Test Definition: GUSAP

Guselkumab Quantitation with Antibodies, Serum

Overview

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

Testing Algorithm

For more information see Ulcerative Colitis and Crohn Disease Therapeutic Drug Monitoring Algorithm.

Special Instructions

- Ulcerative Colitis and Crohn Disease Therapeutic Drug Monitoring Algorithm

Method Name

GUS: Liquid Chromatography Mass Spectrometry (LC-MS)
GUSAB: Electrochemiluminescent Bridging Immunoassay (ECLIA)

NY State Available

Yes

Specimen

Specimen Type

Serum

Specimen Required

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: 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.

Specimen Minimum Volume

Serum: 0.75 mL

Reject Due To

Gross hemolysis	OK
Gross lipemia	Reject
Gross icterus	OK
Heat-treated specimens	Reject

Specimen Stability Information

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

Clinical & Interpretive

Clinical Information

Guselkumab (Tremfya; Johnson and Johnson) is a fully human IgG1 lambda therapeutic monoclonal antibody used for the treatment of moderate to severe ulcerative colitis (UC) and Crohn disease (CD), as well as plaque psoriasis and psoriatic arthritis. Guselkumab targets interleukin (IL) 23A (IL-23p19) binding with high affinity to the p19 subunit and inhibiting further action.

Therapeutic drug monitoring (TDM) has become standard of care in the gastroenterology practice for biologic therapies used in CD and UC. TDM is routinely used to assess loss of response to therapy and proactively manage patients taking tumor necrosis factor inhibitors (eg, infliximab and adalimumab), alpha-4-beta7 integrins (vedolizumab), and IL-12/23 blockers (ustekinumab). With the approval of guselkumab for inflammatory bowel disease, TDM is expected to play an important role in managing loss of response to therapy and guide decision making for use of monotherapy or combination therapy.

The dosing of guselkumab varies according to the condition it is prescribed to treat. Patients with psoriatic arthritis and plaque psoriasis receive 100 mg subcutaneously at weeks 0 and 4 and every 8 weeks thereafter. Patients with UC are treated with 3 intravenous infusions of 200 mg each at weeks 0, 4, and 8, followed by 100 mg or 200 mg subcutaneously at week 12 and every 4 weeks thereafter. Mean steady state trough serum guselkumab concentration was 1.2 mcg/mL in both psoriatic arthritis and plaque psoriasis patients. UC mean steady-state trough concentrations were 1.4 and 10.7 mcg/mL, with 100 mg and 200 mg dose at maintenance stage, respectively. CD mean steady-state trough concentrations

were 1.2 and 10.1 mcg/mL, with 100 mg and 200 mg dose at maintenance stage, respectively.

Guselkumab, like other therapeutic monoclonal antibodies, is immunogenic. Clinical trials have shown that antibodies-to-guselkumab occur at rates of about 6% to 9% for plaque psoriasis, 2% for psoriatic arthritis, 11% for UC, and 5% for CD. The presence of anti-drug antibodies against therapeutic monoclonal antibodies has been shown to impact clinical efficacy, either by accelerated clearance or by inhibition of target binding. Assessment for the presence of antibodies to guselkumab (ATG) may be important for the management of patients, especially for those individuals with sub-therapeutic trough concentrations of guselkumab. For those individuals demonstrating loss of response in the context of sub-therapeutic drug concentrations, the presence of ATG may indicate the need to transition to another treatment approach. In contrast, those individuals with sub-therapeutic drug concentrations in the absence of detectable ATG may benefit from dose escalation.

Reference Values

GUSELKUMAB QUANTITATION:
Guselkumab lower limit of quantitation = 0.5 mcg/mL

ANTIBODIES TO GUSELKUMAB:
<9.8 ng/mL

Interpretation

The presence of detectable anti-guselkumab antibodies may be associated with increased guselkumab clearance and lower circulating concentrations of guselkumab in serum. Low trough concentrations of guselkumab may be correlated with loss of response to the drug.

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.

Clinical Reference

1. Janssen Biotech, Inc. Highlights of prescribing information: Tremfya (guselkumab) 2017. Updated September 2025. Accessed October 2, 2025. Available at www.janssenlabels.com/package-insert/product-monograph/prescribing-information/TREMFYA-pi.pdf
2. The efficacy and safety of guselkumab induction therapy in patients with moderately to severely active ulcerative colitis: Results from the Phase 3 QUASAR Induction Study. Gastroenterol Hepatol (N Y). 2023;19(7 Suppl 3):9-10
3. Peyrin-Biroulet L, Allegretti JR, Rubin DT, et al. Guselkumab in patients with moderately to severely active ulcerative colitis: QUASAR Phase 2b Induction Study. Gastroenterology. 2023;165(6):1443-1457. doi:10.1053/j.gastro.2023.08.038

4. Danese S, Panaccione R, Feagan BG, et al. Efficacy and safety of 48 weeks of guselkumab for patients with Crohn's disease: maintenance results from the phase 2, randomized, double-blind GALAXI-1 trial. Lancet Gastroenterol Hepatol. 2024;9(2):133-146
5. Shao J, Vetter M, Vermeulen A, et al. Combination therapy with guselkumab and golimumab in patients with moderately to severely active ulcerative colitis: Pharmacokinetics, immunogenicity and drug-drug interactions. Clin Pharmacol Ther. 2024;115(6):1418-1427
6. Ladwig PM, Barnidge DR, Willrich MA. Quantification of the IgG2/4 kappa monoclonal therapeutic eculizumab from serum using isotype specific affinity purification and microflow LC-ESI-Q-TOF mass spectrometry. J Am Soc Mass Spectrom. 2017;28(5):811-817
7. Ladwig PM, Barnidge DR, Willrich MAV. Mass spectrometry approaches for identification and quantitation of therapeutic monoclonal antibodies in the clinical laboratory. Clin Vaccine Immunol. 2017;24(5):e00545-16
8. Sharma K, da Silva BC, Hanauer SB. The role of immunogenicity in optimizing biological therapies for inflammatory bowel disease. Expert Rev Gastroenterol Hepatol. 2025;19(3):243-258

Performance

Method Description

Guselkumab Quantitation:
Guselkumab is extracted from serum and measured by liquid chromatography mass spectrometry.(Unpublished Mayo method)

Guselkumab Antibodies:
Testing for antibodies to guselkumab is accomplished using a laboratory-developed immunoassay.(Unpublished Mayo method)

PDF Report

No

Day(s) Performed

Weekly

Report Available

2 to 9 days

Specimen Retention Time

14 days

Performing Laboratory Location

Mayo Clinic Laboratories - Rochester Superior Drive

Fees & Codes

Fees

- Authorized users can sign in to Test Prices for detailed fee information.
- Clients without access to Test Prices can contact Customer Service 24 hours a day, seven days a week.
- Prospective clients should contact their account representative. For assistance, contact Customer Service.

Test Classification

This test was developed and its performance characteristics determined by Mayo Clinic in a manner consistent with CLIA requirements. It has not been cleared or approved by the US Food and Drug Administration.

CPT Code Information

80299
83520

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
GUSAP	Guselkumab QN with Antibodies, S	In Process

Result ID	Test Result Name	Result LOINC® Value
622837	Guselkumab, S	In Process
623122	Guselkumab Ab, S	In Process
623291	GUSAB Interpretation	77202-0