To: members of UPHS clinical staff

From: Leslie M Shaw, PhD, Michael C Milone, MD, PhD, JoAnn Gardiner, BS, MS, Ping Wang, PhD

Date: November 16, 2020

RE: Infliximab therapy monitoring test procedure

New Infliximab(Remicade) serum drug concentration monitoring test procedure effective November 16, 2020.

The Toxicology laboratory has validated and implemented a new test procedure for Infliximab (IFX) serum drug measurement using liquid chromatography-tandem mass spectrometry (LC-MSMS).

Infliximab, trade name Remicade, is a chimeric mouse/human IgG1 *κ* monoclonal antibody targeting TNF-α. This biological drug is FDA-approved for management of Crohn's disease and ulcerative colitis in adult and pediatric patients as well as for rheumatoid arthritis and psoriatic arthritis. The new procedure replaces IFX testing currently sent out to ARUP laboratory.

This testing requires a trough serum sample collected into a serum separator tube obtained just prior to the next IFX infusion after completion of the induction phase of the dosing schedule and at later times dependent on the patient's therapeutic response. The reference range for Crohn's disease and inflammatory bowel disease is >5 µg/mL. When the concentration is ≤ 5 µg/mL, the sample will be reflexively sent out for IFX antibody testing.

Testing schedule: IFX testing will be performed Mon, Weds, Friday on samples received by 9am. Results will be reported next business day. TAT for anti-IFX testing will be one week from the date the sample is sent out.

EPIC ordering information:

Test name is: Infliximab Quantitation with Reflex Antibody Testing.

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