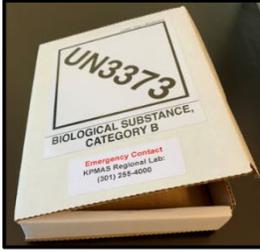


Kaiser Permanente MidAtlantic States (KPMAS) COVID-19 Self-Collection Kit (At-home collection), IVD, Rx only For Use Under an Emergency Use Authorization (EUA) Only

Kit includes:

 <p style="text-align: center;">Biohazard bag (95 kPa) with - Nasal swab - Saline collection tube - Specimen label - Absorbent sheet</p>	 <p style="text-align: center;">Shipping box</p>	 <p style="text-align: center;">Pre-paid, pre-labeled FedEx return envelope</p>	 <p style="text-align: center;">Table Mat</p>
			 <p style="text-align: center;">Alcohol Prep Pad</p>

This COVID-19 collection kit is suitable for the following age groups:

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

Return your specimen on the same day you collect it by one of the following ways:

- **Mailed overnight via FedEx:** Locate FedEx Express drop box and pick up schedule at www.fedex.com/labreturn. **Note: FedEx pick up is not available on Saturday or Sunday.**
- **Dropped off at the designated on-site (KPMAS facility) COVID-19 Kit Drop Box or brought to the on-site laboratory** (see provided Drop-Off Information Sheet or visit <https://insider.kaiserpermanente.org/learn-more-about-laboratory-covid-19-testing>).

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
- No specimen label on the collection tube
- No written date and/or time of collection
- Not shipped in the provided **FedEx** UN3373 Pak (not applicable, if dropped off at on-site drop box or lab)
- 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 authorized laboratories. 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 1-13-2022)

If you have a question or need further assistance, please contact Kaiser Permanente Member Services:

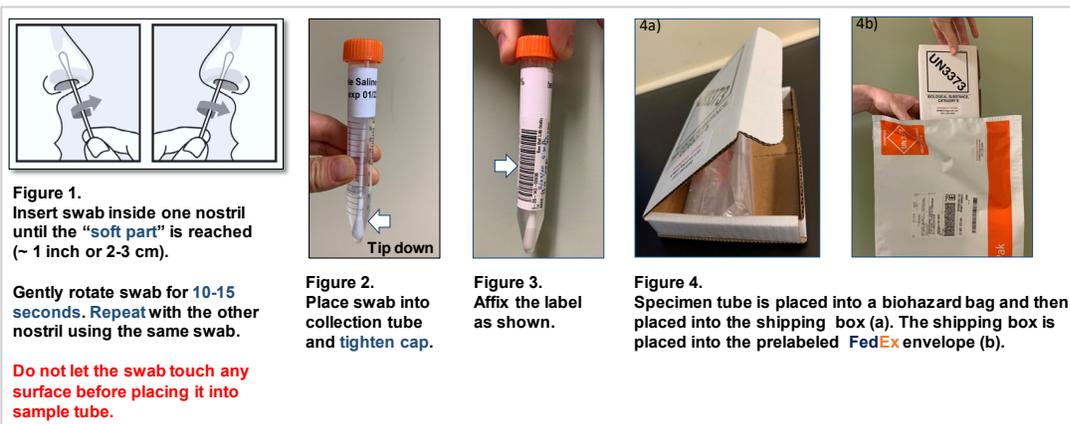
KPMAS COVID-19 Self-Collection Kit Instruction (At-Home)

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 a clean surface or 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 for adults; less than ½ inch for young children).
 - 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.
— **Stop**, if your specimen will be dropped off in person (see provide Drop-Off Information Sheet or <https://insider.kaiserpermanente.org/learn-more-about-laboratory-covid-19-testing>)
— **Continue** the following steps, if your kit will be mailed by FedEx.
 - 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 pickup is **not available** on Saturday or Sunday.



*If you are an adult (18 years and up) collecting the sample from a child (2-13 years):

- 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.
- 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.

KPMAS COVID-19 Self-Collection Kit, IVD, Rx only In person Drop-Off Option

Instead of returning your sample by FedEx, you may drop off your specimen at one of the Kaiser Permanente locations below. This method of return is strongly recommended for faster result turn-around-time.

Instructions for specimen drop-off at KP Drop Box ONLY:

1. Sample Collection:

Please complete all steps on the KPMAS COVID-19 Self Collection Kit Instructions through step **#6a** (see Picture 1). Do not package your sample into the white shipping box or FedEx bag.

2. Specimen Drop-Off at your chosen Medical Center:

Please drop the specimen **ONLY** into the Box labeled “**COVID-19 Kit Drop Box**” (Picture 2).

If you have any question, the screeners and administrative staff will be happy to help to locate the Drop Box.

- ❖ COVID-19 Specimen Drop Boxes (preferred) and on-site Laboratories at all KP-MAS locations accept COVID-19 Self-Collection Kit specimen returns **Monday-Friday 8:00 A.M. - 4:30 P.M.**

- ❖ The following locations have expanded hours:

Monday-Friday	8:00 A.M. - 8:30 P.M.
Saturday/Sunday	8:00 A.M. - 4:30 P.M.

Reston
1890 Metro Center Dr
Reston, VA 20190

White Marsh
4920 Campbell Blvd
Nottingham, MD 21236

- ❖ The following locations are open **24 hours a day, 7 days a week:**

S. Baltimore
1701 Twin Spring Rd
Halethorpe, MD 21277

Gaithersburg
655 Watkins Mill Rd
Gaithersburg, MD 20879

Largo
1221 Mercantile Ln
Upper Marlboro, MD 20774

Tysons Corner
8008 Westpark Dr
McLean, VA 22102

Woodbridge
14139 Potomac Mills Rd.
Woodbridge, VA 22192



Picture 1. Specimen ready for drop-off at KP-MAS Drop Box



Picture 2. KP-MAS Drop Box

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Kaiser Permanente MidAtlantic States (KPMAS) COVID-19 Self-Collection Kit (On-site collection), IVD, Rx only For Use Under an Emergency Use Authorization (EUA) Only



This COVID-19 collection kit is suitable for the following age groups:

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

Return your specimen on the same day you collect it by one of the following ways:

- Specimen is left in the collection room, if collected in the KPMAS Laboratory.
- Dropped off at the designated on-site (KPMAS facility) COVID-19 Kit Drop Box or Laboratory (see provided Drop-Off Information Sheet or visit <https://insider.kaiserpermanente.org/learn-more-about-laboratory-covid-19-testing>).

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
- No specimen label on the collection tube
- No written date and/or time of collection
- 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 authorized laboratories. 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 1-13-2022)

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 Self-Collection Kit Instruction (On-site)

Please **read all instructions carefully** watch the **video instruction** before collecting sample. Go to <https://vimeo.com/605966169/ff2d3e00fd> or scan the **QR code** using smartphone.



Instructions for the person collecting the specimen:*

1. **Wash** your hands with soap for 20 seconds or use hand sanitizer/provided alcohol prep pad until dry.
2. **Set out the kit** (swab and pre-labeled saline tube**) on a clear surface or table mat (if provided).
3. **Label:**
 - a. Confirm your **name and date of birth** on the sample label that is affixed to the saline tube
 - b. Clearly write **date and time** of sample collection on the sample label.
4. **Swab** (see Figure 1)
 - a. Insert the swab into one nostril until the “soft part” is reached (~1 inch for adults; less than ½ inch for young children).
 - 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 (cotton tip pointing downward), 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. **Place** the specimen tube into the **biohazard bag** containing the white absorbent sheet and seal the bag.
7. **Specimen Submission:**
 - a. **If collected at KPMAS Laboratory:** Place the sealed biohazard bag on the table mat and leave in room. Let the Phlebotomist know that you are done as you are leaving.
 - b. **If collected at KPMAS facility other than Laboratory:** Drop off specimen at the on-site **COVID-19 Kit Drop Box (Figure 3)** or bring it to the on-site laboratory (see provided *Drop-Off Information Sheet* or visit <https://insider.kaiserpermanente.org/learn-more-about-laboratory-covid-19-testing> for more information. If you have any question, please reach out to the screeners at the front entrance or administrative staff.

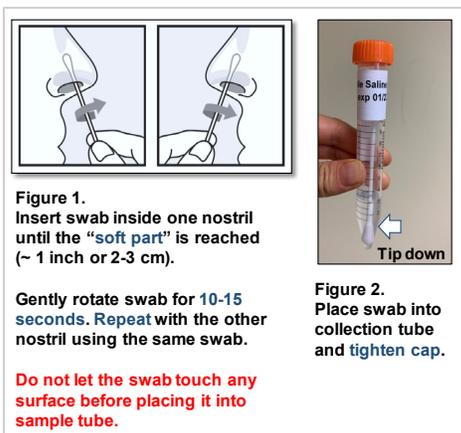


Figure 3. KPMAS COVID-19 Kit Drop Box

***If you are an adult (18 years and up) collecting the sample from a child (2-13 years):**

- 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.
- 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.