binx health At-home Nasal Swab COVID-19 Sample Collection Kit - for individual shipping

Instructions for Use - Please read ALL instructions prior to collecting a sample

Activate the Sample Collection Kit online before use

1. Open and unpack the sample collection kit, placing the contents on a clean surface.
   The sample identification label is pre-printed with the activation code.

   Activate the kit at www.mybinxhealth.com/activate
   If you are a returning user, log in to your account before activating the kit.
   If you do not receive an email notification after activation please contact support at support@mybinxhealth.com

   Important! The sample may be rejected if it has not been activated at mybinxhealth.com/activate before it is sent to the laboratory.

2. The sample identification label is pre-printed with the activation code.
   The label may ask for your name, date of birth, and date, time and timezone you collected your sample.
   Complete the label with any of the requested information.

   Apply the label lengthways on the long side of the tube.

Collect the sample

3. The person collecting the sample should wash their hands thoroughly with soap and water for 20 seconds.

   Twist the tube cap to remove the swab.

   Important! Do not touch the swab tip!

4. Insert the soft tip of the swab into the nostril. Insert no more than ¾ of an inch (1.5 cm) for an adult and less than ½ inch (1 cm) for younger children.

   Sample the nasal membrane by rotating the swab in a circular path against the inside of the nostril four (4) times for a total of 15 seconds.

   Gently remove the swab.

   Important! If you are collecting a specimen from a child, be careful not to insert the swab too far into the child’s nostril.

   Repeat using the same swab for the other nostril.

   It is important to collect the sample from both nostrils.

   If, during the collection process, you, or the person you are collecting the sample from, feels any discomfort, stop collecting the sample immediately and contact binx by emailing support@mybinxhealth.com or calling 844-692-4691

   Without touching the swab tip, place the swab (tip first) into the tube and close securely.

Return the Sample Collection Kit the same day it was collected

5. Place the tube containing the swab in the sample bag containing the absorbent pad.

   Seal the bag by tearing off the strip and folding the top of the bag over.

   The person who collected the sample should wash their hands thoroughly with soap and water for 20 seconds.

6. Place the sample bag in the cardboard box and close securely.

   Place the box inside the return envelope and seal.

   Return using UPS before the last pickup of the day by going to wwwapps.ups.com/pickup/schedule or take the envelope to any UPS access point or store.

For IVD Use Only | Rx Only
For Use Under Emergency Use Authorization

RES-ART-0010 v3.0 | MAY 2021
### Instructions for Use - Please read ALL instructions prior to collecting a sample

#### Before using the kit
- Ensure all instructions are carefully followed.
- Not following these instructions may lead to incorrect results or rejection of the sample.

**The Sample Collection Kit contains:**
- Cardboard shipping box
- Sterile swab and tube
- Instructions for Use
- Sample bag with absorbent pad
- Pre-paid return envelope
- Sample identification label

#### Collection of samples
- If this sample collection kit is being used to obtain a nasal swab sample from a child 5-13 years of age, the specimen should be collected by a parent or guardian.
- For children 14-17 years of age, and for adults, swabs may be self-collected. Self-collection of samples from children 14-17 years of age should be performed under adult supervision.

- **This sample collection kit should not be used to collect a sample from a child under the age of five**

#### What happens next?
- **Return the sample via UPS**
  - UPS may stop collecting at 4pm, or earlier, so check before you begin the collection process.
  - Send the activated, completed kit using the pre-packaged printed return label.

- **The sample will be processed**
  - The laboratory performs quality checks and processes the sample. You will be contacted if there are any issues.

- **You will be able to access the result**
  - The results will be reviewed and then securely transmitted to your personal binx dashboard.
  - Log in to mybinxhealth.com/login to review the results.
  - If the test result is positive, a licensed healthcare professional will reach out to you with next steps.

#### The sample may be rejected if:
- The sample is not activated before being returned to the laboratory.
- The sample is not sent on the same day it was collected.
- The sample is incorrectly labeled or there is missing information.
- The sample is incorrectly packaged.

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; and
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.

Got any questions about the collection process? Contact binx at support@mybinxhealth.com or call 844-692-4691

Please turn over for step by step instructions to collect your sample
Activate the Sample Collection Kit online before use

1. Open and unpack the sample collection kit, placing the contents on a clean surface.
   The sample identification label is pre-printed with the activation code.

2. Activate the kit at www.mybinxhealth.com/activate
   If you are a returning user, log in to your account before activating the kit.
   If you do not receive an email notification after activation please contact support at support@mybinxhealth.com

Important! The sample may be rejected if it has not been activated at mybinxhealth.com/activate before it is sent to the laboratory.

3. The sample identification label is pre-printed with the activation code.
   The label may ask for your name, date of birth, and date, time and timezone you collected your sample.
   Complete the label with any of the requested information.

4. Apply the label lengthways on the long side of the tube.

Collect the sample

5. The person collecting the sample should wash their hands thoroughly with soap and water for 20 seconds.

6. Twist the tube cap to remove the swab.

Important! Do not touch the swab tip!

7. Insert the soft tip of the swab into the nostril. Insert no more than ⅓ of an inch (1.5 cm) for an adult and less than ¼ an inch (1 cm) for younger children.
   Sample the nasal membrane by rotating the swab in a circular path against the inside of the nostril four (4) times for a total of 15 seconds.
   Gently remove the swab.

Important! If you are collecting a specimen from a child, be careful not to insert the swab too far into the child’s nostril.

8. Repeat using the same swab for the other nostril.
   It is important to collect the sample from both nostrils.

If, during the collection process, you, or the person you are collecting the sample from, feels any discomfort, stop collecting the sample immediately and contact binx by emailing support@mybinxhealth.com or calling 844-692-4691

9. Without touching the swab tip, place the swab (tip first) into the tube and close securely.

Return the Sample Collection Kit the same day it was collected

10. Place the tube containing the swab in the sample bag containing the absorbent pad.

Important! If you are under 18 years of age, please ask your parent or guardian to assist with packaging the sample and arranging for shipment of the Sample Collection Kit to the laboratory.

11. Seal the bag by tearing off the strip and folding the top of the bag over.

12. The person who collected the sample should wash their hands thoroughly with soap and water for 20 seconds.

13. Place the sample bag in the cardboard box and close securely.

14. Place the box inside the return envelope and seal.

To minimize shipping delays return the sample the same day it was collected (Monday through Friday).
Drop off at the return location as soon as possible and on the same day as sample collection.

For IVD Use Only | Rx Only

For Use Under Emergency Use Authorization

RES-ART-0011 v3.0 I MAY 2021
binx health At-home Nasal Swab COVID-19 Sample Collection Kit - for return at a drop-off location

Instructions for Use - Please read ALL instructions prior to collecting a sample

Before using the kit

Ensure all instructions are carefully followed.

Not following these instructions may lead to incorrect results or rejection of the sample.

The Sample Collection Kit contains:

- Cardboard shipping box
- Sterile swab and tube
- Instructions for Use
- Sample bag with absorbent pad
- Return envelope
- Sample identification label

After using the kit, please check that:

- You have successfully activated the kit online and received confirmation.
- The sample identification label has been placed onto the swab tube and all requested information has been filled out

Collection of samples

If this sample collection kit is being used to obtain a nasal swab sample from a child 5-13 years of age, the specimen should be collected by a parent or guardian.

For children 14-17 years of age, and for adults, swabs may be self-collected. Self-collection of samples from children 14-17 years of age should be performed under adult supervision.

This sample collection kit should not be used to collect a sample from a child under the age of five

What happens next?

Return the sample

Return the activated, completed sample kit using the return envelope on the same day at the designated drop-off location.

The sample will be processed

The laboratory performs quality checks and processes the sample. You will be contacted if there are any issues.

You will be able to access the result

The results will be reviewed and then securely transmitted to your personal binx dashboard.

Log in to mybinxhealth.com/login to review the results.

If the test result is positive, a licensed healthcare professional will reach out to you with next steps.

The sample may be rejected if:

- The sample is not activated before being returned to the laboratory.
- The sample is not dropped off at the designated drop-off location the same day it was collected.
- The sample is incorrectly labeled or there is missing information.
- The sample is incorrectly packaged.

Got any questions about the collection process? Contact binx at support@mybinxhealth.com or call 844-692-4691

Please turn over for step by step instructions to collect your sample.

For IVD Use Only | Rx Only For Use Under Emergency Use Authorization

RES-ART-0011 v3.0 I MAY 2021
Activate the Sample Collection Kit online before use

1. Open and unpack the sample collection kit, placing the contents on a clean surface.

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   If you are a returning user, log in to your account before activating the kit.
   If you do not receive an email notification after activation please contact support at support@mybinxhealth.com
   **Important!** The sample may be rejected if it has not been activated at mybinxhealth.com/activate before it is sent to the laboratory.

3. The sample identification label is pre-printed with the activation code.
   The label may ask for your name, date of birth, and date, time and timezone you collected your sample. Complete the label with any of the requested information.
   Apply the label lengthways on the long side of the tube.

4. Collect the sample

5. The person collecting the sample should wash their hands thoroughly with soap and water for 20 seconds.

6. Remove the swab from the packaging by its plastic handle.
   **Important! Do not touch the swab tip!**

7. Insert the soft tip of the swab into the nostril. Insert no more than ⅝ of an inch (1.5 cm) for an adult and less than ⅝ an inch (1 cm) for younger children.
   Sample the nasal membrane by rotating the swab in a circular path against the inside of the nostril four (4) times for a total of 15 seconds.
   Gently remove the swab.

8. **Important!** If you are collecting a specimen from a child, be careful not to insert the swab too far into the child’s nostril.
   Repeat using the same swab for the other nostril.
   It is important to collect the sample from both nostrils.

9. Without touching the swab tip, place the swab (tip first) into the tube and close securely.

10. Return the Sample Collection Kit the same day it was collected

11. Place the tube containing the swab in the sample bag containing the absorbent pad.
    Seal the bag by tearing off the strip and folding the top of the bag over.

12. The person who collected the sample should wash their hands thoroughly with soap and water for 20 seconds.

13. Place the sample bag in the cardboard box and close securely.

14. Place the box inside the return envelope and seal.

Return using UPS before the last pickup of the day by going to wwwapps.ups.com/pickup/schedule or take the envelope to any UPS access point or store.

For IVD Use Only | Rx Only

For Use Under Emergency Use Authorization

RES-ART-0018 v2.0 | MAY 2021
### Instructions for Use - Please read ALL instructions prior to collecting a sample

#### Before using the kit

Ensure all instructions are carefully followed.

Not following these instructions may lead to incorrect results or rejection of the sample.

The Sample Collection Kit contains:

- Cardboard shipping box
- Sterile swab and tube
- Instructions for Use
- Sample bag with absorbent pad
- Pre-paid return envelope
- Sample identification label

#### Collection of samples

If this sample collection kit is being used to obtain a nasal swab sample from a child 5-13 years of age, the specimen should be collected by a parent or guardian.

For children 14-17 years of age, and for adults, swabs may be self-collected. Self-collection of samples from children 14-17 years of age should be performed under adult supervision.

This sample collection kit should not be used to collect a sample from a child under the age of five.

#### After using the kit, please check that:

- You have successfully activated the kit online and received confirmation.
- The sample identification label has been placed onto the swab tube and all requested information has been filled out.

#### The sample may be rejected if:

- The sample is not activated before being returned to the laboratory.
- The sample is not sent on the same day it was collected.
- The sample is incorrectly labeled or there is missing information.
- The sample is incorrectly packaged.

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; and

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.

Got any questions about the collection process? Contact binx at support@mybinxhealth.com or call 844-692-4691

Please turn over for step by step instructions to collect your sample

For IVD Use Only | Rx Only | For Use Under Emergency Use Authorization

RES-ART-0018 v2.0 | MAY 2021
### Activate the Sample Collection Kit online before use

1. Open and unpack the sample collection kit, placing the contents on a clean surface.
2. Activate the kit at [www.mybinxhealth.com/activate](http://www.mybinxhealth.com/activate)
   - If you are a returning user, log in to your account before activating the kit.
   - If you do not receive an email notification after activation please contact support at support@mybinxhealth.com

**Important!** The sample may be rejected if it has not been activated at [mybinxhealth.com/activate](http://mybinxhealth.com/activate) before it is sent to the laboratory.

3. The sample identification label is pre-printed with the activation code.
   - The label may ask for your name, date of birth, and date, time and timezone you collected your sample. Complete the label with any of the requested information.
4. Apply the label lengthways on the long side of the tube.

### Collect the sample

5. The person collecting the sample should wash their hands thoroughly with soap and water for 20 seconds.
6. Remove the swab from the packaging by its plastic handle.

**Important! Do not touch the swab tip!**

7. Insert the soft tip of the swab into the nostril.
   - Insert no more than ⅓ of an inch (1.5 cm) for an adult and less than ⅓ an inch (1 cm) for younger children.
   - Sample the nasal membrane by rotating the swab in a circular path against the inside the nostril four (4) times for a total of 15 seconds. Gently remove the swab.

**Important!** If you are collecting a specimen from a child, be careful not to insert the swab too far into the child’s nostril.

8. Repeat using the same swab for the other nostril.
   - It is important to collect the sample from both nostrils.
   - If, during the collection process, you, or the person you are collecting the sample from, feels any discomfort, stop collecting the sample immediately and contact binx by emailing support@mybinxhealth.com or calling 844-692-4691

9. Without touching the swab tip, place the swab (tip first) into the tube and close securely.

### Return the Sample Collection Kit the same day it was collected

10. Place the tube containing the swab in the sample bag containing the absorbent pad.
    - Seal the bag by tearing off the strip and folding the top of the bag over.

**Important!** If you are under 18 years of age, please ask your parent or guardian to assist with packaging the sample and arranging for shipment of the Sample Collection Kit to the laboratory.

11. The person who collected the sample should wash their hands thoroughly with soap and water for 20 seconds.

12. Place the sample bag in the cardboard box and close securely.

13. Place the box inside the return envelope and seal.

14. To minimize shipping delays return the sample the same day it was collected (Monday through Friday). Drop off at the return location as soon as possible and on the same day as sample collection.

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For [IVD] Use Only | Rx Only

For Use Under Emergency Use Authorization

RES-ART-0019 v2.0 | MAY 2021
binx health At-home Nasal Swab COVID-19 Sample Collection Kit - for return at a drop-off location

Instructions for Use - Please read ALL instructions prior to collecting a sample

### Before using the kit
Ensure all instructions are carefully followed.
Not following these instructions may lead to incorrect results or rejection of the sample.

**The Sample Collection Kit contains:**
- Cardboard shipping box
- Sterile swab and tube
- Instructions for Use
- Sample bag with absorbent pad
- Return envelope
- Sample identification label

### Collection of samples
*If this sample collection kit is being used to obtain a nasal swab sample from a child 5-13 years of age, the specimen should be collected by a parent or guardian.*

For children 14-17 years of age, and for adults, swabs may be self-collected. Self-collection of samples from children 14-17 years of age should be performed under adult supervision.

**This sample collection kit should not be used to collect a sample from a child under the age of five**

### What happens next?
**Return the sample**
Return the activated, completed sample kit using the return envelope on the same day at the designated drop-off location.

**The sample will be processed**
The laboratory performs quality checks and processes the sample. You will be contacted if there are any issues.

**You will be able to access the result**
The results will be reviewed and then securely transmitted to your personal binx dashboard.

Log in to [mybinxhealth.com/login](http://mybinxhealth.com/login) to review the results.

If the test result is positive, a licensed healthcare professional will reach out to you with next steps.

### The sample may be rejected if:
- The sample is not activated before being returned to the laboratory.
- The sample is not dropped off at the designated drop-off location the same day it was collected.
- The sample is incorrectly labeled or there is missing information.
- The sample is incorrectly packaged.

Got any questions about the collection process? Contact binx at support@mybinxhealth.com or call 844-692-4691

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RES-ART-0019 v2.0 | MAY 2021