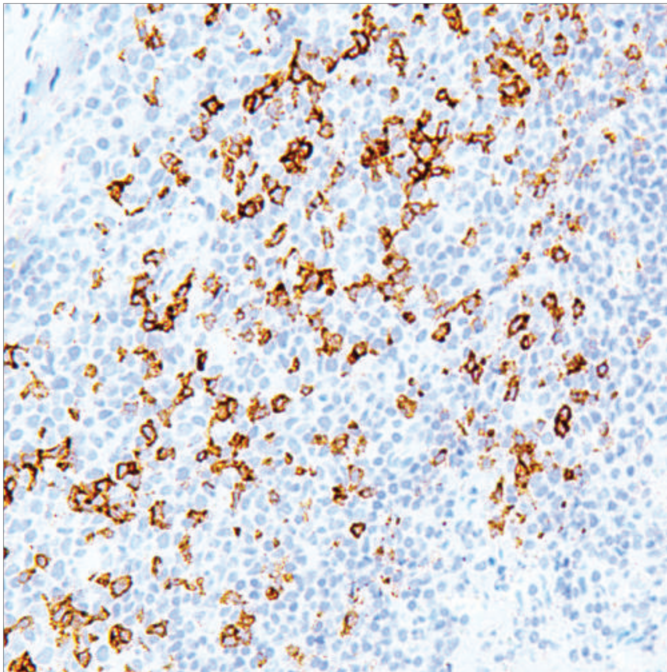
GeneAb™

PD-1

Clone: IHC001 | **Source:** Mouse Monoclonal | **Positive Control:** Tonsil



GeneAb™ PD-1 (IHC001) on tonsil tissue

Product Information

REF	Description
IHC001-100	0.1 ml Concentrate
IHC001-1	1.0 ml Concentrate
IHC001-7	7.0 ml Pre-dilute, Ready-to-Use
IHC001-PC	Positive control slides, 3 slides/case

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1. Intended Use

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

The PD-1 (IHC001) antibody is intended for qualified laboratories to qualitatively identify by light microscopy the presence of associated antigens in sections of formalin-fixed, paraffin-embedded tissue sections using IHC test methods. Use of this antibody is indicated, subsequent to clinical differential diagnoses of diseases, as an aid in the identification of different cancers within the context of antibody panels, the patient's clinical history and other diagnostic tests evaluated by a qualified pathologist.

2. Summary and Explanation

Programmed Death 1 (PD-1) is a member of the CD28/CTLA-4 family of T-cell regulators, expressed as a co-receptor on the surface of activated T-cells, B-cells, and macrophages. New studies have suggested that the PD-1/PD-L1 signaling pathway may be linked to anti-tumor immunity, as PD-L1 has been shown to induce apoptosis of activated T-cells or inhibit activity of cytotoxic T-cells. In comparison to CD10 and bcl-6, PD-1 is expressed by fewer B-cells and has therefore been considered a more specific and useful diagnostic marker for angioimmunoblastic T-cell lymphoma. Therapies targeted toward the PD-1 receptor have shown remarkable clinical responses in patients with various types of cancer, including non–small cell lung cancer, melanoma, and renal-cell cancer.

3. Principles and Procedures

Visualization of the antigen present in tissue sections is accomplished in a multi-step immunohistochemical staining process, in conjunction with a horseradish peroxidase (HRP) or alkaline phosphatase (AP) linked detection system. The process involves the addition of the stated antibody (primary antibody) to a tissue slide, followed by a secondary antibody (link antibody) which specifically binds to the primary antibody. A chromogenic substrate is then added which reacts with the enzyme complex, resulting in a colorimetric reaction at the site of the antigen. Results are interpreted using a light microscope.

4. Materials and Methods

Reagents Provided

Product	Optimized Buffer Composition
Predilute	Antibody Diluent Buffer
Concentrate	Tris Buffer, pH 7.3 - 7.7, with 1% BSA and <0.1% Sodium Azide
Recommended working dilution range	1:100 - 1:200

Reconstitution, Mixing, Dilution, and Titration

The prediluted antibody does not require any mixing, dilution, reconstitution, or titration; the antibody is ready-to-use and optimized for staining.

The concentrated antibody requires dilution in the optimized buffer, to the recommended working dilution range (see Reagents Provided).

Storage and Handling

Store at 2-8°C. Do not freeze.

When stored correctly, the antibody is stable until the date indicated on the label.

To ensure proper stability and delivery of the antibody after each run, replace the cap and immediately place the bottle in a refrigerator in an upright position.

Positive and negative controls should be simultaneously run with unknown specimens, as there are no conclusive characteristics to suggest instability of the antibody. If such an indication of instability is suspected, contact GenomeMe® Customer Service at **info@GenomeMe.ca**.

Specimen Collection and Preparation for Analysis

Each tissue section should be fixed with 10% neutral buffered formalin, cut to the applicable thickness (4μm), and placed on a glass slide that is positively charged. The prepared slide may then be baked for a minimum of 30 minutes in a 53-65°C oven (do not exceed 24 hours).

Note: Performance evaluation has been shown on human tissues only. Variable results may occur due to extended fixation time or special processes of specific tissue preparations.

5. Instructions For Use

Recommended Staining Protocols for the PD-1 (IHC001) antibody:

Manual Use:

1. **Pretreatment:** Perform heat-induced epitope retrieval (HIER) at pH 9 for 10 to 30 minutes.

2. **Peroxide Block:** Block in peroxidase blocking solution for 5 minutes at room temperature. (Not required if using Alkaline Phosphatase System)

3. **Primary Antibody:** Apply antibody directly (Pre-dilute) or dilute antibody 1:100-1:200 (Concentrate) before applying. Incubate antibody for 10 to 30 minutes at room temperature.

4. **Secondary Antibody:** Incubate for 20 to 30 minutes at room temperature.

5. **Substrate Development:** Incubate DAB or Fast Red for 5 to 10 minutes at room temperature.

6. **Counterstain:** Counterstain with hematoxylin for 0.5 to 5 minutes, depending on the hematoxylin used. Rinse with distilled water and blueing solution for 30 seconds.

7. Dehydrate and apply coverslip.

Automated Staining System:

The stated primary antibody has been validated using Leica® Biosystems' BOND-MAX Autostainer, applying IHC Protocol F. The following edits are recommended for the protocol:

a) Marker Incubation Time: 30 Minutes

b) Heat-induced epitope retrieval (HIER) is recommended using Bond ER Solution 2 for 30 minutes.

For all other automated IHC staining systems, please refer to the corresponding user manual for specific instructions.

6. Quality Control Procedures and Interpretation of Results

The immunohistochemical staining process results in a colorimetric reaction at the site of the antigen, localized by the primary antibody. A qualified pathologist must interpret the patient results only once the positive and negative control tissues have been analyzed.