

DETERMINATION OF L-ASPARAGINASE ACTIVITY LEVELS IN HUMAN CLINICAL SAMPLES TAKEN FROM PATIENTS UNDERGOING CHEMOTHERAPEUTIC TREATMENT FOR LEUKEMIA

NEXT Bio-Research Services, LLC, dba NEXT Molecular Analytics, has just completed its second year of providing a laboratory derived test to measure the enzyme activity of L-asparaginase in patients who have been treated with Oncaspar[®], Asparlas[®], Erwinaze[®], or Rylaze[®] (recombinant Erwinaze). We have surpassed 10000 clinical samples assayed. This test has been validated to meet CLIA and CAP standards, and under applicable principles of Good Laboratory Practices. This assay is performed in our Clinical Laboratory Improvement Amendments (CLIA) certified laboratory to monitor the asparaginase activity level during a patient's treatment.



The test is intended to monitor asparaginase levels during the course of patient treatment, and has proved most useful to clinicians who are facing the prospect of ineffective treatment due to the presence of neutralizing antibodies and/or accelerated clearance. The test will help ensure that adequate asparaginase activity is present during treatment. L-asparaginase is a high molecular weight enzyme which often induces an immune response in a significant percentage of treated patients.⁽¹⁾ As a result,

hypersensitivity to L-asparaginase is a clinically relevant issue regardless of the source from which the drug is prepared.⁽²⁾ An "algorithm" of when to test clinical samples has been developed.⁽³⁾

The assay is done on a serum or plasma sample obtained from the patient after treatment. A minimal volume of sample (0.3 mL serum or plasma) is required which is sent to our lab on cold packs using sample collection kits that we provide. The results are returned in short-order, usually by the close of business the same day that the sample is received. In essence our LDT assay offers real time therapeutic monitoring.

The cost per test is \$165.00 (subject to change with adequate notice).

About NEXT Molecular Analytics

NEXT is a comprehensive contract research organization which provides integrated research and development sciences and clinical testing services to physicians and life science investigators in biotechnology and pharmaceutical companies, academic institutions, and in several different government agencies. Contact NEXT at 1-844-812-7415 (email info@nextmolecular.com) for more information about this test, to inquire about our menu of clinical test services, or to order your sample collection kits.

- (1) Woo MH, Hak LJ, Storm MC et al. Hypersensitivity or development of antibodies to asparaginase does not impact treatment outcome of childhood acute lymphoblastic leukemia. *Journal of Clinical Oncology*, 2000;18:1525-1532.
- (2) Raetz EA, Salzer WL. Tolerability and efficacy of L-asparaginase therapy in pediatric patients with acute lymphoblastic leukemia. *Journal of Pediatric Hematology Oncology*, 2010; 32:554-563.
- (3) Bleyer A, Asselin B, Koontz S, Hunger S. *Pediatr Blood Cancer* . 2015;62: 1102-1105.

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