Therapeutic Drug Monitoring by HPLC-MS (CPT-Various)

**Clinical Use/Background:** Therapeutic drug monitoring is an important tool for the clinical management of patients receiving pharmacotherapy, particularly in psychiatry and pain management. There is evidence of therapeutic and economic benefits of monitoring these drugs to avoid adverse effects, intoxication, no response or non-compliance. To assist in identifying potentially dangerous drug interactions, our pain management drug test profiles include both illicit and prescription drugs. Pain management drug testing is performed at levels appropriate for drugs prescribed in pain treatment. Proteopath’s pain management profiles include specimen validity testing to identify dilute, adulterated, or substituted specimens that may affect test results.

**Specimen Requirements:** 1.5 mL Serum from a Plain Red Top tube separated from cells immediately or 5 ml Urine in an appropriately sealed container.

**Specimen Stability:** Serum should be refrigerated and < 1 week old for submission, frozen serum acceptable up to 30 days. Urine can be kept at room temperature if submitted same day otherwise, it should be refrigerated if transport to lab > 5 days.

**Specimen Rejection Criteria:** Urine with visual contaminants, serum not separated from cells, serum from gel-barrier tube, EDTA specimens, Heparin specimens.

**Shipping/Transport/Hours of Operation:** Laboratory operates from 7:30 am to 5:00pm, please deliver specimens to Sarofim Research Building, Institute for Molecular Medicine, 1825 Pressler Street, Suite 511, Houston, TX 77030. Specimens may be mailed in accordance with local, state and federal law and must comply with D.O.T. standards for transportation of biological hazards.

**Turnaround Time:** 4 days from receipt in lab.

**Methodology:** LC-MS-MS, LC-MS TOF.

This test was developed and its performance characteristics determined by ProteoPath Dx Laboratory. The U.S. Food and Drug Administration (FDA) has not approved or cleared this test. However, FDA approval or clearance is currently not required for clinical use of this test. The results are not intended to be used as the sole means for clinical diagnosis or patient management decisions. ProteoPath Dx Laboratory is authorized under Clinical Laboratory Improvement Amendments (CLIA) to perform high-complexity testing.

**Reference Range:** Therapeutic ranges for the various prescription drug compounds vary and prescribing information for a specific prescription drug should be followed according to manufacturer’s specifications. Prescribing information and appropriate levels may be obtained from a reliable source such as the Physician’s Desk Reference.