

## Cytokeratin Cocktail (AE1 & AE3)

Mouse Monoclonal Antibody

SAM-QHD- MM45-10 tests

QHD-MM45-100 tests

Document Number: IFU-MM45-Cytokeratin Cocktail (AE1 & AE3), 05312018  
Release Date: 05/31/2018, IFU-284 Rev A

Source	Clone	Species	Isotype	Primary Antibody Diluent
Supernatant	AE1 & AE3	Mouse	AE1-IgG/k AE3-IgG/k	NA
Epitope: Not Determined Species Reactivity: Human				

Catalog Number	Description
SAM-QHD-MM45-10 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-MM45-100 tests	15mL Ready 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. Cytokeratin Cocktail (AE1 & AE3) Mouse Monoclonal Primary Antibody is intended for laboratory use in the detection of the cytokeratin and protein in formalin-fixed, paraffin-embedded tissue stained in qualitative immunohistochemistry (IHC) testing. The results using this product should be interpreted by a qualified pathologist in conjunction with the patient's relevant clinical history, other diagnostic tests and proper controls.

### Summary and Explanation

Anti-Cytokeratin cocktail (AE1 & AE3) is the broad-spectrum keratin antibody cocktail. It is composed of mouse monoclonal antibody AE1 that recognizes the acidic type I keratins 10, 14, 15, 16, 19, and AE3 that reacts with the basic type II keratins 1, 2, 3, 4, 5, 6, 7, and 8. Both clones were generated using epidermal keratin as immunogen.<sup>1-3</sup> This antibody detects carcinomas of different organ origin, but is most frequently negative in hepatocellular carcinoma, chromophobe RCC, adrenal cortical carcinoma, some clear cell renal cell carcinomas, and renal oncocytoma.<sup>1,2</sup> This antibody cocktail can cross-react with other intermediate filaments, such as glial fibrillary acidic protein, giving a false-positive staining in glial tumors.<sup>4</sup>

### 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 ready 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.

### 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](http://www.StatLab.com).

1. Quantum HD HRP Detection Kit (Cat. No.: QHD-U-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. Quantum HD AP Detection Kit (Cat. No.: QHD-U-15-HRP-KIT)
7. Wash Buffer (Cat. No.: QHD-015)
8. 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.

### Warnings and Precautions

1. This antibody contains less than 0.1% sodium azide. Concentrations less than 0.1% are not reportable as hazardous materials<sup>5</sup>.
2. Sodium azide (NaN<sub>3</sub>) 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<sup>5</sup>.
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<sup>7</sup>.
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 user must validate any such change.
7. The SDS is available upon request.



### Specimen Collection and Preparation

Tissues fixed in 10% formalin are suitable for use prior to paraffin embedding<sup>8,9</sup>.

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 at: ihctech@statlab.com or call us at (800) 442-3573.

### Cellular Localization and Positive Tissue Control

Positive Tissue Control	
Tissue	Visualization
Breast	Cytoplasmic
Lung	Cytoplasmic
Colon	Cytoplasmic
Skin	Cytoplasmic

### 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<sup>10</sup>. 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<sup>11</sup>. 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 superior sensitivity of these unique reagents, the recommended incubation times may not be applicable to other detection systems, as results may vary. The data sheet recommendations and protocols are based on exclusive use of products manufactured for StatLab. 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. Battifora H. Clinical applications of the immunohistochemistry of filamentous proteins. Am J Surg Pathol. 1988; 12:24.
2. Cooper D, et al. Classification of human epithelia and their neoplasms using monoclonal antibodies to keratins: strategies, applications, and limitations. Lab Invest. 1985; 52:243-56.
3. Gown AM, et al. Monoclonal antibodies to human intermediate filament proteins. III. Analysis of tumors. AM J Clin Pathol. 1985; 84:413.
4. Kriho UK, et al. Keratin expression in astrocytomas: An immunofluorescent and biochemical reassessment. Virehows Arch. 1997; 431:139-47.
5. U.S. 29CFR 1910.1200, OSHA Hazard Communication and EC Directive 91/155/EC.
6. Center for Disease Control, 1976, National Institute of Occupational Safety and Health, 1976.
7. 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.
8. Kiernan, Microscopy Today 00-1 pp. 8-12, (2000)
9. Sheehan and Hrapchak, Theory and Practice of Histotechnology, Second Edition, Battelle Press, 1980
10. Nadji and Morales, AR Ann N.Y. Acad Sci 420:134-9, 1983
11. Omata M et al, Am J Clin Pathol 73(5): 626-32, 1980

