VDSP Overview and Meeting Agenda

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for the
Vitamin D Standardization Program (VDSP)

Meeting Agenda

- Importance of standardized laboratory measurement of vitamin D
- VDSP system to promote standardization
- Impact of standardization
- Working together to promote standardization

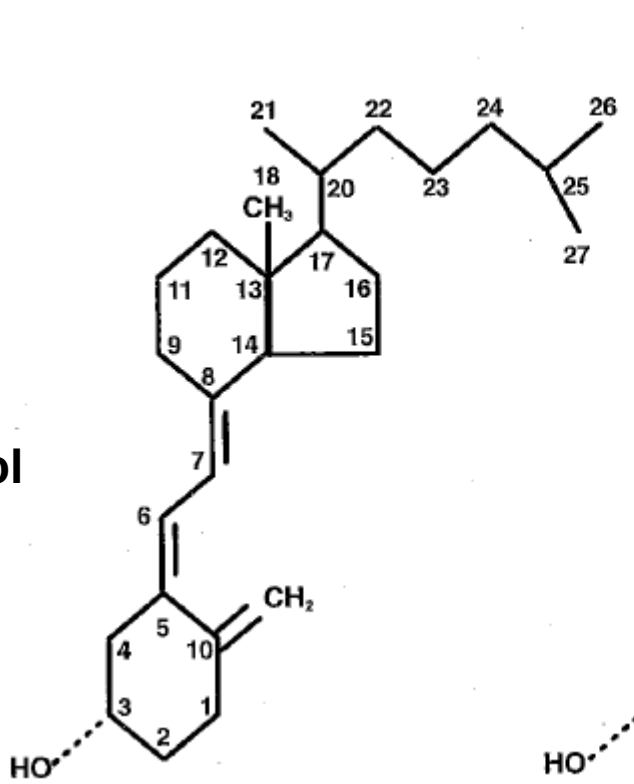
VDSP Goal

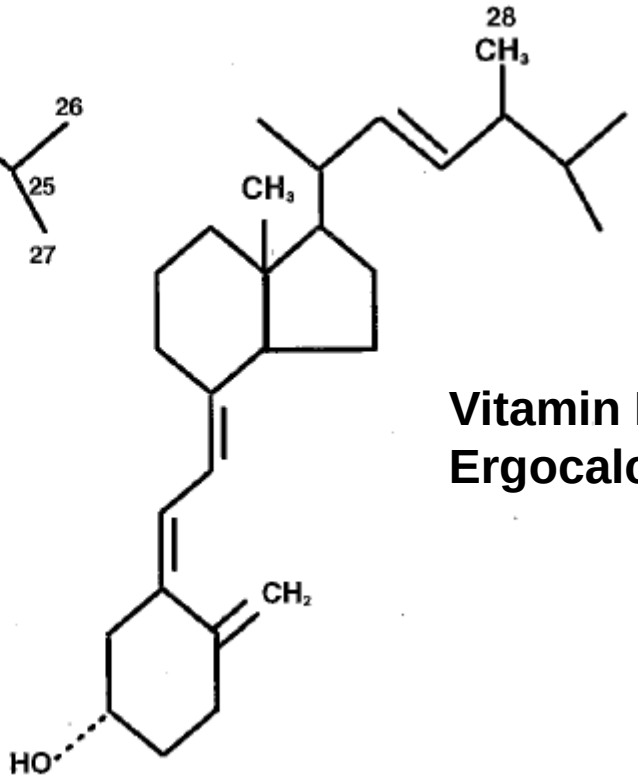
Promote the standardized laboratory measurement of total 25-hydroxyvitamin D – a measure of vitamin D status – in order to improve clinical and public health practice worldwide.

***Note**: 25-hydroxyvitamin D is abbreviated as 25(OH)D*

Nutritional Forms of Vitamin D

Vitamin D3 or Cholecalciferol



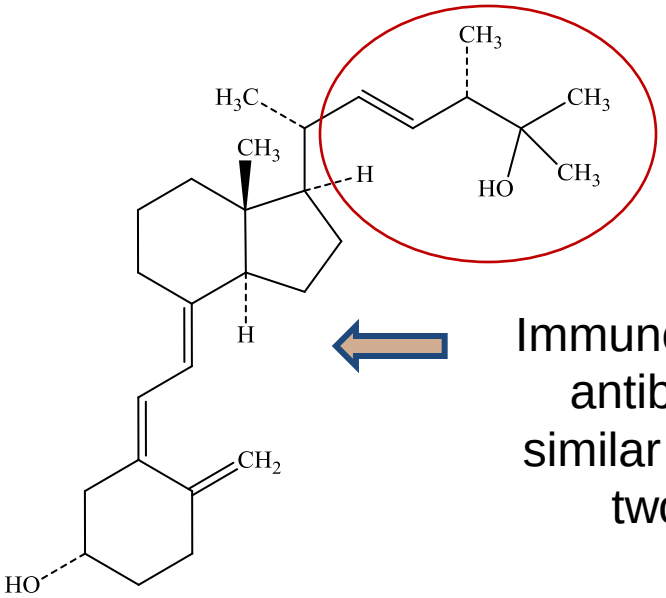


Vitamin D2 or Ergocalciferol

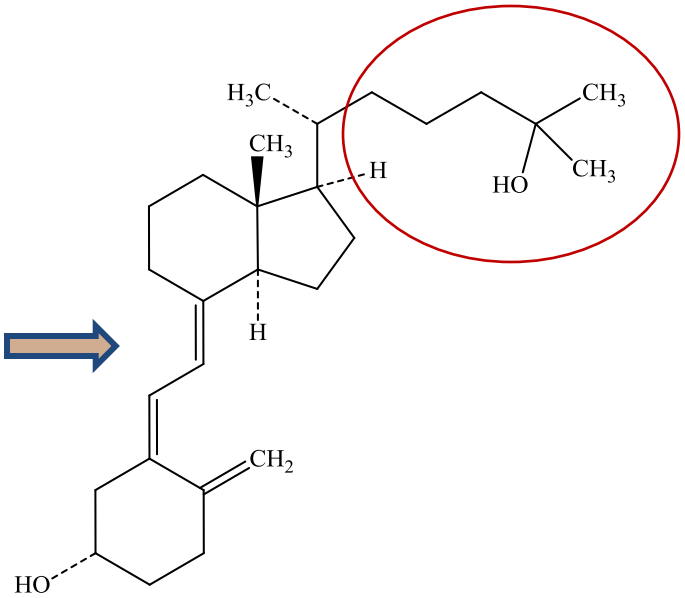
Molecular Formula:	**$C_{27}H_{44}O$**	**$C_{28}H_{44}O$**
Molecular Weight:	**384.6 g/mole**	**396.65 g/mole**

Structural Forms for 25(OH)D

The two primary metabolites of interest differ only in the side chains



Immunoassays utilize antibody against similar regions of the two analytes



	25-hydroxyvitamin D_2	25-hydroxyvitamin D_3
Molecular Formula:	$C_{28}H_{44}O_2$	$C_{27}H_{44}O_2$
Molecular Weight:	412.65 g/mole	400.63 g/mole

Vitamin D Status Measurement

Total 25-Hydroxyvitamin D or 25(OH)D

- Total 25(OH)D is defined as

  Total 25(OH)D = $25(OH)D_2 + 25(OH)D_3$*

- Units: ng/mL or nmol/L where:

  ng/ml * 2.5 ≈ nmol/L

*** Assumes that Vitamin D_2 and D_3 are of equal biological value.**

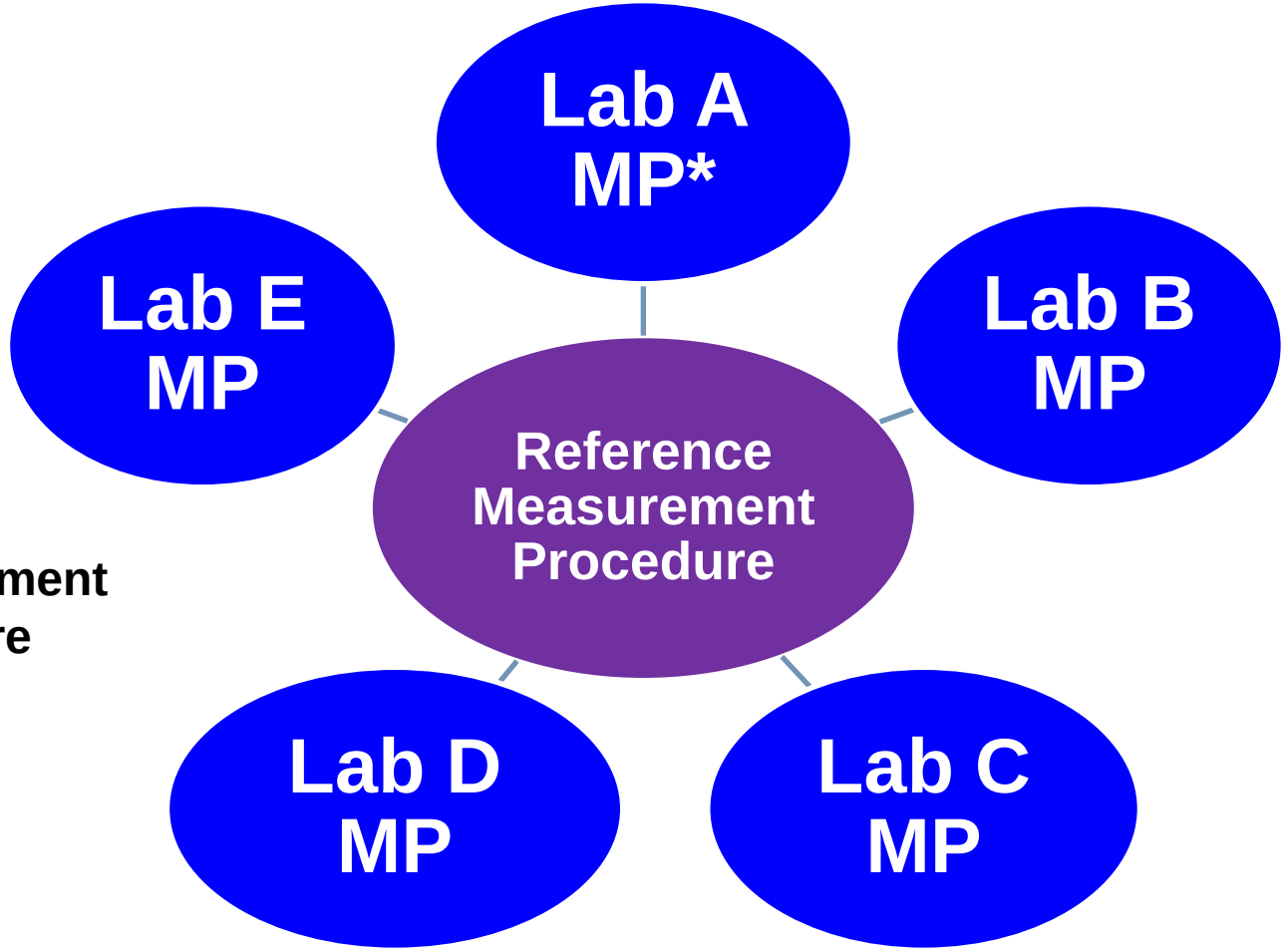
What is a standardized laboratory measurement?

A standardized laboratory measurement is one that is accurate and comparable over time, location, and laboratory procedure.

What is a standardized laboratory measurement of Total 25(OH)D?

A standardized laboratory measurement of ***25(OH)D*** is one that is accurate and comparable to the ***NIST and Ghent Reference Measurement Procedures (RMPs)*** over time, location, and laboratory procedure.

Standardization Does Not Require a Single Analytic Approach



* Measurement Procedure

Effects of Standardization

- Harmonization of laboratories and methods
- Laboratories report “true” value – based on NIST and Ghent RMPs*
- Standardization leads to more informed decision making by physicians, policy makers and others.

* Tai S et al. Anal Chem 2010;82:1942-1949.
* Stepman HCM et al. Clin Chem 2011;57:441-448.

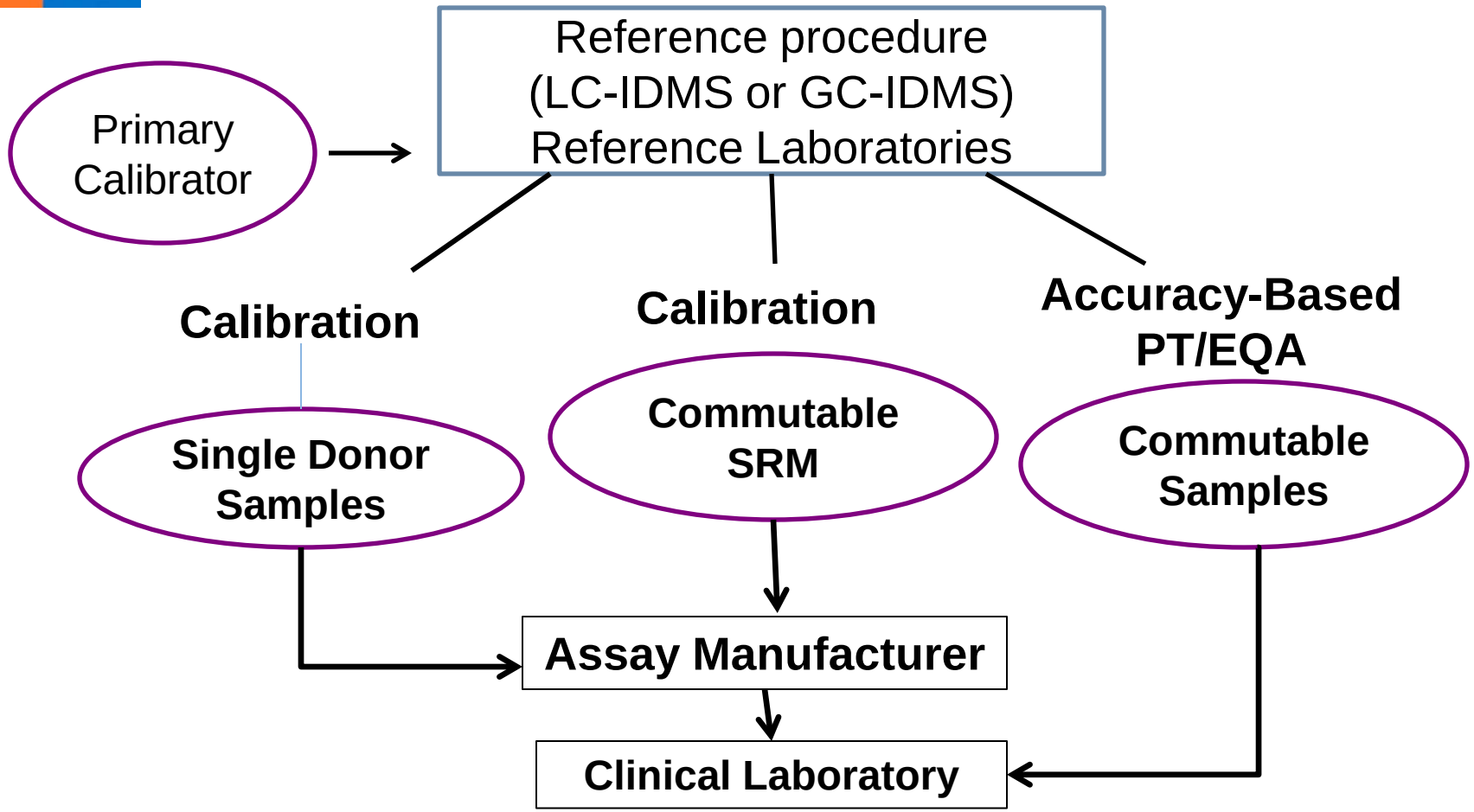
VDSP Objectives

1. Standardize vitamin D measurement in national health surveys worldwide.
2. Promote standardized 25(OH)D measurement by:
   - Assay manufacturers
   - Clinical and research laboratories
3. Conduct an international research program devoted to:
   - Improving the laboratory measurement of 25(OH)D.
   - Documenting and studying differences in standardized 25(OH)D concentrations among national surveys worldwide.

VDSP Reference Measurement System Components

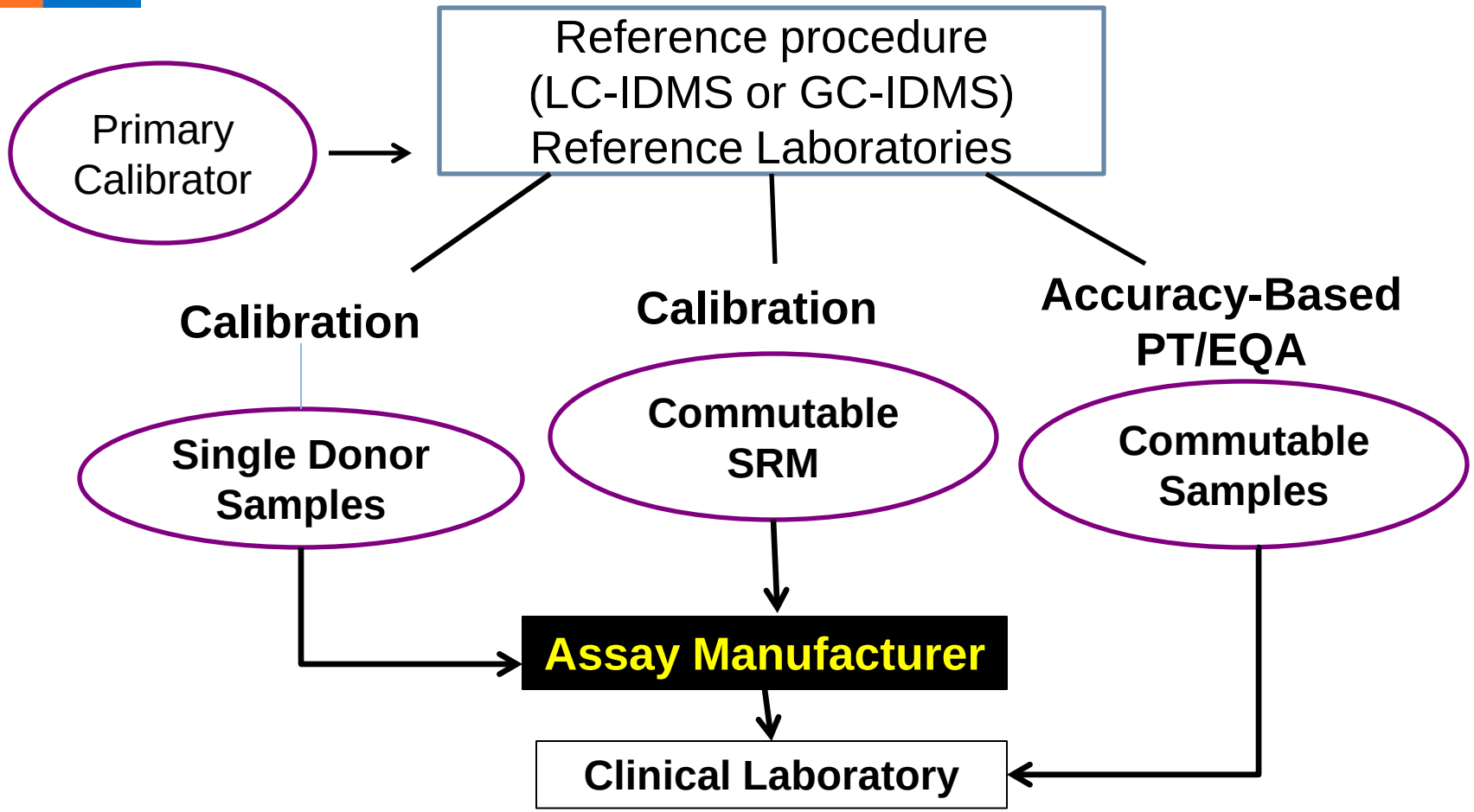
- NIST & Ghent RMPs
- NIST Standard Reference Materials (SRM)
- CDC Vitamin D Standardization-Certification Program
- Accuracy-Based Quality Assurance Programs
- Study designs for standardizing completed studies

Calibration Traceability Scheme*



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

Calibration Traceability Scheme*



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

VDSP Research Agenda

- NIST methods development
- Biological value of 3-epi-25(OH)D3
- Reporting of 24R,25(OH)2D values by DEQAS
- Commutability study – 2nd more extensive study
- Compare standardized national survey data
- Promote standardization of completed studies

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 %CV? Is it ≤ 10%
- What's your assay's Bias? Is it ≤ 5%

References

Sempos C et al. Scand J Clin & Lab Inv 2012;72(Suppl 243): 32-40.

Thienpont L et al. Scand J Clin & Lab Inv 2012;72(Suppl 243): 41-49.

Thank you!

Importance of Standardization in National Health Surveys

- Essential in setting, monitoring and updating evidence-based medical practice guidelines.
- Provide reference ranges
- Promote commercial standardization.
- The first step, however, is *Standardization*.