Arginase-1

Prediluted Rabbit Monoclonal Antibody

Control Number: 901-3058VP-092017

VP Echelon™ Series

Catalog Number: **AVI 3058 G**

Description: 6.0 ml, prediluted

Dilution: Ready-to-use

Intended Use:

For In Vitro Diagnostic Use

Arginase-1 [EP261] is a rabbit monoclonal antibody that is intended for laboratory use in the qualitative identification of arginase-1 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:

Arginase-1 (ARG-1) is a key enzyme of the urea cycle found in liver that catalyzes the conversion of L-arginine into L-ornithine and urea. ARG-1 is a highly specific and sensitive marker of benign and hepatocellular carcinoma (HCC) which is now a key target for the differential diagnosis of HCC from metastatic tumors to the liver (1-3). ARG-1 is very specific and has been shown to be more sensitive than Hep Par 1 and Glypican 3 in hepatocellular carcinomas (1-2).

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.

Source: Rabbit monoclonal

Species Reactivity: Human

Clone: EP261 (previously known as EPR6672(B))

Isotype: IgG

Total Protein Concentration: ~10 mg/ml. Call for lot specific Ig concentration.

Epitope/Antigen: Arginase-1

Cellular Localization: Cytoplasmic and nuclear

Positive Control: Normal liver

Known Applications:

Immunohistochemistry (formalin-fixed paraffin-embedded tissues)

Supplied As: Buffer with protein carrier and preservative

Storage and Stability:

Store at 2ºC to 8ºC. 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.

Protocol Recommendations:

Using ***ultra*VIEW Detection Kit**

Pretreatment Solution (recommended): CC1

Pretreatment Protocol: Mild

Primary Antibody: Incubate for 32 minutes at 37°C.

Technical Note:

Biocare's VP-Echelon Series of predilutes have been developed for use with Ventana® Medical Systems, BenchMark® XT Immunohistochemistry Staining System in combination with Ventana® Detection Kits and Ventana® Prep Kit Dispensers.

Performance Characteristics:

See Tables 1 and 2 for expected results.

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 listed are not applicable to other detection systems, as results may vary. 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 (NaN_3) 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) (4)
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. (5)
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.

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References:

1. Fujiwara M, *et al.* Arginase-1 is a more sensitive marker of hepatic differentiation than HepPar-1 and Glypican-3 in fine-needle aspiration biopsies. Cancer Cytopathol 2012; 120:230-7.
2. Timek DT, *et al.* Arginase-1, HepPar-1, and Glypican-3 are the most effective panel of markers in distinguishing hepatocellular carcinoma from metastatic tumor on fine-needle aspiration specimens. Am J Clin Pathol. 2012; 138:203-10.
3. Yan BC, *et al*. Arginase-1: A new immunohistochemical marker of hepatocytes and hepatocellular neoplasms. Am J Surg Pathol. 2010; 34(8):1147-54.
4. 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."
5. 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.

Produced using Abcam's RabMAb® technology. RabMAb® technology is covered by the following U.S. Patents, No. 5,675,063 and/or 7,429,487.

Table 1: Specificity of rabbit monoclonal antibody Arginase-1 was determined by testing formalin-fixed, paraffin-embedded normal tissues.

Tissue	# Positive/Total tissues	Tissue	# Positive/Total tissues
Adrenal gland	0/3	Ovary	0/3
Bladder, urinary	0/3	Pancreas	2/3
Bone marrow	1/1	Parathyroid	0/3
Eye	0/2	Pituitary gland	0/2
Breast	0/3	Placenta	0/3
Brain, cerebellum	0/3	Prostate	0/3
Brain, cerebral cortex	0/3	Skin	2/2
Fallopian tube	0/3	Spinal Cord	0/2
Esophagus	0/3	Spleen	2/2
Stomach	0/3	Skeletal Muscle	0/3
Intestine, small intestine	0/3	Testis	0/3
Intestine, colon	0/3	Thymus	0/3
Intestine, rectum	0/3	Thyroid	0/3
Heart	0/3	Tonsil	0/3
kidney	3/5	Ureter	0/3
Liver	3/3	Uterus cervix	0/3
Lung	0/3	Uterus endometrium	0/3

Table 2: Sensitivity of rabbit monoclonal antibody Arginase-1 was determined by testing formalin-fixed, paraffin-embedded neoplastic tissues.

# Positive/ Total tissues	Pathology
52/56 (92.9%)	Liver (Hepatocellular carcinoma)
0/40	Breast (Infiltrating duct carcinoma)
0/12	Melanoma (Epitheloid, Plasmacyte, Rhabdoid)
1/71 (1.4%)	Kidney (Clear Cell carcinoma, Nephroblast, Transitional)
9/89 (10.1%)	Pancreas (Ductal Adenocarcinoma)
3/64 (4.6%)	Prostate (Adenocarcinoma)
0/12	Testis (Seminoma)
1/80 (1.25%)	Ovary (Serous papillary)
1/77 (1.29%)	Lung (Squamous carcinoma, Adenocarcinoma)
0/184	Colon (Adenocarcinoma, Mucinous and Papillary)
0/46	Endocrine Tumors (Thyroid-Adrenal gland, Papillary carcinoma)

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