

ARG-1 (EP261)

Rabbit anti-human Arginase-1 (ARG-1) Monoclonal Antibody (Clone EP261)

REFERENCES AND PRESENTATIONS¹

LabVision ready-to-use (manual or AutoStainer)

MAD-000667QD-3 MAD-000667QD-7 MAD-000667QD-12

Ready-to-use (MD-Stainer)² MAD-000667QD-3/V MAD-000667QD/V

concentrated MAD-000667Q - 1:50 recommended dilution

COMPOSITION

Anti-human ARG-1 rabbit monoclonal antibody purified from serum and prepared in 10mM PBS, pH 7.4, with 0.2% BSA and 0.09% sodium azide

INTENDED USE IVD: Immunohistochemistry (IHC) on paraffin embedded tissues. Not tested on frozen

tissues or Western-Blotting

CLONE: EP2613 Ig ISOTYPE: rabbit IgG

IMMUNOGEN: A synthetic peptide corresponding to

residues in human ARG-1 protein.

SPECIES REACTIVITY: In vitro diagnostics in humans.

Not tested in other species

DESCRIPTION AND APPLICATIONS: Arginase is a manganese metalloenzyme that catalyzes the hydrolysis of arginine to generate ornithine and urea. Arginase I and II are isoenzymes which differ in subcellular localization, regulation, and possibly function. Arginase I is a cytosolic enzyme, which is expressed mainly in the liver as part of the urea cycle, whereas arginase II is a mitochondrial protein found in a variety of tissues.

Antibody to ARG-1 labels hepatocytes in normal tissues and granulocytes in peripheral blood. ARG-1 is

a sensitive and specific marker for identification of hepatocellular carcinoma.

This antibody is very useful in distinguishing between: 1) liver metastases of various adenocarcinomas and hepatocellular carcinoma (HCC), which can be a real diagnostic challenge, especially in small biopsies or material from fine needle aspiration (FNA) and 2) the distinction between different histological variants of HCC and cholangiocarcinoma. Specifically, the ARG-1 antibody is key in the diagnosis of scirrhous hepatocellular carcinoma, where specific markers for adenocarcinomas are generally positive while HepPar-1 in some cases it may be negative. In addition, several studies have shown that ARG-1 antibody is HepPar-1 sensitive than immunohistochemical diagnosis of hepatocellular carcinoma while the second is usually negative in poorly differentiated hepatocellular carcinomas and can be positive in adenocarcinomas of pancreatic, gastric, colic origin or even cholangiocarcinoma. However. isolated cases of pancreatic adenocarcinomas and cholangiocarcinomas presented focal staining against ARG-1. In this line, it should be considered that the ARG-1 antibody does not allow differential diagnosis between benign, dysplastic and malignant hepatocyte lesions.

IHC POSITIVE CONTROL: Liver

VISUALIZATION: Cell cytoplasm and nuclei

IHC RECOMMENDED PROCEDURE:

- 4µm thick section should be taken on charged slides; dry overnight at 60°C
- Deparaffinise, rehydrate and HIER (heat induced epitope retrieval) - boil tissue in the Pt Module using Vitro S.A EDTA buffer pH84 for 20 min at 95°C. Upon completion rinse with 3-5 changes of distilled or deionised water followed by cooling at RT for 20 min
- Endogenous peroxidase block Blocking for 10 minutes at room temperature using peroxidase solution (ref. MAD-021540Q-125)
- Primary antibody: incubate for 20 minutes [The antibody dilution (when concentrated) and protocol may vary depending on the specimen preparation and specific application. Optimal conditions should be determined by the individual laboratory]

⁴ Ref: MAD-004072R/D





Rev.: 2020-09-21

¹ These references are for presentation in vials of Low Density Polyethylene (LDPE) dropper. In case the products are used in automated stainers, a special reference is assigned as follows:

^{- /} L: Cylindrical screw-cap vials (QD-3 / L, QD-7 / L, QD-12 / L). - / N: Polygonal screw-cap vials (QD-3 / N, QD-7 / N, QD-12 / N). For different presentations (references / volumes) please contact the

² For Technical specifications for MD-Stainer, please contact your distributor.

³ ARG-1 clone EP261 is manufactured using Epitomics's RabMAb® technology under U.S. Patent Nos. 5,675,063 and 7,402,409



- For detection use Master Polymer Plus Detection System (HRP) (DAB included; ref. MAD-000237QK)
- Counterstaining with haematoxylin and final mounting of the slide

STORAGE AND STABILITY: Stored at 2-8°C. Do not freeze. Once the packaging has been opened it can be stored until the expiration date of the reagent indicated on the label. If the reagent has been stored under other conditions to those indicated in this document, the user must first check its correct performance taking into account the product warranty is no longer valid.

WARNINGS AND PRECAUTIONS:

- 1. Avoid contact of reagents with eyes and mucous membranes. If reagents come into contact with sensitive areas, wash with copious amounts of water.
- 2. This product is harmful if swallowed.
- 3. Consult local or state authorities with regard to recommended method of disposal.
- 4. Avoid microbial contamination of reagents.

SAFETY RECOMMENDATIONS

This product is intended for laboratory professional use only. The product is NOT intended to be used as a drug or for domestic purposes. The current version of the Safety Data Sheet for this product can be downloaded by searching the reference number at www.vitro.bio or can be requested at regulatory@vitro.bio.

BIBLIOGRAPHY

- Sparkes RS, Dizikes GJ, Klisak I, Grody WW, Mohandas T, Heinzmann C, Zollman S, Lusis AJ, Cederbaum SD. The gene for human liver arginase (ARG1) is assigned to chromosome band 6q23. Am J Hum Genet. 1986 Aug;39(2):186-93
- Grody WW, Klein D, Dodson AE, Kern RM, Wissmann PB, Goodman BK, Bassand P, Marescau B, Kang SS, Leonard JV, et al. Molecular genetic study of human arginase deficiency. Am J Hum Genet. 1992 Jun;50(6):1281-90
- 3. Uchino T, Haraguchi Y, Aparicio JM, Mizutani N, Higashikawa M, Naitoh H, Mori M, Matsuda I. Three novel mutations in the liver-type arginase gene in three unrelated Japanese patients with argininemia. Am J Hum Genet. 1992 Dec;51(6):1406-12
- Uchino T, Snyderman SE, Lambert M, Qureshi IA, Shapira SK, Sansaricq C, Smit LM, Jakobs C, Matsuda I. Molecular basis of phenotypic variation in patients with argininemia. Hum Genet. 1995 Sep;96(3):255-60

- Krings G, Ramachandran R, Jain D, Wu TT, Yeh MM, Torbenson M, Kakar S. Immunohistochemical pitfalls and the importance of glypican 3 and arginase in the diagnosis of scirrhous hepatocellular carcinoma. Mod Pathol. 2013 Jun;26(6):782-91
- Fatima N, Cohen C, Siddiqui MT. Arginase-1: a highly specific marker separating pancreatic adenocarcinoma from
 - hepatocellular carcinoma. Acta Cytol. 2014;58(1):83-8
- Timek DT, Shi J, Liu H, Lin F. 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 Aug;138(2):203-10
- 8. Fujiwara M, Kwok S, Yano H, Pai RK. Arginase-1 is a more sensitive marker of hepatic differentiation than HepPar-1 and glypican-3 in fine-needle aspiration biopsies. Cancer Cytopathol. 2012 Aug 25;120(4):230-7
- Radwan NA, Ahmed NS. The diagnostic value of arginase-1 immunostaining in differentiating hepatocellular carcinoma from metastatic carcinoma and cholangiocarcinoma as compared to HepPar-1. Diagn Pathol. 2012 Oct 30;7:149

LABEL AND BOX SYMBOLS

Explanation of the symbols of the product label and box:

\subseteq	Expiration date
Å.	Temperature limit
***	Manufacturer
Σ	Sufficient content for <n> assays</n>
REF	Catalog number
LOT	Lot code
(i)	Refer to the instructions of use
IVD	Medical product for <i>in</i> vitro diagnosis.
e-SDS	Material safety data sheet



(E IVD