Test Update 733

Posted Date 10/07/2020
Effective Date 10/14/2020
Update Type Replacement Test
CPT Code 80299, 82397

TEST CHANGE

Ustekinumab (Stelara) and Ustekinumab Antibodies

Order Code: FUKAU

CPT Code: 80299, 82397

Referral Laboratory: Mayo Medical Laboratories

REPLACEMENT TEST

Ustekinumab QN with Antibodies, Serum

Order Code: USEK

CPT Code: 80299, 83520

Referral Laboratory: Mayo Medical Laboratories

Effective October 14, 2020 MLabs will be discontinuing Ustekinumab (Stelara) and Ustekinumab Antibodies

(FUKAU) and replacing the test with Ustekinumab QN with Antibodies, Serum (USEK) per Mayo Medical Laboratories.

Collection Instructions: Collect approximately 1 mL of whole blood in a serum separator tube (SST) or red top immediately before next dose of drug administration (trough level). Centrifuge and aliquot the serum into a plastic tube and ship refrigerated (preferred) or frozen.

Methodology: Enzyme-Linked Immunosorbent Assay (ELISA)

Analytic Time: Test set up Tuesday and Friday, 1 day analytic time

Reference Range:

USTEKINUMAB QN, S:

Limit of quantitation is 0.3 mcg/mL

In inflammatory bowel disease, at post-induction measurement (week 8), concentrations above3.5 mcg/mL are associated with good outcomes

For maintenance stages:

Concentrations > or =1.0 mcg/mL are associated with clinical response and clinical remission

Concentrations > or =4.5 mcg/mL are associated with mucosal healing

USTEKINUMAB AB, S:

Limit of quantitation is 10 AU/mL

Absent: <10 AU/mL

Present: > or =10 AU/mL

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