

# Cytokeratin 20 (CK20)

Concentrated and Prediluted Monoclonal Antibody  
901-062-052423

**BIOCARE**  
M E D I C A L

Available Product Formats				
Format	Catalog Number	Description	Dilution	Diluent
Concentrate	CM 062 A, C	0.1, 1.0 mL	1:100	Van Gogh Yellow
Predilute	PM 062 AA, H	6.0, 25 mL	Ready-to-use	N/A
intelliPATH FLX	IP 062 G10	10 mL	Ready-to-use	N/A
ONCORE	OAI 062 T60	60 tests	Ready-to-use	N/A
ONCORE Pro	OPAI 062 T60	60 tests	Ready-to-use	N/A
Q Series— For Leica BOND-III	ALI 062 G7	7.0 mL	Ready-to-use	N/A

## Intended Use:

For In Vitro Diagnostic Use

Cytokeratin 20 (CK20) [Ks20.8] is a mouse monoclonal antibody that is intended for laboratory use in the qualitative identification of cytokeratin 20 (CK20) protein 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:

Cytokeratin 20 is 46 kDa intermediate filament protein that has been identified with expression primarily restricted to gastric and intestinal epithelium, urothelium, and Merkel cells. Cytokeratin 20 has been shown as a unique type I keratin that is expressed in adenocarcinomas of the colon, stomach, pancreas and bile system. It is also expressed in mucinous ovarian tumors, transitional cell carcinomas of the urinary tract, and Merkel cell carcinomas. CK20 is essentially non-reactive in squamous cell carcinomas and adenocarcinomas of the breast, lung, and endometrium, as well as non-mucinous tumors of the ovary and small cell carcinomas. Cytokeratin 20 is often used in conjunction with CK7 and other antibodies in distinguishing colon carcinomas (CK20+) from ovarian, pulmonary, and breast carcinomas.

## 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, a one-step or two-step detection procedure can be applied. A one-step procedure will feature an enzyme labeled polymer that binds the primary antibody. A two-step procedure will feature a linker antibody added to bind to the primary antibody. An enzyme-labeled polymer is then added to bind the linker antibody. These detections of the bound antibodies are evidenced by a colorimetric reaction.

**Source:** Mouse monoclonal

**Species Reactivity:** Human; others not tested

**Clone:** Ks20.8

**Isotype:** IgG2a

**Protein Concentration:** Call for lot specific Ig concentration.

**Epitope/Antigen:** CK20

**Cellular Localization:** Cytoplasmic

**Positive Tissue Control:** Colon carcinoma

## Known Applications:

Immunohistochemistry (formalin-fixed paraffin-embedded tissues)

**Supplied As:** Buffer with protein carrier and preservative

## Storage and Stability:

Store at 2°C to 8°C. The product is stable to the expiration date printed on the label, when stored under these conditions. Do not use after expiration date. Diluted reagents should be used promptly; any remaining reagent should be stored at 2°C to 8°C.

## Protocol Recommendations (intelliPATH FLX® and manual use):

**Peroxide Block:** Block for 5 minutes with Peroxidized 1.

**Pretreatment:** Perform heat retrieval using Diva or Reveal Decloaker. Refer to the Diva or Reveal Decloaker data sheet for specific instructions.

**Protein Block (Optional):** Incubate for 5-10 minutes at RT with Background Punisher.

## Protocol Recommendations (intelliPATH FLX and manual use)

### Cont'd:

**Primary Antibody:** Incubate for 30 minutes at RT.

**Probe:** Incubate for 10 minutes at RT with a secondary probe.

**Polymer:** Incubate for 10-20 minutes at RT with a tertiary polymer.

**Chromogen:** Incubate for 5 minutes at RT with Biocare's DAB - OR - Incubate for 5-7 minutes at RT with Warp Red.

### Counterstain:

Counterstain with hematoxylin. Rinse with deionized water. Apply Tacha's Bluing Solution for 1 minute. Rinse with deionized water.

### intelliPATH FLX Automated Slide Stainer:

IP062 is intended for use with the intelliPATH FLX. Refer to the User Manual for specific instructions for use. When using the intelliPATH FLX, peroxide block with intelliPATH FLX Peroxidase Blocking Reagent (IPB5000) may be performed following heat retrieval.

### Technical Note:

This antibody, for intelliPATH FLX and manual use, has been standardized with MACH 4 detection system. Use TBS for washing steps.

## Protocol Recommendations (ONCORE™ Automated Slide Staining System):

OAI062 is intended for use with the ONCORE. Refer to the User Manual for specific instructions for use. Protocol parameters in the Protocol Editor should be programmed as follows:

**Protocol Name:** CK20

**Protocol Template (Description):** Ms HRP Template 1

**Dewaxing (DS Option):** DS2

**Antigen Retrieval (AR Option):** AR2, low pH; 101°C

**Reagent Name, Time, Temp.:** CK20, 30 min., 25°C

## Protocol Recommendations (ONCORE™ Pro Automated Slide Staining System):

OPAI062 is intended for use with the ONCORE Pro. Refer to the User Manual for specific instructions for use. Protocol parameters in the Protocol Editor should be programmed as follows:

**Protocol Name:** CK20

**Protocol Template (Description):** Ms HRP Template 1

**Dewaxing (DS Option):** DS2-50

**Antigen Retrieval (AR Option):** AR2, low pH; 101°C

**Block Option:** Buffer

**Reagent Name, Time, Temp.:** CK20, 30 min., 25°C

## Protocol Recommendations (Ventana BenchMark ULTRA):

PM062 is compatible for use with the BenchMark ULTRA. Refer to the User Manual for specific instructions for use. Recommended protocol parameters are as follows:

**Template/Detection:** OptiView DAB IHC

**Pretreatment Protocol:** CC1 64 minutes

**Peroxidase:** Pre-Primary Peroxidase Inhibitor

**Primary Antibody:** 32 minutes, 36°C

 Biocare Medical

60 Berry Drive  
Pacheco, CA 94553

USA



Rev: 062117

Tel: 800-799-9499 | www.biocare.net | Fax: 925-603-8080

 EMERGO EUROPE

Westervoortsedijk 60  
8827 AT Arnhem

The Netherlands

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## **Protocol Recommendations (Q Series – For Leica BOND-III):**

ALI062 is intended for use with the Leica BOND-III. Refer to the User Manual for specific instructions for use. Recommended protocol parameters are as follows:

**Protocol Name:** IHC Protocol F + Blocker

**Detection:** Bond Polymer Refine

**HIER:** 5 min with ER1

**Peroxide Block:** 5 min

**Background Block:** 10 min

**Marker (Primary Antibody):** 15 min

**Post Primary:** 8 min

**Polymer:** 8 min

**Mixed DAB Refine:** 10 min

**Hematoxylin:** 5 min

## **Limitations:**

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. Due to the superior sensitivity of these unique reagents, the recommended incubation times and titers listed are not applicable to other detection systems, as results may vary. The data sheet recommendations and protocols are based on exclusive use of Biocare products. Ultimately, it is the responsibility of the investigator to determine optimal conditions.

## **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 (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. (Center for Disease Control, 1976, National Institute of Occupational Safety and Health, 1976) (3)
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 in contact with sensitive areas, wash with copious amounts of water. (4)
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. Perry A, Parisi JE, Kurtin PJ. Metastatic adenocarcinoma to the brain: an immunohistochemical approach. Hum Pathol. 1997 Aug;28(8):938-43.
2. Sack MJ, Roberts SA. Cytokeratins 20 and 7 in the differential diagnosis of metastatic carcinoma in cytologic specimens. Diagn Cytopathol. 1997 Feb;16(2):132-6.
3. 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."
4. 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.

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