AccuDiag™ nDNA IFA Kit

REF 320608D

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

nDNA IFA	
Principle	Indirect Fluorescent Antibody Method
Detection	Qualitative & Semi-Quantitative
Sample	10 µL serum/plasma
Incubation Time	80 minutes
Shelf Life	12 Months from the manufacturing date

PRODUCT FEATURES

- Easy to use with minimal equipment and expertise
- High sensitivity and specificity
- Versatile tool to detect wide range of antigens and antibodies
- Visual Intrepretation of results using Fluorescence microscope

INTENDED USE

Diagnostic Automation, Inc. nDNA IFA Kit is pre-standardized assay for the qualitative and semi-quantitative determination of antibodies to native DNA by the Indirect Fluorescent Antibody (IFA) technique and is for *In Vitro* diagnostic use.

SIGNIFICANCE AND SUMMARY

Anti-Native Deoxyribonucleic Acid (nDNA) antibodies are frequently found in sera from patients with active spontaneous systemic lupus erythematosus (SLE) and some drug-induced lupus syndromes (1-9). The presence of nDNA antibodies is indicative of active SLE and correlates closely with the onset of lupus nephritis (5, 10-13). The specificity of nDNA antibodies for SLE is much greater than antinuclear antibodies (5, 12). Therefore, detection of nDNA antibodies provides valuable diagnostic, as well as prognostic information for the differential diagnosis of SLE (5, 10-13). The presence of nDNA antibodies in known SLE sera is considered an indication of recurrent active disease or poor response to therapy (5, 13). Consequently, periodic monitoring of nDNA antibodies in SLE patients aids in evaluating the clinical course of the disease and its response to therapy (5, 10-13). DNA antibodies were discovered in sera of patients with SLE more than 15 years ago (1-4). Since then, DNA antibodies have been studied by a number of techniques, including gel diffusion (1, 14-15), complement fixation (2, 14 and 16), agglutination (17, 18), DNA spot tests (13, 19), radioimmuno-electrophoresis (20), counter-immunoelectrophoresis (20, 21) and ammonium sulfate precipitation (10, 23, and 24). Considerable effort has been made to determine the specificity of nDNA antibodies. It is now apparent that antibodies have been found which react with either nDNA or denatured single stranded (sDNA) or both (8, 12, 14, and 20). nDNA antibodies are thought to correlate with the clinical activity of the disease (2, 5, 10, and 25). In addition, antibodies to DNA have been eluted from the kidneys of patients with SLE and one report demonstrated the presence of DNA-Anti-DNA complexes in sera from patients with active SLE (26). However, these antibodies have been found in patients with and without active lupus nepharitis (27, 28).

The Diagnostic Automation Inc. nDNA IFA is based on the use of the *Crithidia luciliae* kinetoplast substrate first described by Aarden, *et al* (29). Recent reports from a number of investigators have shown this method to be a useful laboratory test to detect nDNA antibodies in patients with systemic lupus erythematosus (30-33). These studies also indicate that the IFA nDNA Test System is comparable to the radioimmunoassay method for detecting nDNA antibodies.

ASSAY PRINCIPLE

Diagnostic Automation, Inc. nDNA IFA Test System is a pre-standardized indirect fluorescent antibody assay for the qualitative and semi-quantitative determination of nDNA antibodies in patient and control sera. The reaction occurs in two steps:

1. Step one; If nDNA antibodies are present, a reaction between nDNA antibodies and the kinetoplast of the *C. luciliae* substrate takes place in the first step.
2. Step two; goat anti-human immunoglobulin labeled with fluorescein isothiocyanate (FITC) is added to the substrate. If the patient's sera contain nDNA antibody, a positive apple-green fluorescent antigen-antibody reaction will be observed when the Slides are examined with the fluorescence microscope. A positive reaction is recognized as an intense staining reaction in the small kinetoplasts of the *C. luciliae*.

SPECIMEN COLLECTION & PREPARATION

1. Diagnostic Automation, Inc. recommends that the user carry out specimen collection in accordance with CLSI document M29: Protection of Laboratory Workers from Occupationally Acquired Infectious Diseases. 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.
2. Only freshly drawn and properly refrigerated sera obtained by approved aseptic venipuncture procedures with this assay (34, 35). No anticoagulants or preservatives should be added. Avoid using hemolyzed, lipemic, or bacterially contaminated sera.
3. 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 which 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 (37).

REAGENTS

Materials provided with the kit

Each Test System contains the following components in sufficient quantities to perform the number of tests indicated on packaging label. **NOTE: Conjugate and Controls contain a combination of Proclin (0.05% v/v) and Sodium Azide (<0.1% w/v) as preservatives. Sample Diluent contains Sodium Azide (<0.01% w/v) as a preservative.**

1. ***C. luciliae* Substrate Slides:** Ten,10-well Slides with blotter.
2. **Conjugate:** Goat anti-human immunoglobulin labelled with fluorescein isothiocyanate (FITC). Contains phosphate buffer with BSA and counterstain. One, 3.5mL, amber-capped, bottle. Ready to use.
3. **Positive Control (Human Serum):** Will produce positive apple-green staining of the kinetoplast in the *C. luciliae* organisms. One, 0.5mL, red-capped, vial. Ready to use.
4. **Negative Control (Human Serum):** Will produce no detectable nDNA staining. One 0.5mL, green-capped, vial Ready to use.
5. **Sample Diluent:** One, 30mL, green-capped, bottle containing phosphate-buffered-saline. Ready to use. **NOTE: The Sample Diluent will change color when combined with serum.**
6. **Phosphate-buffered-saline (PBS):** pH 7.2 ± 0.2. Empty contents of each buffer packet into one liter of distilled or deionized water. Mix until all salts are thoroughly dissolved. Four packets, sufficient to prepare 4 liters.
7. **Mounting Media (Buffered Glycerol):** Two, 3.0 mL, white-capped, dripper tipped vials.

Notes:

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. Small serological, Pasteur, capillary, or automatic pipettes.
2. Disposable pipette tips.
3. Small test tubes, 13 x 100mm or comparable.
4. Test tube racks.
5. Staining dish: A large staining dish with a small magnetic mixing set-up provides an ideal mechanism for washing Slides between incubation steps.
6. Cover slips, 24 x 60mm, thickness No. 1.
7. Distilled or deionized water.
8. Properly equipped fluorescence microscope.
9. 1 Liter Graduated Cylinder.
10. Laboratory timer to monitor incubation steps.
11. Disposal basin and disinfectant (i.e.: 10 % household bleach – 0.5% Sodium Hypochlorite).

The following filter systems, or their equivalent, have been found to be satisfactory for routine use with transmitted or incident light darkfield assemblies:

TRANSMITTED LIGHT Light Source: Mercury vapor 200W or 50W		
Excitation Filter	**Barrier Filter**	**Red Suppression Filter**
KP490	K510 or K530	BG38
BG12	K510 or K530	BG38
FITC	K520	BG38
Light Source: Tungsten – Halogen 100W		
KP490	K510 or K530	BG38

INCIDENT LIGHT Light Source: Mercury vapor 200, 100, 50W			
Excitation Filter	**Dichroic Mirror**	**Barrier Filter**	**Red Suppression Filter**
KP500	TK510	K510 or K530	BG38
FITC	TK510	K530	BG38
Light Source: Tungsten – Halogen 50 and 100W			
KP500	TK510	K510 or K530	BG38
FITC	TK510	K530	BG38

ASSAY PROCEDURE

1. Remove Slides from refrigerated storage and allow them to warm to room temperature (20 – 25°C). Tear open the protective envelope and remove slides. **Do not apply pressure to flat sides of protective envelope.**
2. Identify each well with the appropriate patient sera and Controls. **NOTE: The Controls are intended to be used undiluted**. Prepare a 1:10 dilution (e.g.: 10µL of serum + 90µL of Sample Diluent or PBS) of each patient serum. **The Sample Diluent will undergo a color change confirming that the specimen has been combined with the Diluent**.
   Dilution Options:
   a. Users may titrate the Positive Control to endpoint to serve as a semi-quantitative (1 + Minimally Reactive) Control. In such cases, the Control should be diluted two-fold in Sample Diluent or PBS. When evaluated by DAI, an endpoint dilution is established and printed on the Positive Control vial (± one dilution). It should be noted that due to variations within the laboratory (equipment, etc), each laboratory should establish its own expected end-point titer for each lot of Positive Control.
   b. When titrating patient specimens, initial, and all subsequent dilutions should be prepared in Sample Diluent or PBS only.
3. With suitable dispenser (listed above), dispense 20µL of each Control and each diluted patient sera in the appropriate wells.
4. Incubate Slides at room temperature (20-25°C) for 30 minutes.
5. Gently rinse Slides with PBS. **Do not direct a stream of PBS into the test wells.**
6. Wash Slides for two, 5 minute intervals, changing PBS between washes.
7. Remove Slides from PBS one at a time. Invert Slide and key wells to holes in blotters provided. Blot Slide by wiping the reverse side with an absorbent wipe. CAUTION: Position the blotter and Slide on a hard, flat surface. Blotting on paper towels may destroy the Slide matrix. **Do not allow the Slides to dry during the test procedure.**
8. Add 20µL of Conjugate to each well.
9. Repeat steps 4 through 7.
10. Apply 3-5 drops of Mounting Media to each Slide (between the wells) and coverslip. Examine Slides immediately with an appropriate fluorescence microscope.

Note: If delay in examining Slides is anticipated, seal coverslip with clear nail polish and store in refrigerator. It is recommended that Slides be examined on the same day as testing.

RESULTS

1. Titers less than 1:10 are considered negative.
2. Positive Test: Any observed apple-green staining of the small kinetoplast of the *C. luciliae* substrate organism, at a 1:10 dilution based on a 1+ to 4+ scale. 1+ is considered a weak reaction, and 4+ a strong reaction. All sera positive at 1:10 should be titered to endpoint dilution. This is accomplished by making a 1:10, 1:20, 1:40, etc. serial dilution of all positives. The endpoint is the highest dilution that produces a positive reaction.
3. Staining of both the small kinetoplast and the adjacent larger *C. luciliae* nucleus simultaneously should be interpreted as a positive test.
4. Polar staining at the base of the flagella is not significant.
5. Staining of the nucleus only should not be interpreted as a positive test.

Note: A prozone phenomenon may occur at low patient sera dilutions. It is suggested that retesting of the patient specimen be performed at a higher dilution (i.e., 1:40 or 1:80) when this phenomenon is suspected.

QUALITY CONTROL

1. Every time the assay is run, a Positive Control, a Negative Control and a Buffer Control must be included.
2. It is recommended that one read the Positive and Negative Controls before evaluating test results. This will assist in establishing the references required to interpret the test sample. If Controls do not appear as described, results are invalid.
   a. Negative Control - characterized by the absence of fluorescent staining of the kinetoplast. Staining of the nucleus only and/or staining of the basal body should be interpreted as a negative test.
   b. Positive Control - characterized by any apple-green fluorescent staining of the kinetoplast. Staining of the basal body **in conjunction with** the kinetoplast should be considered a positive result.
3. Additional Controls may be tested according to guidelines or requirements of local, state, and/or federal regulations or accrediting organizations.

NOTES:

a. The intensity of the observed fluorescence may vary with the microscope and filter system used.

b. The kinetoplast is generally located closer to the basal body than the nucleus; however, because of the fluid nature of the endoplasm, the location of the kinetoplast may vary from cell to cell (36).

c. Read only single, well-defined organisms in each field. Not all organisms will appear optimal; morphology may vary between organisms because of fixation, their stages of growth, and/or their orientation on the Slide as they dried (36).

EXPECTED RANGES OF VALUES

The expected value in normal population are negative at a 1;10 starting dilution. However, certain drugs may induce a positive nDNA antibody test (5, 6).

PERFORMANCE CHARACTERISTICS

The DAI nDNA IFA Test System was evaluated in parallel with a reference ANA test procedure employing rat liver as the substrate. Fifty-two ANA positive sera obtained from patients with various diagnoses, including SLE, were retested with the IFA nDNA Test System. The following table summarizes the comparative ANA and nDNA results.

Summary of DAI IFA nDNA Test System Comparative Study: ANA vs nDNA in Various Diseases

Number of Patients	Diagnosis	Number of ANA Positives	Number of nDNA Positives
11	Systemic lupus	11	9
8	Hypertension or uremia	8	0
3	Scleroderma	3	0
4	Rheumatoid Arthritis	4	0
1	Sjögren's Syndrome	1	0
5	Open Heart Surgery	5	0
20	Other or No diagnosis	20	0
52*		*52	9*

*The data shown in the above table reveals the relative specificity of the nDNA test for systemic lupus erythematosus. Of the 11 patients with a diagnosis of SLE, 9 were proven to be in acute stage lupus nephritis as determined by renal biopsy evaluation. The two SLE patients with negative nDNA antibody tests were absent of active kidney disease. None of the remaining patients with other diseases contained nDNA antibodies in their sera although all 41 had positive ANA titers ranging from 1:40 to 1:40,000.

Specificity: The DAI IFA nDNA Test System is capable of detecting IgG, IgA, and IgM antibody classes based on gel diffusion and immuno-electrophoretic analysis of the FITC labeled anti-human immunoglobulin conjugate.

Interference Study: An investigation was performed to assess the potential impact of commonly encountered interfering substances on the DAI IFA nDNA Test System. This investigation was conducted using information from CLSI document EP7-A2 (*Interference Testing in Clinical Chemistry – Approved Guideline, Second Edition*) as a guideline. Briefly, three serum samples were obtained. The samples could be characterized as follows: negative for nDNA (~1 IU/mL), low positive for nDNA antibody (~200 IU/mL) and high positive for nDNA antibody (~1000 IU/mL). Interfering substances were spiked into each of the three serum samples at two (high and low) different concentrations. Matrix controls were prepared to account for the spiking process. The interferents used and the amount spiked is shown below:

Interferent	High	Low	Matrix
Albumin (Human)	50 mg/mL	35 mg/mL	Serum
Bilirubin	0.15 mg/mL	0.01 mg/mL	Serum-10% PBS
Cholesterol	2.5 mg/mL	1.5 mg/mL	Serum-10% Ethanol
Hemoglobin	200 mg/mL	100 mg/mL	Serum
Intralipids	7.5 mg/mL	3 mg/mL	Serum
Triglycerides	5 mg/mL	1.5 mg/mL	Serum-10% Ethanol

The results of the study showed that there was no affect on the interpretation of the specimens. Thus, the DAI IFA nDNA Test System is not at risk of yieldingerroneous results due to the presence of the interfering substances tested herein.

Cross Reactivity Study: An investigation was performed to evaluate other commonly found autoantibodies for their potential to cross react with the substrate in the DAI IFA nDNA Test System. Five positive specimens each were purchased that had significant levels of autoantibody IgG to the following autoantigens; centromere, SSA, SSB, Jo-1 and Scl-70. These 25 serum samples were tested on the DAI IFA nDNA Test System and all 25 specimens yielded negative results. This study indicates that the DAI IFA nDNA Test System is not susceptible to cross reactivity from other common autoantibodies.

Limits of Detection: At the time of this investigation, the World Health Organization (WHO) dsDNA standard (wo/80) was no longer available. In the absence of this standard, a well-characterized dsDNA positive serum specimen was utilized to establish the LOD. This specimen was thoroughly evaluated with an FDA-cleared dsDNA immunoassay that reported in IU/mL, and was found to contain ~3000 IU/mL of anti-dsDNA antibody. Using this specimen, it was determined that the LOD of the DAI IFA nDNA Test System was 8.33 IU/mL.

Intra-Lot Reproducibility: This study was conducted using one lot of DAI IFA nDNA Test System. Three specimens of varying levels of reactivity were acquired. They represented one negative sample (~1 IU/mL), one moderate positive sample (~200 IU/mL) and one strong positive sample (~1000 IU/mL). Each sample was tested in 10 replicate wells of the IFA slide. The results of this study appear in the table below:

The 10 replicates of the high positive serum (1000IU/ml) all yielded a 4+ result.
The 10 replicates of moderate positive serum (200IU/ml) all yielded a 2+ result.
The 10 replicates of negative serum (1IU/ml) all remained negative

Inter-Lot Reproducibility: This study was conducted using three different lots of the DAI IFA nDNA Test System. Three specimens of varying levels of reactivity were acquired. They represented one negative sample (~1 IU/mL), one moderate positive sample (~200 IU/mL) and one strong positive sample (~1000 IU/mL). Each sample was tested in duplicate wells of the IFA slide, once per day for five days.

		High Positive Serum					Medium Positive Serum					Negative Serum				
		Day 1	Day 2	Day 3	Day 4	Day 5	Day 1	Day 2	Day 3	Day 4	Day 5	Day 1	Day 2	Day 3	Day 4	Day 5
Lot # 1-DA16050011	Dup (1)	4+	4+	4+	4+	4+	2+	2+	2+	2+	2+	0	0	0	0	0
	Dup (2)	4+	4+	4+	4+	4+	2+	2+	2+	2+	2+	0	0	0	0	0
Lot # 2-DA16050012	Dup (1)	4+	4+	4+	4+	4+	2+	2+	2+	3+	3+	0	0	0	0	0
	Dup (2)	4+	4+	4+	4+	4+	2+	2+	2+	3+	3+	0	0	0	0	0
Lot # 3-DA16050058	Dup (1)	4+	4+	4+	4+	4+	2+	2+	2+	2+	2+	0	0	0	0	0
	Dup (2)	4+	4+	4+	4+	4+	2+	2+	2+	2+	2+	0	0	0	0	0

The nDNA results from the intra-lot and inter-lot/inter-day experiments met the respective acceptance criteria defined above. Thus, the nDNA IFA Test System has been demonstrated to yield highly reproducible results in an intra-lot and inter-lot fashion.

LIMITATIONS OF THE ASSAY

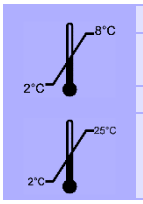
1. The DAI IFA nDNA Test System is a diagnostic aid. It is therefore imperative that the nDNA antibody results be interpreted in light of the patient's clinical condition by a medical authority.
2. SLE patients undergoing steroid therapy may have negative test results (5, 8, and 9).
3. Some drugs, particularly hydralazine, may induce nDNA antibody production (5, 6, and 8).

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 Slide do not contain viable organisms. However, consider the Slide **potentially bio-hazardous materials** and handle accordingly.
4. The Controls are **potentially bio-hazardous 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 Center 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 each room temperature (20-25°C) before starting the assay.** Return unused reagents to their original containers immediately and follow storage requirements.
6. Improper washing could cause false positive or false negative results. Be sure to minimize the amount of any residual PBS, by blotting, before adding Conjugate. Do not allow the wells to dry out between incubations.
7. The Sample Diluent, Conjugate, and Controls 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. This preservative may by toxic if ingested.
8. Dilution or adulteration of these reagents may generate erroneous results.
9. Never pipette by mouth. Avoid contact of reagents and patient specimens with skin and mucous membranes.
10. Avoid microbial contamination of reagent. Incorrect results may occur.
11. Cross contamination of reagents and/or samples could cause erroneous results.
12. Reusable glassware must be washed and thoroughly rinsed free of all detergents.
13. Avoid splashing or generation of aerosols.
14. Do not expose reagents to strong light during storage or incubation.
15. Allowing the slide packet to equilibrate to room temperature prior to opening the protective envelope will protect the wells and blotter from condensation.

16. 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.
17. 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.
18. Do not apply pressure to slide envelope. This may damage the substrate.
19. The components of this Test System are matched for optimum sensitivity and reproducibility. Reagents from other manufacturers should not be interchanged. Follow Package insert carefully.
20. Unopened/opened components are stable until the expiration date printed on the label, provided the recommended storage conditions are strictly followed. Do not use beyond the expiration date. Do not freeze.
21. Evans Blue Counterstain is a potential carcinogen. If skin contact occurs, flush with water. Dispose of according to local regulations.
22. Do not allow slides to dry during the procedure. Depending upon lab conditions, it may be necessary to place slides in a moist chamber during incubations.

STORAGE CONDITIONS



Unopened Test System
Mounting Media, Conjugate, Sample Diluent, Slides, Positive and Negative Controls
Rehydrated PBS (Stable for 30 days)
Phosphate-buffered-saline (PBS) Packets

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MANUFACTURER AND BRAND DETAILS

ISO 13485:2016

bsi ISO 13485 Quality Management for Medical Devices CERTIFIED

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Date Adopted	**2023-07**
Brand Name	**AccuDiag™**
REF 320608D	**AccuDiag™ - nDNA IFA**
EC REP	**CEpartner4U, Esdoornlaan 13, 3951 DB Maarn, The Netherlands** www.cepartner4u.eu
Revision Date: 2019-11-19	

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