Overview

Useful For

Aids in diagnosing oligodendroglioma tumors and predicting the response of an oligodendroglioma to therapy

May be useful in tumors with a complex "hybrid" morphology requiring differentiation from pure astrocytomas to support the presence of oligodendrogial differentiation/lineage

Indicated when a diagnosis of oligodendroglioma, both low-grade World Health Organization (WHO, grade II) and anaplastic (WHO, grade III) is rendered

Strongly recommended when a diagnosis of mixed oligoastrocytomas is rendered

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>_I099</td>
<td>Interphases, 25-99</td>
<td>No, (Bill Only)</td>
<td>No</td>
</tr>
<tr>
<td>_I300</td>
<td>Interphases, &gt;=100</td>
<td>No, (Bill Only)</td>
<td>No</td>
</tr>
<tr>
<td>_IL25</td>
<td>Interphases,</td>
<td>No, (Bill Only)</td>
<td>No</td>
</tr>
<tr>
<td>_PADD</td>
<td>Probe, +1</td>
<td>No, (Bill Only)</td>
<td>No</td>
</tr>
<tr>
<td>_PB02</td>
<td>Probe, +2</td>
<td>No, (Bill Only)</td>
<td>No</td>
</tr>
<tr>
<td>_PB03</td>
<td>Probe, +3</td>
<td>No, (Bill Only)</td>
<td>No</td>
</tr>
<tr>
<td>_PBCT</td>
<td>Probe, +2</td>
<td>No, (Bill Only)</td>
<td>No</td>
</tr>
</tbody>
</table>

Testing Algorithm

This test does not include a pathology consult. If a pathology consultation is requested, PATHC / Pathology Consultation should be ordered and the appropriate FISH test will be ordered and performed at an additional charge.

This test includes a charge for application of the first probe set (2 FISH probes) and professional interpretation of results. Additional charges will be incurred for all reflex probes performed. Analysis charges will be incurred based on the number of cells analyzed per probe set. If no cells are available for analysis, no analysis charges will be incurred.

Chromosomal microarray (CMA/PT / Chromosomal Microarray, Tumor, Formalin-Fixed Paraffin-Embedded), rather than FISH, may be of benefit to evaluate for acquired alterations associated with the molecular classification of glioma. See Cytogenetic Analysis of Glioma in Special Instructions.

Special Instructions

- Incidence of 1p and 19q Losses versus Glioma Subtype and Primary Status
- Cytogenetic Analysis of Glioma

Method Name

Fluorescence In Situ Hybridization (FISH) Using DNA Probes

NY State Available

Yes
Test Definition: GLIOF
1p/19q Deletion, Glioma, FISH, Ts

Specimen

Specimen Type
Tissue

Shipping Instructions
Advise Express Mail or equivalent if not on courier service.

Necessary Information
A reason for referral and pathology report are required in order for testing to be performed. Send information with specimen. Acceptable pathology reports include working drafts, preliminary pathology or surgical pathology reports.

Specimen Required
Submit only 1 of the following specimens:

Specimen Type: Tissue

Preferred: Tissue block

Collection Instructions: Submit a formalin-fixed, paraffin-embedded (FFPE) tumor tissue block. Blocks prepared with alternative fixation methods may be acceptable; provide fixation method used.

Acceptable: Slides

Collection Instructions: Six consecutive, unstained, 5 micron-thick sections placed on positively charged slides, and 1 hematoxylin and eosin-stained slide.

Forms
If not ordering electronically, complete, print, and send an Oncology Test Request (T729) with the specimen.

Specimen Minimum Volume
Four consecutive, unstained, 5-micron-thick sections placed on positively charged slides and 1 hematoxylin and eosin-stained slide

Reject Due To
All specimens will be evaluated at Mayo Clinic Laboratories for test suitability.

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>Tissue</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
Astrocytomas, oligodendrogliomas, and mixed oligoastrocytomas are the major histologic types of human gliomas; histologic differentiation among these tumors can be difficult. It has been shown that specific genetic alterations are highly associated with specific morphologic types of gliomas. In addition, specific genetic alterations seem to predict prognosis (survival), as well as response to specific chemotherapeutic and radiotherapeutic regimens, irrespective of tumor morphology.

Deletions of the short arm of chromosome 1(1p) and long arm of chromosome 19 (19q), are strongly correlated with gliomas of oligodendrogial morphology. Approximately 70%, 50%, and 50% of oligodendrogliomas have deletions of 19q, 1p, and of both 19q and 1p, respectively.

Combined 1p and 19q loss is infrequent in gliomas of astrocytic origin. Thus, the presence of combined 1p/19q loss is strongly suggestive that a glioma is of oligodendrogloma lineage.

Gains of chromosome 19 and of the 19 q-arm are associated with gliomas of astrocytic origin.

Deletions of 1p and of both 1p and 19q also have been associated with response to various chemotherapeutic and radiotherapeutic regimens. These responses have been especially associated with high-grade oligodendrogliomas (anaplastic oligodendrogliomas).

Chromosomal microarray (CMA/ Chromosomal Microarray, Tumor, Formalin-Fixed Paraffin-Embedded), rather than FISH, may be of benefit to evaluate for acquired alterations associated with the molecular classification of glioma. See Cytogenetic Analysis of Glioma in Special Instructions.

Reference Values
An interpretive report will be provided.

Interpretation
The presence of 1p deletion and combined 1p and 19q deletion supports a diagnosis of oligodendroglioma may indicate that the patient may respond to chemotherapy and radiation therapy.

The presence of gain of chromosome 19 supports a diagnosis of high-grade astrocytoma (glioblastoma multiforme).

A negative result does not exclude a diagnosis of oligodendroglioma or high-grade astrocytoma.

Cautions
This test is not approved by the US FDA, and it is best used as an adjunct to existing clinical and pathologic information.

Supportive Data
See Incidence of 1p and 19q Losses Versus Glioma Subtype and Primary Status in Special Instructions. The table summarizes the incidence of 1p deletion, 19q deletion, and combined 1p and 19q deletion in a series of tumors from Mayo Clinic and Johns Hopkins University. The laboratory also has detected a similar incidence of 1p and 19q deletions in a series of 189 high-grade oligodendrogliomas from patients enrolled in a Radiation Therapy Oncology Group (RTOG) trial.

Clinical Reference

Performance

Method Description
The test uses 2 commercially available enumeration strategy probe sets: 1p36(TP73)/1q25(ABL2) and 19p13(D19S221)/19q13.3(EHD2). Formalin-fixed paraffin-embedded tissues are cut at 5 microns and mounted on positively charged glass slides. The selection of tissue and the identification of target areas on the hematoxylin and eosin (H and E)-stained slide is performed by a pathologist. Using the H and E-stained slide as a reference, target areas are etched with a diamond-tipped etcher on the back of the unstained slide to be assayed. The probe sets are hybridized to the appropriate target areas. For each probe set, 2 technologists each analyze 50 interphase nuclei (100 total for each probe set) with the results expressed as a ratio of the total number of 1p36:1q and 19q13.3:19p signals.(Unpublished Mayo method)

PDF Report
No

Day(s) and Time(s) Test Performed
Samples processed Monday through Sunday.

Results reported Monday through Friday; 8 a.m.-5 p.m.

Analytic Time
8 days

Maximum Laboratory Time
12 days

Specimen Retention Time
Slides and H&E used for analysis are retained by the laboratory in accordance to CAP and NYS requirements. Client provided paraffin blocks and extra unstained slides (if provided) will be returned after testing is complete.

Performing Laboratory Location
Test Definition: GLIOF
1p/19q Deletion, Glioma, FISH, Ts

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 using an analyte specific reagent. 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

88271x2, 88291- DNA probe, each (first probe set), Interpretation and report

88271x2- DNA probe, each; each additional probe set (if appropriate)

88271x1- DNA probe, each; coverage for sets containing 3 probes (if appropriate)

88271x2- DNA probe, each; coverage for sets containing 4 probes (if appropriate)

88271x3- DNA probe, each; coverage for sets containing 5 probes (if appropriate)

88274- w/modifier 52- Interphase in situ hybridization, <25 cells, each probe set (if appropriate)

88274- Interphase in situ hybridization, 25 to 99 cells, each probe set (if appropriate)

LOINC® Information

<table>
<thead>
<tr>
<th>Test ID</th>
<th>Test Order Name</th>
<th>Order LOINC Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>GLIOF</td>
<td>1p/19q Deletion, Glioma, FISH, Ts</td>
<td>In Process</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>52107</td>
<td>Result Summary</td>
<td>50397-9</td>
</tr>
<tr>
<td>52109</td>
<td>Interpretation</td>
<td>69965-2</td>
</tr>
<tr>
<td>52108</td>
<td>Result</td>
<td>62356-1</td>
</tr>
<tr>
<td>CG739</td>
<td>Reason For Referral</td>
<td>42349-1</td>
</tr>
<tr>
<td>52110</td>
<td>Specimen</td>
<td>31208-2</td>
</tr>
<tr>
<td>52111</td>
<td>Source</td>
<td>31208-2</td>
</tr>
<tr>
<td>52112</td>
<td>Tissue ID</td>
<td>80398-1</td>
</tr>
<tr>
<td>52113</td>
<td>Method</td>
<td>49549-9</td>
</tr>
<tr>
<td>54579</td>
<td>Additional Information</td>
<td>48767-8</td>
</tr>
<tr>
<td>53836</td>
<td>Disclaimer</td>
<td>62364-5</td>
</tr>
</tbody>
</table>

Document generated February 6, 2021 at 2:25pm CST
<table>
<thead>
<tr>
<th>Result ID</th>
<th>Test Result Name</th>
<th>Result LOINC Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>52114</td>
<td>Released By</td>
<td>18771-6</td>
</tr>
</tbody>
</table>