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Specimen Information

AAS22-3003-0000114

Specimen Type: Serum

Date Collected: 01/10/2022
Date Received: 01/11/2022 15:48
Date Reported: 01/11/2022 16:08

Patient Information

Name: **Test Patient**

Date of Birth: 12/07/1955
Requisition # testreq2

Sex: Male
Age: 66

CPT Codes: 82657 x2, 83516. Clinical History: DLI 01/03/2022 TLI 13:55

Physician Information

TESTING
TESTPRACTICECREATEDON0826
123 NOWHERE STREET
ANYWHERE CITY, VA 23294

Phone: 804-965-9225
Fax: 804-545-1686

Asparaginase-Drug UnSpecified Results

Patient MRN: 7515699

Sample ID: 4856541

Calibration of the asparaginase assay is dependent on the exact formulation of L-asparaginase administered to the patient.

ACTIVITY

If the administered drug was Rylaze, the asparaginase activity is: 0.852 IU/mL

If the administered drug was Oncaspar, the asparaginase activity is: 0.721 IU/mL

If the administered drug was Erwinaze, the asparaginase activity is: 1.003 IU/mL

ANTIBODIES

Asparaginase-Antibodies are: Detected

Assay Methodologies and Limitations of Asparaginase-Drug UnSpecified™

Asparaginase Enzyme Activity Quantification Assay utilizes a spectrophotometry/absorbance-based enzyme-coupled kinetic reaction. Measurements of unknown samples are made against a standard curve generated from E. coli L-asparaginase with each run. Calculations for Rylaze®, Erwinaze® and Oncaspar® were empirically derived and utilize a correction factor that has been correlated to the E. coli L-asparaginase activity. Since Asparaginase concentrations can vary widely from patient to patient there is no reference range for this assay.

The Asparaginase antibody assay is an ELISA based assay and is only intended to report the presence or absence of antibodies against Asparaginase. This assay does not specifically identify neutralizing antibodies. Antibodies should not be present in normal human serum but may be present in patients on Asparaginase therapy.

These tests were developed and their performance characteristics determined by Granger Genetics. Neither assay has been cleared or approved by the FDA. The laboratory is regulated under CLIA as qualified to perform high-complexity testing. This test is used for clinical purposes. It should not be regarded as investigational or for research.