ONCORE DAB Chromogen

DAB Chromogen and Buffer for the ONCORE
Automated Slide Stainer
901-6056K-032918

ONCORE

BIOCARE MEDICAL

Catalog Number: **ORI 6056K T201**

Description: Up to 189 tests

Intended Use:
For In Vitro Diagnostic Use
ONCORE DAB Chromogen consists of two solutions for the staining of formalin-fixed, paraffin-embedded (FFPE) tissues, as part of an immunohistochemistry (IHC) procedure using a horseradish peroxidase (HRP) detection system, on Biocare Medical's ONCORE Automated Slide Stainer. The clinical interpretation of any staining or its absence should be complemented by morphological studies and proper controls and should be evaluated within the context of the patient's clinical history and other diagnostic tests by a qualified pathologist. This product requires ONCORE Software version 2.5.xx or higher for proper usage.

Summary & Explanation:
Immunohistochemistry (IHC) permits the visual identification of specific protein antigens in tissues for diagnostic purposes. Following application of the primary antibody, the presence of a target antigen is visualized by the sequential application of an enzyme-antibody conjugate that binds the primary antibody, and a chromogen reagent, to produce a colored reaction product that is visible by light microscopy. 3,3'-Diaminobenzidine (DAB) is a widely used chromogen for immunohistochemical staining with horseradish peroxidase (HRP) detection systems. In the presence of peroxidase enzyme, DAB produces a brown precipitate that is insoluble in alcohol and xylene. ONCORE DAB Chromogen contains two solutions: DAB chromogen and the corresponding buffer. It is intended for use with an HRP detection system in an IHC staining procedure on the ONCORE Automated Slide Stainer. ONCORE DAB Chromogen is specifically formulated for on-rack mixing of DAB Chromogen and DAB Buffer, without the need for pre-mixing by the user. A mixing vial is required for each unique run of the ONCORE.

Known Applications:
Immunohistochemistry (FFPE tissues)

Reagents Provided:
ONCORE DAB Chromogen is comprised of two solutions, DAB Chromogen and DAB Buffer, intended for use on the ONCORE Automated Slide Stainer:

DAB Chromogen (ORI6054 T67) up to 63 tests per vial, 3 vials x 1.2 mL
DAB Buffer (ORI6055 T67) up to 63 tests per vial, 3 vials x 15.5 mL
10 Mixing Vials, 7.5mL capacity (if needed, additional mixing vials sold separately, order ONC015)

Reconstitution, Dilution and Mixing:
DAB Chromogen and DAB Buffer do not require mixing before use. To account for dead volume, an additional 431uL of mixed DAB chromogen and buffer (2 tests) is required for each use of a mixing vial.

Materials and Reagents Required But Not Provided:
Reagents and materials, such as primary antibodies, detection kits, chromogens and ancillary reagents are not provided. Refer to the ONCORE Automated Staining System User Manual for a complete list of materials and reagents required.

Storage and Stability:
Store at 2ºC to 8ºC. Do not use after expiration date printed on vial. DAB Chromogen may become pink to brown in color over time. This change in color is expected and does not affect staining performance. Avoid exposure to direct sunlight.

Instructions for Use:
Load both DAB Chromogen and DAB Buffer reagent vials in the reagent tray along with one Mixing Vial in Position #40 of the ONCORE Automated Slide Stainer before beginning a staining run. DAB Chromogen and DAB Buffer will be mixed before use in the mixing vial at the appropriate time and then applied to each slide, according to the programmed staining protocol. Refer to the appropriate antibody data sheet for the recommended staining protocol. Refer to the ONCORE Automated Staining System User Manual for detailed instructions on instrument operation and additional protocol options. Washing and reusing of mixing vials is not recommended.

Precautions:
1. This product is intended for *in vitro* diagnostic (IVD) use.
2. DAB Chromogen is a suspected carcinogen. DAB Chromogen may be harmful or cause irritation if exposed to skin or eyes. Avoid contact with reagents and wear disposable gloves when handling reagents.
3. 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. Avoid contacting the skin and mucous membranes with reagents and specimens, and follow standard laboratory precautions to prevent exposure to eyes and skin. If reagents or specimens come in contact with sensitive areas, wash with copious amounts of water. (3)
4. Microbial contamination of reagents may result in an increase in nonspecific staining.
5. The SDS is available upon request and is located at http://biocare.net.

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

Limitations:
These reagents have been optimized for use with ONCORE antibodies, detections and ancillary reagents. The protocols for a specific application can vary. These include, but are not limited to fixation, heat-retrieval method, incubation times, and tissue section thickness. Third party primary antibodies may be used on the ONCORE; however, appropriate antibody concentration may depend upon multiple factors and must be empirically determined by the user. 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.

References:
1. Taylor CR, Cote RJ. Immunomicroscopy: A Diagnostic Tool for the Surgical Pathologist. 3rd Ed. Philadelphia: Saunders Elsevier, 2006.
2. Dabbs DJ. Diagnostic Immunohistochemistry: Theranostic and Genomic Applications. 3rd Ed. Philadelphia: Saunders Elsevier, 2010.
3. Clinical and Laboratory Standards Institute (CLSI). Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline-Fourth Edition (M29-A4) Wayne, PA 2014.

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