

An Integrated Multifunction POC Platform for Cell Analysis, Immunoassay, and Hematology Testing



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Acknowledgement
NIH (SBIR)
NC State Dept. of Commerce
NC Biotechnology Center
SBTDC

Early Diagnosis = Early Intervention = Better Outcome



1. Bring advanced Reference Lab diagnostic tests to Point-of-Care
2. Affordable easy-to-use system that combines routine testing with specialty testing

Global Health (Access)

Greater than 15% world population is without access to healthcare, primarily due to affordability and availability issues (1 billion people)

US Health (Cost) :

6.5% US population do not get the care they need due to cost (CDC)

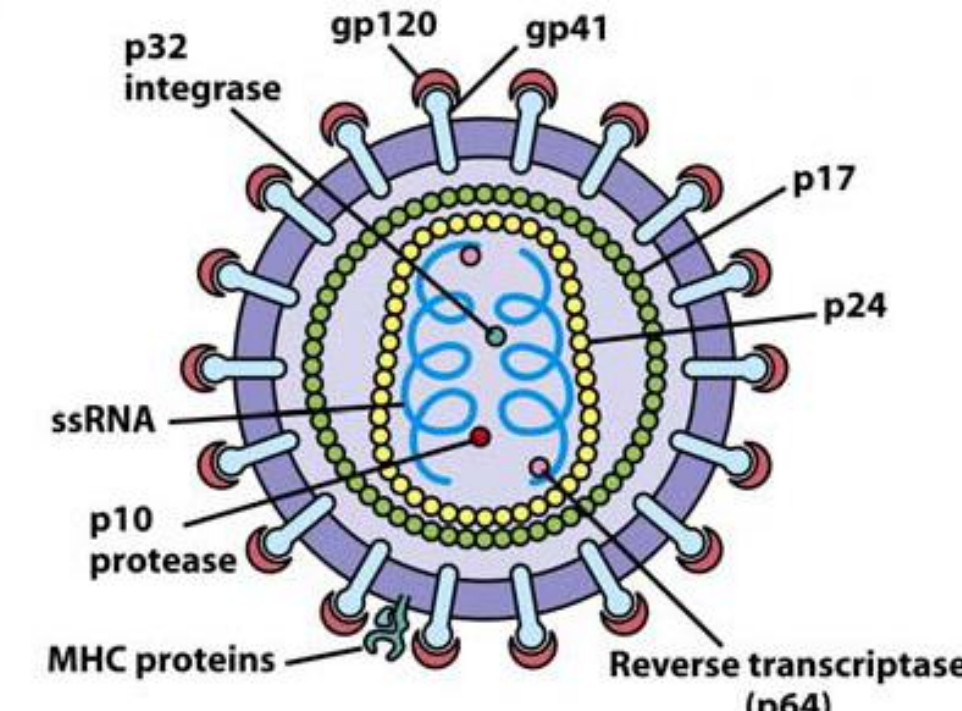
Growing Opportunity:

Point-of-Care Testing is one of fastest growing segments of IVD, 5 year forward CAGR of 8-10%, Hematology in emerging markets growing at 20-25% CAGR

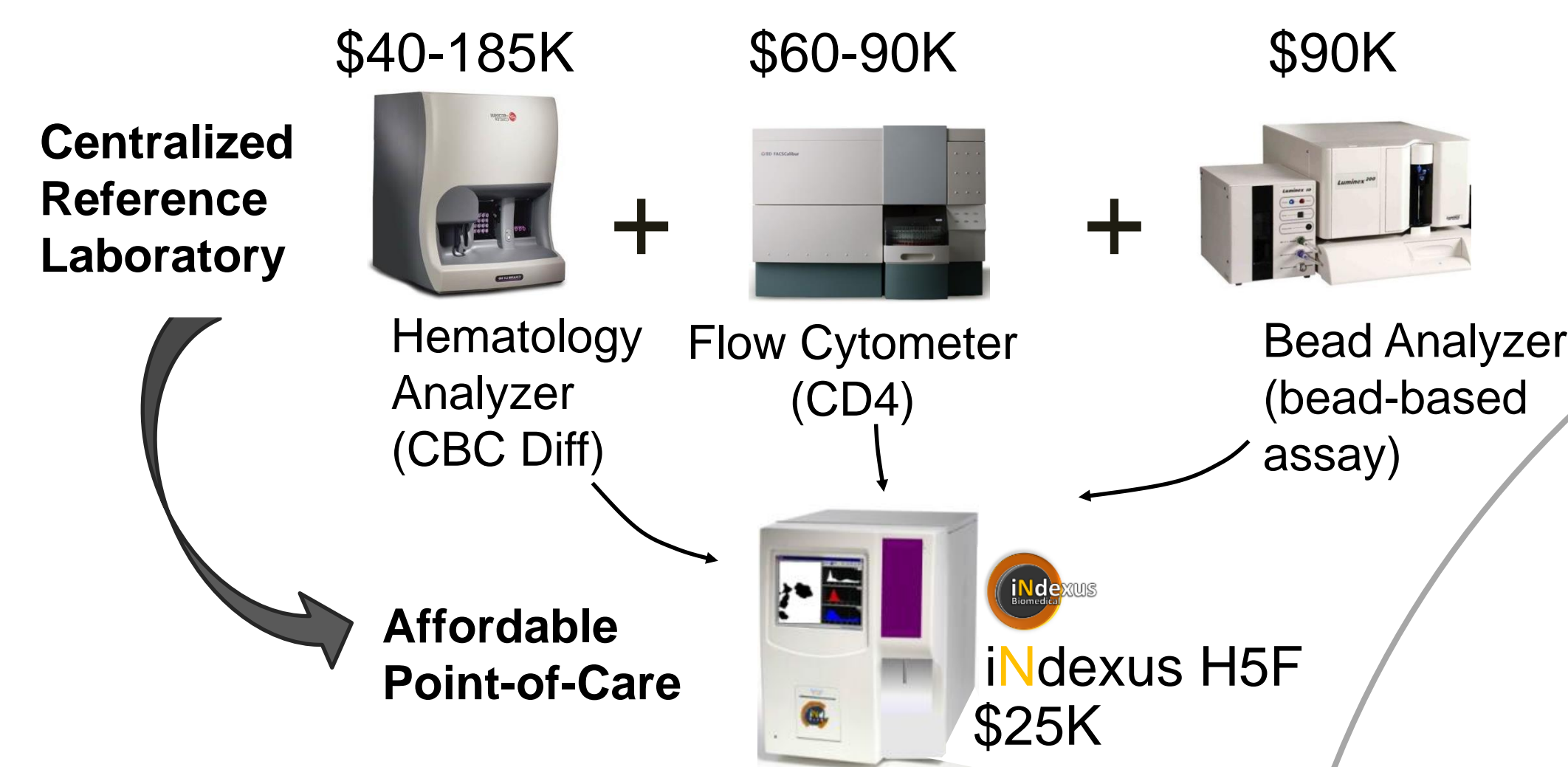
Comprehensive Diagnostic Tests for the HIV Patient at the Primary Care Center



HIV p24
HIV Antibody
CD4 Count
CBC

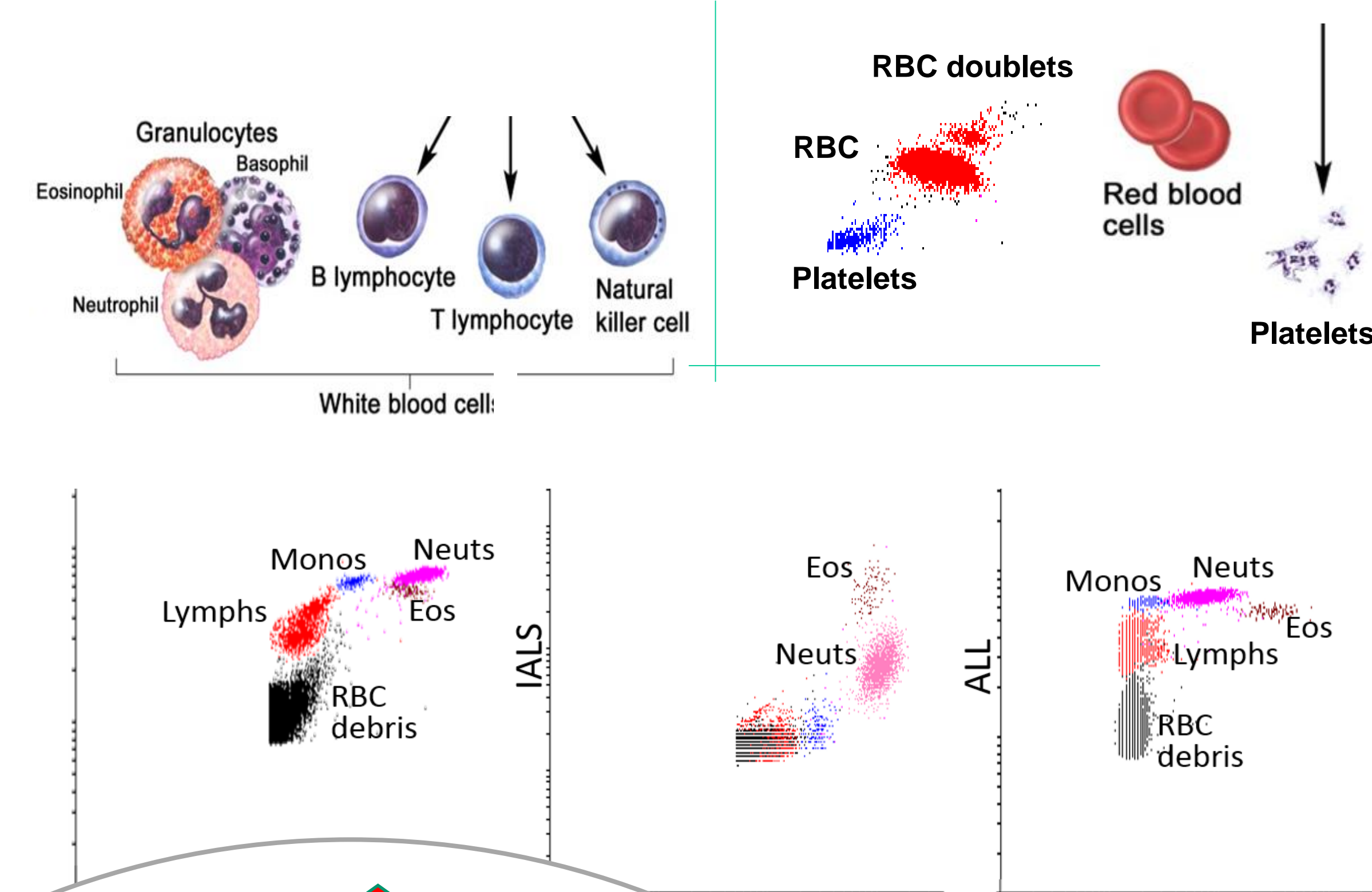


Advanced diagnostic and monitoring tests on a single low-cost platform for routine blood tests

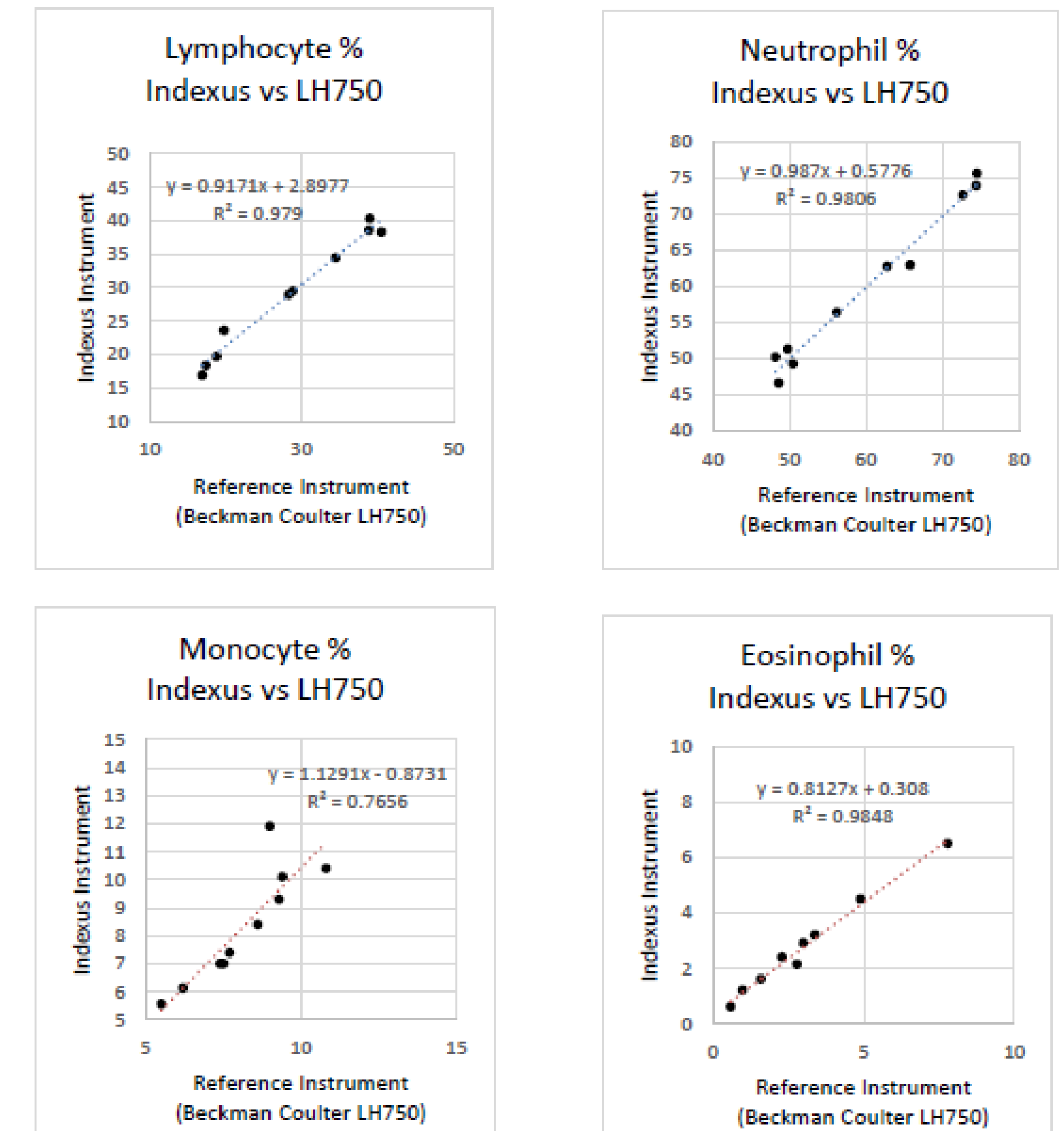


Hematology Analysis

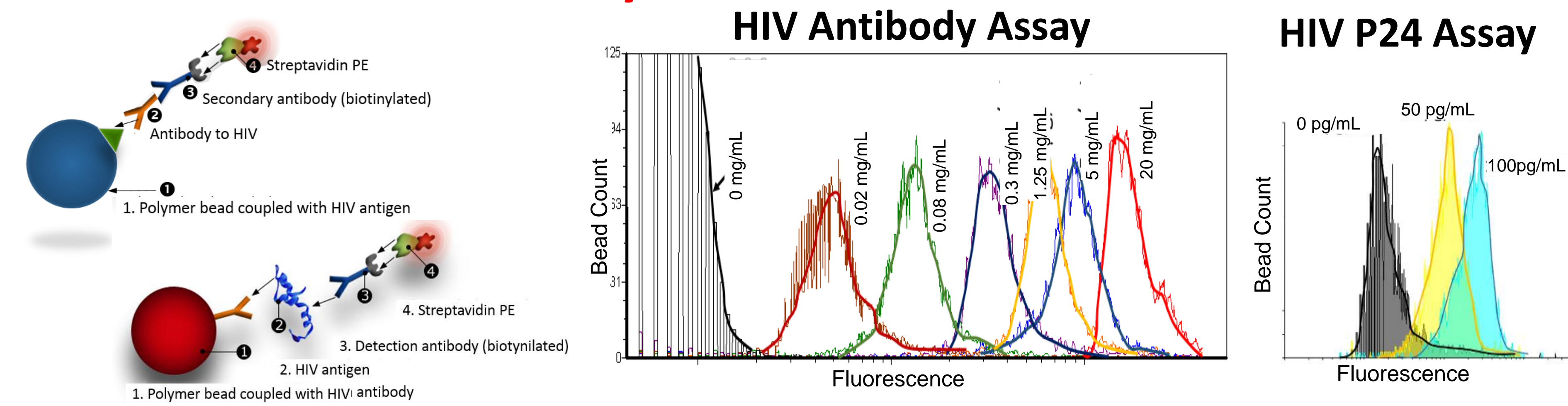
Counting cells by morphological differences (light scatter)



Correlation with Beckman LH750



Bead Based Immunoassays



1.2 billion CBCs prescribed annually

Over 30 parameters on blood cells

Hematology CBC-Diff

Bead-based Assays: HIV, HBV, HCV, Cardiac, Cancer

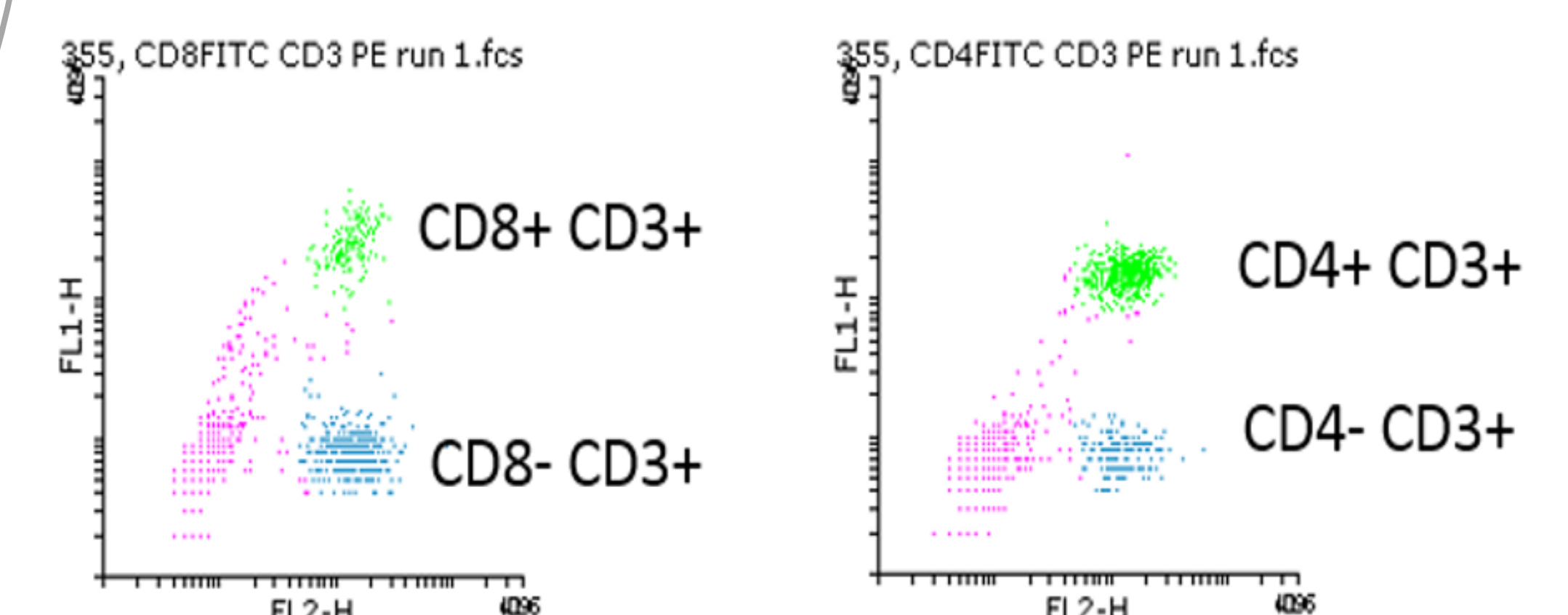
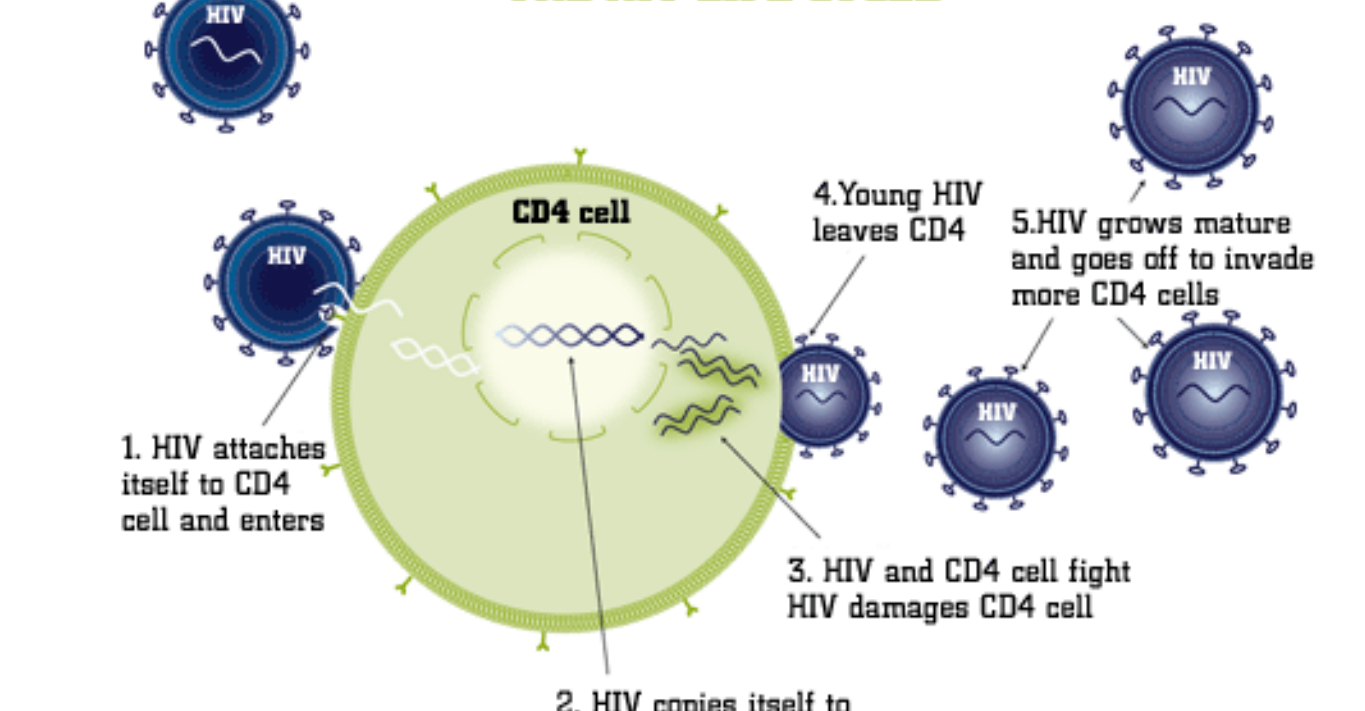
Flow Cytometry CD4/CD8 Leukemia Lymphoma

Measures multiple biomarkers for disease diagnosis

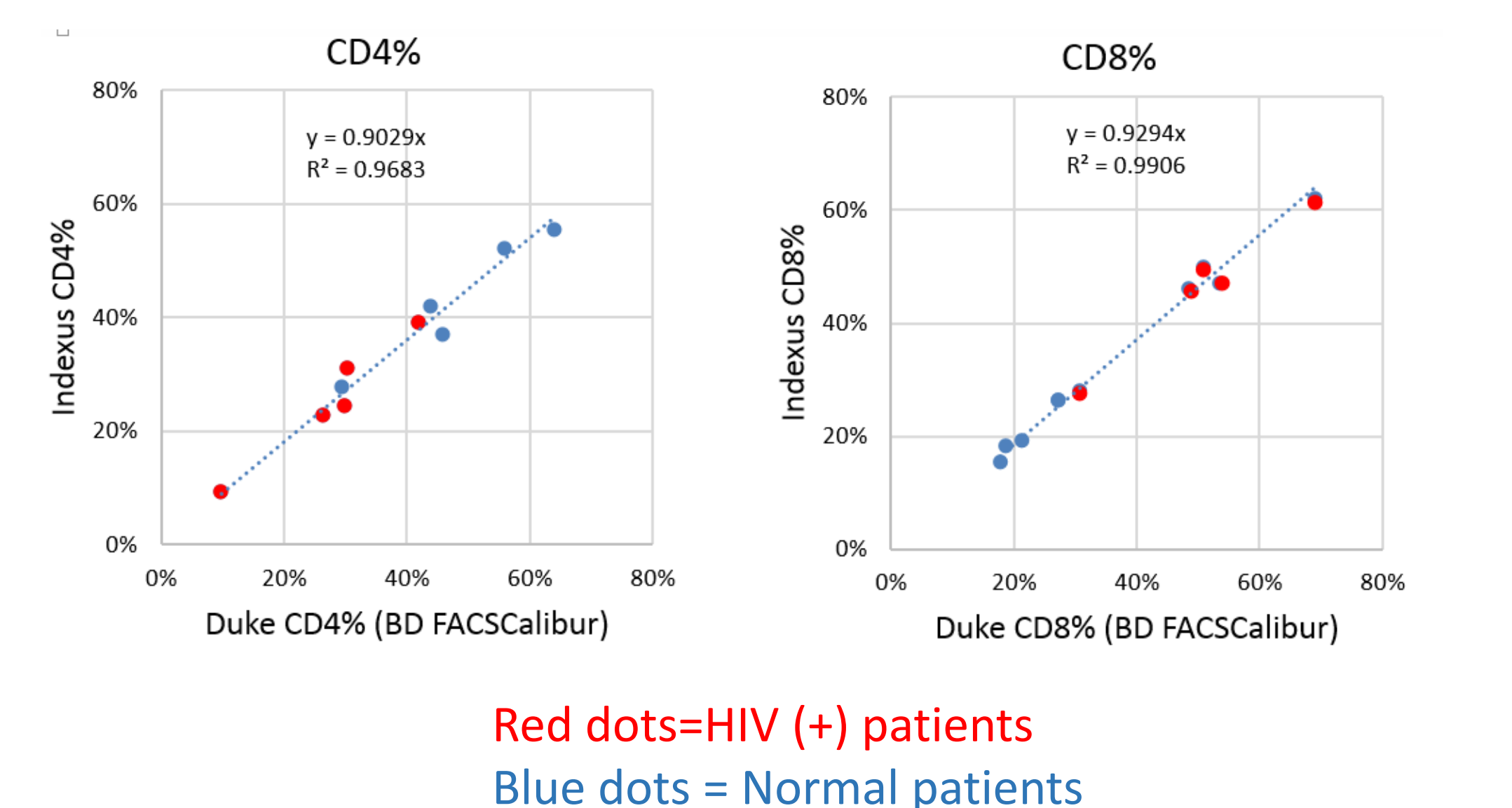
Measures immunologically important white cell subsets

CD4 Counting by antibody-based gold standard method

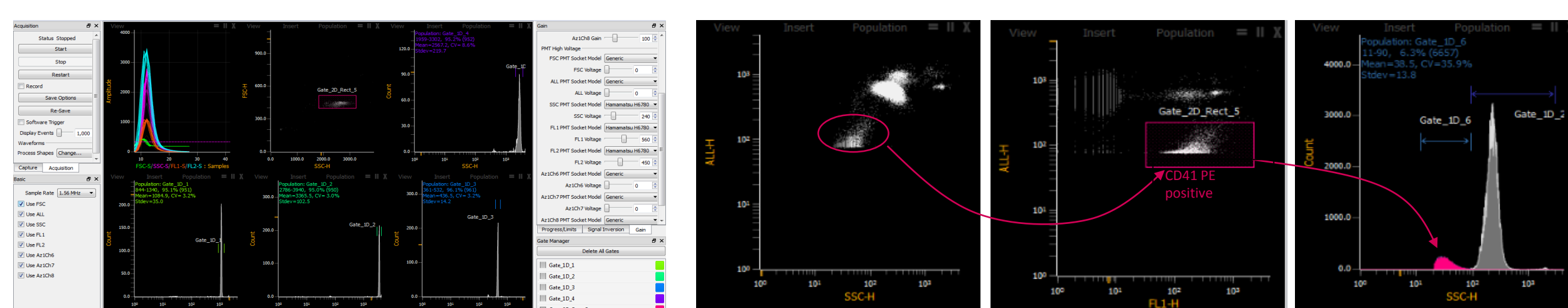
THE HIV LIFE CYCLE



Correlation with BD FACSCalibur



Versatile Instrument Hardware and Software Design, Scalable and Menu Expandable



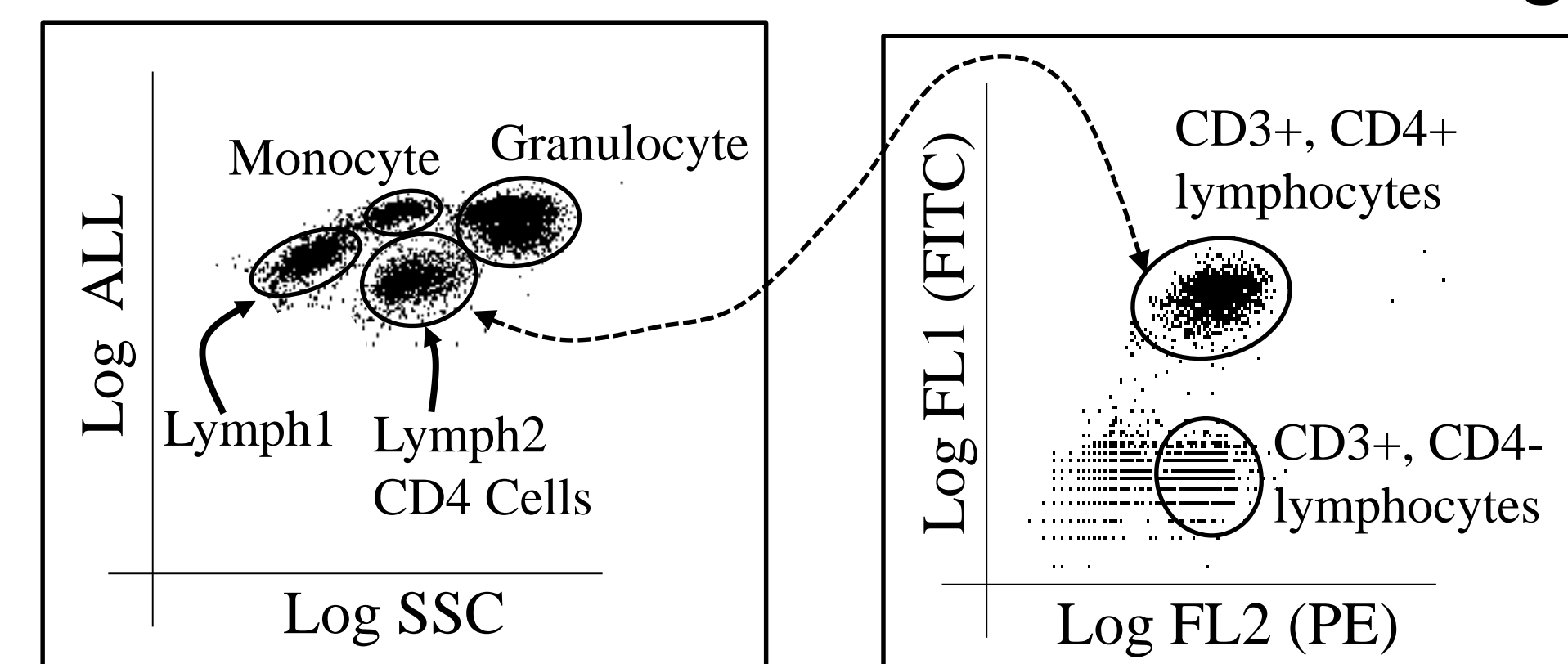
- Originally designed for the POC and primary care centers, the instrument can be configured for the military and civilian mobile clinics for field deployment
- Menu-expandable system, allows new assays to be added without hardware change
- Core technology is scalable to build higher throughput instruments for the Reference Lab (LabCorp/Quest Laboratories)
- Modular multifunctional design will permit derivative products to be sold to the life sciences research and veterinary markets

Future Test Menu

- Hepatitis A, B and C
- Organ Function Tests
- Confirmatory tests for leukemia and lymphoma
- Biomarkers assays for cancer
- Vector borne diseases, including dengue, chikungunya, malaria
- Cardiac and kidney biomarkers assays

Label-free CD4 Counts

A new method for low-cost CD4 screening



Collaboration Opportunities

Indexus provides Consulting Services in the following areas:
(contact cdeka@indexusbiomed.com or phone 919-824-0419)

- SBIR/STTR Grant writing and submissions
- Systems Engineering and Design of Medical Devices under FDA and ISO 13485
- Implementation and maintenance of Quality Systems Management Processes
- Training & Implementation of New Product Development (NPD) Process and Six-sigma

We seek collaborations in the following technical areas:

- Lyophilized room temperature storable immunoassay reagents
- New biomarkers for diseases (cardiac, cancer, kidney)
- Clinical studies