Client: Example Client ABC123
123 Test Drive
Salt Lake City, UT 84108
UNITED STATES

Physician: Doctor, Example

Patient: Patient, Example

DOB	4/5/2004
Sex:	Female
Patient Identifiers:	01234567890ABCD, 012345
Visit Number (FIN):	01234567890ABCD
Collection Date:	01/01/2017 12:34

Infliximab or Biosimilar Activity and Neutralizing Antibody

ARUP test code 2008320

Infliximab Activity

Not Detected (Ref Interval: >=0.65)

INTERPRETIVE INFORMATION: Infliximab or biosimilar Activity, NAb

This test measures the capacity of infliximab to neutralize TNF activity. Additionally, infliximab neutralizing antibodies (NAb) are titered, reporting the minimal serum dilution at which blocking of infliximab activity is no longer observed.

This test is used to evaluate secondary response failures to infliximab therapy. Secondary response failure is defined as loss of clinical response after initial improvement of clinical signs and symptoms. Therapeutic decision should rest on both the clinical response and the knowledge of the fate of the drug including the emergence of immunogenicity in individual patients.

Circulating infliximab levels have been shown to vary considerably between patients. These differences relate to route and frequency of administration and patient-related features such as age, gender, weight, drug metabolism, and concomitant medications such as methotrexate and other immunosuppressants.

Clinical Interpretation of Infliximab and Antibody Testing Results in the Context of Treatment Failure

Infliximab Activity	Infliximab Neutralizing Antibody Titer	Interpretation
Not Detected	Not Detected	Sub-therapeutic dose. A higher dosage of infliximab or shortening the dosing interval may be appropriate.
Not Detected	Detected	Likely immune-mediated treatment failure. A change to another anti-TNF drug may be appropriate.
Detected - Below Target*	N/A	Sub-therapeutic dose. A higher dosage of infliximab or shortening the dosing interval may be appropriate.
Detected - Above Target*	N/A	A change to another type of therapy (not targeting

H=High, L=Low, *=Abnormal, C=Critical

TNF) may be appropriate if patient is not responding.

* AGA recommended target trough concentration for reactive monitoring of patients with active IBD on maintenance therapy is 5 ug/mL or greater for infliximab (Feuerstein JD et al, Gastroenterology 2017; 153:827-834). The AGA makes no recommendation regarding the use of routine, proactive therapeutic drug monitoring in adults with quiescent IBD treated with anti-TNF agents.

This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the US Food and Drug Administration. This test was performed in a CLIA certified laboratory and is intended for clinical purposes.

Infliximab Neutralizing Antibody Titer	1:32
EER Infliximab	See Note Access ARUP Enhanced Report using the link below: -Direct access:

VERIFIED/REPORTED DATES

Procedure	Accession	Collected	Received	Verified/Reported
Infliximab Activity	21-148-104342	5/28/2021 10:30:00 AM	5/29/2021 4:29:23 PM	5/31/2021 5:35:00 AM
Infliximab Neutralizing Antibody Titer	21-148-104342	5/28/2021 10:30:00 AM	5/29/2021 4:29:23 PM	5/31/2021 4:24:00 PM
EER Infliximab	21-148-104342	5/28/2021 10:30:00 AM	5/29/2021 4:29:23 PM	5/31/2021 5:35:00 AM

END OF CHART