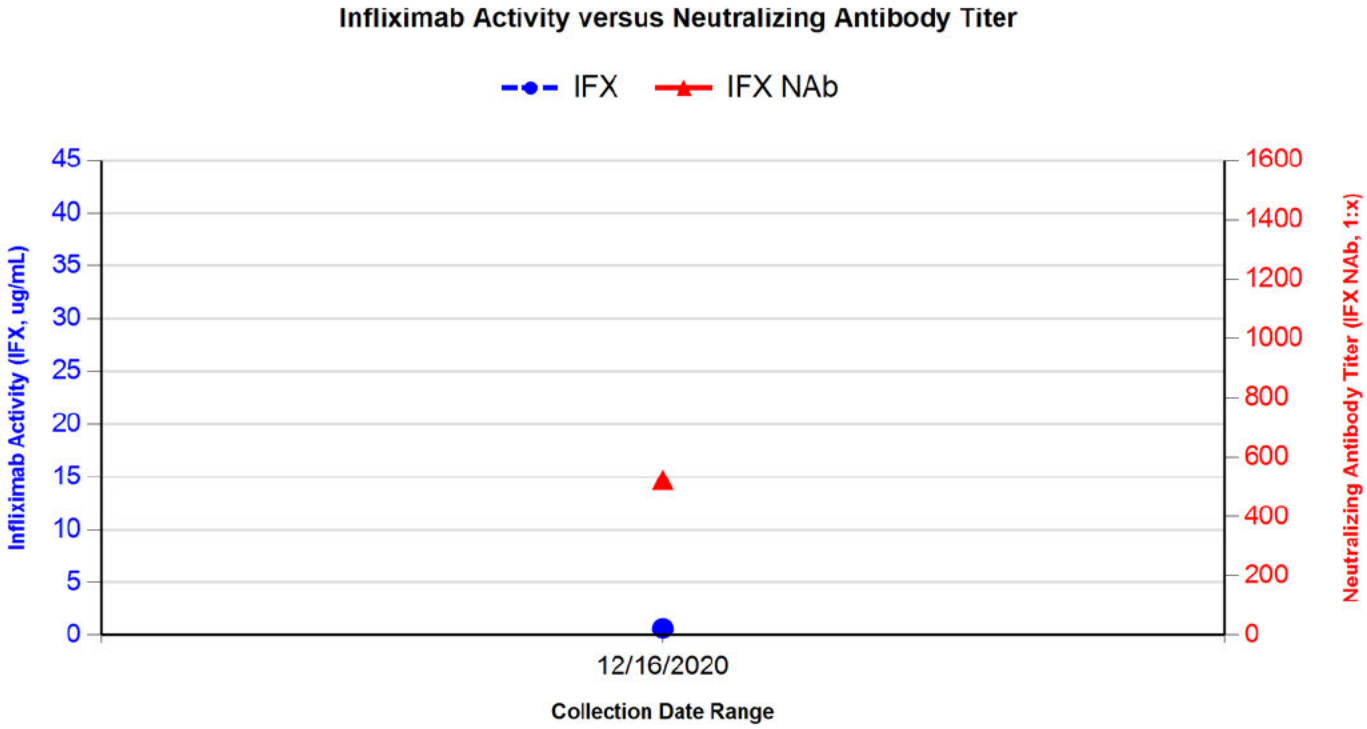
Infliximab or Biosimilar Activity and Neutralizing Antibody

ARUP LABORATORIES

Patient [redacted] DOB: [redacted] Age: 47 Gender: F **Patient Identifiers** [redacted] **Visit Number (FIN):** [redacted]	Client: [redacted] Physician: [redacted]	ARUP Test Code: 2008320 Collection Date: 12/16/2020 Received in lab: 12/17/2020 Completion Date: 12/19/2020

Patient History *

Collection Date	Infliximab Activity (IFX) ug/mL	Neutralizing Antibody (IFX NAb) Titer	Accession Number
12/16/2020	Not Detected	1:525	20-351-140310



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. 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

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 ≥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.

Test developed and characteristics determined by ARUP Laboratories. See Compliance Statement B: aruplab.com/CS