Test Definition: FCZAC

Certolizumab and Anti-Certolizumab Antibody, DoseASSURE CTZ

Overview

Useful For

Provides certolizumab drug concentration and anti-certolizumab antibodies in order to optimize treatment and facilitate clinical decision-making.

This assay may be helpful in any patient on certolizumab therapy for Crohn's disease, psoriasis, or other autoimmune condition.

Method Name

Electrochemiluminescence immunoassay (ECLIA); Surface Plasmon Resonance

NY State Available

Yes

Specimen

Specimen Type

Serum

Specimen Required

Specimen Type: Serum
Container/Tube: Red or SST
Specimen Volume: 2 mL
Collection Instructions: Draw blood in a plain red-top tube(s), serum gel tube(s) is acceptable. Spin down and send 2 mL of serum frozen in a plastic vial.
To avoid delays in turnaround time when requesting multiple tests, **please submit separate frozen specimens for each test requested**.

NOTE: 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.

Specimen Minimum Volume

0.60 mL (Note: This volume does not allow for repeat testing.)

Reject Due To

Gross hemolysis	Gross reject; Mild OK
Gross lipemia	Reject

Gross icterus	NA
Other/Tissue/Swab	Specimens other than indicated

Specimen Stability Information

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

Clinical & Interpretive

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

MAYO CLINIC LABORATORIES

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PDF Report
No

Day(s) Performed
Tuesday

Report Available
10-21 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