HPV Cocktail Broad Spectrum (HPV-1, 6, 11, 16, 18 and 31)

Concentrated and Prediluted Cocktail Antibody

Control Number: 901-177-081617

Catalog Number:	**ACI 177 BK, CK**	**API 177 AA**
Description:	0.5, 1.0 ml, concentrated	6.0 ml, prediluted
Dilution:	1:100-1:200	Ready-to-use
Diluent:	HPV Diluent	N/A

Intended Use:

For In Vitro Diagnostic Use

HPV Cocktail Broad Spectrum (HPV-1, 6, 11, 16, 18 and 31) [BPV-1/1H8 + CAMVIR -1] is a mouse monoclonal antibody cocktail that is intended for laboratory use in the qualitative identification of proteins of HPV subtypes 1, 6, 11, 16, 18 and 31 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.

FOR DISTRIBUTION OUTSIDE THE UNITED STATES ONLY.

Summary and Explanation:

The broad spectrum HPV antibody was produced (1H8) against SDS-disrupted bovine papillomavirus type 1 (BPV-1) and used to identify the product of the L1 open reading frame (ORF) of BPV-1. IH8 was found to be reactive with purified major capsid protein (MCP). The antibody was tested with ELISA and with an immunofluorescent technique and detected HPV-1, 6, 11, 16, 18, and 31 in formalin-fixed paraffin embedded biopsy specimens. The CAMVIR-1 antibody was raised against the major capsid protein L1 of human papillomavirus type 16, using a recombinant vaccinia virus that expresses the L1 protein, as a target for screening. This antibody reacted with a 56 kilodalton protein in cells infected with L1-vaccinia virus, and the protein was present in HPV16. A panel of p16 and Ki-67 can be used for further evaluation.

CAMVIR-1 may also be used separately for phenotyping HPV-16. Other HPV isotypes may also be reactive with the Broad Spectrum HPV antibody, but have not been tested.

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. After labeling the antigen with a primary antibody, a secondary antibody is added to bind to the primary antibody. An enzyme label is then added to bind to the secondary antibody; this detection of the bound antibody is evidenced by a colorimetric reaction.

Source: Mouse monoclonal

Species Reactivity: Human; others not tested

Clone: BPV-1/1H8 + CAMVIR-1

Isotype: IgG + IgG2a

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

Epitope/Antigen: HPV Cocktail Broad Spectrum (HPV-1, 6, 11, 16, 18 and 31)

Cellular Localization: Nuclear

Positive Control: Infected cervical biopsy

Known Applications:

Immunohistochemistry (formalin-fixed paraffin-embedded tissues)

Supplied As: Buffer with protein carrier and preservative
HPV Diluent (PD906)

Storage and Stability:

Store at 2ºC to 8ºC. 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 2ºC to 8ºC.

Protocol Recommendations:

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

Pretreatment Solution (recommended): Reveal or Diva

Pretreatment Protocol:

Heat Retrieval Method: Retrieve sections under pressure using Biocare's Decloaking Chamber, followed by a wash in distilled water; alternatively, steam tissue sections for 45-60 minutes. Allow solution to cool for 10 minutes then wash in distilled water.

Protein Block: Incubate for 5-10 minutes at RT with Biocare's Background Punisher.

Primary Antibody: Incubate for 30 minutes at RT.

Probe: Incubate for 10 minutes at RT with a secondary probe.

Polymer: Incubate for 10 minutes at RT with a tertiary 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:

Counterstain with hematoxylin. Rinse with deionized water. Apply Tacha's Bluing Solution for 1 minute. Rinse with deionized water.

Technical Note:

This antibody has been standardized with Biocare's MACH 4 detection system. It can also be used on an automated staining system and with other Biocare polymer detection kits. 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:

Refer to CLSI Quality Standards for Design and Implementation of Immunohistochemistry Assays; Approved Guideline-Second edition (I/LA28-A2) CLSI Wayne, PA USA (www.clsi.org). 2011

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.

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Rev 062117

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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 (NaN_3) 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) (2)
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 in contact with sensitive areas, wash with copious amounts of water. (3)
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.

References:

1. Cowsert LM, Pilacinski WP, Jenson AB. Identification of the bovine papillomavirus L1 gene product using monoclonal antibodies. Virology. 1988 Aug;165(2):613.
2. Center for Disease Control Manual. Guide: Safety Management, NO. CDC-22, Atlanta, GA. April 30, 1976 "Decontamination of Laboratory Sink Drains to Remove Azide Salts."
3. Clinical and Laboratory Standards Institute (CLSI). Protection of Laboratory Workers from Occupationally Acquired Infections; Approved guideline-Fourth Edition CLSI document M29-A4 Wayne, PA 2014.

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