

# MPO (p-ANCA) Antibody IgG GENLISA® ELISA

**REF** : KBD756

Ver 2.2

**IVD**

Enzyme Immunoassay for Quantitative determination of MPO  
(p-ANCA) Antibody IgG in human serum and plasma

|                                                                                     |                             |                                                                                     |                                |
|-------------------------------------------------------------------------------------|-----------------------------|-------------------------------------------------------------------------------------|--------------------------------|
| <b>IVD</b>                                                                          | For In-vitro Diagnostic Use | <b>REF</b>                                                                          | Catalog Number                 |
|  | Store At                    | <b>LOT</b>                                                                          | Batch Code                     |
|  | Manufactured By             |  | Biological Risk                |
|  | Expiry Date                 |  | Consult Operating Instructions |

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**REF** KBD756

 96 tests

**Krishgen Pudgala LLP**

 Unit Nos#318/319, Shah & Nahar, Off Dr E Moses Road, Worli, Mumbai 400018. India.  
 Tel: +91-22-49198700 | email: sales@krishgenpudgala.com

**Introduction:**

Myeloperoxidase (MPO) is an important enzyme contained in the lysosome of neutrophils and has a pivotal role in the host defense. Its main function is the production of substances with antimicrobial activity, such as hypochlorous acid. MPO exerts its function in the intracellular phagolysosomes, and it can be also released by both neutrophils and macrophages in extracellular environments, where it is involved in the production of oxidants and proinflammatory substances.

Autoantibodies against the protein MPO are frequently detected in a specific class of autoimmune vasculitides known as Anti-neutrophil cytoplasmic autoantibodies (ANCA) associated vasculitis (AAV). These vasculitides are characterized by the presence of autoantibodies against cytoplasmic components of neutrophils that may have, cytoplasmatic staining (c-ANCA) or a particular staining (p-ANCA).

The mechanism of autoimmunity for ANCA antigens is not still being evaluated. Activated neutrophils can undergo apoptosis creating NETs, which are involved in the induction of inflammation. Persistence of NETs during the infection can lead to an autoimmune response. Increased expression of MPO and PR3 in neutrophils and monocytes can influence the pathogenic autoimmune response leading to ANCA-neutrophils activation.

ANCA-associated vasculitides is classified as small vessel vasculitides (SW), which predominantly affect the small vessels, intraparenchymal arteries, arterioles, capillaries and venules. ANCA-associated vasculitides are necrotising vasculitis characterised by a lack of immune deposits in vessel walls causing conditions such as Microscope polyangitis (MPA) and Granulomatosis with polyangitis (GPA, formerly known as Wagner's syndrome).

The frequency of serotype (MPO or PR3) clinical manifestation and geographic distribution of ANCA-associated vasculitides varies, suggesting a role of the environment and the genetic background of patients affected by this category of pathologies.

**Intended Use:**

The MPO (p-ANCA) Antibody IgG GENLISA® ELISA is intended for the quantitative determination of MPO (p-ANCA) Antibody IgG in human serum and plasma.

**Principle:**

The MPO (p-ANCA) Antibody IgG GENLISA® ELISA is an indirect enzyme linked immunosorbent assay for quantitative determination of IgG antibody present in the human serum and plasma. The Microtiter wells are pre-coated with specific neutrophil myeloperoxidase. Samples and Controls are pipetted into microwells and MPO (p-ANCA) Antibody IgG present in sample binds to the antigen coated on the wells. Anti-human-IgG: HRP Conjugate is pipetted and incubated to form an immune complex. After washing microwells in order to remove any non-specific binding, the substrate solution is added to microwells and color develops proportionally to the amount of MPO (p-ANCA) Antibody IgG present in the sample. Color development is then stopped by addition of stop solution. Absorbance is measured at 450 nm.

**Materials Provided:**

1. Coated Microtiter Plate (96 wells) – 1 no
2. Standards (0, 10, 20, 40, 160 AU/ml) –1.2 ml/vial
3. Positive Control – 1.2 ml
4. Negative Control – 1.2 ml
5. Sample Diluent – 100 ml
6. Anti-human-IgG:HRP Conjugate – 15 ml
7. (10X) Wash Buffer – 50 ml
8. TMB Substrate – 15 ml
9. Stop Solution –15 ml
10. Instruction Manual – 1 no

**Materials to be provided by the End-User:**

1. Microtiter Plate Reader able to measure absorbance at 450 nm.
2. Adjustable pipettes and multichannel pipettor to measure volumes ranging from 25 ul to 1000 ul.
3. Deionized (DI) water.
4. Wash bottle or automated microplate washer.
5. Graph paper or software for data analysis.
6. Timer.
7. Absorbent Paper.

**Handling/Storage:**

1. Store main kit components at recommended storage temperature indicated on the component label.
2. Before using, bring all components to room temperature (18-25°C). Upon assay completion return all components to appropriate storage conditions.
3. The Substrate is light-sensitive and should be protected from direct sunlight or UV sources.

**Health Hazard Warnings:**

1. Reagents that contain preservatives may be harmful if ingested, inhaled or absorbed through the skin. Refer to the MSDS online for details.
2. To reduce the likelihood of blood-borne transmission of infectious agents, handle all serum and/or plasma in accordance with NCCLS regulations.

**Sample Preparation and Storage:**

Specimens should be clear and non-hemolyzed. Samples should be run at a number of dilutions to ensure accurate quantitation.

1. Extract as soon as possible after specimen collection as per relevant procedure. The samples should be tested as soon as possible after the extraction. Alternately the extracted samples can be kept in -20°C. Avoid repeated freeze-thaw cycles.
2. **Serum-** Coagulate at room temperature for 10-20 minutes; centrifuge for 20-min at 2000-3000 rpm. Remove the supernatant. If precipitation appears, recentrifuge.
3. **Plasma-** Use EDTA or citrate plasma as an anticoagulant, mix for 10-20 minutes; centrifuge for 15-min at 2000-3000 rpm. Remove the supernatant carefully. If precipitation appears, recentrifuge.  
**Note:** Grossly hemolyzed samples are not suitable for use in this assay.

**Preparation of Samples:**

All serum or plasma samples must be pre-diluted 1:100 with sample diluent; for example, 10 ul of sample should be diluted with 990 ul of sample diluent.

**Reagent Preparation:**

1. Allow all components to reach 2-8°C prior to use in the assay.
2. (1X) Wash Buffer Dilution: To make (1X) Wash Buffer, add 50 ml of (10X) Wash Buffer to 450 ml of DI water. This is the working solution.

**Test Procedure:**

1. Add **100 ul Diluted Sample, Standards, Positive Controls and Negative Control** into appropriate wells.
2. Incubate at Room Temperature for **60 minutes**.
3. Aspirate and wash plate 5 times with **(1X) Wash Buffer** and blot residual buffer by firmly tapping plate upside down on absorbent paper. Wipe of any liquid from the bottom outside of the microtiter wells as any residue can interfere in the reading step. All the washes should be performed similarly.
4. Add **100 ul Anti-Human-IgG:HRP Conjugate** into each well except blank wells. Mix well.

5. Incubate at Room Temperature for **30 minutes**.
6. Aspirate and wash plate 5 times with **(1X) Wash Buffer** and blot residual buffer by firmly tapping plate upside down on absorbent paper. Wipe of any liquid from the bottom outside of the microtiter wells as any residue can interfere in the reading step. All the washes should be performed similarly.
7. Add **100 ul** of **TMB Substrate** to all wells.
8. Incubate at Room Temperature for 15 minutes in the dark.
9. Add **100 ul** of **Stop Solution**. Read result with an ELISA reader at 450 nm within 5 minutes of stopping the reaction.

#### Calculation of Results:

Determine the Mean Absorbance (net of Blank) for each set of duplicate Standards and Samples. Using graph paper, plot the average value (absorbance 450 nm) of each standard on the Y-axis versus the corresponding concentration of the standards on the X-axis. Draw the best fit curve through the standard points. To determine the unknown MPO (p-ANCA) Antibody IgG concentrations, find the unknown's Mean Absorbance value on the Y-axis and draw a horizontal line to the standard curve. At the point of intersection, draw a vertical line to the X-axis and read the MPO (p-ANCA) Antibody IgG Concentration. If samples were diluted, multiply by the appropriate dilution factor.

Software which is able to generate a 4-PL (2<sup>nd</sup> order), or cubic spline is best recommended for automated results.

#### Measuring Range:

The assay measuring range (AMR) is 2.30-160 AU/ml

Any value that reads below 2.30 AU/ml should be reported as "< 2.30 AU/ml". Any value that reads above 160 AU/ml should be reported as "> 160 AU/ml".

#### Metrology And Traceability:

The calibrators of this kit are traceable to the European Reference Material for MPO (p-ANCA) Antibody IgG in Human serum.

#### Uncertainty of Measurement:

The uncertainty associated with the measurement of the assay calibrators (Std0 – Std4) was determined following "Expression of Measurement Uncertainty in Laboratory Medicine, Approved Guideline". The uncertainty for each calibrator level was assessed over a minimum of 5 days (1 run per day) by 3 different operators. Result from one representative lot:

| Calibrator | Mean Conc. (AU/ml) | 95% Ci (AU/ml) |       | Calibrator uncertainty Uc (AU/ml) |
|------------|--------------------|----------------|-------|-----------------------------------|
| CAL0       | <LoB               | NA             |       | N/A                               |
| CAL1       | 10.2               | 9.5            | 10.9  | 0.3                               |
| CAL2       | 20.2               | 19.3           | 21.1  | 0.6                               |
| CAL3       | 39.8               | 36.2           | 43.4  | 0.5                               |
| CAL4       | 160.2              | 139.8          | 180.6 | 1.9                               |

#### Expected Values:

The following ranges were determined using the MPO (p-ANCA) Antibody IgG assay and are provided for information only. The 90% reference interval for apparently healthy adults were calculated by a non-parametric method following guidance from CLSI C28-A3 "Defining Establishing and Verifying Reference Intervals in the Clinical Laboratory").

|                            |           |
|----------------------------|-----------|
| No. of subjects            | 73        |
| Mean (AU/ml)               | 2.54      |
| SD (AU/ml)                 | 1.65      |
| Median (AU/ml)             | 2.36      |
| Reference Interval (AU/ml) | 1.07-3.90 |

The above ranges should be considered as guidelines only. It is recommended that each laboratory establish its own expected range based upon its own patient population.

#### Interpretation of Results:

| Concentration | Interpretation                                                                                                          |
|---------------|-------------------------------------------------------------------------------------------------------------------------|
| < 16 AU/ml    | The sample should be considered negative                                                                                |
| 16-20 AU/ml   | The sample should be graded equivocal and repeat testing / sampling should be performed according to internal practices |
| ≥ 20 AU/ml    | The sample should be considered Positive                                                                                |

The above index and interpretation should be considered as guidelines only. Positive results should be verified concerning the entire clinical status of the patient. Also, every decision for therapy should be taken on an individual patient basis.

It is recommended that each laboratory establishes its own normal and pathological ranges of anti-MPO.

#### Performance Characteristics:

Representative performance data are shown. Results obtained at individual laboratories may vary.

#### Detection Capability:

The limit of blank (LoB) limit of detection (LoD) and limit of quantitation (LoQ) were determined with guidance from CLSI EP17-A2, "Protocols for Determination of Limits of Detection and Limits of Quantitation" using 6 blanks and 6 low level samples.

| Sensitivity                 | Concentration |
|-----------------------------|---------------|
| Limit of Blank (LoB)        | 0.62 AU/ml    |
| Limit of Detection (LoD)    | 1.37 AU/ml    |
| Limit of Quantitation (LoQ) | 2.30 AU/ml    |

#### Trueness:

Trueness has been demonstrated through a recovery test of the MPO (p-ANCA) Antibody IgG assay with the European Reference Material ERM®- DA476/IFCC MPO (p-ANCA) Antibody IgG in human serum. The assessment indicated recovery was 100% ± 15%.

#### Precision:

Precision of the MPO (p-ANCA) Antibody IgG assay was determined by performing a complex precision study.

#### Repeatability:

Assessment combines within run, between run, between day and between operator variability. A total of 6 serum samples were assayed in 5 replicates once a day for 5 days by 3 operators.

Data from one representative lot is shown below,

|        |    |                    | (Repeatability) |      |
|--------|----|--------------------|-----------------|------|
| Sample | n  | Mean Conc. (AU/ml) | SD              | CV%  |
| 1      | 75 | 16.08              | 0.90            | 5.6% |
| 2      | 75 | 26.21              | 1.03            | 3.9% |
| 3      | 75 | 42.54              | 2.52            | 5.9% |
| 4      | 75 | 62.87              | 3.99            | 6.3% |
| 5      | 75 | 98.18              | 3.67            | 3.7% |
| 6      | 75 | 143.10             | 7.22            | 5.0% |

**Reproducibility:**

Assessment combines within run, between run, between day and between operator variability and between reagent lot variability.

A total of 6 samples were assayed in 5 replicants once a day for 5 days by 3 operators.

Results for the combined data from two lots are shown below.

|        |     |                    | (Reproducibility) |      |
|--------|-----|--------------------|-------------------|------|
| Sample | n   | Mean Conc. (AU/ml) | SD                | CV%  |
| 1      | 150 | 15.92              | 1.30              | 8.2% |
| 2      | 150 | 26.16              | 2.07              | 7.9% |
| 3      | 150 | 42.93              | 3.94              | 9.2% |
| 4      | 150 | 62.63              | 5.80              | 9.3% |
| 5      | 150 | 98.64              | 8.45              | 8.6% |
| 6      | 150 | 143.54             | 9.41              | 6.6% |

**Linearity:**

Linearity was established based on CLSI EP-06. "Evaluation of the Linearity of Quantitative Measurement Procedures". A serial dilution of high and low serum samples was prepared to create a panel from above the upper limit of linearity (ULL) to below the lower limit of quantitation (LLOQ).

For Anti-MPO concentration by MPO (p-ANCA) Antibody IgG assay, the measurement procedure shows linearity for the interval from 0.33 to 169.34 AU/ml within the allowable derivation of linearity (ADL) of  $\pm 15\%$  or  $\leq 2.3$  AU/ml for concentrations below LLoQ.

**Sensitivity and Specificity:**

The sensitivity and specificity were determined with guidance from CLSI EP-24 "Assessment of the Diagnostic Accuracy of Laboratory Tests Using Receiver Operating Characteristics Curves". Using 73 negative and 73 positive samples run on a single run on a single reagent lot.

|            |          | KBD756   |          |       |
|------------|----------|----------|----------|-------|
|            |          | Positive | Negative | Total |
| True State | Positive | 70       | 3        | 73    |
|            | Negative | 0        | 73       | 73    |
| Total      |          | 70       | 76       | 146   |

Sensitivity: 95.9%

Specificity: 100%

|               | Likelihood ratio [95% CI] | Predictive value [95% CI] |
|---------------|---------------------------|---------------------------|
| Positive test | -<br>(19.2 to -)          | 1.00<br>(- to -)          |
| Negative test | 0.04<br>(1.01 to 0.11)    | 0.96<br>(0.89 to 0.99)    |

**Interference:**

The specificity of the MPO (p-ANCA) Antibody IgG assay was assessed by evaluation of a panel of 40 samples known to be positive to other autoantibodies, paraproteins and immune complexes.

Samples from 4 different disease states were assessed on the MPO (p-ANCA) Antibody IgG assay and any observed positive result were confirmed by measurement with an alternative commercially available Anti-MPO assay.

| Disease                    | No. of samples tested | Positive samples detected | Interference confirmed |
|----------------------------|-----------------------|---------------------------|------------------------|
| Rheumatoid factor          | 2                     | 0                         | No                     |
| Paraproteinemia            | 1                     | 0                         | No                     |
| Lactose intolerance        | 2                     | 0                         | No                     |
| Inflammatory bowel disease | 2                     | 0                         | No                     |

The following samples were classified according to the autoantibody presence are distinguished between “specific” and “non-specific” where:

- “specific” samples contain only the clone for which they have been selected, and
- “non-specific” samples include a range of multiple clones, with different affinity and avidity

| Disease            | No. of samples tested | Positive samples detected | Interference confirmed |
|--------------------|-----------------------|---------------------------|------------------------|
| Anti PR-3 (c-ANCA) | 5                     | 0                         | No                     |
| Anti dsDNA         | 5                     | 0                         | No                     |
| Anti Sm            | 3                     | 0                         | No                     |
| Anti SS-A Ro       | 3                     | 0                         | No                     |
| Anti Cardiolipin   | 4                     | 0                         | No                     |
| Anti TG            | 5                     | 0                         | No                     |
| Anti tTG           | 3                     | 0                         | No                     |
| Anti TPO           | 5                     | 0                         | No                     |

The following substances do not interfere with a bias of  $\geq \pm 15\%$  in the MPO (p-ANCA) Antibody IgG assay when the concentrations are below the stated threshold presented in the following table:

| Potentially Interfering Reagent | Threshold Concentration |
|---------------------------------|-------------------------|
| Bilirubin Conjugated            | 15 mg/dl                |
| Bilirubin Unconjugated          | 15 mg/dl                |
| Haemoglobin                     | 200 mg/dl               |
| Total Protein                   | 10 g/dl                 |
| Triglycerides                   | 500 mg/dl               |

#### Serum-plasma study:

The Anti-MPO (p-ANCA) assay matrix comparison study was performed to evaluate the difference across tube types (serum separator tubes (SST) lithium heparin plasma, sodium heparin plasma and K2 EDTA plasma) versus the control samples (red top serum, without additive) following CLSI EP35-Ed1 guidelines. A total of 20 samples (16 native, 4 spiked) to cover the range of 2.30 to 134.33 ng/ml were evaluated. Linear regression analysis was performed on the comparative data.

| Sample Type     | Slope (95% CI)         | Intercept (AU/ml) (95% CI) | Correlation Coefficient (r) |
|-----------------|------------------------|----------------------------|-----------------------------|
| SST             | 1.09<br>(1.07 to 1.11) | -0.79<br>(-1.50 to -0.09)  | 1.00                        |
| Lithium Heparin | 0.99<br>(0.96 to 1.02) | 0.63<br>(-0.61 to 1.88)    | 1.00                        |
| Sodium Heparin  | 0.97<br>(0.96 to 0.98) | 0.50<br>(0.03 to 0.97)     | 1.00                        |
| EDTA            | 1.09<br>(1.06 to 1.11) | 0.03<br>(-1.06 to 1.11)    | 1.00                        |

#### Cut-off:

A total of 32 samples were evaluated to determine the assay cut-off, of which 24 are considered normal and 8 from patients analytically defined as having autoimmune vasculitides. Receiver operating characteristic (ROC) curve was performed, and Youden Index calculated to determine the assay cut off.

The highest Youden index value corresponded to 19.0 AU/ml with a 20% grey zone applied which corresponds to 20% of the cut-off value. The Grey Zone (GZ) Area to be considered for the MPO (p-ANCA) Antibody IgG assay is the following:

| MPO (p-ANCA) Antibody IgG |             |
|---------------------------|-------------|
| Grey Zone                 | 16-20 AU/ml |

Any value that reads <16 AU/ml should be considered negative.

Any value that reads >20 AU/ml should be considered positive.

**Limitations of Use:**

- The presence of immune complexes or other Immunoglobulin aggregates in the patient sample may cause an increased level of non-specific binding and produce false positives in this assay.
- As in the case of any diagnostic procedure, results must be interpreted in conjunction with the patient's clinical presentation and other information available to the physician.
- The performance characteristics of this assay have not been established in a paediatric population.
- Heterophilic antibodies in human serum can react with reagent immunoglobulins, interfering with *in vitro immunoassays*. Patients routinely exposed to animals or to animal serum products can be prone to this interference and anomalous values may be observed.

**Waste Management:**

Reagents must be disposed of in accordance with local regulations.

All materials that have come into contact with samples and reagents must be disposed of in accordance with country, state and local regulations.

**Safety Precautions:**

- **This kit is For In-vitro Diagnostic Use only.** Follow the working instructions carefully.
- The expiration dates stated on the kit are to be observed. The same relates to the stability stated for reagents.
- Do not use or mix reagents from different lots.
- Do not use reagents from other manufacturers.
- Avoid time shift during pipetting of reagents.
- All reagents should be kept in the original shipping container.
- Some of the reagents contain small amount of sodium azide (< 0.1 % w/w) as preservative. They must not be swallowed or allowed to come into contact with skin or mucosa.
- Source materials maybe derived from human body fluids or organs used in the preparation of this kit were tested and found negative for HBsAg and HIV as well as for HCV antibodies. However, no known test guarantees the absence of such viral agents. Therefore, handle all components and all patient samples as if potentially hazardous.
- Since the kit contains potentially hazardous materials, the following precautions should be observed.
  - Do not smoke, eat or drink while handling kit material.
  - Always use protective gloves.
  - Never pipette material by mouth.
  - Wipe up spills promptly, washing the affected surface thoroughly with a decontaminant.
- In any case GLP should be applied with all general and individual regulations to the use of this kit.



**LIMITED WARRANTY**

Krishgen Pudgala LLP does not warrant against damages or defects arising in shipping or handling, or out of accident or improper or abnormal use of the product; against defects in products or components not manufactured by Krishgen Pudgala LLP, or against damages resulting from such non-Krishgen Pudgala LLP made products or components. Krishgen Pudgala LLP passes on to customer the warranty it received (if any) from the maker thereof of such non-Krishgen made products or components. This warranty also does not apply to product to which changes or modifications have been made or attempted by persons other than pursuant to written authorization by Krishgen Pudgala LLP.

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Krishgen Pudgala LLP, 2026.

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Off Mankoli-Anjur Phata Road. Village Dapode, Bhiwandi 421302.

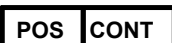
**Regulatory Status:**

|                  |        |
|------------------|--------|
| CE Marked        | Europe |
| FDA registered   | USA    |
| CDSCO registered | India  |

**SCHEMATIC ASSAY PROCEDURE**

|   |                                                                                                                                                                                                                                                                                                                  |
|---|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1 | Add <b>100 ul Diluted Sample, Standards, Positive Controls and Negative Controls</b> into appropriate wells.                                                                                                                                                                                                     |
| 2 | Incubate at Room Temperature for 60 minutes.                                                                                                                                                                                                                                                                     |
| 3 | Aspirate and wash plate 5 times with <b>(1X) Wash Buffer</b> and blot residual buffer by firmly tapping plate upside down on absorbent paper. Wipe of any liquid from the bottom outside of the microtiter wells as any residue can interfere in the reading step. All the washes should be performed similarly. |
| 4 | Add <b>100 ul Anti-Human-IgG:HRP Conjugate</b> into each well except blank wells. Mix well.                                                                                                                                                                                                                      |
| 5 | Incubate at Room Temperature for 30 minutes.                                                                                                                                                                                                                                                                     |
| 6 | Aspirate and wash plate 5 times with <b>(1X) Wash Buffer</b> and blot residual buffer by firmly tapping plate upside down on absorbent paper. Wipe of any liquid from the bottom outside of the microtiter wells as any residue can interfere in the reading step. All the washes should be performed similarly. |
| 7 | Add <b>100 ul of TMB Substrate</b> to all wells.                                                                                                                                                                                                                                                                 |
| 8 | Incubate on shaker at Room Temperature for <b>15 minutes</b> in the dark.                                                                                                                                                                                                                                        |
| 9 | Add <b>100 ul of Stop Solution</b> . <b>Read result with an ELISA reader at 450 nm</b> within 15 minutes of stopping the reaction.                                                                                                                                                                               |

## SYMBOLS KEY

|                                                                                     |                              |
|-------------------------------------------------------------------------------------|------------------------------|
|    | Microtiter Plate (96 wells)  |
|    | Standards                    |
|    | Positive Control             |
|    | Negative Control             |
|    | Anti-Human-IgG:HRP Conjugate |
|    | Sample Diluent               |
|    | (10X) Wash Buffer            |
|   | TMB Substrate                |
|  | Stop Solution                |
|  | Consult Instructions for Use |
|  | Catalog Number               |
|  | Expiration Date              |
|  | Storage Temperature          |