

## Overview

### Useful For

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

### 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 \(IHTOA\).](#)

### Reflex Tests

Test Id	Reporting Name	Available Separately	Always Performed
IHMTO	IHC Multiplex, Tech Only	No	No

### 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 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

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

**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

- Information on accessing digital images of immunohistochemical (IHC) stains and the manual requisition form can be accessed through this website: [www.mayocliniclabs.com/test-info/ihc/index.html](http://www.mayocliniclabs.com/test-info/ihc/index.html)
- 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: [www.mayocliniclabs.com/test-info/ihc/faq.html](http://www.mayocliniclabs.com/test-info/ihc/faq.html)

### 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  
Cytology smears  
Nonformalin fixed tissue  
Nonparaffin embedded tissue  
Noncharged slides  
ProbeOn slides

### Specimen Stability Information

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

## Clinical & Interpretive

### Clinical Information

Prostatic intraepithelial neoplasia (PIN) cocktail-2 is a cocktail including 2 antibodies directed against p63 (nuclear) and P504S (cytoplasm) used in the diagnosis of high-grade PIN and prostate cancer. p63 stains the nuclei of normal myoepithelial cells that surround the prostatic epithelial cells. This myoepithelial layer is lost in carcinoma. P504S is abnormally expressed in high-grade PIN and prostate cancer epithelial cells, but is normally expressed in epithelial cells of the renal tubules, gall bladder and bronchi, and in hepatocytes.

### 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 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 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.

### Clinical Reference

1. Hameed O, Sublett J, Humphrey PA: Immunohistochemical stains for p63 and alpha-methyl-CoA racemase, versus a cocktail comprising both, in the diagnosis of prostatic carcinoma: a comparison of the immunohistochemical staining of

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- 430 foci in radical prostatectomy and needle biopsy tissues. *Am J Surg Pathol.* 2005 May;29(5):579-587
2. Molinie V, Fromont G, Sibony M, et al: Diagnostic utility of a p63/alpha-methyl-CoA-racemase (p504s) cocktail in atypical foci in the prostate. *Mod Pathol.* 2004 Oct;17(10):1180-1190
3. Tacha DE, Miller RT: Use of p63/P504S monoclonal antibody cocktail in immunohistochemical staining of prostate tissue. *Appl Immunohistochem Mol Morphol.* 2004 Mar;12(1):75-78
4. Comperat E, Renard-Penna R, Ondet V, Cancel-Tassin G, Cussenot O: Diagnosis of prostate cancer in one day: The benefits of cytology in tumour detection. *Cytopathology.* 2021 Mar;32(2):211-216. doi: 10.1111/cyt.12930

## Performance

### Method Description

Immunohistochemistry on sections of paraffin-embedded tissue.(Cartun RW, Taylor CR, Dabbs DJ: Techniques of immunohistochemistry: Principles, pitfalls, and standardization. In: Dabbs DJ, ed. *Diagnostic Immunohistochemistry*. 5th ed. Elsevier; 2019:1-46)

### PDF Report

No

### Specimen Retention Time

Until staining is complete.

### Performing Laboratory Location

Rochester

## Fees & Codes

### 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