



Vitamin **D** and  
type **2** diabetes

# Central Laboratory: University of Vermont

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## Laboratory for Clinical Biochemistry Research (LCBR)

**Lab Director:** Dr. Russell P. Tracy

**Lab QA/QC Director:** Dr. Michael R. Lewis

**Lab Coordinator:** Elaine Cornell

**D2d Project Manager:** Rebekah Boyle

# Central Laboratory Functions

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- Development and implementation of specimen collection and handling protocols to ensure consistency throughout study
- Assay work: HbA1c, glucose, insulin, urinary calcium and creatinine
- Biospecimen repository design, implementation, and maintenance
- Quality assurance and quality control

# LCBR: Brief Overview

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- Major areas of focus: Atherosclerosis, thrombosis, diabetes, and aging
- Biomarkers: Inflammation, coagulation, endocrinology, bone metabolism
- Techniques: Immunoassays (including multiplex), enzymatic assays, SNP and sequence analyses; others as indicated

# Core Lab, Repository Examples

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- NIDDK: Look AHEAD (coag core lab)
- NHLBI: MESA, CHS, JHS (repos), HFSCRN
- NIA: CALERIE, Health ABC
- NINDS: REGARDS
- NCI: TREC (site core lab, repository)
- NIAID: SMART (inflam'n/coag core lab)
- NCCAM: GEM

# Quality Assurance

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- Extramural QA/PT programs
- WHO standards for calibration
- Short-term QA/QC: reagents purchased in large lots; Westgard multi-rule control
- Long-term QA/QC: samples from 20+ normal donors tested multiple times over the course of a study to address drift
- CLIA-certified laboratory for general chemistry and hematology assays



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# Colchester Research Facility

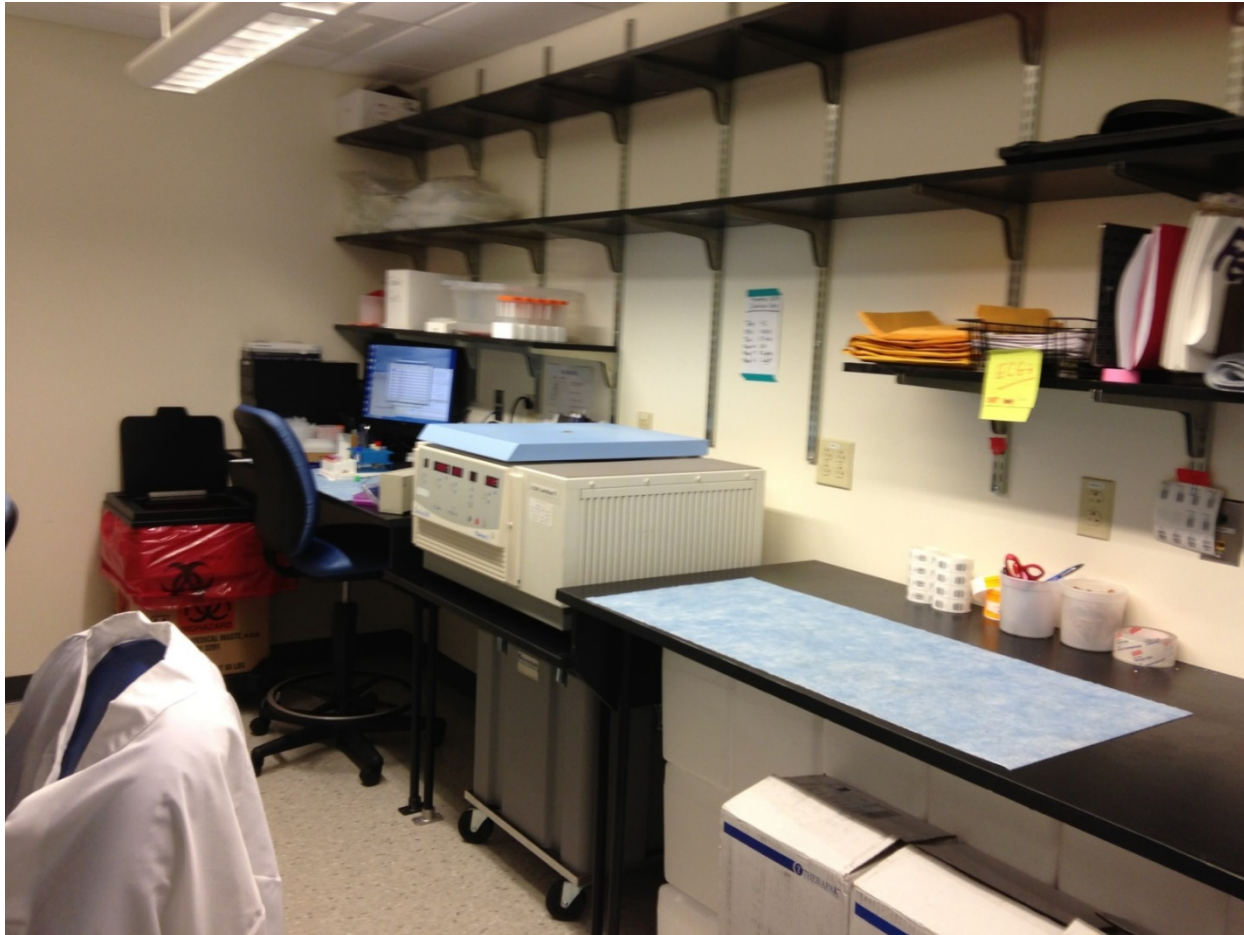
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# D2d Laboratory



# Baseline / Annual Visit Kits



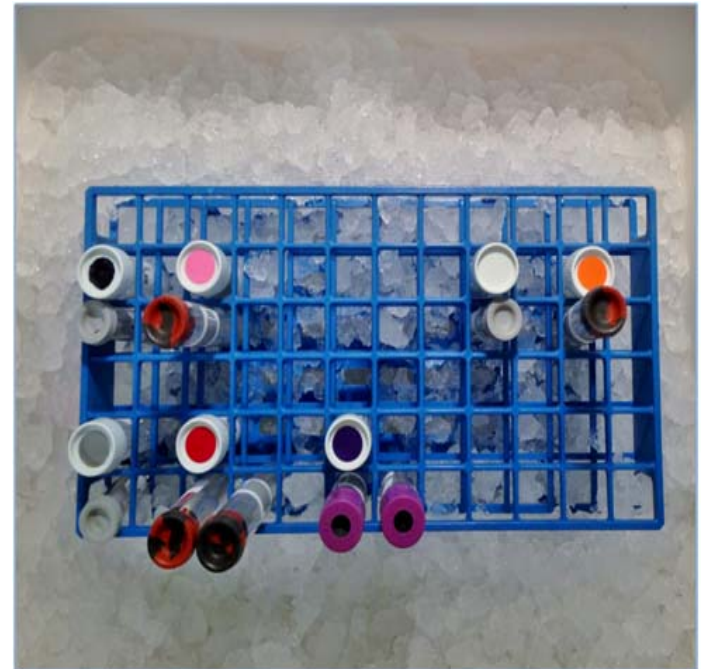
**Kit with contents inside**



**Kit with contents outside**

# Samples Post-Centrifugation

- **Prepare** tube rack with labelled transfer tubes
- **Arrange** color coded tubes to match collection Vacutainer tube example; red: 10mL Fasting SST tube
- **Aliquot** while the blood collection tubes and transfer tubes are on ice (unless otherwise noted).



# Refrigerated Shipments



**Place each tube in separate 50 mL conical tubes to serve as a secondary container during shipping.**

**Place a thick rubber band around the tubes and seal in a Ziploc bag with absorbent sleeve.**

**The Ziploc bag and absorbent material are for compliance with commercial carrier specifications.**



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# Assays: Baseline Samples

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- Fasting plasma glucose (FPG)
  - 2h plasma glucose (OGTT)
  - Hemoglobin A1c (HbA1c)
  - Urinary calcium/creatinine (Ca/Cr)
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- Note: Screening visit labs performed at clinical sites, not central laboratory

# Assays: Subsequent Visits

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- M03: urinary Ca/Cr
- M06, M18, M30, M42
  - FPG, HbA1c
- M12, M24, M36, M48
  - FPG, HbA1c, 2hPG (from OGTT)
- Confirmatory OGTTs
- Specimens stored for future testing: 30 min PG, insulin (0/30/120 min), lipids, CRP, 25(OH)D, urinary albumin/Cr

# Biospecimen Repository

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# Repository Facts and Figures

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- >150 freezers (-80°C or -145°C)
- >3M samples from >70K participants
- Temperature controlled environment with generator back-up capacity
- Alarm system notifies staff of deviation in unit temp and permits remote monitoring
- Building access is limited; intrusion alarms
- Member, Int'l Soc for Biol Envir Repositories



# D2d Biospecimen Repository

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- Baseline and annual visits
  - 4-8 ml serum, 4-8 ml EDTA plasma
  - ~15 ml urine (with and without boric acid)
  - Baseline only: PaxGene DNA
- Month 6
  - 4-8 ml serum, 4-8 ml EDTA plasma
- Repository to be transferred to NIDDK at end of study per protocol



# Central Lab Contact Info

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**LCBR Address:** University of Vermont  
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## Staff Contact Information:

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# Our Team

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<http://www.med.uvm.edu/lcbr>