type
TECHONLY

Advisory Information
This test includes only technical performance of the stain (no pathologist interpretation is performed). If diagnostic consultation by a pathologist is required order PATHC / Pathology Consultation.

Shipping Instructions
Attach the green pathology address label and the pink Immunostain Technical Only label included in the kit to the outside of the transport container.

Specimen Required

Supplies: Immunostain Technical Only Envelope (T693)

Specimen Type: Tissue

Preferred: 2 Unstained positively charged glass slide (25- x 75- x 1-mm) per test ordered; sections 4-microns thick.

Acceptable: Formalin-fixed, paraffin-embedded (FFPE) tissue block

Digital Image Access
1. Information on accessing digital images of immunohistochemical (IHC) stains and the manual requisition form can
Test Definition: P16
p16 (INK4a/CDKN2A) IHC, Tech Only

be accessed through this website: www.mayocliniclabs.com/test-info/ihc/index.html

2. Clients ordering stains using a manual requisition form will not have access to digital images.

3. Clients wishing to access digital images must place the order for IHC stains electronically. Information regarding digital imaging can be accessed through this website: www.mayocliniclabs.com/test-info/ihc/faq.html

Forms
If not ordering electronically, complete, print, and send a Immunohistochemical (IHC)/In Situ Hybridization (ISH) Stains Request (T763) with the specimen.

Reject Due To

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

Specimen Stability Information

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

Clinical and Interpretive

Clinical Information

p16 (INK4a/CDKN2A) is a cell cycle regulatory protein that is overexpressed in cervical dysplasia related to human papilloma virus (HPV) infection. Nuclear and cytoplasmic staining is seen in dysplastic squamous cervical epithelial cells infected with HPV, but not in normal cells. A subset of pancreatic islet cells and dendritic cells show expression of p16, and can serve as positive control.

Interpretation

This test includes only technical performance of the stain (no pathologist interpretation is performed). Mayo Clinic cannot provide an interpretation of tech only stains outside the context of a pathology consultation. If an interpretation is needed, refer to PATHC / Pathology Consultation for a full diagnostic evaluation or second opinion of the case. All material associated with the case is required. Additional specific stains may be requested as part of the pathology consultation, and will be performed as necessary at the discretion of the Mayo pathologist.

The positive and negative controls are verified as showing appropriate immunoreactivity and documentation is retained at Mayo Clinic Rochester. If a control tissue is not included on the slide, a scanned image of the relevant quality control tissue is available upon request. Contact 855-516-8404.

Interpretation of this test should be performed in the context of the patient's clinical history and other diagnostic tests by a qualified pathologist.
Cautions
Age of a cut paraffin section can affect immunoreactivity. Stability thresholds vary widely among published literature and are antigen-dependent. Best practice is for paraffin sections to be cut fresh.

Clinical Reference

2. Doxtader EE, Katzenstein AL: The relationship between p16 expression and high-risk human papillomavirus infection in squamous cell carcinomas from sites other than uterine cervix: a study of 137 cases. Human Pathol 2012;43:327-332


Performance

Method Description
Immunohistochemistry on sections of paraffin-embedded tissue.(Unpublished Mayo method)

PDF Report
No

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

Analytic Time
1 day

Maximum Laboratory Time
3 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.
Test Definition: P16
p16 (INK4a/CDKN2A) IHC, Tech Only

- 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 has been modified from the manufacturer's instructions. Its performance characteristics were 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
88342-TC, primary
88341-TC, if additional IHC

LOINC® Information

<table>
<thead>
<tr>
<th>Test ID</th>
<th>Test Order Name</th>
<th>Order LOINC Value</th>
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<tbody>
<tr>
<td>P16</td>
<td>p16 (INK4a/CDKN2A) IHC, Tech Only</td>
<td>Order only; no result</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Result ID</th>
<th>Test Result Name</th>
<th>Result LOINC Value</th>
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</thead>
<tbody>
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<td>70836</td>
<td>p16 (INK4a/CDKN2A) IHC, Tech Only</td>
<td>Bill only; no result</td>
</tr>
</tbody>
</table>