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| **S1 Table: Clinical Evaluation Inclusion-Exclusion Criteria final** | | | |
| **Accuracy and Stability** | | | |
|  | **Inclusion Criteria** | | **Exclusion Criteria** |
| **Subject** | * Has been infected with HIV and willing to provide written informed consent to draw venous and capillary blood. * If a minor, parent(s) or guardian(s) are willing to provide informed consent to draw blood from the child. * Agrees to grant access to her/his CD4 testing medical records for pre-screening. * Agrees to disclose age and gender * Agrees to disclose co-morbid conditions information: Malaria, Tuberculosis, Anemia, Sickle Cell Anemia, Infections, Thalassemia and other current medical conditions. * Agrees to disclose current medications | * Unwillingness to provide written informed consent. * Unwillingness to disclose medical information regarding previous CD4 testing results. * Unwillingness to disclose medical information regarding co-morbid conditions and current medications. * Enrolled specimens may be subsequently excluded from the study if found to be unsuitable for testing; for example, clotting or hemolysis identified by visual inspection. | |
| **Specimen** | * Venous blood collected in a blood collection tube with EDTA anticoagulant and stored at room temperature (20-25°C) and according to the collection tube manufacturer’s guidelines until enrollment. * Venous blood drawn within an adequate time to perform post-enrollment staining within 24 hours. * Venous blood of acceptable quality for flow cytometry testing (e.g., no hemolysis or clots and acceptable pre-analytical handling). * Venous blood of sufficient volume: >1mL for Sample Preparation. * Capillary blood applied onto the PEO/IUO BD CD4/%CD4/Hb cartridge. | * Enrolled specimens may be subsequently excluded from the study if found to be unsuitable for testing; for example, clotting or hemolysis identified by visual inspection. | |
| **Reference Intervals** | | | |
| **Subject** | * Hematological normal male and female subjects of 13 to 65 years of age willing to provide written informed consent * If minor, parent(s) are willing to provide informed consent to draw blood from the minor. * Agrees to disclose age and gender * Agrees to complete Donor’s Questionnaire | * Unwillingness to provide written informed consent. * Diagnosis of hypereosinophylia * Experiencing acute infections (viral or bacterial) * Diagnosis of parasite infestations * Diagnosis of chronic infectious, for example: HIV, TB or other * Diagnosis of hematopoietic disorder, for example: leukemia or myeloproliferative disorders * Anemia * Chronic administration of prescribed prednisone or other corticosteroid medication | |
| **Specimen** | * Venous blood collected in a blood collection tube with EDTA anticoagulant and stored at room temperature (20-25°C) and according to the collection tube manufacturer’s guidelines until enrollment * Venous blood drawn within an adequate time to perform post-enrollment staining within 24 hours * Of acceptable quality for flow cytometry testing (e.g., no hemolysis or clots and acceptable pre-analytical handling) * Of sufficient volume: >1,000μL for Sample Preparation * Capillary blood * Capillary blood meets requirements for specimen donation as required. | * Enrolled specimens may be subsequently excluded from the study if found to be unsuitable for testing; for example, if visual inspection prior to acquisition shows clotting or hemolysis. * If an enrolled specimen (with adequate time post-draw to enroll for study testing) cannot be tested within 24 hours due to unanticipated difficulties, this specimen would be excluded from the study testing. | |