DR. PABLO O. TORRE MEMORIAL HOSPITAL
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Document Code:	DPOTMH–E-55-P01-S08
Effective Date:	06-30-2022
Document Type:	Standard Operating Procedure
Page Number:	1 of 3
Department/Section:	Clinical Chemistry
Document Title:	**ANTINUCLEAR ANTIBODY ASSAY (ANA) QUALITATIVE**

PURPOSE:

To describe in detail how to prepare and process the Anti-Nuclear Antibody Assay (ANA) Qualitative test correctly and always in the same manner. The ANA (Antinuclear Antibody) test is one of the primary tests for helping to diagnose a suspected autoimmune disorder or rule out conditions with similar signs and symptoms.

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 Medical Technologist shall use a new plastic pipette for each sample. Pull plastic pipette out by grasping one end and use the paddle end for mixing reagent with sample.

4. The Medical Technologist shall rock the slide gently for no longer than 2 minutes after mixing reagents with sample.

5. The Medical Technologist shall not perform more than 6 tests at one time.

6. The Medical Technologist shall use only thoroughly cleaned equipment.

7. The Medical Technologist shall not test lipemic sera since no specific agglutination may occur.

8. 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.

PROCEDURE:

1. Bring all test reagents and sample to room temperature.
2. Use a clean plastic pipette to draw up and place 1 free falling drop of each undiluted sample into its identified ring of the disposable slide. Retain each pipette for mixing. (Step5)
3. Remove the tops of both positive and negative control. Invert each plastic vial and squeeze to express free falling drop of control into its identified ring.
4. Mix the Immuno/lex-sle latex reagent by mixing gentle shaking. Add 1 free falling drop of reagent to each control and sample.
5. Using the flattened end of the appropriate plastic pipette as a stirrer (Step2), thoroughly mix each sample with reagent within the full area of the ring. Discard the pipette/stirrer.
6. Slowly rock the slide for exactly 1 minutes and observe for agglutination under high intensity light.
7. Record results.

REFERENCES:

1. Immunolex-SLE package insert.
2. https://serfinitymedical.com/products/immuno-lex-sle-rapid-test-kit-latex-agglutination-test-systemic-lupus-erythematosus-sle-clia-moderate-complexity-100-tests

APPROVAL:

	Name/Title	Signature	Date
Prepared by:	**ALEXIS F. CORDIA JR., RMT** Section Head, Clinical Chemistry		07/01/2022
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

KEY TASKS	PERSON RESPONSIBLE
1. Brings all test reagents and sample to room temperature.	Medical Technologist
2. Uses a clean plastic pipette to draw up and place 1 free falling drop of each undiluted sample into its identified ring of the disposable slide.	
3. Removes the tops of both positive and negative control. Inverts each plastic vial and squeeze to express free falling drop of control into its identified ring.	
4. Mixes the Immuno/lex-sle latex reagent by mixing gentle shaking. Adds 1 free falling drop of reagent to each control and sample.	
5. Mixes each sample with reagent within the full area of the ring using the flattened end of the appropriate plastic pipette as a stirrer	
6. Rocks the slide for exactly 1 minutes and observe for agglutination under high intensity light.	
7. Records results.	

APPROVAL:

	Name/Title	Signature	Date
Prepared by:	**ALEXIS F. CORDIA JR., RMT** Section Head, Clinical Chemistry		07/07/2022
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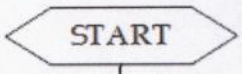
FLOWCHART



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Uses a clean plastic pipette to draw up and place 1 free falling drop of each undiluted sample into its identified ring of the disposable slide

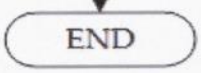
Removes the tops of both positive and negative control. Inverts each plastic vial and squeeze to express free falling drop of control into its identified ring

Mixes the Immuno/lex-sle latex reagent by mixing gentle shaking. Adds 1 free falling drop of reagent to each control and sample

Mixes each sample with reagent within the full area of the ring using the flattened end of the appropriate plastic pipette as a stirrer

Rocks the slide for exactly 1 minutes and observe for agglutination under high intensity light

Records results



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