

## EZ Prep Concentrate (10X)

**REF**

950-102

05279771001

**IVD**

### INTENDED USE

Ventana Medical Systems' (Ventana) EZ Prep Concentrate (10X) solution (EZ Prep) is used for paraffin removal from tissue samples during immunohistochemistry and *in situ* hybridization reactions, and to dilute 2X SSC during stringency washes during *in situ* hybridization reactions carried out on Ventana automated slide stainers.

This product is designed for use on BenchMark Series automated slide stainers.

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

### PRINCIPLE OF THE PROCEDURE

Removal of paraffin embedding media from tissue sections on Ventana automated slide stainers is accomplished by combining heat, a mild detergent solution (EZ Prep) and vortex mixing. Heating melts the paraffin in the tissue sections. The detergent reduces the surface tension of the aqueous solution, assisting in release of the melted paraffin from the tissue and glass surfaces, which allows it to float to the surface of the aqueous pool. The vortex mixing prevents the paraffin from being re-deposited on the slide allowing it to be efficiently removed by rinsing.

### MATERIALS AND METHODS

#### Reagent Provided

One 2 L bottle of EZ Prep Concentrate (10X) contains an aqueous-based detergent solution with 0.5% ProClin 300 as a preservative.

#### Reconstitution, Mixing, Dilution, Titration

EZ Prep Concentrate (10X) must be diluted with nine parts of distilled or deionized water prior to use.

1. Check the spigot to ensure it is in the off position before adding water to the carboy.
2. Fill a graduated 20 L carboy approximately three quarters full with distilled or deionized water.
3. Pour the entire contents of the 2 L EZ Prep Concentrate (10X) bottle into the carboy.
4. Fill the carboy to the 20 L graduation mark with distilled or deionized water. If large quantities of bubbles form during the filling procedure, allow the solution to sit until the bubbles have dissipated.
5. Place the cap on the container, mix the solution well to ensure that the concentrate is thoroughly mixed with the water. The diluted EZ Prep (1X) solution is ready to use.

#### Materials Required But Not Provided

Distilled or deionized water is required for dilution. Additional reagents including but not limited to Ventana primary antibodies, probes, detection kits, and ancillary components are not provided.

#### Storage and Handling

Store at room temperature (15-30°C). Do not freeze.

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.

EZ Prep must be examined for microbial contamination prior to use. The signs indicating contamination or instability of this product are turbidity of the solution, odor development, or precipitation. At the first sign of possible reagent contamination or instability, call your local support representative.

### 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 protective clothing and gloves.

3. ProClin 300 is used as a preservative in this solution. It is classified as an irritant and may cause sensitization through skin contact. Take reasonable precautions when handling. Avoid contact of reagents with eyes, skin, and mucous membranes. Use protective clothing and gloves.
4. Avoid microbial contamination of product, as this could produce incorrect results.
5. Consult local or state authorities with regard to recommended method of disposal.
6. Refer to the product Safety Data Sheet for additional information.

### INSTRUCTIONS FOR USE

The diluted EZ Prep (1X) solution is poured into the appropriate position (EZ Prep) of the automated fluidics module on the Ventana automated slide stainer. EZ Prep (1X) is applied automatically as required by the procedure being run.

Ventana reagents have been developed for use on a Ventana automated slide staining system in combination with Ventana detection kits and accessories. Recommended staining protocols for the automated slide stainers are described in the package insert of the primary antibody or probe of interest. The parameters for the automated procedures can be displayed, printed, and edited according to the procedure in the Operator's Manual. Other operating parameters for the automated slide stainers have been preset at the factory. For more detailed instructions and additional protocol options refer to your Operator's Manual.

### PERFORMANCE CHARACTERISTICS

EZ Prep solution is used for dewaxing tissue samples for immunohistochemistry exclusively on BenchMark Series automated slide staining platforms. EZ Prep was tested with a variety of antibodies representing Breast, Lymphoma, and Leukemia panels at various incubation times with specific tissue types. The antibodies included PR, ER, Ki67, p53, CD5, CD3, CD10, CD79a, Bcl-2, CD15, CD30, Cyclin D1, Synaptophysin, Keratin, CD8, CD4, and Vimentin.

Inter and intra run reproducibility of staining was determined by taking the difference in staining intensity from each of 3 slides per case between 3 runs. The intensity of staining from slide to slide within and between runs when read by three qualified pathologists did not vary by more than one reading grade for all cases. In all cases the tissue samples were read and found acceptable for staining appropriateness and quality of morphological cellular staining.

### TROUBLESHOOTING

1. If all the paraffin is not removed, repeat the deparaffinization procedure.
2. For more information, refer to the instrument Operator's Manual or contact your local support representative.

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