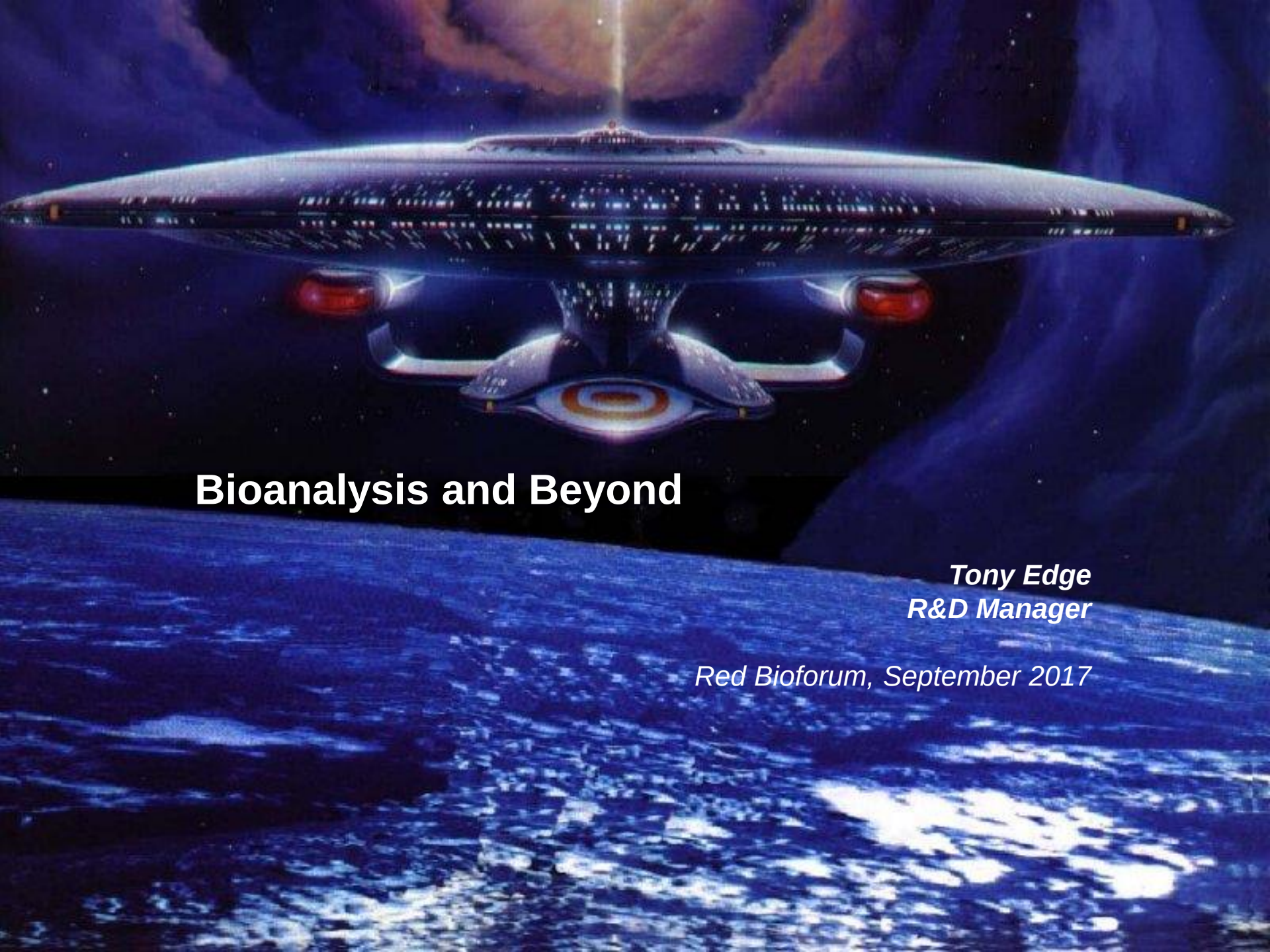


Bioanalysis and Beyond

Tony Edge
R&D Manager

Red Bioforum, September 2017

Introduction

Review of current technologies

- Sample Handling
- Sample Preparation

Where are the challenges and drivers

- Ion Suppression
- Regulatory

What technologies are there today?

- Tubes, DBS

Technologies of the future that are available today

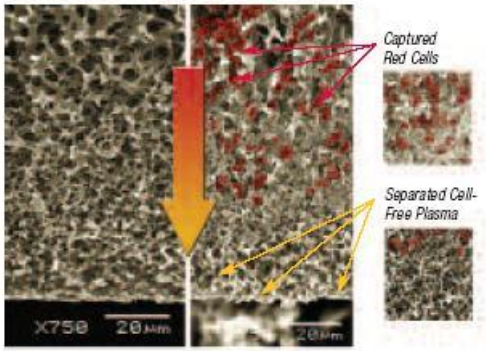
- CD
- Direct analysis

Let our imagination go wild

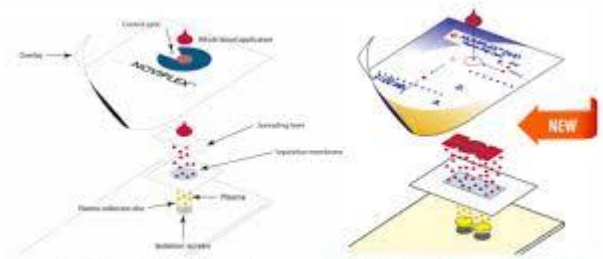
Current Technology – Sample Handling

Current Sampling Devices

PALL Pall Corporation



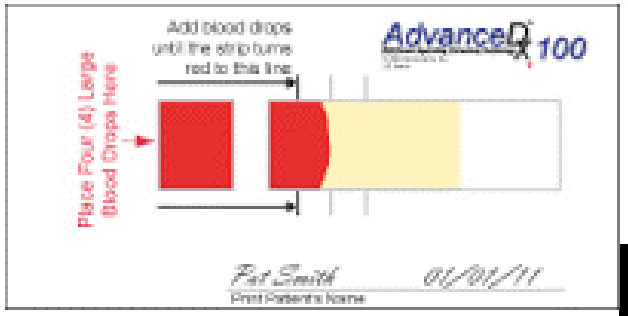
SHIMADZU



Noviplex Plasma Prep Card Noviplex Duo Plasma Prep Card

hemaPEN™ Workflow

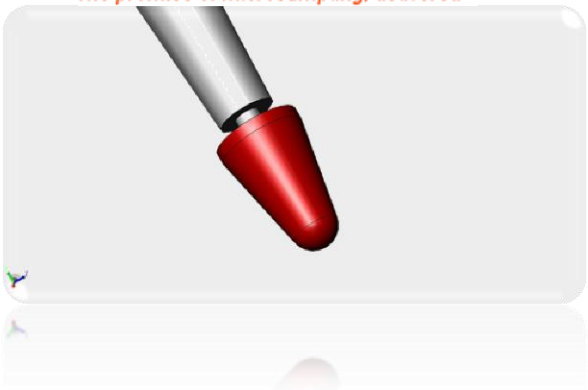
TRAJAN



bmf Boston Microfluidics

neoteryx™

The promise of microsampling, delivered

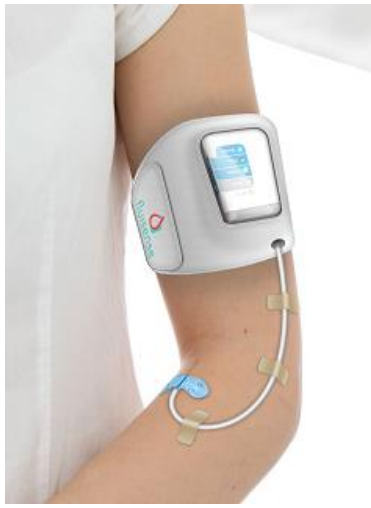


SPME

Current Sampling Devices

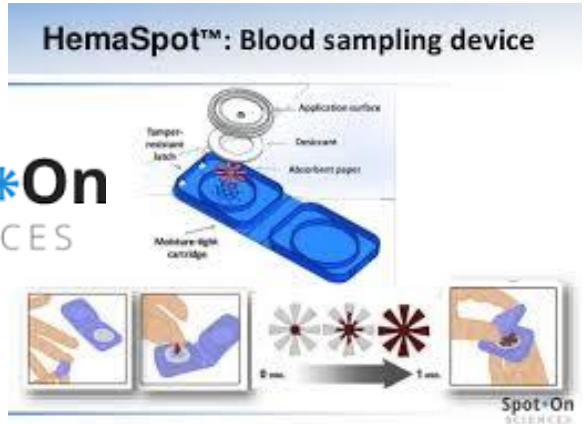
SeventhSense BIOSYSTEMS

Tasso



fluisense®

Spot*On SCIENCES

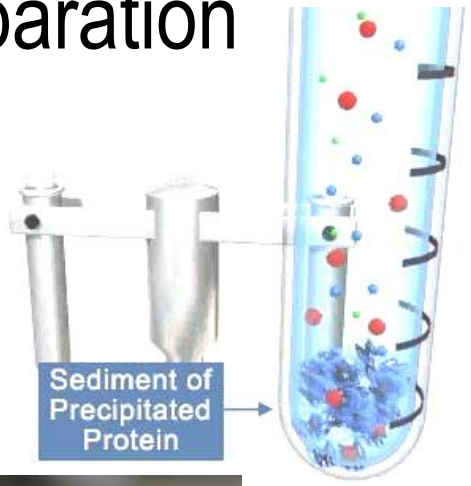


Current Technology – Sample Preparation

Protein Precipitation

100µl of plasma + 300µl ACN

Centrifugation / filtration

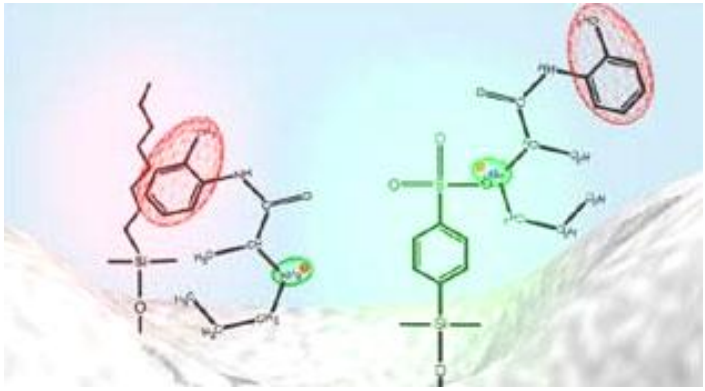


SPE Phases

Reverse Phased

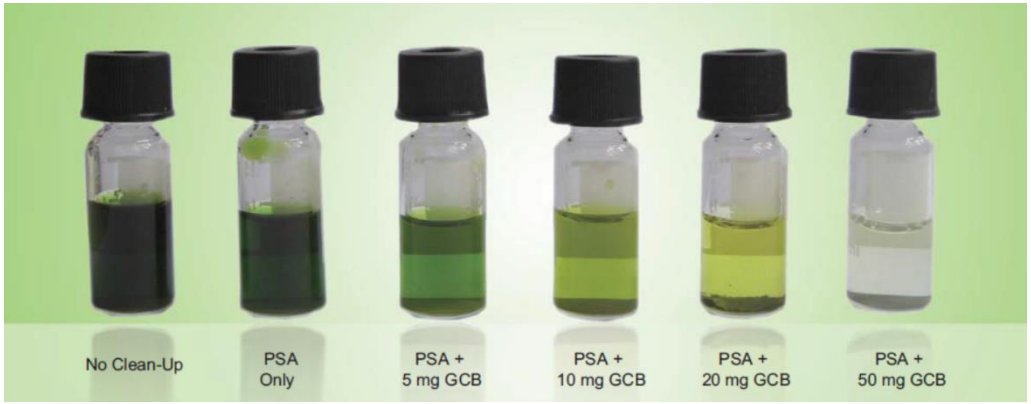
Mixed Mode

Liquid-Liquid Extraction



Other Approaches

Quechers

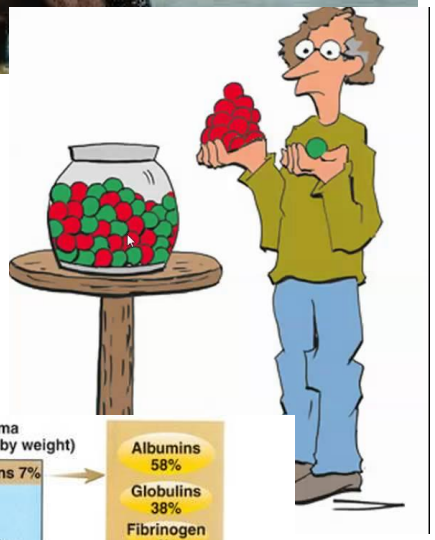


TFC

SLE, Ligand binding assays, immunodiagnostics, ultracentrifugation, ultrafiltration…….

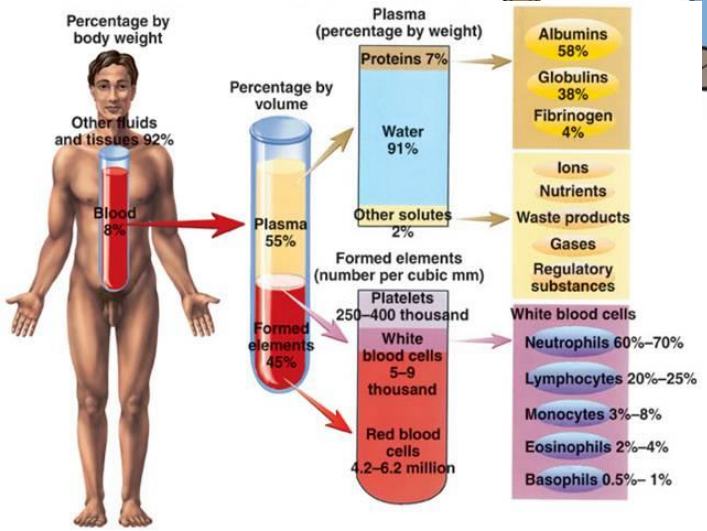
Current Challenges

Collection of known sample volume

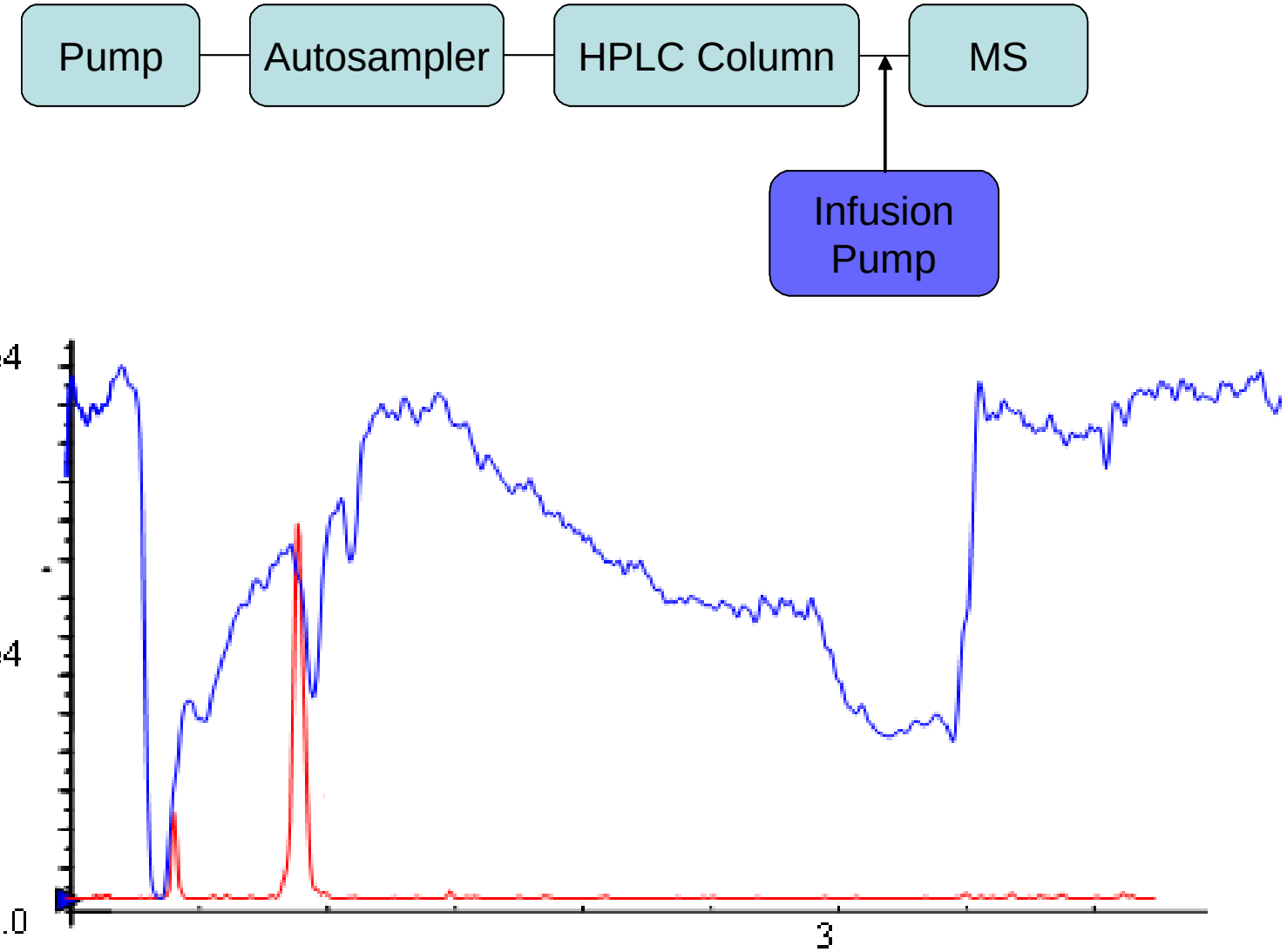


Collection of representative sample

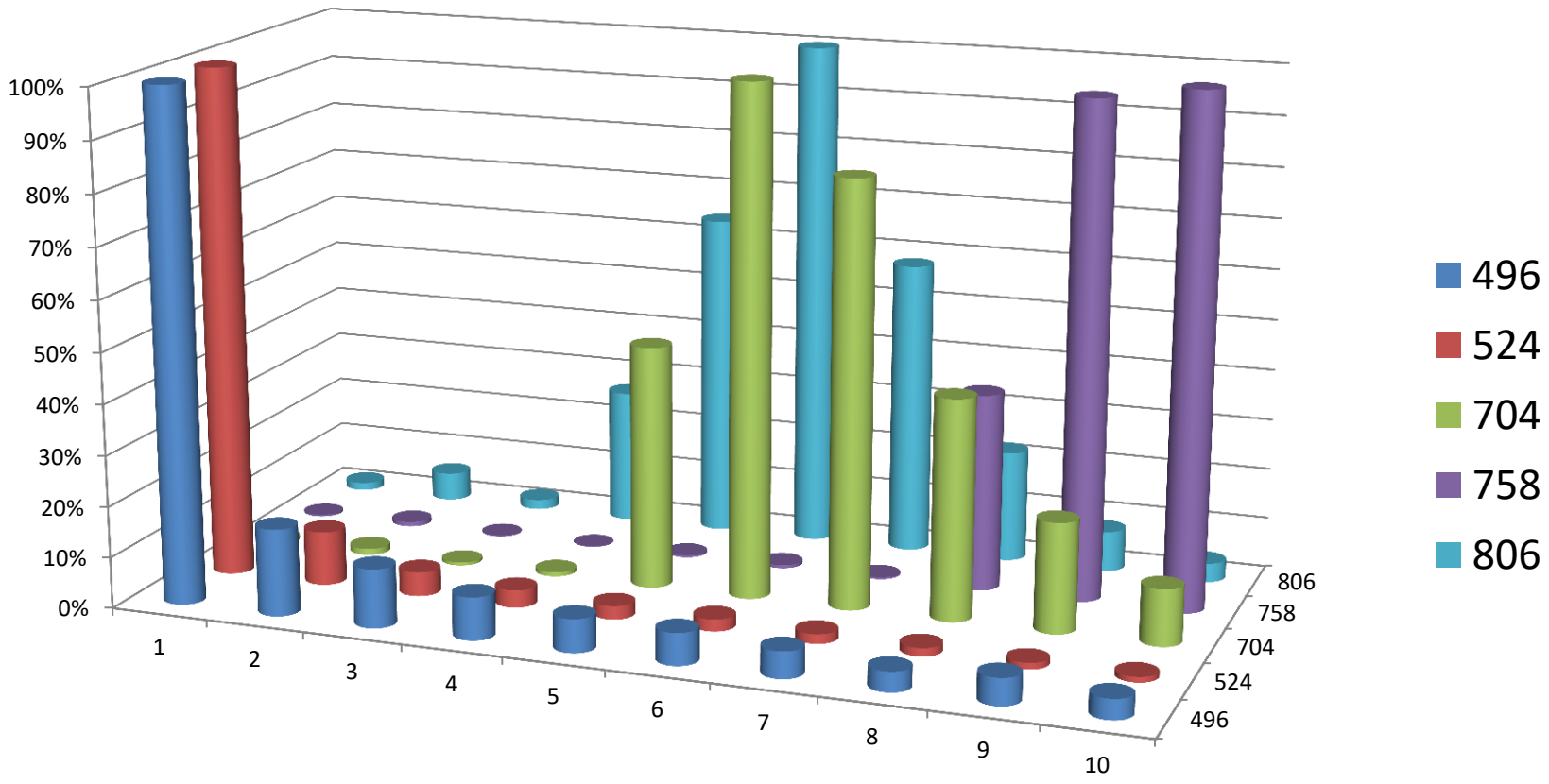
Removal of matrix components



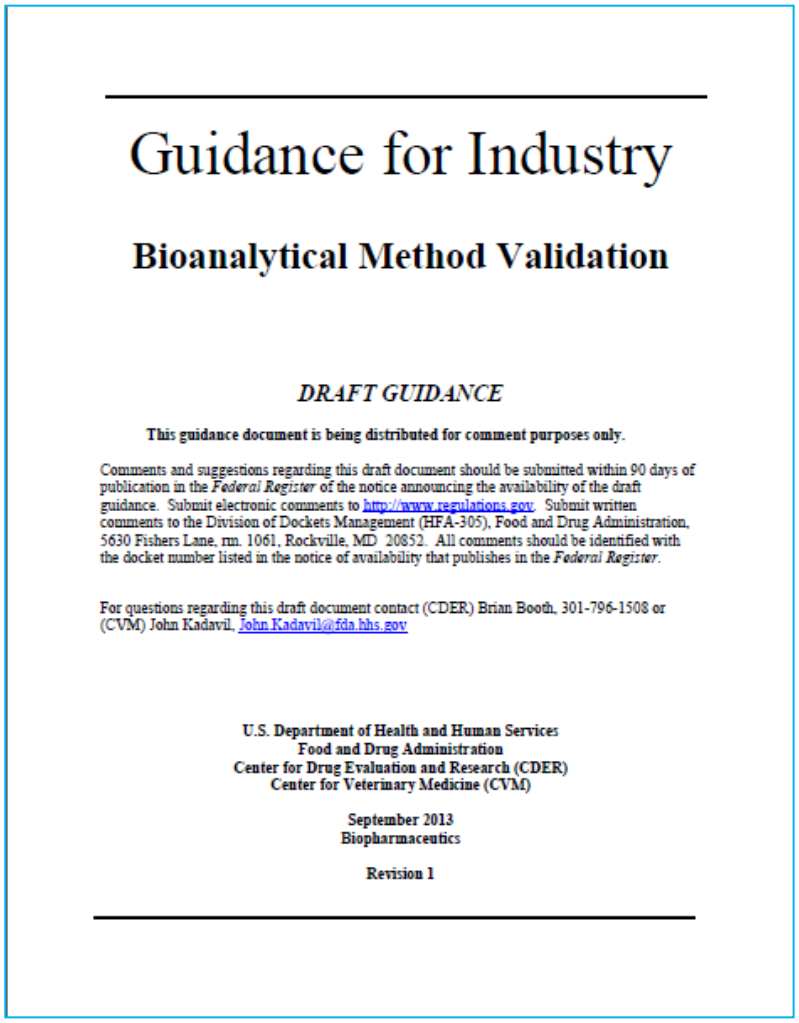
Current Challenges – Ion Suppression



Current Challenges – Matrix Removal



Current Challenges



Guidance for Industry

Bioanalytical Method Validation

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

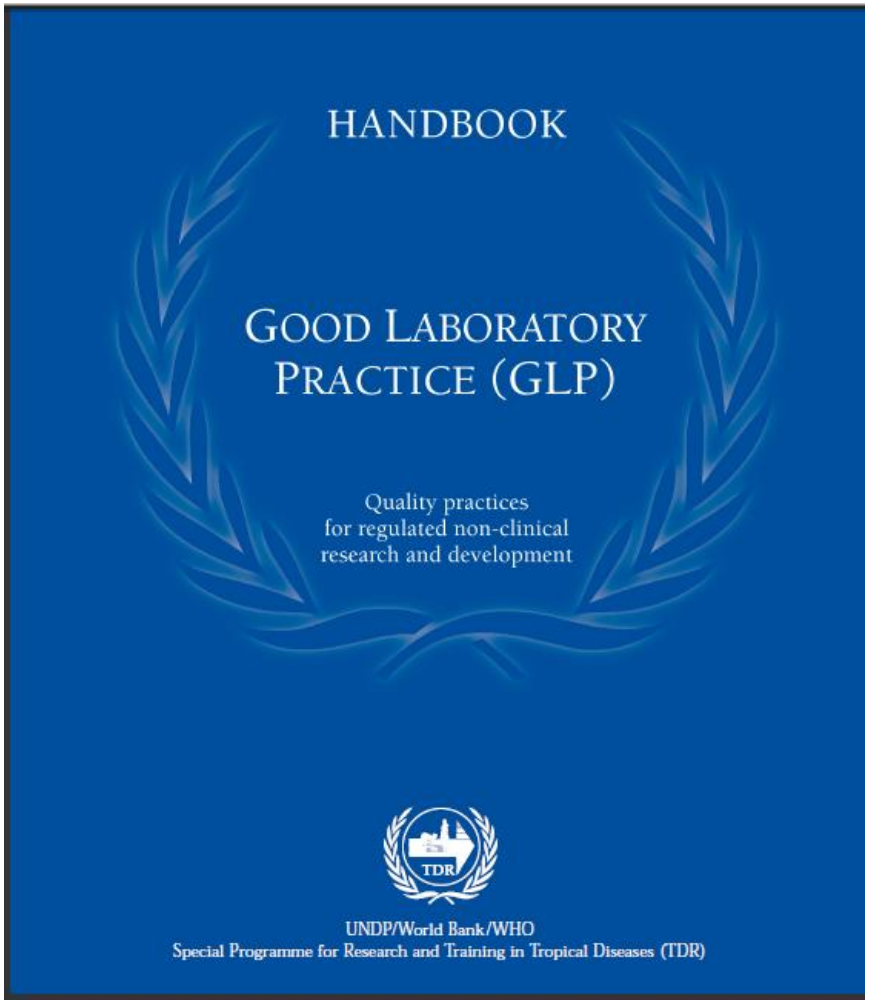
Comments and suggestions regarding this draft document should be submitted within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document contact (CDER) Brian Booth, 301-796-1508 or (CVM) John Kadavil, John.Kadavil@fda.hhs.gov

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Veterinary Medicine (CVM)

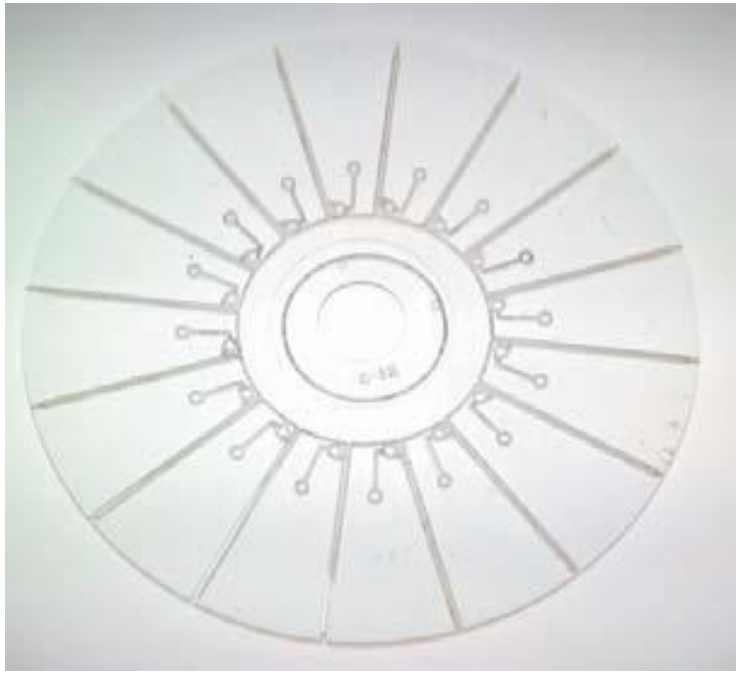
September 2013
Biopharmaceutics

Revision 1



Analysis using a CD player

Feasible to etch a CD with channels and link to in built detector in CD player



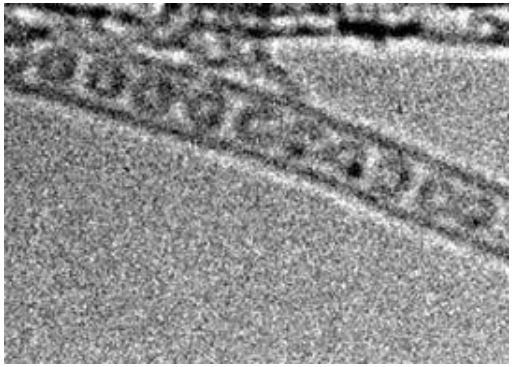
Moving away from a Central Laboratory to Shops

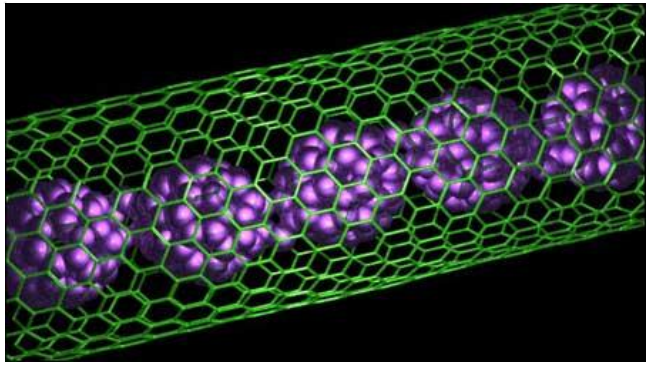
Patients take their own samples

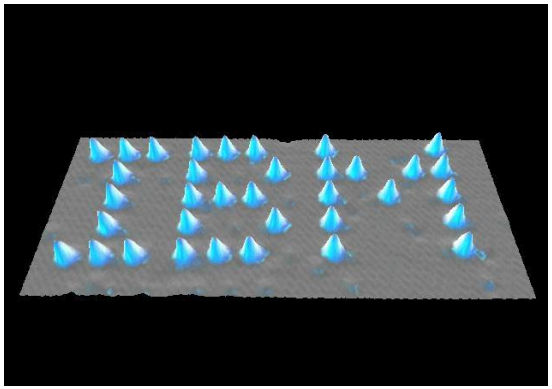
- Analysis done in 1-2 hours (c.f. old style photographs)
- Have central analytical laboratories

Taking Samples

- Miniaturisation
  - 3D Printing of columns
  - Miniature sample collection devices
  - Integrate into a watch design



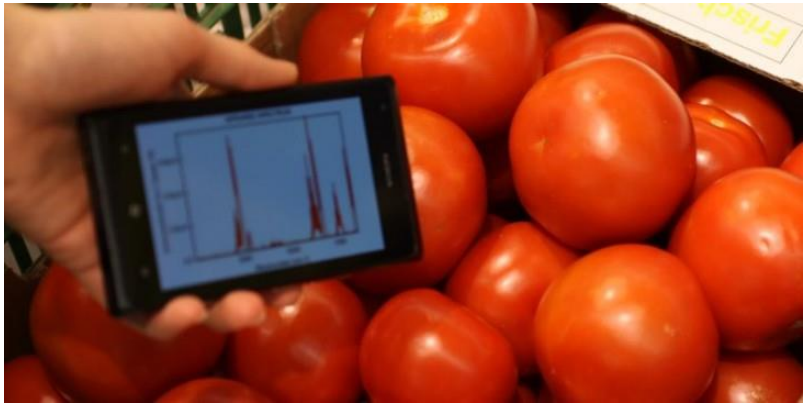




Tricorders – The Future of Bioanalysis?

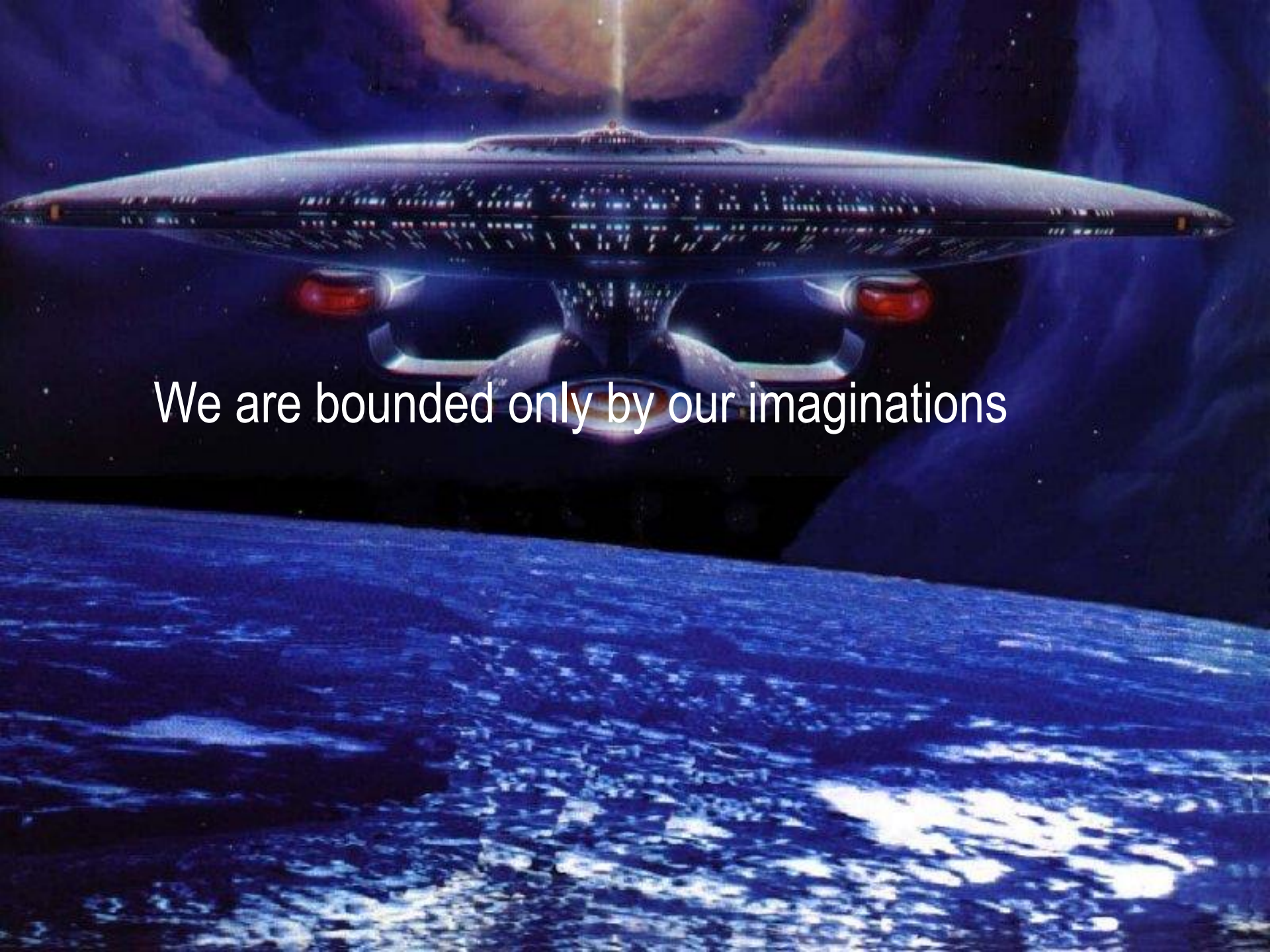
Vital Technologies Corporation sold "Official Star-Trek Tricorder Mark 1“

- Comprised of clock, thermometer, barometer, colorimeter



Direct analysis

- Use of IPhone app
- MRI, DESI, MS, DART, LDTD


We are bounded only by our imaginations