In providing this draft MOU, this document serves as a reference for your consideration only. It is not intended as, and should not be construed as, **legal advice**. Please consult your own legal counsel for compliance purposes as appropriate.

## HEALTH CENTER COVID-19 TESTING SUPPLY PROGRAM PARTNERSHIP MEMORANDUM OF UNDERSTANDING

This memorandum of understanding is between CHC and PARTNER, with respect to the distribution of Quidel QuickVue At-Home OTC COVID-19 Testing Kits. Through the HRSA Health Center COVID-19 Testing Supply Program, HRSA has provided testing kits to CHC at no cost to ensure testing kits COVID-19 tests are made available equitably to populations and settings in their service area that are in need of testing, especially populations at greatest risk from adverse outcomes related to COVID-19 and those disproportionately affected by COVID-19.

Upon receipt, the PARTNER agrees that it will adhere to all of the requirements that are applicable to PARTNER outlined in the HRSA COVID-19 Testing Supply Program Conditions of Participation and Site Selection Form—HHS COVID-19 Testing Supply Program Agreement attached hereto as Exhibit A and incorporated herein by reference.

# of HRSA Test Kits Distributed:	
Location of Distribution:	
Date of Distribution:	
Signed and agreed to:	
Ву:	Ву:
Name: <u>CHC</u>	Name: <u>PARTNER</u>
Title:	Title:
Date:	Date:

## **EXHIBIT A**

## HRSA COVID-19 Testing Supply Program Conditions of Participation and Site Selection Form

## 1. HHS COVID-19 Testing Supply Program Agreement

ORGANIZATION IDENTIFICATION				
Organization's legal name:				
Organization telephone number:		Email (must be a monitored email and serve as dedicated contact for the HHS COVID-19 Testing Supply Program):		
		Contact for the Fill o Covid-19 T	esting Supply 1 Togram).	
Organization address:				
RESPONSIBLE OFFICER				
For the purposes of this Agreement, in addition to Organization, the Responsible Officer identified below will be accountable for compliance with the conditions specified in Agreement.				
Chief Executive Officer (or Chief Fiduciary)				
Last r	name:	First name:	Middle initial:	
Т:41				
Title:				
Telep	hone number:	Email:		
Address:				
AGREEMENT REQUIREMENTS				
I understand this is an agreement between the Organization and HHS. To receive COVID-19 testing				
supplies at no cost for use by patients and the community in which it is located, the Organization				
agrees that it will adhere to the following requirements:				
	Organization must make use of testing supplies in conformance with the Food and Drug			
1.	Administration's (FDA) Emergency Use Authorization (EUA) for the specific test kits provided, the EUA Fact Sheet for Health Care Providers, and all other FDA authorized accompanying			
'-	materials (and as the FDA may revise the EUA and accompanying materials), and consister			
	with all requirements, recommendations, and other guidance of HHS.			
•	Organization must not sell or seek reimbursement for the testing supplies that the federal			
2.	government provides at no cost to Organization.			

- Organization must provide the tests regardless of the recipient's ability to pay administration or related fees or coverage status. Organization may not seek any reimbursement, including through balance billing, from the test recipient.
- Organization must comply with FDA EUA requirements for use of testing supplies, including ensuring that appropriate storage, inventory management and administration methods are in place.
- Organization must order testing supplies available under the HRSA COVID-19 Testing Supply Program through the HHS-designated systems. Organization must report the number of testing supplies that are in stock, expired, or wasted using the HHS designated diagnostic ordering system.
- Organization must comply with all applicable federal, state, local or territorial laws that impact the distribution of self-tests or COVID-19 test administration to patients and within the community. Organization must comply with applicable patient assent or consent laws for administration of COVID-19 tests.
- Organization must have processes to ensure timely and proper acceptance of testing supplies. Those processes must include, but are not limited to, procedures for accepting delivery through commercial delivery services. Organization must report any testing supplies that are damaged upon delivery pursuant to the process provided by the delivery service and to HHS within 24 hours. HHS will provide procedures for reporting.
- Organization may use contractors to perform some or all of Organization's duties under Agreement. Organization must ensure that any contractor performs its duties in full compliance with Agreement and Organization is responsible under Agreement for any non-compliance with Agreement by any of its contractors. Furthermore, any knowledge concerning or resulting from performance of Agreement by any of Organization's contractors is imputed to Organization.

By registering for the HRSA COVID-19 Testing Supply Program, I certify that all relevant officers, directors, employees, and agents of Organization involved in handling testing supplies understand and will comply with Agreement requirements listed above.

Organization is subject to applicable statutes and regulations governing each federal healthcare program and any HHS-sponsored COVID-19 relief program for program-specific conditions. Reimbursement for distributing over the counter tests is not available under any federal healthcare program or any HHS-sponsored COVID-19 relief program.

Non-compliance with the terms of Agreement may result in suspension or termination from the HHS COVID-19 Testing Supply Program and criminal and civil penalties under federal law, including but not limited to the False Claims Act, 31 U.S.C. § 3729 *et seq.*, and other related federal laws, including but not limited to 18 U.S.C. §§ 1001, 1035, 1347, 1349.

HHS may terminate this Agreement with two weeks written notice.

Organization may cease its participation in the HHS COVID-19 Testing Supply Program. To do so, Organization must provide written notice to HHS no later than two weeks before Organization wishes to end its participation. During that period of at least two weeks, Organization must comply with Agreement and Organization will not receive any further deliveries of testing supplies.

Should HHS desire to modify the terms of this Agreement, HHS will provide Organization with at least two weeks written notice of the modified terms. If Organization does not agree with the changes, Organization may withdraw from the agreement with two weeks written notice.

By entering into Agreement, Organization does not become a government contractor under the Federal Acquisition Regulation.

Coverage under the Public Readiness and Emergency Preparedness (PREP) Act extends to Organization if it complies with the PREP Act and the PREP Act Declaration of the Secretary of Health and Human Services.<sup>1</sup>

□ Check the box to agree with the above-stated requirements

<sup>&</sup>lt;sup>1</sup> See Pub. L. No. 109-148, Public Health Service Act § 319F-3 and § 319F-4, 42 U.S.C. § 247d-6d and 42 U.S.C. § 247d-6e; 85 Fed. Reg. 15,198, 15,202 (March 17, 2020), and as amended.