Adalimumab Activity with Reflex to Antibody

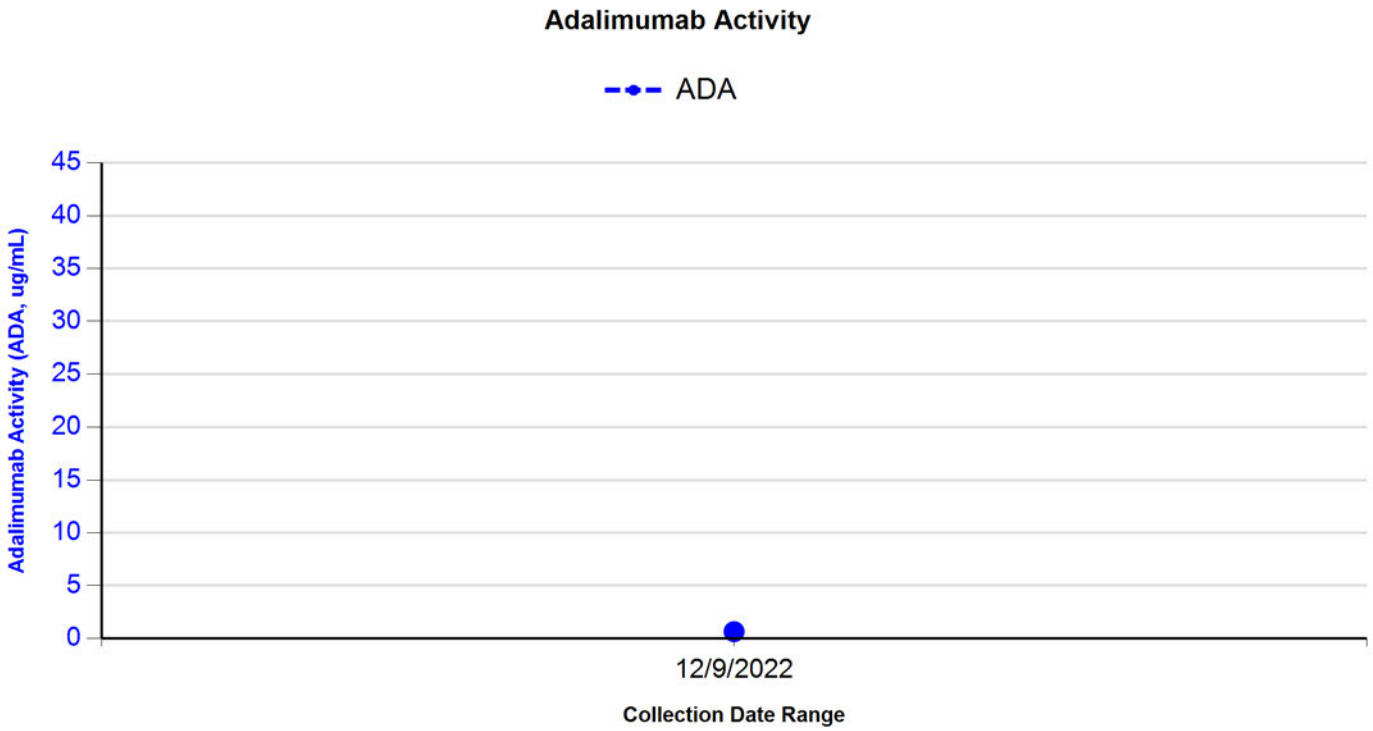
Patient: [redacted]
DOB: [redacted] Age: 84 Sex: F
Patient Identifiers: [redacted]
Visit Number (FIN): [redacted]

Client: [redacted]
Physician: [redacted]

ARUP Test Code: 2013605
Collection Date: 12/09/2022
Received in lab: 12/13/2022
Completion Date: 12/14/2022

Patient History *

Collection Date	Adalimumab Activity (ADA) ug/mL	Accession Number
12/9/2022	Not Detected	22-343-143925



Cutoff values are 0.65 ug/mL for adalimumab 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 adalimumab to neutralize TNF activity. If adalimumab is not detected, testing for neutralizing antibodies (NAb) will be performed. Adalimumab NAb titer is obtained by identifying the minimal serum dilution at which blocking of adalimumab activity is no longer observed.

This test is used to evaluate secondary response failures to adalimumab 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

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

Circulating adalimumab 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 Adalimumab with Reflex to Antibody Testing Result in the Context of Treatment Failure

IF Adalimumab Activity is...	AND Adalimumab Neutralizing Antibody Titer is...	THEN...
Not Detected	Not Detected	Sub-therapeutic dose. A higher dosage of adalimumab 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 adalimumab 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 ≥7.5 ug/mL for adalimumab (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.

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END OF CHART