



ihc DAB 1:1 Kit

K50002-030, 300 tissue stains*

K50002-015, 150 tissue stains*

Summary and Explanation:

The Novodix ihc DAB 1:1 Kit is intended for *in vitro* diagnostic use. The kit can also be used with the Novodix ihcDirect® immunohistochemistry test kits and other *in vitro* diagnostic applications. The Novodix ihc DAB 1:1 Kit contains DAB 1:1 chromogen (3,3'-diaminobenzidine), part# C30018-###ML and DAB 1:1 Diluent, part# C30019-###ML. DAB working solution should be made fresh prior to performing the assay by adding equal volumes of the DAB 1:1 chromogen to the DAB 1:1 Diluent. This DAB Working Solution will then serve as a substrate for polyHRP (pHRP) enzymes.

Principle of Procedure:

The ready-to-use ihcDirect pHRP antibody conjugate is applied to pretreated or frozen tissue sections, where it binds to the matching antigen. After a thorough washing step, the DAB Working Solution is applied to the tissue. The antibody-linked pHRP catalyzes the DAB to form visible brown color precipitates at the site of the antibody-antigen reaction. The specimen may then be further processed or counterstained with hematoxylin and a coverslip applied. Results are viewed and interpreted using a light microscope.

Reagents Provided:

| K50002-### Kit Components | Σ | Component Part Numbers | Items /Kit | Sizes |
|---------------------------|--------------|------------------------------|------------|-----------------|
| DAB 1:1 | 150* 300* | C30018-7.5ML C30018-015ML | 1 1 | 7.5ml 15ml |
| DAB 1:1 Diluent | 150* 300* | C30019-7.5ML C30019-015ML | 1 1 | 7.5 ml 15 ml |

* At estimated volume of 100 µL DAB Working Solution per tissue

Preparation of DAB 1:1 Working Solution:

To prepare the DAB 1:1 Working Solution, combine 1 part (e.g. 200µL) of the DAB 1:1 chromogen reagent (C30018-###ML) with 1 part (e.g. 200µL) of the DAB 1:1 Diluent reagent (C30019-###ML). Mix well prior to use.

Storage and Handling:

The ihc DAB 1:1 Kit should be stored at 2-8°C. Do not freeze. DAB 1:1 Working Solution should be made fresh prior to use and is stable at 2-8°C during the day the reagents are made. This kit is suitable for use until expiry date when stored at 2-8°C. Do not use the product after expiration date. If reagents are stored under any conditions other than those specified in the package insert, they must be verified by the user. Once mixed, avoid storing the Working Solution in direct light.

Instructions for Use DAB 1:1 Working Solution:

For ihcDirect assay applications, users should determine the appropriate DAB 1:1 Working Solution incubation time depending upon the application, e.g. frozen or formalin-fixed paraffin-embedded (FFPE) tissues, per the assay protocol published in the instructions for use. Thoroughly rinse off free HRP-antibody conjugates from the tissues with Novodix ihc Wash Buffer or similar PBS wash buffer before application of ihc DAB Working Solution.

Positive and negative controls should be run simultaneously with patient specimens. If an unexpected staining pattern is observed on control tissues or patient samples which cannot be explained by variations in laboratory procedures

or a problem with the ihc DAB 1:1 Kit is suspected, contact Novodix Technical Support or your local distributor immediately. Within the US call 1 (888) 439-2716 ext. 2 or 1 (510) 342-3043 ext. 2.

For technical support or further information about Novodix test kits and products please contact Novodix Technical Support or your local distributor.

Warnings and Precautions:

- Take reasonable precautions when handling reagents. Use protective equipment such as disposable gloves and lab coats when handling suspected carcinogens or toxic materials. Read Safety Data Sheets (SDS) prior to use.
 - WARNING! The DAB 1:1 Kit contains 3,3'-diaminobenzidine which may cause genetic effects and/or cancer. If exposed or concerned, seek medical attention. See DAB SDS for more information.
- The kit should be stored at 2-8°C. Once mixed, avoid storing the Working Solution in direct light.
- Avoid contact of reagents with eyes and mucous membranes. If reagents come in contact with sensitive areas, wash with copious amounts of water.
- Patient specimens and all materials that come into contact with patient specimens should be handled as bio-hazardous materials and disposed of appropriately.
- Consult local or state authorities with regard to recommended method of disposal of bio-hazardous and hazardous chemical waste materials.
- Avoid microbial contamination of reagents.
- Solutions containing sodium azide or other inhibitors of peroxidase activity should not be used in diluting the peroxidase substrate.
- Variations in color intensity of the stock and working solutions may be seen between lots of this product. These variations will not affect the product stability or the intensity of the staining.

| ihc DAB 1:1 Kit Key to Symbols | | | |
|--------------------------------|---|--|------------------------------------|
| | <i>In vitro</i> diagnostic medical device | | DAB 1:1 chromogen reagent |
| | Catalog Number | | DAB 1:1 Diluent reagent |
| | Use by: YYYY-MM-DD | | Health Hazard |
| | Consult Instruction for Use | | Manufacturer |
| | Batch Code | | Temperature Limitation |
| | Contains sufficient for < n > tests | | Authorized European Representative |
| | CE Mark | | |

Instructions for Use (IFU) Access:

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