

NCI-FDA-NIST Workshop on Standards in Molecular Diagnostics

Nadarajen [Nada] A Vydelingum, Ph.D.
Cancer Biomarkers Research Group
Division of Cancer Prevention
National Cancer Institute



DCP Division of
Cancer Prevention

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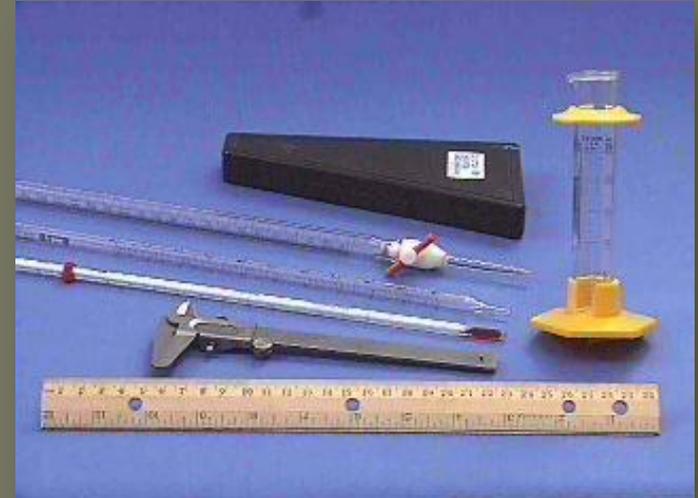
Friday, December 7, 2012
8:00 am - 5:00 pm

Neuroscience Center Building
Conference Room C
6001 Executive Boulevard
Rockville, MD 20852

Contact: AnnaLisa Gnoleba (gnolebaad@mail.nih.gov)

Measuring

- ❖ Volume
- ❖ Temperature
- ❖ Mass



Expert Rev Mol Diagn, 2003 Mar;3(2):129-40
Molecular diagnostics: an FDA perspective.
Ardekani,AM, Petricoin, EF 3rd, Hackett JL.

The development of a co-operative framework between regulators, product sponsors and technology experts will be essential for realizing the revolutionary promise these platforms could have on the evolution of drug development, regulatory science, the practice of medicine and public health.

Challenges

Significant challenges in standardization of assay methods include:

- Validate both the clinical and analytical performance of the diagnostic
- Standardize pre-analytical variables during specimen collection, stabilization, and processing
- Pay rigorous attention to the analytical performance and validation of the assay
- Meet regulatory requirements

Working Group

- FDA

Lakshman Ramamurthy, M.Sc., Ph.D.

- NIST

Marc L. Salit, Ph.D.

- NCI

Lynn Sorbara, Ph.D.

Nadarajen A. Vydelingum, Ph.D.

Paul Wagner, Ph.D.



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