

Minutes of NKDEP Laboratory Working Group Conference Call on 3/10/03

Participating: Drs. Eckfeldt, Myers, Miller, Greenberg, Caudill (CDC statistician), Hostetter, Ms. Gladstone

The group discussed various approaches to prove commutability of the NIST reference material using the NCCLS EP-14A or some modification of it. The major hurdles appear to be getting enough individual patient samples with creatinines in the range modestly elevated range (i.e., 3 to 5 mg/dL), and 2) getting reference method analyses of the patient sample set. Collection of about 50 mL of blood from patients with moderate renal failure (e.g., creatinines up to about 5 mg/dL) so 50 to 100 0.25-mL aliquots of serum can be prepared from each patient seemed feasible. A few of the aliquots from each patient could then be sent to some lab (e.g., NIST or one of the European reference labs doing IDMS creatinine) to establish reference method values. The remaining samples could be kept at -70 C and then be sent to manufactures upon request along with the NIST reference materials to analyze by their field methods to assess commutability. There would have to be some central site which could serve as a repository of these samples and could ship out a specimen set on request of a creatinine reagent or instrument IVD manufacture. The group thought that we should test the low (female) pool, the AR grade creatinine-supplemented high pool, and a one-to-one mix of these two pools.

The discussion then moved to the potential magnitude of the "matrix bias/non-commutability bias" and what magnitude of "matrix/non-commutability bias" could the present NCCLS EP14-A protocol be expected to detect. Sam Caudill will look at the NCCLS EP14-A protocol to look at what sort of statistical power the protocol regarding the size of non-commutability bias that could be detected. Alternate statistical approaches will also be considered. John offered to send Sam some of the inter-method creatinine comparison data for him to use when modeling some of the statistical power questions. John offered to talk to Mike Welch about the possibility of getting the set of 50 to 100 patient samples analyzed by ID LCMS at NIST. This would be the best site for the analysis, assuming they have the throughput and turnaround time needed.

The group will report back to the full NKDEP Laboratory Working Group on its next conference call.

Action Items:

- 1) John will send Sam the inter-method creatinine comparison data he presented at the BWI meeting.
- 2) John will contact Mike Welch about NIST's running the ID LCMS on a set of 50 to 100 patient samples.
- 3) Sam Caudill will review the NCCLS EP14-A document, try using the data John sends to him in #1 to assess the possible statistical power of the protocol and how it might be improved.