L-asparaginase Activity Assay

Testing for patients undergoing leukemia treatment

Introducing a laboratory developed test (LDT) to determine the enzyme activity of L-asparaginase in patients who have been treated with Oncaspar or Erwinaze. This assay has been validated and is performed in our Joint Commission/CLIA accredited laboratory to monitor the asparaginase activity level during a patient’s treatment.

L-asparaginase is a high molecular weight enzyme which often induces an immune response in a significant percentage of treated patients. As a result, hypersensitivity to L-asparaginase is a clinically relevant issue regardless of the source from which the drug was prepared. There are two forms of hypersensitivity seen in clinical practice. Clinical hypersensitivity ranges from a mild local injection site reaction to full blown anaphylaxis. Since asparaginase derived from E. coli is frequently used as first treatment, patients who develop a reaction are switched to Erwinaze (derived from Erwinia chrysanthemi) to continue their treatment because of the lack of cross-reactivity of anti-E. coli antibodies to Erwinaze.

The second form of hypersensitivity is when antibodies are formed, but the patients do not experience signs of hypersensitivity. Even though there are no outward symptoms, these antibodies can either inactivate the enzyme or enhance the metabolism of asparaginase such that the patient may not have adequate serum activity levels to achieve an anti-leukemic effect (often referred to as “silent inactivation” or “silent hypersensitivity”).

Our L-asparaginase activity test can help physicians identify patients experiencing “silent inactivation” as well as to ensure that adequate asparaginase activity is present during asparaginase treatment. The assay is performed on a serum sample obtained from the patient after treatment. A minimal volume of sample (0.2 mL) is required; and the results are returned overnight. For further information, please contact our customer service team.

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Asparaginase activity is determined by a coupled enzymatic assay. Samples with activities exceeding the upper range of the calibration curve are re-assayed after diluting with blank human serum.

Performance parameters are as follows:

Accuracy: %Error/Bias = 6%
Within-Lab Precision: %CV = 9.7%
Reportable Range: 42mIU / mL to 900nIU / mL

References