Early Detection Research Network

NCI/EDRN/SPORE Lung Cancer Biomarkers Group

Part 1: Request For Reference Sample Sets

Date of Submission:

Investigator: Name: Institution: Address:	 Phone: Fax: E-mail

Specimen Reference Set(s) Requested

Reference Set Requested	Specimen Type
Rapid Pre-validation Set ☐ *Rapid Pre-validation Set A* ☐ *Rapid Pre-validation Set B* *Combined Pre-validation Set* ☐ *Combined Pre-validation Set A* ☐ *Combined Pre-validation Set B*	☐ Serum ☐ Plasma

Minimum volume of each sample required: (microliters)	Expected length of study: months

Institutional Approval

Do you have IRB approval to work with the requested samples?	☐ Yes: Institution: Approval number: ☐ No ☐ Pending: Expected date:

Funding

How will testing of the Reference Sample Set(s) be funded?	☐ Current NIH-funded grant: Grant No. Annual Direct Costs: Funding Period: ☐ Other sponsorship: Please provide a letter of commitment from the sponsoring agency, company, or foundation. ☐ Other: specify:

Part II: Scientific Proposal

Using the standard PHS 398 Continuation Page (http://grants.nih.gov/grants/funding/phs398/continuation.doc) address the following items as outlined below (3-5 pages recommended)

I. **Clinical Relationship**: Clearly state the clinical question that you are trying to address: early detection or diagnosis. If other clinical questions are to be addressed (e.g., risk assessment or prognosis) provide a rationale. How would the Reference Set(s) samples expedite addressing the intended clinical question?

II. **Background and Significance**: Clearly state the scientific rationale of the proposal for using the requested Reference Set(s) samples. Describe your biomarker/platform and how you came upon its discovery/development for potential application in cancer detection.

III. **Preliminary Data & Methods:** Provide sufficient information describing how experiments were performed, details on convenience discovery samples used, and presentation of data in terms of specificity, sensitivity, and variance of your measurements. Explicit description of your studies will facilitate review considerations. Figures and other supporting documentation can be appended to your proposal. The application is expected to contain at least preliminary analysis of lung cancer samples.

IV. **Data Analysis Plan:** Provide adequate detail concerning how statistical analysis of your data generated from the Reference Set(s) samples will be performed and a justification that the requested References Set(s) is/are large enough to demonstrate the utility of the biomarker. Describe the statistical resources at your disposal. If you require statistical support, the EDRN/SPOREs can assist you with this.

V. **Collaboration:** In this section state your agreement to deposit all primary data and processed data obtained using the Reference Set(s) samples with the EDRN Data Management and Coordinating Center (DMCC) within one year after receiving the samples. EDRN/SPORE programs may compare this data as a reference with other biomarkers applied to the same samples. Unblinding of the samples will occur after you provide this data.

VI. **Future Plans**: If the biomarker is found to have promising performance characteristics, the EDRN/SPORE programs might be interested in working with you to proceed to Phase II clinical validations. Address each specific scenario below according to your intentions:

   a. Do you plan to approach EDRN/SPOREs for funding and collaboration in proceeding to a Phase II validation study? If not, do you have other resources where validation can be accomplished? Describe clearly other resources at your disposal and how they are sufficient to complete a larger Phase II validation study if you will not seek funding support from the NCI.
   b. Are you amenable to working within the collaborative framework of EDRN/SPOREs in proceeding to Phase II studies?
   c. If deemed beneficial, will you be amenable to including your biomarker into a larger panel of biomarkers for Phase II validation conducted by other NCI programs?
   d. If refinements will improve the performance of the biomarker test, will you concur with further development of the test? Will it be advantageous to include resources of the EDRN for this purpose?