

## Overview

### Useful For

Aiding in the identification of high-grade prostatic intraepithelial neoplasia and prostate cancer

### 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 (IHC)

### 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 "Attention Pathology" address label (T498) and the pink Immunostain Technical Only label included in the kit to the outside of the transport container.

### Specimen Required

**Specimen Type:** Tissue

**Supplies:** Immunostain Technical Only Envelope (T693)

**Container/Tube:** Immunostain Technical Only Envelope

**Preferred:**

-Formalin-fixed, paraffin-embedded tissue block

OR

-2 Unstained, positively charged glass slides (25- x 75- x 1-mm) per test ordered; sections 4-microns thick

**Acceptable:** None

### Digital Image Access

1. Information on accessing digital images of immunohistochemical (IHC) stains and the manual requisition form can be accessed through this website: <https://news.mayocliniclabs.com/pathology/digital-imaging/>
2. Clients ordering stains using a manual requisition form will not have access to digital images.
3. Clients wishing to access digital images must place the order for IHC stains electronically. Information regarding digital imaging can be accessed through this website: <https://news.mayocliniclabs.com/pathology/digital-imaging/#section3>

### 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 Cytology smears Nonformalin fixed tissue Nonparaffin embedded tissue Noncharged slides ProbeOn slides Snowcoat slides	Reject
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### Specimen Stability Information

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

### Clinical & Interpretive

#### Clinical Information

The prostate triple assay consists of 3 antibodies P63, HMW KRT (34betaE12), and P504S. This multiplex is used in the

diagnosis of high-grade prostatic intraepithelial neoplasia (PIN) and prostate cancer. P63 (nuclear) and HMW KRT (cytoplasmic) are expressed in normal myoepithelial cells that surround the prostatic epithelial cells (detected with 3,3'-diaminobenzidine chromogen). This myoepithelial layer is lost in carcinoma. P504S (cytoplasmic) is abnormally expressed in high-grade PIN and prostate cancer epithelial cells (detected with fast red chromogen).

**Interpretation**

This test does not include pathologist interpretation, only technical performance of the stain. If interpretation is required, order PATHC / Pathology Consultation for a full diagnostic evaluation or second opinion of the case.

The positive and negative controls are verified as showing appropriate immunoreactivity. If a control tissue is not included on the slide, a scanned image of the relevant quality control tissue is available upon request; call 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.

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. Rathod SG, Jaiswal DG, Bindu RS. Diagnostic utility of triple antibody (AMACR, HMWCK and P63) stain in prostate neoplasm. *J Family Med Prim Care*. 2019; 8(8):2651-2655. doi:10.4103/jfmpc.jfmpc\_432\_19
2. Ng VW, Koh M, Tan SY, Tan PH. Is triple immunostaining with 34betaE12, p63, and racemase in prostate cancer advantageous? A tissue microarray study. *Am J Clin Pathol*. 2007;127(2):248-253. doi:10.1309/JCFW75KGFWQUHVQD
3. Jiang Z, Li C, Fischer A, et al. Using an AMACR (P504S)/34betaE12/p63 cocktail for the detection of small focal prostate carcinoma in needle biopsy specimens. *Am J Clin Pathol*. 2005;123(2):231-236. doi:10.1309/1g1nk9dbgfnb792l
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**

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No

**Day(s) Performed**

Monday through Friday

**Report Available**

1 to 3 days

**Specimen Retention Time**

Until staining is complete.

**Performing Laboratory Location**

Rochester

**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 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**

88344-TC

**LOINC® Information**

Test ID	Test Order Name	Order LOINC® Value
PTRIP	P63/KRT/P504S IHC, Tech Only	No LOINC Needed

Result ID	Test Result Name	Result LOINC® Value
610457	P63/KRT/P504S IHC, Tech Only	No LOINC Needed