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:
1. One slide will be stained with hematoxylin and eosin and returned.
2. Broken or cracked unstained slides will be rejected. Stained slides that were broken and repaired (ie, double mounted) at the client site will not be rejected, as, in most cases, they can still be reviewed under the microscope. However, due to the double mounting, digital scanning cannot be performed.

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

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
Broken or cracked unstained slides	Reject
Broken or cracked stained slides that cannot be repaired	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

Broken or cracked unstained slides are not compatible with the instrumentation used in our performing laboratories and will be rejected. Additional material may be requested.

Attempts will be made to repair broken or cracked stained slides; however, if they are unable to be repaired (ie, shattered in transit), they will be rejected and discarded due to safety concerns.

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

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

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