



PROCUREMENT JUSTIFICATION FORM (PJF)

This form must accompany all contract requests and sole source requisitions (RQS) over \$5,000 submitted to the Office of State Procurement Services.

INSTRUCTIONS: Please provide the requested information in the white spaces below. All responses (except signatures) must be typed; no hand-written forms will be accepted. See the guidance document posted with this form on the Procurement Services intranet site (Forms page) for additional instructions.

PART I: OVERVIEW			
Department Office/Division/Program:	DHHS/MCDCP//Infectious Disease Prevention/HIV-STD Program		
Department Contract Administrator or Grant Coordinator:	Chris Moiles / Storm Dexter		
(If applicable) Department Reference #:	CD0-24-5193		
Amount: (Contract/Amendment/Grant)	\$ 63,925.00	Advantage CT / RQS #:	RQS-10A-20240703000000000022
CONTRACT	Proposed Start Date:	6/1/2024	Proposed End Date: 5/31/2025
AMENDMENT	Original Start Date:		Effective Date:
	Previous End Date:		New End Date:
GRANT	Project Start Date:		Grant Start Date:
	Project End Date:		Grant End Date:
Vendor/Provider/Grantee Name, City, State:	OraSure Technologies, Inc. Philadelphia, PA		
Brief Description of Goods/Services/Grant:	Provider of Hepatitis C Virus (HCV), HIV rapid antibody test kits and Rapid HIV home-test kits		

PART II: JUSTIFICATION FOR VENDOR SELECTION			
Check the box below for the justification(s) that applies to this request. (Check all that apply.)			
<input type="checkbox"/>	A. Competitive Process	<input type="checkbox"/>	G. Grant
<input type="checkbox"/>	B. Amendment	<input type="checkbox"/>	H. State Statute/Agency Directed
<input checked="" type="checkbox"/>	C. Single Source/Unique Vendor	<input type="checkbox"/>	I. Federal Agency Directed
<input type="checkbox"/>	D. Proprietary/Copyright/Patents	<input type="checkbox"/>	J. Willing and Qualified
<input type="checkbox"/>	E. Emergency	<input type="checkbox"/>	K. Client Choice
<input type="checkbox"/>	F. University Cooperative Project	<input type="checkbox"/>	L. Other Authorization

Please respond to ALL of the questions in the following sections.

PART III: SUPPLEMENTAL INFORMATION

1. Provide a more detailed description and explain the need for the goods, services or grant to supplement the response in Part I.

Maine CDC's Human Immunodeficiency Virus (HIV), Sexually Transmitted Diseases (STD), and Hepatitis Program provides HIV and hepatitis C screening tests to partner agencies for uninsured and high-risk individuals in accordance with federal program requirements. To efficiently conduct this screening in a community-based setting, which is often Clinical Laboratory Improvement Amendments (CLIA) waived, rapid tests are provided. By establishing a proforma with OraSure, funding is secured to provide screening for rapid HIV/HCV test kits, and FDA-approved rapid HIV self-test kits.

2. Provide a brief justification for the selected vendor to supplement the response in Part II. Reference the RFP number, if applicable.

OraSure is currently the only company that produces the oral FDA-approved CLIA waived rapid HIV screening tests. They are the only manufacturer of FDA-approved CLIA waived rapid HCV screening tests. OraSure also has the only FDA-approved rapid HIV self-test. Having HIV self-test kits available in non-health care settings is one of the priority objectives in the US CDC grant that supports the Maine CDC HIV Prevention Program. Having a proforma contract with this vendor will allow the HIV Prevention Program to order and distribute HIV self-test kits, rapid HIV screening tests, and rapid HCV screening tests to our community partners who serve high-risk individuals. This vendor allows greater flexibility to provide testing services while adhering to the state and US CDC recommendations. Having a proforma agreement allows for a more efficient means of distributing test kits to at-risk populations. The proforma process aligns with pending changes in the upcoming RFP for HIV/STD/HCV testing subcontracts that would start during the length of this agreement. Maine DHHS does not produce rapid HIV and HCV screening tests.

3. Explain how the negotiated costs or rates are fair and reasonable; or how the funding was allocated to grantee.

Each individual screen is the equivalent of a potential conventional laboratory screen, and equivalent with Medicaid reimbursable rates

4. Describe the plan for future competition for the goods or services.

The Program will continue to monitor for new testing technologies and modalities that would be best applicable to serve Maine constituents. If other vendors or rates are preferable, Program will reassess the nature and justification of this agreement

PART IV: AMERICAN RESCUE PLAN ACT (ARPA) / MAINE JOBS & RECOVERY PLAN (MJRP)

Does this request utilize ARPA/MJRP funds?

Yes, MJRP funds (023) – If Yes, please attach the approved Business Case(s).

Yes, ARPA funds (025) – If Yes, please be aware of the requirements from awarding federal agencies.

No – If No, proceed to Part V.

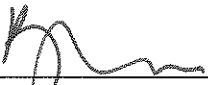
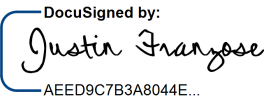
PART V: CONFLICTS OF INTEREST (COI); CONTRACT WITH THE STATE

Maine law contains Conflict of Interest statutes directed to State Departments, State Officers, and Employees Generally under MRS Title 5, §18 and §18-A, in harmony with MRS Title 17, §3104.

The requesting department signatory understands and acknowledges Maine's Conflict of Interest statutes.

PART VI: APPROVALS

The signatures below indicate approval of this procurement request.

Signature of requesting Department's Commissioner (or designee):		
Typed Name:	Ben Munn	Date: 9/9/24
Signature of DAFS Procurement Official:	 <small>DocuSigned by: Justin Franzose AEED9C7B3A8044E...</small>	
Typed Name:	Justin Franzose	Date: 9/26/2024