

Patient: [REDACTED]

DOB: [REDACTED] Age: 35

Patient Identifiers: [REDACTED]

Visit Number (FIN): [REDACTED]

Gender: [REDACTED]

Client: [REDACTED]

Physician: [REDACTED]

ARUP Test Code: 2013612

Collection Date: 12/17/2020

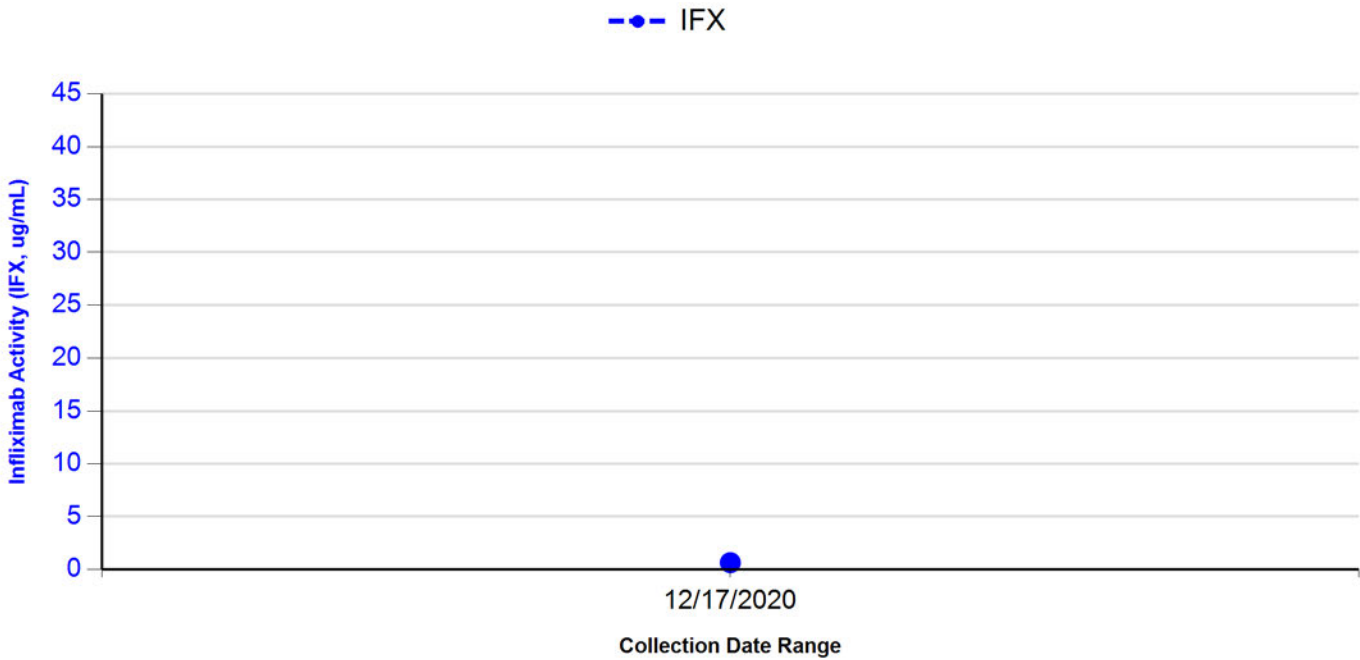
Received in lab: 12/18/2020

Completion Date: 12/18/2020

**Patient History \***

<u>Collection Date</u>	<u>Infliximab Activity (IFX) ug/mL</u>	<u>Accession Number</u>
12/17/2020	Not Detected	20-352-112370

**Infliximab Activity**



Cutoff values are 0.65 ug/mL for infliximab and 1:20 for antidrug antibody (NAb).

\*Consecutive test results are displayed on this chart; however, this result set may be incomplete due to variations in the demographic information submitted for prior tests. If the information on this chart appears incomplete, please consult this patient's prior charts.

**Interpretive Comments**

This test measures the capacity of infliximab to neutralize TNF activity. If infliximab is not detected, testing for neutralizing antibodies (NAb) will be performed. Infliximab NAb titer is obtained by identifying 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



Patient: [REDACTED]  
ARUP Accession: 20-352-112370

# Infliximab or Biosimilar Activity with Reflex to Antibody

Patient: [REDACTED] | Date of Birth: [REDACTED] | Gender: [REDACTED] | Physician: [REDACTED]  
Patient Identifiers: [REDACTED] | Visit Number (FIN): [REDACTED]

the clinical response and the knowledge of the fate of the drug including the emergence of immunogenicity in individual patients.

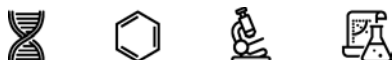
Circulating infliximab levels have been shown to vary considerably between patients. These differences relate to route and frequency of administration and patient-related features such as age, gender, weight, drug metabolism, and concomitant medications such as methotrexate and other immunosuppressants.

## Clinical Interpretation of Infliximab with Reflex to Antibody Testing Result in the Context of Treatment Failure

IF Infliximab Activity is...	AND Infliximab Neutralizing Antibody Titer is...	THEN...
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 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  $\geq 5$  ug/mL 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 U.S. Food and Drug Administration. This test was performed in a CLIA certified laboratory and is intended for clinical purposes.



Patient: [REDACTED]  
ARUP Accession: 20-352-112370  
[REDACTED]