AccuDiag™ ANCA Screen IgG ELISA Kit

REF 1681-P1

IVD See External Label 2°C-8°C Σ 96 Tests

ANCA Screen ELISA	
Principle	Indirect ELISA
Detection	Qualitative
Sample	10 µL serum/plasma
Incubation Time	90 minutes
Sensitivity	94.9%
Specificity	97.4%
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. ANCA Screen ELISA test system is intended for the qualitative detection of anti-Myeloperoxidase and/or anti-Proteinase-3 IgG antibody in human serum. It is intended to be used as an aid in the diagnosis of various autoimmune vasculitic disorders characterized by elevated levels of anti-neutrophil cytoplasmic antibodies (ANCA). MPO and/or PR-3 may be associated with autoimmune disorders such as Wegener's Granulomatosis, ICGN, MPA and PRS. The DAI ANCA Screen ELISA test is for *In Vitro* diagnostic use.

SIGNIFICANCE AND SUMMARY

Anti-neutrophil cytoplasmic antibody (ANCA) was initially described by Davies, *et al* in 1982. Since this initial discovery, ANCA has been found to be associated with a number of Systemic Vasculitides (SV). ANCA is now recognized 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 highlrecommended 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, Inc. ANCA Screen ELISA test system is designed to detect IgG class antibodies to MPO and/or PR3 in human sera. Creation of the sensitized wells of plastic microwell strips occurred using passive adsorption with a mixture of MPO and PR3 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 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. Only freshly drawn and properly refrigerated sera obtained by approved aseptic venipuncture procedures should be used in this assay. 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° and 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 kit contains the following components in sufficient quantities to perform the number of tests indicated on packaging label. **Note: The following reactive**

reagents contain sodium azide as a preservative at a concentration of <0.1% (w/v): Controls, Calibrators and Sample Diluent.

1. **Plate:** 96 wells configured in twelve, 1x 8-well, strips coated with a mixture of Myeloperoxidase (MPO) and Proteinase-3 (PR3) enzymes (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).Ready to use. One, 15 mL, white- capped bottle. Ready to use.
3. **Positive Control (Human Serum):** One, 0.35ml, 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-cap, bottle containing Tween-20, bovine serum albumin and phosphate-buffered-saline. Ready to use. NOTE: **The Sample 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**

The following components are not kit lot number dependent and may be used interchangeably with the ELISA assays: TMB, Stop Solution, and Wash Buffer.

Note: Kit also contains:

1. Component list containing lot specific information is inside the kit 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 to 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. (example: 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 Blank, one Negative Control, three Calibrators and one Positive Control) per run. A Reagent Blank should be run 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 5X**.**

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 were added.
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 were added.
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 was added. 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 ASSAY 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.

RESULTS

1. Calculations:

a. *Correction Factor*: A cutoff OD value for positive samples has been determined by the manufacturer and correlated to the Calibrator. The correction factor (CF) will allow you to determine the cutoff value for positive samples and to correct for slight day-to-day variations in test results. The correction factor is determined for each lot of kit components and is printed on the Component List located in the kit 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 b.

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

B. Interpretations:

Index Values or OD ratios are interpreted as follows:

	Index Value or OD Ratio
Negative Specimens	≤ 0.90
Equivocal Specimens	0.91 to 1.09
Positive Specimens	≥ 1.10

1. An OD ratio ≤0.90 indicates no significant amount of antibodies to MPO or PR-3 were detected.
2. An OD ratio ≥1.10 indicates that antibodies specific to MPO and/or PR-3 were detected. The results of this test system are qualitative; ratio values in the reactive range are not indicative of the amount of antibody present.
3. Specimens with OD ratio values in the equivocal range (0.91 - 1.09) should be retested in duplicate. Report any two of the three results which agree. Test repeatedly equivocal specimens by an alternate serologic procedure and/or re-evaluated by drawing another sample one to three weeks later.

QUALITY CONTROL

1. Each time the assay is run, the calibrator must be run in triplicate. A reagent blank, negative control, and positive control must also be included in each assay.
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 of the remaining two values.
3. The mean OD value for the calibrator, positive control, and negative control 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 is 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

Comparative Study:

An in-house comparative study was conducted to demonstrate the equivalence of the DAI ANCA Screen ELISA Test System to another commercially available ANCA IgG ELISA Test System using 316 specimens; 196 disease-state specimens, 113 specimens sent to a reference laboratory in the Northeastern United States for routine ANCA serology, and 7 specimens previously tested and found to be reactive for ANCA. Tables 1 and 2 summarize the results of the investigation.

Table 1: Clinical Specimens Summary

	Age					
n	Male	Female	High	Low	Mean	**Comments**
45	18	27	82	14	54.7	Wegener's Granulomatosis
41	21	20	100	22	63.2	Idiopathic Necrotizing and Crescentic Glomerulonephritis
41	16	25	87	20	63.1	Microscopic Polyarteritis
39	17	22	94	11	60.8	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 reference laboratory for routine ANCA serology

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

		DAI ANCA Screen IgG ELISA			
		Positive	**Negative**	**Equivocal***	**Total**
Commercial ANCA ELISA Test	**Positive**	148	8	0	156
	Negative	3	113	4	120
	Equivocal*	15	22	3	40
	Total	166	143	7	316

***Equivocal specimens were excluded from all calculations.**

Relative Sensitivity = 148/156 = 94.9% **95% Confidence Interval**= 91.4 to 98.3%**
Relative Specificity = 113/116 = 97.4% **95% Confidence Interval**= 94.5 to 100%**
Relative Agreement = 261/272 = 96.0% **95% Confidence Interval**= 93.6 to 98.3%**

**95% confidence intervals calculated using the exact method.

Precision and Reproducibility:

To evaluate both intra-assay and inter-assay reproducibility, six samples were tested, eight replicates each, on each of three days. These results were then used to calculate mean unit values, standard deviations, and percent CV. Two of the specimens were strong positives, two were clearly negative, and two were near the assay cutoff. The results of the study have been summarized below.

Tables 3: DAI ANCA Screen IgG ELISA Precision Testing Results

	Intra-Assay Reproducibility								
	Day 1			Day 2			Day 3		
Sam-ple	Mean Ratio	StD	% CV	Mean Ratio	StD	% CV	Mean Ratio	StD	%CV
1	7.40	0.25	3.4	7.10	0.21	3.0	7.60	0.30	3.9
2	5.89	0.20	3.4	5.59	0.30	5.4	5.90	0.32	5.4
3	1.00	0.07	6.7	0.90	0.05	5.6	1.14	0.07	6.1
4	0.97	0.07	7.6	0.78	0.06	7.7	0.96	0.07	7.3
5	0.17	0.01	5.3	0.18	0.02	8.3	0.21	0.03	11.9
6	0.08	0.01	6.0	0.06	0.01	20.7	0.08	0.01	12.5

	Inter-Assay Reproducibility, All Days Combined		
Sample #	Mean Ratio	StD	% CV
1	7.40	0.34	4.6
2	5.80	0.30	5.2
3	1.00	0.11	11.0
4	0.90	0.11	12.2
5	0.18	0.02	11.1
6	0.07	0.02	21.4

Cross Reactivity:

To evaluate the potential cross-reactivity to other autoantibodies, eight specimens which were positive for antibodies to nuclear antigens (ANA) on HEp-2 cells were tested. Two of the specimens demonstrated a homogenous pattern, two demonstrated a nucleolar pattern, two demonstrated the centromere pattern, and two demonstrated a speckled pattern. The results of this study have been summarized in Table 5 below. The results of this investigation indicate that cross reactivity with other antinuclear antibodies is not likely.

Table 4: Results of the Cross Reactivity Investigation

	ANA Hep-2 IFA Results		DAI ANCA Screen ELISA Results	
Sample #	Pattern	Endpoint Titer	O.D. values	Ratio
1	Homogenous	1:1280	0.066	0.36
2	Homogenous	1:640	0.019	0.10
3	Speckled	1:2560	0.044	0.24
4	Nucleolar	1:1280	0.101	0.56
5	Centromere	1:1280	0.050	0.28
6	Centromere	1:1280	0.035	0.19
7	Speckled	1:5120	0.051	0.28
8	Nucleolar	1:10240	0.028	0.15

LIMITATIONS OF THE ASSAY

1. Do not make a diagnosis on the basis of the DAI ANCA Screen ELISA results alone. Interpret test results in conjunction with clinical evaluation and results of other diagnostic procedures.
2. The performance characteristics of this device have not been established for lipemic, hemolyzed and icteric specimens; therefore, do not use these specimen types with this assay.
3. Although the DAI ANCA Screen will detect antibodies to both MPO and PR-3, the assay will not differentiate between the two. Positive ANCA Screen specimens should be tested on the Diagnostic Automation, Inc. individual MPO and PR-3 ELISAs to determine which antibody is present.
4. The results of this assay are not diagnostic proof of the presence or absence of disease. Do not start immunosuppressive therapy based only on a positive result.

EXPECTED RANGES OF VALUES

A study was conducted that evaluated 90 normal donor sera from Northeastern United States for ANCA autoantibodies. Of the 90 tested, one (1.1%) was positive and one (1.1%) was equivocal. In another study using 105 specimens sent to a reference laboratory in Northeastern United States, fourteen (14/105 = 13.3%) were positive for ANCA antibodies. Taken together, these studies demonstrate that the incidence of ANCA is relatively rare.

PRECAUTIONS

1. For *In Vitro* Diagnostic Use.
2. Follow normal precautions exercised in handling laboratory reagents should be followed. 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, the strips should be considered **potentially biohazardous materials** and handled 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 Biosafety 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 Blood borne Pathogens (9).
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, and calibrator 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 upon 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: Neutralize any liquid waste at an acidic pH before adding to a 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 kit.

STORAGE CONDITIONS

1. Store the unopened kit between 2° and 8°C.
2. Coated microwell strips: Store between 2° and 8°C. Extra strips should be immediately resealed with desiccant and returned to proper storage. Strips are stable for 60 days after the envelope has been opened and properly resealed and the indicator strip on the desiccant pouch remains blue.
3. Conjugate: Store between 2° and 8°C. DO NOT FREEZE.
4. Calibrator, Positive Control and Negative Control: Store between 2° and 8°C.
5. TMB: Store between 2° and 8°C.
6. Wash Buffer concentrate (10X): Store between 2° and 25°C. Diluted wash buffer (1X) is stable at room temperature (20° to 25°C) for up to 7 days or for 30 days between 2° and 8°C.
7. Sample Diluent: Store between 2° and 8°C.
8. Stop Solution: Store between 2° and 25°C.

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MANUFACTURER AND BRAND DETAILS

ISO 13485:2016

bsi ISO 13485 Quality Management for Medical Devices CERTIFIED

Diagnostic Automation/Cortez Diagnostics, Inc.
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Date Adopted	**2023-09-07**
Brand Name	**AccuDiag™**
REF 1681-P1	**AccuDiag™- ANCA Screen IgG ELISA**
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