

By: Finance Department
Adopted: December 13, 2021
Yes: Brown, Graham, Harvey, Sullivan-Leonard, Velock
No: Johnson
Absent: None

**City of Wasilla
Resolution Serial No. 21-32**

A Resolution Of The Wasilla City Council Authorizing The Purchase Of COVID-19 Antigen Home Test Kits In The Amount Of \$595,515.

WHEREAS, through Resolution Serial No. 20-24 and Ordinance Serial No. 20-28, the City of Wasilla (City) accepted \$18,690,897.67 for Coronavirus relief funds through the Alaska Department of Commerce, Community, and Economic Development for costs that are for necessary expenditures incurred due to the public health emergency with respect to the Coronavirus Disease 2019 (COVID-19); and

WHEREAS, the City remains diligent in its mitigation efforts within our community by encouraging testing for COVID-19 and is able to purchase 25,984 COVID-19 Antigen Home Test Kits (two tests per kit) through Boston BioPharma at a cost of \$22.50 per test kit or \$584,640 plus air freight cost of approximately \$10,875; and

WHEREAS, Mat-Su Health Foundation has expressed support and has agreed to distribute these kits as fast and as diligent as possible to the residents of the City of Wasilla.

NOW, THEREFORE, BE IT RESOLVED, that the Wasilla City Council authorizes the purchase of COVID-19 Antigen Home Test Kits for distribution in cooperation with the Mat-Su Health Foundation.

Source of Funds.

110-4181-499-45-18 City Resiliency and Recovery \$595,515

Effective Date. This resolution takes effect upon adoption.

ADOPTED by the Wasilla City Council on December 13, 2021.



Glenda D. Ledford, Mayor

ATTEST:



Jamie Newman, MMC, City Clerk

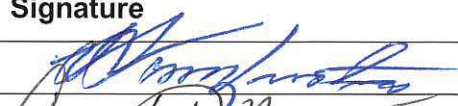
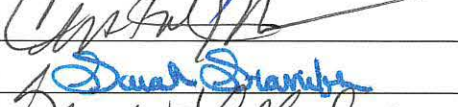
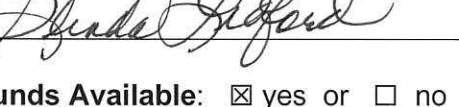
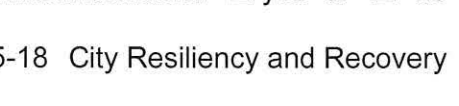
[SEAL]

**City of Wasilla
Legislative Staff Report
Resolution Serial No. 21-32**

A Resolution Of The Wasilla City Council Authorizing The Purchase Of COVID-19 Antigen Home Test Kits In The Amount Of \$595,515.

Originator: Troy Tankersley, Finance Director
Date: 12/2/2021

Agenda of: 12/13/2021

Route to:	Department Head	Signature	Date
X	Finance Director		12-3-21
X	Deputy Administrator		12/3/21
X	City Clerk		12/3/21
X	Mayor		12/4/21

Fiscal Impact: yes or no

Funds Available: yes or no

Account name/number: 110-4181-499-45-18 City Resiliency and Recovery

Attachments: Resolution Serial No. 21-32 (2 pages)
MatSu Health Foundation Letter dated December 2, 2021 (1 page)
Boston BioPharma Quote (8 pages)

Summary Statement: The COVID-19 pandemic has required many residents to seek testing at facilities that require long wait times and appointments.

With the onset of other COVID-19 variants, and to continue encouraging testing for COVID-19, the City has an opportunity to acquire 25,984 test kits for home use. This allows for residents to test for COVID-19 wherever they feel comfortable, without the need of providing sensitive medical information.

The Mat-Su Health Foundation recently acquired the same 25,984 COVID-19 Antigen Home Test Kits for distribution, free of charge to residents across the Mat-Su Borough. Those test kits are completely exhausted. Mat-Su Health Foundation as expressed support and have agreed to distribute as fast and as diligent as possible to the City of Wasilla residents.

The cost of the COVID-19 Antigen Home Test Kit is \$11.25 per test or \$22.50 per test kit (2 tests per test kit) for a total cost of \$584,640. The City wishes to expressly acquire and distribute these kits and to do so requires an air freight cost of approximately \$10,875.

Proposed Action: Adopt Resolution Serial No. 21-32.



**MAT-SU HEALTH
FOUNDATION**

777 N. Crusey Street, Suite A201 • Wasilla, AK 99654
Phone: (907) 352-2863 • Fax (907) 352-2865
www.healthymatsu.org

December 2, 2021

Mayor Glenda Ledford
City of Wasilla
Sent via email to gledford@ci.wasilla.ak.us

Dear Mayor Ledford,

The Mat-Su Health Foundation's mission is to improve the health and wellness of all Alaskans living in the Mat-Su. Over the last 22 months the foundation has stepped into the role of providing COVID-19 information and resources because our cities and borough do not have health powers. Since the beginning of the pandemic, we have launched two multimillion-dollar funding programs to support local organizations impacted by the virus and have led a group of partners including borough and city government officials and healthcare providers in performing public outreach related to the pandemic. In addition, MSHF recently purchased and distributed 26,000 rapid home tests kits throughout the borough. We were able to fund the purchase thanks to CDC monies passed through to the foundation from the cities of Wasilla, Palmer and Houston and the Mat-Su Borough.

The home test kit program has been a resounding success, and most of the 20+ distribution sites have dispensed all of the test kits. We applaud the City of Wasilla using some of its remaining CARES Act funding to purchase additional home test kits. The MSHF is happy to help distribute those to Wasilla residents at our location on Crusey Street. Removing barriers for residents to get tested for COVID-19 is a positive step toward meeting the immediate health needs in our community. While testing has been widely available, it is not always convenient or cost-effective for people to go to a testing site. This program is designed to bring an important tool to anyone who needs it so they can make the decisions that are best for themselves and their families. In addition, one barrier to testing is concern about privacy. Home test kits provide an option that is completely anonymous, free and accessible. One of the distribution sites sent the following anecdote:

"We wish to thank you for the Covid-19 home test kit purchase and distribution. We feel it has been a very successful project: we have many stories of folks who were able to isolate quickly thanks to their home test result, and SO many are very grateful for being able to test prior to Thanksgiving and Holiday gatherings and as they travel. We'd be very happy to do this again!"

Other distribution sites initially expressed concern that people would come in and take the entire supply of kits. However, they were pleasantly surprised that residents picked up just one or two so that everyone who needed one would have access.

Should this concept be approved, the foundation will make the kits available in our building's two vestibules, open to the public from 8 am – 5 pm Monday through Friday. In addition to handling distribution, we will widely publicize the availability of the kits so that every Wasilla resident who wants to be tested in their own home is able to do so. We request that the City of Wasilla provide storage space for the kits because our location does not have adequate space and will work with the city to address logistics.

We appreciate this opportunity to continue to partner with the City of Wasilla. Covid-19 testing that is widely available, free, and private is an important strategy for keeping our businesses open, our children in school, and our residents healthy and safe.

Elizabeth Ripley
President and CEO

Cc: Tony Tankersley, City of Wasilla Director of Finance, ttankersley@ci.wasilla.ak.us



Sales Order Form

Product: CareStart™ COVID-19 Antigen Home Test

Order Date	Dec 2, 2021
------------	-------------

Sales Order No.	
-----------------	--

Buyer Billing Details	
Company Name	City of Wasilla
Address	290 Herning Avenue
Floor, Suite, Unit	
City	Wasilla
State	AK
ZIP	99654-7091
Contact Person	Troy Tankersley
Position	Director of Finance
Phone	907-373-9084
Email	ttankersley@ci.wasilla.ak.us

Buyer Shipping Details	
Company Name	City of Wasilla
Address	TBD
Floor, Suite, Unit	
City	Wasilla
State	AK
ZIP	
Contact Person	
Position	
Phone	
Email	

Product Code	Description	Quantity	Unit Price (\$)	Total Price (\$)
RCPM-00271 (2 tests per pack)	CareStart™ COVID-19 Antigen Home Test	25,984	\$ 22.50	\$ 584,640.00
Delivery Date	TBD		Shipping (\$)	\$ 10,875.00
Shipping Terms	CIF Wasilla, Alaska		Taxes (\$)	\$ 0.00
Shipping Method	Air freight and insurance		Total (\$)	\$ 595,515.00
Payment Terms	100% prepayment			
Payment Method	<input type="checkbox"/> Check <input checked="" type="checkbox"/> ACH transfer <input type="checkbox"/> Wire transfer			

Payment Info			
Beneficiary	Boston Biopharma, Inc.	Account No.	3340 6320 9324
Name of Bank	Bank of America	SWIFT	BOFAUS3N
Bank Address	700 W Crossville Road, Roswell, GA 30075, USA	Routing No.	026009593

On signing this order, Buyer hereby acknowledges and affirms that: *(check the statements below)*

- Buyer agrees to the Sales Order Terms and Conditions defined overleaf and incorporated by reference herein;
- Buyer is an end user organization and the Consumer of the Product, not a reseller;
- Buyer understands that the full quantity of Product purchased will be used solely by the Buyer;
- Buyer is not authorized to resell any quantity of Product purchased from Boston Biopharma;
- Buyer has been provided with **CareStart™ COVID-19 Antigen Home Test Fact Sheet For Individuals**.

Accepted and Acknowledged by Buyer	
Date	Dec 2, 2021
Signer Name	
Signer Position	
Signature†	

Accepted and Acknowledged* by Seller	
Date	
Signer Name	
Signer Position	
Signature	

† Please fill in all fields before signing the order.
The order cannot be edited once it is signed by the Buyer.

* subject to the Sales Order Terms and Conditions

Sales Order Terms and Conditions

Product: CareStart™ COVID-19 Antigen Home Test

- 8.2. If Buyer timely notifies Seller of any Nonconforming Goods, Seller shall, in its sole discretion, (i) replace such Nonconforming Goods with conforming Goods, or (ii) credit or refund the Price (as defined below) for such Nonconforming Goods. Buyer shall ship, at its expense and risk of loss, the Nonconforming Goods to the address provided by the Seller. If Seller exercises its option to replace Nonconforming Goods, Seller shall, after receiving Buyer's shipment of Nonconforming Goods, deliver to Buyer, at Buyer's expense and risk of loss, the replaced Goods to the Delivery Point.
- 8.3. Buyer acknowledges and agrees that the remedies set forth in Section 8.2 are Buyer's exclusive remedies for the delivery of Nonconforming Goods. Except as provided under Section 8.2, all sales of Goods to Buyer are made on a one-way basis and Buyer has no right to return Goods purchased under this Agreement to Seller. Refunds, credits and exchanges are granted only in such cases as described in Section 8.2.
9. Price.
- 9.1. Buyer shall purchase the Goods from Seller at the price (the "Price") set forth on the Sales Order. Prices stated are subject to change without notice in the event of (i) alterations in specifications, quantities, designs, or delivery schedules and/or (ii) increases in the cost of fuel, power, material supplied, or labor.
- 9.2. All Prices are exclusive of all sales, use and excise taxes, and any other similar taxes, duties and charges of any kind imposed by any governmental authority on any amounts payable by Buyer. Buyer shall be responsible for all such charges, costs and taxes; provided, that, Buyer shall not be responsible for any taxes imposed on, or with respect to, Seller's income, revenues, gross receipts, personnel or real or personal property or other assets. Buyer shall, at its sole cost and expense, provide all such further documents and instruments, and take all such further acts, necessary to establish if Seller must collect any sales tax, and any other similar taxes, duties and charges of any kind imposed by any governmental authority, with respect to the transaction contemplated by this Agreement.
10. Payment Terms.
- 10.1. Buyer shall pay Seller 50% of the total Price at the time of placing the order and the remaining 50% of the purchase amount at time of shipment without any discount, set-off or suspension as specified in Seller's invoice. Buyer shall make all payments hereunder in US dollars, by check, wire transfer or ACH transfer.
- 10.2. Buyer shall pay interest on all late payments at the lesser of the rate of 5% per month or the highest rate permissible under applicable law, calculated daily and compounded monthly. Buyer shall reimburse Seller for all costs incurred in collecting any late payments, including, without limitation, attorneys' fees.
- 10.3. If there is any reasonable doubt by the Seller concerning Buyer's ability to pay the full amount stated in the Sales Order shall entitle Seller to require security for payment from Buyer that Seller deems sufficient before performing its obligations under the Sales Order. If Buyer does not pay any amount due, Seller may, without prejudice to Seller's other lawful remedies (a) declare immediately due and payable all Buyer's obligations to Seller, (b) change credit or other terms for future deliveries, (c) suspend or discontinue any further deliveries until Buyer pays all overdue amounts, or (d) repossess the Products. Buyer agrees to reimburse Seller for all costs and fees incurred in collecting any sums
- 10.4. In addition to all other remedies available under these Terms or at law (which Seller does not waive by the exercise of any rights hereunder), if Buyer fails to pay any amounts when due hereunder and such failure continues for two (2) business days following written notice thereof, Seller shall be entitled to (a) declare immediately due and payable all Buyer's obligations to Seller, (b) change credit or other terms for future deliveries, (c) suspend or discontinue any further deliveries until Buyer pays all overdue amounts, or (d) repossess the Goods.
- 10.5. Buyer shall not withhold payment of any amounts due and payable by reason of any set-off of any claim or dispute with Seller, whether relating to Seller's breach, bankruptcy or otherwise.
11. Limited Warranty.
- 11.1. Seller warrants to Buyer that, at the time of delivery, the Goods will comply with the specifications stated in Buyer's purchase order.
- 11.2. EXCEPT FOR THE WARRANTY SET FORTH IN SECTION 11.1, SELLER MAKES NO WARRANTY WHATSOEVER WITH RESPECT TO THE GOODS, INCLUDING ANY (a) WARRANTY OF MERCHANTABILITY; (b) WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE; (c) WARRANTY OF TITLE; OR (d) WARRANTY AGAINST INFRINGEMENT OF INTELLECTUAL PROPERTY RIGHTS OF A THIRD PARTY; WHETHER EXPRESS OR IMPLIED BY LAW, COURSE OF DEALING, COURSE OF PERFORMANCE, USAGE OF TRADE OR OTHERWISE.
- 11.3. Products manufactured by a third party ("Third Party Product") may constitute, contain, be contained in, incorporated into, attached to or packaged together with, the Goods. Third Party Products are not covered by the warranty in Section 11.1. For the avoidance of doubt, SELLER MAKES NO REPRESENTATIONS OR WARRANTIES WITH RESPECT TO ANY THIRD PARTY PRODUCT, INCLUDING ANY (a) WARRANTY OF MERCHANTABILITY; (b) WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE; (c) WARRANTY OF TITLE; OR (d) WARRANTY AGAINST INFRINGEMENT OF INTELLECTUAL PROPERTY RIGHTS OF A THIRD PARTY; WHETHER EXPRESS OR IMPLIED BY LAW, COURSE OF DEALING, COURSE OF PERFORMANCE, USAGE OF TRADE OR OTHERWISE.
- 11.4. The Seller shall not be liable for a breach of the warranty set forth in Section 11.1 unless (i) Buyer gives written notice of the defect, reasonably described, to Seller within six (6) months of the date of delivery and within five (5) business days of the time when Buyer discovers or ought to have discovered the defect; (ii) Seller is given a reasonable opportunity after receiving the notice to examine such Goods and Buyer (if requested to do so by Seller) returns such Goods to Seller's place of business at Seller's cost for the examination to take place there; and (iii) Seller reasonably verifies Buyer's claim that the Goods are defective. Buyer's failure to make such claim within such time frames shall constitute Buyer's irrevocable acceptance of the Goods and Buyer's acknowledgment that the Goods fully comply with this Agreement.

Sales Order Terms and Conditions

Product: CareStart™ COVID-19 Antigen Home Test

- 11.5. The Seller shall not be liable for a breach of the warranty set forth in Section 11.1 if (i) Buyer makes any further use of such Goods after giving such notice; (ii) the defect arises because Buyer failed to follow Seller's oral or written instructions as to the storage, installation, commissioning, use or maintenance of the Goods; (iii) the defect is caused by damage in transit (iii) Buyer alters or repairs such Goods without the prior written consent of Seller.
- 11.6. Subject to Section 11.4 and Section 11.5 above, Seller shall, in its sole discretion, either (i) repair or replace such Goods (or the defective part) or (ii) credit or refund the price of such Goods at the pro rata contract rate provided that, if Seller so requests, Buyer shall, at Seller's expense, return such Goods to Seller.
- 11.7. THE REMEDIES SET FORTH IN SECTION 11.6 SHALL BE THE BUYER'S SOLE AND EXCLUSIVE REMEDY AND SELLER'S ENTIRE LIABILITY FOR ANY BREACH OF THE LIMITED WARRANTY SET FORTH IN SECTION 11.1.
12. Limitation of Liability.
- 12.1. IN NO EVENT SHALL SELLER BE LIABLE TO BUYER OR ANY THIRD PARTY FOR ANY LOSS OF USE, REVENUE OR PROFIT, DIMINUTION IN VALUE, OR FOR ANY CONSEQUENTIAL, INDIRECT, INCIDENTAL, SPECIAL, EXEMPLARY, OR PUNITIVE DAMAGES WHETHER ARISING OUT OF BREACH OF CONTRACT, TORT (INCLUDING NEGLIGENCE) OR OTHERWISE, REGARDLESS OF WHETHER SUCH DAMAGES WERE FORESEEABLE AND WHETHER OR NOT SELLER HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES, AND NOTWITHSTANDING THE FAILURE OF ANY AGREED OR OTHER REMEDY OF ITS ESSENTIAL PURPOSE.
- 12.2. IN NO EVENT SHALL SELLER'S AGGREGATE LIABILITY ARISING OUT OF OR RELATED TO THIS AGREEMENT, WHETHER ARISING OUT OF OR RELATED TO BREACH OF CONTRACT, TORT (INCLUDING NEGLIGENCE) OR OTHERWISE, EXCEED THE TOTAL OF THE AMOUNTS PAID BY BUYER TO SELLER FOR NONCONFORMING GOODS HEREUNDER.
13. Insurance. During the term of this Agreement and for a period of one (1) year thereafter, Buyer shall, at its own expense, maintain and carry insurance in full force and effect which includes, but is not limited to, commercial general liability (including product liability) in a sum no less than is reasonable for similarly situated companies, with financially sound and reputable insurers. Upon Seller's request, Buyer shall provide Seller with a certificate of insurance from Buyer's insurer evidencing the insurance coverage specified in these Terms. The certificate of insurance shall name Seller as an additional insured. Buyer shall provide Seller with thirty (30) days' advance written notice in the event of a cancellation or material change in Buyer's insurance policy. Except where prohibited by law, Buyer shall require its insurer to waive all rights of subrogation against Seller's insurers and Seller.
14. Compliance with Law. Buyer shall comply with all applicable laws, regulations and ordinances. Buyer shall maintain in effect all the licenses, permissions, authorizations, consents and permits that it needs to carry out its obligations under this Agreement. Buyer shall comply with all export and import laws of all countries involved in the sale of the Goods under this Agreement or any resale of the Goods by Buyer. Buyer assumes all responsibility for shipments of Goods requiring any government import clearance. Seller may terminate this Agreement if any governmental authority imposes antidumping or countervailing duties or any other penalties on Goods.
15. Termination. In addition to any remedies that may be provided under these Terms, Seller may terminate this Agreement with immediate effect upon written notice to Buyer, if Buyer (i) fails to pay any amount when due under this Agreement and such failure continues for two (2) business days after written notice of nonpayment; (ii) has not otherwise performed or complied with any of these Terms, in whole or in part; or (iii) becomes insolvent, files a petition for bankruptcy or commences or has commenced against it proceedings relating to bankruptcy, receivership, reorganization or assignment for the benefit of creditors. Buyer may not cancel or modify this Agreement except upon written agreement with Seller. If Buyer cancels or modifies this Sales Order, Buyer shall compensate Seller for all costs and damages resulting therefrom, including (without limitation) lost profits, allocable overhead, commodity market losses and all other incidental and consequential damages.
16. Waiver. No waiver by Seller of any of the provisions of this Agreement is effective unless explicitly set forth in writing and signed by Seller. No failure to exercise, or delay in exercising, any right, remedy, power or privilege arising from this Agreement operates, or may be construed, as a waiver thereof. No single or partial exercise of any right, remedy, power or privilege hereunder precludes any other or further exercise thereof or the exercise of any other right, remedy, power or privilege.
17. Confidential Information. All non-public, confidential or proprietary information of Seller, including but not limited to specifications, samples, patterns, designs, plans, drawings, documents, data, business operations, customer lists, pricing, discounts or rebates, disclosed by Seller to Buyer, whether disclosed orally or disclosed or accessed in written, electronic or other form or media, and whether or not marked, designated or otherwise identified as "confidential" in connection with this Agreement is confidential, solely for the use of performing this Agreement and may not be disclosed or copied unless authorized in advance by Seller in writing. Upon Seller's request, Buyer shall promptly return all documents and other materials received from Seller. Seller shall be entitled to injunctive relief for any violation of this Section. This Section does not apply to information that is (a) in the public domain; (b) known to Buyer at the time of disclosure; or (c) rightfully obtained by Buyer on a non-confidential basis from a third party.
18. Force Majeure. The Seller shall not be liable or responsible to Buyer, nor be deemed to have defaulted or breached this Agreement, for any failure or delay in fulfilling or performing any term of this Agreement when and to the extent such failure or delay is caused by or results from acts or circumstances beyond the reasonable control of Seller including, without limitation, acts of God, flood, fire, earthquake, explosion, governmental actions, war, invasion or hostilities (whether war is declared or not), terrorist threats or acts, riot, or other civil unrest, national emergency, revolution, insurrection, epidemic, lockouts, strikes or other labor disputes (whether or not relating to either party's workforce), or restraints or delays affecting carriers or inability or delay in obtaining supplies of adequate or suitable materials, materials or telecommunication breakdown or power outage, provided that, if the event in question continues for a continuous period in excess of thirty (30) days, Buyer shall be entitled to give notice in writing to Seller to terminate this Agreement.

Sales Order Terms and Conditions

Product: CareStart™ COVID-19 Antigen Home Test

19. **Assignment.** Buyer shall not assign any of its rights or delegate any of its obligations under this Agreement without the prior written consent of Seller. Any purported assignment or delegation in violation of this Section is null and void. No assignment or delegation relieves Buyer of any of its obligations under this Agreement.
20. **Relationship of the Parties.** The relationship between the parties is that of independent contractors. Nothing contained in this Agreement shall be construed as creating any agency, partnership, joint venture or other form of joint enterprise, employment or fiduciary relationship between the parties, and neither party shall have authority to contract for or bind the other party in any manner whatsoever.
21. **No Third-Party Beneficiaries.** This Agreement is for the sole benefit of the parties hereto and their respective successors and permitted assigns and nothing herein, express or implied, is intended to or shall confer upon any other person or entity any legal or equitable right, benefit or remedy of any nature whatsoever under or by reason of these Terms.
22. **Governing Law.** All matters arising out of or relating to this Agreement is governed by and construed in accordance with the internal laws of the State of Delaware without giving effect to any choice or conflict of law provision or rule (whether of the State of Delaware or any other jurisdiction) that would cause the application of the laws of any jurisdiction other than those of the State of Delaware.
23. **Submission to Jurisdiction.** Any legal suit, action or proceeding arising out of or relating to this Agreement shall be instituted in the courts of the State of Delaware, and each party irrevocably submits to the exclusive jurisdiction of such courts in any such suit, action or proceeding.
24. **Notices.** All notices, request, consents, claims, demands, waivers and other communications hereunder (each, a "Notice") shall be in writing and addressed to the parties at the addresses set forth on the face of the Sales Order or to such other address that may be designated by the receiving party in writing. All Notices shall be delivered by personal delivery, nationally recognized overnight courier (with all fees pre-paid) or electronic mail (with confirmation of transmission) or certified or registered mail (in each case, return receipt requested, postage prepaid). Except as otherwise provided in this Agreement, a Notice is effective only if the party giving the Notice has complied with the requirements of this Section.
25. **Severability.** If any term or provision of this Agreement is invalid, illegal or unenforceable in any jurisdiction, such invalidity, illegality or unenforceability shall not affect any other term or provision of this Agreement or invalidate or render unenforceable such term or provision in any other jurisdiction.
26. **Survival.** Provisions of these Terms which by their nature should apply beyond their terms will remain in force after any termination or expiration of this Agreement including, but not limited to, the following provisions Insurance, Compliance with Laws, Confidential Information Governing Law and Submission to Jurisdiction.

B. Product-Specific Conditions **CareStart™ COVID-19 Antigen Home Test | Rapid Diagnostic Test for the Detection of SARS-CoV-2 Antigen**

1. This product has not been FDA cleared or approved, but has been authorized by FDA under an EUA (Emergency Use Authorization) for non-prescription home use with:
 - 1.1. self-collected direct anterior nasal (nares) swab samples from individuals aged 14 years or older or
 - 1.2. adult collected anterior nasal swab samples from individuals aged 2 years or older.
2. This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens.
3. The emergency use of this product (under EUA number **EUA210314**) is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb3(b)(1), unless the declaration is terminated or authorization is revoked sooner.
4. This test is to be performed only using direct anterior nasal swab specimens collected from individuals with or without symptoms or other epidemiological reasons to suspect a COVID-19 infection, when tested twice over two or three days with at least 24 hours and not more than 48 hours between tests.

FACT SHEET FOR INDIVIDUALS

Access Bio, Inc.

CareStart™ COVID-19 Antigen Home Test

August 2, 2021

Coronavirus
Disease 2019
(COVID-19)

You are provided this Fact Sheet because you obtained the *CareStart*™ COVID-19 Antigen Home Test for testing yourself or dependents for the proteins from the virus that causes COVID-19. The intended use of this test is for testing twice over two or three days with at least 24 hours and no more than 48 hours between tests.

This Fact Sheet contains information to help you understand the risks and benefits of using this test for the detection of proteins from the virus that causes 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 which is a new virus in humans causing a contagious respiratory illness. COVID-19 can present with a mild to severe illness, although some people infected with COVID-19 may have no symptoms at all. Older adults and people of any age who have underlying medical conditions have a higher risk of severe illness from COVID-19. Serious outcomes of COVID-19 include hospitalization and death. The SARS-CoV-2 virus can be spread to others not just while one is sick, but even before a person shows signs or symptoms of being sick (e.g., fever, coughing, difficulty breathing, etc.). A full list of symptoms of COVID-19 can be found at the following link: <https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html>.

What is the *CareStart*™ COVID-19 Antigen Home Test?

The *CareStart*™ COVID-19 Antigen Home Test is a type of test called an antigen test. Antigen tests are designed to detect proteins from the virus that causes COVID-19 in anterior nasal swabs.

The *CareStart*™ COVID-19 Antigen Home Test is intended for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 from individuals with or without symptoms tested twice over two or three days with at least 24 hours and no more than 48 hours between tests.

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 you and your healthcare provider make informed recommendations about your care.
- The results of this test may help limit the potential 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 because proteins from the virus that causes COVID-19 were found in your sample. 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). If you test positive with the *CareStart*™ COVID-19 Antigen Home Test you should self-isolate and seek follow-up care with your healthcare provider as additional testing may be necessary. Your healthcare provider as additional testing may be necessary. Your healthcare provider will work with you to determine how best to care for you based on your test result(s) along with your medical history, and your symptoms.

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.

FACT SHEET FOR INDIVIDUALS

Access Bio, Inc.

CareStart™ COVID-19 Antigen Home Test

August 2, 2021

Coronavirus
Disease 2019
(COVID-19)

What does it mean if I have a negative test result?

A negative test result means that proteins from the virus that causes COVID-19 was not found in your sample. It is possible for this test to give a negative result that is incorrect (false negative) in some people with COVID-19. This means you could possibly still have COVID-19 even though the test is negative. The amount of antigen in a sample may decrease the longer you have symptoms of infection. In symptomatic people, specimens collected after you have had symptoms for more than five days may be more likely to be negative compared to a molecular assay.

If you test negative and continue to experience COVID-19 like symptoms of fever, cough and/or shortness of breath you should seek follow up care with your healthcare provider. For example, your healthcare provider may suggest you need another test to determine if you have contracted the virus causing COVID-19. If you are concerned about your COVID-19 infection status after testing or think you may need follow up testing, please contact your healthcare provider.

What is serial testing?

Serial testing is when a single person is tested for COVID-19 more than once. Because antigen tests are less sensitive than other COVID-19 tests and false results may occur, repeated testing may identify more individuals with COVID-19 infection than a single test. By repeating testing, it may be possible to more quickly identify cases of COVID-19 infection and reduce spread of infection. Additional testing with molecular COVID-19 test may be necessary, depending on your individual risk factors and test results.

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

What are the differences between antigen tests and other COVID-19 tests?

There are different kinds of tests for diagnosing COVID-19. Molecular tests (also known as PCR tests) detect genetic material from the virus. Antigen tests detect proteins from the virus. Antigen tests are very specific for the virus, but are not as sensitive as molecular tests. This means that a positive result is highly accurate, but a negative result does not rule out infection.

If your test result is negative, you should discuss with your healthcare provider whether an additional molecular test would help with your care, and when you should discontinue home isolation. If you will not have an additional test to determine if you are contagious, the CDC currently recommends that you should stay home until three things have happened:

- You have had no fever for at least 24 hours (that is one full day of no fever without the use of medicine that reduces fevers)

AND

- Other symptoms of COVID-19 are improving (for example, when your cough or shortness of breath has improved) **Loss of taste and smell may persist for weeks or months after recovery and need not delay the end of isolation

AND

- At least 10 days have passed since your symptoms first appeared.

For more information, the CDC has provided guidelines on how to prevent the spread of COVID-19 if you are sick: <https://www.cdc.gov/coronavirus/2019-ncov/downloads/sick-with-2019-nCoV-fact-sheet.pdf>.

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.

FACT SHEET FOR INDIVIDUALS

Access Bio, Inc.

August 2, 2021

Coronavirus
Disease 2019
(COVID-19)

CareStart™ COVID-19 Antigen Home Test

Is this test FDA-approved or cleared?

No. This test is not yet approved or cleared by the United States FDA. FDA may issue an Emergency Use Authorization (EUA) when certain criteria are met, which includes that there are no adequate, approved, available alternatives. 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 authorization is revoked by FDA (after which the test may no longer be used).

What are the approved alternatives?

There are no approved available alternative antigen tests. Any tests that have received full marketing status (e.g., cleared, approved), as opposed to an EUA, by FDA can be found by searching the medical device databases here: <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases>. A cleared or approved test should be used instead of a test made available under an EUA, when appropriate and available. FDA has issued EUAs for other tests that can be found at: <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#2019-ncov>.

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.
