

TEST CHANGE

Fibrillarin (U3 RNP) Antibody, IgG 2012173, U3 FIB Specimen Requirements: Patient Preparation: Collect: Serum separator tube. Specimen Preparation: Transfer 1 mL serum to an ARUP standard transport tube.Standard Transport Tube. (Min: 0.5 mL) Transport Temperature: Refrigerated. Also acceptable: Frozen. Unacceptable Conditions: Grossly hemolyzed or severely lipemic. Remarks: Stability: After separation from cells: Ambient: 48 hours; Refrigerated: 2 weeks; Frozen: 1 month (avoid repeated freeze/thaw cycles).year Methodology: **Qualitative Immunoblot** Performed: Tue, Thu, Sat Reported: 1-4 days Note: CPT Codes: 86235

New York DOH Approval Status: This test is New York DOH approved.

Interpretive Data:

The presence of fibrillarin (U3-RNP) IgG antibodies in association with an ANA IFA nucleolar pattern is suggestive of systemic sclerosis (SSc). In SSc, these antibodies are associated with distinct clinical features, such as younger age at disease onset, frequent internal organ involvement (pulmonary hypertension, myositis and renal disease). Fibrillarin antibodies are detected more frequently in African American patients with SSc compared to other ethnic groups. Strong correlation with ANA IFA results is recommended.

In a <u>multiethnic</u> cohort of SSc patients (n=98), U3-RNP antibodies detected by immunoblot had an agreement of 98.9 percent with the gold standard immunoprecipitation (IP) assay. Approximately 71 percent (5/7) of the borderline U3-RNP results with ANA nucleolar pattern in this cohort were IP negative.

This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the US Food and Drug Administration. This test was



performed in a CLIA certified laboratory and is intended for clinical purposes.

Reference Interval:

Negative