Q2C-55536

COVID-19 MASTER AGREEMENT – SIGNATURE PAGE

ABBOTT RAPID DX NORTH AMERICA, LLC, 30 SOUTH KELLER ROAD, SUITE 100, ORLANDO, FLORIDA 32810

Customer Shipping Address:		**Billing Address:** XXXXXXXXXXXXXXXX Same as Shipping Address	
Customer Name	Collin County Health Care Services	Name	Collin County Auditor
Street Address	825 N McDonald St Ste 130	Address	2300 Bloomdale Rd Ste. 3100
City, State, ZIP	McKinney, TX 75069-2146	City, State, ZIP	McKinney, TX 75071
Customer Number (s)		Phone	972-548-4731
National Account Affiliation		Sales Rep / Territory	Lisa Wright
Customer Point of Contact	Tyler Connelly	Term	Not to Exceed 9/30/2022

Customer identified above ("Customer") and Abbott Rapid Dx North America, LLC ("Abbott") agree to enter into this Master Agreement, including this Signature Page, the General Terms and Conditions and the Membership Exhibit, as each may be amended from time to time (collectively, the "Agreement"). By signing below through their duly authorized representatives, Abbott and Customer agree to be legally bound by the Agreement effective as of the date of Abbott's signature hereto (the "Effective Date").

EMERGENCY USE AUTHORIZATION. The Product (defined in the General Terms and Conditions below) has not been U.S Food and Drug Administration ("FDA") cleared or approved. The Product has been authorized by the FDA under an emergency use authorization for use by authorized laboratories and patient care settings, and has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens (the "EUA"). The Product is only authorized 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 Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner (the "EUA Period").

In connection with the EUA, Abbott is providing Customer with the Fact Sheet for Healthcare Providers attached hereto as Attachment 1 (the "HCP Fact Sheet") and the Fact Sheet for Patients attached hereto as Attachment 2 (the "Patient Fact Sheet", and with the HCP Fact Sheet, the "Fact Sheets"). Customer shall include the Patient Fact Sheet and/or HCP Fact Sheet with all Product result reports, as applicable. Any supply of the Product hereunder shall be subject to the EUA and the information set forth in the Fact Sheets, and Customer shall make its patients aware of the EUA and the Fact Sheets.

Customer shall notify relevant public health authorities of its intent to run the Product prior to initiating such testing and have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate. Customer shall only use the Product as outlined in the package insert and in accordance with the authorized labeling. Customer shall require that any authorized personnel using the Product (i) shall have been appropriately trained in performing and interpreting the results of the Product and (ii) shall use appropriate personal protective equipment when handling the Product.

Customer shall collect information on the performance of the Product and report to DMD/OHT7-OIR/OPEQ/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 significant deviations from the established performance characteristics of the Product of which it 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.

PRODUCTS

Reagents

Abbott Catalog#	Description	Total Volume (Tests)	Net Test Price	Net Kit Price	Purchase Commitment
190-000	ID NOW™ COVID-19 (24T)	4,008	$ 41.00	$984.00	$164,328.00

Controls & Calibrators

Abbott Catalog #	Description	Net Price
190-080	ID NOW COVID-19 Combo Swab Kit (12 neg & 12 pos)	$350.00

Abbott-Owned Equipment

Customer further acknowledges and agrees that the Total Equipment Value for the Abbott-Owned Equipment shall be deemed to be incorporated into the Product price during the Term of the Agreement.

Abbott Catalog#	Description	Total Qty.	Equipment Value (Each)	Total Equipment Value
NAT-024	ID NOW™ Instrument	0	$8,500.00	$ 0.00
IDNOWPRINT	ID NOW™ Printer BOM (Includes Cable and Cord)	0	$350.00	$ 0.00
L22XWU1200	Universal Barcode Scanner	0	$305.00	$ 0.00

NOTICES. Notices regarding this Agreement shall be given as follows:

To Abbott:	With Copy To:	To Customer:
Abbott Rapid Dx North America, LLC 30 South Keller Road, Suite 100, Orlando, Florida 32810 ATTN: Contracting Department	Abbott Rapid Diagnostics Legal Abbott Laboratories 100 Abbott Park Road Abbott Park, Illinois 60064-3500 ATTN: DVP & Associate General Counsel	At the applicable [billing or shipping] address set forth on this Signature Page

THE PARTIES HAVE AGREED TO AND ACCEPTED THIS AGREEMENT:

CUSTOMER

Signature: _____

Printed Name: _____

Title: _____

Date: _____

ABBOTT RAPID DX NORTH AMERICA, LLC

Signature: DocuSigned by: Katie Silverman 531A2ADD4EDB49D...

Printed Name: Katie Silverman

Title: Director, Contracting and Pricing

Date: _____

COVID-19 MASTER AGREEMENT – GENERAL TERMS AND CONDITIONS

A. PRODUCTS. Subject to Section C, as of the Product Availability Date, Abbott shall make available to Customer and, if applicable, to the customer(s) listed on the attached Membership Exhibit, the ID NOW COVID-19 EUA test products ("Products") listed on the Signature Page at the prices set forth therein. Abbott and Customer may, from time to time, mutually agree in writing to add a System Member to the Membership Exhibit.

B. EQUIPMENT. Abbott agrees to provide Customer, for Customer's use, the Abbott-owned equipment ("Abbott-Owned Equipment") identified on the Signature Page. Customer agrees to accept the identified Abbott-Owned Equipment. The terms and conditions in the Abbott-Owned Equipment Terms and Conditions Section apply to all Abbott-Owned Equipment provided under this Agreement.

C. SUPPLY ALLOCATION. Notwithstanding anything to the contrary in the Agreement: (i) at any time and from time to time, Abbott may have limited inventory or no inventory of one or more Products and/or the Abbott-Owned Equipment, and Abbott shall not incur any liability to Customer for any failure to supply or any delayed supply of Products and/or the Abbott-Owned Equipment; and (ii) Abbott reserves the right, in its sole discretion and without liability, to allocate supply of the Products and/or the Abbott-Owned Equipment, and to immediately discontinue supplying any Product, and any such action will not constitute a breach by Abbott under this Agreement.

D. DISCLOSURE. Any discounts, rebates or other price reductions (collectively referred to herein as "discounts") issued by Abbott to Customer constitute a discount under applicable law (42 U.S.C. Section 1320a-7b(b)(3)(A)). Upon Customer's written request, Abbott shall provide detail pertaining to such discounts and the allocation of total net purchase dollars for Products, equipment, services, and miscellaneous purchases, as applicable. Customer may have an obligation to report such discounts to any State or Federal program that provides reimbursement to Customer for the items to which the discount applies, and, if so, Customer must fully and accurately report such discounts. Further, Customer should retain invoices and other price documentation and make them available to Federal or State officials upon request.

E. PURCHASE COMMITMENT. Subject to Section C above, Abbott agrees to sell, and Customer agrees to purchase, the Product at the prices and volumes indicated on the Signature Page under the Reagents table for the duration of the Term of this Agreement (the "Purchase Commitment"). Customer acknowledges and agrees that the Total Equipment Value for the Abbott-Owned Equipment shall be deemed to be incorporated into the Product price during the Term of the Agreement. Abbott will review Customer's compliance with the Purchase Commitment during the Term. If Customer fails to meet the Purchase Commitment at the end of the Term, then Customer may elect to extend the Term for an additional two (2) months (the "Extension Term"). If Customer elects not to extend the Term and/or does not fulfill their Purchase Commitment at the end of the Extension Term, then Customer agrees that the amount equal to the shortfall between the actual aggregate price of Products purchased by Customer and the Purchase Commitment shall become immediately due to Abbott.. If Customer purchases any Product from an authorized distributor, then such purchases shall count toward the Purchase Commitment; it being understood that any such purchases shall, in addition, otherwise be subject to separate terms and conditions between Customer and such authorized distributor. Customer acknowledges and agrees that, in any event, the Product is subject to EUA, the Fact Sheets and the terms of this Agreement. In the event that Abbott is unable to supply a Product under this Agreement and unable to provide a replacement product, Abbott shall suspend the Purchase Commitment for the applicable Product for the duration of time in which the Product is unavailable and adjust the Purchase Commitment accordingly for the current Contract Year.

F. TERMINATION. If Customer breaches any of the terms of this Agreement, Abbott may, in its sole discretion and without further liability, immediately terminate this Agreement and/or repossess the Abbott-Owned Equipment, in addition to all its other rights and remedies. This Agreement shall automatically terminate upon the end of the EUA Period. Within thirty (30) days following to the end of the Term, Customer shall (i) enter into a Master Agreement for use of the Abbott-Owned Equipment listed on the Price Exhibit with other ID Now-related products; (ii) purchase the Abbott-Owned Equipment by providing a billable purchase order to Abbott using a mutually agreed upon price; or (iii) carefully package and return the Abbott-Owned Equipment pursuant to the terms of this Agreement.

G. CONFIDENTIALITY. The terms of this Agreement are confidential and, except as otherwise required by law, Customer shall not disclose such terms to any third party without Abbott's prior written consent, provided that Customer shall be permitted to disclose the terms of this Agreement to the extent required by applicable law or as reasonably required by Customer's attorneys, accountants and other professional advisors who are under an obligation of confidentiality to Customer. Customer acknowledges and agrees that Abbott may share information under this Agreement, including pursuant to the rules of the stock exchange on which the securities of Abbott are traded, or to the extent requested by any governmental entity. The provisions of this paragraph shall survive termination or expiration of this Agreement.

H PAYMENT TERMS; SHIPPING. Payment terms are net thirty (30) days and will be made in accordance with VTCA Chapter 2251.021 Time for Payment by Government Entity. Past due balances may be subject to a service charge of one and one-half percent (1.5%) per month (or the highest rate allowed by law, if lower than one and one-half percent (1.5%) per month). Unless Customer is fully exempt from all taxes, Customer shall pay all taxes, federal, state and local, which may be imposed upon the use, possession, ownership, or lease of any product; such taxes shall be added to the invoice. Customer shall reimburse Abbott for any such tax paid by Abbott. If Customer is tax exempt, Customer must provide a tax-exempt certification to Abbott prior to the Effective Date of this Agreement. Shipping charges are prepaid and added to each invoice. Products will be shipped Free Carriage Alongside (FCA) point of shipment.

I. PRODUCT RETURNS AND ACCEPTANCE. Unless Customer provides written notice to Abbott, no later than ten (10) calendar days after delivery of the applicable Product and/or Abbott-Owned Equipment, of (1) subject to Section C, any discrepancy between the type or quantity of Products and/or Abbott-Owned Equipment ordered and the type or quantity of Products and/or Abbott-Owned Equipment delivered or (2) any failure of such Product and/or Abbott-Owned Equipment to materially comply with the warranty set forth in Section J below, Customer shall be deemed to have accepted ("Acceptance") such Product and/or equipment. All returns shall be governed by Abbott's return policy, which Abbott shall provide to Customer upon request. If Customer experiences difficulty with the Product, Customer may call Abbott Technical Support at 877-441-7440, option 2. If Customer experiences a problem with an order or shipment, Customer may call Abbott Customer Service at 877-441-7440, option 1.

J WARRANTY. Abbott warrants and represents that Products delivered to carrier for shipment to Customer, or delivered directly to Customer, will commence on Acceptance and continue for the shelf life of the Product: (1) materially conform to published specifications set forth in the applicable Abbott package insert(s); (2) not be adulterated or misbranded within the meaning of the U.S. Food, Drug and Cosmetic Act; and (3) be of good quality and free from defects in materials and workmanship. Except as to warranties specifically set forth in this paragraph, the only other warranties made by Abbott with respect to Products and Abbott-Owned Equipment are those specifically and expressly stated as warranties in the Abbott package insert specifications and manuals. ABBOTT MAKES NO OTHER WARRANTIES; EXPRESS OR IMPLIED, INCLUDING BUT NOT LIMITED TO, WARRANTIES AS TO MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT OR ANY OTHER MATTER. Notwithstanding the foregoing, any warranties provided by Abbott will not apply to any Product or Abbott-Owned Equipment if (a) it has been misused, altered, damaged or used other than in accordance with the applicable Abbott package insert and/or operating manual (including product dating); (b) it has been used in combination with other articles, substances or reagents (or any combination thereof) not provided or recommended for use by Abbott with such Product or Abbott-Owned Equipment; (c) the serial or lot number of any Product or Abbott-Owned Equipment has been altered, defaced, or removed; or if any repair is attempted by personnel who has not been authorized by Abbott to perform such repair; or (d) the Product or Abbott-Owned Equipment was purchased from an unauthorized distributor (subsections (a) through (d), collectively, "Warranty Exclusions"). If any Product or Abbott-Owned Equipment does not comply with the warranty set forth in this paragraph, as Customer's sole and exclusive remedy, Abbott shall, at its discretion, repair or replace the applicable Product at no additional expense to Customer.

K. DISCLAIMER. To the fullest extent allowed by applicable law, customer assumes all risk for the suitability of the test results obtained by using the Product and/or Abbott-Owned Equipment hereunder, and the consequences which flow therefrom. Customer assumes all risk when any of the Warranty Exclusions apply to the Products and/or Abbott-Owned Equipment. To the full extent permitted by applicable law, Abbott's maximum aggregate and total liability for all claims under this Agreement is limited to the amount paid to Abbott by Customer for the Products and/or Abbott-Owned Equipment giving rise to the claim. IN NO EVENT SHALL ABBOTT BE LIABLE FOR ANY PUNITIVE, CONSEQUENTIAL, INDIRECT, INCIDENTAL OR SPECIAL DAMAGES OR LOSSES OF ANY NATURE WHATSOEVER (INCLUDING WITHOUT LIMITATION, LOST REVENUE, LOST PROFITS, OR LOST BUSINESS) ARISING OUT OF THIS AGREEMENT OR THE USE OF PRODUCTS, EQUIPMENT, SERVICES, OR MISCELLANEOUS PURCHASES OR ANY FAILURE BY ABBOTT TO SUPPLY PRODUCTS, EQUIPMENT, SERVICES, OR MISCELLANEOUS PURCHASES HEREUNDER.

L. USE OF PRODUCTS. The Products purchased under this Agreement are for Customer's own use and not for resale or distribution to any third party. Customer agrees not to (1) resell any Abbott Product or equipment; (2) use the Products, as applicable, past their expiration date and (3) use any Product or Equipment in any manner inconsistent with its intended use. Upon reasonable notice, Abbott or its designee may, at its expense, audit all relevant books and records of Customer to confirm Customer's compliance with the restrictions on resale set forth herein. Any such audit shall be conducted during Customer's normal business hours.

M. MISCELLANEOUS. This Agreement, together with all other exhibits and items specifically referenced herein, constitute the entire understanding between Customer and Abbott with respect to the subject matter contained within the Agreement and supersedes prior agreements concerning the same. All terms and conditions contained in any form issued by Customer shall be null and void and entirely superseded by the terms and conditions of this Agreement, except for those items proposed by

Customer and specifically accepted in writing by a duly authorized representative of Abbott. Except where otherwise stated herein, this Agreement may not be altered or amended except by written agreement signed by both parties. Orders received for Products on this Agreement are subject to acceptance by Abbott. Customer will not use Abbott's or its affiliates' names, logos or other indicia in any publicity, advertising, announcement, brochure, customer list or website, in any media now known or hereinafter invented, without prior written consent from Abbott Public Affairs or its designee. Neither party may assign or transfer this Agreement without the other party's prior written consent, except that Abbott may assign this Agreement to an affiliate without Customer's consent. The parties are independent contractors. This Agreement does not create or otherwise imply that there is any relationship of employment, agency, franchise, joint venture, partnership or other similar legal relationship among the parties. No party has the authority to bind or act on behalf of any other party except as otherwise expressly stated in this Agreement. The terms set forth in Sections D, G and J-N shall survive termination or expiration of the Agreement. This Agreement is entered into by and for the sole benefit of the enumerated parties to this Agreement. Nothing in this Agreement shall be interpreted or construed to provide any benefits to any third party or to otherwise create a third-party beneficiary under this Agreement.

N. ALTERNATIVE DISPUTE RESOLUTION. Intentionally Omitted.

O. Venue. - This agreement will be governed and construed according to the laws of the State of Texas. This agreement is performable in Collin County, TX. Or State of Texas

Q. Force Majeure. No party shall be liable or responsible to the other party, nor be deemed to have defaulted under or breached this Agreement, for any failure or delay in fulfilling or performing any term of this Agreement (other than the payment of money), when and to the extent such failure or delay is caused by or results from acts beyond the affected party's reasonable control, including, without limitation: acts of God; flood, fire or explosion; war, invasion, riot or other civil unrest; actions, embargoes or blockades in effect on or after the date of this Agreement; or national or regional emergency (each of the foregoing, a "Force Majeure Event"). A party whose performance is affected by a Force Majeure Event shall give notice to the other party, stating the period of time the occurrence is expected to continue and shall use diligent efforts to end the failure or delay and minimize the effects of such Force Majeure Event.

ABBOTT-OWNED EQUIPMENT TERMS AND CONDITIONS

Intentionally Omitted.

MEMBERSHIP EXHIBIT

ABBOTT RAPID DX NORTH AMERICA, LLC, 30 SOUTH KELLER ROAD, SUITE 100, ORLANDO, FLORIDA 32810

This Membership Exhibit permits Abbott to accept purchase orders for Products from the Customer "Ship and Bill To" entities ("System Members") listed below, and permits Abbott to ship Products and invoice System Members directly for such Products. Customer represents that it has the authority to bind each System Member to this Agreement, and each System Member shall be bound by this Agreement, as if such System Member signed this Agreement. Customer and System Members shall be collectively responsible for meeting the Purchase Commitment in this Agreement. If any System Member fails to comply with the terms and conditions of this Agreement, Customer shall be liable for such noncompliance. For purposes of this Agreement, each reference to "Customer" in this Agreement shall also be deemed a reference to a "System Member".

System Members

System Member Name	Street Address	City, ST and Zip Code
		,

ATTACHMENT 1

FACT SHEET FOR HEALTHCARE PROVIDERS

ID NOW COVID-19 – Abbott Diagnostics Scarborough, Inc. Updated: June 1, 2020

Coronavirus Disease 2019 (COVID-19)

This Fact Sheet informs you of the significant known and potential risks and benefits of the emergency use of the ID NOW COVID-19.

The ID NOW COVID-19 is authorized for use on respiratory specimens collected from individuals who are suspected of COVID-19 by their healthcare provider.

All patients whose specimens are tested with this assay will receive the Fact Sheet for Patients: ID NOW COVID-19.

What are the symptoms of COVID-19?

Many patients with confirmed COVID-19 have developed fever and/or symptoms of acute respiratory illness (e.g., cough, difficulty breathing). The current information available to characterize the spectrum of clinical illness associated with COVID-19 suggests that symptoms include cough, shortness of breath or dyspnea, fever, chills, myalgias, headache, sore throat or new loss of taste or smell. Based on what is known about the virus that causes COVID-19, signs and symptoms may appear any time from 2 to 14 days after exposure to the virus. Based on preliminary data, the median incubation period is approximately 5 days, but may range 2-14 days.

Public health officials have identified cases of COVID-19 infection throughout the world, including the United States, which may pose risks for public health. Please check the CDC webpage for the most up to date information.

What do I need to know about COVID-19 testing?

Current information on COVID-19 for healthcare providers is available at CDC's webpage, *Information for Healthcare Professionals* (see links provided in "Where can I go for updates and more information" section).

- The ID NOW COVID-19 can be used to test direct nasal, nasopharyngeal or throat swabs.
- The ID NOW COVID-19 should be ordered for the detection of COVID-19 in individuals who are suspected of COVID-19 by their healthcare provider.
- The ID NOW COVID-19 is authorized for use in laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high and moderate complexity tests.
- The ID NOW COVID-19 Test is authorized to be distributed and used in patient care settings using the ID NOW Instrument outside of the clinical laboratory environment.

This test is to be performed only using respiratory specimens collected from individuals who are suspected of COVID-19 by their healthcare provider.

Specimens should be collected with appropriate infection control precautions. Current guidance for COVID-19 infection control precautions are available at the CDC's website (see links provided in "Where can I go for updates and more information" section).

Use appropriate personal protective equipment when collecting and handling specimens from individuals suspected of having COVID-19 as outlined in the CDC *Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 (COVID-19)*. For additional information, refer to CDC *Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons Under Investigation (PUIs) for Coronavirus Disease 2019 (COVID-19)* (see links provided in "Where can I go for updates and more information" section).

What does it mean if the specimen tests positive for the virus that causes COVID-19?

A positive test result for COVID-19 indicates that RNA from SARS-CoV-2 was detected, and the patient is infected with the virus and presumed to be contagious. Laboratory test results should always be considered in the context of clinical observations and epidemiological data in making a final diagnosis and patient management decisions. Patient management should follow current CDC guidelines.

The ID NOW COVID-19 has been designed to minimize the likelihood of false positive test results. However, in the event of a false positive result, risks to patients could include the following: a recommendation for isolation of the patient, monitoring of household or other close contacts for symptoms, patient isolation that might limit contact with family or friends and may increase contact with other potentially COVID-19 patients, limits in the ability to work, the delayed diagnosis and treatment for the true infection causing the symptoms, unnecessary prescription of a treatment or therapy, or other unintended adverse effects.

All laboratories and healthcare providers in patient care settings using this test must follow the standard testing and reporting guidelines according to their appropriate public health authorities.

Report Adverse events, including problems with test performance or results, to MedWatch by submitting the online FDA Form 3500 (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home) or by calling **1-800-FDA-1088**

What does it mean if the specimen tests negative for the virus that causes COVID-19?

A negative test result for this test means that SARS-CoV-2 RNA was not present in the specimen above the limit of detection. However, a negative result does not rule out COVID-19 and should not be used as the sole basis for treatment or patient management decisions. A negative result does not exclude the possibility of COVID-19. Negative results should be treated as presumptive and, if inconsistent with clinical signs and symptoms or necessary for patient management, should be tested with an alternative molecular assay.

When diagnostic testing is negative, the possibility of a false negative result should be considered in the context of a patient's recent exposures and the presence of clinical signs and symptoms consistent with COVID-19. The possibility of a false negative result should especially be considered if the patient's recent exposures or clinical presentation indicate that COVID-19 is likely, and diagnostic tests for other causes of illness (e.g., other respiratory illness) are negative. If COVID-19 is still suspected based on exposure history together with other clinical findings, retesting with an alternative method should be considered by healthcare providers in consultation with public health authorities.

Risks to a patient of a false negative include: delayed or lack of supportive treatment, lack of monitoring of infected individuals and their household or other close contacts for symptoms resulting in increased risk of spread of COVID-19 within the community, or other unintended adverse events.

What is an EUA?

The United States FDA has made this test available under an emergency access mechanism called an Emergency Use Authorization (EUA). The EUA is supported by the Secretary of Health and Human Service's (HHS's) declaration that circumstances exist to justify the emergency use of in vitro diagnostics (IVDs) for the detection and/or diagnosis of the virus that causes COVID-19.

An IVD made available under an EUA has not undergone the same type of review as an FDA-approved or cleared IVD. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, available alternatives, and based on the totality of scientific evidence available, it is reasonable to believe that this IVD may be effective in the detection of the virus that causes COVID-19.

The EUA for this test is in effect for the duration of the COVID-19 declaration justifying emergency use of IVDs, unless terminated or revoked (after which the test may no longer be used).

Where can I go for updates and more information?

CDC webpages:

General: https://www.cdc.gov/COVID19
Healthcare Professionals: https://www.cdc.gov/coronavirus/2019-nCoV/guidance-hcp.html
Information for Laboratories: https://www.cdc.gov/coronavirus/2019-nCoV/guidance-laboratories.html
Laboratory Biosafety: https://www.cdc.gov/coronavirus/2019-nCoV/lab-biosafety-guidelines.html
Isolation Precautions in Healthcare Settings: https://www.cdc.gov/coronavirus/2019-ncov/infection-control/control-recommendations.html
Specimen Collection: https://www.cdc.gov/coronavirus/2019-nCoV/guidelines-clinical-specimens.html
Infection Control: https://www.cdc.gov/coronavirus/2019-ncov/infection-control/index.html

FDA webpages:

General: www.fda.gov/novelcoronavirus
EUAs:(includes links to patient fact sheet and manufacturer's instructions) https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations

Abbott Diagnostics Scarborough, Inc.:

Abbott Diagnostics Scarborough, Inc.
10 Southgate Road
Scarborough, ME, USA, 04074

Customer Support:
+1 855 731-2288
ts.scr@abbott.com

Technical Support:
+1 855 731-2288
ts.scr@abbott.com

Website:
https://www.alere.com/en/home/product-details/id-now-COVID-19.html

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Report Adverse events, including problems with test performance or results, to MedWatch by submitting the online FDA Form 3500 (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home) or by calling **1-800-FDA-1088**

ATTACHMENT 2

Abbott

FACT SHEET FOR PATIENTS

ID NOW COVID-19 –
Abbott Diagnostics Scarborough, Inc.

June 1, 2020

Coronavirus Disease 2019 (COVID-19)

You are being given this Fact Sheet because your sample(s) was tested for the Coronavirus Disease 2019 (COVID-19) using the ID NOW COVID-19 test.
This Fact Sheet contains information to help you understand the risks and benefits of using this test for the diagnosis of COVID-19. After reading this Fact Sheet, if you have questions or would like to discuss the information provided, please talk to your healthcare provider.

- **For the most up to date information on COVID-19 please visit the CDC Coronavirus Disease 2019 (COVID-19) webpage:**
- https://www.cdc.gov/COVID19

What is COVID-19?
COVID-19 is caused by the SARS-CoV-2 virus. The virus can cause mild to severe respiratory illness and has spread globally, including the United States. The current information available to characterize the spectrum of clinical illness associated with COVID-19 suggests that symptoms include cough, shortness of breath or difficulty breathing, fever, chills, muscle pain, headache, sore throat or new loss of taste or smell.

What is the ID NOW COVID-19 test?
The test is designed to detect the virus that causes COVID-19 in respiratory specimens, for example nasal or oral swabs.

Why was my sample tested?
You were tested because your healthcare provider believes you may have been exposed to the virus that causes COVID-19 based on your signs and symptoms (e.g., fever, cough, difficulty breathing), and/or because:

- You live in or have recently traveled to a place where transmission of COVID-19 is known to occur, and/or
- You have been in close contact with an individual suspected of or confirmed to have COVID-19.

Testing of the samples will help find out if you may have COVID-19.

What are the known and potential risks and benefits of the test?

Potential risks include:

- Possible discomfort or other complications that can happen during sample collection.
- Possible incorrect test result (see below for more information).

Potential benefits include:

- The results, along with other information, can help your healthcare provider make

- **Where can I go for updates and more information?** The most up-to-date information on COVID-19 is available at the CDC General webpage: https://www.cdc.gov/COVID19. In addition, please also contact your healthcare provider with any questions/concerns.

Abbott

FACT SHEET FOR PATIENTS

ID NOW COVID-19 –
Abbott Diagnostics Scarborough, Inc.

June 1, 2020

Coronavirus Disease 2019 (COVID-19)

informed recommendations about your care.
- The results of this test may help limit the spread of COVID-19 to your family and others in your community.

What does it mean if I have a positive test result?
If you have a positive test result, it is very likely that you have COVID-19. Therefore, it is also likely that you may be placed in isolation to avoid spreading the virus to others. There is a very small chance that this test can give a positive result that is wrong (a false positive result). Your healthcare provider will work with you to determine how best to care for you based on the test results along with medical history, and your symptoms.

What does it mean if I have a negative test result?
A negative test result means that the virus that causes COVID-19 was not found in your sample. For COVID-19, a negative test result for a sample collected while a person has symptoms usually means that COVID-19 did not cause your recent illness.

However, it is possible for this test to give a negative result that is incorrect (false negative) in some people with COVID-19. This means that you could possibly still have COVID-19 even though the test is negative. If this is the case, your healthcare provider will consider the test result together with all other aspects of your medical history (such as symptoms, possible exposures, and geographical location of places you have recently traveled) in deciding how to care for you.

It is important that you work with your healthcare provider to help you understand the next steps you should take.

Is this test FDA-approved or cleared?
No. This test is not yet approved or cleared by the United States FDA. When there are no FDA-approved or cleared tests available, and other criteria are met, FDA can make tests available under an emergency access mechanism called an Emergency Use Authorization (EUA). The EUA for this test is supported by the Secretary of Health and Human Service's (HHS's) declaration that circumstances exist to justify the emergency use of in vitro diagnostics for the detection and/or diagnosis of the virus that causes COVID-19. This EUA will remain in effect (meaning this test can be used) for the duration of the COVID-19 declaration justifying emergency of IVDs, unless it is terminated or revoked by FDA (after which the test may no longer be used).

TB000038 Rev. 3

- **Where can I go for updates and more information?** The most up-to-date information on COVID-19 is available at the CDC General webpage: https://www.cdc.gov/COVID19. In addition, please also contact your healthcare provider with any questions/concerns.