

VDSP: So Far and Plans for the Future

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for the Vitamin D Standardization Program (VDSP)



A Brief Chronology

- 2004: Mary Francis Picciano (1946-2010) and NIST collaboration (Karen Phinney, lead): RMP and SRM 972 & 2972
- 2005: Collaborations Graham Carter (DEQAS)
 & Linda Thienpont at Ghent University.
- 2007: Vitamin D and Health in the 21st Century
- 2009: Release of SRMs 972 and 2972
- 2010: 1st VDSP meeting, Bethesda, MD (15 Nov)



A Brief Chronology

- 2011: JCTLM approval of NIST & Ghent RMPs VDSP Interlaboratory & commutability (Oct)
- 2012: CDC Standardization-Certification Program DEQAS becomes Accuracy-Based EQA
- 2013: CAP nominates representative to VDSP
- 2013: VDSP Meeting, Nov 14 sponsorship by AACC, IFCC and PATH



VDSP Reference Measurement System Components

- NIST & Ghent RMPs
- NIST Standard Reference Materials (SRM)
- CDC Vitamin D Standardization-Certification Program
- Accuracy-Based Quality Assurance Programs
- Study designs for standardizing completed studies



Plans for the Future #1

- Publish:
 - NIST and Ghent Comparison
 - Interlaboratory Comparison Study Results
 - Commutability Results
 - Baseline data from DEQAS on accuracy and precision among assays
 - Standardized results from national health and nutrition surveys



Plans for the Future #2

- Continue analytical methods development
- Search for ways to improve serum samples used in calibration
- Promote standardization of completed studies
- Work with medical and professional societies to promote standardization in both clinical laboratories and in funded research



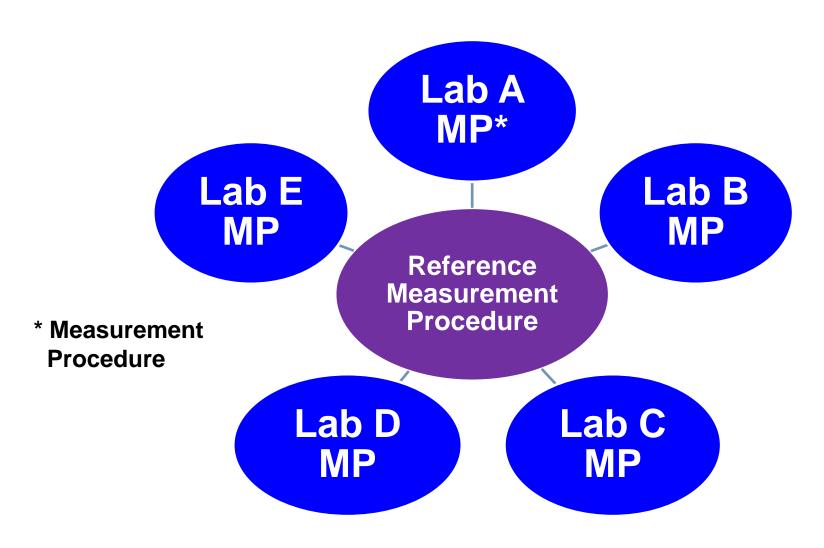
Plans for the Future #3

Work with individual:

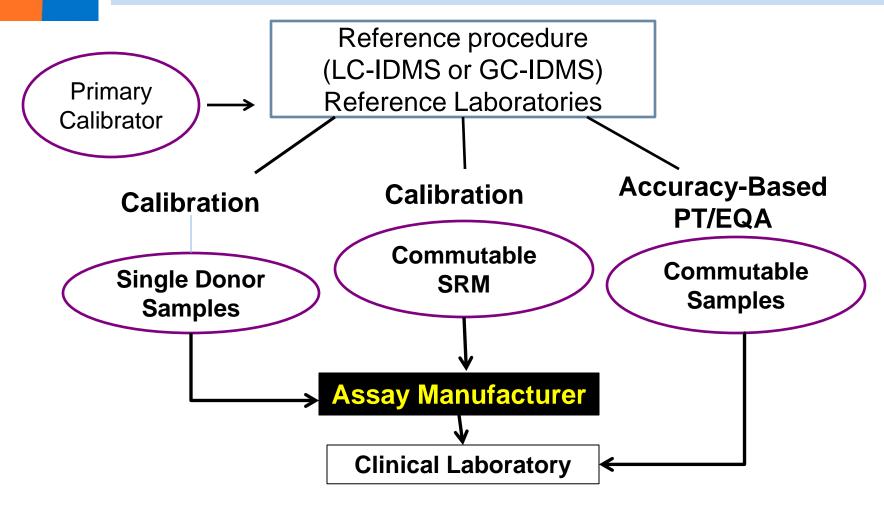
- Assay manufacturers to help them improve accuracy and precision
- <u>Laboratories</u> through PT/EQA programs to help improve their accuracy and precision



Standardization Does Not Require a Single Analytic Approach



Calibration Traceability Scheme*



^{*} Adapted from: Myers G. Steroids 2008;73:1293-1296



Steps You Can Take to Achieve Standardization

- NIST SRMs: 972a and 2972
- CDC's Vitamin D Standardization-Certification Program -
 - Immunoassay manufacturers
 - Commercial and large clinical laboratories
- Accuracy-Based Quality Assurance Programs:
 - CAP
 - DEQAS
 - NIST-NIH VitDQAP
- Send us your suggestions for improving VDSP



Suggested Assay Performance Limits Based on Biological Variation*

Measurements	CV (%)	Bias (%)
Reference Labs	≤ 5%	≤ 1.7%
"Routine" Labs	≤ 10%	≤ 5%

^{*}Stöckl D et al. Clin Chim Acta 2009;408:8-13



Ask yourself?

- What's your assay's <u>%CV</u>? Is it ≤ 10%
- What's your assay's Bias? Is it ≤ 5%



Thank you!



Thank you - NIST!



Thank you sponsors - AACC,IFCC,PATH!



Thank you - Moderators, Speakers & Discussants!



Thank you - VDSP Members!



VDSP Contributors

- ODS: Overall Coordination
 - Paul Coates
 - Joseph Betz
 - Claudia Faigen
 - Joyce Merkel
 - Mary Frances Picciano*
 - Christopher Sempos**
 - Paul Thomas
 - Anne Thurn
 - Elizabeth Yetley
- International Organizations:
- AACC Gary Myers
- **IFCC** lan Young
- **CAP** Andrew Hoofnagle
- DEQAS
 - Graham Carter
 - Julia Jones
 - Jayne Shannon
 - * Deceased
 - ** VDSP Coordinator

Reference Laboratories

- USA NIST
 - Stephen Wise
 - Lane Sander
 - Karen Phinney
 - Susan Tai
 - Johanna Camara
 - Mary Bedner
 - Katrice Lippa
 - Carolyn Burdette
- Belgium: Ghent University
 - Linda Thienpont
 - Linde De Grande
 - Katleen Van Uytfanghe
- CDC Standardization-Certification Program
 - Hubert Vesper
 - Julianne Botelho



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Thank you – Meeting Organizers!



Meeting Organizers

- Paul Coates, Ph.D.
- Anne Thurn, Ph.D.
- Michael Bykowski
- Claudia Faigen
- Michael Labuda

- Megan Lyons
- Joyce Merkel, M.S., R.D.
- Kimberly Potter
- Cindy Rooney
- Paul Thomas, R.D.



Thank you - Meeting Attendees!