Posting Date: August 12, 2021

Closing Date: August 12, 2021 11:30 a.m. ET

Reference Number: 21-000412

To: NCI Bid Board

From: Tanya Proctor
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Subject: NCI Bid Board Posting – Clia serum testing

The Laboratory of Tumor Immunology and Biology (LTIB) functions as a multidisciplinary and interdisciplinary translational research programmatic effort with the goal of developing novel immunotherapies for cancer. The LTIB strategic plan focuses on the development of novel immunotherapeutics, not only as monotherapies, but more importantly, in combination with other immune-mediating modalities, and other conventional or experimental therapies, as part of an immuno-oncology programmatic effort. Within this effort are several research groups and a clinical trials group, and multiple collaborations with intramural and extramural scientific and clinical investigators, and with investigators in the private sector.

The National Cancer Institute plans to purchase Clia serum testing from Guardant Health, Inc. This is not a request for competitive quotation. However, if any interested party believes it can meet the attached requirements, it may submit a statement of capabilities. The capability statement must be in writing and must contain information and material in sufficient detail to allow NCI to determine is the party can fully meet this requirement. The capability statement must be received in the contracting office by 11:30 AM on August 22, 2021 ET. A determination by the Government not to compete this requirement based upon responses to this notice is solely within the discretion of the Government. Information received will be considered solely for the purpose of determining whether to conduct a competitive procurement.

Sole Source Justification:

Guardant360 sequences 83 cancer-associated genes to identify somatic alterations. Cell-free DNA (cfDNA) is extracted from plasma, enriched for targeted regions, and sequenced using the Illumina platform and hg19 as the reference genome. The types of genomic alterations detected by Guardant360 include single nucleotide variants, gene amplifications, fusions, short insertions/deletions and splice site disrupting events. Microsatellite Instability (MSI) is assessed for all cancer types by evaluating somatic changes in the length of repetitive sequences on the Guardant360 panel. Tumor mutational burden (TMB) score is calculated for all cancer types from somatic SNVs and indels in exons of ~500 genes detected in cfDNA, followed by adjusting for tumor shedding levels and the size of the panel.

Attached Documents:
SF18
Statement of Work
FAR Clause 52.213-4 Simplified Acquisitions Terms and Conditions (JAN 2014) is applicable and available in full text upon request