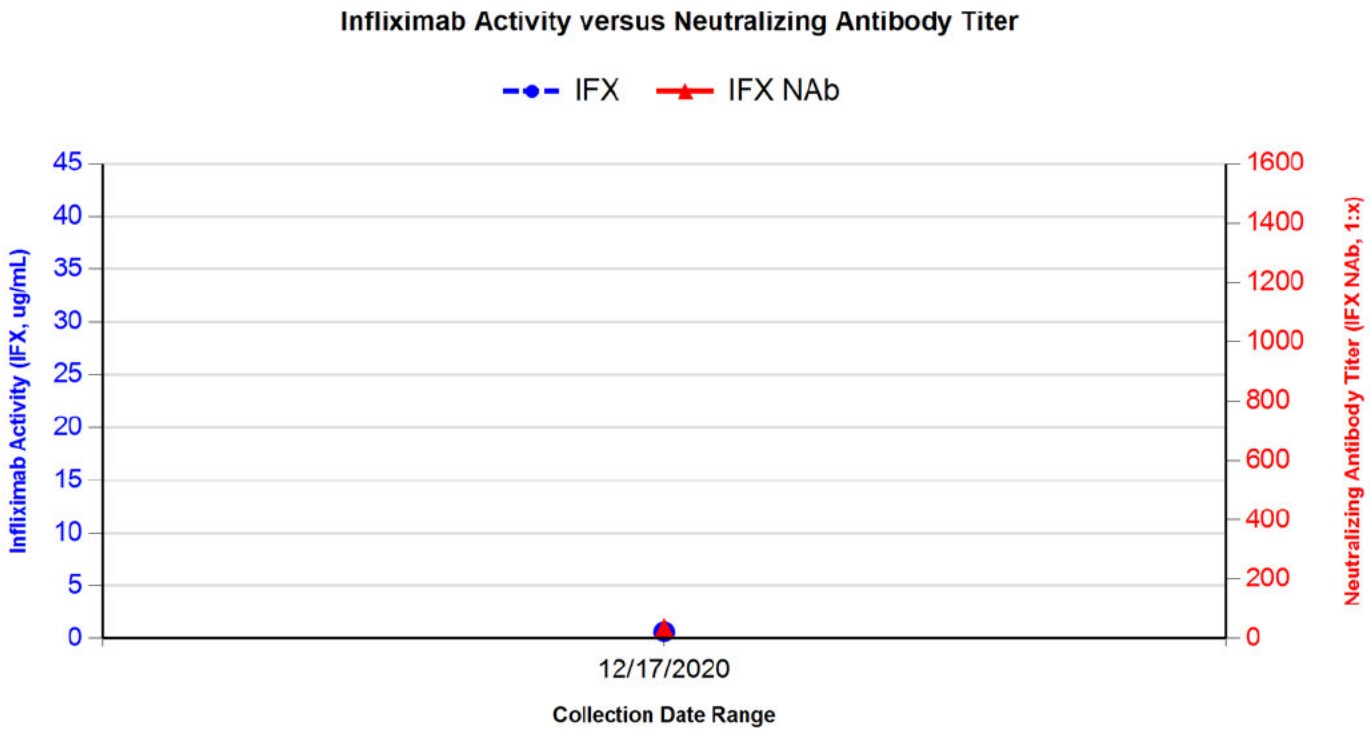
Infliximab or Biosimilar Reflex to Neutralizing Antibody Confirmation

ARUP LABORATORIES

Patient: [redacted] DOB: [redacted] Age: 35 Gender: M **Patient Identifiers:** [redacted] **Visit Number (FIN):** [redacted]	Client: [redacted] Physician: [redacted]	ARUP Test Code: 2013615 Collection Date: 12/17/2020 Received in lab: 12/18/2020 Completion Date: 12/19/2020

Patient History *

Collection Date	Infliximab Activity (IFX) ug/mL	Neutralizing Antibody (IFX NAb) Titer	Accession Number
12/17/2020	Not Detected	1:34	20-352-112370



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

Interpretive Data: This test measures the capacity of infliximab to neutralize TNF-alpha 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

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.

IF Infliximab Activity is...	AND Infliximab Neutralizing Antibody Titer is...	THEN...
Not Detected	Not Detected	A higher dosage of infliximab or shortening the dosing interval may be appropriate.
Not Detected	1:20 or greater	A change to another anti-TNF-alpha drug may be appropriate.
0.65 ug/mL or greater	Not Applicable	A change to another type of therapy (not targeting TNF-alpha) may be appropriate, if the patient did not respond adequately to infliximab therapy.

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.