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

Nasal swab specimens collected at-home 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.

INTENDED USE

The binx health At-home Nasal Swab COVID-19 Sample Collection Kit is intended for use to collect anterior nasal (nasal) swab specimens at home (which includes in a community- based setting), from individuals 18 years and older (self-collected), 14 years and older (self-collected under adult supervision), or 5 years and older (collected with adult assistance) when suspected of COVID-19 by a healthcare provider.

Dry swab 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 that 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 when used consistent with its authorization.

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.
For use for specimen collection from individuals 5 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 (the "Kit") via the binx web application (https://app.mybinxhealth.com) for themselves, or on behalf of minors 5 years of age or older. 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. The ordering process includes an assessment by a healthcare professional (HCP) licensed in the individual's state who will provide prescriptions for testing for individuals suspected of COVID-19. If indicated based upon the HCP assessment, an 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 and be provided links to helpful resources about COVID-19. In community-based settings, the Kits can be centrally issued and collected.

The Kit is used to collect RNA from nasal swab specimens and can be transported and stored at room temperature for a total of 120 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 requesting individual in a cardboard shipping box or distributed from a central location for those in a community-based setting in either a cardboard shipping box or a sealed polypropylene bag. Each kit includes (i) instructions for use, (ii) a dry, sterile polyester swab in a tube (or peel pouch), (iii) a sample identification label, (iv) specimen bag with absorbent pad, and (v) a 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 collected, the swab is inserted into the tube and packaged for shipping or drop off at a previously determined collection site. Each Kit is intended to be returned 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 (or parent or guardian, as applicable) 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 (or parent or guardian), 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.

Name	Description
Mailer	binx-branded mailer (box)
Swab & Tube	polyester swab in a peel pouch and separate tube or a polyester swab/tube combination
Sample Bag	Two-pocket Bag with absorbent pad
Label	Pre-printed label
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 will be provided either by individual HCPs identified by binx or by using an HCP network who, collectively, enable binx to work with patients in all 50 states and are supported by healthcare professionals and non-clinical patient care coordinators, as necessary.

All individuals taking the test (or the parent or guardian) 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 HCP is made available at all points in the process to ask questions and/or to receive other information/education

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, and must otherwise meet receiving requirements imposed by the testing laboratory:

- **Labeling** – Improperly/inadequately labeled specimens that cannot be resolved are rejected
- **Expired shipping time** – If a specimen is received > 120 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.

2) A positive template control is needed to verify that the assay run is performing as intended and is used for every run.

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) serves to monitor for any cross-contamination 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.

The binx protocol is the same whether the test is ordered through an individual HCP or an HCP network, and allows for real-time communication between binx, the patient (or parent or guardian) and the HCP 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, as applicable, inconclusive). In the case of positive or indeterminate results, HCPs make phone calls and outreach attempts as soon as possible after the result is reported in order to speak to the individual (or parent or guardian) 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.
- 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 the HCP to public health agencies as required.

In the case of indeterminate results:

- Individuals will receive a call from the HCP reporting the result 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, HCP consultations are available to anyone who requests one regardless of test result. All individuals have the opportunity to follow up with the HCP 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:

To support use of the binx health at-home nasal swab COVID-19 collection kit with extended shipping times, a simulated shipping study was conducted to evaluate the effect of temperature variation on the stability of SARS-CoV-2 RNA during transport of the dry nasal swab specimens. The shipping study was designed to simulate the extreme temperature conditions that could be experienced during the summer and winter months. The summer and winter thermal profiles tested in the study are shown below and were intended to replicate worst case scenario shipping conditions for an initial wait at the customer's house before shipping and then a subsequent shipping cycle.

Table 1. Winter Profile

Temperature	Cycle Period	Cycle Period Hours	Total Time Hours
-10°C	1	8	8

18°C	2	8	16
-10°C	3	24	40
10°C	4	35	75
-10°C	5	45	120

Table 2. Summer Profile

Temperature	Cycle Period	Cycle Period Hours	Total Time Hours
40°C	1	8	8
22°C	2	8	16
40°C	3	24	40
30°C	4	35	75
40°C	5	45	120

Contrived positive nasal specimens were prepared by spiking 50 µL of heat-inactivated SARS-CoV-2 virus at 2x and 5x LoD concentrations as prepared in SARS-CoV-2 negative anterior nasal swab matrix onto dry swabs. Testing included 25 negative specimens. The contrived positive samples and negative samples were held dry for the designated duration of time for the simulated shipping study (Day 0 measurement tested within 4 hours of preparation or mock collection; Day 3 tested at 72 hours post collection; and Day 5 tested between 120-122 hours of preparation) and were then rehydrated and tested as per the EUA of a laboratory authorized for processing of specimens collected with the binx health at-home nasal swab COVID-19 collection kit. 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.

For both the winter and summer profiles, 20/20 2x LoD positive contrived samples and 5/5 5x LoD positive contrived samples were reported as positive after exposure to the simulated shipping conditions. The mean of the Ct values for each gene target and number of specimens positive for each target were similar before and after simulated shipping scenario (within 3 Cts), with no evidence of significant degradation of the SARS-CoV-2 RNA. All SARS-CoV-2 negative specimens were reported as negative after enduring the extreme temperature conditions. Results from the intermediate time point appear as expected/do not raise stability concerns.

Table 3. Summary of Results from the Simulated Shipping Study Using Contrived Samples Winter Profile

Sample Group	Test Point	N	Mean Ct (# positive for target/# tested)			Positive (%)
			N Gene	ORF1ab	S Gene	
Negative	Day 0[1]	25	Und[3]	Und[3]	Und[3]	0 (0)
	Winter[2]	25	Und[3]	Und[3]	Und[3]	0 (0)
Low Positive 2X LoD 20 copies/µL	Day 0[1]	20	27.1 (20/20)	27.5 (15/20)	25.9 (5/20)	20/20 (100)
	Winter[2]	20	28.9 (20/20)	28.6 (15/20)	27.1 (5/20)	20/20 (100)
High Positive 5X LoD 50 copies/µL	Day 0[1]	5	27.0 (5/5)	29.8 (3/5)	21.8 (2/5)	5/5 (100)
	Winter[2]	5	27.7 (5/5)	31.9 (3/5)	23.0 (2/5)	5/5 (100)

1 Day 0 = Testing performed within 4 hours of collection
2 Testing performed at the conclusion of the thermal excursions described in Table 1
3 Und=Undetermined value

Table 4. Summary of Results from the Simulated Shipping Study Using Contrived Samples Summer Profile

Sample Group	Test Point	N	Mean Ct (# positive for target/# tested)			Positive (%)
			N Gene	ORF1ab	S Gene	
Negative	Day 0[1]	25	Und[3]	Und[3]	Und[3]	0 (0)
	Summer[2]	25	Und[3]	Und[3]	Und[3]	0 (0)
Low Positive 2X LoD 20 copies/µL	Day 0[1]	20	27.2 (20/20)	27.5 (15/20)	25.9 (5/20)	20/20 (100)
	Summer[2]	20	29.9 (20/20)	28.9 (15/20)	27.7 (5/20)	20/20 (100)
High Positive 5X LoD 50 copies/µL	Day 0[1]	5	27.0 (5/5)	29.8 (3/5)	21.8 (2/5)	5/5 (100)
	Summer[2]	5	29.3 (5/5)	32.0 (3/5)	24.0 (2/5)	5/5 (100)

1 Day 0 = Testing performed within 4 hours of collection
2 Testing performed at the conclusion of the thermal excursions described in Table 2
3 Und=Undetermined value

These data support the use of the binx health at-home nasal swab COVID-19 collection kit for at ambient temperature transport and storage of anterior nasal swab specimens collected at home for up to 120 hours from the time of collection.

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 the table below. 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	**30**
	Negative	0	30	**30**
	Total	**30**	**30**	**60**
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 for adults aged 18 and over

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, seven were aged 65 and over and 12 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	20/30 (66.6%)
	Male	10/30 (33.3%)
Age	18-64	23/30 (76.7%)
	65+	7/30 (23.3%)
Education Level	Doctorate Degree	0/30 (0%)
	Professional Degree	1/30 (3.3%)
	Masters Degree	7/30 (23.3%)
	Bachelor's Degree	7/30 (23.3%)
	Associate Degree	3/30 (10.0%)
	Some College Credit (no Degree)	6/30 (20.0%)
	Trade/Technical/Vocational Training	3/30 (10.0%)
	High School Graduate	3/30 (10.0%)

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, 2, or 3 in these categories (indicating very easy, or easy to use, or a neutral response) for 90% or more of respondents categorized the collection kit and the sample collection process as being easy to use. Results of the study support the ease of use of the kit for unobserved specimen collection for adults.

(b) Human usability study for minors aged 5-17

A human usability study was conducted to validate the binx health At-home Nasal Swab COVID-19 Sample Collection Kit for effective (observed) home-collection and mailing of samples to a CLIA-certified lab for testing. Following online recruitment and consenting of parents or legal guardians ("Consenting Adult"), Kits were shipped to each Consenting Adult's address. Nasal swab samples were collected at home following a simple set of self-collection instructions, under remote (online) observation by a clinician. Verbal assent was obtained from all minors who provided samples. For minors aged between 5-13 years, the Consenting Adult collected the study sample. For minors aged between 14-17 years, the minor self-collected their sample under observation of the Consenting Adult. The first 15 Consenting Adults with minors aged between 5-13 and the first 15 Consenting Adults with minors aged between 14-17 that were eligible for the study and who registered their details, received a kit, 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 15 Consenting Adults who collected samples from their minor aged 5-13, six had not completed college education. None of the participants had prior laboratory experience or experience with home specimen collection. The age of the minors participating in the study spanned the full age range of 5-17.

The characteristics/demographics of the minors participating in the study was as follows:

Characteristics of Study Population		**N/N (%)**
Gender	Female	15/30 (50.0%)
	Male	15/30 (50.0%)
Age	5	2/30 (6.7%)
	6	3/30 (10.0%)
	7	0/30 (0%)
	8	4/30 (13.3%)
	9	2/30 (6.7%)
	10	1/30 (3.3%)
	11	0/30 (0%)
	12	1/30 (3.3%)
	13	2/30 (6.7%)
	14	5/30 (16.7%)
	15	5/30 (16.7%)
	16	2/30 (6.7%)
	17	3/30 (10.0%)

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 Consenting Adults and the 15 minors aged between 14-17 who collected their own samples under observation of a Consenting Adult. Responses to questions posed in the usability survey were graded on a five-point Likert scale along with yes/no answers and free-text responses. For the majority of questions relating to usability and ease of use for those who collected samples, scores of 1, 2 or 3 in these categories (indicating very easy, or easy to use, or a neutral response) were received, supporting the collection kit and the sample collection process as being easy to use. Five respondents indicated they were uncertain what to do if they had questions during sample collection. Eight participants reported some level of discomfort from specimen collection. Finally, one third of minors who obtained their own sample stated that they needed help while collecting the specimen. Based on survey feedback from the usability study and in an effort to align with other home collection kits authorized for specimen collection from minors, the following changes were implemented in the Instructions for Use:

1. Highlighted sponsor contact information in red font
2. Added text to clarify appropriate distance swab should be inserted during collection
3. Edited age limit warning/comments to facilitate collection of specimens from children 5-13 years of age and 14-17 years of age.

WARNINGS:

- This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA.
- This product has been authorized only for the home collection and maintenance of anterior nasal swab specimens as an aid in detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens.
- The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of medical devices under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.