Captia™ ANA Screen

REF 2339000 96 Tests

Pour d'autres langues | Para outras línguas
Für andere Sprachen | Για τις άλλες λώσσες
Para otras lenguas | För andra språk
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INTENDED USE

The Trinity Biotech Antinuclear Antibody (ANA) Screen ELISA is a qualitative Enzyme-Linked Immunosorbent Assay (ELISA) intended to screen for the presence of antinuclear antibodies (ANAs) in human serum as an aid in the diagnosis of certain systemic rheumatic diseases. This assay collectively detects, in one well, total ANAs against double stranded DNA (dsDNA, nDNA), histones, SS-A(Ro), SS-B(La), Sm, Sm/RNP, Scl-70, Jo-1, and centrometric antigens, along with sera positive for Immunoflurescent (IFA) Hep-2 ANAs. **For *in vitro* diagnostic use. High complexity test.**

INTRODUCTION

Antinuclear antibodies (ANAs) directed against a variety of macromolecules occur in extraordinarily high frequency in systemic rheumatic diseases.[1] Although these antibodies were first associated with systemic lupus erythematosus (SLE), the list of implicated diseases has expanded and many rheumatic diseases are characterized by the presence of one or more of these ANAs. For instance, anti-SS-A(Ro) and anti-SS-B(La) antibodies are associated with SLE and Sjogren's Syndrome (SS), anti-dsDNA and anti-Sm antibodies with SLE, anti-histone antibodies with SLE and Drug Induced Lupus, anti-RNP antibodies with mixed connective tissue disease, (MCTD) and SLE, anti-Scl-70 antibodies with scleroderma (progressive systemic sclerosis [PSS]), anti-Jo-1 antibodies with polymositis and dermatomyositis and anti-centromere antibodies with CREST syndrome.[2,3,4]

The immunofluorescence assay (IFA) has been used as the standard method in the detection of ANAs.[5] Although IFA is a sensitive test, it is laborious when testing large numbers of patient samples and is subject to errors from human interpretation and from variability in fluorescent microscopes.[1] The IFA Hep-2 ANA test is also subject to the following concerns: it is sometimes insensitive to certain sera containing antibodies to SS-A, SS-B, Sm, or dsDNA[6] and it tends to find sera positive in a large number of patients who do not develop systemic rheumatic diseases within a follow-up two year period.[7] The ELISA test system is an excellent alternative to the IFA test system for screening patient's serum for the presence of ANA's of clinical significance. The ELISA test system efficiently screens large numbers of patient samples and reduces human error.

The Trinity Biotech ANA Screen ELISA collectively detects, in one well, total ANAs against double stranded DNA (dsDNA, nDNA) histones, SS-A(Ro), SS-B(La), Sm, Sm/RNP, Scl-70, Jo-1 and centromeric antigens, along with sera positive for IFA Hep-2 ANAs. Sera positive on the Trinity Biotech ANA Screen ELISA should be tested for the specific autoantibodies indicative of various systemic rheumatic diseases.

PRINCIPLE OF THE ASSAY

Purified antigens (dsDNA, histones, SS-A(Ro), SS-B(La), Sm, Sm/RNP, Scl-70, Jo-1, centromere and other antigens extracted from the Hep-2 nucleus) are bound to microwells. Antibodies to these antigens, if present in diluted serum, bind in the microwells. Washing of the microwells removes unbound serum antibodies. Horseradish peroxidase (HRP) conjugated anti-human IgG immunologically binds to the bound patient antibodies forming a "conjugate – antibody – antigen" sandwich. Washing of the microwells removes unbound conjugate. An enzyme substrate in the presence of bound conjugate hydrolyzes to form a blue color. The addition of an acid stops the reaction forming a yellow end product. The intensity of the color is measured photometrically at 450 nm.

KIT PRESENTATION

MATERIALS SUPPLIED

Each kit contains the following components in sufficient quantities to perform the number of tests indicated on the package label.

1. ANA Antigen Coated Microassay Plate: 96 wells, configured in twelve 1x8 strips, stored in a foil pouch with desiccant. (96T: one plate)
2. ELISA Frame: Use to hold antigen-coated wells. Retain the frame for future use.
3. Serum Diluent Type VI: Ready to use. Use to dilute Positive Control, Cutoff Calibrator, Negative Control, and patient samples 1:41. Use for Reagent Blank. Avoid unnecessary contamination. Contains < 0.1% sodium azide as a preservative. (96T: two bottles, 30 mL each)
4. Positive Control: Stabilized human serum. Dilute 1:41 in Diluent at same time and in same manner as samples; gives an ANA number greater than 1.0. (96T: one vial, 0.4 mL) *
5. Cutoff Control (Calibrator): Stabilized human serum. Dilute 1:41 in Diluent at same time and in same manner as samples. Used to calculate sample's ANA number. (96T: one vial, 0.4 mL) *
6. Negative Control: Stabilized human serum. Dilute 1:41 in Diluent at same time and in same manner as samples; gives an ANA number less than 1.0 (96T: one vial, 0.4 mL)*
7. Horseradish-peroxidase (HRP) Conjugate, goat anti-human IgG: Ready to use (96T: one bottle, 15 mL)
8. Wash Buffer Type IV (concentrate): add 60 mL concentrate + 940 mL deionized or distilled water. Mix thoroughly. (96T: one bottle, 60 mL)
9. Chromogen/Substrate Solution Type III: Tetramethylbenzidine (TMB), ready to use. If allowed to evaporate, a precipitate may form in the reagent wells. (96T: one bottle, 15 mL)
10. Stop Solution Type II: Ready to use, to stop color development. Contains sulfuric and hydrochloric acids. (96T: one bottle, 15 mL)

*** Note: serum vials may contain excess volume.**

Stop Solution Type II, TMB Chromogen/Substrate Type III, Wash Buffer Type IV (concentrate), and Serum Diluent Type VI are not kit lot number dependent, but may only be used for Trinity Biotech ANA Screen ELISA assay's. Please check that the appropriate Trinity Biotech Reagent Type (Type I, Type II, etc.) is used for the assay.

ADDITIONAL REQUIREMENTS

- Wash bottle, automated or semi-automated microwell plate washing system.
- Micropipettes, including multichannel, capable of accurately delivering 10-200 µL volumes (less than 3% CV).
- One liter graduated cylinder.
- Paper towels.
- Test tube for serum dilution.
- Distilled or deionized water (dH_20), CAP (College of American Pathology) Type 1 or equivalent.
- Timer capable of measuring to an accuracy of +/- 1 second (0 to 60 minutes).
- Single or dual wavelength microplate reader with 450 nm filter. If dual wavelength is used, set the reference filter to 600-650 nm. Read the Operator's Manual or contact the instrument manufacturer to establish linearity performance specifications of the reader.

STORAGE AND STABILITY

The kit is stabilized for ambient shipment. All kit components should be stored between 2° and 8°C and can be used until the expiration date printed on the labels. Once the antigen-coated plate's foil pouch has been opened, the wells are stable for 30 days.

PRECAUTIONS

SAFETY

1. For *in vitro* diagnostic use only.
2. Do not pipette by mouth.
3. Components containing human serum have tested negative for HBsAg and HIV antigens. This does not assure the absence of these antigens; sera should be considered potentially hazardous These materials should be handled as recommended in the CDC/NIH Health manual, Biosafety in Microbiological and Biomedical Laboratories, 1993.[10]
4. Sodium azide is a toxic substance and is used in some reagents. In case of contact with eyes and skin, flush immediately with copious amounts of water. Sodium azide may react with lead and copper plumbing to form explosive metal azides. On disposal of reagents flush with a large volume of water to help prevent azide build-up.
5. The Stop Solution contains a dilute acid solution. Use with care to avoid contact with skin and eyes. Avoid exposure to bases, metals, or other compounds which may react with acids. Spills should be cleaned up immediately.
6. Dispose of all wastes in accordance with applicable national and/or local regulations.
7. Waste material containing patient samples or biological products should be considered biohazardous when disposing or treating.
8. Chemical reagents should be handled in accordance with Good Laboratory Practices.
9. Clean up all spills immediately and thoroughly. Disinfect the area for any spills involving biohazardous materials. Dispose of all contaminated materials appropriately.
10. Do not use kit beyond its expiration date. The date is printed on kit boxes.

PROCEDURAL

1. All materials must be at room temperature (21 to 25 °C).
2. Do not use Controls or Calibrator from different kit lots. Do not use expired reagents.
3. Avoid contamination of reagents, dispensing pipettes, and microtiter wells. Use new dispensing pipettes for all samples. Do not interchange caps. Always keep bottle capped when not in use. Do not reuse the microtiter wells or pipettes. Avoid pipettes contaminated with peroxidase.
4. All wells should be handled in the same sequence and the same manner throughout the test. The test should be performed without interruptions.
5. Gently and completely swirl each bottle of liquid reagent and sample before use.
6. Make accurate 1:41 dilutions.
7. Make all dilutions in uncontaminated Diluent. Prepare all dilutions before starting test. Always use fresh sample dilutions.
8. Always run a Positive Control, a Calibrator and a Negative Control. Always blank against Diluent.
9. Humidity affects the antigen-coated wells; do not open pouch until it reaches room temperature. Calculate the number of wells required for the current assay, remove them from the room temperature foil pouch. Align them on the Frame, then add samples immediately. Unused wells should be returned immediately to the resealed foil pouch with desiccant.
10. Incubation times affect ELISA results. Do not allow any of the controls, samples or HRP Conjugate to incubate in the strip wells for more than 40 minutes. For best results, use 1mL mini-tubes to prepare sample dilutions. Transfer all solutions into wells with an 8-channel Micropipettor or equivalent.
11. After each incubation, thoroughly wash the microtiter wells with 200 to 300 µL Wash Solution per well. Be sure to remove all liquid before proceeding to next step. Fill wells, then invert and rapidly flick away the liquid. After complete washing, blot the plate on a paper towel.
12. Allow for 1 mL of Conjugate for each strip to be run. Transfer amount to an appropriate container. Discard excess transferred Conjugate.
13. Allow for 1 mL of Substrate for each strip to be run. Transfer amount to an appropriate container. Discard excess transferred Substrate.

SPECIMEN COLLECTION AND STORAGE

1. Aseptically collect blood samples in untreated tubes by venipuncture and prepare serum using accepted technique.[11]
2. Allow blood to clot; separate serum immediately. Serum containing visible particulate matter can be spun down utilizing slow speed centrifugation.

3. Sera may be stored up to five days at 2 to 8 °C. If a further delay in testing is needed, store frozen at -20 to -70 °C in a non-defrosting freezer. Avoid multiple freeze/thaw of patient samples.
4. Avoid using hemolyzed, lipemic, or bacterially contaminated sera.
5. **Caution: Do not heat inactivate sera as this may cause false positive results**.

METHODS FOR USE

PREPARATION FOR THE ASSAY

1. Collect all reagents, samples and dilutions necessary before starting assay.
2. Wash Solution
   - Because the Wash Concentrate contains salt, crystals may form in the concentrated solution. For proper preparation of the Wash Solution, complete the following steps:
   - Empty contents of Wash Concentrate bottle, including any crystals, into a 1 L bottle.
   - If any crystals remain in the Wash Concentrate bottle, remove them by adding some deionized water to the bottle; mix and pour all contents into the 1 L bottle.
   - Add deionized water to the 1 L bottle to bring the final volume of the solution to 1 liter.
   - Place a stir bar in the 1 L bottle and place on a stir plate. Stir the diluted Wash Solution for a few minutes until all crystals are dissolved. If no stir plate is available, cover the top of the Wash Solution and gently invert back and forth until the crystals are dissolved. Avoid excessive bubbles.
   - Diluted Wash Solution is stable for 14 days at 2 - 8 ºC.
   - Retain for future use.
3. Allow Diluent to come to room temperature before use. Mix thoroughly. Use Diluent to make all dilutions. Avoid unnecessary contamination.
4. Assign and record wells for controls and samples.
5. Make 1:41 dilutions of the Controls, Calibrator and specimens (e.g., 10 µL sample + 400 µL Diluent).
6. Do not use any reagents that show signs of leakage.

ASSAY PROCEDURE

1. Place the desired number of strips into a microwell frame. Allow five (5) Control/Calibrator determinations (one Negative Control, three Calibrators and one Positive Control) per run. A reagent blank (RB) should be run on each assay. Check software and reader requirements for the correct Calibrator/Control configuration. Return unused strips to the sealable bag with desiccant, seal and immediately refrigerate.

Example Configuration:

Plate Location	Sample Description	Plate Location	Sample Description
1A	RB	2A	Patient #3
1B	NC	2B	Patient #4
1C	Cal	2C	Patient #5
1D	Cal	2D	Patient #6
1E	Cal	2E	Patient #7
1F	PC	2F	Patient #8
1G	Patient #1	2G	Patient #9
1H	Patient #2	2H	Patient #10

RB = Reagent Blank - Well without serum addition run with all reagents. Utilized to blank reader.
NC = Negative Control
Cal = Calibrator
PC = Positive Control

2. Dilute test sera, Calibrator, Positive and Negative Controls sera 1:41 (e.g., 10 µL + 400 µL) in Serum Diluent. (For manual dilutions, dispense the sample diluent into the test tube first and then add the patient serum.)
3. To individual wells, add 100 µL of the appropriate diluted Calibrator, Controls and patient sera.
4. Incubate each well at room temperature (21 to 25 °C) for **thirty (30) minutes.** (Do not incubate diluted sera in wells for more than 40 minutes.)
5. Aspirate or shake out liquid from all wells. Using semi-automated or automated washing equipment, add 200 µL - 300 µL of diluted Wash Buffer to each well. Aspirate or shake out to remove all liquid. Repeat the wash procedure four (4) times (for a total of five (5) washes). After the final wash, blot the plate on paper toweling to remove all liquid from the wells.

****IMPORTANT NOTE:** Regarding steps 5 and 8, insufficient or excessive washing will result in assay variation and will affect validity of results. Therefore, for best results the use of semi-automated or automated equipment set to deliver a volume to completely fill each well (200 to 300 µL) is recommended. Please contact Trinity Biotech with any questions regarding appropriate wash equipment. A total of up to five 95) washes may be necessary with automated equipment. **Complete removal of the wash buffer after the last wash is critical for the accurate performance of the test. Also, visually ensure that no bubbles are remaining in the wells.**

6. Add 100 µL Conjugate to each well, including reagent blank. Avoid bubbles upon addition as they may yield erroneous results.
7. Shake plate gently. Incubate each well at room temperature (21 to 25 °C) for **thirty (30) minutes.** (Do not incubate Conjugate in wells for more than 40 minutes.)
8. Repeat wash as described in Step 5.
9. Add 100 µL Chromogen/Substrate Solution to each well, including reagent blank, maintaining a constant rate of addition across the plate.
10. Shake or tap plate gently to disperse color. Incubate each well at room temperature (21 to 25 °C) for **thirty (30) minutes.**
11. Stop reaction by addition of 100 µL of Stop Solution following the same order of addition used to add the Substrate, including reagent blank well. Tap the plate gently along the outsides, to mix contents of the wells.
12. The developed color should be read within 30 minutes on an ELISA plate reader equipped with a 450 nm filter. If dual wavelength is used, set the reference filter to 600-650 nm. Zero the reader on the reagent blank well, then read the color of the controls and patient wells. The Positive Control well should show yellow color. The calibrator well should show moderate color. The Negative Control well should show little color. The reagent blank well should show little color or be clear.

QUALITY CONTROL

In order for a test to be valid, all of the following criteria must be met:
1. A Positive Control, Calibrator, Negative Control and reagent blank must be included with each test run.
2. The values for each Control and Calibrator must be within the specified range printed on the component list included with each kit lot number.
3. The reagent blank must be ≤ 0.200 when zeroed against air.
4. Refer to NCCLS C24A for guidance on appropriate Quality Control practices.[12]
5. **If above criteria are not met on repeat, contact Trinity Biotech Technical Services.**

INTERPRETATION

CALCULATIONS

Determine the ANA number* for each patient specimen (or control) using the following

$$\frac{\text{OD of Test Sample}}{\text{Mean OD of Calibrator}} = \text{ANA\# of Test Sample}$$

*ANA numbers are qualitative.

ANALYSIS

The following is intended as a guide to interpretation of Trinity Biotech ANA Screen ELISA results. Each laboratory is encouraged to establish its own criteria for test interpretation based on sample populations encountered.

ANA#	Interpretation
< 1.0	Negative
≥ 1.0	Positive

Microplate wells must be read with an ELISA reader set to 450 nm. Results should be read after adding the Stop Solution (Step 11) and reported as follows:
Positive: A positive response is indicated by a yellow color; the calculated ANA numbers are greater than or equal to 1.0.
Negative: A negative response is indicated by a colorless, or less intense yellow color; the calculated ANA numbers are less than 1.0.

EXPECTED VALUES

The Trinity Biotech ANA Screen ELISA test expected values and positive distribution for the various sera positive for antibodies of clinical significance are summarized below:[9]

Trinity Biotech ANA Screen ELISA

Antibody Specificity	Number of Samples	Low ANA #	High ANA #
SS-A	18	3.6	8.1
SS-B	2	1.3	8.8
SS-A/B	9	2.1	11.2
Sm	18	3.5	12.0
RNP	13	2.3	9.2
Scl-70	16	7.7	15.1
Jo-I	13	1.4	7.8
dsDNA	13	1.4	7.8
Histones	7	9.0	17.1
Centromere	13	1.3	4.8

LIMITATIONS OF USE

As with other ANA diagnostic tests, the results are to be used as an aid in diagnosis. Confirmation testing for specific antibodies should be run if a positive assay is obtained. A positive result suggests certain diseases and should be confirmed by clinical findings.

PERFORMANCE CHARACTERISTICS

SENSITIVITY

Sensitivity can be defined as the ability of the test to give a positive result for serum samples that should be positive. The sensitivity performance of the Trinity Biotech ANA Screen ELISA was established in the following manner:

Fifty-nine (59) sera obtained from a variety of clinical sources with monospecific antibodies of clinical significance were tested on the Trinity Biotech ANA Screen ELISA. All of these ANA monospecific sera were positive on the Trinity Biotech ANA Screen ELISA. The results are summarized below:[9]

ELISA ANA Screening Test - Antibody Specificity

Antibody specificity	# of positives (%)	SS-A	SS-B	Sm	SmRNP	Scl-70	Jo-1	dsDNA	Histones	Centro
SS-A/Ro	9 of 9 (100%)	+	-	-	-	-	-	-	-	-
SS-B/La	1 of 1 (100%)	-	+	-	-	-	-	-	-	-
SS-A/B	7 of 7 (100%)	+	+	-	-	-	-	-	-	-
Sm	9 of 9 (100%)	-	-	+	-	-	-	-	-	-
RNP	6 of 6 (100%)	-	-	-	+	-	-	-	-	-
Scl-70	5 of 5 (100%)	-	-	-	-	+	-	-	-	-
Jo-1	5 of 5 (100%)	-	-	-	-	-	+	-	-	-
dsDNA	8 of 8 (100%)	-	-	-	-	-	-	+	-	-
Histones	3 of 3 (100%)	-	-	-	-	-	-	-	+	-
Centromere	6 of 6 (100%)	-	-	-	-	-	-	-	-	+

Three hundred seventy-one IFA Hep-2 ANA positive sera obtained from a variety of clinical sources were tested on the Trinity Biotech ELISA ANA Screening test. The results are summarized below: [9]

IFA Hep-2 ANA Titer	ANA ELISA Screen Results	Number Of Samples	%
≥ 1:160	Positive	220	91
≥1:160	Negative	22	9
1:40 – 1:80	Positive	72	56
1:40 – 1:80	Negative	57	44[8]

Thirty-eight Lupus patient sera obtained from a variety of clinical sources were tested on the Trinity Biotech ANA Screen ELISA. All of the Lupus patient sera were positive on the Trinity Biotech ANA Screen ELISA.[9]

SPECIFICITY

Specificity can be defined as the ability of the test to give a negative result for "normal" sera. The specificity performance of the Trinity Biotech ANA Screen ELISA was established using 70 "normal" sera obtained from a volunteer blood donor testing facility. One donor had antibodies to dsDNA and was thus not considered to be "normal". Sixty-four of the remaining 69 were negative on Trinity Biotech ANA Screen ELISA test, thus yielding a 92.8% specificity.[9]

COMPARATIVE PERFORMANCE

One hundred eighty sera obtained from a variety of clinical sources were tested on four different predicate devices and the Trinity Biotech ANA Screen ELISA for comparison purposes. The predicate devices were: 1) ELISA ENA Plus Screening test (for the detection of antibodies to SS-A, SS-B, Sm, Sm/RNP, Scl-70 or Jo-1), 2) ELISA anti-dsDNA, 3) ELISA anti-Histones, and 4) IFA Hep-2 ANA used for the purpose of detecting anti-centromeric antibodies. One hundred and ten (110) of the sera were positive on one or more of these predicate assays, while 70 were "normal" sera negative on all four of the predicate assays.[9]

Four hundred and sixty-nine sera obtained from a variety of clinical sources were tested on the IFA Hep-2 ANA and the Trinity Biotech ANA Screen ELISA test for comparison purposes. The overall agreement was 86.1%.[9]

PRECISION

Intra-assay precision was determined by testing a strong positive control and a weak positive control with a replication of 18. The CV's were 6.6 and 9.5%, respectively. Inter-assay precision was determined by testing a strong positive control and a weak positive control in a total of 24 assays. The CV's were 6.8 and 8.3%, respectively.[9]

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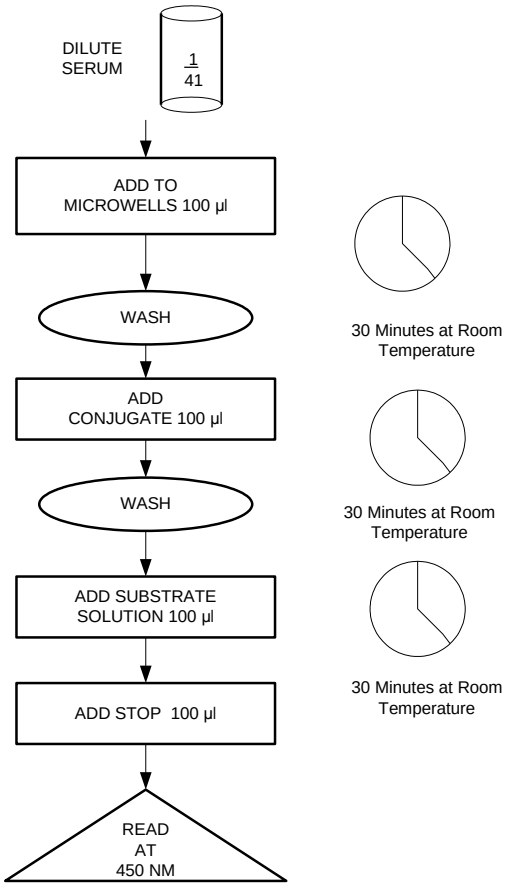
CAPTIA™ ANA SCREEN SUMMARY OF ASSAY PROCEDURE



ORDERING INFORMATION

KIT		Captia™ ANA Screen Test Kit
Catalog No.	Item	Quantity
2339000	Captia™ ANA Screen Test Kit	96 Tests


Manufactured

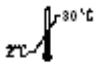
EC REP
Authorized Representative


Consult accompanying documents


Use by

Caution, consult accompanying documents


Store at 2-8ºC


Store at 2-30ºC

CONTROL + +
High Pos or Positive Control

CONTROL +
Low Pos or Cut-Off Control

CONTROL -
Negative Control

REF
Product Number

LOT
Lot

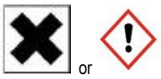
CAL
Calibrator

C.F.
Coefficient Factor

RNG
Range

STD
Standard

IVD
For *In Vitro* Diagnostic use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