

Request for Proposals – PSW RCE
Benchtop Device for Detection of Botulinum Neurotoxin in Clinical Samples

An antibody-based capture assay with enzymatic endpoint has provided attomolar detection sensitivities for botulinum neurotoxin A in serum. We seek proposals for projects to migrate this assay to a bench-top device for application in the public health and clinical laboratories for the detection of this and other botulinum neurotoxins in clinical samples. While not the primary aim of this solicitation, we anticipate that such a device could also be used for botulinum neurotoxin in food and environmental samples. We also anticipate that a device meeting the specifications below would also be of novel utility for the measurement of other proteins and substances, including therapeutic agents, in the blood and other patient samples.

The device should meet these specifications:

- (1) Capable of handling samples, with no or minimal prior processing, of serum, blood, feces, or enema fluid in volumes of 0.5 ml or greater.
- (2) Achievement in the device of the same sensitivity that was obtained in the research laboratory assay.
- (3) Turnaround time for processing and read-out for the assay of 60 minutes or less.
- (4) A format that allows for the processing of multiple samples in a single run, including known controls for a standard curve. The device must have the capability of conducting multiple sequential runs with time intervals between runs on the order of minutes.
- (5) Provision of a control for background enzymatic activity.
- (6) The performance of the device should be validated with a mouse bioassay for botulinum toxin.
- (7) Retail cost of \$10,000 or less for a production model of the device.
- (8) Wholesale cost per sample of \$5 or less.

Prospective applicants should consult on the details of capture enzymatic assay with Dr. Markus Kalkum of the Beckman Research Institute of the City of Hope (MKalkum@coh.org; phone (626) 471-7131). *The single successful proposal will be funded for up to \$250,000 direct costs per year for up to 5 years, depending on progress.* The PSW RCE will assist with the evaluation and validation of the device, by offering opportunities for trials with clinical samples and direct comparisons with the mouse bioassay.

Applications should include an unsigned NIH face page, NIH Checklist, NIH biosketches for key personnel, NIH Other Support page for key personnel, up to 2 pages of prior results, up to 5 pages for experimental design, 1 page business plan for product development, and up to 2 pages of references (with hyperlinks to on-line versions). They should be sent to: pswrce@uci.edu. Deadline: April 11, 2008. Contact Alan Barbour, M.D. (abarbour@uci.edu; (949) 824-5626) for questions.