

CA19-9(C241:5:1:4), MAb

Instruction For Use

IVD



[Product Name]

CA19-9(C241:5:1:4), MAb

[Catalog No.]

CCM-0170

[Components]

Antibody Type	Mouse Monoclonal	Clone	C241:5:1:4
Isotype	IgG1/k	Epitope/Antigen	CA19-9
Species Reactivity	Human; others not tested	Cellular Localization	Cell membrane and cytoplasm

[Specification]

Presentation	Dilution	Volume
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]

CA19 - 9 levels are elevated in the blood, mainly in patients suffering from carcinomas of the gastrointestinal tract. Generally, higher levels of CA19 - 9 are more indicative of malignancy compared to lower levels. Nevertheless, extremely high levels can sometimes be observed in patients with benign conditions like cirrhosis. CA19 - 9 is not specific enough to be used as a screening test. Among various applications, it is most useful in differentiating pancreatic cancer from pancreatitis. The specificity for diagnosing pancreatic cancer improves as the CA19 - 9 levels increase. Specifically, high levels of CA19 - 9 demonstrate a specificity of greater than 97%.

[Storage and Validity]

Store at 2-8°C. 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°C (±5°C) 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°C, 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°C ~ 25°C.

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.
 - 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.



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4.1.4 Add CA19-9 Antibody Reagent or Blank Control Reagent:

- Remove the wash buffer and add 100 µL of CA19-9 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 cell membrane and cytoplasm without background staining.
- Negative staining: No yellow or brown-yellow color appears in the expected cells within the tissue.

2. Presence of CA19-9 Antigen:

- Positive staining indicates the presence of CA19-9 antigen on the tissue section.
- Determine this based on positive control and blank control experiments.

3. Low Possibility of CA19-9 Antigen:

- Negative staining suggests a low possibility of CA19-9 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 CA19-9 positive and negative pairs of photos according to the product instructions for immunohistochemistry testing, and locate cell membrane and cytoplasm accurately. The positive photos show yellow or brown-yellow color without background coloring, and the CA19-9 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.

[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.



Henan Celnovte Biotechnology Co., Ltd.

Address: N0.1 Cuizhu Street, Bldg. 109, Hi-tech District, Zhengzhou, Henan, China. 450000

Tel: +86(371)-56596916 | www.celnovte.com

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[Version]

Revision date: 2026-06-05
Version: 02; Delete item 6 under [Precautions]: Not confirmed for use on non-10% neutral formalin-fixed tissues.

Symbol	Used for	Symbol	Used for
	Expiration Date		Consult instructions for use
	Lot Number		For In Vitro Diagnostic Use.
	Storage Temperature		Manufacturer
	Catalogue number		Date of manufacture