

## Protease 1

REF

760-2018

IVD

05266688001

Σ

250

### INTENDED USE

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

Ventana Medical Systems' (Ventana) Protease 1 is an endopeptidase (alkaline protease) of the serine protease family and cleaves antigens (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 VENTANA automated slide stainers.

The clinical interpretation of any staining, or the absence of staining, must be complemented by morphological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient's clinical history and other diagnostic tests. Caution: U.S. Federal law restricts this device to sale by or on the order of a physician.

### SUMMARY AND EXPLANATION

Enzymatic digestion using VENTANA Protease 1 prior to primary antibody application often increases immunoreactivity.<sup>1</sup> Digestion is followed by primary antibody application and is used in combination with VENTANA detection kits.

### PRINCIPLE OF THE PROCEDURE

Protease 1 is a high activity enzyme formulation that cleaves proteins in the tissue section, exposing the antigen for binding by the primary antibody. Protease 1 has been optimized for digestion of well-fixed tissues. This preparation provides consistent results for antigens requiring extensive digestion for optimal staining.

### MATERIALS AND METHODS

#### Reagent Provided

Protease 1 contains sufficient reagent for 250 tests.

One 25 mL dispenser of Protease 1 contains approximately 0.38 mg/mL alkaline protease enzyme activity in an enzyme stabilizing solution containing 0.01% sodium azide.

#### Reconstitution, Mixing, Dilution, Titration

No reconstitution, mixing, dilution, or titration is required. This reagent is optimized for use on a VENTANA automated slide stainer in combination with VENTANA primary antibodies, detection kits and ancillary reagents.

#### Materials Required But Not Provided

Reagents, such as VENTANA primary antibodies, probes, detection kits, and ancillary components, are not provided.

#### Storage and Handling

Store at 2-8°C. Do not freeze.

To ensure proper reagent delivery and stability, replace the dispenser cap after every use and immediately place the dispenser in the refrigerator 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.

#### Specimen Collection and Preparation for Analysis

Formalin-fixed, paraffin-embedded tissues are suitable for use with this reagent when used with VENTANA primary antibodies, detection kits, ancillary reagents, and automated slide stainers. The recommended tissue fixative is 10% neutral buffered formalin.<sup>2</sup> Variable results may occur as a result of prolonged fixation or special processes such as decalcification of bone marrow preparations.

### WARNINGS AND PRECAUTIONS

1. For *in vitro* diagnostic (IVD) use.
2. Take reasonable precautions when handling reagents. Avoid contact of reagents with eyes, skin, and mucous membranes. Use disposable gloves and wear suitable protective clothing when handling suspected carcinogens or toxic materials.
3. If reagents come in contact with sensitive areas, wash with copious amounts of water. Avoid inhalation of reagents.
4. Avoid microbial contamination of product, as this could produce incorrect results.
5. Symptoms of over exposure may include skin and eye irritation and irritation to mucous membranes and upper respiratory tract. Toxic through ingestive, subcutaneous, intravenous, and perhaps other routes. Highly toxic when ingested.
6. Consult local or state authorities with regard to recommended method of disposal.
7. For supplementary safety information, refer to the product Safety Data Sheet and the Symbol and Risk Phrase Guide located at [www.ventana.com](http://www.ventana.com).

### INSTRUCTIONS FOR USE

Protease 1 has been optimized to provide consistent enzymatic digestion of formalin-fixed, paraffin-embedded tissue. It is to be used in combination with VENTANA primary antibodies, detection kits, and ancillary reagents on a VENTANA automated slide stainer.

Protease 1 is loaded onto the reagent tray on the VENTANA automated slide stainer. Protease 1 is applied automatically as required for the procedure being run. Refer to the appropriate primary antibody package insert for the recommended staining protocol and to the instrument Operator's Manual for detailed instructions and additional protocol options.

### SUMMARY OF EXPECTED RESULTS

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. Refer to the appropriate primary antibody package insert for expected patient sample results. Appropriate tissue control results verify the reagents and system are working properly.

### TROUBLESHOOTING

1. If all of the paraffin has not been removed, there may be no staining. Repeat the deparaffinization procedure.
2. See the table below for troubleshooting specific antibody staining.

If specific antibody staining is...	Try this...
Too intense	Repeat the staining run and shorten the Protease incubation time by 4 minute intervals until the desired staining intensity is achieved.
Too weak	Repeat the staining run and extend the Protease incubation time by 4 minute intervals until the desired staining intensity is achieved.
Too intense or too weak and modifying the Protease incubation time does not achieve the desired result	Check if Protease 2 or Protease 3 may be a better reagent to use for the specific application of interest.

3. If tissue sections wash off the slide, slides should be checked to ensure that they are positively charged.
4. For corrective action, refer to the automated slide stainer Operator's Manual 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. Sheehan DC, Hrapchak BB. *Theory and Practice of Histotechnology*, 2nd Edition. St. Louis, MO: The C.V. Mosby Company, 1980.



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