# Protease 1

REF 760-2018

05266688001

IVD Σ 250

## INTENDED USE

Protease 1 is an endopeptidase (alkaline protease) of the serine protease family and cleaves proteins in the tissue section, allowing primary antibodies to recognize and bind epitope(s). The reagent is intended for enzymatic digestion of sections of routine formalin-fixed, paraffin-embedded tissue on a Benchmark IHC/ISH instrument.

This reagent is intended for in vitro diagnostic (IVD) use.

## PRINCIPLE OF THE PROCEDURE

Protease 1 is used with antibodies, accessory reagents and the BenchMark IHC/ISH instrument to achieve appropriate immunohistochemistry (IHC) staining.

Enzymatic digestion of tissue with proteases prior to primary antibody application often increases immunoreactivity.[1] Protease 1 is a high activity enzyme formulation that cleaves proteins in the formalin-fixed, paraffin-embedded (FFPE) tissue section, exposing the antigen for binding by the primary antibody. Digestion is followed by primary antibody application and is used in combination with VENTANA detection kits. Protease 1 may be used for antigens requiring extensive digestion for optimal staining.

## MATERIAL PROVIDED

Protease 1 contains sufficient reagent for 250 tests.

One 25 mL dispenser of Protease 1 contains approximately 0.38 mg/mL alkaline protease in a Tris-based enzyme stabilizing solution containing sodium azide.

### Reconstitution, Mixing, Dilution, Titration

No reconstitution, mixing, dilution, or titration is required. Further dilution may result in loss of staining specificity.

## MATERIALS REQUIRED BUT NOT PROVIDED

Additional reagents including but not limited to VENTANA primary antibodies, probes, detection and staining kits, and ancillary components, are not provided.

Not all products listed in the method sheet may be available in all geographies. Consult your local support representative.

The following reagents and materials may be required for staining but are not provided:

1. General purpose laboratory equipment
2. BenchMark IHC/ISH instrument

## STORAGE AND STABILITY

Upon receipt and when not in use, store at 2-8°C. Do not freeze.

To ensure proper reagent delivery and the stability of the product, replace the dispenser cap after every use and immediately place the dispenser in the refrigerator, store in an upright position.

This reagent is expiration dated. When properly stored, the reagent is stable to the date indicated on the label. Do not use reagent beyond the expiration date.

## WARNINGS AND PRECAUTIONS

1. For in vitro diagnostic (IVD) use.
2. For professional use only.
3. CAUTION: In the United States, Federal law restricts this device to sale by or on the order of a physician. (Rx Only)
4. Do not use beyond the specified number of tests.
5. Materials of human or animal origin should be handled as biohazardous materials and disposed of with proper precautions. In the event of exposure, the health directives of the responsible authorities should be followed.[2,3]
6. Avoid contact of reagents with eyes and mucous membranes. If reagents come in contact with sensitive areas, wash with copious amounts of water.
7. Avoid microbial contamination of product as it may cause incorrect results.
8. For further information on the use of this device, refer to the BenchMark IHC/ISH instrument User Guide, and instructions for use of all necessary components located at dialog.roche.com.
9. Consult local and/or state authorities with regard to recommended method of disposal.
10. Product safety labeling primarily follows EU GHS guidance. Safety data sheet available for professional user on request.
11. To report suspected serious incidents related to this device, contact the local Roche representative and the competent authority of the Member State or Country in which the user is established.

## INSTRUCTIONS FOR USE

Refer to the appropriate primary antibody method sheet for the recommended staining protocol and to the instrument User Guide for detailed instructions and additional protocol options.

Protease 1 is loaded onto the reagent tray on the Benchmark IHC/ISH instrument. Protease 1 is applied automatically as required for the procedure being run.

For more details on the proper use of this device, refer to the inline dispenser method sheet associated with P/N 760-2018.

## PERFORMANCE CHARACTERISTICS

### ANALYTICAL PERFORMANCE

Protease 1 is used for enzymatic digestion of FFPE tissue sections, allowing primary antibodies to recognize and bind epitope(s) during IHC applications on BenchMark IHC/ISH instruments. Protease 1 is a high activity enzyme formulation. Expected results are quantitative only when testing the sensitivity and specificity of each specific antigen. As a stand-alone reagent, this product cannot be tested for sensitivity and specificity.

Multiple VENTANA primary antibodies have been developed with VENTANA proteases in IHC applications. As part of the testing for those assays, the following performance characteristics were demonstrated for VENTANA proteases:

1. Within-run, between-day, and between-instrument precision on a BenchMark IHC/ISH instrument.
2. Sensitivity and specificity of staining across a range of normal and neoplastic tissue types and assay-specific target tissues.

All studies met their acceptance criteria.

## TROUBLESHOOTING

1. If the specific antibody staining is too intense, repeat the staining run and shorten the protease incubation time by 4-minute intervals until the desired staining intensity is achieved.
2. If the specific antibody staining is too weak, repeat the staining run and extend the protease incubation time by 4-minute intervals until the desired staining intensity is achieved.
3. If modifying the protease incubation time does not achieve the desired result, Protease 2 (Cat. No. 760-2019 / 05266696001) or Protease 3 (Cat. No. 760-2020 / 05266718001) may be more suitable for the specific application of interest.
4. For corrective action, refer to the instrument User Guide or contact your local support representative.

## REFERENCES


1. Brozman, M. Immunohistochemical analyses of formaldehyde and trypsin- or pepsin-treated material. Acta Histochem. 1978:63(2);251-560.
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.


NOTE: A point (period/stop) is always used in this document as the decimal separator to mark the border between the integral and the fractional parts of a decimal numeral. Separators for thousands are not used.

## Symbols

Ventana uses the following symbols and signs in addition to those listed in the ISO 15223-1 standard (for USA: see dialog.roche.com for definition of symbols used):

| | |
|---|---|
| GTIN | Global Trade Item Number |
| UDI | Unique Device Identifier |
|  | Indicates the entity importing the medical device into the European Union |

## REVISION HISTORY

| Rev | Updates |
|---|---|
| E | Updates to title block. |

## INTELLECTUAL PROPERTY



## CONTACT INFORMATION

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