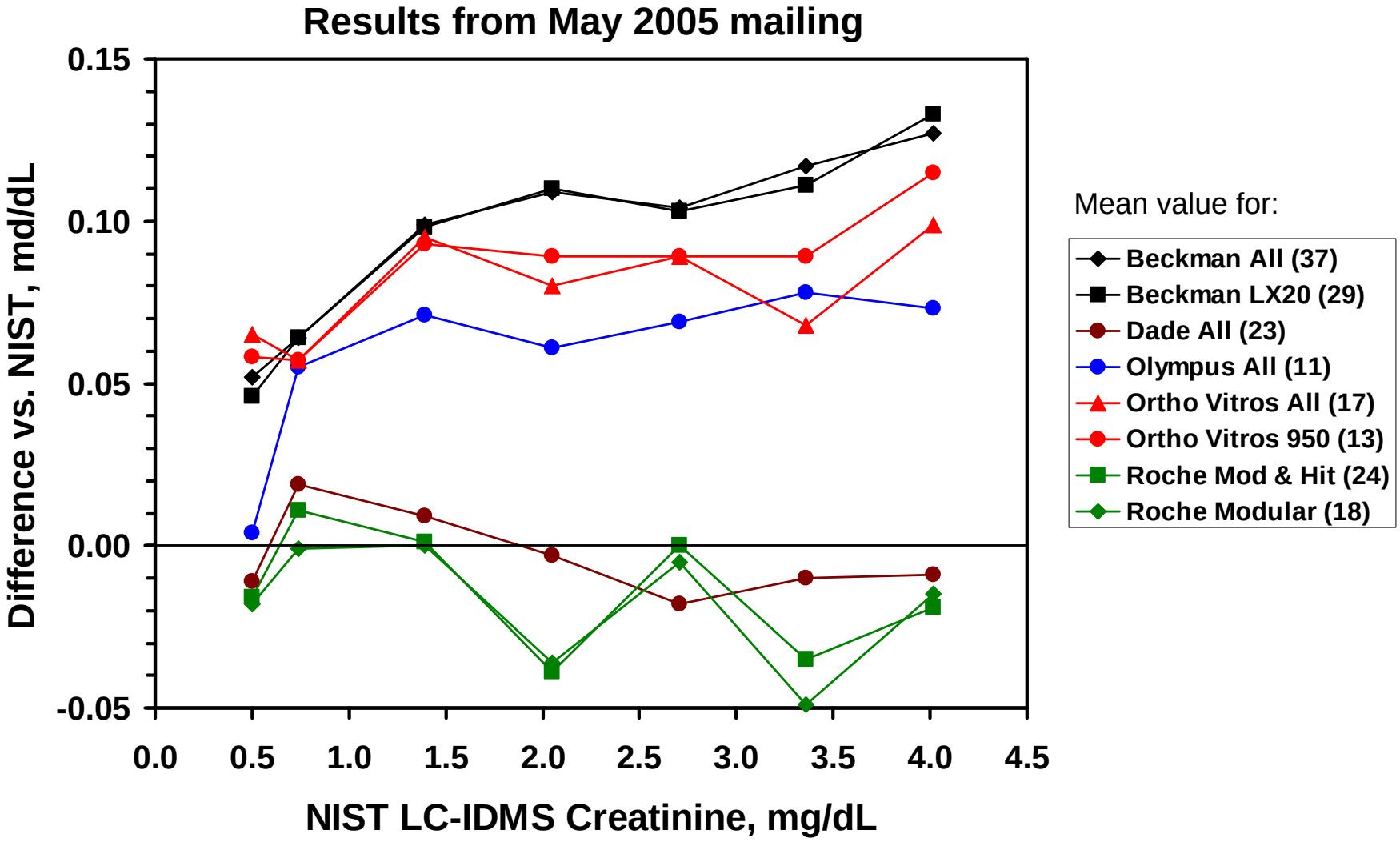
Creatinine Accuracy Calibration Verification/Linearity Survey LN25

- Normal concentration pool prepared from fresh female off-the-clot serum (NCCLS C-37A)
- Normal pool was spiked with crystalline creatinine to prepare a high concentration sample
- Intermediate concentrations (LN03-06) were prepared by admixture of LN02 and LN07
- Low sample (LN01) was prepared by dilution of LN02 with phosphate buffered saline
- NIST value assigned normal (LN02) and high (LN07) samples by LC-IDMS; other concentrations by admixture and dilution ratios

Creatinine Accuracy Calibration Verification/Linearity Survey LN24



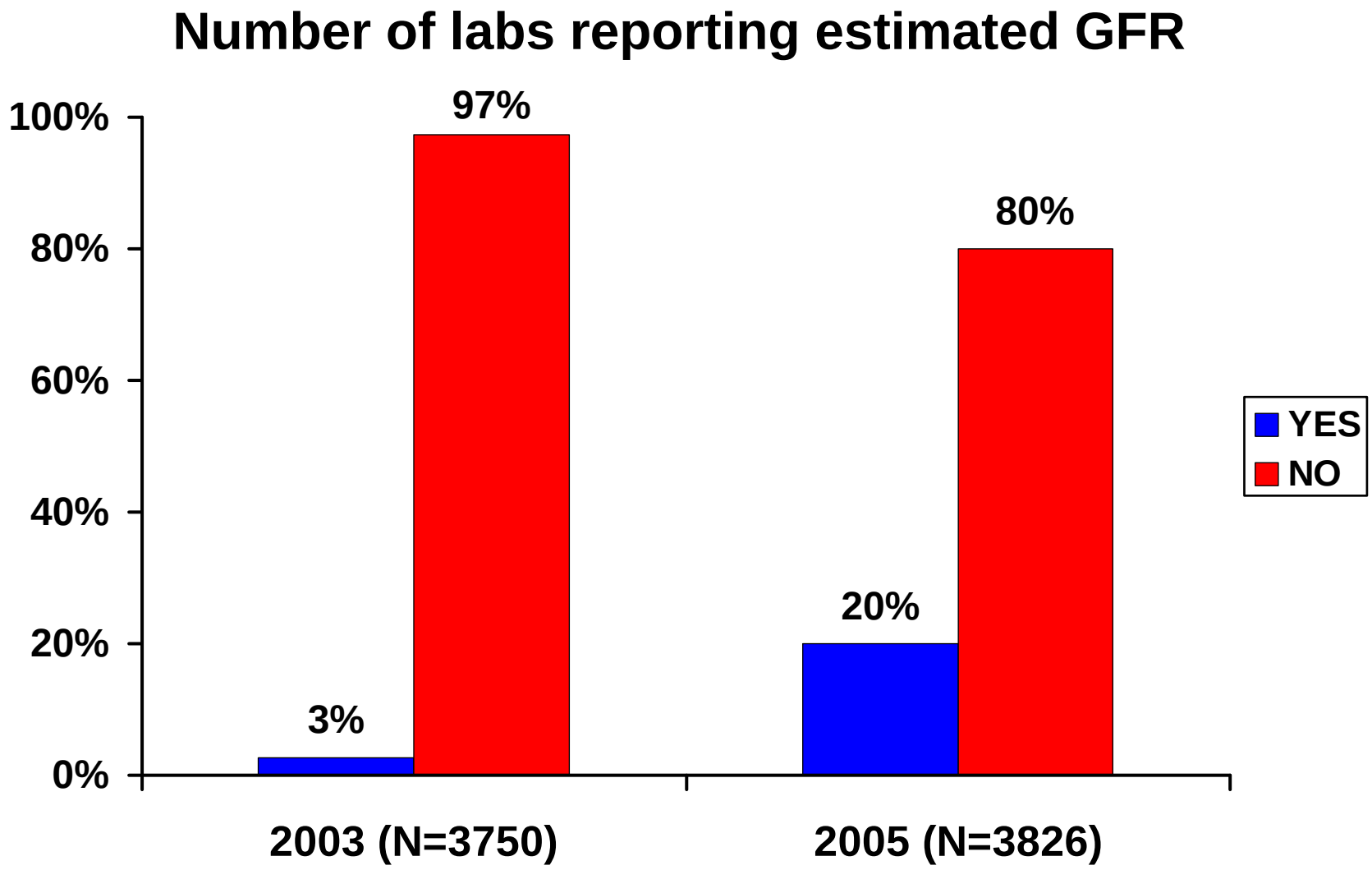
Creatinine Accuracy Calibration Verification/Linearity Survey LN24

Results from May 2005 mailing

Within method group CV, %

	N	LN24-01	LN24-02	LN24-03	LN24-04	LN24-05	LN24-06	LN24-07
NIST value, mg/dL		0.501	0.739	1.394	2.049	2.705	3.360	4.015
Beckman All	37	7.6	2.6	1.7	2.2	1	1.5	1.5
Beckman LX20	29	7.4	2.8	1.5	2.2	1	1.5	1.3
Dade All	23	4.1	7.6	0.8	3.1	2.2	2.1	1.7
Olympus All	11	3.7	2.1	4.3	1.2	2.1	2.4	2.4
Ortho Vitros All	17	7.4	2.5	1.4	1.9	0.6	2	1.4
Ortho Vitros 950	13	7.7	2.9	1.5	1.9	0.6	1.7	1.1
Roche Mod & Hit	24	11.1	8	1.5	0.9	2.4	2.3	2.2
Roche Mod	18	10.6	6.9	1.7	1	2.3	1.3	2.3

Comprehensive Chemistry Survey



SRM 967 Commutability Study

Purpose: **Establish commutability of SRM 967 for serum creatinine routine methods**

Materials:

- **SRM 967**
  - **Level I – 0.80 mg/dL (70 µmol/L)**
  - **Level II – 4.0 mg/dL (355 µmol/L)**
- **CAP LN-24**
  - **LN24-01 (diluted)/0.501 mg/dL (44.3 µmol/L)**
  - **LN24-02 (base pool)/0.739 mg/dL (65.3 µmol/L)***
  - **LN24-07 (high pool)/4.015 mg/dL (354.9 µmol/L)***

*** NIST value assigned**

SRM 967 Commutability Study - continued

Materials:

- **Patient Samples**
  - **20 samples collected from patients in the hypertension, diabetes, and transplant evaluation clinics at the University of Minnesota**
  - **Concentration range 0.50-5.0 mg/dL (44-442 µmol/L)**
  - **0.25 ml aliquots**
  - **Routine methods – Beckman CX3*, Roche (Jaffé)*, Roche (enzymatic)*, Vitros*, Dade Dimension**

Analytical Scheme:

- **Routine Methods – single batch analysis/ triplicate measurements**
- **Reference Method – duplicate measurements**

Timeline to introduce standardized creatinine and revised estimating equation

- **Revised equation for estimating GFR available in 2005**
  - **Further validation will occur for ethnic groups with possible further revision of equation**
- **SRM 967 with commutability validation available in late 2005/early 2006**
- **CDC reference measurement procedure (LC-IDMS) and serum panel available in 2006.**
- **Transition to new calibration of routine methods will require 6-24 months: complete late 2007-2008**
  - **Manufacturers have already recalibrated to IDMS**
  - **Manufacturers can make adjustments to existing lots in the field**
  - **Manufacturers will recalibrate with introduction of new lots**

Reference range recommendations?

1. **Manufacturer could provide magnitude of calibration change as a correction factor to the creatinine reference ranges**

2. **Replace traditional creatinine reference ranges (do not report) with estimated GFR as a standardized clinical interpretation of creatinine**

3. **Creatinine clearance reference range will be clinically different and should be discontinued?**

Next steps

1. **Deploy standardization program**
   - **Target date to complete implementation of traceability and new estimating equation**
2. **Deploy education program**
3. **Coordination with IFCC and other professional organizations**
4. **Coordination with pharmacy professional organizations**
5. **Inform LIS/HIS computer software providers**
6. **Develop guidelines for pediatric estimating equations**