

## Overview

### Useful For

[Identification of pathological forms of TDP-43 in neurodegenerative diseases](#)

### Reflex Tests

Test Id	Reporting Name	Available Separately	Always Performed
IHTOI	IHC Initial, Tech Only	No	No
IHTOA	IHC Additional, Tech Only	No	No

### 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

### Ordering Guidance

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

[Mayo Clinic is preparing to migrate to a new slide scanning solution and will need to temporarily suspend digital imaging for tech-only IHC/ISH orders received after June 17. We will send a follow-up notification by September 1st indicating when digital imaging resumes. We appreciate your patience as we improve our digital imaging solution.](#)

## 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

Tissue/Other	Wet/frozen tissue Cytology smears Nonformalin fixed tissue Nonparaffin embedded tissue Noncharged slides ProbeOn slides
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## Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
TECHONLY	Ambient (preferred)		
	Refrigerated		

## Clinical & Interpretive

### Clinical Information

TAR DNA-binding protein 43 (TDP-43) has multiple functions in transcriptional repression, translational regulation, and pre-mRNA splicing. In normal cells, TDP-43 is found in the nucleus, whereas in affected cells TDP-43 is phosphorylated and found in intracytoplasmic inclusions and neurites. The phosphoTDP-43-specific antibody will only stain the intracytoplasmic inclusions and neurites, thus highlighting the patterns that are hallmarks for amyotrophic lateral sclerosis (ALS) and frontotemporal lobular degeneration.

### 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

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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 within 6 weeks.

**Clinical Reference**

1. Ling JP, Pletnikova O, Troncoso JC, et al: TDP-43 repression of nonconserved cryptic exons is compromised in ALS-FTD. *Science* 2015 Aug 7;349(6248):650-655
2. Hasegawa M, Arai T, Nonaka T, et al: Phosphorylated TDP-43 in frontotemporal lobar degeneration and amyotrophic lateral sclerosis. *Ann Neurol* 2008 Jul;64(1):60-70
3. Lee EB, Lee VM, Trojanowski JQ: Gains or losses: molecular mechanisms of TDP43-mediated neurodegeneration. *Nat Rev Neurosci* 2011 Nov 30;13(1):38-50
4. Smethurst P, Sidle KCL, Hardy J: Review: Prion-like mechanisms of transactive response DNA binding protein of 43 kDa (TDP-43) in amyotrophic lateral sclerosis (ALS). *Neuropathol Appl Neurobiol* 2015;41(5):578-597
5. Serrano GE, Intorcia A, Carew J, et al: Feasibility Study: Comparison of Frontal Cortex Needle Core Versus Open Biopsy for Detection of Characteristic Proteinopathies of Neurodegenerative Diseases. *J Neuropathol Exp Neurol* 2015;74(9):934-942

**Performance****Method Description**

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

**PDF Report**

No

**Day(s) Performed**

Monday through Friday

**Report Available**

1 to 3 days

**Specimen Retention Time**

Until staining is complete.

**Performing Laboratory Location**

Rochester

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**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 Regional Manager. For assistance, contact [Customer Service](#).

**Test Classification**

This test has been cleared, approved, or is exempt by the US Food and Drug Administration and is used per manufacturer's instructions. Performance characteristics were verified by Mayo Clinic in a manner consistent with CLIA requirements.

**CPT Code Information**

88342-TC, primary

88341-TC, if additional IHC

**LOINC® Information**

Test ID	Test Order Name	Order LOINC® Value
PHTDP	Phospho TDP43 IHC, Tech Only	Order only;no result

Result ID	Test Result Name	Result LOINC® Value
71489	Phospho TDP43 IHC, Tech Only	Bill only; no result