NCI-FDA-NIST
Workshop on Standards in Molecular Diagnostics

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

Neuroscience Center Building
Conference Room C
6801 Executive Boulevard
Rockville, MD 20852

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Measuring

- Volume
- Temperature
- Mass
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**
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  Nadarajen A. Vydelingum, Ph.D.
  Paul Wagner, Ph.D.