

Patient ID <b>SA00159249</b>	Patient Name <b>SAMPLE REPORT, FCZAC A</b>	Birth Date <b>1974-12-31</b>	Sex <b>F</b>	Age <b>48</b>
Order Number <b>SA00159249</b>	Client Order Number <b>SA00159249</b>	Ordering Physician <b>CLIENT,CLIENT</b>	Report Notes	
Account Information <b>C7028846 DLMP Rochester</b>		Collected <b>28 Mar 2023 10:00</b>		

## Certolizumab and Anti-Certo Ab

### Certolizumab

**Y036**
**<1.0 ug/mL**

Quantitation Limit: &lt; 1.0 ug/mL

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

#### COMMENTS:

- The optimal drug concentration depends upon patient-specific factors including co-morbidities, disease and desired therapeutic endpoint.
- In Crohn's Disease patients
- Certolizumab (CTZ) trough concentrations >20 ug/mL have been associated with greater clinical remission.(1)
- Higher CTZ trough concentrations >27.5 ug/mL have been associated with radiologic healing and symptom response. (2)
- Week 6 CTZ > 30 ug/mL corresponded to higher clinical remission rates. (3)
- In Rheumatoid Arthritis patients
- CTZ trough concentrations >23 ug/mL corresponded to more favorable EULAR response rates. (4)
- This certolizumab pegol drug assay measures the free fraction of certolizumab pegol (antibody-unbound certolizumab pegol) when serum anti-certolizumab pegol antibodies are present.

### Anti-Certolizumab Antibody

**Y036**
**40 ng/mL**

Quantitation Limit: &lt; 40 ng/mL

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

#### COMMENTS:

- In Crohn's disease, the incidence of anti-certolizumab antibodies has ranged from 3.3% to 25.3% (6). In rheumatoid arthritis, immunogenicity rates have been 7% (5) and 37% (4).
- Anti-drug antibody positivity should be interpreted in the context of the concomitant free drug level.
- The concomitant free certolizumab pegol drug concentration (reported above) is the pharmacodynamically active drug when anti-certolizumab pegol antibodies are present.
- Serial measurements over time may be helpful to assess the impact of immunogenicity on the free drug level.
- This anti-certolizumab pegol antibody assay is drug-tolerant, i.e. the detection of anti-certolizumab pegol antibodies is not impeded by the presence of certolizumab pegol in serum.
- All positive anti-certolizumab pegol antibody results are verified by a confirmatory test.

#### References:

1. Vande Casteele N et al. Gastroenter 2017;153:835–857.
2. Ramos GP et al. Gastroenter 2018;154(6):S826–7.
3. Sandborn W et al. Inflamm Bowel Dis 2012;18:S23.
4. Jani M et al. Ann Rheum Dis 2017;76:208–213.
5. Cimzia (R) (package insert). UCB, Inc. Smyrna, GA. 2016.
6. Vermeire S et al. Ther Adv Gastroenterol 2018;11:1–13.

These tests were developed and their performance characteristics determined by LabCorp. They have not been cleared or approved by the Food and Drug Administration. However, both drug and anti-drug antibody assays have been developed and validated in accordance with FDA Guidance for Industry documents: Bioanalytical Method Validation (2013) and Assay Development and Validation for Immunogenicity Testing of Therapeutic Protein Products (2016).

**Received: 29 Mar 2023 12:42**
**Reported: 31 Mar 2023 09:47**

#### Performing Site Legend

Code	Laboratory	Address	Lab Director	CLIA Certificate
Y036	Esoterix Endocrinology	4301 Lost Hills Road, Calabasas Hills, CA 91301		