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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.
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| **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.
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| **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
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| **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.
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