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STATE OF NEW HAMPSHIRE



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Nicholas A. Toumpas Commissioner

Marcella Jordan Bobinsky Acting Director

May 15, 2015

Her Excellency, Governor Margaret Wood Hassan and the Honorable Executive Council State House Concord, New Hampshire 03301

REQUESTED ACTION

Authorize the Department of Health and Human Services, Division of Public Health Services, to pay various approved proficiency vendors listed on Attachment A, for proficiency testing programs that are currently required and for other proficiency testing that may become necessary, in an amount estimated at \$68,065 to be effective July 1, 2015 or date of Governor and Council approval, whichever is later, through June 30, 2017. 40.67% Federal/ 54.82% General/ 4.51% Other Funds.

Funds are anticipated to be available in SFY 2016 and SFY 2017, upon the availability and continued appropriation of funds in the future operating budget, with authority to adjust amounts within the price limitation and adjust encumbrances between State Fiscal Years through the Budget Office if needed and justified, without approval from Governor and Executive Council.

05-95-90-902510-5171 HEALTH AND SOCIAL SERVICES, DEPT OF HEALTH AND HUMAN SVS, HHS: DIVISION OF PUBLIC HEALTH, BUREAU OF INFECTIOUS DISEASE CONTROL, EMERGENCY PREPAREDNESS

Fiscal Year	Class/Object	Class Title	Job Number	Total Amount
SFY 2016	020-500239	Current Expenses	90077023	\$350
SFY 2016	020-500239	Current Expenses	90077024	\$7,655
	•		2016 Sub-Total	\$8,005
SFY 2017	020-500239	Current Expenses	90077023	\$350
SFY 2017	020-500239	Current Expenses	90077024	\$7,655
			2017 Sub-Total	\$8,005
			Sub Total	\$16,010

05-95-90-903010-8276 HEALTH AND SOCIAL SERVICES, DEPT OF HEALTH AND HUMAN SVS, HHS: DIVISION OF PUBLIC HEALTH, BUREAU OF LABORATORY SERVICES, FOOD EMERGENCY RESPONSE NETWORK

Fiscal Year	Class/Object	Class Title	Job Number	Total Amount	
SFY 2016	020-500239	Current Expenses	90069017	\$5,775	
SFY 2017	020-500239	Current Expenses	90069017	\$5,900	
			Sub Total	\$11,675	

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05-95-90-903010-7966 HEALTH AND SOCIAL SERVICES, DEPT OF HEALTH AND HUMAN SVS, HHS: DIVISION OF PUBLIC HEALTH, BUREAU OF LABORATORY SERVICES, PUBLIC HEALTH LABORATORIES

Fiscal Year	Class/Object	Class Title	Job Number	Total Amount
SFY 2016	020-500239	Current Expenses	90059000	\$10,500
SFY 2016	020-500239	Current Expenses	90187700	\$9,580
			2016 Sub-Total	\$20,080
SFY 2017	020-500239	Current Expenses	90059000	\$10,700
SFY 2017	020-500239	Current Expenses	90187700	\$9,600
			2017 Sub-Total	\$20,300
			Sub Total	\$40,380
			TOTAL	\$68,065

EXPLANATION

In accordance with the Clinical Laboratory Improvement Amendments of the Federal Centers for Medicare & Medicaid Services, which licenses the New Hampshire Public Health Laboratories to perform laboratory testing on clinical specimens, the Public Health Laboratories must participate in a proficiency testing program that reflects the complexity of testing performed in the laboratory. This requirement is defined in the Clinical Laboratory Improvement Amendments Subpart H, Section 493 "Participation in Proficiency Testing for Laboratories Performing Non-waived Testing of Moderate Complexity and High Complexity". The purpose of proficiency testing is to assure the accuracy of test results in order to avoid jeopardizing the diagnosis and treatment of patient conditions or allowing the spread of disease. The standard process for a proficiency testing program is: "unknown" samples are sent to the Public Health Laboratories; the samples are tested using the Public Health Laboratories' standard procedures; test results are returned to the issuing proficiency agency; the results are reviewed and compared to the results of other participants; a grade is determined; and the Public Health Laboratories must document successful participation in accordance with the Clinical Laboratory Improvement Amendments requirements.

Additional proficiency testing is also being required for new releases of test methods for both clinical specimens and non-clinical samples. Although some testing may not be covered by the Clinical Laboratory Improvement Amendments requirements, the testing performed is in accordance with the chemical terrorism program in the Public Health Laboratories and agreements with the Centers for Disease Control and Prevention, and for environmental and food samples, agreements with the Environmental Protection Agency, the National Environmental Laboratory Accreditation Conference Institute, the Food and Drug Administration, and the United States Department of Agriculture. It is anticipated that the requirements for proficiency testing will increase as new methods are approved.

Proficiency vendors are laboratories, businesses, and organizations that have been approved under the Clinical Laboratory Improvement Amendments regulations or other federal agencies, to provide proficiency testing programs for the scope of testing performed at the Public Health Laboratories. A vendor may specialize in only a single proficiency or a group of proficiencies. There is no single source for all proficiency materials that are required by the Public Health Laboratories. Federal agencies have identified and approved the vendors on the attached list, to provide specific proficiency testing for the Public Health Laboratories.

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The cost for each proficiency, which may be referred to as an "enrollment" or "subscription" fee, is set by the vendor and is not open to negotiation. As each vendor serves as a mechanism to "certify" successful participation in a Clinical Laboratory Improvement Amendments approved program, or other approved proficiency program, it would be unethical for a vendor to offer different prices to different participating laboratories; therefore, no Requests for Proposals were issued. Additional vendors will be added to the attached list of current vendors and utilized as they are identified and approved by each federal regulatory agency.

Proficiency programs typically cover a 12-month period. Based on historical costs, the estimated cost is \$33,860 for SFY 2016 and \$34,205 for SFY 2017 (See attachment A). The proficiencies are paid unencumbered.

Should Governor and Executive Council not authorize this request, the Public Health Laboratories will not be able to comply with licensing regulations and continue testing for arboviruses, HIV, sexually transmitted diseases, tuberculosis, hepatitis, parasites, fungi, and foodborne pathogens; as well as testing non-clinical samples such as animals for rabies, food, water, powders and other substances, for biological and chemical agents.

Area served: Statewide.

Source of Funds is 40.67% Federal Funds from US Food and Drug Administration and US Centers for Disease Control and Prevention, 54.82% General Funds, and 4.51% Other Funds (Agency Income and Transfers from Other Agencies).

In the event that the Federal Funds become no longer available, General Funds will not be requested to support this program.

Respectfully submitted,

Marcella Jordan Bobinsky

Acting Director

Approved by:

Nicholas A. Toumpas

Commissioner

Attachment A

Bureau of Laboratory Services Listing of Proficiency Vendors

Vendor#	Name		SFY 2016 Estimate	SFY 2017 Estimate	TOTAL
163228 B001	Absolute Standards, Inc. 44 Rossotto Dr. Hamden, CT 06514-1335		\$2,800.00	\$2,800.00	\$5,600.00
169137 B001	American Proficiency Institute 1159 Business Park Drive Traverse City, MI 49686		\$1,975.00	\$2,000.00	\$3,975.00
170690 B001	AOAC International 481 No. Frederick Ave., Ste. 500 Gaithersburg, MD 20877		\$3,800.00	\$3,900.00	\$7,700.00
170659 B001	Assoc of American Pesticide Control Officials (AAPCO 2414 Elm Drive White Bear Lake, MN 55110)	\$350.00	\$360.00	\$710.00
168674 B001	College of American Pathologists 325 Waukegan Road Northfield, IL 60093-2750		\$9,850.00	\$10,050.00	\$19,900.00
168748 B001	Environmental Resources Assoc (ERA) 6000 W. 54th Ave Arvada, CO 80002		\$2,500.00	\$2,500.00	\$5,000.00
176511 B001	Insti Natl Desante Publique (INSPQ) 945 Ave Wolfe Sainte-Foy, Quebec QC G1V 5B3		\$450.00	\$450.00	\$900.00
171536 B001	Organic Standard Solutions Int'l PO Box 30712 Charleston, SC 29407		\$2,205.00	\$2,205.00	\$4,410.00
171193 B001	Protocol Analytical, LLC SPEX 203 Norcross Ave. Metuchen, NJ 08840		\$4,500.00	\$4,500.00	\$9,000.00
176001 P001	Remel, Inc. 12076 Santa Fe Drive, P.O. Box 14428 Lenexa, KS 62215		\$330.00	\$340.00	\$670.00
175643 R001	Sigma-Aldrich, Inc PO Box 535182 Atlanta, GA 30353-5182		\$2,500.00	\$2,500.00	\$5,000.00
169351 B001	Wisconsin Department of Agriculture (WDATCP) Po Box 93598 Milwaukee WI 53293-0598		\$1,100.00	\$1,100.00	\$2,200.00
177724 B003	Wisconsin State Laboratory of Hygiene 465 Henry Mall Madison, WI 53706-1578		\$1,500.00	\$1,500.00	\$3,000.00
		Γotal	\$33,860.00	\$34,205.00	\$68,065.00