

October 20, 2020

**EMERGENCY USE AUTHORIZATION (EUA) SUMMARY  
BINX HEALTH AT-HOME NASAL SWAB COVID-19 SAMPLE COLLECTION KIT**

For *in vitro* Diagnostic Use

Rx Only

For use under Emergency Use Authorization (EUA) only

**For use by people 18 years of age or older**

**At-home self-collected nasal swab specimens collected with the binx health At-home Nasal Swab COVID-19 Sample Collection Kit will be sent to laboratories that have been designated by binx health, Inc. that are certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a and meet requirements to perform high complexity tests and run the specimens collected from the binx health At-home Nasal Swab COVID-19 Sample Collection Kit on an *in vitro* diagnostic (IVD) molecular test that is indicated for use with the binx health At-home Nasal Swab COVID-19 Sample Collection Kit for self-collection of nasal swab specimens.**

**INTENDED USE**

The binx health At-home Nasal Swab COVID-19 Sample Collection Kit is intended for use by individuals for self-collection of nasal swab specimens at home, when determined by a healthcare provider to be appropriate based on the results of an online COVID-19 questionnaire.

Specimens collected using the binx health At-home Nasal Swab COVID-19 Sample Collection Kit are transported at ambient temperature for testing at an authorized laboratory. SARS-CoV-2 RNA from the nasal swabs is maintained in the specimen packaging and is only for use in molecular diagnostic testing performed using an *in vitro* diagnostic (IVD) test for the detection of SARS-CoV-2 that is indicated for use with the binx health At-home Nasal Swab COVID-19 Sample Collection Kit.

Testing is limited to laboratories designated by binx health, Inc. that are certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, and meet requirements to perform high complexity tests and that run the specimens collected from the binx health At-Home Nasal Swab COVID-19 Sample Collection Kit on an *in vitro* diagnostic (IVD) molecular test that is indicated for use with the binx health At-Home Nasal Swab COVID-19 Sample Collection Kit for self-collection of nasal swabs.

The binx health At-home Nasal Swab COVID-19 Sample Collection Kit is only for use under the Food and Drug Administration's Emergency Use Authorization.

**SPECIAL CONDITIONS FOR USE STATEMENTS**

For Emergency Use Authorization (EUA) only.

For prescription use only.

For *in vitro* diagnostic use only.

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For use by people 18 years of age or older.

The binx health At-home Nasal Swab COVID-19 Sample Collection Kit is only authorized for use in conjunction with an *in vitro* diagnostic (IVD) test for the detection of SARS-CoV-2 that is indicated for use with this collection device.

## **DEVICE DESCRIPTION**

Individuals may request the binx health At-home Nasal Swab COVID-19 Sample Collection Kit (or the “Kit”) via the binx web application (<https://app.mybinxhealth.com>). Individuals will be presented with information relating to how the binx process works, what COVID-19 is, and the symptoms with which it may present, as well as warnings to ensure that those individuals who may be experiencing severe symptoms not delay in seeking in-person urgent care. Persons who are at increased risk for severe illness from COVID-19 will be advised to consult with their healthcare provider before using the test. In order for an individual to add the Kit to their cart and checkout, they will be required to complete an eligibility screening questionnaire which will be reviewed by the Physician Wellness Network (PWN) to determine if testing is appropriate. The PWN will determine test eligibility and write prescriptions for testing. If a test is approved, a patient’s order for a Kit will be processed and completed by binx, and a request will be sent via binx’s electronic interface to the logistics partner for test order fulfillment. Those determined ineligible for testing will be notified that testing is not currently recommended along with links to helpful resources about COVID-19.

The Kit is used to collect RNA from a nasal swab specimens and can be transported and stored at room temperature for a total of 56 hours. The binx health At-home Nasal Swab COVID-19 Sample Collection Kit is a method for collecting viral RNA for use in molecular COVID-19 diagnostic assays indicated for use with the Kit.

The Kit is delivered to the patient in a cardboard shipping box which includes (i) instructions for use, (ii) a dry, sterile polyester swab in a tube, (iii) an identification label, (iv) specimen bag with absorbent pad, and (v) a pre-paid return envelope. The individual using the Kit to collect nasal swabs performs the steps to collect the specimen according to the Instructions For Use. After nasal swab specimens have been self-collected (unsupervised), the swab is inserted into the tube and packaged for shipping. Each Kit is intended to be returned via UPS at ambient conditions on the same day as sample collection in accordance with the standards put forth for the transport of suspected COVID-19 samples.

Each laboratory designated by binx health, Inc. for receipt of binx health At-home Nasal Swab COVID-19 Sample Collection Kit specimens shall process samples in accordance with an accessioning SOP that defines the criteria for verification, routing, acceptance and rejection of clinical samples and documentation of results.

Completed test results are sent for review to a licensed healthcare professional. Negative test results are provided via binx’s secure online portal. If the results are positive or indeterminate (i.e., invalid or inconclusive), the healthcare professional’s care team will attempt to make outreach to the patient via telephone to deliver the results and provide appropriate education. Indeterminate

results will include a recommendation to get re-tested. Upon completion of outreach protocols, the results will be released to the patient, by the licensed healthcare professional, via the online portal.

## **REAGENTS AND MATERIALS**

The binx health At-home Nasal Swab COVID-19 Sample Collection Kit consists of the items listed in the table below.

<b>Name</b>	<b>Description</b>
Mailer	binx-branded mailer (box)
Swab & Tube	Polyester swab with plastic applicator and plastic transport tube
Sample Bag	95kPa Two-Pocket Bag with absorbent pad
Label	Pre-printed label to attach to tube after sample is collected
Envelope	Polyethylene shipping envelope with return label and UN3373 markings
Instructions	User instructions for binx at-home collection kit

## **MEDICAL OVERSIGHT AND PROCESS TO BE USED**

Medical Oversight of the process is primarily provided by the third-party physician network, PWN Health (PWN). PWN Health designed the health screening questions and implementation algorithm utilized at the point of customer purchase on the digital platform as well as all aspects relating to patient messaging and outreach. An alternative physician network may be used provided that all patient messaging, oversight and outreach is consistent with that provided by PWN.

PWN is an independent company that employs or contracts with physicians licensed in all 50 states, with healthcare professionals, and non-clinical patient care coordinators as support staff. Patient care coordinators are overseen by multiple layers of clinical and non-clinical professionals. The Clinical Director meets with the team on a weekly basis to discuss quality metrics, address broad clinical issues, and enhance all process elements as necessary. There is a real-time escalation process that provides for a feedback loop and ongoing training. Physicians and healthcare providers are routinely trained on all aspects of care programs and are also monitored for quality, undergoing full credentialing and ongoing certification assessment in states in which they are licensed. The Chief Medical Officer of PWN, working with a team of external advisors and experts, ultimately oversees all aspects of the care program and conducts routine checks on all facets of patient care support.

The PWN COVID-19 care program for molecular PCR testing is highlighted below.

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Eligibility for testing is based on CDC published guidelines in conjunction with HHS priority levels.

The eligibility assessment focuses on three main inputs:

1. Symptoms
  - a. Includes initial triage of severely ill to in-person or emergency care while further segmenting into those with mild/non-limiting symptoms and no symptoms at all
2. Exposure
  - a. Includes forms of exposure such as workplace, school, healthcare settings, congregate settings.
  - b. Exposure also covers specific elements of CDC criteria such as referral for testing by testing by a healthcare provider or health department
3. Medical and Personal History
  - a. Includes comorbidities and age to stratify for risk
  - b. Individuals with No Known Exposure and No Symptoms are not currently eligible for a test kit

All individuals taking the test will receive education and information both before and after the test on symptom monitoring including when to seek in-person or emergency care, isolation precautions, health hygiene, and other critical points to limit the spread of the disease and to optimize outcome

The opportunity to contact a physician/healthcare provider is made available at all points in the process to ask questions and/or to receive other information/education

**PATIENT EXCLUSION CRITERIA:**

- Patients with no symptoms and no known exposure risks
- Individuals with severe symptoms as they are directed to seek immediate care

**INSPECTION OF SPECIMENS:**

**Applies to specimens received from patients using home collection kit**

Specimens collected using the binx health At-home Nasal Swab COVID-19 Sample Collection Kit should be checked for the following criteria before entering the work flow:

- **Labeling** – Improperly/inadequately labeled specimens that cannot be resolved are rejected
- **Expired shipping time** – If a specimen is received  $\geq 56$  hours from the collection date/time, the specimen is rejected.
- **Improper return of sample packaging** - sample not returned in supplied packing materials; sample not in correct collection/transport tube; sample integrity appears compromised
- **Missing Information** - customer did not adequately annotate specimen as to date and time of specimen collection

## **CONTROLS TO BE USED WITH THE COVID-19 TEST**

All test controls must be examined prior to interpretation of patient results. If the controls are not valid, the patient results cannot be interpreted.

- 1) A negative (no template) control is needed to eliminate the possibility of sample contamination on the assay run and is used on every assay plate. This control is molecular grade, nuclease-free water.
- 2) A positive template control is needed to verify that the assay run is performing as intended and is used on every assay plate starting at master mix. The positive template control does not include RNase P target and will result as “undetermined” for that marker.
- 3) An internal control targeting RNase P is needed to verify that nucleic acid is present in every sample and is used for every sample processed. This also serves as the extraction control to ensure that samples resulting as negative contain nucleic acid for testing.
- 4) A negative extraction control (optional) is a previously characterized SARS-CoV-2 negative patient sample. It serves both as a negative extraction control to monitor for any cross-contamination that occurs during the extraction process, as well as an extraction control to validate extraction reagents and successful RNA extraction.

## **INTERPRETATION OF RESULTS**

All test controls must be examined prior to interpretation of patient results. If the controls are not valid, the patient results cannot be interpreted.

PWN’s protocol provides for real-time communication throughout the testing process, including when the individual is waiting for the test kit, while the individual is waiting for results, and after the result is provided. Educational materials include information on maintaining social distancing or isolation, monitoring for severe symptoms, and seeking care when necessary and adheres to both CDC and HHS guidelines. Patient care coordinators, other healthcare professionals, and physicians are available at all times throughout this process for questions/concerns.

COVID-19 test results are divided into positive, negative, and indeterminate (invalid or inconclusive). PWN makes phone calls and outreach attempts as soon as possible after the result is reported in order to speak to the individual and provide education and additional information.

In the case of positive results:

- Individuals will receive notification of their result. A healthcare professional will attempt to call the patient no less than three times to explain the results. A follow-up letter will be sent in the case that they cannot be reached after multiple attempts.
- Call and outreach attempts will be made promptly from the time of receiving the test results.

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- Outreach calls provide: result of the test, counseling on the disease and next steps based on immediate symptoms including isolation vs. in-person or emergency care, and the opportunity to have a telehealth consult with a physician or trained healthcare provider licensed in the state of where the individual is located
- Results are reported by PWN to public health agencies as required.

In the case of indeterminate results:

- Individuals will receive a result reporting call and a letter in the case that they cannot be reached after multiple attempts.
- Call and outreach attempts will be made promptly from the time of receiving the test results.
- Outreach calls provide: result of the test, recommendation to get re-tested, counseling on the disease and next steps based on immediate symptoms including isolation vs in-person or emergency care, and the opportunity to have a telehealth consult with a physician or trained healthcare provider licensed in the state where the individual is located

Additionally, physician or trained healthcare provider consultations are available to anyone who requests one regardless of test result. All individuals have the opportunity to follow up with the physician or trained healthcare provider with regards to what to watch for, specific symptoms, self-quarantine questions as appropriate, and when to seek care with necessary parameters provided.

## **PERFORMANCE EVALUATION**

### **1) binx health At-home Nasal Swab COVID-19 Sample Collection Kit Sample Stability Studies:**

Shipping stability of dry spun polyester swabs has been demonstrated by Quantigen Biosciences, Inc. with support from The Gates Foundation and UnitedHealth Group, and Quantigen Biosciences, Inc. has granted right to reference to binx health, Inc. for the applicable COVID-19 swab stability data for the purposes of obtaining an EUA for at-home swab collection to support COVID-19 testing. The Quantigen Biosciences study demonstrated 56-hour stability at ambient temperature for dry anterior nares spun polyester swabs. Therefore, the stability of anterior nares samples collected using dry spun polyester swabs was not further evaluated by binx health, Inc.

### **2) Dry swab rehydration Validation:**

To demonstrate that dry spun polyester swabs were acceptable specimen types for testing for SARS-CoV-2, a validation study was performed on swabs reconstituted in saline following dry storage. The reconstitution process was validated by testing 30 replicates at 2X LoD (spiked with the SeraCare AccuPlex SARS-CoV-2 Verification Panel (Part#: 0505-0129)) diluted in SARS-CoV-2 negative nasal swab matrix and 30 negatives (no spiked target). The swabs were stored dry for 24 hours before being reconstituted in 2.5 mL of 0.85% saline by incubating for 30-minutes at room temperature. Following incubation, samples were vortexed vigorously for 20 seconds at high speed. Samples were tested using the designated authorized assay. Results are summarized in Table 1. There was 100% agreement with expected results for all positive contrived samples and all negative samples were non-reactive for SARS-CoV-2 assay targets.

**Summary of reconstitution validation results**

		Expected result		
		Positive Result	Negative Result	Total Replicates
Contrived, reconstituted samples	Positive	30	0	<b>30</b>
	Negative	0	30	<b>30</b>
	<b>Total</b>	<b>30</b>	<b>30</b>	<b>60</b>
Positive Agreement		100% (95% CI 88.65-100%) (30/30)		
Negative Agreement		100% (95% CI 88.65-100%) (30/30)		

**3) Self-collection Validation:**

A human usability study was conducted to validate the binx health At-home Nasal Swab COVID-19 Sample Collection Kit for effective (unobserved) home-collection and mailing of samples to a CLIA-certified lab for testing. Following online recruitment and consenting of study participants, Kits were shipped to each participant's address. Nasal swab samples were collected by study participants at home, following a simple set of self-collection instructions. The first 30 participants eligible for the study who registered their details, received a test, obtained a nasal swab specimen and returned it for testing and who completed the study questionnaire, were included in the final study dataset. Of the 30 participants, five were aged 65 and over and eight possessed no college education. None of the participants had prior laboratory experience or experience with home specimen collection.

The characteristics/demographics of participants was as follows:

Characteristic of Study Population		N/N (%)
Gender	Female	19/30 (63%)
	Male	11/30 (37%)
Age	18-64	25/30 (83%)
	65+	5/30 (17%)
Education Level	Doctorate Degree	2/30 (7%)
	Professional Degree	1/30 (3%)
	Masters Degree	2/30 (7%)
	Bachelor's Degree	8/30 (27%)
	Associate Degree	6/30 (20%)
	Some College Credit (no Degree)	3/30 (10%)
	Trade/Technical/Vocational Training	4/30 (13%)
High School Graduate	4/30 (13%)	

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Participants returned the samples to the testing laboratory which checked that the packaging was intact, evaluated them according to acceptance/rejection criteria contained in the study design and tested them for the endogenous human RNase P gene. All 30 participant samples tested positive for RNase P, indicating the presence of human nucleic acid in all cases.

A usability survey was completed by each of the 30 participants, with responses to questions posed in the usability survey graded on a five-point Likert scale along with yes/no answers and free-text responses. For questions relating to usability and ease of use, a score of 1 or 2 in these categories (indicating very easy, or easy to use) for 90% or more of respondents categorized the collection kit and the sample collection process as being easy to use. The only question for which a score of under 90% was recorded was related to Kit registration/activation, although ultimately all participants were able to properly activate their Kits. Following this feedback, binx health, Inc. will continue to monitor usability of the Kit and to improve the Kit activation process and Webpage interface.

#### **WARNINGS:**

- This home collection kit has not been FDA cleared or approved.
- This home collection kit has been authorized by FDA under an EUA for use by authorized laboratories.
- This home collection kit has been authorized only for the home collection and maintenance of nasal swab specimens as an aid in detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens.
- This home collection kit in combination with the authorized test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of medical devices 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. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.