

# Standardization & Validation of Immune Monitoring

- Cytokine and Chemokine Immunoassay Quantification
  - Multiplex vs. Singleplex validation
  - Regulatory aspects and benefits of GMP and CLIA validated assays
  - Sample types and sample handling
  - QC: Levy- Jennings plots for lot-to-lot standardization
  - Rejection/Acceptance Criteria
  
- Standards and Controls
  - Recombinant vs. native standards
  - In-plate controls: 3 levels (H, M, L) incorporation of pooled donor native controls.

## *ex vivo* Immune Biomarker Monitoring in the Clinic

- The Challenge of Collecting active PBMCs in the Clinic
  - Multi-step processing, variable time intervals & temperature, preservation, transportation
  - Loss of signaling elements (granulocytes, platelets, RBCs)
  - Rejection/Acceptance Criteria?
- Whole Blood Cultures – Standardization and Incorporation into Clinical Trials
  - Novel technology; validation, reproducibility, and suitability for the clinic.
  - Cytokine, Chemokine and gene expression end-points.
  - Monitoring for Safety (Immunotoxicity) and Pharmacodynamics in cancer trials.