INTENDED USE

The SCIMEDX Corporation anti-Myeloperoxidase (anti-MPO) test is a semi-quantitative indirect enzyme immunoassay (EIA) kit for the *in vitro* diagnostic detection in human serum of autoantibodies specific for myeloperoxidase antigen. The test is intended as an aid in the diagnosis of conditions associated with raised anti-neutrophil cytoplasmic antibodies (ANCA) and is not definitive in isolation. MPO-ANCA is associated with polyarteritis and necrotising glomerulonephritis. Autoantibody levels represent one parameter in a multicriterion diagnostic process.

CLINICAL SIGNIFICANCE

In 1939, Friedrich Wegener described a disease called "rhinogenic granulomatosis". Early in the disease granulomas are found that, like the rheumatic nodules, develop independently from the vessels in the connective tissue. During the generalized stage, one will usually find the granuloma in close relation to the vessels in different regions of the body, sometimes in only one, sometimes in all organs. The systemic vasculitis occurs later. The connective tissue diseases are associated with autoantibodies to various non-organ-specific antigens, particularly nuclear antigens.(1) Autoantibodies to neutrophils have been known for a long time. As early as 1964 a granulocyte-specific antinuclear factor was reported. (2) The use of an ethanol fixation technique for granulocyte-specific antinuclear antibodies (GS-ANA) is the standard today. The cytoplasmic staining of granulocytes was first published in 1982 in a report of Australian patients with segmental necrotising glomerulonephritis.(3) Four more patients were reported with vasculitis and glomerulonephritis. (4) In 1985, van der Woude (5) showed that the antineutrophil cytoplasmic autoantibodies (ANCA) occurred with Wegener's granulomatosis, and as a result the interest in these antibodies has increased significantly.(6) These antibodies, now termed ANCA, have proven useful for the diagnosis of disease in systemic vasculitis.

In the immunofluorescence test for antineutrophil cytoplasmic antibodies, staining patterns that are different from the granular cytoplasmic pattern produced by the antibodies to the 29 kD serine protease have been recognized; in particular, a perinuclear pattern has been observed. This pattern is produced from antibodies against two other myeloid lysosomal enzymes - myeloperoxidase (MPO) and human leukocyte elastase. MPO antibodies have been identified by Falk and Jennette (7,8) in patients with idiopathic or vasculitis-associated crescentic glomerulonephritis. Anti-MPO antibodies have also been demonstrated in patients with classic polyarteritis, Churg-Strauss syndrome,(10) and polyangiitis overlap syndrome without renal manifestations of vasculitis. The presence of antibodies to MPO or Proteinase 3 (PR3) have proven to be highly specific and sensitive for this group of disorders, and useful in the clinical analysis of patients suspected of having vasculitis.(9-12)

Further identification and purification of the ANCA antigen has resulted in antibody detection by enzyme immunoassay for both MPO and PR3. (13) Simultaneous testing for MPO and PR3 antibodies is recommended. (6)

PRINCIPLE OF THE TEST

Diluted sera are incubated in assigned wells and antibodies present in the specimen will bind to the Myeloperoxidase antigen on the wells. Unbound antibodies are rinsed off and a second incubation with goat anti-human IgG conjugated to the enzyme Alk.phosphatase follows. Unbound conjugate is rinsed off and the bound conjugate is visualized by incubation with pNPP substrate that turns yellow when degraded by the enzyme. After addition of the Stop Solution the reacted substrate turns yellow and the intensity of the developed color is recorded at 405 nm, and correlates directly with the titer of the anti-MPO in the specimen. The whole assay can be performed in less than 2 hours.

KIT COMPONENTS

ITEM	CONTENTS	QUANTITY
1.	Antigen coated wells	12 X 8 wells
2.	Calibrators: (Ready to Use) 320, 80, 20, 5 EU/mL	1 ea. x 1.0 mL
3.	Positive Control (Ready to Use)	1 x 1.0 mL
4.	Negative Control (Ready to Use)	1 x 1.0 mL
5.	Goat antihuman IgG - Alk. Phos. Conjugate	1 X 15 mL
6.	Sample Diluent (Ready To Use)	1 x 75 mL
7.	EIA Wash buffer (10X)	1 X 100 mL
8.	pNPP Substrate (Ready To Use)	1 X 15 mL
9.	Stop Solution (Ready to Use)	1 X 30 mL

NOTE: Liquid reagents contain the preservative Proclin 300™

MATERIALS REQUIRED BUT NOT PROVIDED

- Tube rack in a microplate configuration.
- Multichannel pipettor of 50 - 250 µL range, and micropipettors of 200 - 1000 µL and 2 - 20 µL ranges, and Pipette tips.
- Graduated cylinder.
- Cover for microplate.
- Clean containers for diluted Wash Buffer.
- Reservoirs (disposable).
- Test tubes or cluster tubes.
- Lint free paper towels.
- Calibrated microplate reader adjusted to read at 405 nm.
- Timer (30 min. range).
- Distilled or deionized water.

PRECAUTIONS

1. **Caution**: All blood products should be treated as potentially infectious. Human source materials from which this product was derived were found to be nonreactive for Hepatitis-B surface antigen (HBsAg), HCV, and Human Immunodeficiency Virus (HIV) 1 & 2 antibody when tested in accordance with current FDA required tests. No known test methods can offer total assurance that products derived from human blood will not transmit HIV, Hepatitis or other potentially infectious agents. Therefore, these reagents and all patients' specimens should be handled at Biosafety Level 2 as recommended for any potentially infectious human serum or blood specimen in the CDC/NIH manual - "Biosafety in Microbiology and Biomedical Laboratories", 1984 or latest edition.
2. Reagents in this kit contain 0.1% Proclin 300™ as a preservative.
3. For *in vitro diagnostic use* only.
4. All components in this kit have been tested and standardized as a unit. Do not intermix components from different kit lots or other manufacturer's kits.
5. All reagents must be at room temperature (21 - 26°C) before running the assay. Temperature WILL affect the absorbances of the assay, but will not change the EU values calculated from the standard curve.
6. Use only distilled or deionized water and clean glassware.
7. Stop Solution should be handled carefully as it can cause burns or irritation to the skin and eyes. If contact occurs, flush immediately with water.
8. Negative and Positive Controls, as well as the Calibrators, must be run with each assay.
9. Use separate pipette tips for each sample, control and reagent to avoid cross contamination.
10. Use reservoirs only for single reagents. This especially applies to the substrate reservoir. Using a reservoir for dispensing a substrate solution that had previously been used for the conjugate solution may turn the Substrate Solution yellow.
11. Mix the contents of the microplate wells thoroughly to ensure good test results.
12. Do not let wells dry during assay; add reagents immediately after completing the rinsing steps.
13. Do not use reagents past their expiration date.
14. Do not reuse microwells and do not pour reagents back into vials as reagent contamination may occur.
15. Incubation times and temperatures other than those specified may give erroneous results.
16. No assurance is given that these reagents are free of microbial or fungal contamination.
17. If sodium hypochlorite (bleach) solution is being used as a disinfectant, do not expose to work area during actual test procedure because of potential interference with enzyme activity.
18. **CAUTION:** Liquid waste at acid pH must be neutralized prior to adding to sodium hypochlorite solutions (bleach) to avoid formation of poisonous gas.

STABILITY AND STORAGE

1. The kits should be stored at 2 - 8°C. Do not freeze.
2. Discoloration of the liquid Substrate ranging from light yellow to intense yellow indicates substrate deterioration and the material should not be used.
3. The Ready to Use Conjugate, Calibrators, and Controls are stable up to the expiration dates listed on the respective bottle labels when stored at 2-8°C. Never freeze the solutions.
4. Diluted 1X Wash Buffer remains stable for 90 days at 2 - 8°C.
5. After opening the foil pouch, unused microplate strips coated with the protein antigens should be resealed with the desiccant provided.

SERUM COLLECTION

A whole blood sample should be collected by qualified personnel using approved aseptic venipuncture techniques. Obtain and/or clarify serum samples containing visible particulate matter by centrifugation. The samples may be stored at 2 - 8°C if testing is to be done within 5 days. If stored longer, they should be frozen at -20°C or lower. Do not use a frost-free freezer which may allow the specimens to go through freeze-thaw cycles that can denature the IgG antibody and cause spurious results. Do not use hyperlipemic, hemolytic, heat treated or contaminated samples.

PREPARATION OF REAGENTS AND SAMPLES

1. Bring **all** reagents to room temperature before use. Remove the number of strips being used for the day's testing and replace the remainder in foil pouch with desiccant at 2-8°C.
2. Sample Diluent (blue): "Ready To Use".
3. Calibrators (blue) : The Calibrators are Ready to Use and the assigned values are indicated on their labels. **Do not dilute further**.
4. Positive and Negative Controls: Ready to use. **Do not dilute further.**
5. Patient's Sera: Dilute each patient serum 1:50 with Sample Diluent. Prepare dilutions (10µL + 490µL) in cluster tubes. Mix by inverting the tubes a few times or use a vortex on a low speed.
6. Assign each well the appropriate sample. For better accuracy, duplicate wells for the Calibrators, samples and Controls may be run. Use well A-1 as a reagent blank if a reference wavelength of 620 nm is not available on the reader. This "blank" well should contain assay diluent, conjugate and substrate.
7. Conjugate: Ready to Use. Do Not dilute further.
8. pNPP liquid Substrate: Ready To Use.
9. Wash Buffer (10X): Dilute the buffer 1 + 9 using distilled or deionized water or by pouring total contents into a graduated cylinder and add distilled or deionized water to 1,000 ml final volume. Mix thoroughly and store the 1X solution at 2 - 8°C.
10. Stop Solution: Ready To Use.

ASSAY PROCEDURE

1. Transfer 100 µL/well of Sample Diluent into well A-1 for Blank, if appropriate (see # 6 above). Transfer 100µL of Calibrators, Controls and each diluted sample to the corresponding position in the microwell strips. Cover the microwells and incubate for **30** minutes at room temperature.
2. Wash 3 times with 300 µL/well of 1X Wash Buffer. If washing is done manually, empty the plate by shaking into a suitable container and blotting inverted on a paper towel.
3. Dispense 100 µL of ready to use Conjugate into each well (including A-1) using a multichannel pipettor. Cover the microwells and incubate for **30** minutes at room temperature.
4. Wash as described above in step # 2.
5. Add 100 µL of Substrate Solution to all wells using a multichannel pipettor. Cover the microwells and incubate at room temperature for **30** minutes.
6. Terminate the reaction by adding 100 µL of Stop Solution to each well using a multichannel pipettor. Shake the plate for 10 – 20 seconds to mix. Be careful not to splash the solution from the wells. The wells must be read within 30 minutes after stopping the reaction.
7. Results: Zero the reader on well A-1 and read the absorbance of the wells at 405 nm **or** use the reference wavelength of 620 nm in an appropriate microplate reader.
   NOTE: The wavelength of microplate or strip reader used should be set at 405 nm. If a reference wavelength is not available, use a reagent blank consisting of diluent, conjugate, and substrate. The absorbance of the reagent blank (A-1) is automatically subtracted from each well

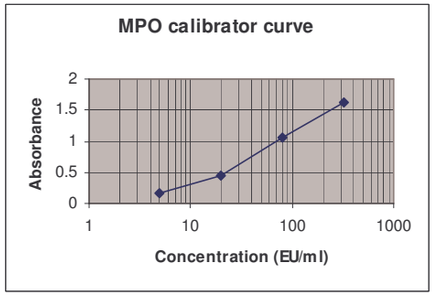
before calculations are done. The absorbance at 405 nm of the samples, Controls and the Calibrators must always be determined at the same time. Do not subtract the absorbance value of the reagent blank (A-1) if a reference wavelength is used.

CALCULATION OF RESULTS

Calibrators:

1. This kit contains 4 vials of Calibrator antibody levels. A curve constructed from the concentration of the Calibrators versus their absorbances is used to calculate the EU/ml of autoantibody in the tested specimen.
2. Since International Standards are not yet available for the whole range of SCIMEDX kits, the EU/ml given are calibrated using internal control sera. Where available, SCIMEDX provides kits which are calibrated in International Units according to internationally recognized standards.
3. Graph Method:
   A. Plot the absorbance values for the Calibrators on the linear ordinate (Y axis) against the corresponding EU/ml on the logarithmic abscissa (X-axis) using log/lin graph paper.
   B. Locate the point corresponding to the absorbance value (Y-axis) of each specimen and read its corresponding EU/ml from the X-axis.

Example: Using log/lin graph paper, the following standard curve is plotted:



From the assay the absorbance of the Positive Control is : 1.004

1. The absorbance is found on the Y-axis;
2. The line is followed to the standard curve;
3. From the curve the line is followed to the X-axis to locate the EU/mL for the sample.
4. The value for the Control in this example is: 47.7 EU/mL

4. Dilution of Serum
   Samples which give absorbances above the top Calibrator (320 EU/mL) are out of the range of this assay, and should be stated as >320 EU/mL. Such samples may be diluted as appropriate. A further 1:5 dilution is recommended. When calculating the results for a diluted sample, the concentration obtained must be corrected by the dilution factor (X 5).
5. EIA Software Program:
   If using an EIA reader with the appropriate software for data reduction, choose log/lin for X/Y axis and point-to-point or equivalent as your choice for a curve fitting program.
   NOTE: Assigned values for the calibrators are expressed as EU/ml and are located on the label.

INTERPRETATION OF RESULTS

Antibody EU/ml values are reported as a decimal number (10.2 EU/ml). The numeric value should be used

Positive = Equal to or greater than 15 EU/mL.
Equivocal = 5.1 – 14.9 EU/mL
Negative = Equal to or less than 5 EU/mL

Samples with values in the Equivocal (Borderline) range should be considered suspect for disease since a low level of antibody is detected. The sample should be repeated with a fresh dilution or a new sample should be obtained at a later time and tested. If the patient remains Equivocal, antibody status should be monitored. It should be noted that in any assay measuring antibody, it is not the concentration but the activity of the antibody present in the sample that is determined. Antibody activity is affected by a number of parameters, such as avidity and affinity.

Antibody EU/mL values are reported as an integer or whole number. The numeric value, without a decimal point, should be used.

QUALITY CONTROL

Positive and Negative Controls are supplied with the kit. The controls verify test performance, test integrity and operator reliability. Good laboratory practice dictates running the positive and negative control each time the kit is used. If a result within the confidence limit (as listed on the label) of the positive and negative control is not obtained, test results are not valid.

If a repeat assay is performed, always run each Control and use fresh dilutions of the patient samples, regardless of when the dilutions were made.

If sufficient results cannot be obtained, contact the SCIMEDX Technical Service Department.

LIMITATIONS

1. The antibody titer obtained from individual samples does not necessarily correlate with disease severity and should not be reported as such. Antibodies from different patients may have different avidities. Paired sera run at the same time under the same conditions will give a better indication of the disease process.
2. The values obtained from this assay are intended to be an aid to diagnosis only. Each physician must interpret the results in light of the patient's history, physical findings and other diagnostic procedures.
3. Discrepancies between IFA and EIA methodologies may be due to the fact that ANCA antigens contain additional specificities such as cathepsin, lactoferrin and elastase. Due to sequence similarities some cross-reactivity is possible. In addition, a small number of SLE patients, especially SLE with neurologic disease, will have antibodies to myeloid elastase, cathepsin and lactoferrin.[16,17] In certain diseases (UC and/or PSC), a similar ANCA pattern has been identified but does not react with MPO in ELISA. [18,19]
4. If IFA is used as a screen, and atypical ANCA patterns are observed, these should be considered "suspect" and further testing by EIA is recommended.
5. The results of the assay are not diagnostic proof of the presence or absence of any vasculitic disease and, therefore, immunosuppressive therapy should not be started based solely on a positive result from this assay.
6. Reproducible results depend on careful pipetting, observation of incubation periods and temperature, as well as rinsing the test strips and thorough mixing of all prepared solutions.
7. Do not scratch coated wells during washing and aspiration. Dispense and fill all reagents without interruption. While dispensing, check that all wells are filled evenly with Washing solution and that there are no residues in the wells.
8. Instructions for using appropriate photometers are to be observed; check adjustment of proper wavelength and reference wavelength respectively.
9. Use fresh serum or samples frozen only once and thawed. Samples that are improperly stored or are subjected to multiple freeze-thaw cycles may yield spurious results.
10. Proper washing of the microwells is critical for reducing the potential of nonspecific reactions or residues causing false positive reactions. The use of automated washing equipment may require 4-5 rinses for each washing step..

EXPECTED RESULTS

Published clinical studies have demonstrated that <1% of patients who had suspected diagnosis of vasculitis and/or glomerulonephritis exhibited a positive C- or P-ANCA pattern.[10]

Studies have been published which demonstrated a high percentage of MPO antibodies in various systemic vasculitic disease states. These studies have shown up to 92% positive incidence of anti-MPO in Systemic Small Vessel Vasculitis, polyarteritis, primary Glomerulonephritis and Rapidly Progressive Glomerulonephritis confirmed patients.[11,12].

The following table shows the incidence of MPO antibodies in the various diseases obtained from clinical studies performed in the evaluation of anti-MPO antibody in serum.

Disease State	Total Tested	No. MPO Negative	No. MPO 6 - 20 EU/mL	No. MPO 21-80 EU/mL	No. MPO >81 EU/mL
Wegener's	43	41	2	0	0
ICGN	40	15	5	14	6
PAN	4	4	0	0	0
PRS	7	1	1	1	4
No DX	44	33	4	6	1
MPA	20	4	3	4	9
CGN	5	3	1	1	0
UC	6	5	1	0	0
SLE	17	16	0	0	1
All other Autoimmune	29	29	0	0	0
All other vasculitic	13	8	2	3	0

ICGN = Idiopathic Crescentic Glomerulonephritis; PAN = Polyarteritis Nodosa; PRS = Pulmonary Renal Syndrome; No DX = No Diagnosis; MPA = Microscopic Polyarteritis; CGN = Crescentic Glomerulonephritis; UC = Ulcerative Colitis; SLE = Systemic Lupus Erythematosus

PERFORMANCE CHARACTERISTICS

Comparison

A study was performed using 252 patient samples that were clinically characterized as ANCA positive or negative and 104 normal blood donors from a blood bank. These samples were assayed in the Scanlisa MPO kit and the results compared to the reference ELISA MPO kit. Of the 252 samples, 193 were also tested by p-ANCA IFA. The results yielded a sensitivity of 98.7% and 98.1%, specificity of 99.0% and 98.7%, and agreement of 98.6% and 98.4% to the reference ELISA kit and IFA respectively. Three samples were equivocal in the Scanlisa kit and negative in both reference tests. These three samples were not used in the calculations of sensitivity and specificity.

		Reference MPO ELISA +	-	Total
Scanlisa MPO	+	149	2	151
	-	2	200	202
	Equiv	0	3	3
	Total	151	205	356

Relative Sensitivity = 98.7% (95% C.I. = 95.3 – 99.8%)
Relative Specificity = 99.0% (excluding equivocals) (95% C.I. = 96.5 – 99.9%)
Relative Agreement = 98.6% (excluding equivocals) (95% C.I. = 97.1 – 99.7)

		Reference p-ANCA IFA +	-	Total
Scanlisa MPO	+	108	1	109
	-	2	79	81
	Equiv	0	3	3
	Total	110	83	193

Relative Sensitivity = 98.1% (95% C.I. = 96.6 – 99.8%)
Relative Specificity = 98.7% (excluding equivocals) (95% C.I. = 93.2 – 100%)
Relative Agreement = 98.4% (excluding equivocals) (95% C.I. = 95.5 – 99.7)

Cross Reactivity

A study was performed using 56 positive patient samples that were tested for other autoimmune disease state markers. The samples were run on the Scanlisa kit and compared to the reference ELISA results. No cross reactivity was observed in the Scanlisa MPO kit demonstrating that diseases such as SLE, myopathy, dermatitis, cirrhosis, polymyositis, rheumatoid arthritis, etc., do not interfere with the assay.

Reproducibility

Five sera (3 positive, 1 equivocal, and 1 negative) were run in 16 replicates for Intra-Run reproducibility. The following EU/mL results were obtained:

	Serum 1	Serum 2	Serum 3	Serum 4	Serum 5
MEAN	352	134	51	7.2	0.0
S.D.	9.1	6.7	2.6	0.9	0.6
% C.V.	2.6	5.0	5.2	13.6	7.4

Five positive sera were run on 3 lots of Scanlisa MPO kits to evaluate the Inter-Lot reproducibility. The following EU/mL results were obtained:

Serum 1	Serum 2	Serum 3	Serum 4	Serum 5

MEAN	275.7	132.7	75.9	35.1	13.5
S.D.	9.4	5.9	7.2	3.0	2.0
% C.V.	3.4	4.5	9.5	8.6	14.8

Five positive sera were run on 4 separate days to evaluate the Inter-Day reproducibility. The following EU/mL results were obtained:

	Serum 1	Serum 2	Serum 3	Serum 4	Serum 5
MEAN	337.1	220.9	113.2	39.5	14.2
S.D.	4.7	4.8	2.3	2.8	1.4
% C.V.	1.4	2.2	2.0	7.0	9.7

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