Early Detection Research Network

Part 1: Request For Specimen Reference Sets

Date of Submission:

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

Specimen Reference Set(s) Requested

Collaborative Group Oversight	Organ Site	Specimen Type
☐ Breast & Gynecological ☐ Colorectal & Other GI ☐ Lung & Upper Aerodigestive ☐ Prostate & Other Urologic	_____ (e.g. lung, ovary, colon, etc)	☐ Serum ☐ Plasma ☐ Other: Specify _____

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 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. (3-5 pages recommended)

I. **Clinical Relationship**: Clearly state the clinical question that you are trying to address: risk assessment, early detection, diagnosis or prognosis. How would the reference samples expedite addressing the intended clinical question?

II. **Background and Significance**: Clearly state the scientific rationale of the proposal for using the requested specimen reference set(s). 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 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 after your proposal.

IV. **Data Analysis Plan:** Specify whether you will need a training set in addition to a blinded test set. Provide adequate detail concerning how statistical analysis of your data coming from these 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, EDRN can assist you with this.

V. **Collaboration:** In this section state your willingness to deposit all raw data obtained using the reference set(s) with the EDRN Data Management and Coordinating Center (DMCC). EDRN may compare this data as a reference with other biomarkers applied to the same sets.

VI. **Future Plans**: If the biomarker is found to have promising performance characteristics, the EDRN 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 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 help from the EDRN.
   b. Are you amenable to working within the collaborative framework of EDRN 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?
   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 EDRN for this purpose?