

CK HMW + p63, 2X

Mouse Monoclonal Antibody Cocktail

Control Number: 901-3124K-082417

Catalog Number: OAI 3124K T90**Description:** 90 tests, 13 mL, concentrated (2X)**Dilution:** 1:2**Diluent:** Van Gogh Yellow**Intended Use:**

For In Vitro Diagnostic Use

CK HMW + p63, 2X is a mouse monoclonal antibody cocktail that is intended for laboratory use in the qualitative identification of high molecular weight cytokeratin (CK 1, 5, 10, 14) and p63 proteins by immunohistochemistry (IHC) in formalin-fixed paraffin-embedded (FFPE) human tissues. The clinical interpretation of any staining or its absence should be complemented by morphological studies using proper controls and should be evaluated within the context of the patient's clinical history and other diagnostic tests by a qualified pathologist.

Summary and Explanation:

High molecular weight cytokeratins are expressed in a variety of normal and neoplastic epithelial tissues (1). In prostate, CK HMW [34 β E12] has been shown to be a useful marker of basal cells of normal glands and prostatic intraepithelial neoplasia (PIN), a precursor lesion to prostatic adenocarcinoma; whereas invasive prostatic adenocarcinoma typically lacks a basal cell layer (2,3).

p63, a homolog of the tumor suppressor p53, has been identified in proliferating basal cells in the epithelial layers of a variety of tissues, including epidermis, cervix, urothelium and prostate (4). p63 was detected in nuclei of the basal epithelium in normal prostate glands; however, it was not expressed in malignant tumors of the prostate (5).

Studies have shown that combinations of CK HMW [34 β E12] and p63 may be useful in the evaluation of normal prostate glands, PIN and prostatic adenocarcinoma (6,7).

CK HMW + p63, 2X is provided as a concentrated antibody cocktail suitable for the addition of other primary antibodies desired by the user. A 2-fold dilution of CK HMW + p63, 2X is intended to create a ready-to-use antibody cocktail for use on the ONCORE Automated Slide Stainer.

Known Applications:

Immunohistochemistry (formalin-fixed paraffin-embedded tissues)

Principle of Procedure:

Antigen detection in tissues and cells is a multi-step immunohistochemical process. The initial step binds the primary antibody to its specific epitope. After labeling the antigen with a primary antibody, an enzyme labeled polymer is added to bind to the primary antibody. The detection of the bound antibody is evidenced by a colorimetric reaction.

Reagent Provided:

CK HMW + p63, 2X is provided as a concentrated antibody cocktail of anti-CK HMW and anti-p63 antibodies in buffer with carrier protein and preservative, along with three ONCORE Improv Reagent Vials.

Antibody	anti-CK HMW	anti-p63
Clone	34 β E12	4A4
Source	Mouse monoclonal	Mouse monoclonal
Isotype	IgG1/kappa	IgG2a/kappa
Epitope/ Antigen	CK HMW [34 β E12]	p63
Cellular Localization	Cytoplasmic	Nuclear
Staining	Brown (DAB)	Brown (DAB)

Reconstitution, Dilution and Mixing:

CK HMW + p63, 2X is provided as a concentrated antibody cocktail. A 1:2 dilution to produce a final volume of 26 mL is recommended before use. The user may select additional antibodies to be added to create a customized primary antibody cocktail; however, it is the responsibility of the user to validate performance of any customized primary antibody cocktail.

Each ONCORE Improv Reagent Vial may be filled with a minimum of 8.0 mL of ready-to-use primary antibody cocktail and tagged for 30 tests. Refer to the ONCORE Automated Slide Staining System User Manual (RFID Editor) for instructions on proper use and tagging of vials.

Storage and Stability:

Store at 2°C to 8°C. Do not use after expiration date printed on vial. If reagents are stored under conditions other than those specified in the package insert, they must be verified by the user.

Species Reactivity: Human; others not tested**Positive Tissue Control:** Normal prostate glands**Protocol Recommendations (ONCORE Automated Slide Staining System):**

OAI3124 is intended for use with the ONCORE Automated Slide Staining System. Refer to the ONCORE Automated Slide Staining System User Manual for specific instructions on its use. Protocol parameters in the ONCORE Automated Slide Stainer Protocol Editor should be programmed as follows:

Protocol Name: (Choose appropriate name for ready-to-use cocktail)**Protocol Template (Description):** Multiplex 2 Template 1**Dewaxing (DS Option):** DS Buffer**Antigen Retrieval (AR Option):** AR2, low pH; 101°C**Reagent Name, Time, Temp.:** (Same as protocol name), 30 min., 25°C**Limitations:**

These reagents have been optimized for use with ONCORE detections and ancillary reagents. The optimum antibody dilution and protocols for a specific application can vary. These include, but are not limited to fixation, heat-retrieval method, incubation times, tissue section thickness, and detection kit used. Third party primary antibodies may be used on the ONCORE Automated Slide Stainer; however, appropriate antibody concentration may depend upon multiple factors and must be empirically determined by the user. Ultimately, it is the responsibility of the investigator to determine optimal conditions. The clinical interpretation of any positive or negative staining should be evaluated within the context of clinical presentation, morphology and other histopathological criteria by a qualified pathologist. The clinical interpretation of any positive or negative staining should be complemented by morphological studies using proper positive and negative internal and external controls as well as other diagnostic tests.

Quality Control:

Refer to CLSI Quality Standards for Design and Implementation of Immunohistochemistry Assays; Approved Guideline-Second edition (I/LA28-A2). CLSI Wayne, PA, USA (www.clsi.org). 2011

Precautions:

1. This antibody contains less than 0.1% sodium azide. Concentrations less than 0.1% are not reportable hazardous materials according to U.S. 29 CFR 1910.1200, OSHA Hazard communication and EC Directive 91/155/EC. Sodium azide (NaN₃) used as a preservative is toxic if ingested. Sodium azide may react with lead and copper plumbing to form highly explosive metal azides. Upon disposal, flush with large volumes of water to prevent azide build-up in plumbing. (Center for Disease Control,

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Precautions Cont'd:

- 1976, National Institute of Occupational Safety and Health, 1976) (8)
2. Specimens, before and after fixation, and all materials exposed to them should be handled as if capable of transmitting infection and disposed of with proper precautions. Never pipette reagents by mouth and avoid contacting the skin and mucous membranes with reagents and specimens. If reagents or specimens come into contact with sensitive areas, wash with copious amounts of water. (9)
3. Microbial contamination of reagents may result in an increase in nonspecific staining.
4. Incubation times or temperatures other than those specified may give erroneous results. The user must validate any such change.
5. Do not use reagent after the expiration date printed on the vial.
6. The SDS is available upon request and is located at <http://biocare.net/>.

Troubleshooting:

Follow the antibody specific protocol recommendations according to data sheet provided. If atypical results occur, contact Biocare's Technical Support at 1-800-542-2002.

References:

1. Moll R, *et al.* The catalog of human cytokeratins: patterns of expression in normal epithelia, tumors and cultures cells. *Cell*. 1982 Nov; 31(1):11-24.
2. Bostwick DG, Qian J. High-grade prostatic intraepithelial neoplasia. *Mod Pathol*. 2004 Mar; 17(3):360-79.
3. Humphrey PA. Diagnosis of adenocarcinoma in prostate needle biopsy tissue. *J Clin Pathol*. 2007 Jan; 60(1):35-42.
4. Yang A, *et al.* p63, a p53 homolog at 3q27-29, encodes multiple products with transactivating, death-inducing, and dominant-negative activities. *Mol Cell*. 1998 Sep; 2 (3):305-16.
5. Signoretti S, *et al.* p63 is a prostate basal cell marker and is required for prostate development. *Am J Pathol*. 2000 Dec; 157(6):1769-75.
6. Shah RB, *et al.* Comparison of the basal cell-specific markers, 34betaE12 and p63, in the diagnosis of prostate cancer. *Am J Surg Pathol*. 2002 Sep; 26(9):1161-8.
7. Shah RB, *et al.* Usefulness of basal cell cocktail (34betaE12 + p63) in the diagnosis of atypical prostate glandular proliferations. *Am J Clin Pathol*. 2004 Oct; 122(4):517-23.
8. Center for Disease Control Manual. Guide: Safety Management, NO. CDC-22, Atlanta, GA. April 30, 1976 "Decontamination of Laboratory Sink Drains to Remove Azide Salts."
9. Clinical and Laboratory Standards Institute (CLSI). Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline-Fourth Edition CLSI document M29-A4 Wayne, PA 2014.