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	Effective Date:	06-30-2022
	Document Type:	Standard Operating Procedure
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	Department/Section:	Clinical Chemistry
	Document Title:	ANTI-dsDNA

PURPOSE:

To describe in detail how to prepare and process the Anti-dsDNA test correctly and always in the same manner. ANTI-dsDNA is an enzyme-linked immunosorbent assay (ELISA) for the quantitative detection of dsDNA autoantibodies in human serum. The presence of antibodies to dsDNA can be used in conjunction with clinical findings and other laboratory tests to aid in the diagnosis of Systemic Lupus Erythematosus (SLE).

SCOPE:


Applies to all Clinical Chemistry Section Staff of Laboratory Department of Dr. Pablo O. Torre Memorial Hospital (DPOTMH)

PERSON RESPONSIBLE:

Doctors, Nurses, Medical Technologists, Pathologists, Patients

GENERAL GUIDELINES:

1. The Medical Technologist shall bring all reagents and test samples to room temperature before use. Exercise care to avoid cross contamination of reagents and samples.
2. Plasma shall not be used instead of serum since fibrinogen may cause nonspecific agglutination of the latex.
3. The procedure shall be done on the BEST 2000 Autoimmunity Analyzer following its procedures and protocols.
4. The Medical Technologist shall use only thoroughly cleaned equipment.
5. The Medical Technologist shall not test lipemic, icteric, and hemolyzed specimens.
6. Serum samples shall be stored at 2-8°C for up to 48 hours prior to testing period. If longer storage is necessary, sera shall be frozen at -20°C.


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PRINCIPLE:

A highly purified calf thymus dsDNA is bound to the wells of polystyrene microwell plate under conditions that will preserve the antigen in its native state. Pre-diluted patients sera are added to separate wells, allowing any dsDNA antibodies present to bind to the immobilized antigen. Unbound sample is washed away and an enzyme labelled anti-human IgG conjugate is added to each well. A second incubation allows enzyme-labelled anti-human IgG to bind to any patient antibodies, which have become attached to the microwells. After washing away any unbound enzyme labeled anti-human IgG, the remaining enzyme activity is measured by adding chromogenic substrate and measuring the intensity of the color that develops. The assays can be evaluated spectrophotometrically by measuring and comparing the color intensity that develops in patient wells with the color in the control wells.

PROCEDURE:

1. Turn on the machine first before opening the software by inserting the key on the right side to lock and hold the cover and switching on the button on the lower right portion of the instrument.
2. Double click the REVELATIONS DSX software on the desktop. The dialog box will appear after. Please select the first option which is: CONNECT TO DSX (ON PORT 1) and click DO IT.
3. You will be directed to the default page of the software, please check if each initialization result indicates "ALL TEST PASSED".
4. Click NEW button on the toolbars and select WORK LIST. Then select "ADD ASSAYS" using a new batch of samples.
5. Enter the names of the sample and select the specific tests to be performed by clicking "NEW PLATE". Choose assays from the list and click open. The scheduled assay will now appear on the upper portion which means that it is already scheduled. Then choose which test will be performed for each sample. Click "OK".

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Click The green forward button then the fast forward button. Fill in the LOT NAME, LOT NUMBER AND EXPIRY DATE and click Check button.

6. Load the plate, showing the assay and number of strips required. Fill the plate identifier with the format: ASSAY, MONTH, DATE, YEAR. Click the check button. Next, load calibrators and controls as indicated by their position. Press enter or click check as fluids are being loaded. Load reagents, wash buffers and consumables in their respected indicated positions. Make sure that solid and liquid waste are empty and click ok.




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Verified:	MONICA B. VILLANUEVA, RMT, PhD Laboratory Manager		07-13-2022
	MELANIE ROSE B. ZERRUDO, MD, FPSP Chair, Department of Pathology		07-13-2022
Reviewed:	DENNIS C. ESCALONA, MN, FPSQua Quality Assurance Supervisor		07-13-2022
Recommending Approval:	ROSARIO D. ABARING, MAN, PhD Ancillary Division Officer		07-13-2022
	FREDERIC IVAN L. TING, MD OIC - Total Quality Division		7/19/22
Approved:	GENESIS GOLDI D. GOLINGAN President and CEO		9/7/22

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KEY TASKS	PERSON RESPONSIBLE
1. Turns on the machine first before opening the software by inserting the key on the right side to lock and holds the cover and switching on the button on the lower right portion of the instrument.	Medical Technologist
2. Double clicks the REVELATIONS DSX software on the desktop, selects CONNECT TO DSX (ON PORT 1) and clicks DO IT.	
3. Checks if each initialization result indicates "ALL TEST PASSED" after being directed to the default page of the software.	
4. Clicks NEW button on the toolbars and select WORKLIST. Selects "ADD ASSAYS" using a new batch of samples.	
5. Enters the names of the sample and selects the specific tests to be performed by clicking "NEW PLATE". Chooses assays from the list and click open.	
6. Fills in the LOT NAME, LOT NUMBER AND EXPIRY DATE and click Check button.	
7. Loads the plate, showing the assay and number of strips required. Fills the plate identifier with the format: LOT NAME, LOT NUMBER AND EXPIRY	

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DATE and clicks Check button.	
8. Loads reagents, wash buffers and consumables in their respective indicated positions.	
9. Makes sure that solid and liquid waste are empty and click ok.	

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FLOWCHART



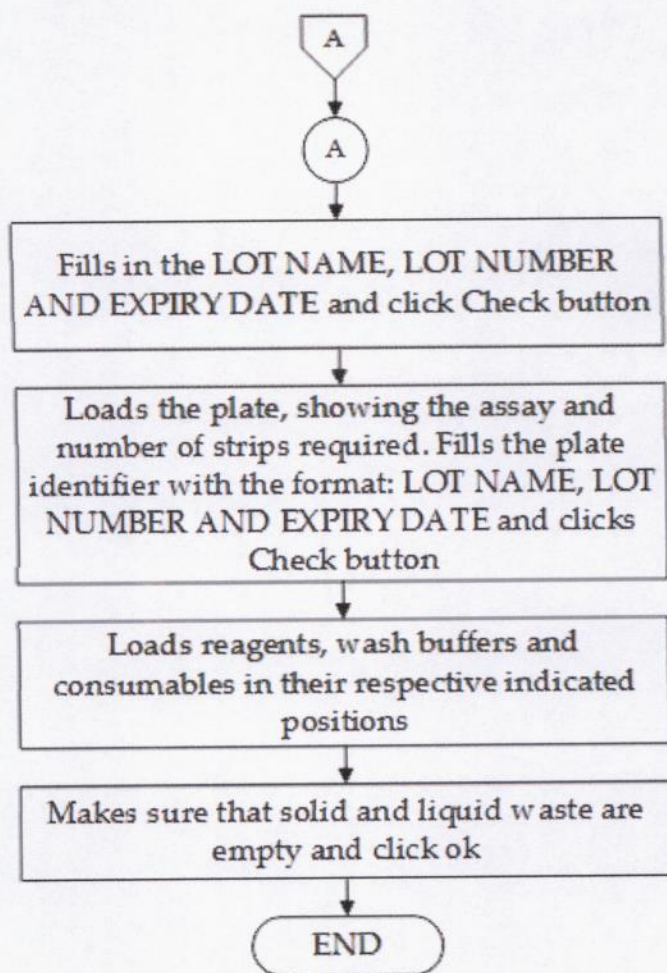



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FLOWCHART



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