

Kaiser Permanente MidAtlantic States (KPMAS) COVID-19 Home Collection Kit, IVD, Rx only

For Use Under an Emergency Use Authorization (EUA) Only



This home collection kit is suitable for the following age groups:

- **18 years and up:** Self-collect
- o 14 years and up: Self-collect under adult supervision
- 2 years and up: Collect with adult assistance*

Before collecting your nasal swab sample, please visit www.fedex.com/labreturn to find FedEx drop box locations and pickup schedules.

You <u>must</u> bring your sample to a drop box on <u>the same day</u> you collect it, before the last Express pick up. FedEx pick up is not available on <u>Saturday or Sunday</u>.

Important:

Sample will not be tested if the specimen is returned to the laboratory in any of the following conditions:

- No nasal swab inside the saline collection tube
- \circ No specimen label on the collection tube
- No written date and/or time of collection
- Not shipped in the provided **FedEx** UN3373 Pak
- o No nasal specimen material present on the swab (examined microscopically in the lab)
- o Sample arrived to the laboratory more than 48 hours after collection

Disclaimer: This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA for use by the authorized laboratory. This product has been authorized only for the 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 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. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner. (updated 3-15-21)

If you have a question or need further assistance, please contact Kaiser Permanente Member Services: 1-800-777-7902 (toll free); TTY: 1-301-879-6380



KPMAS COVID-19 Home Collection Kit Instruction

Please read all instructions carefully watch the video instruction before collecting sample. Go to https://youtu.be/2Uf3vQCfYv4 or scan the QR code using smartphone.

Instructions for the person collecting the specimen*:

- 1. Wash your hands with soap for 20 seconds.
- 2. Set out the kit (swab, saline** tube, and label) on the provided table mat.
- 3. Label:
 - a. Confirm your name and date of birth on the provided specimen (barcoded) label.
 - b. Clearly write date and time of sample collection on the specimen label.
 - c. Affix the specimen label on the specimen tube as shown in Figure 3.
- 4. Swab (see Figure 1)
 - a. Insert the swab into one nostril until the "soft part" is reached (~1 inch or 2-3 cm).
 - b. Rotate the swab inside the nostril for about 10-15 seconds and withdraw.
 - c. Repeat with the other nostril using the same swab.
- 5. Open the sample tube, place the swab inside of tube, close the cap tightly, and check for leakage (see Figure 2). * If the provided swab is too long for the collection tube, break or bend the handle to make it fit inside the tube.
- 6. Package:
 - a. Place the specimen tube into the biohazard bag containing the white absorbent sheet and seal the bag.
 - b. **Wipe** your hands with the provided alcohol prep pad.
 - c. Place the biohazard bag into the shipping box and close the box (Figure 4a).
 - d. Place the shipping box into the pre-labeled **FedEx** envelope and seal the envelope (Figure 4b).
- 7. Ship: Deliver the postage paid, pre-labeled FedEx return pack to a FedEx drop box.
 - Note: Please bring your sample to a drop box on the same day you collect it before the last Express pick up schedule. Fedex pick is not available on Saturday or Sunday.



Insert swab inside one nostril until the "soft part" is reached (~ 1 inch or 2-3 cm).

Gently rotate swab for 10-15
seconds. Repeat with the other
nostril using the same swab.

Do not let the swab touch any surface before placing it into sample tube.



Figure 3. Affix the label Place swab into collection tube as shown. and tighten cap.



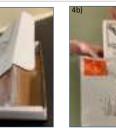


Figure 4. Specimen tube is placed into a biohazard bag and then placed into the shipping box (a). The shipping box is placed into the prelabeled FedEx envelope (b).



- If possible, have another adult help by positioning the young child on his/her lap while you collect the sample.
- Communicate with the child and talk through the steps, explaining the procedure.

Figure 2.

- Do not continue if the child has any pain or asks to stop.

** Warning: When handling saline, avoid contact with eyes and keep out of reach of children 13 and under.

Video Appointment is not required for home collection. Should you need further assistance, contact Kaiser Permanente Member Services:1-800-777-7902 (toll free); TTY: 1-301-879-6380.

