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Rev. 2.1
KEY-CODE CMC43900021

MUC6 (MRQ-20)

For In Vitro Diagnostic Use (IVD)
English: Instructions For Use

Presentation
Anti-MUC6 is a mouse monoclonal antibody from supernatant diluted in phosphate buffered saline, pH 7.4, with protein base, and preserved with sodium azide.

Applications
Mucins are high molecular weight glycoproteins which constitute the major component of the mucus layer that protects the gastric epithelium from chemical and mechanical aggressions. In humans, at least 14 mucin genes have been identified that code for the mucin proteins. They are designated as MUC1, MUC2, MUC3, MUC4, MUC5AC, MUC5B , MUC6 , MUC7, MUC8, MUC9, MUC11, MUC12, MUC13 and MUC16.

Mucin genes are expressed in a regulated cell- and tissue-specific manner. The stomach provides a good example of such differential expression of mucin genes. MUC1 is detected in mucous cells of the surface epithelium and neck region of the gastric antrum, as well as in pyloric glands and oxynthic glands of the body region. MUC5AC is highly expressed in foveolar epithelium of both body and antrum, whereas MUC6 protein expression is limited to mucous neck cells of the body and pyloric glands of the antrum. The mucin expression pattern of gastric carcinoma is heterogeneous. It includes mucins normally expressed in gastric mucosa (MUC1, MUC5AC and MUC6) and de novo expression of the intestinal mucin MUC2.

The heterogeneous pattern of mucin expression, including the expression of the intestinal mucin MUC2, may provide new insights into the differentiation pathways of gastric carcinoma. Pinto-de-Sousa et al. have shown in a comprehensive study of gastric carcinomas evaluated for expression of several mucins (MUC1, MUC2, MUC5AC and MUC6) that: (1) mucin expression is associated with tumor type (MUC5AC with diffuse and infiltrative carcinomas and MUC2 with mucinous carcinomas) but not with the clinico-biological behavior of the tumors; and (2) mucin expression is associated with tumor location (MUC5AC with antrum carcinomas and MUC2 with cardia carcinomas), indirectly reflecting differences in tumor differentiation according to tumor location.

The following generalities apply to the patterns of Mucin expression:

MUC5AC expression:
preferentially expressed in the normal stomach and respiratory tract
- GI & pancreatobiliary ACAs
- Esophageal CAs (67%)
- Gastric CAs (58%)
- Colonic CAs (6-25%)
- Pancreatic ductal CAs (73%)
- Cholangiocarcinomas (45%)
- Endocervical ACAs (70%)
- Endometrial ACAs (22%)
- Lung ACAs (14%)

MUC1+/MUC2-/MUC5AC+ pattern:
- Endocervical adenoCAs (50%)
- Pancreatic ductal adenoCAs (64%)

MUC1+/MUC2-/MUC5AC- pattern:
- Ductal and lobular breast CAs (100%)
- Urothelial CAs (bladder) (93%)
- Renal CAs (75%)
- Ovarian ACAs of various types
- Most pulmonary adenocarcinomas (81%)
- Endometrial (78%) adenoCAs (small subset expresses MUC5AC)

MUC1-/MUC2-/MUC5AC- pattern:
- Hepatocellular CA
- Adrenocortical CA
- Prostate CA

Associated products: MUC1, MUC2, MUC5AC, TAG-72, MOC-31, CEA

Reactivity	Paraffin, frozen
Control	Stomach, associated adenocarcinomas
Visualization	Cytoplasmic
Stability	Up to 36 months; store at 2-8°C
Isotype	IgG_1

Antibody color does not affect performance

Description	**Ventana®* Cat. No.**
50 test dispenser	760-4390

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EC REP EMERGO EUROPE
Molenstraat 15, 2513 BH, The Hague, NL.

CE *Material Safety Data Sheet available upon request.*

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Preparation
1. Cut 3-4 µm section of formalin-fixed, paraffin-embedded tissue and place on positively charged slides; dry overnight at 58° C.

Recommended Ventana®* Staining Procedure
1. Load slides, antibody, and UltraView™ detection kit dispensers onto BenchMark®* instrument.
2. Select CC1 Mild pretreatment.
3. Antibody incubation should be set for 16 minutes at 37° C.
4. Start the run.
5. When the staining run is complete, move slides from instrument and rinse well with wash buffer.
6. Coverslip.

References
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5. O'Connell FP, Wang HH, Odze RD. Utility of immunohistochemistry in distinguishing primary adenocarcinomas from metastatic breast carcinomas in the gastrointestinal tract. Arch Pathol Lab Med. 2005 Mar;129(3):338-47.
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Inline Dispenser Preparation, Handling & Storage Instructions

Preparing For Use:

Where Used: For NexES® IHC, BenchMark® Series and Discovery® automated instruments, software version 8.0 and higher.

STEP 1: Shipping Key Removal
To remove the Shipping Key (shown in Figure A), remove the Nozzle Cap, hold the dispenser upright and pull the Key Tab to disengage it from each end. DO NOT cover the nozzle tip as it could permanently damage the dispenser. DO NOT depress the dispenser while removing the key as it could waste reagent. Discard the shipping key.

STEP 2: Preparing the Dispenser for Use
Remove the Nozzle Cap and place on the Nozzle Cap Holder. Fluid may be present inside the Nozzle Cap. Install the dispenser on the reagent carousel. The Inline Dispenser has been designed to be "Prepared for Use" by the NexES software Version 8.0 or higher. Before each run, the software will detect a new dispenser on the carousel and prime it automatically. Manually priming the dispenser is not necessary and should NEVER be done as it could waste reagent and decrease the number of available dispenses.

Note - All earlier software installations: After removing the shipping key, remove the nozzle cap and CHARGE THE DISPENSER BY RAPIDLY PUMPING 3 to 4 TIMES, keeping the dispenser in an upright position. Charging is only necessary prior to first time use. (See Inspect Prime Before Use section.)

STEP 3: Dispenser Storage & Handling
To insure reliable operation, the dispenser must always be capped when not in use and should NEVER be manually dispensed. (See the Do's and Don't section.)

Do's and Don't-

DO:
1. Check priming chamber and meniscus before each use. (See Inspect Prime Before Use).
2. Store nozzle cap on dispenser. A holder is provided.
3. Cap dispenser when not in use to prevent evaporation. Dispensers mounted on the reagent tray can be capped (from underneath the tray) when not in use.
4. Store dispensers in an upright position in a rack and on the reagent carousel.
5. When mounting the dispenser on the carousel, grasp the coupler to avoid accidental manual dispensing.

DON'T:
1. Do not manually dispense when inverted (upside down). Prime will be lost and may be impossible to restore.
2. Do not manually dispense with the nozzle cap in place. This can permanently damage the dispenser.
3. Do not manually dispense or prime prior to each use. This is not necessary and wastes reagent.
4. Do not hold the barrel in the down position. Fluid can leak from the dispenser when the barrel is depressed.
5. Do not stack carousels with dispensers installed. This can cause the dispensers to leak.

Inspect Prime Before Use:

Remove the nozzle cap and refer to Fig. B.

Dispenser Is Ready For Use When:

1. A meniscus is present in the area shown in Figure B.
2. The priming chamber contains liquid.

If one or both of these conditions is not satisfied, consult Signs of Trouble and What to Do section.

Signs Of Trouble & What To Do:

1. Priming chamber empty. If there is no liquid in the priming chamber, re-prime the dispenser (see Re-Priming the Dispenser section).
2. Meniscus absent. If no meniscus is visible in the nozzle area, manually charge the dispenser once. If this does not resolve the condition, re-prime the dispenser (see Re-Priming the Dispenser section). If condition reoccurs, contact your local Ventana Customer Support Center.
3. Leaking dispenser. External fibers (from clothing or other sources) can cause dispenser to leak. Use in a clean environment.
4. Blocked dispenser. The normal performance characteristics of the dispenser are such that particulates (i.e., fibers, precipitation) could cause a dispenser blockage. A sign of blockage could include higher reagent volume than expected, remaining within the dispenser, after a period of use. Blockage is also evidenced by the failure of the dispenser to yield fluid upon manual dispense, which can be tested by the steps listed in the Re-Priming the Dispenser section. If blockage is suspected (or if foreign material is observed in the dispenser), contact the Ventana Customer Support Center.

NOTE: DO NOT manually dispense or prime the dispenser unless absolutely necessary. Although Ventana pre-filled dispensers have been overfilled to insure a sufficient number of tests, manual dispensing or priming can cause insufficient tests remaining in the dispenser and may cause undesirable staining results.

Consult individual reagent package inserts for information on the utilization of appropriate Quality Control Procedures.

Re-priming The Dispenser:

Once primed, the dispenser should not lose prime if handled correctly. If re-priming is necessary, proceed as follows:
1. Aim the dispenser tip at a waste container. Remove the nozzle cap and depress the barrel (top of the dispenser). This should dispense a drop.
2. If no drop is dispensed, repeat Step 1, above, several times until a drop is ejected.
3. If a drop is ejected, proceed with instructions in Inspect Prime Before Use on this page.
4. If no drop is ejected, or inspection for prime (Step 3) fails, contact your local Ventana Customer Support Center.

Contacting Ventana Technical Consultation Center

If your dispenser does not look or perform as expected, please contact your local Ventana Customer Support Center for advice or return information. Please have the dispenser Lot Number (from the reagent label) handy when you call.

CONTACT INFORMATION:
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EC REP

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Figure A

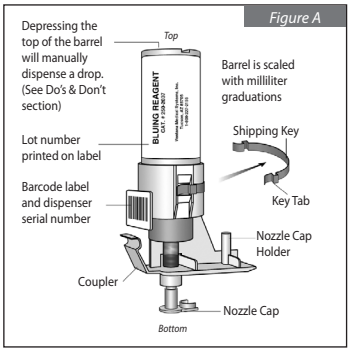

Figure B