# 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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