MAYO CLINIC LABORATORIES

# Test Definition: GUS

Guselkumab, Serum

## Overview

### Useful For

Assessing the response to guselkumab therapy

Assessing the need for dose escalation

Evaluating the potential for dose de-escalation or discontinuation of therapy

Monitoring patients who need to be above a certain guselkumab concentration to improve the odds of a clinical response for therapy optimization

### Testing Algorithm

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

### Special Instructions

- Ulcerative Colitis and Crohn Disease Therapeutic Drug Monitoring Algorithm

### Method Name

Liquid Chromatography Mass Spectrometry (LC-MS)

### NY State Available

Yes

## Specimen

### Specimen Type

Serum

### Ordering Guidance

Therapeutic drug monitoring of guselkumab may be useful when assessing response to therapy is difficult or when patients need to be above a certain therapeutic concentration to improve the odds of a clinical response for therapy optimization, dose increases, or de-escalation or discontinuation of therapy.

### Specimen Required

**Supplies:** Sarstedt Aliquot Tube, 5 mL (T914)
**Collection Container/Tube:**
**Preferred:** Serum gel
**Acceptable:** Red top
**Submission Container/Tube:** Plastic vial
**Specimen Volume:** 0.5 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.

## Forms

If not ordering electronically, complete, print, and send Gastroenterology and Hepatology Test Request (T728) with the specimen.

## Specimen Minimum Volume

Serum: 0.25 mL

## Reject Due To

| | |
|---|---|
| Gross hemolysis | OK |
| Lipemia | Reject |
| Gross icterus | OK |

## Specimen Stability Information

| Specimen Type | Temperature | Time | Special Container |
|---|---|---|---|
| Serum | Refrigerated (preferred) | 28 days | |
| | Ambient | 7 days | |
| | 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 inflammatory bowel disease (IBD), 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), IL-12/23 blockers (ustekinumab). With the approval of guselkumab for IBD, 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 is immunogenic, like other therapeutic monoclonal antibodies. Clinical trials have shown 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.

### Reference Values

Lower limit of quantitation = 0.5 mcg/mL

### Interpretation

The optimal therapeutic concentration of guselkumab associated with favorable outcomes in inflammatory bowel disease is not known at this time. In ulcerative colitis, the recommendation is to use the lowest concentration that maintains response. The approved dosing regimen for ulcerative colitis involves an initial induction phase with intravenous infusions followed by maintenance doses with subcutaneous injections. According to the guselkumab package insert, mean steady-state trough serum guselkumab concentration ranged from 1.2 to 10.7 mcg/mL, depending on the dosing regimen used.(1)

Other therapeutic thresholds vary according to the disease, treatment regimen, and response or lack of response to therapy.

### Cautions

Lipemic samples will be rejected.

### Clinical Reference

1. Tremfya (guselkumab). Package insert. Johnson and Johnson; 2017. Updated March 2025. Accessed September 21, 2026. Available at www.janssenlabels.com/package-insert/product-monograph/prescribing-information/TREMFYA-pi.pdf
2. 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
3. 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
4. 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
5. 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
6. 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

## Performance

### Method Description
Guselkumab is extracted from serum and measured by liquid chromatography mass spectrometry.(Unpublished Mayo method)

### PDF Report
No

### Day(s) Performed
Wednesday

### Report Available
2 to 9 days

### Specimen Retention Time
2 weeks

### 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

### LOINC® Information

| Test ID | Test Order Name | Order LOINC® Value |
|---|---|---|
| GUS | Guselkumab, S | 112387-6 |

| Result ID | Test Result Name | Result LOINC® Value |
|---|---|---|
| 622837 | Guselkumab, S | 112387-6 |