



Test Definition: DLL3

Delta-Like 3 Protein (SP347),
Semi-Quantitative Immunohistochemistry,
Manual, Tissue

Overview

Useful For

Diagnosis of small cell lung carcinoma (SCLC), large cell neuroendocrine carcinoma (LCNEC), amongst other tumors

Method Name

Immunohistochemistry (IHC)

NY State Available

Yes

Specimen

Specimen Type

Special

Shipping Instructions

Attach the green "Attention Pathology" address label (T498) to the outside of the transport container before putting into the courier mailer.

Necessary Information

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

Specimen Required

A minimum of 100 tumors cells are required for interpretation of DLL3 expression.

Specimen Type: Tissue

Supplies: Pathology Packaging Kit (T554)

Submit:

Formalin-fixed, paraffin-embedded tissue block

OR

3 Unstained glass, "positively charged" slides with 4-microns formalin-fixed, paraffin-embedded tissue

Additional Information: One slide will be stained with hematoxylin and eosin and returned.

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

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| | |
|---|--------|
| Wet/frozen tissue | Reject |
| Decalcified paraffin embedded tissue | Reject |
| Cytology smears | Reject |
| Nonformalin fixed tissue including alcohol-formalin-acetic acid (AFA), 95% ethanol, PREFER fixatives or zinc formalin | Reject |
| Nonparaffin embedded tissue | Reject |
| Noncharged slides | Reject |
| ProbeOn slides | Reject |
| Snowcoat slides | Reject |

Specimen Stability Information

| Specimen Type | Temperature | Time | Special Container |
|---------------|---------------------|------|-------------------|
| Special | Ambient (preferred) | | |
| | Refrigerated | | |

Clinical & Interpretive

Clinical Information

Delta-like 3 protein (DLL3) is an atypical Notch ligand induced by the neuroendocrine transcription factor, ASCL-1. DLL3 is expressed on the cell membrane and in the cytoplasm of tumor cells.

Reference Values

An interpretive report will be provided.

Interpretation

Positivity for delta-like 3 protein is determined by immunoreactivity of any tumor cells within a specimen with an intensity ranging from 1 to 3+.

Cautions

A minimum of 100 tumor cells must be present for interpretation. If criterion is not met, DLL3 expression cannot be evaluated following testing.

This test has been validated for non-decalcified paraffin-embedded tissue specimens fixed in 10% neutral buffered formalin at Mayo Clinic in Rochester, Minnesota. Specimens are recommended to be placed in formalin within 1 hour of acquisition and fixed between 6 and 72 hours. This assay has not been validated on tissue or cellblocks subjected to alternative fixatives or decalcification.

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 within 6 weeks.

The charge of glass slides can be affected by environmental factors and subsequently may alter slide staining. Sending unsuitable glass slides can result in inconsistent staining due to poor slide surface chemistry.

Best practices for storage of positively charged slides:

- Minimize time slides are stored after being unpackaged
- Limit exposure to high humidity and heat
- Minimize exposure to plastics

Clinical Reference

1. Saunders LR, Bankovich AJ, Anderson WC, et al. A DLL3-targeted antibody-drug conjugate eradicates high-grade pulmonary neuroendocrine tumor-initiating cells in vivo. *Sci Transl Med*. 2015;7(302):302ra136. doi:10.1126/scitranslmed.aac9459
2. Xie H, Boland JM, Maleszewski JJ, et al. Expression of delta-like protein 3 is reproducibly present in a subset of small cell lung carcinomas and pulmonary carcinoid tumors. *Lung Cancer*. 2019;135:73-79. doi:10.1016/j.lungcan.2019.07.016
3. Xie H, Kaye FJ, Isse K, et al. Delta-like protein 3 expression and targeting in merkel cell carcinoma. *Oncologist*. 2020;10:810-817. doi:10.1634/theoncologist.2019-0877
4. Magaki S, Hojat SA, Wei B, So A, Yong WH. An introduction to the performance of immunohistochemistry. *Methods Mol Biol*. 2019;1897:289-298. doi:10.1007/978-1-4939-8935-5_25

Performance**Method Description**

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

PDF Report

No

Day(s) Performed

Monday through Friday

Report Available

5 to 7 days

Specimen Retention Time

Until reported

Performing Laboratory Location

Mayo Clinic Laboratories - Rochester Main Campus

Fees & 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 account representative. 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. It has not been cleared or approved by the US Food and Drug Administration.

CPT Code Information

88360

LOINC® Information

| Test ID | Test Order Name | Order LOINC® Value |
|---------|----------------------------------|--------------------|
| DLL3 | DLL3(SP347)Semi-Quant IHC,Manual | In Process |

| Result ID | Test Result Name | Result LOINC® Value |
|-----------|------------------------------------|---------------------|
| 603333 | Interpretation | 59465-5 |
| 603334 | Participated in the Interpretation | No LOINC Needed |
| 603335 | Report electronically signed by | 19139-5 |
| 603336 | Material Received | 81178-6 |
| 603337 | Disclaimer | 62364-5 |
| 603338 | Case Number | 80398-1 |