

Risankizumab Quantitation with Antibodies, Serum

Test ID: RISAP

Useful for:

Evaluation of patients with limited primary (initial) response to or secondary loss of response to risankizumab

Profile Information:

Test ID	Reporting Name	Available Separately	Always Performed
RISA	Risankizumab, S	Yes	Yes
RISAB	Risankizumab Ab, S	No	Yes

Methods:

RISA: Liquid Chromatography Mass Spectrometry (LC-MS)

RISAB: Electrochemiluminescent-Bridging Immunoassay (ECLIA)

Reference Values:

RISANKIZUMAB QUANTITATION:

Risankizumab lower limit of quantitation =1.0 mcg/mL

RISANKIZUMAB ANTIBODIES:

Antibodies to risankizumab: <20.0 ng/mL

Specimen Requirements:

Patient Preparation: For 12 hours before specimen collection, patient **should not** take multivitamins or dietary supplements (eg, hair, skin, and nail supplements) containing biotin (vitamin B7).

Supplies: Sarstedt Aliquot Tube, 5 mL (T914)

Container/Tube:

Preferred: Red top

Acceptable: Serum gel

Specimen Volume: 1.5 mL

Collection Instructions:

1. Draw blood immediately before next scheduled dose (trough specimen).
2. Within 2 hours of collection, centrifuge, and aliquot serum into a plastic vial.

Minimum Volume: 0.75 mL

Specimen Stability Information:

Specimen Type	Temperature	Time
Serum	Refrigerated (preferred)	28 days
	Frozen	28 days

Cautions:

Clinical management decisions for patients receiving risankizumab treatment should not be based solely on quantitation of risankizumab or assessment of antibodies to risankizumab (ATRs). Test results must be interpreted within the clinical context of the patient.

Therapeutic ranges have not been established for risankizumab quantitation. Therapeutic concentrations of risankizumab may vary according to the disease (eg, Crohn disease vs psoriatic arthritis vs plaque psoriasis). The limit of quantitation of the liquid chromatography time-of-flight (TOF) mass spectrometry method is 1.0 mcg/mL and reported in place of a reference interval with every test report.

Interference with the ATR assay, in the form of depressed signal, was observed in samples containing more than 400 ng/mL biotin.

CPT Code:

80299

82397

Day(s) Performed: Weekly

Report Available: 2 to 9 days

Questions

Contact Amy Ennis, Laboratory Resource Coordinator at 800-533-1710.