Board Office Use: Legislative File Info.				
File ID Number 21-2450				
Introduction Date	October 13, 2021			
Enactment Number	21-1674			
Enactment Date	10/13/2021 CJH			



## **Board Cover Memorandum**

**To** Board of Education

**From** Kyla Johnson-Trammell, Superintendent

Curtiss Sarikey, Chief of Staff

Meeting Date October 13, 2021

Subject Approve Contract with Abbott Rapid Dx North America LLC and Resolution No.

2122-0109 Authorizing Use of Sole Source Exception to Public Bidding

Action

Approve Contract with Abbott Rapid Dx North America LLC and Resolution No. 2122-0109 Authorizing Use of Sole Source Exception to Public Bidding

Background & Discussion

The Board of Education, via Resolution No. 2122-0003 - Requiring COVID-19 Testing At All School Sites, has directed the District to provide biweekly testing at each school site, with priority for unvaccinated students, schools in higher-transmission zip codes, and while maintaining the District's current Rapid Response testing systems (which provide, among other things, the testing necessary for modified quarantine). The California Department of Public Health ("CDPH") has selected and approved the Abbott Binax tests for Rapid Antigen testing, but the State has been experiencing testing supply shortages. As stated by CDPH in a communication to participating districts on September 17, 2021: "Due to a recent high demand for testing and a nationwide shortage of Abbott BinaxNOW tests, many organizations interested in the CDPH Rapid Antigen Testing Program were notified about delays in shipping out antigen kits. We want to reassure you that CDPH is receiving a limited supply of antigen kits from Abbott each week and that these kits are prioritized for K-12 schools." As such, the District is purchasing tests directly from Abbott to ensure we have a stable supply of tests for our community.

**Fiscal Impact** 

Not to exceed \$1,440,514.73 Resource 3212, ESSER II

## Attachment(s)

- Resolution No. 2122-0109 Authorizing Use of Sole Source Exception for Abbott Rapid Dx North America LLC
- VA FSS Contract 36F79721D0073
- PO22-01380

# RESOLUTION OF THE BOARD OF EDUCATION OAKLAND UNIFIED SCHOOL DISTRICT

### **RESOLUTION NO. 2122-0109**

## AUTHORIZING USE OF SOLE SOURCE EXCEPTION TO PUBLIC BIDDING FOR CONTRACT WITH ABBOTT RAPID DX NORTH AMERICA LLC

**WHEREAS,** the Oakland Unified School District ("District") has a need to contract with Abbott Rapid Dx North America LLC for COVID-19 tests;

**WHEREAS**, the contemplated contract is in an amount of \$1,440,514.73;

**WHEREAS**, under Public Contracts Code section 20111, a contract in this amount would ordinarily require competitive bidding;

WHEREAS, one exception to this competitive bidding requirement is the "sole source" exception, which applies where there is only one supplier of a needed good or service (*Los Angeles Gas & Electric Corporation v. Los Angeles* (1920) 188 Cal. 307; *Hodgeman v. City of San Diego* (1942) 53 Cal.App.2d 610; *County of Riverside v. Whitlock* (1972) 22 Cal.App.3d 863); and

### WHEREAS,

- The Board of Education has directed staff to set up biweekly testing at all OUSD school sites,
- The California Department of Public Health has only one Rapid Antigen test approved for use in school districts under a Clinical Laboratory Improvement Amendments waiver, which is the Abbott Binax Now test,
- The California Department of Public Health has contracted with only one lab for processing COVID-19 PCR tests, which is the Valencia Branch Lab (VBL), "a public health laboratory managed and operated by PerkinElmer with the help of various partners. It provides affordable COVID-19 testing support with result turn around time within 24-48 hours of the specimen being received by the laboratory",
- On January 4, 2021, the Veteran's Administration "executed an FSS procurement and awarded a contract, 36F79721 D0073, under schedule 65VII, Invitro Diagnostic, Reagents, Test Kits & Sets for Abbott's BinaxNOW COVID-19 test," communicating that "due to the unprecedented and unforeseen circumstances of current surges in infections, that have arisen during this stage of the COVID-19 pandemic, it is not practical to seek full and open competition for this diagnostic equipment at this time, as increased global demand on the worldwide supply chain has resulted in acute global shortages," and furthermore explaining that "in the case of the national response to the spread of COVID-19, the contracting office in conjunction with the Veterans Health Administration (VHA) Medical Supply Program Management Office (MSPO) Team, has determined that Abbott is a

responsible domestic source for producing the required health and medical resources, specifically the BinaxNOW COVID-19 test kits."

## NOW, THEREFORE, BE IT RESOLVED THAT:

- 1. The Board approves waiving competitive bidding to allow the District to contract directly with Abbott Rapid Dx North America LLC for COVID-19 Tests because Abbott Rapid Dx North America LLC is the sole source for this good.
- 2. The Board hereby approves the contract with Abbott Rapid Dx North America LLC to provide COVID-19 tests.

PASSED AND ADOPTED on, Oakland Unified School District by the following vote:	21,	by	the	Governing	Board	of	the
PREFERENTIAL AYE: None							
PREFERENTIAL NOE: None							
PREFERENTIAL ABSTENTION: None							

PREFERENTIAL RECUSE: None

AYES: Aimee Eng, VanCedric Williams, Gary Yee, Mike Hutchinson, Clifford Thompson, Vice President Benjamin "Sam" Davis

NOES: None

ABSTAINED: None

RECUSED: None

ABSENT: Student Director Samantha Pal, Student Director Natalie Gallegos Chavez, President Shanthi Gonzales

## **CERTIFICATION**

We hereby certify that the foregoing is a full, true and correct copy of a Resolution passed at a Regular Meeting of the Board of Education of the Oakland Unified School District held on \_\_\_\_\_\_, 2021.

Legislative File						
File ID Number:	21-2450					
Introduction Date:	10/13/2021					
Enactment Number:	21-1674					
Enactment Date:	10/13/2021 CJH					
Ву:						

OAKLAND UNIFIED SCHOOL DISTRICT

marboy 10/14/2021

Shanthi Gonzales President, Board of Education

10/14/2021

Kyla Johnson-Trammell Superintendent and Secretary, Board of Education

## **Oakland Unified School District**

**Purchasing Department** 900 High St Oakland, CA 94601 (510) 434-3334 FAX (510) 879-3649 SHIP TO:

DATE 08/30/2021 WAREHOUSE/DISTRIBUTION CENTER 900 HIGH ST

OAKLAND, CA 94601

#### **ORDERED FROM:** FAX: (877) 441-7441

Abbott Rapid Dx North America, LLC 30 S. Keller Rd Suite 100 Orlando, FL 32810

### IMPORTANT INSTRUCTIONS TO VENDOR

1. No payments will be made to any vendor without a valid, OUSD Board Approved or Ratified contract as applicable. (See, e.g. OUSD Board Policy 3312)

**PURCHASE ORDER** 

NO: PO22-01380

- 2. Send itemized invoices to: Accounts Payable at ACCOUNTSPAYABLE@OUSD.ORG or mail to Accounts Payable, 1000 Broadway, Suite 450, Oakland, CA 94607
- 3. Enclose INVOICE & PACKING LIST with ALL shipments.
- 4. No deviation in PRICE or SUBSTITUTION in kind permitted.
- 5. All deliveries F.O.B. Destination unless otherwise specified. If freight is to be charged, prepay, and add to invoice.
- 6. Purchase order number must appear on packing slip.

					7. Standard terms and	conditions located at www.ousd.	org/procurement
	LOCATION LOC					REQUISITIONER Robin Sasada	REQUISITION # VR22-01763
	REQUIRE 13/2021	:D	F.O.B.	TERMS OF PAYMENT	SHIP VIA	BUYER	RPQ#
ITEM	QTY	UNIT		DESCRIPTION		UNIT COST	EXTENSION
1	2,500	EACH	Item # 195-0	00 BINAXNOW COVID19 Profes	ssional	201.01	\$502,525.00
2	8,334	EACIH	Item #195-26	60 BnaxNow COVID OTC		96.48	\$804,064.32
			FSS C	and Unified Abbott Account Nu Contract # 36F79721D0073			
					Order Sub-To Sales Tax Shipping Adjustment	otal	\$1,306,589.32 133,925.41 .00 .00
					Order Total		\$1,440,514.73



## 02- Vendor Response Document M5-Q52A-04-R6

SOLICITATION/CONTRACT/ORDER FOR COMMERCIA OFFEROR TO COMPLETE BLOCKS 17 & 30				AL ITEMS	1. REQUISITION	ON NUMBER	PAGE 1 o 16	f		
2. CONTRACT NO					DER NO./MODIFICATI	ION NO	5. SOLICITATI	ON NO	e collei	TATION ISSUE
36F79721D007		3. AWARD/EFFECTIVE DATE 1/4/2021	VE	N/A	DER NO./MODIFICATI	ION NO.	M5-Q52A-0		6. SOLICI DATE: <b>1/</b>	
7. FOR SOLICITAT		a. NAME: FEDERAL SUPPLY SO	CHEDUL	E HEL	PDESK		b. TELEPHON Calls) <b>(708) 78</b>	E NO. (No Collect <b>36-7737</b>		DUE DATE
9. ISSUED BY		(	CODE		10. THIS ACQUISTIO	N IS				
VA NATIONAL ACQUISITION CENTER FEDERAL SUPPLY SCHEDULE SERVICE 003B6B PO BOX 76, BLDG 37 HINES, IL 60141  OVERNIGHT DELIVERY SHOULD BE MAILED OR HAND DELIVERED TO THE ADDRESS LOCATED IN BLOCK 16				D	SMALL BUSINES HUBZONE SMAI	☐ SMALL BUSINES ☐ WOMEN-OWNED SMALL ☐ HUBZONE SMALL BUSINESS (WOSB) ELIGIBLE UNDER TH ☐ VETERAN OWNED SMALL BUSINESS OWNED SMALL BUSINESS P				THE WOMEN-
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11. DELIVERY FO DESTINATION UN BLOCK IS MARKE	NLESS ED	12. DISCOUNT TERM See Summary o		ırd	13a. THIS CONT RATED ORE DPAS (15 C	DER UNDER		13b. RATING  14. METHOD O		
SEE SCHEDU	LE							RFQ	∐IFB	⊠RFP
15. DELIVER TO			CODE		16. ADMINISTERED				CODE	
		ORDER ISSUED UND ROM THIS SOLICIAT			VA NATIONAL ACQU 1 <sup>ST</sup> AVENUE, 1 BLOC					)3B6B
17a. CONTRACTO	OR/OFFE	EROR CODE			FACILITY CODE	18a. PAYMENT	WILL BE MADE	ВҮ	CODE	
Orlando, FL 3281	30 South Keller Road, Suite 100 Orlando, FL 32810  DUNS 826027364 TELEPHONE NO. 877-441-7440									
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AUTHORIZED FOR LOCAL REPRODUCTION PREVIOUS EDITION IS NOT USABLE

**STANDARD FORM 1449** (REV. 2/2012) Prescribed by GSA - FAR (48 CFR) 53.212



# Addenda to SF 1449 Summary of Award

VA FSS Contract 36F79721D0073<sup>1</sup>

Contractor Name:	Abbott Rapid Dx North America, LLC DBA Alere
Schedule:	65 VII - Invitro Diagnostic, Reagents, Test Kits and Sets
Solicitation Number:	M5-Q52A-04-R6
Performance Period:	January 4, 2021 - January 3, 2025
NAICS:	325413
FSC:	6550

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<sup>&</sup>lt;sup>1</sup> The use of this Government contract to solicit Government business for non-contract products is fraudulent and subject to prosection.

## **Contract Documents**

VA FSS Contract 36F79721D0073 consists of the following documents:

FAR 52.212-4 Contract Terms and Conditions – Commercial Items and Addenda						
FAR 52.212-5 Contract Terms and Conditions Required to Implement Statutes or Executive Orders – Commercial Items						
Program Participation						
Public Law 109-364 Disaster Recove	ery Purchasing Program		☐ No	□ N/A		
Public Health Emergencies under S Services Act, codified at 42 U.S.C. 2		⊠ Yes	☐ No	□ N/A		
AS5000 Pharmaceutical Prime Vend	dor Program	Yes	⊠ No	□ N/A		
Direct-to-Patient Distribution Progr	ram	Yes	⊠ No	□ N/A		
Consignment Agreements	Yes	⊠ No	□ N/A			
Specialty Distribution				•		
[enter Distributor Details (e.g PO	C, Phone #)]	Yes	☐ No	⊠ N/A		
Proposal Information						
Amendment(s)	Yes, all Amendments have been	received 000	01 and 0002			
Proposal	Abbott Rapid Dx North America, 12/22/2020	LLC DBA Aler	e offer dated			
Final Proposal Revision Letter  12/30/2020 Steve Henn, Vice President, Infectious Disease						
Subcontracting Plan						
Awarded Pricing  A copy of the awarded line items with prices (including IFF) is attached hereto and made a part hereof. (See attachment)						

C03\_SF1449\_SOA Rev: Apr 2020 Page 2 of 8

A. Pricing, Terms, and Conditions as agreed to are listed below:

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	S	SIN	% Discount or Discount Range	Maximum Order		
Accepted SINs	5.5	55-8	0.00% The test price is \$200 per kit. The controls are \$60 per kit.	Per Allocation Table		
Basic Discount (covered drug "Dual Pricing")	Not Appli	Not Applicable				
(	SIN	% Discount	or Discount Range	Maximum Order		
Tracking Customer(s)	Therefore purpose of each item offeror's of there is a the offeror offeror's	Abbott Rapids POC has no commercial sales for the offered items.  Therefore, the Price Reductions Clause is not applicable. For the purpose of Clause 552.238-81 Price Reductions (May 2019, Note), for each item the contract shall be predicated on the nexus of the offeror's commercial pricelist (Abbott Rapid Dx North America, LLC Commercial Price Catalog, effective date of December 22, 2020). If there is a decrease in the offeror's pricelist, excluding spot discounts, the offeror is required to extend a price reduction equivalent to the offeror's commercial price list reduction. Price Increases will be governed by the following in conjunction with the Economic Price adjustment Clause, 552.216-70. Price increases are allowable when the offeor increases the commercial pricelist. Should Abbott Rapid Dx North America, LLC sell any of the items commercially, the company shall notify the contracting officer within 10 calendar days and submit an RFM to identify and incorporate a tracking customer and tracking				
Tracking Ratio(s)	NA (See co	omments in T	racking Customer(s) abo	ve)		
Quantity / Tier Discount(s)	None					
Standard Delivery Time	10 Days A	RO				
Expedited Delivery Time	Monday-Friday by 10:30AM EST Saturday by 12:00PM EST Customer responsible for the difference between normal and expedited delivery prices					
FOB Point(s)		FOB Destination to 48 Contiguous States, Washington D.C, Alaska, Hawaii, and Puerto Rico				

Credit Card Acceptance

MPT = Micropurchase Threshold

Yes; cc accepted below, equal to, and above MPT

With no maximum amount

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	In conjunction with Allocation Table:
	The contractor agrees to make available the allocations to the entities
	listed in the allocation table, unless contractor is subject to another
	government order which requires higher priority such as a Defense
	Production Act rated order. Abbott Rapids will inform the CO upon
	receipt of priority rated order that negatively impacts the allocations.
	Abbott Rapid DX North America, LLC shall have no obligation to supply
	volumes in excess of the applicable maximum monthly available
	volume. Contractor recommends to all customers with stated
Minimum Order	volumes that they complete their purchases prior to the last week of
William Graci	any month or during the last week of each month, in order to help ensure patient access to life-saving products, before contractor
	releases commitment allocations as necessary to fill any remaining
	orders for products placed during that month. Notwithstanding the
	foregoing, each monthly allocation under this Agreement shall remain
	available for FSS eligible facilities listed in the allocation table during
	the applicable (or current) month. However, if an entity does not utilize its monthly allocations, Abbott may incorporate those unused tests into its inventory for its own sales and distribution. Allocations shall not be modified without agreement and executed modification by the CO.
Payment Terms	Net 30 Days
	(See Attached)
Return Goods Policy	Abbott Rapid Dx North America, LLC
	Global Business Services (GBS) Orlando Return Goods/Credit Policy
	I.

Warranty Policy	52.212-4 (o) and (p) Government Warranty and Limitation of Liability Clause 52.212-4 (o) (TAILORED)  Warranty: The Contractor warrants and implies that the items delivered hereunder are merchantable and fit for use for the particular purpose described in this contract. In the event that the terms of the contractor's standard commercial warranty conflict with the warranty terms contained in this clause, the terms of this clause will govern this contract, unless some other resolution is specified in the award document. 52.212-4 (p) (TAILORED)  Limitation of liability: Except as otherwise provided by an express warranty, the contractor will not be liable to the Government in a breach of warranty action for consequential damages resulting from any defect or deficiencies in accepted items. In the event that the terms of the contractor's standard commercial warranty/limitation of liability clause(s) place greater limits on the contractor's liability than do the terms contained in this clause, the terms of this clause will govern the contract.
Installation	NA
Rental / Lease Agreement	NA
Training	NA
Service Agreement	NA
Annual Rebate	☐ Yes — See Section D for full rebate terms and conditions ☐ No
Annual Rebate	NA
Other	(See Attached) Abbott Addendum and FSS Government Account Set Up and Order Fulfillment
Commercial Price List	Abbott Rapid Dx North America, LLC Commercial Price Catalog, Effective December 22, 2020
Number of Accepted Items	2
	+

## B. Tracking Customer and the Price Reductions Clause

For the purposes of the Price Reductions clause (552.238-81) and the Modifications clause (552.238-82), the Government and Contractor agree that this contract shall be predicated on the awarded FSS discount off of commercial price list named and identified on pg. 3 and the following customer(s) or category(ies) of customer(s): "CURRENTLY NOT APPLICABLE". During the course of this contract, for any sales under the maximum order, the following price relationship shall be maintined: Abbott Rapids shall notify the contracting officer within 10 calendar days and submit an RFM to identify and incorporate a tracking customer and tracking

<u>ratio.</u>

This is not applicable for deviation sales previously disclosed. If the identified tracking customer contract/agreement has been cancelled, terminated, expired, or the tracking customer has merged with another group, the assigned contract specialist shall be notified within 10 days after the event occurs, and if possible, before the event occurs. At such time, the contractor will negotiate in good faith with the assigned contract specialist in order to establish a successor tracking customer via the Request for Modification process.

## C. Economic Price Adjustment

552.216-70 Economic Price Adjustment Clause – FSS Multiple Award Schedule Contracts of the solicitation applies to all items awarded under this contract.

## D. Annual Rebate

An annual rebate <u>has not been</u> negotiated and awarded under this contract.

## [copy/paste Terms identified in the FPR]

The annual rebate effective date is the first day of the government fiscal year quarter in which the contract is effective. The annual rebate shall be applied at the end of each rebate year. Within 30 calendar days after the end of each rebate year of the contract, the Contractor shall furnish a statement to the assigned Contract Specialist certifying the rebate value of sales made under the contract. Subsequently, the Contractor will receive a bill for collection (BOC) or invoice requesting payment for the rebate amount due. The Contractor will submit payment to the Department of Veterans Affairs, referencing the BOC (invoice) number and the statement, "Annual Rebate under contract <u>36F797XXDXXXX</u>."

Any amount not paid within 30 calendar days from the date of the BOC described above, shall bear interest in accordance with clause 52.232-17, Interest. Any controversies concerning the amount due to the Government shall be subject to the Disputes Clause.

SIN#	ltem#	Product Name	FSS Price without IFF	FSS Price with IFF	Red "A" = Awarded
555-8	195-000	BinaxNOW COVID-19 Ag Card (40CT)	\$200.00	\$201.01	Α
555-8	195-080	BinaxNOW COVID-19 Ag Control Kit (10 Postive)	\$60.00	\$60.30	Α

Awarded Pricing 1 of 1

## BinaxNOW Monthly Allocation Table (a/o 21 Dec 2020)

Allocation Related Questions/Concerns: Binax.Team@HHS.Gov State allocs supply: 8,000,000

Federal agencies supply:

2,000,000

State name	Abbreviation	Tests rounded	Kits allocated
Alabama	AL	118,120	2,953
Alaska	AK	17,600	440
American Samoa	AS	1,320	33
Arizona	AZ	175,360	4,384
Arkansas	AR	72,680	1,817
California	CA	952,120	23,803
Colorado	CO	138,760	3,469
Connecticut	СТ	85,880	2,147
Delaware	DE	23,440	586
District of Columbia	DC	17,000	425
Federated States of Micronesia	FM	2,480	62
Florida	FL	517,520	12,938
Georgia	GA	255,840	6,396
Guam	GU	4,000	100
Hawaii	HI	34,080	852
Idaho	ID	43,040	1,076
Illinois	IL	305,320	7,633
Indiana	IN	162,200	4,055
Iowa	IA	76,000	1,900
Kansas	KS	70,200	1,755
Kentucky	KY	107,640	2,691
Louisiana	LA	112,000	2,800
Maine	ME	32,360	809
Marshall Islands	MH	1,400	35
Maryland	MD	145,680	3,642
Massachusetts	MA	166,080	4,152
Michigan	MI	240,640	6,016
Minnesota	MN	135,880	3,397
Mississippi	MS	71,680	1,792
Missouri	MO	147,880	3,697
Montana	MT	25,720	643
Nebraska	NE	46,600	1,165
Nevada	NV	74,200	1,855
New Hampshire	NH	32,760	819
New Jersey	NJ	214,000	5,350
New Mexico	NM	50,520	1,263
New York	NY	468,760	11,719
North Carolina	NC	252,720	6,318
North Dakota	ND	18,360	459

Northern Mariana Islands	MP	1,240	31
Ohio	ОН	281,640	7,041
Oklahoma	OK	95,320	2,383
Oregon	OR	101,600	2,540
Palau	PW	400	10
Pennsylvania	PA	308,480	7,712
Puerto Rico	PR	76,920	1,923
Rhode Island	RI	25,520	638
South Carolina	SC	124,040	3,101
South Dakota	SD	21,280	532
Tennessee	TN	164,560	4,114
Texas	TX	698,680	17,467
U.S. Virgin Islands	VI	2,520	63
Utah	UT	77,240	1,931
Vermont	VT	15,000	375
Virginia	VA	205,640	5,141
Washington	WA	183,480	4,587
West Virginia	WV	43,160	1,079
Wisconsin	WI	140,280	3,507
Wyoming	WY	13,920	348
State Totals		7,998,760	199,969
	·		

Agency name	Abbreviation Tests rounded	Kits allocated
Department of Veterans Affairs	400,000	10,000
Indian Health Service	831,400	20,785
CDC	143,440	3,586
FEMA	108,600	2,715
Bureau of Prisons	97,800	2,445
White House	18,680	467
DHS	100,000	2,500
Others	300,000	7,500
Total	1,999,920	49,998



#### Return Goods/Credit Policy:

- All requests to return non-equipment merchandise must be reported to and approved by Abbott Rapid Dx North America, LLC within 10 days of the invoice date\*.
- All claims for: 1) product damaged in transit, 2) receipt quantity different from packing list, 3) wrong product shipped or 4) any other shipping differences must be filed with Abbott Rapid Dx North America, LLC within 10 days of receipt of goods.
- Abbott Rapid Dx North America, LLC is not liable for customer ordering errors, inventory that has been
  compromised or damaged while in the customer's possession or refused shipments as a result of customer
  errors.
- If the reason for return is not due to an error caused by Abbott Rapid Dx North America, LLC, the return would be subject to a minimum of 20% restocking fee.
- Abbott Rapid Dx North America, LLC is not responsible for any damaged or lost shipments where the customer
  has chosen to ship the merchandise under their own carrier account, using the carrier of their choice. The
  customer is responsible for filing a carrier claim for collect shipments.
- Once a return request has been approved, Customer Service will prepare a return goods order and issue a Return Goods Authorization (RGA) number. Labels will be provided to the customer for any approved returns.
- Returned product must be received by Abbott Rapid Dx North America, LLC within 30 days of issuance of an RGA number. After 30 days, the RGA number will be cancelled.
- Merchandise returned for reasons other than non-performance must be returned in original unopened, unadulterated packaging. Failure to do so may result in cancellation of the credit memo.
- When a customer is returning product, a certificate of storage must be provided to Abbott Rapid Dx North
  America, LLC, indicating that the merchandise was stored at the proper temperature required for the material.
  Please contact Customer Service for a copy of the Certificate of Storage form or questions regarding proper
  storage conditions for return.
- Damaged shipments received require photos of the damage to verify the claim prior to the credit approval.
- Credits for price adjustments during contract negotiations must be approved by Abbott Rapid Dx North America,
   IIC
- · Any modifications made in a customer contract to this policy will be accepted during the valid contract period.

Contact Abbott Rapid Dx North America, LLC customer service to initiate a return or credit: 877-441-7440 or <a href="mailto:cientservices@abbott.com">cientservices@abbott.com</a>

\*If this invoice includes free or discounted product please note: the value of the special offer(s) the purchaser may receive free from Abbott Rapid Dx North America, LLC under this program a "discounted or other reduction in price" to purchaser under Section 13388[b][3][4] of the Social Security Act [42 U.S.C 1320a-70[b][6]]. Accordingly, purchaser shall disclose this and any other discounts/reduction in price received under this program under any state or federal program which provides costs or charge-based reimbursement to the purchaser for the products and services purchased under this program. Purchaser should retain this pricing information for its files in order to be able to comply with a query from the Secretary of HHS pursuant to 42 C.F.R 1001.95a [h].

## Abbott Rapid Dx North America, LLC Global Business Services (GBS) Orlando

# BinaxNOW™ COVID-19 AG CARD KIT 40T Emergency Use Authorization Customer Set Up & Ordering Process for Federal Supply Schedule Government Customers

**ALL NEW** customers must be qualified as a CLIA Certified entity.

- 1. Submit a completed new account form to <a href="mailto:ARDxUSGovernmentSupport@abbott.com">ARDxUSGovernmentSupport@abbott.com</a> or ssc.serviceassurance@alere.com
  - i. CLIA License # or Copy of CLIA Certification if available by the customer. If not, Abbott will locate on the CDC website
  - ii. Tax Exempt Certificate
  - iii. Customer's first purchase order, if available
  - Any vendor qualification requirements from the customer can be sent to the email above
- 2. Customers can submit their purchase orders to ARDx through the following:
  - ARDxUSGovernmentSupport@abbott.com
  - 877-441-7440 Option 1
- 3. Upon product allocation, if the customer's order quantity exceeds the defined allocation amount, Abbott Customer Service will provide the customer the following options:
  - Keep the remaining quantity on the purchase order open until the next allocation for the customer becomes available.
  - Cancel the remaining quantity open on the purchase order and submit a new purchase order when they need more tests.
    - i. Example: Customer Orders 10,000 tests, but monthly allocation is 5,000 tests. Abbott will ship the 5,000 tests and either keep 5,000 tests open on the existing purchase order or cancel the 5,000 tests to close the order. This will be based on customer preference
- 4. Customers will receive a shipping confirmation with tracking to the email address on file on the day of shipment

#### ABBOTT ADDENDUM

### 1. EMERGENCY USE AUTHORIZATION.

- (a) Abbott's obligation to supply any Product hereunder is contingent upon such Product being commercially available in the U.S. market pursuant to continued regulatory authorization from the United States Food and Drug Administration ("FDA") in accordance with Section 564 of the Federal Food, Drug, and Cosmetic Act ("Emergency Use Authorization" or "EUA") or clearance or approval by the FDA as an in vitro diagnostic.
- (b) Under the EUA, the Products are authorized by the FDA only for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the U.S. Food, Drug and Cosmetic Act (the "Act"), 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner (the "EUA Period"). During the EUA Period, Customer shall use the Products, or cause them to be used, in accordance with the EUA, including, without limitation, ensuring the Products (i) are administered and used by competent and appropriately qualified personnel ("Qualified Personnel") in authorized laboratories or in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance or Certificate of Accreditation, and (ii) are used only for the detection of the presence of antigen protein from SARS-CoV-2, and not for detection of any other viruses or pathogens.
- (c) Customer shall comply with all applicable laws, including without limitation federal, state and local laws, regulations, accepted industry guidelines and the EUA, applicable to Customer's use of the Product and any testing programs operated by Customer, including, without limitation, any obligations to notify relevant public health authorities of Customer's intent to use the Products prior to initiating testing. Customer shall report Product test results to healthcare providers and relevant public health authorities as required by the EUA. Customer shall, and shall cause its Qualified Personnel, to use the Product only in accordance with the authorized labeling under the EUA. Customer shall ensure that all of Qualified Personnel shall: (i) have been appropriately trained in performing Product testing and interpreting test results; (ii) use appropriate personal protective equipment when handling the Products; and (iii) are provided training and monitored on an on-going basis for quality compliance when performing testing using the Products.
- (d) In connection with the EUA, Abbott is providing Customer with the Fact Sheet for Healthcare Providers (the "HCP Fact Sheet") and the Fact Sheet for Patients (the "Patient Fact Sheet", and with the HCP Fact Sheet, the "Fact Sheets") available at https://www.globalpointofcare.abbott/en/product-details/navica-binaxnow-covid-19-us.html. Customer shall include, or cause to be included, such HCP Fact Sheet and/or Patient Fact Sheet with all Product test result reports to healthcare providers and patients, as applicable.
- (e) Customer shall report to Division of Microbiology Devices ("DMD")/Office of Health Technology 7 Office of In Vitro Diagnostics and Radiological Health (OHT7-OIR)/Office of Product Evaluation and Quality (OPEQ)/Center for Devices and Radiological Health (CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) and Abbott (via email: ts.scr@abbott.com) any suspected occurrence of false positive or false negative results and any significant deviations from the established performance characteristics of the Products of which Customer becomes aware. Customer shall ensure that any records associated with the EUA are maintained until otherwise notified by the FDA, and shall make such records available to the FDA for inspection upon request.
- 2. PREP ACT In accordance with the Public Readiness and Emergency Preparedness Act ("PREP Act"), Pub. L. No. 109–148, Division C, Section 2, as amended (codified at 42 U.S.C. § 247d-6d and 42 U.S.C.

247d–6e), as well as the Secretary of HHS's Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID–19 (the "PREP Act Declaration"), 85 Fed. Reg. 15198 (Mar. 17, 2020, effective Feb. 4, 2020), (i) this Agreement is being entered into for purposes of facilitating the manufacture, testing, development, distribution, administration, and use of "Covered Countermeasures" for responding to the COVID-19 public health emergency, in accordance with Section VI of the PREP Act Declaration; (ii) Offeror's performance of this Agreement falls within the scope of the "Recommended Activities" for responding to the COVID-19 public health emergency, to the extent it is in accordance with Section III of the PREP Act Declaration; and (iii) Offeror is a "Covered Person" to the extent it is a person defined in Section V of the PREP Act Declaration. Therefore, in accordance with Sections IV and VII of the PREP Act Declaration as well as the PREP Act (42 U.S.C. § 247d–6d), the government expressly acknowledges and agrees that Offeror shall be immune from suit and liability to the extent and as long as Offerors activities fall within the terms and conditions of the PREP Act and the PREP Act Declaration.