MAYO CLINIC LABORATORIES

NEW TEST

Notification Date: November 8, 2023
Effective Date: December 7, 2023

Ravulizumab Monitoring Panel, Serum

Test ID: RAVMP

Useful for:

Monitoring of complement blockage by ravulizumab

Assessing the response to ravulizumab therapy

Assessing the need for dose escalation

Evaluating the potential for dose deescalation or discontinuation of therapy in remission states

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

Profile Information:

Test ID	Reporting Name	Available Separately	Always Performed
RAVUM	Ravulizumab Complement Blockage, S	No	Yes
RAVU	Ravulizumab, S	Yes	Yes
RAVIN	Ravulizumab Interpretation, S	No	Yes

Methods:

RAVUM: Enzyme-Linked Immunosorbent Assay (ELISA)
RAVU: Liquid Chromatography Tandem Mass Spectrometry, High Resolution Accurate Mass (LC-MS/MS HRAM)

Reference Values:

RAVULIZUMAB COMPLEMENT BLOCKAGE:
> or =46% normal

RAVULIZUMAB:
Lower limit of quantitation =5.0 mcg/mL
>175 mcg/mL: Therapeutic concentration for paroxysmal nocturnal hemoglobinuria and atypical hemolytic uremic syndrome

Specimen Requirements:

Patient Preparation:	1. Fasting preferred. 2. Suggest discontinuing natalizumab at least 4 weeks prior to testing for ravulizumab quantitation in serum. Patient should consult the healthcare provider who prescribed this drug to determine if discontinuation is an option. If not, ok to proceed with testing while taking natalizumab.
Supplies:	Aliquot Tube, 5 mL (T914)
Collection Container/Tube:	Red top (serum gel/SST are **not acceptable**)
Submission Container:	2 Plastic vials
Specimen Volume:	2 mL in 2 plastic vials, each vial containing 1 mL
Collection Instructions:	1. Draw blood immediately before next scheduled dose. 2. Immediately after specimen collection, place the tube on wet ice. 3. After sample has clotted on wet ice, centrifuge at 4 degrees C and aliquot serum into two 5 mL plastic vials. 4. Freeze specimen within 30 minutes of centrifugation. Sample must be placed on dry ice if not frozen immediately.
Minimum Volume:	1 mL in 2 plastic vials, each vial containing 0.5 mL

Specimen Stability Information:

Specimen Type	Temperature	Time
Serum	Frozen	14 days
Serum Red	Frozen	14 days

Cautions:

The complement blockage assay is a functional test and is dependent on correct sampling, storage, and shipping conditions. Both degradation by temperature and consumption of complement components will lead to falsely low function results. These are difficult to differentiate from real complement dysregulation or blockage, and in the event of poor preanalytical handling, ravulizumab concentrations are a more reliable indicator, as they are not subject to stringent temperature stability.

While preanalytic handling can lead to falsely low results, it is far less likely that it would lead to false normal results.

Complement testing may be ordered in several circumstances where standard treatment includes plasmapheresis or plasma exchange. The procedure itself, if traumatic, may activate complement and, therefore, may not be a true reflection of the patient's complement system. The recommendation is to collect blood prior to the plasma exchange whenever possible.

Functional results inconsistent with the clinical history should be verified with a new blood draw.

Specimens should be frozen immediately after collection.

Long term stability is optimal when the sample is kept at -70 degrees Celsius or lower prior to testing.

Results must be interpreted within the clinical context of the patient.

Patients in transition between eculizumab (ECULI / Eculizumab, Serum) and ravulizumab administration will have a result that is the sum of eculizumab plus ravulizumab in circulation. This assay will not clearly differentiate between these specific analytes and must be interpreted with caution.

Patients actively undergoing therapy with both natalizumab and ravulizumab (extremely rare scenario) could present with an assay interference. It is suggested patients discuss with their doctors the possibility of discontinuing natalizumab 4 weeks prior to testing. If discontinuation is not possible, it is ok to proceed with testing.

This test should not form the sole basis for a diagnosis or treatment decisions.

CPT Code:
80299
86161

Day(s) Performed: Varies

Report Available: 3 to 10 days

Questions

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