

## **Development and Validation of a New Clinical Assay:**

### **T cell Proliferation with PHA Mitogen Stimulation Detected by Flow Cytometry**

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**Abstract:** Clinical decision making is often guided by lab results. As knowledge of diseases and disease processes have expanded, so too has the need for changes in our clinical laboratory assays. One example where considerable progress in diagnostics has been made is for Severe Combined Immunodeficiency (SCID), now known to be a collection of adaptive immunodeficiencies with many gene variants and various clinical presentations. SCID is screened for in the US via the newborn screening process, and then confirmed with additional laboratory testing, including analysis of peripheral blood lymphocytes and the lymphocyte stimulation assay (LSTIM). While the LSTIM has been used for many years, it has limitations both from a laboratory standpoint and clinical application standpoint. As the knowledge of SCID has grown, the same assay has been used in confirmatory testing panels, without incorporating a renewed understanding of what the test measures. A new assay based upon the same principles of lymphocyte proliferation as a marker of a functioning immune system using flow cytometry allows for more specific information to be obtained in terms of T-cell proliferation that can help guide clinical decision making. This paper will demonstrate the need for an updated assay and its applications as well as demonstrate good laboratory practices in validating a new clinical assay.