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## The development of a novel 3D printed prototype device to simplify blood cell subset enrichment at clinical sites

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Peripheral blood collection is a relatively non-invasive way to obtain biomarkers during clinical trials. Protein and gene expression changes can be used to assess drug/target engagement and disease state changes. To avoid functional changes in blood cells during storage, cells need to be stored in appropriate buffers. For gene expression analysis, whole blood can be collected in buffers that lyse the cells and protect RNA from degradation, but this obscures changes that may be found only in specific cell types. The separation of specific subsets requires instrumentation and trained personnel not readily available at many clinical sites, and shipping to a processing lab may affect the results. Therefore, a way to enrich for and stabilize blood cell subsets at the site of collection is needed. We have developed a portable 3D printed prototype device that can be operated with minimal training. Blood is collected into a tube containing commercially available polystyrene spheres (PluriSelect) coupled to an antibody specific for a blood cell surface antigen. After a 10 min incubation at room temperature, the tube is inserted into the device, followed by a single washing step. Between the inlet and outlet is a mesh with pores that are smaller than the polystyrene beads. All of the blood cells attached to the beads will remain on the mesh, while the unbound cells will pass through the filter. Using anti-CD3 antibodies, we were able to use FACS to verify that the device is capable of enriching more than 1,000,000 CD3+ cells from 2ml of whole blood with 90% purity. At a clinical site, these cells can be collected and processed at room temperature with minimal manipulation and stored in the appropriate buffer and transported. This prototype device may enable cell type-specific analysis for pharmacokinetic/pharmacodynamic assessments and biomarker discovery.

### Biography

Daniel Horowitz has a BA from Temple University and has worked at Janssen for the past 13 years in the Immunology therapeutic area. Projects include biomarker discovery and development of techniques to help progress compounds through early clinical development. Disease areas include Pulmonary disease and Inflammatory bowel disease.

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