NeoPATH Pro Universal AP Plus Polymer Kit

Micro-polymer detection
902-10101-121125

Available Product Formats	
Catalog Number	**Volume**
NPRR10101KT135	135 tests

Intended Use:
For Research Use Only. Not for use in diagnostic procedures.

Background Information:
The NeoPATH Pro Universal AP Plus Polymer Kit is designed using either a one-step or two-step method for detecting mouse and/or rabbit primary antibodies to form an antibody-enzyme complex. This complex is then visualized using an appropriate substrate/chromogen. In the one-step method a secondary antibody directly linked to the micro-polymer is applied while in the two-step method the secondary antibody is unlabeled, and an additional enzyme linked polymer labeled reagent is sequentially applied. The two-step method is designed to amplify the detection in cases of low expressing antigens.

Fast red is a well-established chromogen used in IHC staining protocols that in the presence of an alkaline phosphatase (AP) enzyme produces a fuchsin red precipitate that is insoluble in organic solvents and can be cover slipped with a permanent mounting media.

Known Applications:
Immunohistochemistry (Formalin-fixed paraffin-embedded tissues)

Materials and Methods:

Reagents Provided:

Kit Catalog No.	Component Catalog No.	Component Description	Quantity x Volume
NPRR10101KT135	NPRR10102T135	NeoPATH Pro Universal AP Plus Probe	1 x 45 mL
	NPRR10103T135	NeoPATH Pro MR AP Plus Polymer	1 x 45 mL
	NPRR10104T45	NeoPATH Pro Warp Red Chromogen	3 x 10 mL
	NPRR10105T135	NeoPATH Pro Warp Red Buffer	1 x 30 mL

* Refer to the Biocare Medical website located at http://biocare.net for information regarding catalog numbers and ordering.

Supplied As:
NeoPATH Pro Universal AP Plus Probe – NPRR10102
Buffered saline solution, pH 7.2-7.4, containing a protein carrier and less than 0.1% sodium azide preservative. See Safety Data Sheet for additional details.

NeoPATH Pro MR AP Plus Polymer – NPRR10103
Buffered saline solution, pH 7.6-7.8, containing a protein carrier and less than 0.01% ProClin 300 and/or less than 0.5% ProClin 950 as a preservative. See Safety Data Sheet for additional details.

NeoPATH Pro Warp Red Chromogen – NPRR10104
Acidic solution with 1.0N Hydrochloric Acid. See Safety Data Sheet for additional details.

NeoPATH Pro Warp Red Buffer – NPRR10105
Buffered solution, pH 8.7 – 8.9, 0.125% ProClin 950 preservative. See Safety Data Sheet for additional details.

Reconstitution, Dilution and Mixing:
The NeoPATH Pro Universal AP Plus Polymer Kit reagent(s) are optimized and ready to use with Biocare IHC antibodies and ancillary reagents. No reconstitution, mixing, dilution, or titration is required.

Species Reactivity:
Mouse and Rabbit IgG heavy and light chains

Storage and Stability:
Store at 2ºC to 8ºC. The product is stable to the expiration date printed on the vial label when stored under these conditions. Do not use after expiration date. Storage under any condition other than those specified must be verified. The kit reagent(s) are ready-to-use and should not be diluted. The stability of user diluted reagents has not been established by Biocare.

Staining Protocol Recommendations
Below are programming and protocol recommendations to assist the user when staining manually and/or using one of Biocare's Automated Staining Platforms for research applications. The user is responsible for further optimizations of the protocol.

NeoPATH Pro Universal AP Plus Polymer Kit is provided in vials ready for use on the NeoPATH Pro Automated Slide Stainer. Uncap the vial and place in the NeoPATH Pro reagent tray. The NeoPATH Pro Automated Slide Stainer will apply reagent as required in the selected protocol. Refer to the appropriate antibody data sheet for the recommended staining protocol. Refer to the NeoPATH Pro Automated Slide Staining System User Manual for detailed instructions on instrument operation and additional protocol options.

Technical Notes:
1. Do not use goat serum as a protein block.
2. Use TBS for washing steps. PBS wash buffers will inhibit alkaline phosphatase staining.

Limitations:
This product is provided for Research Use Only (RUO) and is not for use in diagnostic procedures. Suitability for specific applications may vary and it is the responsibility of the end user to determine the appropriate application for its use.

Precautions:
1. Kit reagent(s) 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)[1]
2. Kit reagents contain less than 0.05% ProClin 300 and/or less than 1% ProClin 950. Wear gloves and protective clothing and take reasonable precautions when handling as ProClin is classified as an irritant and may cause skin contact sensitization. Avoid contact with eyes, skin, and mucous membranes.
3. Handle materials of human or animal origin as potentially biohazardous and dispose of such materials with proper precautions. In the event of exposure, follow the health directives of the responsible authorities where used.[2,3]
4. Specimens, before and after fixation, and all materials exposed to them should be handled as if capable of transmitting infection and disposed of with

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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.[4]
5. Microbial contamination of reagents may result in an increase in nonspecific staining.
6. Incubation times or temperatures other than those specified may give erroneous results. The user must validate any such change.
7. Do not use reagent after the expiration date printed on the vial.
8. To prevent evaporation and ensure maximum test capacity, promptly cap and remove reagents from automated instruments after each run. Leaving reagents exposed can reduce their effectiveness and the number of tests they can provide. Always store reagents as directed to maintain their integrity.
9. The reagent is optimized for use with Biocare antibodies and ancillary reagents. Refer to the primary antibody and other ancillary reagent instructions for use for recommended protocols and conditions for use.
10. Dispose of all used reagents and any other contaminated disposable materials following procedures for infectious or potentially infectious waste. It is the responsibility of each laboratory to handle solid and liquid waste according to their nature and degree of hazardousness and to treat and dispose of it (or have them treated and disposed of) in accordance with any applicable regulations.
11. Follow local disposal regulations for your location along with recommendations in the Safety Data Sheet to determine the safe disposal of this product
12. The SDS is available upon request and is located at http://biocare.net.
13. Report any serious incidents related to this device by contacting the local Biocare representative and the applicable competent authority of the Member State or country where the user is located.

This NeoPATH Pro Universal AP Plus Polymer Kit contains components classified as indicated in the table below in accordance with Regulation (EC) No. 1272/2008.

Hazard	Code	Hazard Statement
	H317	May cause an allergic skin reaction.
N/A	H401 H412	Toxic to aquatic life. Harmful to aquatic life with long lasting effects.

Technical Support:
Contact Biocare's Technical Support at 1-800-542-2002 for questions regarding this product.

References:
1. 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.
2. Occupational Safety and Health Standards: Occupational exposure to hazardous chemicals in laboratories. (29 CFR Part 1910.1450). Fed. Register.
3. Directive 2000/54/EC of the European Parliament and Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work.
4. 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.