EMA(E29),MMab

Instruction For Use

IVD

[Product Name]

EMA(E29),MMab

[Catalog No.]

CEM-0041

[Components]

Antibody Type	Mouse Monoclonal	**Clone**	E29
Isotype	IgG_{2a}/k	**Epitope/Antigen**	EMA
Species Reactivity	Human; others not tested	**Cellular Localization**	Cytoplasm and cell membrane

[Specification]

Presentation	Dilution	Volume
Concentrate	1:50-1:150	0.1mL
Concentrate	1:50-1:150	0.2 mL
Predilute	Ready-to-Use	1 mL
Predilute	Ready-to-Use	3 mL
Predilute	Ready-to-Use	6 mL

[Intended Use]

For In Vitro Diagnostic Use.

This antibody is intended for use in immunohistochemical (IHC) applications on formalin-fixed, paraffin-embedded (FFPE) tissues. Clinical interpretation of staining results should be supplemented by morphological analysis using appropriate controls , and must be assessed within the context of the patient's clinical history and other diagnostic findings by a qualified pathologist.

[Summary and Explanation]

The Epithelial Membrane Antigen (EMA) antibody recognizes a mucin-like glycoprotein that serves as a useful pan-epithelial marker. It is particularly valuable for detecting early metastatic foci of carcinomas in the bone marrow or liver.

EMA demonstrates broad reactivity, staining both normal and neoplastic epithelial cells from various tissue types, including: Mammary epithelium,Sweat glands,Squamous epithelium. However, it is important to note that certain tumor types are consistently EMA-negative, such as:Hepatocellular,Carcinoma Adrenal Carcinoma,Embryonal Carcinomas.
In these EMA-negative cases, the presence of keratin positivity can help differentiate these tumor types from others. Conversely, EMA positivity can be a helpful diagnostic feature for identifying meningiomas, as it can assist in distinguishing these tumors from other intracranial neoplasms.

In summary, the EMA antibody is a versatile pan-epithelial marker that has various applications in the detection of carcinoma metastases and the differential diagnosis of certain tumor types based on its expression pattern or lack thereof.

[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. Bake the sections in an oven at 60℃ (±5℃) for 30 to 60 minutes. Users can adjust the temperature and time as needed according to the actual situation.
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]

1. Instruments and Equipment Required for Testing: Pipette, Induction cooker, Timer, Incubation box, staining rack, Stainless steel pressure cooker, Optical microscope (40 x~400x)

2. Solution Preparation:
2.1 Wash buffer: prepared by dilution of concentrated wash buffer (10×).
2.2 DAB staining solution: prepared by mixing DAB substrate and DAB buffer at a ratio of 1:20.

3. Test Temperature Conditions: Maintain a temperature of 18℃ ~ 25℃.

4. Test Procedure:
4.1. Manual Test Steps:
4.1.1 Dewaxing and Hydration:
- Place paraffin sections in fresh xylene, soak twice for 10 minutes each time.
- Remove excess liquid and place the sections in absolute ethanol, soak twice for 5 minutes each time.
- Remove excess liquid and place the sections in 95% ethanol for 5 minutes.
- Remove excess liquid and place the sections in 85% ethanol for 5 minutes.
- Remove excess liquid and place the sections in 70% ethanol for 5 minutes.
- Rinse with purified water for 5 minutes.

4.1.2 Antigen Repair:
- Heat the antigen retrieval solution II to boiling in a pressure cooker on an induction cooktop.
- Place the dewaxed and hydrated sections onto a heat-resistant staining rack , and insert the rack into the pressure cooker.
- Cover the pressure cooker and continue heating until steam is generated. After 2.5 minutes, remove the pressure cooker from the heat source and allow it to cool naturally for 5 minutes.
- Cool under running tap water, release the pressure, open the lid, and wait until the liquid in the pot cools to room temperature before removing the sections.
- Soak the sections twice in purified water for 3 minutes each time.

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- Soak the sections in the wash buffer once for 3 minutes.
Note: Ensure that the sections are always immersed in the repair solution during antigen repair.

4.1.3 Add the Endogenous Peroxidase Blocking:
- Remove the wash buffer and add 100 μL of peroxidase block to the tissue area to be tested. Incubate for 5 minutes at room temperature.
- Soak the sections twice in wash buffer for 5 minutes each time.

4.1.4 Add EMA Antibody Reagent or Blank Control Reagent:
- Remove the wash buffer and add 100 μL of EMA antibody reagent or blank control reagent. Incubate at room temperature for 60 minutes.
- Soak the sections twice in the wash buffer for 5 minutes each time.

4.1.5 Add Anti-Mouse/Rabbit HRP Polymer:
- Remove the wash buffer and add 100 μL of Anti-Mouse/Rabbit HRP Polymer dropwise. Incubate for 30 minutes.
- Soak the sections twice in the wash buffer for 5 minutes each time.

4.1.6 Chromogenic Reaction
- Remove the wash buffer and add 100 μL of freshly prepared DAB color development solution dropwise. Incubate for 5 to 8 minutes. Observe the staining results under an optical microscope; generally, observation should not exceed 10 minutes.
4.1.7 Counterstaining:
- Rinse with purified water, apply 100 μL of hematoxylin staining solution, and incubate for 3–5 minutes. Rinse with purified water to return the blue color.
Note: Adjust the incubation time and intensity of hematoxylin staining solution to achieve the desired staining results. Overstaining or insufficient staining may affect the accuracy of the results.

4.1.8 Dehydration, transparent and mounting.
- Soak in 70% ethanol for 2min;
- Soak in 85% ethanol for 2min;
- 95% ethanol for 2min;
- Then soak twice in absolute ethanol for 2 minutes each time.
- Finally, clear in xylene, and mount with neutral resin and a coverslip.

4.2 Instrument test steps
For specific test methods, refer to the operation manual of the fully automatic IHC stainer(Models: CNT300, CNT320, CNT330, CNT360).

[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 cytoplasm and cell membrane without background staining.
- Negative staining: No yellow or brown-yellow color appears in the expected cells within the tissue.

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

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 EMA positive and negative pairs of photos according to the product instructions for immunohistochemistry testing, and locate cytoplasm and cell membrane accurately.The positive photos show yellow or brown-yellow color without background coloring, and the EMA negative 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 staining was performed on tissue sections from the same source containing the target antigen, using three different batches of the product. No significant differences were observed in staining intensity or localization across the tested batches.

[Troubleshooting]

Please follow the antibody-specific protocol recommendations outlined in the provided datasheet. If atypical or unexpected results are observed, 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.

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[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]

Revision date: 2026-03-13

Version: 02; Delete item 6 under [Precautions]: Not confirmed for use on non-10% neutral formalin-fixed tissues.

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