

# Joint Committee for Traceability in Laboratory Medicine

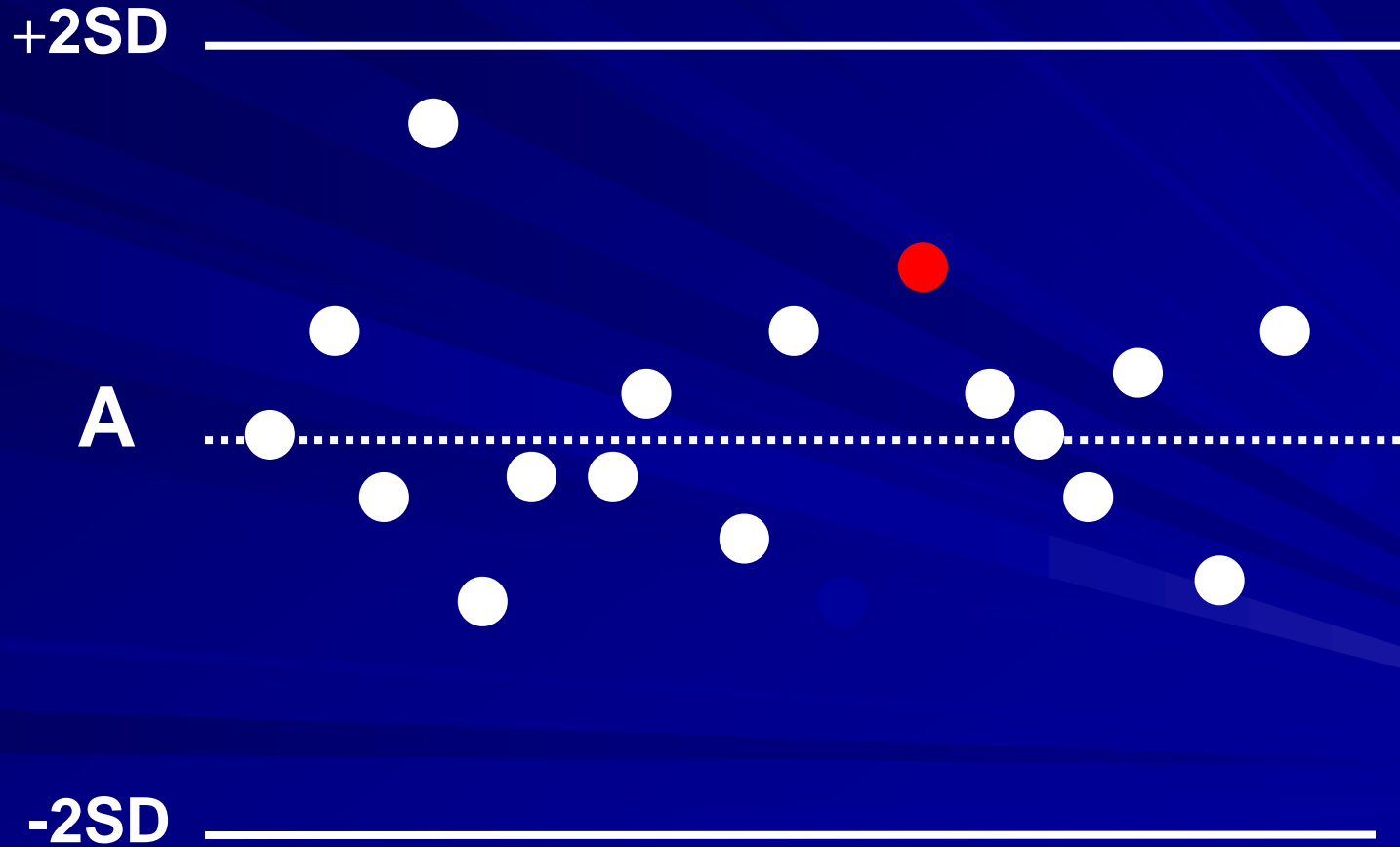
Robert M. Kisabeth, M.D.

December 2004

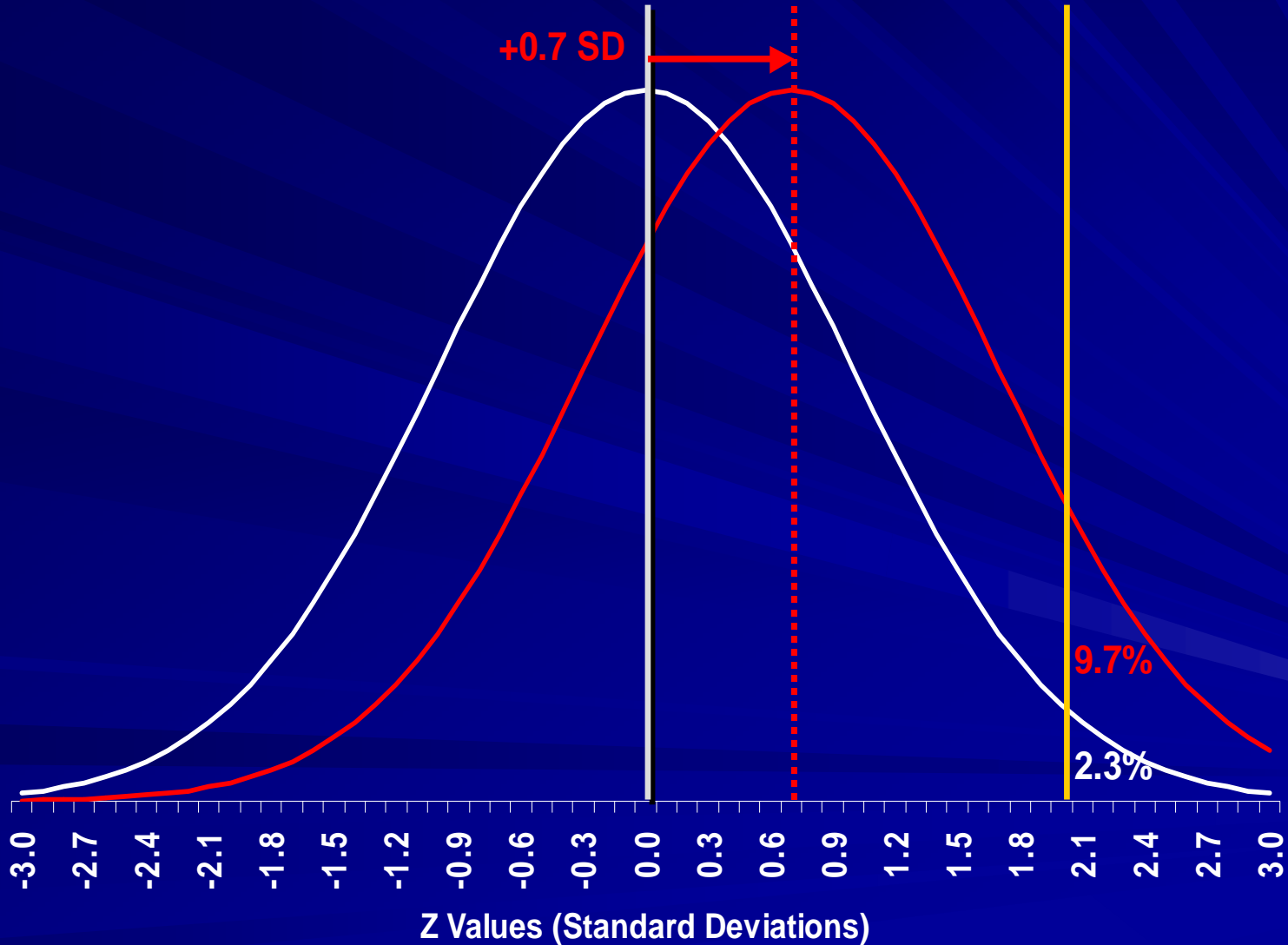
# Analytic Bias

- Bias directly affects test values
- Small analytic changes can produce major shifts in frequency distributions of clinical test values

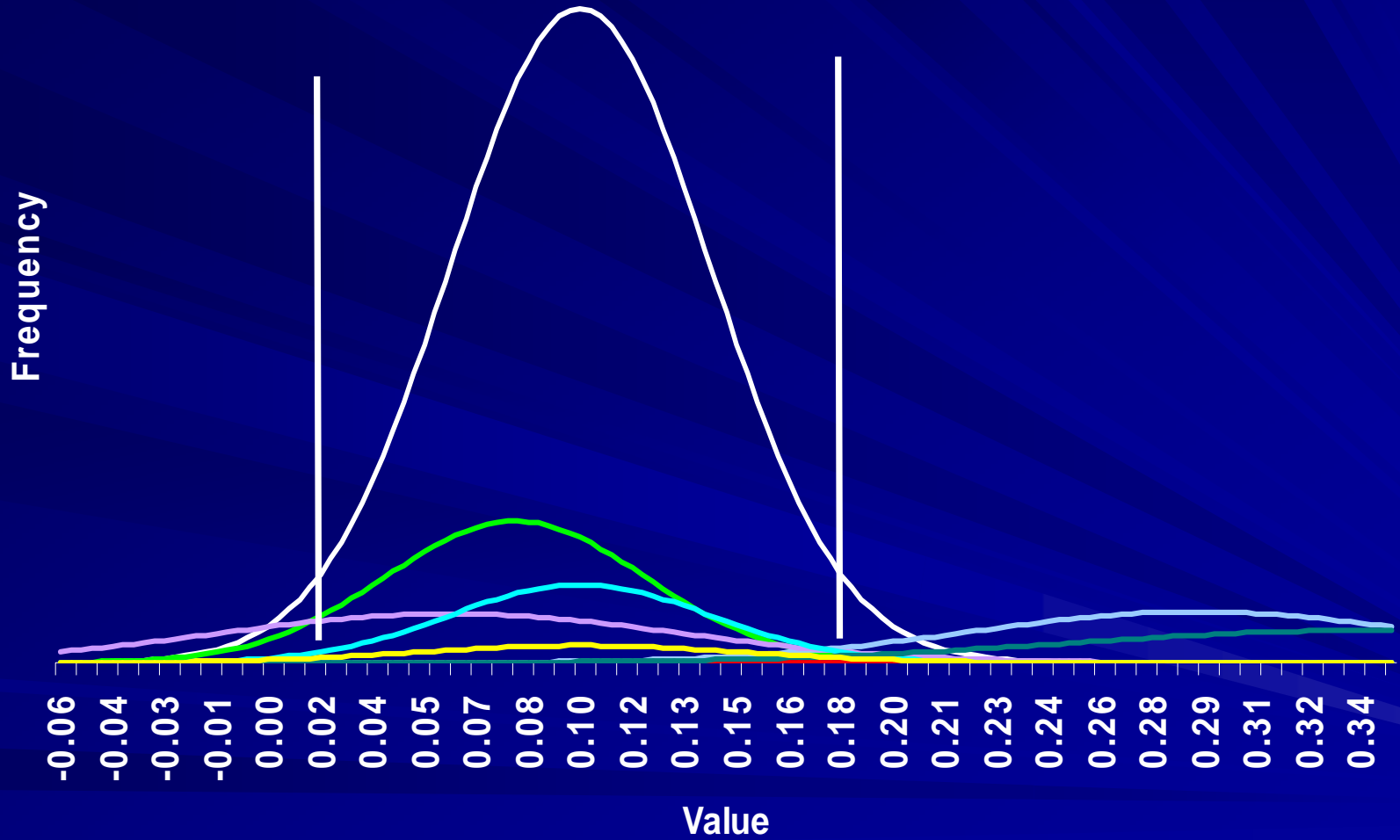
# Daily Plot of Assay Control



# PSA - 0.7 SD Shift

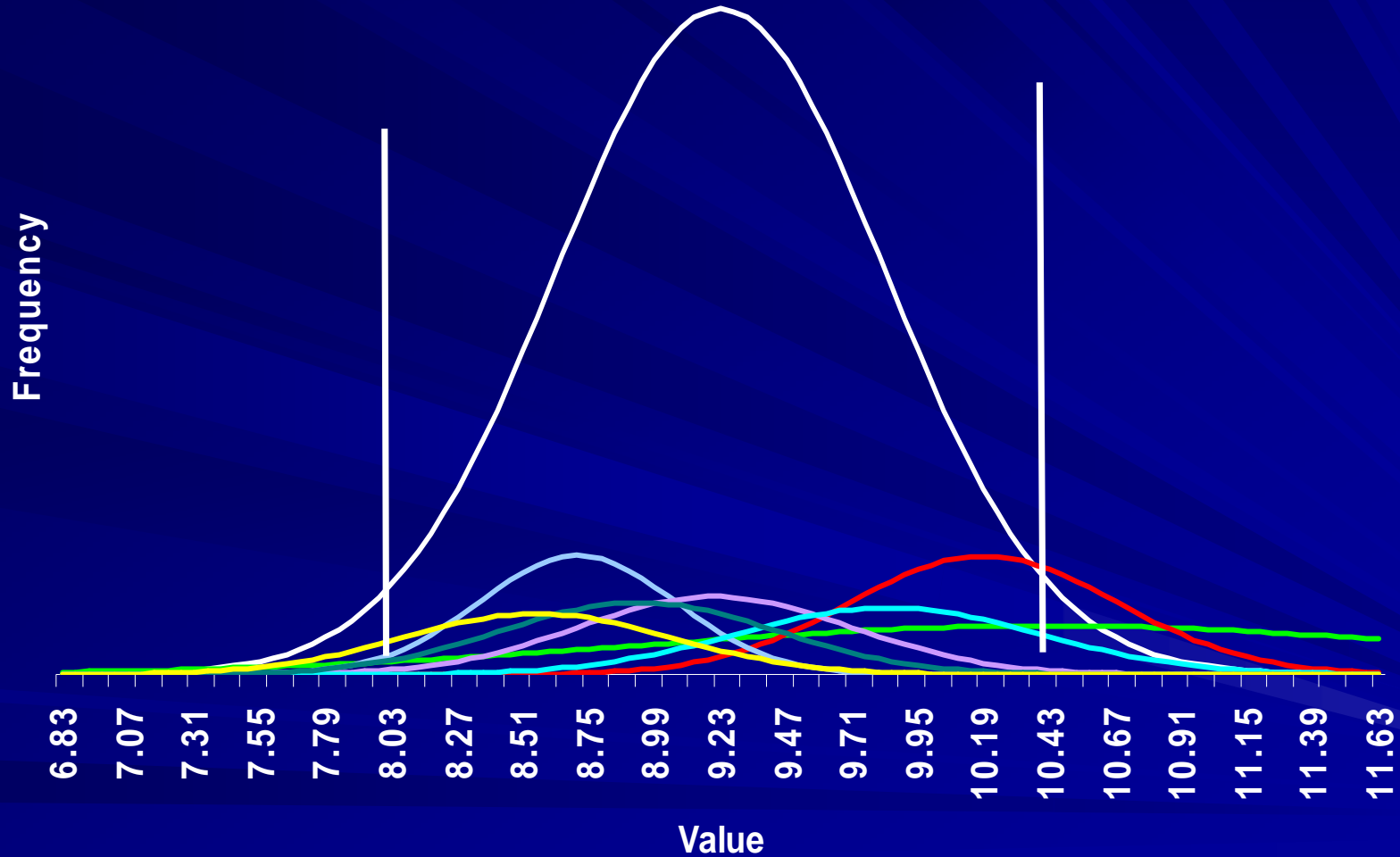


# Specimen K-18 - PSA



- |          |          |              |            |
|----------|----------|--------------|------------|
| — AxSYM  | — Access | — "ACS 180 2 | — Centaur  |
| — Dim HM | — IMX    | — ACS 180    | — Tandem E |

# Specimen K-19 - PSA



- Axsym
- Access
- Dim HM
- Immuno-1
- IMX
- ACS 180 2
- Centaur
- Elecsys

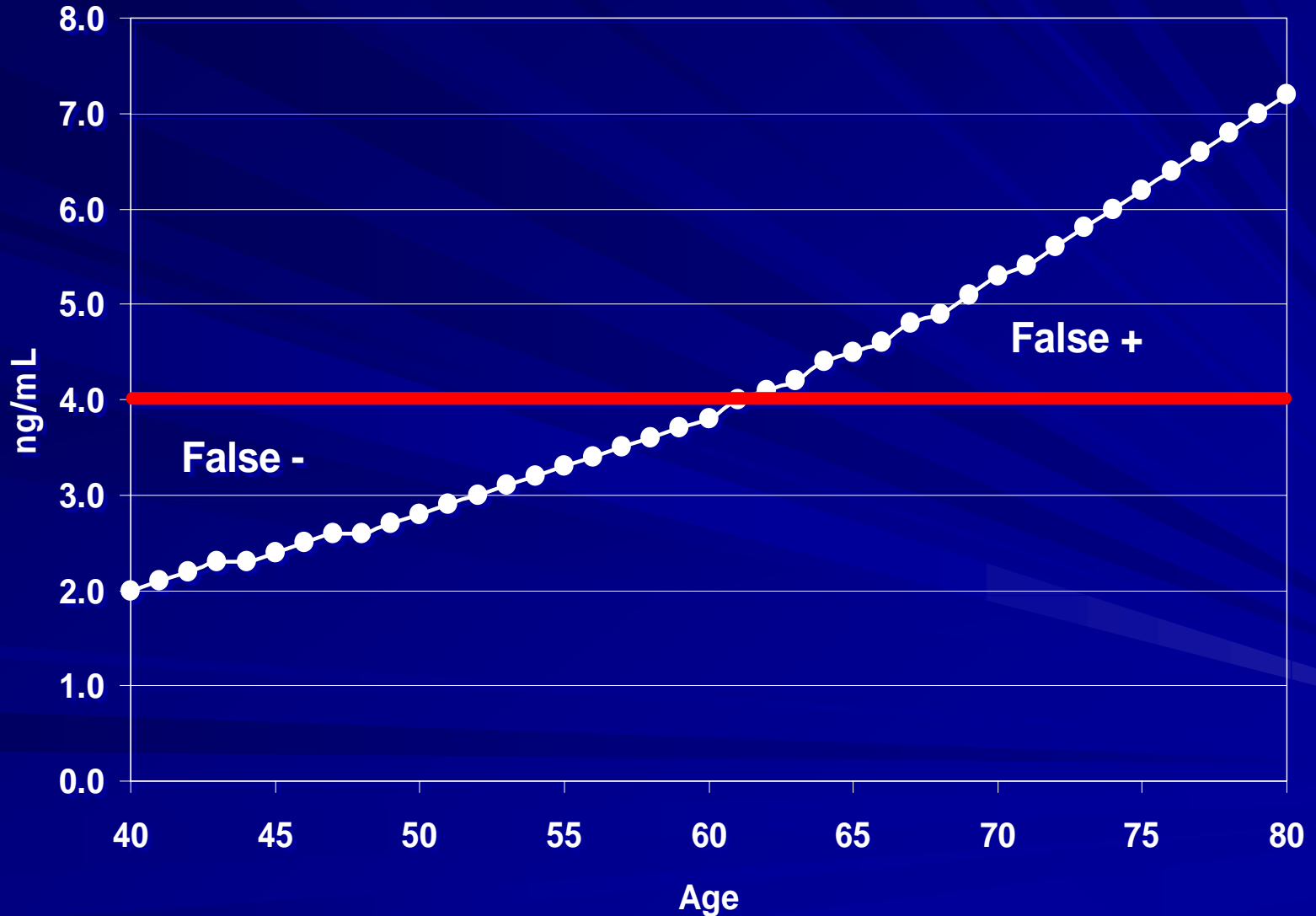


# Case Studies - Mayo

- Starting Point - Critical Analytes
  - Cholesterol, Triglycerides, HDL, LDL
  - Glycated Hemoglobin
  - Creatine Kinase, CK MB and Troponin
  - Prostatic Specific Antigen (PSA)



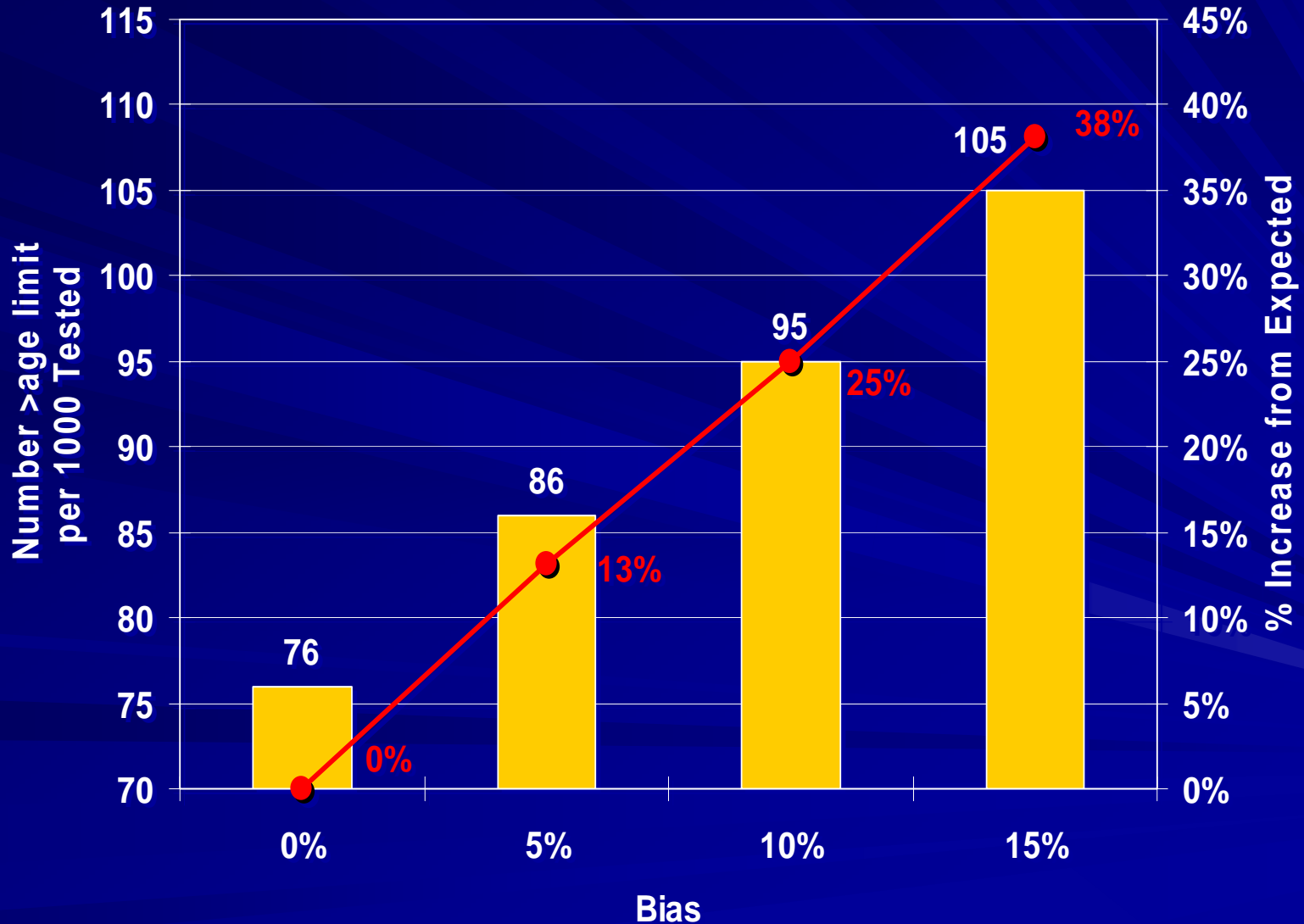
# PSA Reference Range



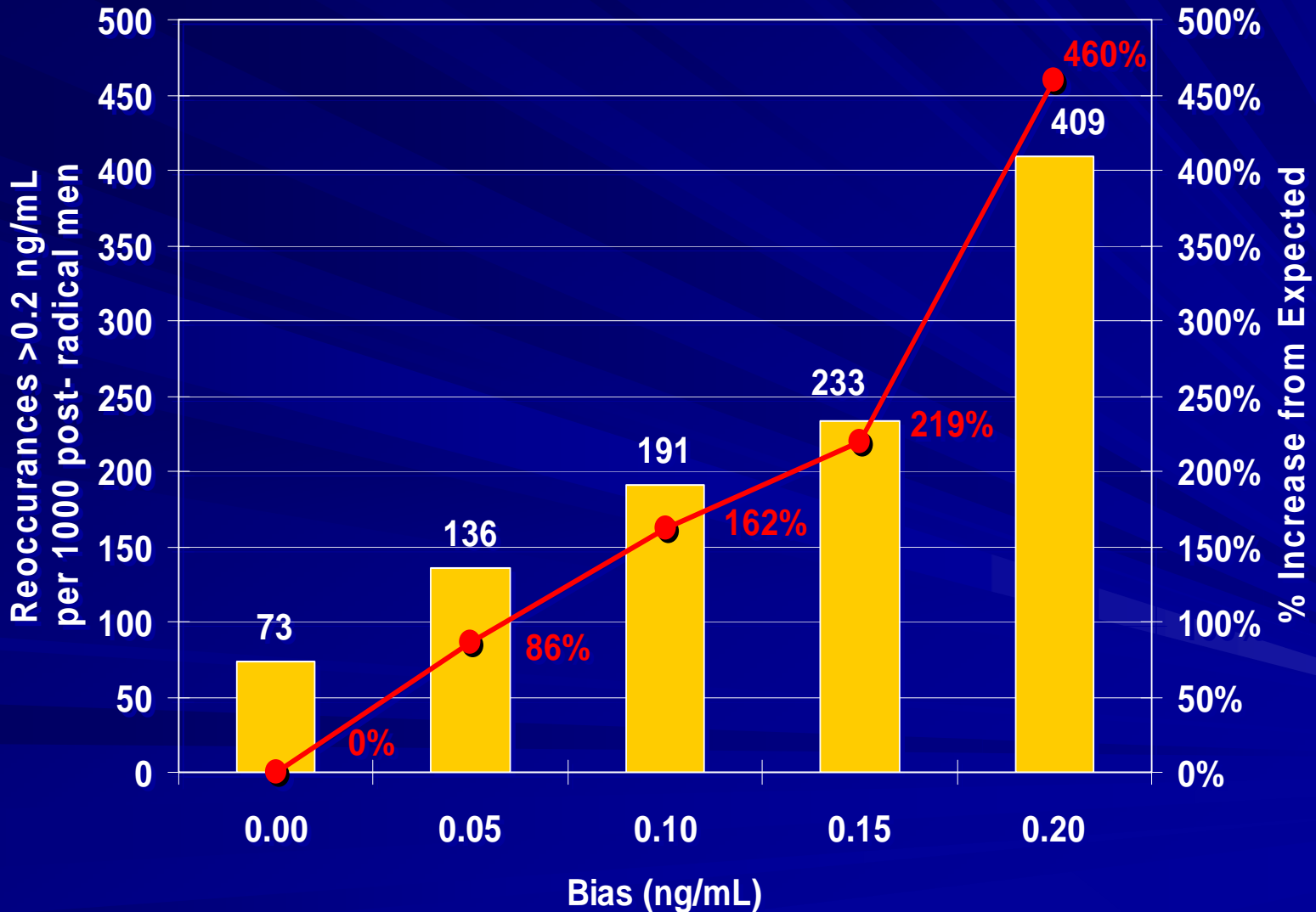




# Effect of Positive Bias on PSA



# Effect of Low End Bias on PSA





# PSA - Cost Comparison

Average charge at Mayo of prostate biopsy: **\$2,710**

Charges for prostate bx/1000 lives, age 60-74, w/out age adjusted ref range: **\$406,500**

Charges for prostate bx/1000 lives, age 60-74, with age adjusted ref range: **\$243,900**

Total reduction in prostate bx charges/1000 lives with age adjusted reference range: **\$162,600**



**(Clinical Chemistry. 2001;47:631-634.)**

**Preoperative Serum Prostate-specific Antigen (PSA) Below 10  $\mu\text{g/L}$  Predicts Neither the Presence of Prostate Cancer Nor the Rate of Postoperative PSA Failure**

**Thomas A. Stamey**

**Stanford University, Department of Urology S-287, Stanford University School of Medicine, Stanford, CA**

# PSA Blinded Specimen

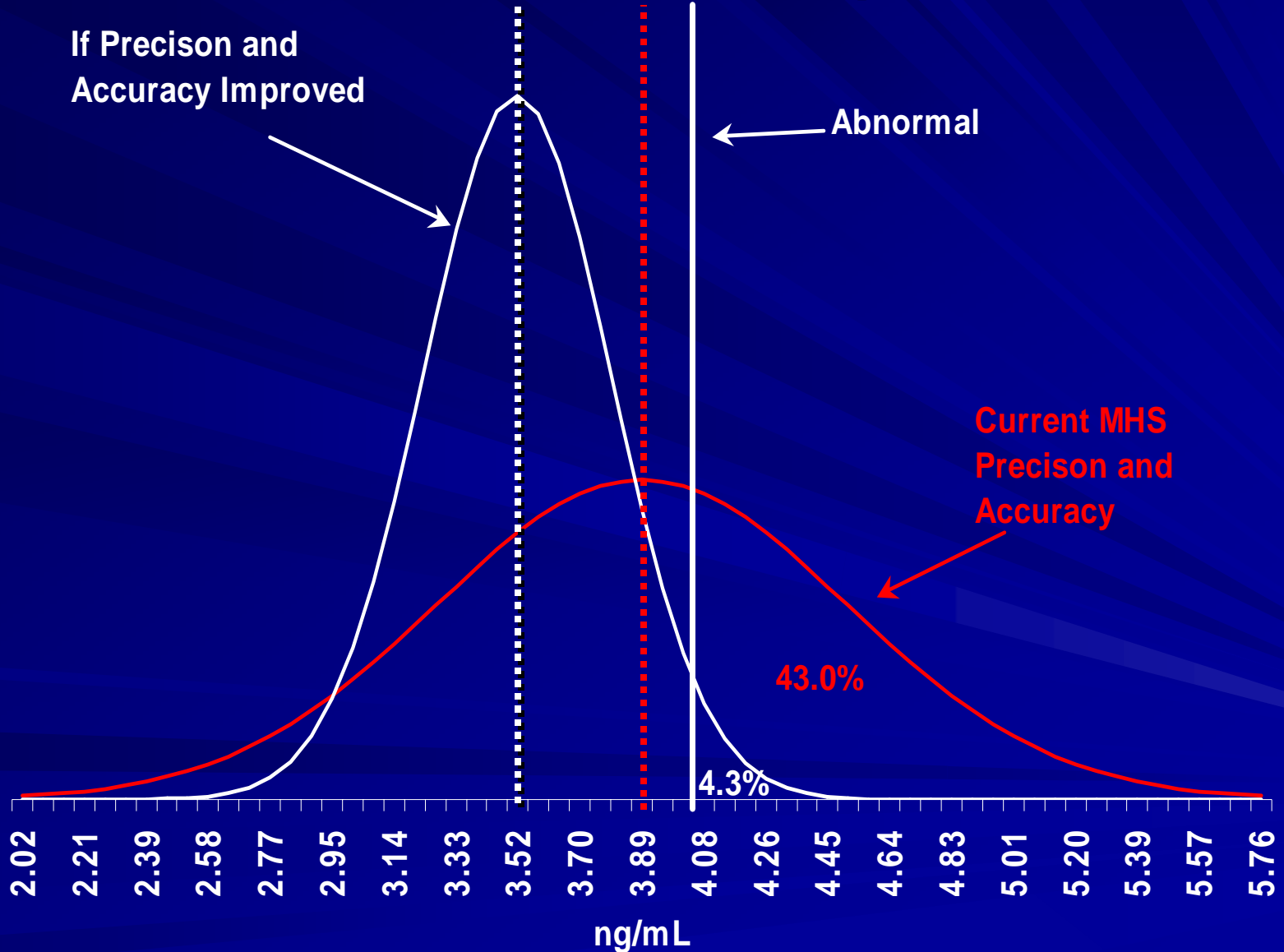


Figure 1

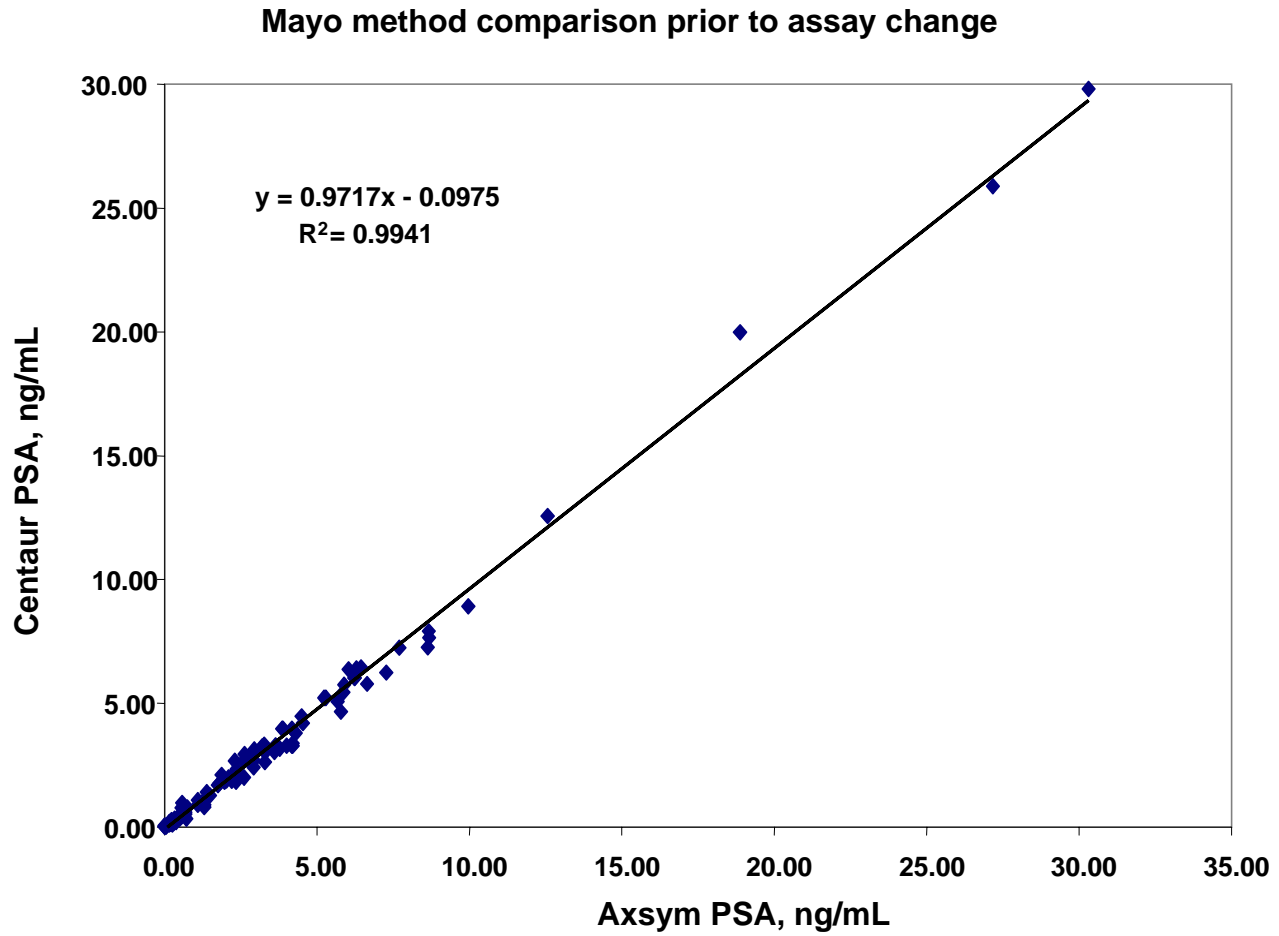
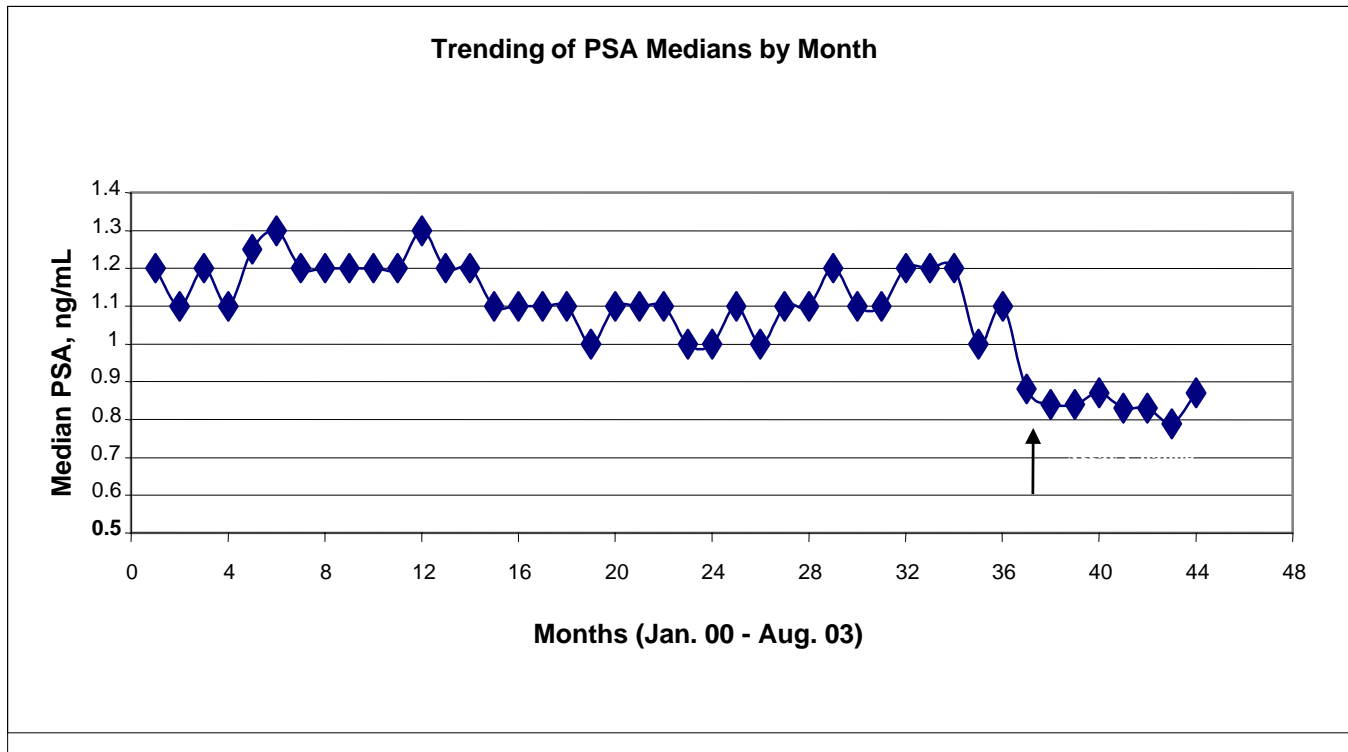
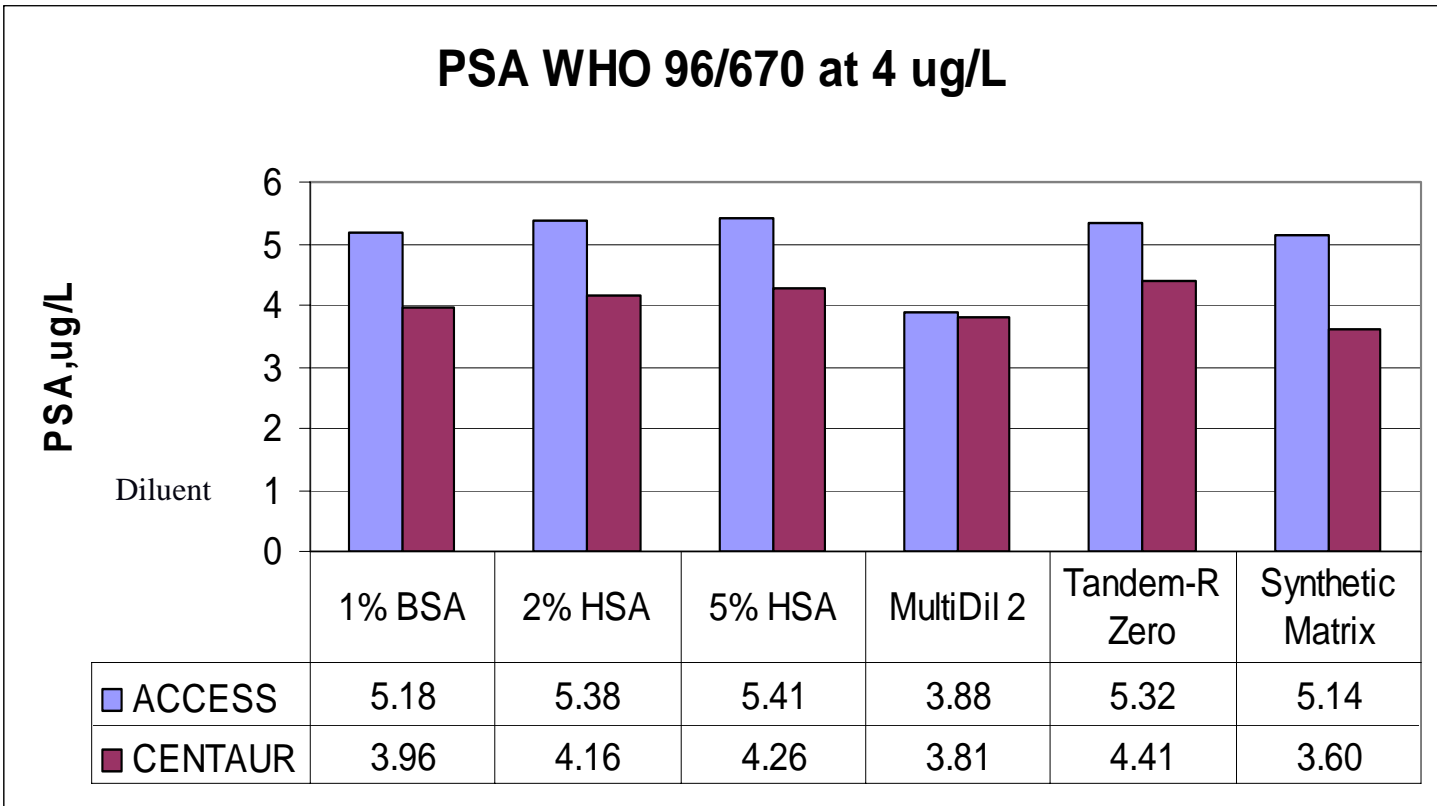


Figure 2



**Figure 3**

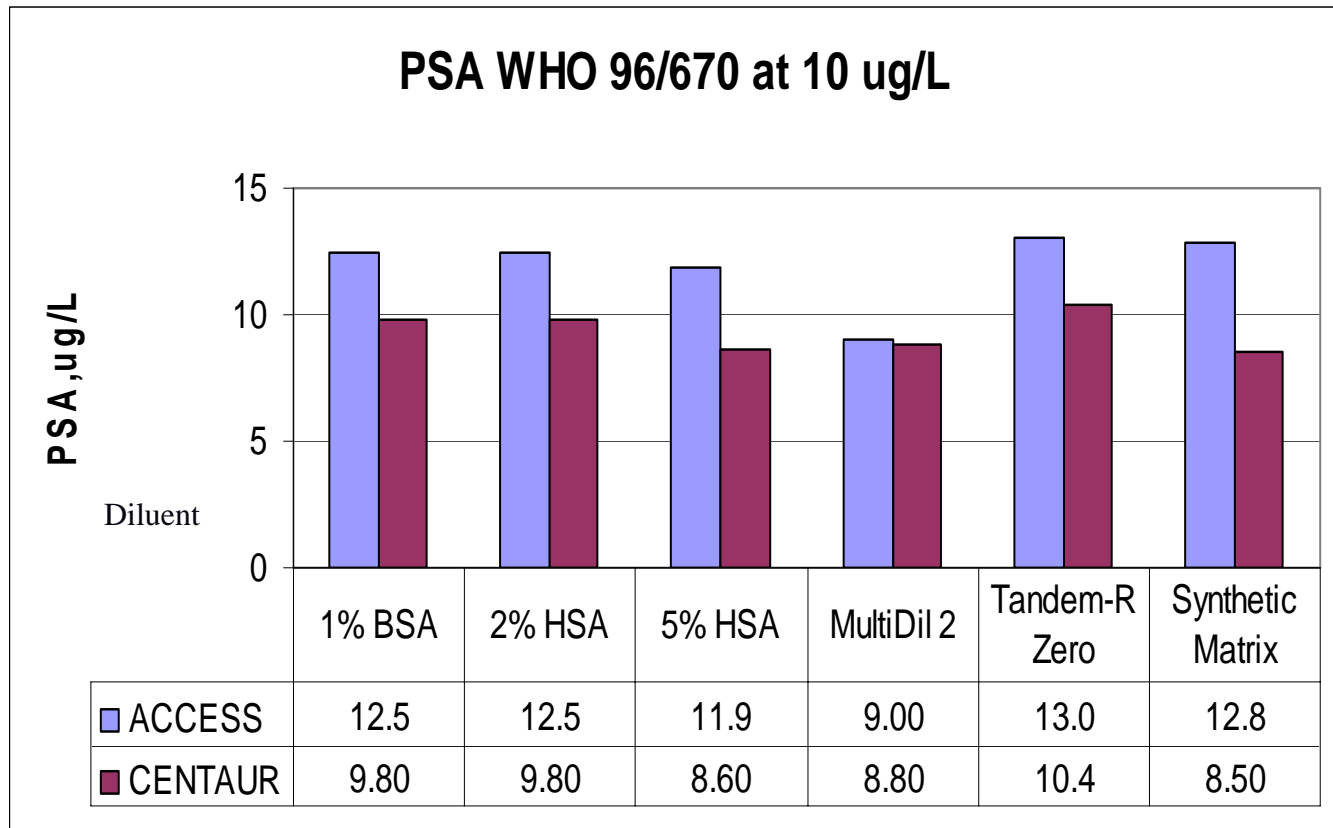
**Panel A**





**Figure 3**

**Panel B**



**Figure 3**

**Panel C**

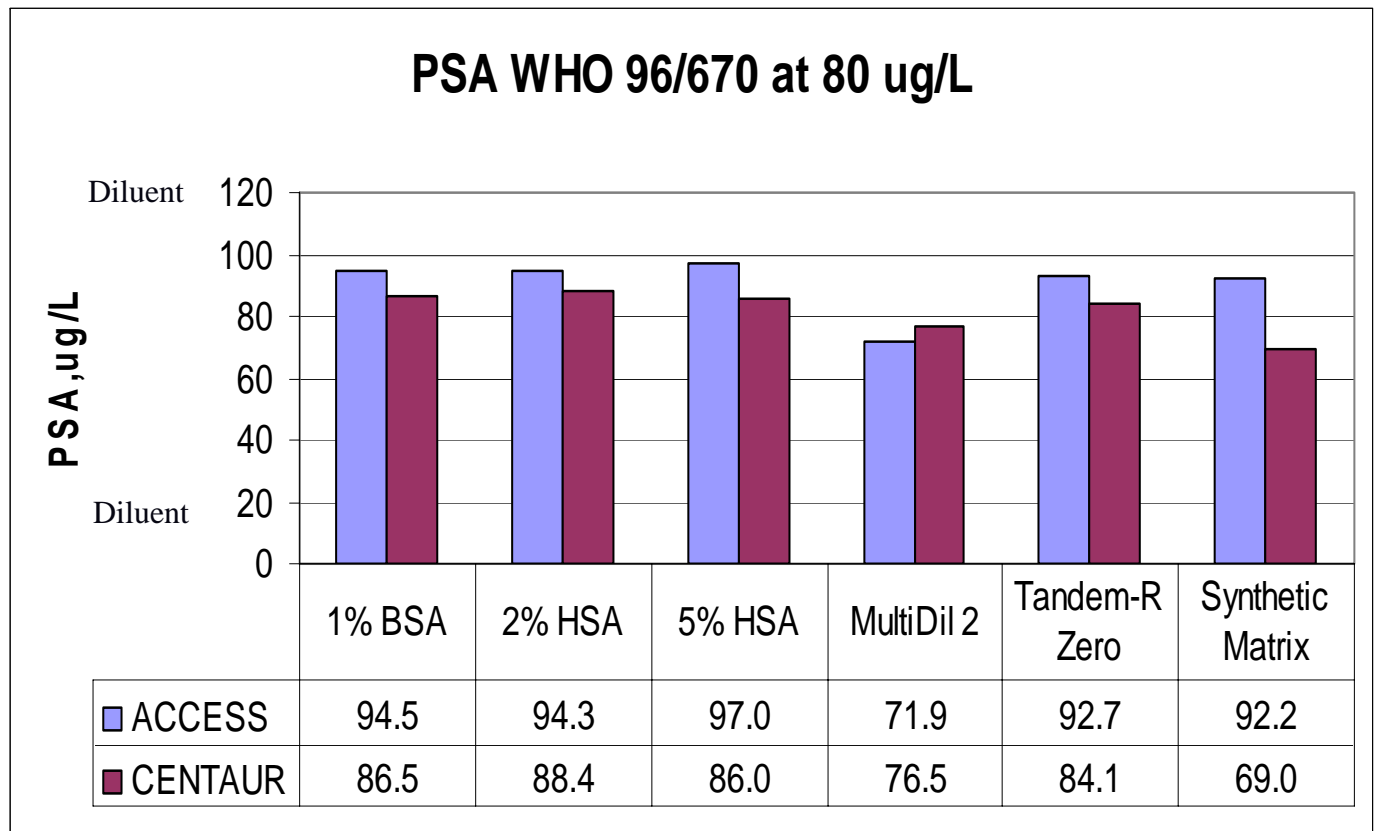


Figure 4

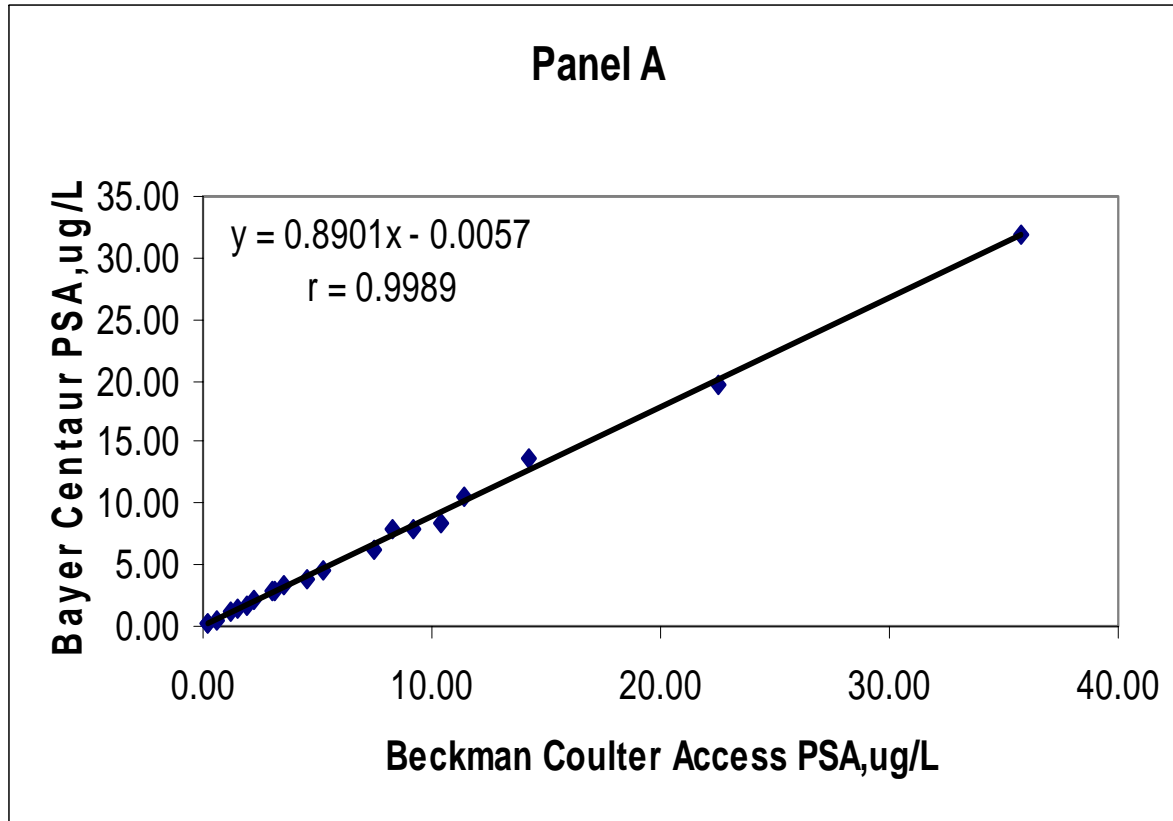


Figure 4

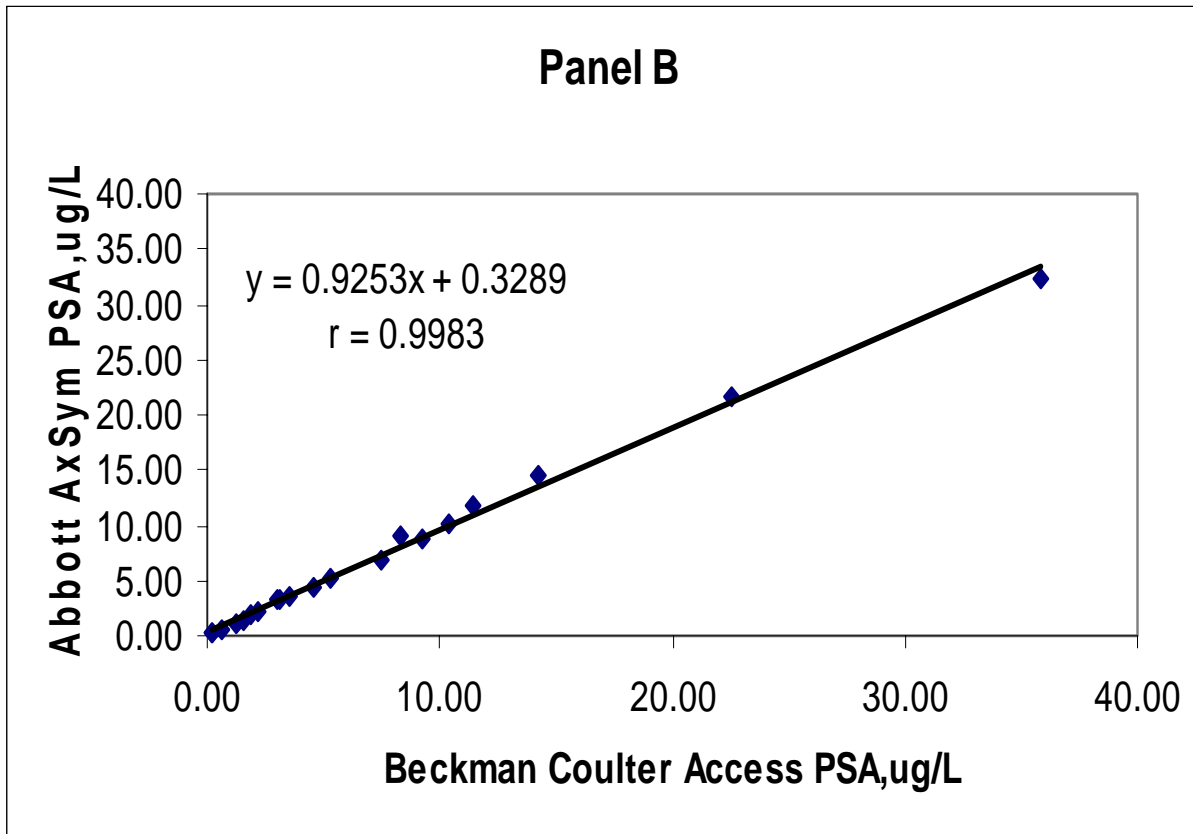


Figure 4

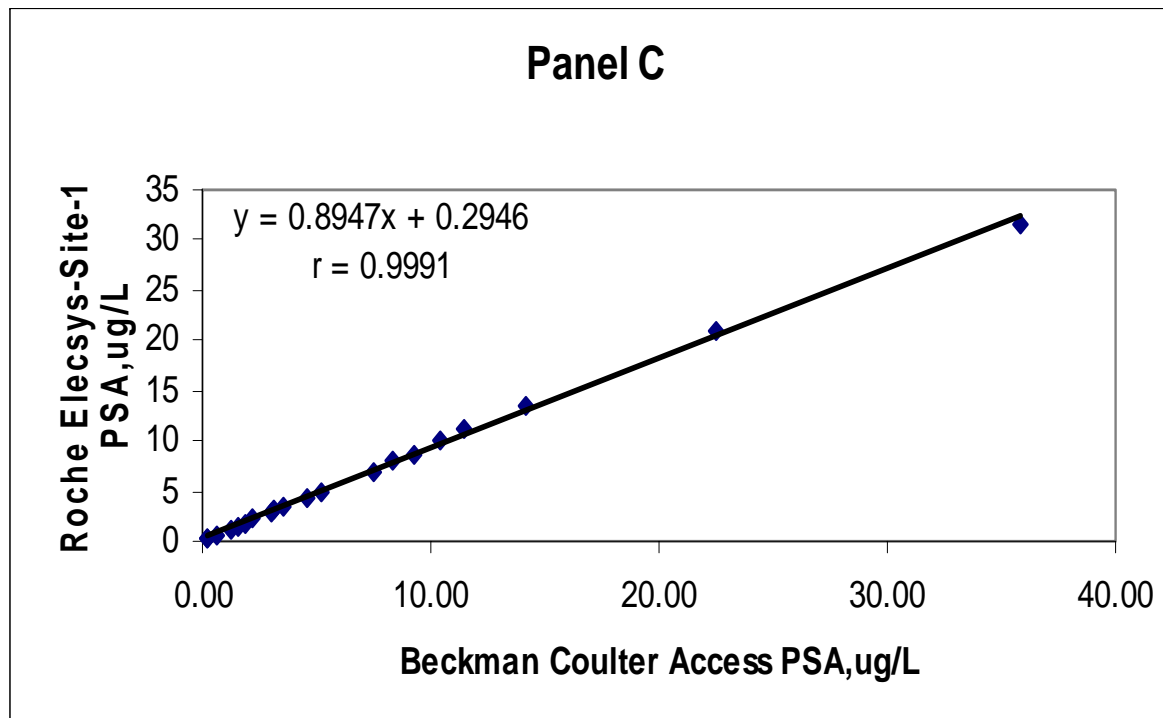
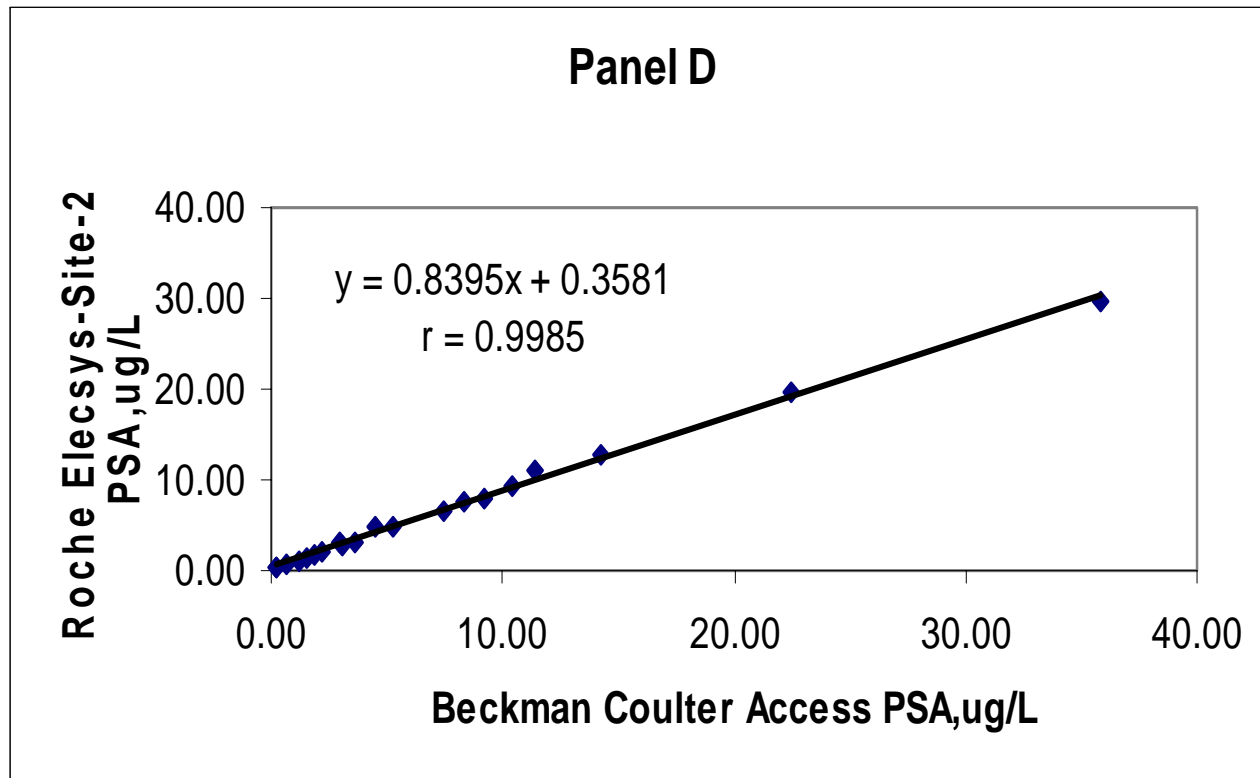
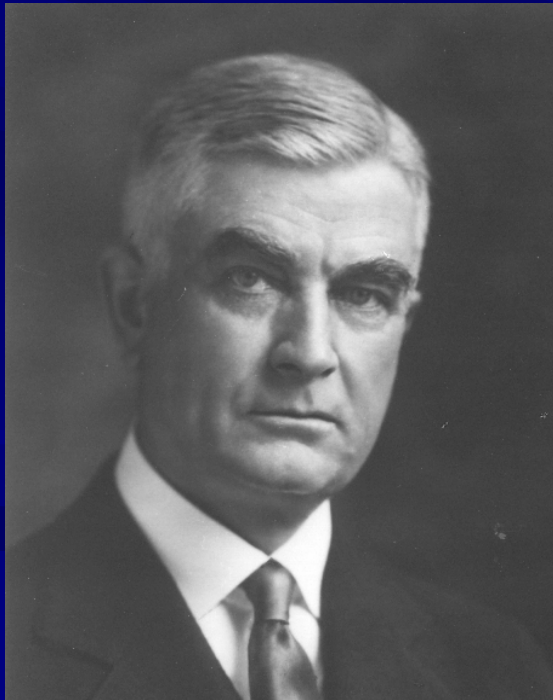


Figure 4



# Wisdom

*“Have we thought enough of wisdom, which moves knowledge and makes it useful?”*



William J. Mayo, 1938