



**COMMISSIONERS COURT  
COMMUNICATION**

COURT ORDER NUMBER \_\_\_\_\_

PAGE 1 OF 5

DATE: 12/3/2024

**SUBJECT: APPROVAL OF EXEMPTION FROM COMPETITIVE BIDDING  
REQUIREMENTS - PURCHASE OF DRUG REAGENTS, CONTROLS,  
EQUIPMENT PARTS, AND PROFICIENCY TESTING MATERIALS -  
PUBLIC HEALTH - VARIOUS VENDORS**

**\*\*\* CONSENT AGENDA \*\*\***

**COMMISSIONERS COURT ACTION REQUESTED**

It is requested that the Commissioners Court approve an exemption from Competitive Bidding Requirements for the Purchase of Reagents, Controls, Equipment Parts, and Proficiency Testing Materials, for Public Health. The vendors that provide these supplies are the following:

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, Inc.	Reagents
Life Technologies Corporation	Supplies, reagents, controls, and equipment parts
Phenova, Inc.	Proficiency testing materials
QIAGEN, LLC	Controls and reagent
Revvity, Inc.	Supplies, reagents, controls, and equipment parts
Roche Diagnostics Corporation	Supplies, reagents, controls, and equipment parts
Wisconsin State Laboratory of Hygiene	Proficiency testing materials

**BACKGROUND**

Under the County Purchasing Act. exemptions to the competitive bidding requirements are allowed for certain types of purchases. State bidding statute, Section 262.024(a)(2) deals with those exemptions allowable when approved by the Commissioners Court.

The Public Health Department provided a letter of explanation, citing regulatory agency-established protocols which dictate the use of specific drug reagents and controls and participation in proficiency testing.

The exemption is twelve (12) months, effective March 7, 2025 through March 6, 2026.

Therefore, it is the joint recommendation of Public Health and Purchasing that the Commissioners Court grant an exemption from Competitive Bidding Requirements for Purchase of Drug Reagents, Controls, Equipment Parts, and Proficiency Testing Materials.

SUBMITTED BY	Purchasing	PREPARED BY:	Wanyu Chen
		APPROVED BY:	Christopher Lax, CPSM, CPSD, CPCP



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REFERENCE NUMBER: \_\_\_\_\_ DATE: 12/3/2024 PAGE 2 OF 5

## **FISCAL IMPACT**

Annual expenditures are estimated to be approximately \$352,000.00. Orders are placed on an as-needed basis. Funding is available in the following accounts:

- T0400-2025 Public Health Funds/5100011000 Public Health/521061 Lab Supplies
- F0043-2025 DSHS-CPS – Bioterrorism Preparedness/5100011000 Public Health/521061 Lab Supplies
- F0054-2025 DSHS-Infectious Disease Control Unit/FLU-LAB/5100011000 Public Health/521061 Lab Supplies
- F0071-2025 DSHS-Milk and Dairy Products Division/Fee for Service/5100011000 Public Health/521061 Lab Supplies
- F0089-2025 DSHS-ELC/LRN COVID-19-LAB PPP/5100011000 Public Health/521061 Lab Supplies
- F0105-2025 DSHS-STD/HIV Disease Intervention Specialist/5100011000 Public Health/521061 Lab Supplies
- F0108-2025 CDC Public Health Infrastructure, Workforce, Data Modernization Program/5100011000 Public Health/ 521061 Lab Supplies
- F0389-2025 DSHS-ELC/LRN COVID-19-LAB EXPANSION/5100011000 Public Health/521061 Lab Supplies
- F0489-2025 DSHS-ELC/LRN COVID-19-LAB-SPHL/5100011000 Public Health/521061 Lab Supplies



## Public Health

W. BRIAN BYRD, M.D., Local Health Authority & Health Director

CATHERINE A. COLQUITT, M.D., Medical Director

October 23, 2024

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





## TAKINGS IMPACT ASSESSMENT CHECKLIST

Complete this form for any county action that involves the adoption of a regulation, policy, guideline, court resolution, or order.

Project/Regulation Name: Approval of Exemption from Competitive Bidding Requirements - Purchase of Drug Reagents, Controls, Equipment Parts, and Proficiency Testing Materials - Public Health - Various Vendors

County Department: PURCHASING

Contact Person: Melissa Lee, C.P.M., A.P.P.

Phone Number for Contact Person: (817) 884-3245

Type of TIA Performed: SHORT TIA or FULL TIA. Circle one after answering the questions in Sections II and III below.

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### I. Stated Purpose

Attach to this checklist an explanation of the purpose of the regulation, policy, guideline, court resolution, or order.

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**Note: The remainder of this Takings Impact Assessment Checklist should be completed in consultation with the Criminal District Attorney's Office.**

### II. Potential Effect on Private Real Property

1. Does the county action require a physical invasion, occupation, or dedication of real property?

Yes \_\_\_\_\_ No √

2. Does the county action limit or restrict a real property right, even partially, or temporarily?

Yes \_\_\_\_\_ No √

If you answered yes to either question, go to Section III. If you answered no to both, STOP HERE and circle SHORT TIA at the top of the form.

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