Overview

Useful For
As a prognostic factor for patients with neuroblastoma
As an aid to treatment decisions in some patients with neuroblastoma

Reflex Tests

<table>
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<th>Test ID</th>
<th>Reporting Name</th>
<th>Available Separately</th>
<th>Always Performed</th>
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Testing Algorithm
This test does not include a pathology consultation. 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.

This assay detects MYCN amplification observed in paraffin-embedded tissue from patients being evaluated for a neuroblastoma. For testing blood or bone marrow, order MNBF / Neuroblastoma, 2p24 (MYCN) Amplification, FISH, Blood or Bone Marrow.

Method Name
Fluorescence In Situ Hybridization (FISH)

NY State Available
Yes

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: Four 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
Two 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>
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<tr>
<th>Specimen Type</th>
<th>Temperature</th>
<th>Time</th>
<th>Special Container</th>
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<tbody>
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<td>Tissue</td>
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<tr>
<td></td>
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Clinical and Interpretive

Clinical Information
Neuroblastoma is a solid tumor that occurs in early childhood and is usually found in the adrenal glands, but rarely is found in other areas of the body. Approximately 25% of all neuroblastomas have amplification of the \( MYCN \) oncogene, located on chromosome 2 at p24.1. Amplification of the \( MYCN \) oncogene correlates with an unfavorable prognosis and aggressive disease.

This test is not diagnostic for neuroblastoma. Other tumors including medulloblastoma, retinoblastoma, astrocytoma,
and small cell lung cancer may have amplification of MYCN.

**Reference Values**

An interpretive report will be provided.

**Interpretation**

MYCN gene amplification is detected when the percent of cells with an abnormality exceeds the normal cutoff for the MYCN probe.

A positive result is consistent with MYCN gene amplification.

A negative result suggests no MYCN gene amplification. However, this result does not exclude the diagnosis of neuroblastoma.

**Cautions**

This test is not approved by the U.S. Food and Drug Administration and is best used as an adjunct to existing clinical and pathologic information.

Fixatives other than formalin (eg, Prefer, Bouin's) may not be successful for FISH assays, however nonformalin-fixed samples will not be rejected.

Paraffin-embedded tissues that have been decalcified are generally unsuccessful for FISH analysis. The pathologist reviewing the hematoxylin and eosin-stained slide may find it necessary to cancel testing.

**Supportive Data**

FISH analysis was performed on 52 formalin-fixed, paraffin-embedded specimens, including 22 neuroblastoma specimens from 17 patients, 20 normal adrenal glands, and 10 Wilm's tumors. Of the 22 neuroblastoma specimens, 2 exhibited MYCN amplification and 20 were within normal limits. Fourteen of the neuroblastoma specimens were previously tested by Southern blot analysis and the 2 cases exhibiting amplification by FISH were also shown to be amplified by Southern blot. The remaining 12 specimens were normal by both FISH and Southern blot analysis. All 20 normal adrenal glands and 9 of the Wilm's tumors were within normal limits. One of the Wilm's tumors exhibited duplication of MYCN. A different mechanism is responsible for duplication of the MYCN oncogene and does not lead to MYCN protein overexpression.

**Clinical Reference**

1. World Health Organization Classification of Tumours. Pathology and Genetics of Tumours of Soft Tissue and Bone. Edited by CDM Fletcher, K Unni, F Mertens: IARC:Lyon 2002, pp 150-152


Test Definition: MYCNF
MYCN, Neuroblastoma, FISH, Ts


### Performance

#### Method Description

The test is performed using a commercially available probe set for MYCN and the centromere region of chromosome 2 (D2Z1). 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 set is hybridized to the appropriate target areas and 2 technologists each analyze 30 interphase nuclei (60 cells) with the results expressed as a ratio of the total number of MYCN signals compared to the total number of D2Z1 control probe signals. (Unpublished Mayo method)

#### PDF Report

No

#### Day(s) and Time(s) Test Performed

Specimens are processed Monday through Sunday.

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

#### Analytic Time

7 days

#### Maximum Laboratory Time

10 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

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 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 Δçà,¬â€œ DNA probe, each (first probe set), Interpretation and report
88271x2 Δçà,¬â€œ DNA probe, each; each additional probe set (if appropriate)
88271x1 Δçà,¬â€œ DNA probe, each; coverage for sets containing 3 probes (if appropriate)
88271x2 Δçà,¬â€œ DNA probe, each; coverage for sets containing 4 probes (if appropriate)
88271x3 Δçà,¬â€œ DNA probe, each; coverage for sets containing 5 probes (if appropriate)
88274 w/modifier 52 Δçà,¬â€œ Interphase in situ hybridization, <25 cells, each probe set (if appropriate)
88274 Δçà,¬â€œ Interphase in situ hybridization, 25 to 99 cells, each probe set (if appropriate)
88275 Δçà,¬â€œ Interphase in situ hybridization, 100 to 300 cells, each probe set (if appropriate)

LOINC® Information

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