



NEXT Molecular to provide Asparaginase Enzyme Activity Measurements in Support of a Multi-Center Pediatric Clinical Research Study Centered at Children's Hospital of Orange County (CHOC)

L-asparaginase chemotherapy is integral in the treatment of pediatric, adolescent, and young adult (AYA) patients with Acute Lymphoblastic Leukemia (ALL). Its incorporation, as part of a multi-agent chemotherapy regimen, has resulted in improved event free survival in childhood ALL. However, asparaginase therapy with PEG-asparaginase has several potential side effects, including clinical hypersensitivity and infusion reactions. For these reasons, the Children's Hospital of Orange County (CHOC), Orange, CA, under the supervision of Dr. Van T. Huynh, Principal Investigator, has initiated a prospective multi-center clinical research study to evaluate the efficacy of premedicating pediatric and AYA patients with ALL or lymphoblastic leukemia (LLy) receiving PEG-asparaginase. Patients will receive premedication with steroids and anti-histamine (H1 and H2) blockers to decrease the rate of hypersensitivity reactions and subsequent therapeutic drug monitoring (TDM) will be performed.

The clinical research study is expected to enroll upwards of 325 participants and as many as 1000 samples are anticipated for evaluation of asparaginase levels. NEXT offers its own laboratory derived test to measure asparaginase levels in patients being treated with any of the current therapeutic biologics. This test was implemented in our lab by the same investigators who originally commercialized the test and has been validated under CLIA requirements and under applicable principles of Good Laboratory Practices. In 2019, NEXT completed more than 2600 analyses of samples received from more than 75 different domestic and international institutions. NEXT has provided sample analysis for CHOC since 2017. Assay results are returned by the close of business the same day that the sample is received, thereby providing the clinician real-time therapeutic monitoring of his patient with respect to asparaginase activity levels. NEXT is delighted to have been selected by CHOC to provide this critical service in helping to combat this disease. Contact us at info@nextmolecular.com.