Diagnostic Automation / Cortez Diagnostics, Inc.
IMMUNO DIAGNOSTICS

AccuDiag™
FTA-ABS Double Stain (Syphilis) IFA Kit

REF 351010-DS

Test	FTA-ABS Double Stain (Syphilis)IFA
Method	IFA Fluorescent Treponemal Antibody-Absorption Double Stain
Principle	Qualitative
Sample	50 µL serum
Total Time	~ 6 Hours
Shelf Life	12 Months from the manufacturing date
Sensitivity	N/A

INTENDED USE

Diagnostic Automation, Inc. Fluorescent Treponemal Antibody-Absorption Double Stain (FTA-ABS DS) Test System is designed to confirm positive non-treponemal reagin tests for syphilis and is for In Vitro diagnostic use. This product is not FDA cleared (approved) for use in testing (i.e., screening) blood or plasma donors.

SUMMARY AND EXPLANATION

Serological procedures for syphilis are currently divided into two general groups of tests:

1. The non-treponemal antigen reagin screen tests, of which the Venereal Disease Research Laboratory (VDRL) and Rapid Plasma Reagin Card (RPR) procedures are the most frequently employed.
2. The treponemal antigen tests, of which the Fluorescent Treponemal Antibody-Absorption (FTA-ABS), and more recently, the Fluorescent Treponemal AntibodyAbsorption Double Stain (FTA-ABS DS) tests are the most commonly, employed confirmatory test procedures (1 - 9).

Although the non-treponemal tests such as the RPR procedure provide a relatively simple and reliable means to screen syphilis patients, they also produce a significant number of biologically false positive (BFP) reactions. These reactions are defined as patients whose sera give a positive RPR reaction (usually weakly reactive or titer less than 1:8), a negative FTA-ABS and no history or physical findings to suggest syphilis (10 - 11). Consequently, a RPR positive screen should be confirmed with a more specific test for syphilis such as the FTA-ABS procedure. Biological false positive results may, on occasion, be associated with acute and chronic infections; while up to 20% BFP may be associated with patients with lepromatous leprosy, certain drugs, pregnancy, autoimmune disease such as systemic lupus, and other diseases where hypergammaglobulinemia develops (11 - 15). Approximately 10% of BFP are attributed to aging alone, particularly in the eighth decade (10). Some patients with chronic BFP may also produce positive FTA-ABS results (11). Most of these reactions are usually borderline. Although the FTA-ABS procedure is more specific, the relatively low incidence of false positive FTA-ABS reactions emphasizes the need to interpret serological results in light of patient's complete history and clinical picture. The FTA-ABS procedure is the method most recommended for confirming positive reagin tests (5, 6). When the FTA-ABS test was compared to other procedures, the FTA-ABS test was shown to provide greater sensitivity and clinical correlation, particularly in untreated cases of syphilis (6, 11, and 12).

The FTA-ABS DS Test System enables workers performing the test to use microscopes equipped with incident illumination. In the FTA-ABS DS Test System, a class specific rhodamine-labeled (TMRITC) anti-human immunoglobulin G (IgG) globulin is used as a primary reagent and a fluorescein labeled (FITC) ant treponemal globulin is used as a counterstain reagent (1 - 4).

Expected Serological Findings in Untreated Syphilis			
Phase	Latent Period	RPR	FTA-ABS
Primary Stage	2-6 weeks	Reactive	Reactive
Secondary Stage	9-12 weeks	Reactive (High Titers)	Reactive
Early Latent Stage	6 months – 2 years	Reactive(Decreasing Titers)	Reactive
Late Stage	10-40 years	Approximately 50% Reactive	Reactive

TEST PRINCIPLE

Diagnostic Automation, Inc. IFA FTA-ABS Test System is a modification of the standard FTA-ABS test designed to confirm positive non-treponemal screen reagin tests for syphilis. The Diagnostic Automation, Inc. IFA FTA-ABS DS Test System employs nonviable T. pallidum (Nichols strain) cells as a substrate (antigen). These substrate cells are reacted with specially treated patient sera in the first step (see Methods Section). If treponemal antibodies are present in the patient sera, an antigen-antibody reaction takes place between the substrate cells and the circulating anti-treponemal antibodies in the patient sera. In the second step, anti-human globulin labeled with rhodamine is added to the T. pallidum substrate cells. In the third step, anti-treponemal FITC-labeled globulin is used as a counterstain reagent. The substrate cells are then examined with a fluorescence incident illuminator microscope. The FITC selection of filters is used first to read the FITC reaction to determine the presence or absence of treponemes without the use of a darkfield condenser. The intensity of rhodamine staining is graded on a scale of 1+ to 4+, or as negative (no fluorescence).

MATERIALS AND COMPONENTS

Materials provided with the test kits

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. Sorbent contains Thimerosal as a preservative (0.02% w/v).**

1. **Treponema pallidum Substrate Slides:** contain fixed T. pallidum (Nichols strain) substrate (antigen) standardized to produce optimum reactivity. Ten, 10-well Slides with dessicant pouch.
2. **Conjugate:** Goat anti-human globulin labeled with rhodamine (TMRITC). Contains phosphate buffer with BSA. One, 3.5mL, amber-capped, bottle.Ready to use.
3. **Conjugate:** Anti-treponemal globulin labeled with fluorescein isothiocyanate (FITC). Contains phosphate buffer with BSA. One, 3.5mL, ambercapped, bottle. Ready to use.
4. **Reactive Control (Human Serum):** Will produce positive apple-green staining. One, 1.0mL, red-capped, vial. Ready to use. The 1+ Minimally Reactive Control is a PBS dilution of this Reactive Control. See step 3 of the Assay Procedure for details.
5. **Non-Specific Control (Human Serum):** Will produce no specific Treponemal staining. One, 1.0mL, green-capped, vial. Ready to use.

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6. **Sorbent:** Standardized product of a Reiter treponeme culture. Sorbent removes nonspecific human serum antibodies that may interfere with the FTA-ABS test. One, 20.0mL, green-capped, bottle. Ready to use.
7. **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. Six packets, sufficient to prepare 6 liters.
8. **Mounting Media (Buffered Glycerol):** Two, 3.0mL, white-capped, dripper tipped vials.

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. 1 Liter Graduated Cylinder.
9. Laboratory timer to monitor incubation steps.
10. Disposal basin and disinfectant (i.e.: 10 % household bleach – 0.5% Sodium Hypochlorite).
11. Water Bath: 56º C.
12. Incubator: 35 – 37 º C.
13. Properly equipped fluorescence microscope. The below filter combinations or their equivalent have proven satisfactory for routine use with mercury light source only.

The exciter, dichroic and barrier filter combinations, together with recommended band pass ranges are shown in the table below. Consult the microscope manufacturer for the appropriate filter combinations for a particular microscope.

FITC		
Exciter Filter	Dichroic Mirror	Barrier Filter
470-490nm	510nm	515nm
RHODAMINE		
Exciter Filter	Dichroic Mirror	Barrier Filter
530-560nm	580nm	580nm

SPECIMEN COLLECTION AND 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. 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 (23).

ASSAY PROCEDURE

1. Heat all test sera and Controls for 30 minutes in a water bath adjusted to 56°C prior to testing. **NOTE: Previously heated sera should be reheated for at least 10 minutes prior to re-testing.**
2. 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.**
3. Dilute the Reactive and Non-Specific Controls 1:5 in both PBS and Sorbent (e.g.: 50µL of serum + 200µL of Sorbent or PBS). Prepare the 1+ Minimally Reactive Control directly from the heated Reactive Control aliquot. The recommended dilution factor is noted on the Reactive Control vial. Dilution is made in PBS.
   a. Example:
   b. 1+ = 1:400 or 1+ = 1 part reactive serum + 399 parts PBS,
   c. or 100µL sera + 39.9mL PBS = 1:400 dilution.
   d. This would represent the 1+ Minimally Reactive Control.
4. Prepare 1:5 dilutions of all test specimens in Sorbent.
   a. To appropriately labeled tubes, add 200µL of Sorbent.
   b. Add 50µL of heat inactivated serum specimen. Mix well.
5. Reserve 2 wells on the Control Slide. One for the Sorbent Control, the other for the PBS (Conjugate) Control. A total of seven Controls are required according to CDC recommendations for each day's testing (see Interpretation Section). All dilutions must be thoroughly mixed prior to testing.
6. Add 10µL of diluted test and Control sera to each appropriately identified Substrate Slide well. Include 10µL of Sorbent and 10µL of PBS in their respective wells.
7. Incubate at 35 - 37°C for 30 minutes.
8. Rinse Slides briefly with PBS. This is best accomplished by slightly tilting the Slide and flooding the multi-well Slide with a stream of PBS directed between the top and bottom rows of the Slide. Tilt Slide in opposite direction and repeat rinse. The staggered positioning of the test wells minimizes possible cross contamination (see Precautions Section).
9. Wash Slides for two, 5 minute intervals, changing PBS between washes.
10. Rinse Slides for about 5 - 10 seconds in a gentle stream of distilled water as in step 8, and air dry. Slides must be completely dry before proceeding.
11. Place 10µL of anti-human Conjugate (TMRITC) on each well.
12. Repeat steps 7 - 10.
13. Place 10µL of anti-Treponemal Conjugate (FITC) on each well. Incubate 35 - 37°C for 20 minutes.
14. Repeat steps 8 - 10.
15. Place a small amount (4 - 5 drops) of Mounting Media between the two rows of offset wells and coverslip.
16. Read the Slides as soon as possible. If a delay in reading is necessary, place Slides in a dark room and read within 4 hours.
17. Locate and focus treponemes with the fluorescein (FITC) filter system.
18. After the treponemes have been located, dial in the rhodamine filter to read specific red fluorescence.
19. Using the 1+ Minimally Reactive Control Slide as the reading standard, record the intensity of fluorescence according to the chart entitled, "Reading and Reporting Results," in the Interpretation of Results section of this Package Insert.

NOTE: The type and condition of the microscope used may influence the visual appearance of the image obtained. The 1+ reaction may vary due to the type of microscope employed, the light source, age of the bulb, filter assembly, filter thickness, as well as other parameters. As a result, it may be necessary for laboratories to prepare the 1+ minimal reactive at a dilution other than that recommended by the manufacturer. In such cases it may be advisable to employ the use of secondary standards.

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RESULTS

Reading	Intensity of Fluorescence
2+ to 4+	Moderate to strong
1+	Equivalent to Minimally Reactive (1+) Control*
± to < 1+	Visible staining, but less than 1+
-	None or vaguely visible, but without distinct fluorescence
* Retest all specimens with the intensity of fluorescence of (1+)	

Guide for Reading FTA-ABS Test Reading and Reporting Results

Initial Test Reading	Repeat Test Reading	Report
4+, 3+, 2+		Reactive (R)
1+	>1+ 1+ <1+	Reactive (R) **Reactive Minimal (RM)*** Non-Reactive (NR)
<1+		Non-Reactive (NR)
N or ±		Non Reactive (NR)
		• In the absence of historical or clinical evidence of treponemal infection, this test result should be considered equivocal. A second specimen should be submitted for serologic testing.

PERFORMANCE CHARACTERISTICS

The Diagnostic Automation, Inc. IFA FTA-ABS DS Test System and components produce results that are considered to be equivalent to those obtained with the DAI IFA FTA-ABS Test System.

Clinical Studies: The DAI IFA FTA-ABS DS Test System method has been tested in parallel with the standard FTA-ABS procedure and the results are shown in the following 3 tables.

Study No. 1 (3)
Table 1: Confirmatory FTA-ABS DS. Results of 92 Conventional FTA-ABS Tests

Category of Syphilis		DAI IFA FTA-ABS DS Test System			Conventional Test	
Reactive	Borderline	Non-Reactive		Reactive	Borderline	Non-Reactive
Primary	30	0	4	30	1	3
Secondary	26	0	0	26	0	0
Latent	31	1	0	32	0	0
Total	87	1	4	88	1	3

Table 2: Sera from Non-Syphilitic Patients

Category		DAI IFA FTA-ABS DS Test System			Conventional Test	
Reactive	Borderline	Non-Reactive		Reactive	Borderline	Non-Reactive
Presumed Normals	0	0	70	0	0	70
Diseases other than Syphilis	0	0	18	0	0	18
Biological False Positive	0	0	20	0	0	20
Total		108			108	

There were two discrepancies in the first study. The first discrepancy involved a specimen which was negative with the FTA-ABS DS method and borderline with the standard FTA-ABS method. The second discrepancy involved a specimen that was interpreted as borderline with the FTA-ABS DS and as reactive with the standard FTA-ABS method.

Study No. 2 (1) Procedure on 265 sera from syphilitic and non-syphilitic individuals.
Table 3: Comparison of the FTA-ABS DS procedure and the reference FTA-ABS

Category		DAI IFA FTA-ABS DS Test System			**FTA-ABS Reference Test**	
Reactive	Borderline	Non-Reactive		Reactive	Borderline	Non-Reactive
Syphilitic						
Primary	2	1	3	6	0	0
Secondary	7	0	0	7	0	0
Latent	11	0	0	11	0	0
Late	2	0	0	2	0	0
Treated Stage	2	0	0	2	0	0
Congenital (Unknown)	1	0	0	1	0	0
Possible Syphilis						
Stage Unknown	11	0	0	11	0	0
Non-Syphilitic	0	4	221	2	10	213

When testing sera from non-syphilitics with the DAI IFA FTA-ABS DS Test System, fewer borderline reactions were observed than with the FTA-ABS method. No reactive observations were observed with the non-syphilitic sera. When comparing the two methodologies on syphilitic cases, the results were essentially the same, except in primary cases as noted in Table 2.

QUALITY CONTROL

Prepare reactive and nonspecific controls in both PBS buffer and sorbent. Prepare a 1+ Minimally Reactive Control in PBS buffer. PBS buffer and Sorbent Controls should be run with each assay.

It is recommended that the Control Slide be read prior to evaluating test results. This will assist in establishing the references required to interpret the test sample.

Expected Control Readings		
Reactive Control Serum	**Rhodamine Fluorescence**	**FITC Fluorescence**
1:5 in PBS	R (4+)	1 + to 2+
1:5 in Sorbent	R (3+ to 4+)	1+to 2+
Minimally Reactive Control, PBS Dilution	1+	1+ to 2+
Nonspecific Control Serum		
1:5 in PBS	R (2+)	1+ to 2+
1:5 in Sorbent	N	1+ to 2+
Control For nonspecific staining by Conjugate		
PBS	N	1+ to 2+
Sorbent	N	1+ to 2+

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NOTE:

- If the above controls fail to produce the expected reactions, tests may be invalid and must be repeated.
- The nonspecific control in PBS is to ensure that this control is working, and should therefore demonstrate a 2+ fluorescent staining intensity. The nonspecific control in sorbent ensures that the sorbent is working optimally, and should therefore demonstrate a non-reactive appearance without distinct fluorescence.
- Additional controls may be tested according to the guidelines or requirements of local, state, and/or federal regulations or accrediting organizations.
- The PBS buffer and Sorbent are to be placed undiluted in separate wells. The Sorbent and PBS Controls should demonstrate non-reactive appearance without distinct fluorescence.
- Each of the controls in the FTA-ABS Double Stain Test System will demonstrate a 1+ to 2+ fluorescent staining intensity when the FITC filters are employed. The FITC filters are to determine the presence or absence of treponemes.
- DAI has established that following rigorous washing of the multiwell substrate Slides, one may occasionally observe a single reactive Treponemal organism in an otherwise totally negative well. If this should occur the test should be interpreted as non-reactive. In order for a test to be considered positive, a majority of the organisms in any test well must be similarly stained.

LIMITATIONS OF PROCEDURE

1. The FTA-ABS IFA test is not useful in measuring the effectiveness of therapy.
2. Biological false positives may occur at a low frequency.
3. The FTA-ABS IFA test should be employed as a confirmatory test for syphilis (17-19), not as a screening procedure.

EXPECTED VALUES

1. The expected value in normal individuals is a nonreactive (N) result.

PRECAUTION

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 Centers for Disease Control/National Institutes of Health manual "Biosafety in Microbiological and Biomedical Laboratories": current edition; and OSHA's Standard for Bloodborne Pathogens (20).
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 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.
7. The 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 reagents. 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. All 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. Depending upon lab conditions, it may be necessary to place slides in a moist chamber during incubations.
22. **PRECAUTION FOR POSSIBLE CROSS-CONTAMINATION:**
    a. Due to the close proximity of the test areas on the DAI multi-well substrate Slides, it is possible that test sera, controls, and conjugate may occasionally cross-contaminate from one well to the next. Although cross-contamination should not occur if the test procedure is carefully adhered to, the Slides should be examined after each incubation period for possible cross-contamination. The dark blue DAI Slides are designed to facilitate recognition of cross-contamination.
    b. A study by CDC (12) has shown that cross-contamination from a well containing a highly reactive serum to a well containing a negative serum, could result in a false positive reaction within 30 seconds. It is therefore imperative that the technologist guard against possible cross-contamination by carefully following the instructions for rinsing the Slides.

STORAGE

1. Unopened Test System. 2-8°C
2. Mounting Media, Conjugate, Sorbent, Slides, Reactive and Non-Specific Controls. 2-8°C
3. Rehydrated PBS (Stable for 30 days). 2-8°C
4. Phosphate-buffered-saline (PBS) Packets. 2-25°C

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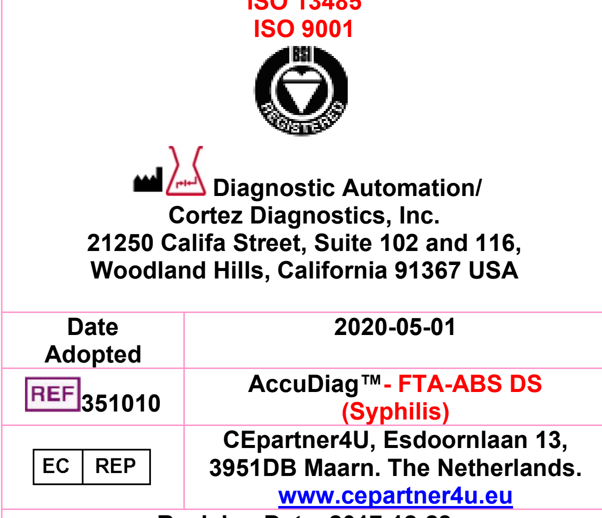

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