CDX2 (RM) Concentrated and Prediluted Rabbit Monoclonal Antibody
901-3144-090517

<table>
<thead>
<tr>
<th>Catalog Number:</th>
<th>ACI 3144 A, B</th>
<th>API 3144 AA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Description:</td>
<td>0.1, 0.5 ml, concentrated</td>
<td>6.0 ml, prediluted</td>
</tr>
<tr>
<td>Dilution:</td>
<td>1:100</td>
<td>Ready-to-use</td>
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<tr>
<td>Diluent:</td>
<td>Da Vinci Green</td>
<td>N/A</td>
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</tbody>
</table>

**Intended Use:**
For In Vitro Diagnostic Use

CDX2 (RM) [EP25] is a rabbit monoclonal antibody that is intended for laboratory use in the qualitative identification of CDX2 protein by immunohistochemistry (IHC) in formalin-fixed paraffin-embedded (FFPE) human tissues. 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:**
CDX2 is a homeobox gene that encodes an intestine-specific transcription factor (1). CDX2 has been useful to establish gastrointestinal origin of metastatic adenocarcinomas and carcinoids and can be especially useful in distinguishing metastatic colorectal adenocarcinoma from tumors of unknown origin (1-7). CDX2 has been shown to be more specific and more sensitive than villin or CK20 (1,4,6). CDX2 has also been shown to be expressed in mucinous ovarian cancer, bladder adenocarcinoma, cholangiocarcinoma and malignant germ cell tumors of the testes (1,2,6-8). Only very rare examples of carcinomas of the genitourinary and gynecologic systems of the gastrointestinal origin of metastatic adenocarcinomas and carcinoids can be especially useful in distinguishing metastatic colorectal adenocarcinoma from tumors of unknown origin (1-7). CDX2 has been shown to be more specific and more sensitive than villin or CK20 (1,4,6). CDX2 has also been shown to be expressed in mucinous ovarian cancer, bladder adenocarcinoma, cholangiocarcinoma and malignant germ cell tumors of the testes (1,2,6-8). Only very rare examples of carcinomas of the genitourinary and gynecologic systems.

**Principle of Procedure:**
Antigen detection in tissues and cells is a multi-step immunohistochemical process. The initial step binds the primary antibody to its specific epitope. A secondary antibody may be applied to bind the primary antibody, followed by an enzyme labeled polymer; or an enzyme labeled polymer may be applied directly to bind the primary antibody. The detection of the bound primary antibody is evidenced by an enzyme-mediated colorimetric reaction.

**Source:** Rabbit monoclonal

**Species Reactivity:** Human; others not tested

**Clone:** EP25

**Isotype:** IgG

**Total Protein Concentration:** ~10 mg/ml. Call for lot specific Ig concentration.

**Epitope/Antigen:** A synthetic peptide corresponding to residues near the C-term of human CDX2 protein

**Cellular Localization:** Nuclear

**Positive Tissue Control:** Normal colon or colon cancer

**Known Applications:** Immunohistochemistry (formalin-fixed paraffin-embedded tissues)

**Supplied As:** Buffer with protein carrier and preservative

**Storage and Stability:**
Store at 2°C to 8°C. Do not use after expiration date printed on vial. If reagents are stored under conditions other than those specified in the package insert, they must be verified by the user. Diluted reagents should be used promptly; any remaining reagent should be stored at 2°C to 8°C.

**Protocol Recommendations:**

**Peroxide Block:** Block for 5 minutes with Biocare's Peroxidized 1.

**Pretreatment:** Perform heat retrieval using Biocare's Diva Decloaker. Refer to the Diva Decloaker product data sheet for specific instructions.

**Primary Antibody:** Incubate for 30 minutes at RT.

**Probe:** N/A

**Polymer:** Incubate for 30 minutes at RT with a secondary-conjugated polymer.

**Chromogen:**
- Incubate for 5 minutes at RT with Biocare's DAB – OR – Incubate for 5-7 minutes at RT with Biocare's Warp Red.
- Counterstain with hematoxylin. Rinse with deionized water. Apply Tacha's Bluing Solution for 1 minute. Rinse with deionized water.

**Protocol Recommendations (Ventana BenchMark ULTRA):**
Refer to the User Manual for specific instructions for use. Recommended protocol parameters are as follows:

- **Template:** U OptiView DAB IHC
- **Pretreatment Protocol:** ULTRA CC1 32 minutes at 100°C
- **Peroxidase:** Pre Primary Peroxidase Inhibitor
- **Primary Antibody:** Incubate for 16 minutes at 36°C
- **Detection:** OptiView

**Technical Note:**
This antibody has been standardized with Biocare's MACH 4 detection system. Use TBS buffer for washing steps.

**Limitations:**
The optimum antibody dilution and protocols for a specific application can vary. These include, but are not limited to fixation, heat-retrieval method, incubation times, tissue section thickness and detection kit used. Due to the superior sensitivity of these unique reagents, the recommended incubation times and titers listed are not applicable to other detection systems, as results may vary. The data sheet recommendations and protocols are based on exclusive use of Biocare products. Ultimately, it is the responsibility of the investigator to determine optimal conditions. The clinical interpretation of any positive or negative staining should be evaluated within the context of clinical presentation, morphology and other histopathological criteria by a qualified pathologist. The clinical interpretation of any positive or negative staining should be complemented by morphological studies using proper positive and negative internal and external controls as well as other diagnostic tests.

**Quality Control:**
Precautions:
1. This antibody contains less than 0.1% sodium azide. Concentrations less than 0.1% are not reportable hazardous materials according to U.S. 29 CFR 1910.1200, OSHA Hazard communication and EC Directive 91/155/EC. Sodium azide (NaN₃) used as a preservative is toxic if ingested. Sodium azide may react with lead and copper plumbing to form highly explosive metal azides. Upon disposal, flush with large volumes of water to prevent azide build-up in plumbing. (Center for Disease Control, 1976, National Institute of Occupational Safety and Health, 1976) (11)
2. Specimens, before and after fixation, and all materials exposed to them should be handled as if capable of transmitting infection and disposed of with proper precautions. Never pipette reagents by mouth and avoid contacting the skin and mucous membranes with reagents and specimens. If reagents or specimens come into contact with sensitive areas, wash with copious amounts of water. (12)
3. Microbial contamination of reagents may result in an increase in nonspecific staining.
4. Incubation times or temperatures other than those specified may give erroneous results. The user must validate any such change.
5. Do not use reagent after the expiration date printed on the vial.
6. The SDS is available upon request and is located at http://biocare.net.

Troubleshooting:
Follow the antibody specific protocol recommendations according to data sheet provided. If atypical results occur, contact Biocare's Technical Support at 1-800-542-2002.

References: