MAYO CLINIC LABORATORIES

Test Definition: MIRI

Mirikizumab, Serum

Overview

Useful For

Assessing the response to mirikizumab 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 mirikizumab 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 mirikizumab 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.

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	28 days	
	Frozen	28 days	

Clinical & Interpretive

Clinical Information

Drug and target:
Mirikizumab (Omvoh, Lilly) is a humanized IgG4 monoclonal antibody that selectively binds the p19 subunit of interleukin 23 (IL23), inhibiting IL23 signaling.

Indications:
Mirikizumab is US Food and Drug Administration-approved for inflammatory bowel disease (IBD). It is used in moderately to severely active ulcerative colitis (UC) and Crohn disease (CD).

Pharmacokinetic highlights:
Mirikizumab has linear pharmacokinetics with dose-proportional exposure. Higher body weight is associated with lower mean concentrations of the drug. Dosing for UC is 300 mg IV at weeks 0, 4 and 8, followed by 200 mg subcutaneous injections at week 12 and every 4 weeks thereafter. Dosing for CD is 900 mg IV at weeks 0, 4 and 8, and 300 mg subcutaneous injections at week 12 and every 4 weeks thereafter. Steady state is achieved after approximately 16 weeks in therapy, and laboratory testing is recommended at trough, after steady state.(1)

Immunogenicity:
During clinical trials, 23% of UC and 13% of CD patients developed anti-drug-antibodies (ADA), with no clinically significant effect of ADA on safety of mirikizumab. In UC subjects only, some of the ADA identified had an association with reduced trough concentrations.

Evidence for therapeutic drug monitoring:
The prescribing information for mirikizumab notes an exposure-response relationship in UC, and in CD, this is not yet fully characterized. Validated therapeutic ranges and trough targets have not been established. Model-based steady state mirikizumab exposures during subcutaneous maintenance doses every 4 weeks in patients with IBD suggest trough concentrations ranging from 1.5 to 3.0 mcg/mL and Cmax (peak) around 10 to 11 mcg/mL.

Reference Values
Lower limit of quantitation = 0.5 mcg/mL

Interpretation
The optimal therapeutic concentration of mirikizumab associated with favorable outcomes in inflammatory bowel disease (IBD) is not known at this time. The recommendation is to use the lowest concentration that maintains response. Model-based analyses suggest steady-state trough concentrations of 1.5 to 3.0 mcg/mL, with peak concentrations of approximately 10 to 11 mcg/mL during subcutaneous maintenance dosing every-4 weeks in patients with IBD.

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. Omvoh (mirikizumab). Package insert. Eli Lilly and Company; 2023. Updated November 2025. Accessed March 9, 2026. Available at https://uspl.lilly.com/omvoh/omvoh.html?s=pi
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. Chua L, Friedrich S, Zhang XC. Mirikizumab pharmacokinetics in patients with moderately to severely active ulcerative colitis: Results from phase III LUCENT studies. Clin Pharmacokinet. 2023;62(10):1479-1491. doi:10.1007/s40262-023-01281-z
5. Kobayashi T, Matsuoka K, Watanabe M, et al. Efficacy and safety of mirikizumab as induction and maintenance therapy for Japanese patients with moderately to severely active ulcerative colitis: a subgroup analysis of the global phase 3 LUCENT-1 and LUCENT-2 studies. Intest Res. 2024;22(2):172-185. doi:10.5217/ir.2023.00043
6. Aslam M, Ali MH, Irfan H. Mirikizumab: A promising breakthrough in Crohn's disease treatment. Health Sci Rep. 2024;7(8):e2294. doi:10.1002/hsr2.2294

Performance

Method Description
Mirikizumab 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
MIRI	Mirikizumab, S	In Process

Result ID	Test Result Name	Result LOINC® Value
623669	Mirikizumab, S	In Process