MSH2 (C2G3), MMab

Instruction For Use

IVD

[Product Name]

MSH2 (C2G3), MMab

[Catalog No.]

CMM-0192

[Components]

Antibody Type	Mouse Monoclonal	**Clone**	C2G3
Isotype	IgG	**Epitope/Antigen**	MSH2
Species Reactivity	Human; others not tested	**Cellular Localization**	Nuclear

[Specification]

Presentation	Dilution	Volume
Predilute	Ready-to-Use	1.5 mL
Predilute	Ready-to-Use	7.5 mL

[Intended Use]

For In Vitro Diagnostic Use.

This antibody is intended for use in Immunohistochemical applications on formalin-fixed paraffin-embedded tissues (FFPE). 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]

MSH2 is an important gene in the human mismatch repair gene family. Human mismatch repair genes play an important role in maintaining the integrity and stability of genetic information and avoiding the production of genetic mutations. At present,MSH2 is used in the study of hereditary non-polypsy colorectal cancer with MLH1, MSH6, PMS2 together.

[Storage and Validity]

Store at 2~8℃. Avoid freezing. Valid for 12 months.
Maintain temperature below room temperature during transport, ensuring it does not exceed one week.
Store at 2-8°C and use within six months after opening.

[Specimen Requirements]

Tissue Preparation: Fresh biopsy or surgical samples fixed in 10% neutral buffered formalin for 8 to 24 hours. Extracted, dehydrated, and paraffin embedded according to specifications. Store wax blocks in a ventilated, dry cabinet at room temperature for 5 years.
Tissue Sectioning: Spread tissue sections (3-5 μm thick) on an adhesive slide. Tap slide rack and absorb excess water droplets with hygroscopic paper. Dry at 60℃ for 30-60 minutes or at 37℃ overnight, then cool to room temperature.
Storage: If stored at room temperature, complete the test within 7 days to maintain antigen distribution. If stored at 2-8℃, complete the test within 3 months to maintain antigen distribution.

[Protocol Recommendations]

This reagent has been optimized on the fully automatic immunohistochemistry stainer and does not require reconstitution, mixing, dilution or titration.
For detailed operating parameters, please refer to the operating manual of the fully automatic immunohistochemistry stainer.

1.Test Procedure:
1.1 Incubation with peroxidase block quenches the activity of endogenous peroxidase.
1.2 Use MSH2 to incubate.
1.3 Linker , rabbit-anti-mouse incubation.
1.4 Use polymer for incubation, and bind the reagent to linker , rabbit-anti-mouse .
1.5 Incubate the antigen-antibody complex with DAB, and finally appear in the form of a brown precipitate, which can be observed under a light microscope.
1.6 Use DAB Enhancer for incubation to enhance color intensity.
1.7 Incubate with hematoxylin and counterstain the sections.
1.8 Use bluing reagent to incubate and blue hematoxylin to enhance the contrast of the staining results.

2.Quality Control
2.1 Positive Control
Positive controls serve as an indication of correct tissue preparation and appropriate staining techniques. Each staining should include a positive pair of photos for comparison under the same test conditions. Known positive tissue controls should only be used to monitor the correct performance of procedures and testing of reagents and are not intended to aid in describing a definitive diagnosis of a patient sample. If the positive tissue control fails to show appropriate positive staining, the results of this batch of experimental test samples should be considered invalid.
2.2 Blank Control
Each staining should include a blank control reagent under the same test conditions for comparison. Blank control reagents are used to stain tissue sections instead of antibodies to judge non-specific staining and provide a better explanation for antigen site-specific staining.

[Results Interpretation]

1. Staining Results:
- Interpret results based on tissue positive control and blank control experiments: positive (+) or negative (-).
- Positive staining: Yellow or brown-yellow coloration in specific nuclear without background staining.
- Negative staining: No yellow or brown-yellow color appears in the expected cells within the tissue.

2. Presence of MSH2 Antigen:
- Positive staining indicates the presence of MSH2 antigen on the tissue section.
- Determine this based on positive control and blank control experiments.
3. Low Possibility of MSH2 Antigen:
- Negative staining suggests a low possibility of MSH2 antigen on the tissue section.
- Base this conclusion on positive control and blank control experiments.

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4. Re-Testing and Quality Control:
- If both tissue positive control and blank control experiments are negative, indicating reagent failure or detection operation error, re-test the samples.
- Conduct quality control on the operation process and test results.

[Limitations]
Due to inherent variability present in immunohistochemical procedures (including fixation time of tissues, dilution factor of antibody, retrieval method utilized, and incubation time), optimal performance should be established through the use of positive and negative controls. Results should be interpreted by a qualified medical professional.

[Validation]
Compliance: Take the MSH2 positive and negative pairs of photos according to the product instructions for immunohistochemistry testing, and locate nuclear accurately.The positive photos show yellow or brown-yellow color without background coloring, and the MSH2negative pairs of photos and the blank control are negative without coloring.

In-batch repeatability: Tissue slices from the same tissue source containing the target antigen were immunohistochemical detected with the same batch number product, and there was no significant difference in the intensity and location of tissue slice staining.

Inter-batch repeatability: Immunohistochemical tests were performed on tissue slices from the same tissue source containing the target antigen with three different batches of products, and there was no significant difference in the intensity and location of tissue slice staining.

[Troubleshooting]
Follow the antibody specific protocol recommendations according to data sheet provided. If atypical results occur, contact Celnovte's Technical Support at Celnovte.com.

[Precautions]
1. For professional users only. Results should be interpreted by a qualified medical professional.
2. Always wear personal protective equipment such as a laboratory coat, goggles, and gloves when handling reagents.
3. Dispose of unused solution with copious amounts of water.
4. Do not ingest reagent. If reagent is ingested, seek medical advice immediately.
5. Avoid contact with eyes. If contact occurs, flush with large quantities of water.
6. Not confirmed for use on non-10% neutral formalin-fixed tissues.

[Symbols]
The following symbols may be found in this IFU or on the product labeling. Some glossary symbols may not be applicable to this product.

Symbol	Used for	Symbol	Used for
	Expiration Date		Consult instructions for use
LOT	Lot Number	IVD	*In Vitro* diagnostic medical device
	Storage Temperature		Manufacturer
REF	Catalogue number		Date of manufacture
CE	CE mark	EC REP	Authorized representative in the European Community

[Version]
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