# CD68 (Clone: KP1)
# Mouse Monoclonal Antibody

| PRODUCT INFORMATION: | | PERFORMANCE CHARACTERISTICS: |
|---|---|---|
| REF | | |
| PM113 | 6ml Ready to use | **Localization:** Cytoplasm |
| PM113 | 3ml Ready to use | **Retrieval Buffer:** EDTA, pH 8.0 / |
| CM113 | 1ml Concentrated | Tris -EDTA, pH 9.0 |
| CM113 | 0.5ml Concentrated | **Incubation:** 30-60 minutes |
| CM113 | 0.1ml Concentrated | **Positive control:** Tonsil, Spleen, |
| HAM113 | 6ml Ready to use | Lymph node |
| HAM113 | 3ml Ready to use | |

## INTENDED USE

**For *in vitro diagnostic* use only**

This antibody is intended for use in qualitatively identifying CD68 antigen by light microscopy in formalin fixed, paraffin embedded (FFPE) tissue sections using immunohistochemical (IHC) detection methodology. Interpretation of any positive or negative staining must be complemented with the evaluation of proper known controls (Positive and Negative) and must be made within the context of the patient's clinical history and other diagnostic tests. A qualified and trained pathologist must perform the evaluation of the test. This antibody is intended to be used after the primary diagnosis of tumor has been made by conventional histopathology using non-immunologic histochemical stains.

## SUMMARY AND EXPLANATION

CD68 is expressed on macrophages and monocytes. KP-1 is important for identifying macrophages in tissue sections. It stains macrophages in a wide variety of human tissues, including Kupffer cells and macrophages in the red pulp of the spleen, in lamina propria of the gut, in lung alveoli, and in bone marrow. KP-1 reacts with myeloid precursors and peripheral blood granulocytes. It also reacts with plasmacytoid T cells which are supposed to be of monocyte/macrophage origin. It shows strong granular cytoplasmic staining of chronic and acute myeloid leukemia and also reacts with rare cases of true histiocyticneoplasia. Tumors of lymphoid origin are usually not stained.

## PRINCIPLE OF THE PROCEDURE

The identification of the antigen on the FFPE tissues is carried out using the above stated antibody. The antigen and antibody complex are visualized using an enzyme coupled (HRP/AP) secondary antibody with specific binding to the primary antibody, this complex is visualized by the enzymatic activation of the chromogen resulting in a visible reaction production of the antigenic site. Each and every step involves precise time and optimal temperature and the results are interpreted using a light microscope by a qualified and trained pathologist.

## REAGENT PROVIDED

**Concentrated format:** CD68 antibody is affinity purified and diluted in antibody diluent with 1% bovine serum albumin (BSA) and 0.05% sodium azide ($NaN_3$).
**Recommended dilutions:** 1:50 – 1:100
The antibody dilution and protocol may vary depending on the specimen preparation and specific application. Optimal conditions should be determined by individual laboratories.
**Pre-diluted format:** PathnSitu's ready to use antibodies are pre-tittered to optimal staining conditions. Further dilution will affect the efficacy of the antibody and may yield to sub-optimal staining.
**Immunogen:** Subcellular fraction of human alveolar macrophages.
**Host, Isotype:** Mouse, IgG1/K

## STORAGE AND HANDLING

**Storage Recommendations:** Store at 2-8°C. When stored at the appropriate conditions, the antibody is stable until expiry. Do not use the antibody after the expiration date provided on the vial in any condition.
To ensure proper reagent delivery and stability, replace the dispenser cap after every use and immediately place the vial into the refrigerated conditions in an upright position. The contents of the vial should be used within 9 months from the opening of the vial.

IVD CE

## SPECIMEN PREPARATION

**Staining Recommendations:**
Routinely processed, FFPE tissues are suitable for use with this primary antibody, when using PathnSitu's Poly Excel HRP/DAB detection system. The recommended tissue fixative is 10% neutral buffered formalin. Variable results may occur as a result of prolonged fixation or special processes such as decalcification. The thickness of the sections should be 2-5µm. Slides should be stained once the sections are made as the antigenicity of the cut sections may diminish over a period of time. It is recommended to stain known positive and negative controls simultaneously with unknown specimens.

## PRECAUTIONS

1. This product should be used by qualified and trained professional users only
2. The product contains < 0.1% of sodium azide as a preservative and is not classified as hazardous, refer to MSDS for further details
3. As with any product derived from biological sources, proper handling procedures should be used
4. Do not use reagents after the expiration date
5. Use protective clothing and gloves, while handling reagents
6. All hazardous materials should be disposed of according to local state and federal regulations
7. Avoid microbial contamination of reagents as it may lead to incorrect results

## STAINING PROCEDURE

**Antigen Retrieval Solution:** Use **Tris-EDTA Buffer (Cat#PS009) or EDTA Buffer (Cat#PS008)** as antigen retrieval solution.
**Heat Retrieval Method**: Retrieve sections under steam pressure for 15 minutes using PathnSitu's MERS (Multi Epitope Retrieval System) for optimal retrieval of the epitopes, allow solution to cool at room temperature, transfer the tissue sections/slides to the distilled water prior to the primary antibody application.
**Primary Antibody:** Cover the tissue sections with primary antibody and incubate for 30-60 min at room temperature when used PathnSitu's PolyExcel Detection System.
**Detection System:** Refer to PathnSitu's PolyExcel HRP/ DAB detection system protocol for optimal staining results.

## QUALITY CONTROL

The recommended positive tissue control for CD68 are Tonsil, Spleen and Lymph node. A positive and negative tissue controls must be run with every staining procedure performed for monitoring the correct performance of processed tissue and test reagents. A negative tissue control provides an indication of non-specific background staining. If the results are not expected in positive and negative controls the test must be considered invalid and the entire procedure must be cross verified. The individual laboratory must establish their own quality control to validate the process and antibody when opening a vial.

## INTERPRETATION OF RESULTS

CD68 stains the Cytoplasm. A qualified experienced/trained pathologist must interpret the results in the patient's sample along with the positive and negative controls.

## PERFORMANCE CHARACTERISTICS

PathnSitu products will undergo thorough a quality control check before it is released to the market. The antibody showed consistent specific and sensitive staining on the multiple positive tissue controls tested, by inter run, intra run and lot based studies. The antibody is stable for the expiry mentioned on the labels which is determined by real time or accelerated methods.

## TROUBLESHOOTING

1. Follow the antibody specific protocol recommendations according to the data sheet provided
2. Tissue staining is dependent on the handling and processing of the tissue prior to staining. Improper fixation, tissue processing, antibody freezing and thawing, washing, drying, heating, sectioning or contamination with other tissues or fluids may produce artifacts, antibody trapping or inaccurate results
3. Do not allow the section to dry out during the entire IHC process



**US Office:**1257, Quarry Ln, Suite150, Pleasanton, CA-94566, USA Ph: +1 925-218-6939,
**India Office:**PS Heights, Plot# A-28/1/11B/B, Road#, 15, Industrial Development Area, Nacharam, Secunderabad-76
Phone: 040-27015544/33,Fax:040-2701 5544 , **E-Mail:** customerservice@pathnsitu.com **Web:** www.pathnsitu.com

4. Excessive or incomplete counter staining may compromise the interpretation of the results
5. If unusual results occur, contact PathnSitu's Technical Support at +91-40-2701 5544 or E-mail:techsupport@pathnsitu.com

## LIMITATIONS AND WARRANTY

Authorized and skilled/trained personnel only may use the product. The clinical interpretation of any test results should be evaluated within the context of the patient's medical history and other diagnostic test results. A qualified trained pathologist must perform the evaluation of the test results. There are no warranties, expressed or implied, which extend beyond the description. PathnSitu is not liable for property damage, personal injury, time or effort on economic loss caused by this product.

## BIBLIOGRAPHY


1. Warnke RA, Pulford KAF, Pallesen G, Ralfkiaer E, Brown DC,Gatter KC, et al. Diagnosis of myelomonocytic and macrophage neoplasms in routinely processed tissue biopsies with monoclonal antibody KP1. Am J Pathol1989; 135:1089-95.
2. Goyert SM. MC12. CD68 workshop panel report. In:Kishimoto T, Kikutani H, von dem Borne AEG, Goyert SM, Mason DY, Miyasaka M, etal.,editors. Leucocyte typing VI.White cell differentiation antigens. Proceedings of the 6th International Workshop and Conference; 1996 Nov 10-14; Kobe, Japan. New York, London: Garland Publishing Inc.; 1997. p. 1015-16.
3. Falini B, Flenghi L, Pileri S, Gambacorta M, Bigerna B, Durkop H, et al. PG-M1: A new monoclonal antibody directed against a fixative-resistant epitope on the macrophage-restricted form of the CD68 molecule. Am J Pathol1993; 142:1359-72.
4. Pulford KAF, Rigney EM, Micklem KJ, Jones M, Stross WP, Gatter KC, et al. KP1: a new monoclonal antibody that detects a monocyte/macrophage associated antigen in routinely processed tissue sections. J ClinPathol1989; 42:414-21.
5. Micklem K, Cordell J, Rigney E, Simmons D, Pulford K, Stross P, et al. M13.1. A macrophage-associated antigen defined by five mAB. In: Knapp W, DörkenB, Gilks WR, Rieber EP, Schmidt RE, Stein H, et al., editors. Leucocyte typing IV. White cell differentiation antigens. Proceedings of the 4th International Workshop and Conference; 1989 Feb 21-25; Vienna, Austria. Oxford, New York, Tokyo: Oxford University Press; 1989. p. 843-46.


## EXPLANATION OF SYMBOLS

LOT **Lot number / Batch number**

**Expiry**

IVD ***In vitro* diagnostic use**

**Storage limitation**

**Date of manufacture**

REF **Catalogue number**

CE **EU compliance**




**US Office:**1257, Quarry Ln, Suite150, Pleasanton, CA-94566, USA Ph: +1 925-218-6939,
**India Office:**PS Heights, Plot# A-28/1/11B/B, Road#, 15, Industrial Development Area, Nacharam, Secunderabad-76
Phone: 040-27015544/33,Fax:040-2701 5544 , **E-Mail:** customerservice@pathnsitu.com **Web:** www.pathnsitu.com