

Gravity Diagnostics

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08 October 2021

Re: COVID-19 Home Test Usability Study

To Whom it May Concern,

My name is J.P Canner, Ph.D., NRCC, MT(AAB),
VP of Regulatory, Clinical, and Research Programs at Gravity
Diagnostics. Gravity Diagnostics is a state-of-the-art CLIA-
certified CAP-accredited laboratory licensed in all 50 states
providing innovative laboratory testing in the areas including
COVID-19 screening. To continue serving you and your community to
the highest standards, we need your input!

We are writing to ask for volunteers to participate in our study with
our **FDA-EUA approved COVID-19 Home Collection Kits** (*Gold
Standard PCR Tests*) to determine ease of usability with patients
between the ages of 2-17 years of age.



**COVID-19 Test
Home Collection Kit**

- Gold Standard PCR Test
- Gentle Lower Nasal Swab

How it works:

1. All participants will be asked to sign user contracts prior to involvement. Participation is strictly voluntary. Participants will be provided with all necessary materials required to complete the study, including one COVID-19 home collection kit per child and all necessary mailing materials.
Note: *Samples from users 2-13 years of age will be parental collected, while samples 14-17 years of age will be self-collected. Collection is a gentle lower nasal swab.*
2. Home Collection kits will be mailed to the participants home address, along with minor consent forms, complete user instructions, and mailing components. Users will be instructed to register the kits online and mail the kits back to the lab for processing.

3. Results will be delivered to the users via email. Upon completion of the testing process, users will receive an exit survey to explain their experience using the Home Collection Kit with their child. Users are required to complete and return exit survey to complete study.

If you and your child would like to participate in this study to help us combat the COVID-19 pandemic, please fill out this [form](#).

Sample Collection Instructions

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1 Register Your Kit & Follow Instructional Video
Use the QR code above to begin registering your kit on our website or go to getmydna.com/register. For the best results, watch our instructional video at getmydna.com/covid-instructions before you start.
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2 Fill Out Sticker Label & Place on Tube
Your kit comes with a blank label sticker, fill out the sticker with name, date of birth, and the date of collection, in pen only, and place the sticker label vertically on the tube. The information must be legible, and match what you used to register your kit. Do not write directly on the tube.
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3 Prepare to Collect
Before collection, make sure to blow your nose, sanitize your collection area, and thoroughly wash your hands for a minimum of 20 seconds with soap and warm water.
Do not use your alcohol prep pads to sanitize the collection area, these are needed later on in the collection process.
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4 Remove Swab from Sleeve
Peel open the sleeve and carefully remove the swab. Make sure not to let the tip of the swab touch anything besides the inside of your nose. Doing so will compromise the specimen leading to a potential false result or no result.
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5 Insert Swab and Rotate 3 Times
Gently insert the swab into one nostril no more than 1.5cm (0.75in). Rotate the swab 3 times with slight pressure.
Repeat this step on the other nostril with the same swab.
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6 Place Swab in Tube & Break on Perforated Line
Place your swab, tip down, into the tube. Break the swab on the perforated line and securely close your tube.
Make sure not to spill your saline liquid as doing so can lead to a potential false result or no result.
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7 Place Tube in Biohazard Bag & Securely Close Bag
Place your tube into the biohazard bag, in the same sealed pouch as the absorbent pad, and securely close the bag.
Do not remove the absorbent pad from the biohazard bag.
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8 Maintain Distance While Awaiting Your Results
Be sure to maintain a minimum of 6ft distance between yourself and others while awaiting your test results.

Return Shipping & Receiving Results on Back →

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Thank you for your time and we look forward to hearing from you.

Sincerely,

James Canner