



## DHVI IVQAC Core Facility

### Mission

To provide laboratory procedures and assays for HIV and Non-HIV clinical studies and trials under Good Lab Practices (GLP). These activities include non-human primate SIV viral load, HIV-1 RNA Viral Load, PBMC processing from Leukopak, HIV-1 WB, Sterility, Mycoplasma, Endotoxin testing, Flow Cytometry acquisition and Elutriation cell separation.

### Leadership / Experience

- **Director: Thomas Denny MSc, MPHil**  
Mr. Denny is a Professor of Medicine in the Duke School of Medicine and is the Senior Associate Director and Chief Operating Officer (COO) of the Duke Human Vaccine Institute (DHVI). He is also the Director and PI of the DHVI IVQAC, a CAP accredited/CLIA-approved, GCLP-compliant unit with ISO accreditations.
- **Manager: Ambrosia Garcia, MS**  
Ambrosia Garcia serves as the IVQAC Core Facility Manager for the last 7 years and has extensive experience in molecular assay development and implementation.

### Services

- **SIV Viral Load**
  - Validated for EDTA rhesus plasma and requires 600 µL of sample. The lower limit of detection for this SIV assay is 250 copies/mL.
- **HIV-1 RNA Viral Load**
  - HIV-1 RNA viral load is quantified using the Roche COBAS AmpliPrep/COBAS Taqman 48 system. It is a real-time PCR assay with a quantifiable range of 20 - 10,000,000 RNA copies/mL (HIV).
- **HIV EIA Ab**
  - HIV serology testing is determined qualitatively using the BioRad HIV-1, 2 + O EIA platform.
- **HIV-1 Western Blot (WB)**
  - WB confirmatory assay is performed using a Bio-Rad Clinical Diagnostics kit. HIV acute disease staging (Fiebig staging based on results from both HIV-1 Ab and WB).
- **Elutriation**
  - Counterflow centrifugation procedure for separation of cell populations on a large-scale. Separation is based on cell size, shape, and density to serve the analytics needs of investigators.

### Services

- **Leukopak Processing**
  - PBMCs are obtained, under GLP, through density gradient centrifugation and are assessed for viability and cell number, aliquoted, cryopreserved, and stored in vapor phase LN2 freezers. The approximate final PBMC cell yield of one Leukopak is  $4.0 \times 10^9$  cells.
- **Sterility Testing for Bacteria/Fungi**
  - This qualitative test involves direct inoculation of the test sample into two different types of media: Tryptic Soy Broth (TSB), also commonly referred to as Soybean-Casein digest, and Fluid Thioglycollate Media (FTM). Inoculated media is monitored for microorganism growth.
- **Sterility Testing for Mycoplasma**
  - This qualitative test utilizes the MycoAlert® test kit to detect the presence of Mycoplasma.
- **Sterility testing for Endotoxin**
  - Testing is done using the Limulus Amebocyte Lysate (LAL) Pyrogen® Plus Single Test Vial Gel Clot Assay. This qualitative assay has a sensitivity of 0.125 EU/mL.

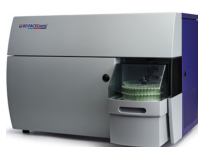
### DHVI IVQAC Core Facility Platforms



QIAAsymphony SP



Avanti J-26XP SP



BD FACSCanto



COBAS AmpliPrep/TaqMan 48



### Recent Projects / Publications

- **Immunization with an SIV-based IDLV Expressing HIV-1 Env 1086 Clade C Elicits Durable Humoral and Cellular Responses in Rhesus Macaques.** Negri D, Blasi M, LaBranche C, Parks R, Balachandran H, Lifton M, Shen X, Denny T, Ferrari G, Vescio MF, Andersen H, Montefiori DC, Tomaras GD, Liao HX, Santra S, Haynes BF, Klotman ME, Cara A. Mol Ther. 2016 Nov;24(11):2021-2032. doi: 10.1038/mt.2016.123. Epub 2016 Jun 21
- **Infection of monkeys by simian-human immunodeficiency viruses with transmitted/founder clade C HIV-1 envelopes.** Asmal M, Luedemann C, Lavine CL, Mach LV, Balachandran H, Brinkley C, Denny TN, Lewis MG, Anderson H, Pal R, Sok D, Le K, Pauthner M, Hahn BH, Shaw GM, Seaman MS, Letvin NL, Burton DR, Sodroski JG, Haynes BF, Santra S. Virology. 2015 Jan 15;475:37-45. doi: 10.1016/j.virol.2014.10.032. Epub 2014 Nov 22
- **Effective treatment of SIVcpz-induced immunodeficiency in a captive western chimpanzee.** Barbican HJ, Jackson-Jewett R, Brown CS, Bibollet-Ruche F, Learn GH, Decker T, Kreider EF, Li Y, Denny TN, Sharp PM, Shaw GM, Lifson J, Acosta EP, Saag MS, Bar KJ, Hahn BH. Retrovirology. 2017 Jun 2;14(1):35. doi: 10.1186/s12977-017-0359-0
- **Neutralization properties of simian immunodeficiency viruses infecting chimpanzees and gorillas.** Barbican HJ, Decker JM, Bibollet-Ruche F, Galimidi RP, West AP Jr, Learn GH, Parrish NF, Iyer SS, Li Y, Pace CS, Song R, Huang Y, Denny TN, Mouquet H, Martin L, Acharya P, Zhang B, Kwong PD, Mascola JR, Verrips CT, Strokappe NM, Rutten L, McCoy LE, Weiss RA, Brown CS, Jackson R, Silvestri G, Connors M, Burton DR, Shaw GM, Nussenzweig MC, Bjorkman PJ, Ho DD, Farzan M, Hahn BH. MBio. 2015 Apr 21;6(2).

### Reservations / Service Requests

- **Sample Submission** – Full-Service, All platforms
  - All experimentation, optimization, and analysis will be performed by Core Staff.
- **Independent Use** – Self-Service, Becton Dickinson FACSCanto only
  - Complete training in the independent operation Available through CoreResearch@Duke
- **Consultation**
  - Assistance in experimental design, analysis and interpretation of data
- Contact **Ambrosia Garcia** to schedule an initial consultation and to discuss sample submission goals and/or training

### Contact Us

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