### Intended Use:

For In Vitro Diagnostic Use

CD68 [KP1] is a mouse monoclonal antibody that is intended for laboratory use in the qualitative identification of CD68 protein by immunohistochemistry (IHC) in formalin-fixed paraffin-embedded (FFPE) human tissues. The clinical interpretation of any staining or its absence should be complemented by morphological studies using proper controls and should be evaluated within the context of the patient's clinical history and other diagnostic tests by a qualified pathologist.

### Summary and Explanation:

The CD68 antigen is a 110 kDa highly glycosylated transmembrane protein which is mainly located in lysosomes. Studies have shown the antibody stains macrophages in many human tissues including Kupffer's cells and macrophages in the red pulp of the spleen, in lung alveoli, in lamina propria of the gut, and in the bone marrow. It reacts with plasmacytoid T-cells that are present in many reactive lymph nodes, and are believed to be of monocyte/macrophage origin. The antibody marks the malignant cells in chronic and acute myeloid leukemia. It is not positive staining of normal and neoplastic mast cells is seen with the antibody, as well as staining of a variable number of cells in malignant melanomas. Studies have shown that CD68 (KP1) is formalin-sensitive and false negatives can occur without proper pretreatment.

### Principle of Procedure:

Antigen detection in tissues and cells is a multi-step immunohistochemical process. The initial step binds the primary antibody to its specific epitope. A secondary antibody may be applied to bind the primary antibody, followed by an enzyme labeled polymer; or an enzyme labeled polymer may be applied directly to bind the primary antibody. The detection of the bound primary antibody is evidenced by an enzyme-mediated colorimetric reaction.

### Protocol Recommendations (ONCORE™ Automated Slide Staining System):

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<tr>
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<th>Ms HRP Template 1</th>
<th>Dewaxing (DS Option)</th>
<th>DS2</th>
<th>Antigen Retrieval (AR Option)</th>
<th>AR1, high pH; 103°C</th>
<th>Reagent Name, Time, Temp.:</th>
<th>CD68, 30 min., 25°C</th>
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<tr>
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CD68 [KP1]
Concentrated and Prediluted Monoclonal Antibody
901-033-101420

Protocol Recommendations (Ventana BenchMark ULTRA):
AVIO33 is intended for use with the BenchMark ULTRA. Refer to the User Manual for specific instructions for use. Recommended protocol parameters are as follows:

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<th>Template/Detection:</th>
<th>OptiView DAB IHC</th>
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<tbody>
<tr>
<td>Pretreatment Protocol:</td>
<td>CC1 16 minutes</td>
</tr>
<tr>
<td>Peroxidase:</td>
<td>Pre Primary Peroxidase Inhibitor</td>
</tr>
<tr>
<td>Primary Antibody:</td>
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Limitations:
The optimum antibody dilution and protocols for a specific application can vary. These include, but are not limited to: fixation, heat-retrieval method, incubation times, tissue section thickness and detection kit used. Due to the superior sensitivity of these unique reagents, the recommended incubation times and titers listed are not applicable to other detection systems, as results may vary. The data sheet recommendations and protocols are based on exclusive use of Biocare products. Ultimately, it is the responsibility of the investigator to determine optimal conditions.

Quality Control:

Precautions:
1. This antibody 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 (NaN₃) 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) (6)
2. Specimens, before and after fixation, and all materials exposed to them should be handled as if capable of transmitting infection and disposed of with proper precautions. Never pipette reagents by mouth and avoid contacting the skin and mucous membranes with reagents and specimens. If reagents or specimens come in contact with sensitive areas, wash with copious amounts of water. (7)
3. Microbial contamination of reagents may result in an increase in nonspecific staining.
4. Incubation times or temperatures other than those specified may give erroneous results. The user must validate any such change.
5. Do not use reagent after the expiration date printed on the vial.
6. The SDS is available upon request and is located at http://biocare.net.

Troubleshooting:
Follow the antibody specific protocol recommendations according to data sheet provided. If atypical results occur, contact Biocare’s Technical Support at 1-800-542-2002.

References:

References Cont’d:

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