Blood Lead Proficiency Testing: Lab Performance & PT Evaluation

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Blood Lead PT Programs

- 4 U.S. Programs
- College of American Pathologists
  - Approx. 275 participants, open enrollment
- NY State Dept
  - Approx. 105 participants, enrollment for NY license
- PA Dept. of Health
  - Approx. 35 participants, enrollment for PA license
- HRSA/Wisconsin
  - Approx. 540 participants, open enrollment

Blood Lead PT Programs

- Sample target value det'd by ≥80% of referees or participant results (peer grading)
  - Must be met for formal PT evaluation of sample
  - Failure to meet = all results are acceptable

- All employ the same acceptability criteria
  - Target value ± 4 μg/dL or 10% for individual samples
  - 80% (4/5 samples) for satisfactory event score
  - 2/3 sat. events = successful cumulative performance

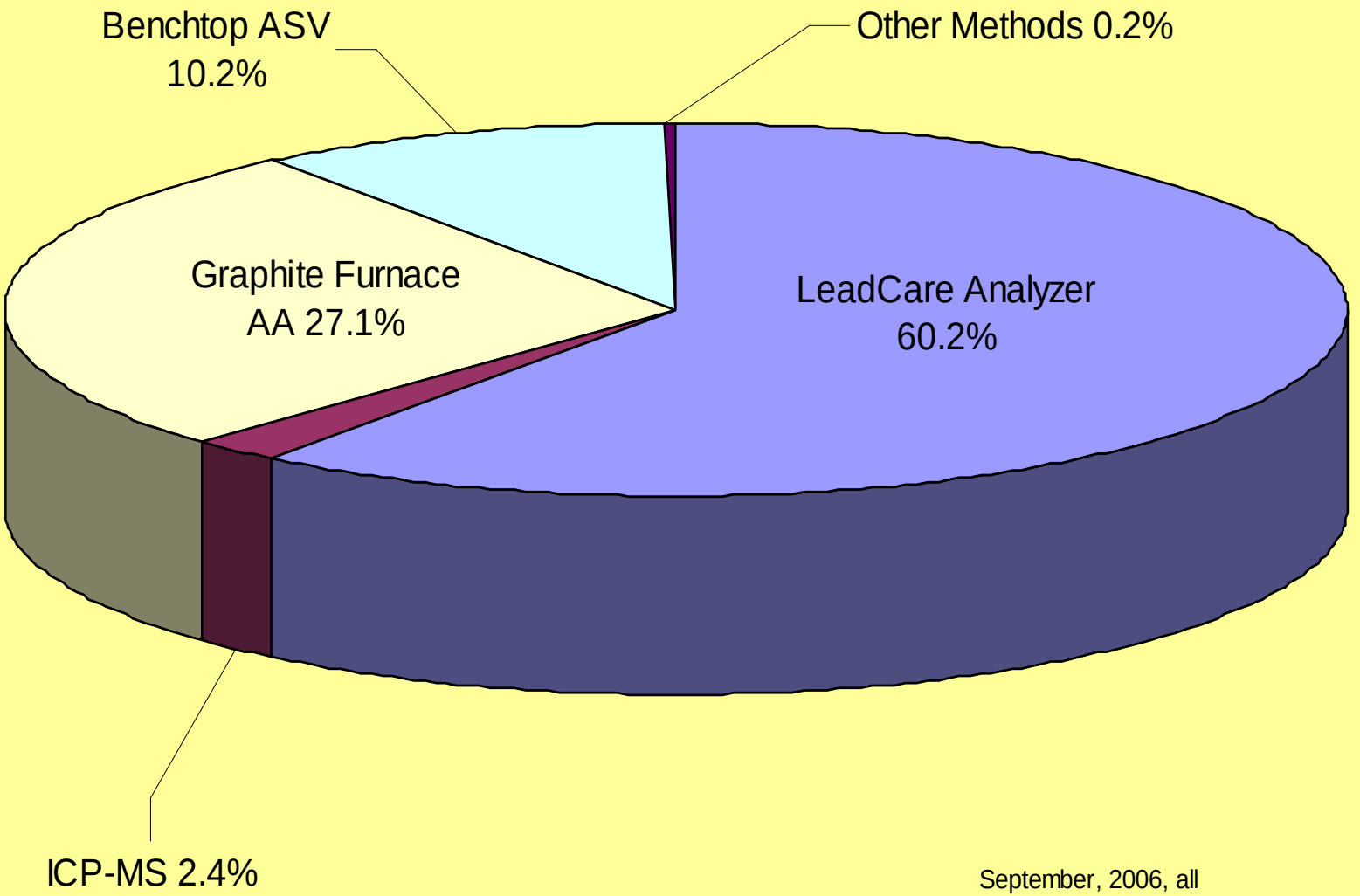
WI Proficiency Program

- Grant-supported; available at no cost to participants
- Specimens are bovine blood, from dosed animals
  - Physiologically bound lead
- ~540 active participants, including ~40 international
- Monthly PT events, 3 specimens/event
- CLIA regulatory events = 3 events/year, 5 specimens

WI PT Program

- Targets for all analytical methods BUT LeadCare® det'd using referee lab values
  - 14 labs, variety of methods and lab types
- LeadCare targets det'd by participant means
  - Required due to sample matrix effects
  - Leadcare labs ~60% of total participants

BLOOD LEAD PT ANALYTICAL METHODS
Total laboratories = 537



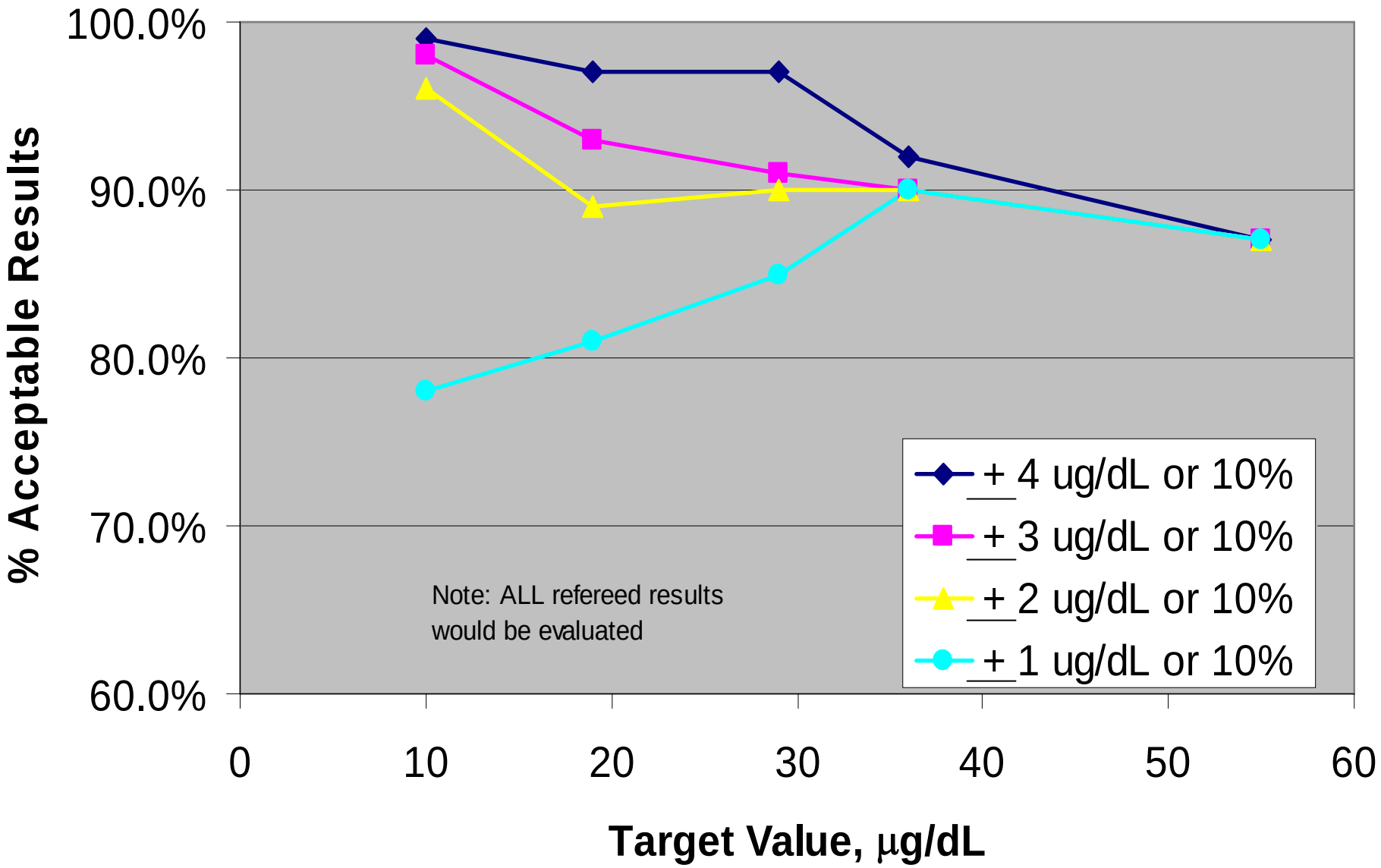
September, 2006, all

PT Impact of Tighter Criteria

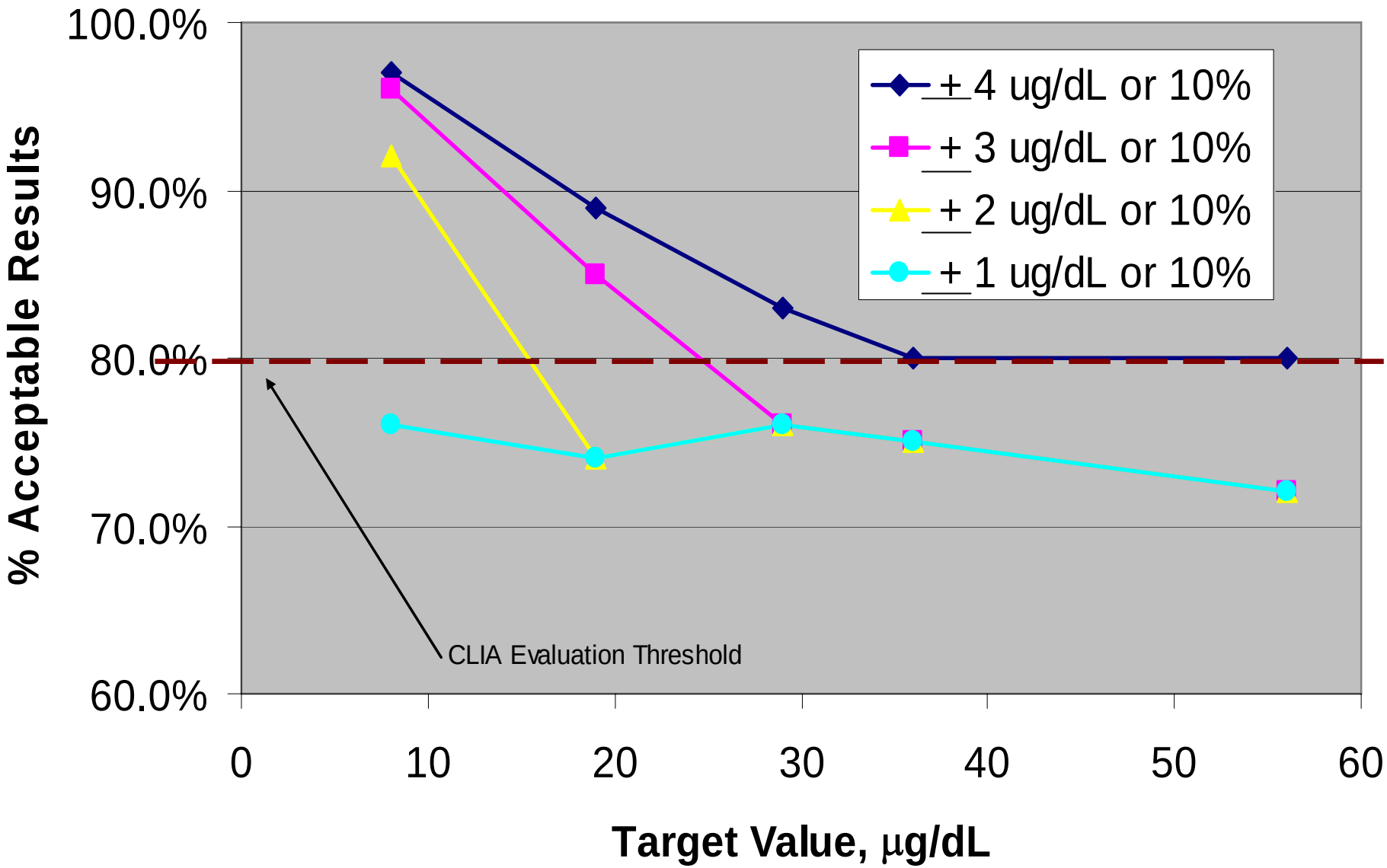
- Impacts of narrowing PT acceptability criteria examined
  - ± 4 μg/dL or 10 % for individual samples
  - ± 3 μg/dL or 10 % for individual samples
  - ± 2 μg/dL or 10 % for individual samples
  - ± 1 μg/dL or 10 % for individual samples

- Looked at May 2006 regulatory event
  - Typical performance profile for participants
  - Wide range of Target values: ~10, 20, 30, 36, 55 μg/dL

% Acceptable results by Sample, Refereed Labs



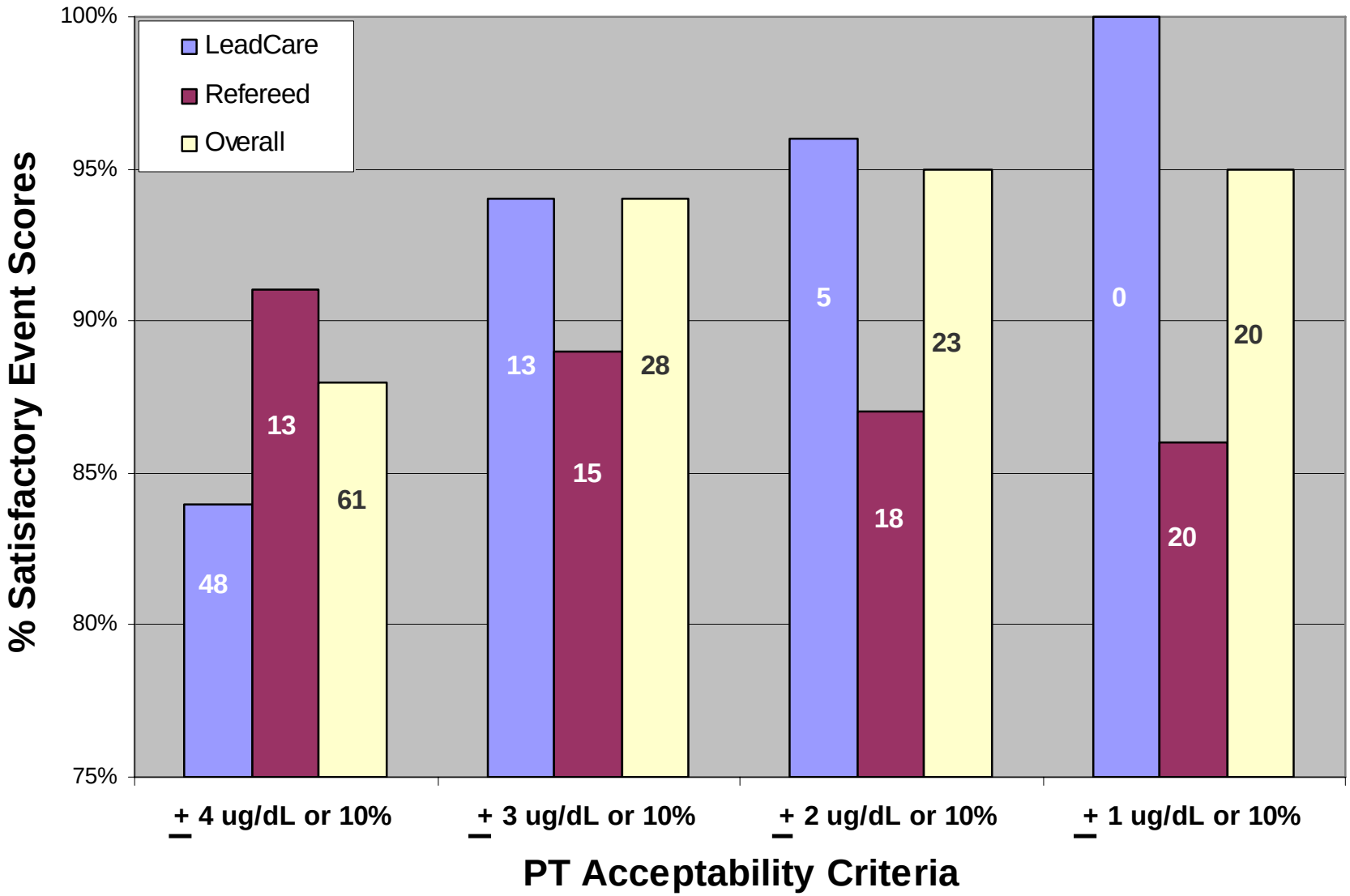
% Acceptable results by Sample, LeadCare



Observations

- Performance inversely correlates with [Pb]
  - All, methods, but performance drop is steeper for LeadCare
- Refereed methods generally outperform LC
- Refereed methods impacted most at ± 1 μg/dL, low [Pb]
- LeadCare labs impacted more by tighter criteria
  - Steep decline in acceptability
  - Quickly falls below necessary consensus for evaluation

PT Event 2006-2 Satisfactory Event Scores



Summary & Opinion

- Labs using LeadCare will get more “free passes” due to non-consensus
  - Other programs (e.g. CAP) using peer grading for all methods should see a similar, but smaller, impact
- Other methods can accommodate reduction to ± 3 μg/dL or 10%, possibly ± 2 μg/dL
- ± 1 μg/dL will significantly increase failures
  - Effect will be more dramatic for samples at lower concentrations
- Impact of LeadCare II ???
  - PT not required