Diagnostic Automation/Cortez Diagnostics, Inc.
IMMUNO DIAGNOSTICS

AccuDiag™ MPO (p-ANCA) IgG ELISA Kit

REF 1441-2

MPO (p-ANCA) IgG ELISA	
Principle	Sandwich Complex
Detection	Qualitative & Semi Quantitative
Sample	10 µL serum
Incubation Time	60 minutes
Sensitivity	97.9%
Specificity	98.9%
Shelf Life	12 Months from the manufacturing date

PRODUCT FEATURES

Very easy to use with little training

Highly specific and consistent assay

Provides accurate results quickly

Reading of results both visually and as absorbance data

INTENDED USE

The Diagnostic Automation, Inc. Myeloperoxidase (MPO) Test System is intended for the qualitative and semi-quantitative detection of IgG-class antibody to myeloperoxidase in human serum. This test is intended to be used as an aid in the diagnosis of various autoimmune vasculitis disorders characterized by elevated levels of anti-neutrophil cytoplasmic antibodies (ANCA). MPO-ANCA may be associated with autoimmune disorders such as Wegener's granulomatosis, ICGN, MPA and PRS. This test is for *In Vitro* diagnostic use.

SIGNIFICANCE AND SUMMARY

Anti-neutrophil cytoplasmic antibody (ANCA) was initially described by Davies, *et al* in 1982 (1). Since this initial discovery, scientists have associated ANCA with a number of Systemic Vasculitides (SV). Scientists now recognize ANCA to include two primary specificities: C-ANCA directed against Proteinase-3 (PR-3), and P-ANCA directed against Myeloperoxidase (MPO). Testing for both P-ANCA and C-ANCA is highly recommended in the laboratory workup of patients who present with clinical features suggestive of SV. The clinical syndromes most frequently associated with ANCA are as follows:

Wegener's granulomatosis(2)
Polyarteritis(3)
"Overlap" Vasculitis (4)
Idiopathic Crescentic Glomerulonephritis (ICGN) (5)
Kawasaki Disease (6)

Although the initial identification of C-ANCA and P-ANCA was based on the indirect immunofluorescence procedures, further identification and purification of PR-3 and MPO has resulted in the development of enzyme immunoassays (ELISA) for both PR-3 and MPO.

ASSAY PRINCIPLE

The Diagnostic Automation Myeloperoxidase (MPO) ELISA test system is designed to detect IgG class antibodies to MPO in human sera. Wells of plastic microwell strips are sensitized by passive adsorption with MPO antigen. The test procedure involves three incubation steps:

1. Test sera (properly diluted) are incubated in antigen coated microwells. Any antigen specific antibody in the sample will bind to the immobilized antigen. The plate is washed to remove unbound antibody and other serum components.
2. Peroxidase Conjugated goat anti-human IgG is added to the wells and the plate is incubated. The Conjugate will react with IgG antibody immobilized on the solid phase in step 1. The wells are washed to remove unreacted Conjugate.
3. The microwells containing immobilized peroxidase Conjugate are incubated with peroxidase Substrate Solution. Hydrolysis of the Substrate by peroxidase produces a color change. After a period of time the reaction is stopped and the color intensity of the solution is measured photometrically. The color intensity of the solution depends upon the antibody concentration in the original test sample.

SPECIMEN COLLECTION & PREPARATION

1. It is recommended that specimen collection be carried out in accordance with CLSI document M29: Protection of Laboratory Workers from Infectious Disease (Current Edition).
2. No known test method can offer complete assurance that human blood samples will not transmit infection. Therefore, all blood derivatives should be considered potentially infectious.
3. Use only freshly drawn and properly refrigerated sera obtained by approved aseptic venipuncture procedures should be used in this assay (7,8). No anticoagulants or preservatives should be added. Avoid using hemolyzed, lipemic, or bacterially contaminated sera.
4. Store sample at room temperature for no longer than 8 hours. If testing is not performed within 8 hours, sera may be stored between 2-8°C for no longer than 48 hours. If delay in testing is anticipated, store test sera at –20°C or lower. Avoid multiple freeze/thaw cycles that may cause loss of antibody activity and give erroneous results. It is the responsibility of the individual laboratory to use all available references and/or its own studies to determine stability criteria for its laboratory. (10)

MATERIALS AND COMPONENTS

Materials provided with the test kit

Each Test System contains the following components in sufficient quantities to perform the number of tests indicated on packaging label.

NOTE: The following components contain Sodium Azide as a preservative at a concentration of < 0.1% w/v): Controls, Calibrators and Sample Diluent.

Reactive Reagents

1. Plate: 96 wells configured in twelve, 1x8- well, strips coated with inactivated Myeloperoxidase antigen. The strips are packaged in a strip holder and sealed in an envelope with desiccant.
2. Conjugate: Conjugated (horseradish peroxidase) goat anti-human IgG (Fc chain specific). One, 15 mL, white- capped bottle. Ready to use.
3. Positive Control (Human Serum): One, 0.35 mL, red-capped, vial.
4. Calibrator (Human Serum): One, 0.5mL, blue-capped vial.
5. Negative Control (Human Serum): One, 0.35mL, green-capped vial.
6. Sample Diluent: One, 30mL, green-capped, bottle containing Tween-20, bovine serum albumin and phosphate-buffered-saline, (pH 7.2 ± 0.2). Ready to use. Note: The Diluent will change color when combined with serum.
7. TMB: One, 15 mL, amber-capped, amber bottle containing 3, 3', 5, 5' – tetramethylbenzidine (TMB). Ready to use.
8. Stop Solution: One, 15 mL, red-capped, bottle containing 1M H_2SO_4, 0.7M HCl. Ready to use.
9. Wash Buffer Concentrate (10X): Dilute 1 part concentrate + 9 parts deionized or distilled water. One, 100mL, clear-capped, bottle containing a 10X concentrated phosphate-buffered-saline and Tween-20 solution (Blue solution). **Note: 1X solution will have a pH of 7.2 ± 0.2.**

Test System also contains:

1. Component Label containing lot specific information inside the Test System box.
2. Package Insert providing instructions for use.

Materials required but not provided

1. ELISA microwell reader capable of reading at a wavelength of 450nm.
   NOTE: Use of a single (450nm), or dual (450/620 - 650nm), wavelength reader is acceptable. Dual wavelength is preferred, as the additional reference filter has been determined to reduce potential interference from anomalies that may absorb light.
2. Pipettes capable of accurately delivering 10 - 200µL.
3. Multichannel pipette capable of accurately delivering 50 - 200µL.
4. Reagent reservoirs for multichannel pipettes.
5. Wash bottle or microwell washing system.
6. Distilled or deionized water.
7. One-liter graduated cylinder.
8. Serological pipettes.
9. Disposable pipette tips.
10. Paper towels.
11. Laboratory timer to monitor incubation steps.
12. Disposal basin and disinfectant (i.e.: 10% household bleach - 0.5% sodium hypochlorite.)

ASSAY PROCEDURE

1. Remove the individual component from storage and allow them to warm to room temperature (20-25°C.)
2. Determine the number of microwells needed. Allow six Control/Calibrator determinations (one Reagent Blank, one Negative Control, three Calibrators and one Positive Control) per run. Run a Reagent Blank on each assay. Check software and reader requirements for the correct Controls/Calibrator configurations. Return unused strips to the resealable pouch with desiccant, seal, and return to storage between 2° and 8°C.

EXAMPLE PLATE SET-UP

	1	2
A	Blank	Patient 3
B	Neg. Control	Patient 4
C	Calibrator	Etc.
D	Calibrator	
E	Calibrator	
F	Pos. Control	
G	Patient 1	
H	Patient 2	

3. Prepare a 1:21 dilution (e.g.: 10µL of serum + 200µL of Sample Diluent) of the Negative Control, Calibrator, Positive Control, and each patient serum. **NOTE: The sample diluent will undergo a color change confirming that the specimen has been combined with the diluent.**
4. To individual wells, add 100µL of each diluted control, calibrator and patient specimen. Ensure that the samples are properly mixed. Use a different pipette tip for each sample.
5. Add 100µL of Sample Diluent to well A1 as a reagent blank. Check software and reader requirements for the correct reagent blank well configuration.
6. Incubate the plate at room temperature (20-25°C) for 25 ± 5 minutes.
7. Wash the microwell strips 5 times.
   a. **Manual Wash Procedure:**
      1. Vigorously shake out the liquid from the wells.
      2. Fill each microwell with Wash Buffer. Make sure no air bubbles are trapped in the wells.
      3. Repeat steps a. and b. for a total of 5 washes.
      4. Shake out the wash solution from all the wells. Invert the plate over a paper towel and tap firmly to remove any residual wash solution from the wells. Visually inspect the plate to ensure that no residual wash solution remains. Collect wash solution in a disposable basin and treat with disinfectant at the end of the day's run.
   b. **Automated Wash Procedure**:
      If using an automated microwell wash system, set the dispensing volume to 300-350µL/well.
      Set the wash cycle for 5 washes with no delay between washes. If necessary, the microwell plate may be removed from the washer, inverted over a paper towel and tapped firmly to remove any residual wash solution from the microwells.
8. Add 100µL of the Conjugate to each well, including reagent blank well, at the same rate and in the same order as the specimens.
9. Incubate the plate at room temperature (20-25°C) for 25 ± 5 minutes
10. Wash the microwells by following the procedure as described in step 7.
11. Add 100µL of TMB to each well, including reagent blank well, at the same rate and in the same order as the specimens.
12. Incubate the plate at room temperature (20-25°C) for 10 to 15 minutes.
13. Stop the reaction by adding 50µL of Stop Solution to each well, including reagent blank well, at the same rate and in the same order as the TMB. Positive samples will turn from blue to yellow. After adding the Stop Solution, tap the plate several times to ensure that the samples are thoroughly mixed.
14. Set the microwell reader to read at a wavelength of 450nm and measure the optical density (OD) of each well against the reagent blank. The plate should be read within 30 minutes after the addition of the Stop Solution.

ABBREVIATED TEST PROCEDURE

1. Dilute Serum 1:21.
2. Add diluted sample to microwell – 100µL/well.
3. ⟶ *Incubate 25 ± 5 minutes.*
4. Wash.
5. Add Conjugate – 100µL/well.
6. ⟶ *Incubate 25 ± 5 minutes.*
7. Wash.
8. Add TMB – 100µL/well.
9. ⟶ *Incubate 10 - 15 minutes.*
10. Add Stop Solution – 50µl/well – Mix.
11. READ within 30 minutes.

Diagnostic Automation/Cortez Diagnostics, Inc.
21250 Califa St, Suite 102 and 116, Woodland Hills, CA 91367 USA Phone: 818-591-3030, Fax: 818-591-8383
Email: onestep@rapidtest.com Website: www.rapidtest.com

RESULTS

The Calibrator within this Test System has been assigned both a Correction Factor for the generation of Index Values and a Calibrator Value for the generation of Unit Values. Based upon testing of normal and disease-state specimens, a maximum normal Unit Value has been determined by the manufacturer and correlated to the Calibrator.

1. **Calculations:**
   a. *Correction Factor*: The manufacturer determined a Cutoff OD Value for positive samples and correlated it to the Calibrator. The Correction Factor (CF) allows for the determination of the Cutoff Value for positive samples. It will also correct for slight day-to-day variations in test results. The Correction Factor is determined for each lot of components and is printed on the Component Label located in the Test System box.
   b. *Cutoff OD Value*: To obtain the cutoff OD value, multiply the CF by the mean OD of the Calibrator determined above. *(CF x mean OD of Calibrator = cutoff OD value)*
   c. *Index Values or OD Ratios*: Calculate the Index Value or OD Ratio for each specimen by dividing its OD value by the cutoff OD from step 2.

Example:

Mean OD of Calibrator	=	0.793
Correction Factor (CF)	=	0.25
Cut off OD	=	0.793 x 0.25 = 0.198
Unknown Specimen OD	=	0.432
Specimen Index Value or OD Ratio	=	0.432 / 0.198 = 2.18

d. Conversion of Optical Density to AAU/mL: The conversion of OD to Unit Value (AAU/mL) can be represented by the following equation: Test Specimen AAU/mL = (A x B) / C Where: AAU/mL = Unknown Unit Value to be determined; A = OD of the test specimen in question; B = Unit Value of the Positive Calibrator (AAU/mL) & C = The mean OD of the Calibrator.

Example:

Test Specimen OD = 0.946	Test Specimen AAU/mL = (0.946 x 155)/0.435
Calibrator OD = 0.435 Calibrator Unit Value = 155 AAU/mL	Test Specimen= 337 AAU/mL

2. **Interpretations:** Index Values or OD ratios are interpreted as follows.

	Unit Values	Index Value or OD Ratio
Negative Specimens	<150 AAU/mL	≤ 0.90
Equivocal Specimens	150 to 180 AAU/mL	0.91 to 1.09
Positive Specimens	>180 AAU/mL	≥ 1.10

Retest specimens with OD Ratio Values in the equivocal range (0.91 – 1.09) in duplicate. Report any two of the three results which agree. Evaluate repeatedly equivocal specimens using an alternate serological method and/or re-evaluate by drawing another sample one to three weeks later.

QUALITY CONTROL

1. Each time the assay is performed, the Calibrator must be run in triplicate. A Reagent Blank, Negative Control, and Positive Control must also be included.
2. Calculate the mean of the three Calibrator wells. If any of the three values differ by more than 15% from the mean, discard that value and calculate the mean using the remaining two wells.
3. The mean OD value for the Calibrator and the OD values for the Positive and Negative Controls should fall within the following ranges:

	OD Range
Negative Control	≤0.250
Calibrator	≥0.300
Positive Calibrator	≥0.500

   a. The OD of the Negative Control divided by the mean OD of the Calibrator should be ≤ 0.9.
   b. The OD of the Positive Control divided by the mean OD of the Calibrator should be ≥ 1.25.
   c. If the above conditions are not met the test should be considered invalid and should be repeated.
4. The Positive Control and Negative Control are intended to monitor for substantial reagent failure and will not ensure precision at the assay cut-off.
5. Additional controls may be tested according to guidelines or requirements of local, state, and/or federal regulations or accrediting organizations.
6. Refer to CLSI document C24: Statistical Quality Control for Quantitative Measurements Procedures for guidance on appropriate QC practices.

PERFORMANCE CHARACTERISTICS

1. **Comparative Study**

Performance of an in-house comparative study demonstrated the equivalence of the DAI ELISA MPO Test System to another commercially available ELISA. Performance was evaluated using 316 samples; 196 disease-state samples, 113 samples which were sent to a reference laboratory in the Northeastern United States for routine ANCA serology, and 7 samples which were previously tested and found to be reactive for ANCA. A summary of the clinical samples appears in Table 1 below. Summarized results of the investigation appear in Table 2 below:

Table 1: Summary of Clinical Samples

			AGE			
n	Male	Female	High	Low	Mean	Comments
45	18	27	82	14	54.7	Disease Category: Wegener's Granulomatosis
41	21	20	100	22	63.2	Disease Category: Idiopathic Necrotizing and Crescentic Glomerulonephritis
41	16	25	87	20	63.1	Disease Category: Microscopic Polyarteritis
39	17	22	94	11	60.8	Disease Category: Pulmonary Renal Syndrome
30	15	15	78	3	43.4	Vasculitis/Glomerulonephritis Disease Controls, Non-ANCA related vasculitis.
7	Information Not Available					Previously tested ANCA positive, no diagnosis available
113	Information Not Available					Specimens sent to a reference laboratory for routine ANCA serology

Table 2: Calculation of Relative Sensitivity, Specificity, and Agreement

		DAI ELISA MPO Test System			
		Positive	Negative	Equivocal*	Totals
Commercial ELISA Test System	+	93	2	1	96
	-	2	195	4	201
	Equivocal*	6	12	1	19
	Totals	101	209	6	316

Relative Sensitivity = 93/95 = 97.9% - 95% Confidence Interval** = 95.0 to 100%
Relative Specificity = 195/197 = 98.9% - 95% Confidence Interval** = 97.6 to 100%
Relative Agreement = 288/292 – 98.6% - 95% Confidence Interval** = 97.3 to 99.9%
*Equivocal samples were excluded from all calculations.
**95% confidence intervals calculated using the exact method.

Diagnostic Automation/Cortez Diagnostics, Inc.

IMMUNO DIAGNOSTICS

2. **Reproducibility**

Six samples were tested to assess reproducibility; three positives, one near the cut off zone, and two negatives. Each sample was tested once a day, in replicates of eight for three days resulting in 24 data points. The intra-assay and inter-assay precision was calculated from the resulting data. The results of the tests are presented in Table 3 below.

Table 3: DAI ELISA MPO Test System:

Intra-assay Reproducibility												
	Day 1			Day 2			Day 3			Inter-Assay Reproducibility; All Days Combined		
Specimen	Mean (AAU/mL)	StD	% CV	Mean (AAU/mL)	StD	% CV	Mean (AAU/mL)	StD	% CV	Mean (AAU/mL)	StD	% CV
1	2269	89	3.9	2037	97	4.8	2160	76	3.5	2155	128	5.9
2	300	19	6.3	320	17	5.3	324	12	3.7	314	19	6.0
3	49	7	14.8	63	7	10.7	57	4	6.6	56	8	14.4
4	144	13	9.3	159	11	7.0	155	7	414	153	12	8.1
5	6	2	30.5	11	3	27.3	13	2	13.4	10	4	38.4
6	3749	116	3.1	3249	114	3.5	3057	67	1.9	3501	230	6.6

3. **Cross Reactivity**

A study was performed to evaluate the assay for potential cross reactivity to other autoantibodies. Eight specimens, which were positive for antibodies to nuclear antigens (ANA) on HEp-2 cells were tested. The results showed that two of the specimens demonstrated a homogeneous pattern, two demonstrated a nucleolar pattern, two demonstrated a centromere pattern, and two demonstrated a speckled pattern. For the summary of the results of this study, see Table below. The results of this investigation indicate that cross reactivity with other antinuclear antibodies is unlikely.

Table 4: Results of the Cross Reactivity Investigation

IFA ANA HEp-2 Results:			DAI ELISA MPO Results:	
Sample No.	Pattern	Endpoint Titer	Optical Density	AAU/mL
1	Homogeneous	1:1280	0.02	36
2	Homogeneous	1:640	0.01	15
3	Speckled	1:2560	0.02	30
4	Nucleolar	1:1280	0.01	25
5	Centromere	1:1280	0.02	28
6	Centromere	1:1280	0.01	10
7	Speckled	1:5120	0.02	30
8	Nucleolar	1:10240	0.00	5

LIMITATIONS OF THE ASSAY

1. Do not make a diagnosis based on the DAI ELISA MPO Test system results alone. Interpret test results in conjunction with the clinical evaluation and results of other diagnostic procedures.
2. Diagnostic Automation, Inc conducted no evaluation of the performance of this assay with lipemic, hemolyzed and icteric specimens; do not test these specimens with this assay.
3. The results of this assay are not diagnostic proof of the presence or absence of disease. Do not start immunosuppressive therapy based solely on a positive result.

EXPECTED RANGES OF VALUES

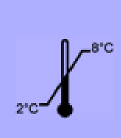
A study conducted evaluated 90 normal donor sera from Southwestern United States for Myeloperoxidase autoantibodies. Of the 90 tested, no samples were positive. In another study using 113 specimens, which were sent to a reference laboratory in Northeastern United States, eight (8/113 = 7.1%) were positive for anti-Myeloperoxidase IgG. Taken together, these studies demonstrate that the incidence of IgG antibody to Myeloperoxidase is relatively rare.

PRECAUTIONS

1. For *In Vitro* Diagnostic Use
2. Follow normal precautions exercised in handling laboratory reagents. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. Wear suitable protective clothing, gloves, and eye/face protection. Do not breathe vapor. Dispose of waste observing all local, state, and federal laws.
3. The wells of the ELISA plate do not contain viable organisms. However, consider the strips **potentially biohazardous materials** and handle accordingly.
4. The Controls are **potentially biohazardous materials.** Source materials from which these products were derived were found negative for HIV-1 antigen, HBsAg and for antibodies against HCV and HIV by approved test methods. However, since no test method can offer complete assurance that infectious agents are absent, these products should be handled at the Bio-safety Level 2 as recommended for any potentially infectious human serum or blood specimen in the Centers for Disease Control/National Institutes of Health manual "Biosafety in Microbiological and Biomedical Laboratories": current edition; and OSHA's Standard for Bloodborne Pathogens.
5. Adherence to the specified time and temperature of incubations is essential for accurate results. **All reagents must be allowed to reach room temperature (20 - 25°C) before starting the assay.** Return unused reagents to refrigerated temperature immediately after use.
6. Improper washing could cause false positive or false negative results. Be sure to minimize the amount of any residual wash solution; (e.g., by blotting or aspiration) before adding Conjugate or Substrate. Do not allow the wells to dry out between incubations.
7. The Sample Diluent, Controls, Conjugate and Wash Buffer contain Sodium Azide at a concentration of < 0.1% (w/v). Sodium Azide has been reported to form lead or copper azides in laboratory plumbing which may cause explosions on hammering. To prevent, rinse sink thoroughly with water after disposing of solution containing Sodium Azide.
8. The Stop Solution is TOXIC if inhaled, has contact with skin or if swallowed. It can cause burns. In case of accident or ill feelings, seek medical advice immediately.
9. The TMB Solution is HARMFUL. It is irritating to eyes, respiratory system and skin.
10. The Wash Buffer concentrate is an IRRITANT. It is irritating to eyes, respiratory system and skin.
11. Wipe the bottom of the plate free of residual liquid and/or fingerprints that can alter optical density (OD) readings.
12. Dilution or adulteration of these reagents may generate erroneous results.
13. Do not use reagents from other sources or manufacturers.
14. TMB Solution should be colorless, very pale yellow, very pale green, or very pale blue when used. Contamination of the TMB with conjugate or other oxidants will cause the solution to change color prematurely. Do not use the TMB if it is noticeably blue in color.
15. Never pipette by mouth. Avoid contact of reagents and patient specimens with skin and mucous membranes.
16. Avoid microbial contamination of reagents. Incorrect results may occur.
17. Cross contamination of reagents and/or samples could cause erroneous results
18. Reusable glassware must be washed and thoroughly rinsed free of all detergents.
19. Avoid splashing or generation of aerosols.
20. Do not expose reagents to strong light during storage or incubation.

21. Allowing the microwell strips and holder to equilibrate to room temperature prior to opening the protective envelope will protect the wells from condensation.
22. Collect the wash solution in a disposal basin. Treat the waste solution with disinfectant (i.e.: 10% household bleach - 0.5% Sodium Hypochlorite). Avoid exposure of reagents to bleach fumes.
23. Caution: Liquid waste at acid pH should be neutralized before adding to bleach solution.
24. Do not use ELISA plate if the indicator strip on the desiccant pouch has turned from blue to pink.
25. Do not allow the conjugate to come in contact with containers or instruments that may have previously contained a solution utilizing sodium azide as a preservative. Residual amounts of sodium azide may destroy the conjugate's enzymatic activity.
26. Do not expose any of the reactive reagents to bleach-containing solutions or to any strong odors from bleach-containing solutions. Trace amounts of bleach (sodium hypochlorite) may destroy the biological activity of many of the reactive reagents within this Test System.

STORAGE CONDITIONS

	Coated Microwell Strips: Immediately reseal extra strips with desiccant and return to proper storage. After opening – strips are stable for 60 days, as long as the indicator strips on the desiccant pouch remains blue.
	Conjugate – DO NOT FREEZE
	Unopened Test System, Calibrator, Positive Control, Negative Control, TMB,Sample Diluent
2°C – 25°C	Stop Solution: 2 - 25°C Wash Buffer (1X): 20-25°C for up to 7 days, 2-8°C for 30 days. Wash Buffer (10X): 2-25°C

REFERENCES

1. Davies D, Moran ME, Niall JF, Ryan GB: Segmental glomerulonephritis with antineutrophil antibody: Possible arbovirus aetiology. Br. J. Med. 285:606, 1982
2. van der Woude FJ, Rasmussen N, Lobatto S, Wiik A, Permin H, van Es LA: Autoantibodies against neutrophils and monocytes: Tools for diagnosis and marker of disease activity in Wegener's granulomatosis. Lancet 1:425-429, 1985.
3. Feehally J, Wheeler DC, Walls J, et al: A case of microscopic polyarteritis associated with antineutrophilia cytoplasmic antibodies. Clin. Nephrol. 27: 214-215, 1987
4. Falk RJ, Becker M, Terrell R, Jennette JC: Antigen specificity of P-ANCA and C-ANCA (Abstract). The 3rd International Workshop on ANCA, Washington, DC 1990: 2-3.
5. Jennette JC, Falk RJ: Anti-neutrophil cytoplasmic autoantibodies with specificity for myeloperoxidase in patients with systemic vasculitis and idiopathic necrotizing and crescentic glomerulonephritis. N.Engl.J. Med. 318: 1651-1657, 1988.
6. Savage COS, Tizard J, Jayne D, et al: Anti-neutrophil cytoplasmic antibodies in Kawasaki disease. Arch. Dis. Child. 64: 360-363, 1989.
7. Procedures for the collection of diagnostic blood specimens by venipuncture. Second Edition: Approved Standard (1984). Published by National Committee for Clinical Laboratory Standards.
8. Procedures for the Handling and Processing of Blood Specimens. NCCLS Document H18-A, Vol. 10, No. 12, Approved Guideline, 1990.
9. U.S. Department of Labor, Occupational Safety and Health Administration: Occupational Exposure to Bloodborne Pathogens, Final Rule. Fed. Register 56:64175- 64182, 1991.
10. Procedures for the Handling and Processing of Blood Specimens for Common Laboratory Tests; Approved Guidelines – 4th Edition (2010). CLSI Document GP44- A4 (ISBN 1-56238-724-3). Clinical and Laboratory Standards Institute, 950 West Valley Road, Suite 2500, Wayne, PA 19087.

MANUFACTURER AND BRAND DETAILS

ISO 13485:2016

Diagnostic Automation/Cortez Diagnostics, Inc.
21250 Califa Street, Suite 102 and 116,
Woodland Hills, California 91367 USA

Date Adopted	2023-09
Brand Name	AccuDiag™
REF 1441-2	AccuDiag™ - MPO (p-ANCA) IgG ELISA
EC REP	CEpartner4U, Esdoornlaan 13, 3951 DB Maarn, The Netherlands. www.cepartner4u.eu

Revision Date: 12-20-2017