

# CDX-2 (EPR2764Y)

For In Vitro Diagnostic Use (IVD)

English: Instructions For Use

## Presentation

Anti-CDX-2 is a rabbit monoclonal from tissue culture supernatant diluted in phosphate buffered saline, pH 7.4, with protein base, and preserved with sodium azide.

## Applications

CDX-2 is a caudal-related homeobox transcription factor whose expression in the adult is normally restricted to the intestinal epithelium. It is implicated in the development and maintenance of the intestinal mucosa. This protein is expressed immunohistochemically in the nuclei of normal intestinal epithelium. Loss of CDX-2 protein expression has been correlated with loss of differentiation in colorectal cancers. Anti-CDX-2 antibody has been useful in distinguishing gastrointestinal origin of metastatic adenocarcinomas and carcinoids. A high percentage of mucinous carcinomas of the ovary also stain positively with this antibody as well as carcinomas from the upper gastrointestinal tract.

<b>Reactivity</b>	Paraffin, frozen
<b>Control</b>	Adenocarcinoma of colon, normal colon
<b>Visualization</b>	Nuclear
<b>Stability</b>	Up to 36 months; store at 2-8°C
<b>Isotype</b>	IgG

*Antibody color does not affect performance*

<b>Description</b>	<b>Ventana® Cat. No.</b>
50 test dispenser	760-4380

## 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 (UltraView™)

1. Load slides, antibody, and UltraView™ detection kit dispensers onto BenchMark® instrument.
2. Select CC1 Standard pretreatment.
3. Antibody incubation should be set for 32 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.

## Recommended Ventana® Staining Procedure (iView™)

1. Load slides, antibody, and iView™ detection kit dispensers onto BenchMark® instrument.
2. Select CC1 Standard pretreatment.
3. Antibody incubation should be set for 32 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

1. Levine PH et al. Diagn Cytopathol. 2006 Mar;34(3):191-5
2. Mazziotta RM et al. Appl Immunohistochem Mol Morphol. 2005 Mar;13(1):55-60
3. Saqi A et al. Am J Clin Pathol. 2005 Mar;123(3):394-404
4. Erickson LA et al. Endocr Pathol. 2004 Fall;15(3):247-52
5. Saad RS et al. Am J Clin Pathol. 2004 Sep;122(3):421-7
6. Kaimaktchiev V et al. Mod Pathol. 2004 Nov;17(11):1392-9
7. Groisman GM et al. Int J Gynecol Pathol. 2004 Jan;23(1):52-7
8. Moskaluk CA et al. Mod Pathol. 2003 Sep;16(9):913-9
9. Werling RW et al. Am J Surg Pathol. 2003 Mar;27(3):303-10

\*Ventana®, UltraView™, iView™, and BenchMark® are registered trademarks of Ventana Medical Systems, Inc. Cell Marque antibodies are developed, manufactured and distributed by Cell Marque Corporation and their sale through Ventana Medical Systems, Inc. does not imply approval, endorsement, or any guarantee of quality or performance of those Cell Marque antibodies by Ventana Medical Systems, Inc.

## 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.

### INTELLECTUAL PROPERTY

BenchMark®, NexES®, Discovery® and Ventana® are registered U.S. trademarks of Ventana Medical Systems, Inc.

Ventana grants user a single-use-only license under the following patents: U.S. Pat. Nos. 6045 759, 6192 945, 6416 713, and 6945 128, and foreign counterparts thereof.

### CONTACT INFORMATION:

Ventana Medical Systems, Inc.  
1910 Innovation Park Drive  
Tucson, Arizona 85755  
U.S.A.  
+1 520 887-2155  
+1 800 227 2155 (USA)

EC	REP
----	-----

Roche Diagnostics GmbH  
Sandhofer Strasse 116  
D-68305 Mannheim  
Germany

