MAYO CLINIC LABORATORIES

Test Definition: FCZAC

Certolizumab and Anti-Certolizumab Antibody, DoseASSURE CTZ

Overview

Method Name
Electrochemiluminescence immunoassay (ECLIA); Surface Plasmon Resonance

NY State Available
Yes

Specimen

Specimen Type
Serum

Specimen Required
Patient Preparation: High serum biotin concentrations in patients taking biotin supplements may cause an interference in this assay. Patients may be advised to stop biotin consumption at least 72 hours prior to sample collection.
Collection Container/Tube:
Preferred: Red top
Acceptable: Serum gel
Submission Container/Tube: Plastic vial
Specimen Volume: 2 mL Serum
Collection Instructions:
1. Allow a minimum clotting time of 30 to 60 minutes.
2. Within 2 hours of collection, centrifuge and aliquot serum into a plastic vial.
3. Send frozen.

To avoid delays in turnaround time when requesting multiple tests, **submit separate frozen specimens for each test requested**.

Specimen Minimum Volume
Serum: 0.6 mL, Note: This volume does not allow for repeat testing.

Reject Due To

Gross hemolysis	Reject
Gross lipemia	Reject
Incorrect specimen type	Reject

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Serum	Frozen (preferred)	14 days	
	Refrigerated	14 days	

Clinical & Interpretive

Clinical Information

Refer to www.labcorp.com/test-menu

Reference Values

Certolizumab:
Quantitation Limit: <1.0 ug/mL

Results of 1 ug/mL or higher indicate detection of certolizumab

Anti-Certolizumab Antibody:
Quantitation Limit: <40 ng/mL

Results of 40 ng/mL or higher indicate detection of anti-certolizumab pegol antibodies.

Cautions

As with other biologics, the optimal certolizumab concentration depends upon patient-specific factors including co-morbidities, disease, and desired therapeutic endpoint.

Trough blood collection (just before the next dose) is suitable because target ranges and therapeutic cut-offs are established by clinical studies that typically evaluate trough concentrations.

Therefore, the timing of specimen collection should be considered when interpreting drug concentrations. Drug half-life should be factored in when evaluating non-trough concentrations.

Adequate drug trough levels do not guarantee clinical efficacy since primary non-response can be due to mechanistic failure.

Lack of clinical response may be due to inadequate drug exposure, immunogenicity or mechanistic mismatch. Positive anti-certolizumab antibodies should be interpreted in the context of the concomitant free certolizumab drug level.

Performance

PDF Report

No

Day(s) Performed
Tuesday

Report Available
10 to 21 days

Performing Laboratory Location
Esoterix Endocrinology

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
These tests were developed and their performance characteristics determined by LabCorp. They have not been cleared or approved by the Food and Drug Administration.

CPT Code Information
80299
82397

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
FCZAC	Certolizumab and Anti-Certo Ab	Not Provided

Result ID	Test Result Name	Result LOINC® Value
Z5637	Certolizumab	87404-0
Z5638	Anti-Certolizumab Antibody	87405-7