

RaPET® s-LE

METHOD: Latex Agglutination

SPECIMEN: Serum

ASSAY TEMPERATURE: Room Temperature

CONTROLS: A Positive and a Negative Control each time of testing.

LIMITATIONS:

- A) Reactions should be read exactly at three (3) minutes following addition of the latex reagent to the serum specimen. A longer reaction time may cause false results due to a drying effect.
- B) Apparent false positive reactions have been associated with sera from patients with other diseases such as Rheumatoid Arthritis, Sjogren Syndrome, Mixed Connective Tissue Disease, Progressive Systemic Sclerosis, and Discoid L.E.
- C) Many widely used drugs may induce a systemic lupus erythematosus syndrome. Hydralazine, isoniazid, procainamide and a number of anti-convulsant drugs fall into this category.

PRINCIPLE: The Stanbio RaPET® s-LE Test provides a suspension of polystyrene latex particles which have been coated with native deoxyribonucleic protein (DNP) by means of an intermediary albumin-saline matrix. The coated latex particles combine with anti-DNP antibodies in serum to give a visible agglutination.

STORAGE: Store RaPET® s-LE reagents at 2-8°C (Refrigerated Temperature)
Do Not Freeze.

PROCEDURE:

- 1) Bring all reagents to room temperature and mix prior to use.
- 2) Place in separate divisions (cells) of the same slide; one drop of patient specimen, one drop of positive control and one drop of negative control using separate pipette/mixers.
- 3) Add one drop of s-LE latex reagent to each cell and mix with the flat end of the appropriate pipette/mixer, spreading the fluid evenly over each cell.
- 4) Rock slide back and forth slowly for exactly three (3) minutes and then observe for agglutination.
- 5) Record results.
- 6) Wash glass slide with a mild detergent and then rinse with distilled water.

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RESULTS: Any degree of agglutination visible within three (3) minutes is to be interpreted as positive. Test is considered s-LE negative when no difference in agglutination is observed between specimen and negative control.

REFERENCE: Stanbio RaPET® s-LE Instruction For Use, RBR.1160

Date of Review/Revision

Reviewed by _____
Lab Director/Supervisor