VEERINDER (VINNY) TANEJA, MBBS; MPH
PUBLIC HEALTH DIRECTOR

CATHERINE A. COLQUITT, M.D.
LOCAL HEALTH AUTHORITY & MEDICAL DIRECTOR

Public Health

December 11, 2023

Melissa Lee, C.P.M., A.P.P.
Tarrant County Purchasing Agent 100
East Weatherford, Suite 303
Fort Worth, Texas 76196

Dear Ms. Lee:

The North Texas Regional Laboratory (NTRL) is requesting that the following vendors be exempted from the competitive bid process because of the special needs of the laboratory.

Bio-Rad Laboratories, Inc.	Supplies, reagents, and controls
College of American Pathologists	Proficiency testing materials
Hardy Diagnostics	Reagents and supplies
IDEXX Distribution, Inc.	Supplies, reagents, and controls
Integrated DNA Technologies	Reagents
Life Technologies Corporation	Supplies, reagents, controls, and equipment parts
Phenova, Inc.	Proficiency testing materials
Revvity, Inc.	Supplies, reagents, controls, and equipment parts
Qiagen LLC	Controls and reagents
Roche Diagnostics Corporation	Supplies, reagents, controls, and equipment parts
Wisconsin State Laboratory of Hygiene	Proficiency testing materials

The NTRL receives public health emergency preparedness funding for participating in the Centers for Disease Control and Prevention's Laboratory Response Network (LRN). To participate in the LRN our laboratory must complete a requalification process annually. One of the requalification requirements states that "Our laboratory agrees to adhere to the LRN-established standard testing algorithm or method within each agent-specific protocol and agrees to use LRN standardized reagents/analytical materials and controls when testing for and reporting on the designated biological and/or chemical threat agent". To ensure the validity of our biological threat testing, the NTRL must strictly adhere to the LRN test protocols.

The NTRL also performs certain clinical diagnostic and infectious disease surveillance tests by using test methods developed in-house. The Clinical Laboratory Improvement Amendments

(CLIA) program published the final rule on the laboratory requirements relating to quality systems in 42 CFR Part 493 on January 24, 2003. In section 493.1253(b)(2) Establishment of performance specifications, the CLIA regulations state that "Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures, or uses a test system in which performance specifications are not provided by the manufacturer) must, before reporting patient test results, establish for each test system the performance specification for the following performance characteristics, as applicable: "...provide evidence that the accuracy, precision, analytical sensitivity, and analytical specificity of the procedure is adequate to meet the clients' needs as determined by the laboratory director and clinical consultant." To comply with these regulations any change in the reagent, analytical material, standard, or control of a test method developed in-house requires a re-verification of the performance specifications at considerable expense to Tarrant County.

The NTRL must also participate in proficiency testing annually to demonstrate competency in clinical diagnostic, environmental, and biological threat testing. Various regulatory programs including CLIA, the National Environmental Laboratory Accreditation Program (NELAP), and the LRN mandate that certified and/or accredited laboratories register and participate with the regulatory agency's approved proficiency testing providers. Changes made to the proficiency testing providers that the NTRL uses could result in unexpected proficiency testing failures with the subsequent burden and cost of corrective actions and the possible suspension of impacted laboratory services.

Rune-Par Nilsson Ph.D.

Rune-Par Nilsson, Ph.D., HCLD (ABB)
Laboratory Services Division Manager