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ISO 13485-2003

	See external label	2°C-8°C	Σ=96 Tests	REF 2557-2

Sm ELISA

Cat. No. 2557-2

INTENDED USE

The Diagnostic Automation, Inc. (DAI) Sm Enzyme-Linked Immunosorbent Assay (ELISA) is a semi-quantitative immunoassay for the detection of IgG antibodies to Sm in human sera. The results of the assay may aid in the diagnosis and treatment of autoimmune connective tissue disorders. For *in vitro* diagnostic use.

SUMMARY

Systemic autoimmune disease is characterized by the presence of circulating auto-antibodies directed to wide variety of cellular antigens. Systemic lupus erythematosis (SLE), commonly referred to as Lupus is the best known of these diseases. Other possible connective tissue diseases include mixed connective tissue disease (MCTD), Sjogren syndrome, sclerodema, and polymyositis/dermatomyositis. The majority can be diagnosed by clinical presentation and their antibody profiles to the various antigens involved, which include dsDNA, SM, RNP, Ro, La, Sm, Jo-1 and Histones. Antibodies directed against the Sm marker are highly specific for patients with SLE and are considered a diagnostic criterion for SLE. Therefore, immunoassays for autoantibodies are useful for diagnostic and prognostic evaluations of autoimmune disease.

Patients with Sm antibodies experience a high frequency of renal an dcentral nervous system complications. The Sm or Smith antigen is composed of nuclear RNA and several polypeptides. Antibodies to Sm are present in approximately 30% of patients with SLE (systemic lupus erythematosis). Sm is a very specific marker for SLE. Sm antibodies are very rare in other autoimmune diseases.

Classically, antibodies to autoimmune antigens are detected by double immunodiffusion. However, the test is lengthy and suffers weak sensitivity. Enzyme-Linked Immunosorbent Assays (ELISAs) combine greater sensitivity with ease of use. Many ELISAs have been developed and validated for detecting autoantibodies to various antigens.

PRINCIPLE OF THE ASSAY

The DAI Sm ELISA test system is designed to detect IgG class antibodies to Sm in human sera. Wells of plastic microwell strips are sensitivized by passive absorption with the specific antigen. The test procedure involves three incubation steps.

1. Diluted test sera are incubated in antigen coated microwells. Any unbound antibodies and other serum components are removed from the plate by washing.
2. Peroxidase Conjugated goat anti-human IgG is added to the wells and the plate is incubated. Unreacted conjugate is removed with washing.
3. Microwells containing the immobilized peroxidase conjugate are incubated with peroxidase Substrate solution. Hydrolysis of the Substrate by peroxidase produces a color change. The reaction is then stopped and the color intensity of the solution is measured photometrically. The color intensity is dependent on the antibody concentration in the original test sample.

COMPONENTS

96 Tests

- **MICROWELL PLATE** 1plate

Sm product No. 2832G
Blank microwell strips fixed on a white strip holder. The plate is sealed in aluminum pouch with desiccant.
8×12/12×8-well strips per plate. Each well contains purified Sm antigens.
The microwell strips can be broken to be used separately. Place unused wells or strips in the plastic sealable storage bag together with the desiccant and return to 2~8°C.

- **NEGATIVE CONTROL** 1vial

Sm product No. 2835G
0.35 ml per vial.
Preservative added.
Ready to use as supplied.
Once open, stable for one month at 2-8°C.

- **POSITIVE CONTROL** 1vial

Sm product No. 2834G
0.35 ml per vial.
Preservatives added.
Ready to use as supplied.
Once open, stable for one month at 2-8°C.

- **CALIBRATOR** 1vial

0. 5 ml per vial.
Preservative and buffer added.
Ready to use as supplied.
Once open, stable for one month at 2-8°C.

- **HRP-CONJUGATE REAGENT** 1vial

15 ml per vial. White cap.
Horseradish peroxidase-conjugated goat anti-human IgG.
Preservative added.
Ready to use as supplied.
Once open, stable for one month at 2-8°C.

- **WASH BUFFER [10X]** 1bottle
  DILUTE BEFORE USE

Blue solution filled in a clear bottle with clear screw cap.
100 ml per bottle
Dilute 1 part concentrate + 9 parts deionized or distilled water.
1X solution will have a pH of 7.2± 0.2. , 20 × PBS (Contains Tween-20 as a detergent).
Once diluted, stable for one week at room temperature or for two weeks when stored at 2-8°C.

- **TMB** 1bottle

Colorless liquid filled in a amber bottle with amber screw cap.
15 ml per bottle.
TMB solution (3,3',5,5'-Tetramethyl benzidine). Contains DMSO≤ 15% (w).
Ready to use as supplied.
Once open, stable for one month at 2-8°C.

- **STOP SOLUTION** 1bottle

Colorless liquid red screw cap
15ml per bottle.
(1.0M H_2SO_4, 0.7M HCl).
Ready to use as supplied.

- **Sample Diluent** 1 bottle

30ml bottle (green cap)
Contains Tween-20, bovine serum albumin and PBS, (pH 7.2±0.2)
Ready to use. Note: Shake well Before Use.
Preservative added.
Note: The sample diluent will change color in the presence of serum.

- **PACKAGE INSERTS** 1copy

ADDITIONAL MATERIALS AND INSTRUMENTS REQUIRED BUT NOT PROVIDED

- Freshly distilled or deionized water.
- Disposable gloves and timer.
- Appropriate waste containers for potentially contaminated materials.
- Disposable V-shaped troughs.
- Dispensing system and/or pipette (single or multichannel), disposable pipette tips.
- Absorbent tissue or clean towel.
- Dry incubator or water bath, 37±0.5°C.
- Microshaker for dissolving and mixing conjugate with samples.
- Microwell plate reader, single wavelength 450nm or dual wavelength 450nm and 630nm.
- Microwell aspiration/wash system.

SPECIMEN COLLECTION, TRANSPORTATION AND STORAGE

1. **Sample Collection:** Either fresh serum or plasma samples can be used for this assay. Blood collected by venipuncture should be allowed to clot naturally and completely – the serum/plasma must be separated from the clot as early as possible as to avoid hemolysis of the RBC. Care should be taken to ensure that the serum samples are clear and not contaminated by microorganisms. Any visible particulate matters in the sample should be removed by centrifugation at 3000 RPM for at least 20 minutes at room temperature, or by filtration on 0.22u filters. Plasma samples collected into EDTA, sodium citrate or heparin may be tested, but highly lipaemic, icteric, or hemolized samples should not be used as they could give erroneous results in the assay. Do not heat inactivate samples. This can cause sample deterioration.
2. **Transportation and Storage:** Store samples at 2-8°C. Samples not required for assaying within 3 days should be stored frozen (-20°C or lower).Multiple freeze-thaw cycles should be avoided. For shipment, samples should be packaged and labeled in accordance with the existing local and international regulations for transport of clinical samples and ethological agents.

SPECIAL INSTRUCTIONS FOR WASHING

1. A good washing procedure is essential to obtain correct and precise analytical data.
2. It is therefore recommended to use a good quality ELISA microplate washer, maintained at the best level of washing performances. In general, no less than 5 automatic washing cycles with dispensing of 350-400µl/well, are sufficient to avoid false positive reactions and high background (all wells turn yellow).
3. To avoid cross-contaminations of the plate with sample or HRP-conjugate, after incubation do not discard the content of the wells, but allow the plate washer to aspirate it automatically.
4. Anyway, we recommend calibrating the washing system on the kit itself in order to match the declared analytical performances. Assure that the microplate washer's liquid dispensing channels are not blocked or contaminated, and sufficient volume of Wash buffer is dispensed each time into the wells.
5. In case of manual washing, we suggest to perform at least 5cycles, dispensing 350-400µl/well and aspirating the liquid for 5times. If poor results (high background) are observed, increase the washing cycles or soaking time per well.
6. In any case, the liquid aspirated out the strips should be treated with a sodium hypochlorite solution(final concentration of 2.5%) for 24 hours, before liquids are disposed in an appropriate way.

STORAGE AND STABILITY

The components of the kit will remain stable through the expiration date indicated on the label and package when stored between 2-8 °C; **do not freeze**. To assure maximum performance of this Sm ELISA kit, during storage protect the reagents from contamination with microorganism or chemicals.

PRECAUTIONS AND SAFETY

This kit is intended **FOR IN VITRO USE ONLY** IVD

FOR PROFESSIONAL USE ONLY

The ELISA assay is a time and temperature sensitive method. To avoid incorrect result, strictly follow the test procedure steps and do not modify them.

1. Do not exchange reagents from different lots, or use reagents from other commercially available kits. The components of the kit are precisely matched as to achieve optimal performance during testing.
2. Make sure that all reagents are within the validity indicated on the kit box and are of the same lot. Never use reagents beyond the expiry date stated on reagents labels or on the kit box.
3. **CAUTION - CRITICAL STEP:** Allow the reagents and samples to stabilize at room temperature(18-30°C) before use. Shake reagent gently before, and return to 2-8°C immediately after use.
4. Use only sufficient volume of sample as indicated in the procedure steps. Failure to do so, may cause in low sensitivity of the assay.
5. Do not touch the bottom exterior of the wells; fingerprints or scratches may interfere with microwell reading.
6. When reading the results, ensure that the plate bottom is dry and there are no air-bubbles inside the wells.
7. Never allow the microplate wells to dry after the washing step. Immediately proceed to the next step. Avoid the formation of air-bubbles when adding the reagents.
8. Avoid assay steps long time interruptions. Assure same working conditions for all wells.
9. Calibrate the pipette frequently to assure the accuracy of samples/reagents dispensing. Always use different disposal pipette tips for each specimen and reagents as to avoid cross-contaminations. Never pipette solutions by mouth.
10. The use of automatic pipettes is recommended.
11. Assure that the incubation temperature is 37°C inside the incubator.
12. When adding samples, avoid touching the well's bottom with the pipette tip.
13. When reading the results with a plate reader, it is recommended to determine the absorbance at 450nm or at 450nm with reference at 630nm.
14. All specimens from human origin should be considered as potentially infectious.
15. Materials from human origin may have been used in the kit. These materials have been tested with tests kits with accepted performance and found negative for antibodies to HIV ½, HCV, TP and HBsAg. However, there is no analytical method that can assure that infectious agents in the specimens or reagents are completely absent. Therefore, handle reagents and specimens with extreme caution as if capable of transmitting infectious diseases. Strict adherence to GLP (Good Laboratory Practice) regulations can ensure the personal safety. Never eat, drink, smoke, or apply cosmetics in the assay laboratory.
16. Bovine derived sera may have been used in this kit. Bovine serum albumin (BSA) and fetal calf sera (FCS) are derived from animals from BSE/TSE free-geographical areas.
17. The pipette tips, vials, strips and sample containers should be collected and autoclaved for 1hour at 121°C or treated with 10% sodium hypochlorite for 30minutes to decontaminate before any further steps for disposal.
18. The Stop solution (1.0M H_2SO_4, 0.7M HCl) is a strong acid. Corrosive. Use it with appropriate care. Wipe up spills immediately or wash with water if come into contact with the skin or eyes. ProClin 300 used as a preservative can cause sensation of the skin.
19. The enzymatic activity of the HRP-conjugate might be affected from dust, reactive chemical, and substances like sodium hypochlorite, acids, alkalins etc. Do not perform the assay in the presence of such substances.
20. Materials Safety Data Sheet (MSDS) available upon request.
21. If using fully automated microplate processing system, during incubation, do not cover the plates with the plate cover. The tapping out of the remainders inside the plate after washing, can also be omitted.

ASSAY PROCEDURE

Step1 Reagents preparation: Allow the reagents and samples to reach room temperature **(18-30°C)** for at least 15-30minutes. Check the Wash buffer concentrate for the presence of salt crystals. If crystals have formed in the solution, resolubilize by warming at 37°C until crystals dissolve. Dilute the stock Wash Buffer with distilled or deionized water. Use only clean vessels to dilute the buffer.

Step2 Numbering Wells: Set the strips needed in strip-holder and number sufficient number of wells including three Negative controls **(e.g. B1, C1, D1)** two Positive controls **(e.g. E1, F1)** and one Blank (**e.g. A1,** neither samples nor HRP-Conjugate should be added into the Blank well). If the results will be determined by using dual wavelength plate reader, the requirement for use of Blank well could be omitted. Use only number of strips required for the test.

Example of controls/samples dispensing scheme

	1	2	3	4	5	6	7	…	…	12
A	Blank	S3								
B	Neg.	…								
C	Neg	…								
D	Neg.									
E	Pos.									
F	Pos.									
G	S1									
H	S2									

Step3 Prepare a 1:21 dilution (e.g.: 10µL of serum + 200µL of Sample Diluent. NOTE: Shake well Before Use) of the Negative Control, Calibrator, Positive Control, and each patient Serum. The sample diluent will undergo a color change confirming that the specimen has been combined with the diluent.

Step4 To individual wells, add 100µL of each diluted control, calibrator and sample. Ensure that the samples are properly mixed. Use a different pipette tip for each sample.

Step5 Washing: At the end of the incubation, remove and discard the plate cover. Wash each well **5times** with Wash buffer. Each time, allow the microwells to soak for 30-60seconds. After the final washing cycle, turn down the plate onto blotting paper or clean towel, and tap it to remove any remaining liquids. Visually inspect the plate to ensure that no residual wash solution remains. Collect wash solution in a disposable basin and treat with 0.5% sodium hypochlorite (bleach) at the end of the days run.

Step6 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.

Step7 Incubate the plate at room temperature (20-25°C) for 25 ± 5 min.

Step8 Wash the microwells by following the procedure as described in step 5.

Step9 Add 100µL of TMB to each well, including the reagent blank well, at the same rate and in the same order as the specimens were added.
Step10 Incubate the plate at room temperature for 10 to 15 minutes.
Step11 Stop the reaction by adding 50µL to 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.
Step12 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.

INTERPRETATION OF RESULTS AND QUALITY CONTROL

A. CALCULATIONS:

1**. 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 on the kit box.

2. **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 Calibrator = cutoff OD value)

3. Index Values or OD Ranges
Calculate the Index Value or OD Ratio for each specimen by dividing its OD value by the cutoff OD from step 2.

Example:

Mean OD of Calibrator	= 0.793
Correction Factor (CF)	= 0.25
Cutoff OD	= 0.793 x 0.25 = 0.798
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

Use the above guidelines when evaluating or interpreting patient specimens. Equivocal specimens should be repeated. Specimens which are repeatedly equivocal should be evaluated using an alternative serological method. Elevated autoantibody levels to Snl-70 may be indicative of a specific rheumatoid disorder.

TEST PERFORMANCE AND EXPECTED RESULTS

The expected value for a normal patient is a negative result. The number of reactives, and the degree of reactivity is dependent upon parameters such as population type being tested, treatment, etc. Each laboratory should establish their own expected values based upon the specimens typically being tested.

Comparative Study:
A comparative study was performed to demonstrate the equivalence of the DAI Sm Elisa test system to other commercially available autoantibody ELISA test systems. The performance of the DAI Elisa's was evaluated using 337 serum specimens; 152 normal donor samples from the northeastern and southeastern United States, and 185 disease-state repository samples previously characterized with respect to autoantibody activity. The results of the investigation have been summarized in Tables 1 and 2 below.

Table 1. Relative Sensitivity,
n=177 Disease State Specimens

Autoantigen	A	B	C	D	Sensitivity
Sm	13	16	3	13	13/13 = 100%

A. Number of specimens reactive on DAI test system.
B. Number of specimens reactive to Commercial test system.
C. Number of discrepant specimens
D. Number of positive specimens in the population after resolution of the discrepant specimens using alternate methodology such as gel immunodiffusion (GID), IFA, and third-party ELISA tests.

Table 2. Relative Specificity;
Normal Donor Specimens

Autoantigen	E	F	G	H	Specificity
Sm	136	137	1	137	136/137 = 99.3%

E. Number of specimens non-reactive on DAI test system.
F. Number of specimens non-reactive on Commercial Elisa test system.
G. Number of discrepant specimens.
H. Number of non-reactive specimens in the population after resolution of the discrepant specimens using alternate methodology such as gel immunodiffusion (GID), IFA, and third-party ELISA tests.

Reproducibility
To assess the intra-assay and inter-assay variability of the test systems, a strong positive, a low positive, and a negative sample for all of the autoantigens were tested eleven times on each of three days. The mean unit value, the standard deviation, and the percent CV were calculated for each sample. The results of this study are depicted in Tables 3-6 below:

Table 3. Intra-Assay Reproducibility
"High Positive" Specimen;
DAI Sm IgG Elisa

	Day 1			Day 2			Day 3		
Antigen	Mean	SD	%CV	Mean	SD	%CV	Mean	SD	%CV
Sm	576	71	12	690	71	10	702	29	4

Table4. Intra-Assay Reproducibility;
"Low Positive" Specimen
DAI Sm IgG Elisa

	Day 1			Day 2			Day 3		
Antigen	Mean	SD	%CV	Mean	SD	%CV	Mean	SD	%CV
Sm	460	43	9	587	52	9	392	28	7

Table5. Intra-Assay Reproducibility;
Negative Specimen;
DAI Sm IgG Elisa

	Day 1			Day 2			Day 3		
Antigen	Mean	SD	%CV	Mean	SD	%CV	Mean	SD	%CV
Sm	12	3	N/A	8	3	N/A	7	1	N/A

Table6. Inter-Assay Reproducibility;
DAI Sm IgG Elisa;
DAI Sm IgG Elisa

	Day 1			Day 2			Day 3		
Antigen	Mean	SD	%CV	Mean	SD	%CV	Mean	SD	%CV
Sm	656	85	13	479	93	19	9	3	N/A

Cross Reactivity
Specimens negative for ANA by HE;-2 IFA and positive for IgG antibody to various antigens such as EBV-VCA, EBNA, HSV-1/2, CMV, Rubella, and/or Toxo, were tested for potential cross reactivity

using the DAI Sm IgG Elisa Test system. All specimens tested were negative on the Elisa, indicating that the potential for cross reactivity with such antibodies is not likely, and therefore should not interfere with the results obtained.

QUALITY CONTROL

1. Each time the assay is run the calibrator must be run in triplicate. A reagent blan, 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 using the remaining two wells.
3. The mean OD value for the Calibrator and the OD values for the Positive and Negative Controls should fall within the following ranges:

	OD Range
Negative Control	≤0.250
Calibrator	≥0.300
Positive Control	≥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 devided by the mean OD of the Calibrator should be ≥1.25.
   c. If the above conditions are not met the test should be considered invalid and should be repeated.
4. The positive Control and Negative control are intended to monitor for substantial reagent failure and will not ensure precision at the assay cut-off.
5. Additional controls may be tested according to guidelines of requirements of local, state, and/or federal regulations or accrediting organizations.
6. Refer to NCCLS document C24: Statistical Quality Control for Quantitative Measurements for guidance on appropriate QC practices.

LIMITATIONS

1. Any positive results must be interpreted in conjunction with patient clinical information and other laboratory testing results.
2. Common sources for mistakes: kits beyond the expiry date, bad washing procedures, contaminated reagents, incorrect assay procedure steps, insufficient aspiration during washing, failure to add samples or reagents, equipment, timing, volumes, sample nature and quality.
3. The prevalence of the marker will affect the assay's predictive values.
4. This is a qualitative assay and the results cannot be use to measure antibodies concentrations.
5. If, after retesting of the initially reactive samples, the assay results are negative , these samples should be considered as non-repeatable (false positive) and interpreted as negative. As with many very sensitive ELISA assays, false positive results can occur due to the several reasons, most of which are related but not limited to inadequate washing step.

INDICATIONS OF INSTABILITY OR DETERIORATION OF REAGENTS

1. Values of the Positive or Negative controls ,which are out of the indicated Quality control range, are indicator of possible deterioration of the reagents and/or operator or equipment errors. In such case, the results should be considered as invalid and the samples must be retested. In case of constant erroneous results classified as due to deterioration or instability of the reagents, immediately substitute the reagents with new ones

VALIDITY

Please do not use this kit beyond the expiration indicated on the kit box and reagent labels

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