Prostate Cocktail p40 (ZRG8) + High Molecular Weight Keratin (34βE12)

Mouse Monoclonal Antibody Cocktail

SAM-QHD- MM400-10 tests

QHD-MM400-100 tests

Document Number: IFU-320_MM400-Prostate Cocktail p40 (ZR8) + HWM Keratin (34βE12)

Release Date: 01/02/2019, Rev A

Source	Clone	Species	Isotype	Primary Antibody Diluent
Supernatent	ZR8 + 34βE12	Mouse	IgG	NA
Epitope: Not Determined			*Species Reactivity: Human*	

Catalog Number	Description
SAM-QHD-MM400-10 tests	2mL Ready To Use antibody for use with StatLab Quantum HD HRP or Quantum HD AP Detection kit on fully automated StatLab Quantum HDx Platform.
QHD-MM400-100 tests	15mLReady To Use antibody for use with StatLab Quantum HD HRP or Quantum HD AP Detection kit on fully automated StatLab Quantum HDx Platform

Intended Use

For In Vitro Diagnostic Use. Prostate Cocktail Monoclonal antibody is intended for qualitative identification by light microscopy or Prostate Cocktail (p40 + 34βE12) antigen in sections of formalin-fixed, paraffin-embedded tissue sections using immunohistochemical (IHC) test methods. Staining results should be interpreted by a qualified pathologist in conjunction with the patient's clinical history, and other diagnostic tests after the primary diagnosis of cancer has been established.

Summary and Explanation

p40 is an antibody that recognizes ΔNp63-a p63 isoform and it is highly specific for squamous/basal cells. It may be a valuable marker in detecting Squamous Cell Carcinoma where p63 is currently used. It recognizes the shortest variant of p53. p40 is superior in specificity to p63 because it does not label lung adenocarcinomas' like p63 does, which eliminates the potential of misinterpreting a positive adenocarcinoma as a squamous cell carcinoma

Anti-Cytokeratin, 34betaE12 is an antibody to high molecular weight cytokeratin that reacts with all squamous and ductal epithelium and stains carcinomas. This antibody recognizes cytokeratins 1,5,10, and 14 that are found in complex epithelia. Anti-Cytokeratin, 34betaE12 shows no reactivity with hepatocytes, pancreatic acinar cells, proximal renal tubules, or endometrial glands; there has been no reactivity with cells derived from simple epithelia. Mesenchymal tumors, lymphomas, melanomas, and neural tumors are unreactive with this antibody with some exceptions. Anti-Cytokeratin, 34betaE12 does label myoepithelial cells and has been shown to be useful in distinguishing prostatic adenocarcinoma from hyperplasia of the prostate. This antibody has also been useful in separating benign from malignant intraductal breast proliferations.[1-6]

Materials and Methods Provided

The stated primary antibody product contains reagent in a vial made for use with the StatLab Quantum HDx IHC slide stainer. The vial is equipped with an RFID tag that is read by the slide stainer to provide product and lot specific information.

This antibody is diluted in Tris Buffer, pH 7.3-7.7, with 1% BSA and <0.1% Sodium Azide.

Storage and Handling

Store at 2-8°C. Do NOT freeze. When stored properly, the reagents are stable to the date indicated on the label. The presence of an unusual odor or precipitate indicates that the antibody is deteriorating and should not be used. Do not use reagents beyond the expiration date printed on the vial. The user must validate any storage conditions other than these specified in the package insert.

Materials and Reagents Needed but Not Provided

The following reagents and materials may be required for staining but are not provided with the primary antibody. Please refer to our website at www.StatLab.com.

1. Quantum HD HRP Detection Kit (Cat. No.: QHD-U3-15-HRP-KIT) OR
1. Quantum HD AP Detection Kit (Cat. No.: QHD-U2-15-HRP-KIT)
2. Quantum HD Retrieval Solution, pH 9.0 (Cat. No.:QHD-003)
3. Quantum HD Retrieval Solution, pH 6.0 (Cat. No.: QHD-002)
4. Quantum HD DS2 (Cat. No.: QHD-007)
5. Quantum HD Block (Cat. No.: QHD-006)
6. Wash Buffer (Cat. No.: QHD-015)
7. Positive and Negative Tissue controls

Storage and Handling

Store at 2-8°C. Do NOT freeze. When stored properly, the reagents are stable to the date indicated on the label. The presence of an unusual odor or precipitate indicates that the antibody is deteriorating and should not be used. Do not use reagents beyond the expiration date printed on the vial. The user must validate any storage conditions other than these specified in the package insert.

Principles of the Procedures

Antigen detection by immunohistochemistry (IHC) is a two-step process involving first, the binding of a primary antibody to the antigen of interest, and second, the detection of bound antibody by a chromogen. The primary antibody may be used in IHC using manual techniques or using automated IHC Staining Systems.

StatLab
Empowering Anatomic Pathology

Warnings and Precautions

1. This antibody contains less than 0.1% sodium azide. Concentrations less than 0.1% are not reportable as hazardous materials.[7]
2. 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.[8]
3. Specimens, before and after fixation and all materials exposed to them, should be handled as if capable of transmitting infections and disposed of with proper precautions.[9]
4. Never pipette reagents by mouth and avoid contacting the skin and mucous membranes with reagents and specimens. If reagents or specimens come in contact with sensitive areas, wash with copious amounts of water.
5. Microbial contamination of reagents may result in an increase in nonspecific staining.
6. Incubation times or temperatures other than those specified may give erroneous results. The use must validate any such change.
7. The SDS is available upon request.
8. Do not use reagents beyond the expiration date printed on the vial.
9. The user must validate any storage conditions other than these specified in the package insert

Specimen Collection and Preparation

Tissues fixed in 10% formalin are suitable for use prior to paraffin embedding.[10,11]

The user is advised to validate the use of the products with their tissue specimens prepared and handled in accordance with their laboratory practices

StatLab Quantum HDx Recommended Staining Procedure:

Instrument Parameters	QHD-U3-HRP-Kit	QHD-U2-AP-Kit
Retrieval Reagent	QHD-High pH	QHD-High pH
Antibody Incubation Time	10-45 minutes	10-45 minutes

Step by Step Procedure:

1. Follow the StatLab Quantum HDx instrument instructions for setting up the reagents on the instrument
2. Load slides, antibodies, and detection kit(s) onto StatLab Quantum HDx instrument according to StatLab Quantum HDx instructions for use
3. Start the run.
4. When the staining is complete, remove the slides from instrument, rinse well with distilled water
5. Dehydrate, Clear and Coverslip

Troubleshooting

Positive and negative controls should be run simultaneously with all patient specimens. If unexpected staining is observed which cannot be explained by variations in laboratory procedures and a problem with the antibody is suspected, contact StatLab IHC Technical Support via Email ihctech@statlab.com or call us at (800) 442-3573

Cellular Localization and Positive Tissue Control

Positive Tissue Control	
Tissue	Visualization
Prostate	xxxx

Limitations of the Procedure

IHC is a complex technique involving both histological and immunological detection methods. Tissue processing and handling prior to immunostaining can also cause inconsistent results. Variations in fixation and embedding or the inherent nature of the tissue may cause variations in results.[12] (Endogenous peroxidase activity or pseudo peroxidase activity in erythrocytes and endogenous biotin may cause non-specific staining depending on detection system used. Tissues containing Hepatitis B Surface Antigen (HBsAg) may give false positive with horseradish peroxidase systems.[13] Improper counterstaining and mounting may compromise the interpretation of results.

Performance Characteristics

The optimum protocols for a specific application can vary. These include, but are not limited to: fixation, heat-retrieval method, incubation times, and tissue section thickness and detection kit used. Due to the sensitivity of these reagents, the recommended incubation times listed may not be applicable to other detection systems, as results may vary. The data sheet recommendations and protocols are based exclusively on StatLab products. Ultimately, it is the responsibility of the investigator to determine optimal conditions. These products are tools that can be used for interpretation of morphological findings in conjunction with other diagnostic tests and pertinent clinical data by a qualified pathologist.

NOTE

There are no expressed or implied warranties which extend beyond this datasheet. StatLab is not liable for personal injury, property damage or economic loss caused by this product

References

1. Gown, AM et al. Monoclonal antibodies to human intermediate filament proteins. II. Distribution of filament proteins in normal human tissues. Am J Pathol 1984; 114:309.

Manufactured for StatLab Medical Products
2090 Commerce Drive
McKinney, Texas 75069
(800) 442-3573
www.StatLab.com

IVD

2. 2. O'Malley, FP et al. Usefulness of immunoperoxidase staining with high-molecular-weight cytokeratin in the differential diagnosis of small-acinar lesions of the prostate gland. Virch Arch A 1990; 417:191.
3. 3. Amin, MB. Analysis of cribriform morphology in prostatic neoplasia using antibody to high-molecular-weight cytokeratins. Arch Pathol Lab Med March 1994; 118:260-264.
4. 4. Wojno, KJ et al. The utility of basal cell-specific anti-cytokeratin antibody (34betaE12) in the diagnosis of prostate cancer. A review of 228 cases. Am J Surg Pathol 1995; 19:251-60.
5. Moinfar, F et al. Use of keratin 35betaE12 as an adjunct in the diagnosis of mammary intraepithelial neoplasia-ductal type--benign and malignant intraductal proliferations. Am J Surg Pathol 1999; 23:1048-58.
6. Yang, XJ et al. Rare expression of high-molecular-weight cytokeratin in adenocarcinoma of the prostate gland: a study of 100 cases of metastatic and locally advanced prostate cancer. Am J Surg Pathol 1999; 23:147-52
7. U.S. 29CFR 1910.1200, OSHA Hazard Communication and EC Directive 91/155/EC.
8. Center for Disease Control, 1976, National Institute of Occupational Safety and Health, 1976.
10 U.S. Department of Health and Human Services: Centers for Disease Control and Prevention. Guidelines for Safe Work Practices in Human and Animal Medical Diagnostic Laboratories, Supplement/Vol 61, January 6, 2012.
11. Kiernan, Microscopy Today 00-1 pp. 8-12, (2000)
12. Sheehan and Hrapchak, Theory and Practice of Histotechnology, Second Edition, Battelle Press, 1980
13. Nadji and Morales, AR Ann N.Y. Acad Sci 420:134-9, 1983
14. Omata M et al, Am J Clin Pathol 73(5): 626-32, 1980

Manufactured for StatLab Medical Products
2090 Commerce Drive
McKinney, Texas 75069
(800) 442-3573
www.StatLab.com

IVD