

Guselkumab Quantitation with Antibodies, Serum

Test ID: GUSAP**Useful for:**

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

Profile Information:

Test ID	Reporting Name	Available Separately	Always Performed
GUS	Guselkumab, S	Yes	Yes
GUSAB	Guselkumab Ab, S	No	Yes

Methods:

GUS: Liquid Chromatography Mass Spectrometry (LC-MS)

GUSAB: Electrochemiluminescent Bridging Immunoassay (ECLIA)

Reference Values:

GUSELKUMAB QUANTITATION:

Guselkumab lower limit of quantitation = 0.5 mcg/mL

ANTIBODIES TO GUSELKUMAB:

<9.8 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).**Container/Tube:****Preferred:**

Serum gel

Acceptable:

Red top

Submission Container/Tube:

Plastic vial

Specimen Volume:

1.1 mL serum

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:

Serum: 0.75 mL

Specimen Stability Information:

Specimen Type	Temperature	Time
Serum	Refrigerated (preferred)	28 days
	Ambient	24 hours
	Frozen	28 days

Cautions:

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

Therapeutic ranges have not been established for guselkumab quantitation. Therapeutic concentrations of guselkumab 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 mass spectrometry method is 0.5 mcg/mL and reported in place of a reference interval with every test report.

Interference with the ATG assay, in the form of depressed signal, was observed in samples containing more than 200 ng/mL biotin.

CPT Code:

80299

83520

Day(s) Performed: Weekly

Report Available: 2 to 9 days

Questions

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