Fast Red Chromogen Kit

Fast Red Chromogen and Buffer for the
ONCORE Automated Slide Stainer
Control Number: 901-6042K-091117

Catalog Number: ORI6042K T60

Description: 60 tests

Intended Use:
For In Vitro Diagnostic Use
Fast Red Chromogen Kit consists of two solutions for the staining of formalin-fixed, paraffin-embedded (FFPE) tissues, as part of an immunohistochemistry (IHC) procedure using an alkaline phosphatase (AP) 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.

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.

Fast Red is a widely used chromogen for immunohistochemical staining with alkaline phosphatase (AP) detection systems. In the presence of alkaline phosphatase enzyme, Fast Red produces a red precipitate.

Fast Red Chromogen Kit contains two solutions: Fast Red chromogen and the corresponding buffer. It is intended for use with an AP detection system in an IHC staining procedure on the ONCORE Automated Slide Stainer.

Known Applications:
Immunohistochemistry (FFPE tissues)

Reagents Provided:
Fast Red Chromogen Kit is comprised of two solutions, Fast Red Chromogen and Fast Red Buffer, intended for use on the ONCORE Automated Slide Stainer:
Fast Red Chromogen (ORI6040 T60) 60 tests
Fast Red Buffer (ORI6041 T60) 60 tests

Reconstitution, Dilution and Mixing:
Fast Red Chromogen and Fast Red Buffer do not require mixing before use.

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. Avoid exposure to direct sunlight.

Instructions for Use:
Load both Fast Red Chromogen and Fast Red Buffer reagent vials in the reagent tray of the ONCORE Automated Slide Stainer before beginning a staining run. Fast Red Chromogen and Fast Red Buffer will be mixed on each individual slide at the appropriate time, 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.

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.

It is recommended that the user validate tissue placement on the microscope slide when staining with Fast Red in order to ensure full tissue coverage. Tissues placed in the Green Zone on the ONCORE IHC Tissue Placement Guide have exhibited superior results.

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

Precautions:
1. This product is intended for *in vitro* diagnostic (IVD) use.
2. Fast Red Chromogen is mildly corrosive and may cause skin or eye irritation. Avoid contact with skin and eyes. If contact occurs, flush affected area with copious amounts of water. Seek medical attention if necessary.
3. Fast Red Buffer is not classified as hazardous. The preservative used in this reagent is Proclin 950 and the concentration is less than 0.25%. Overexposure to Proclin 950 or chromogen can cause skin and eye irritation and irritation to mucous membranes and upper respiratory tract. Wear disposable gloves when handling reagents.
4. Prolonged use of absolute alcohol or xylenes after Fast Red staining may cause fading. If fading is observed, Biocare recommends to air dry slides after hematoxylin and bluing.
5. 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)
6. Microbial contamination of reagents may result in an increase in nonspecific staining.
7. The SDS is available upon request and is located at http://biocare.net.

Troubleshooting:
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.

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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