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# Cognitive Interview Guide: At-Home COVID-19 Test Information

Color Key:

**Purple** – Section headings and titles

**Black** – Text for interviewer to read

**Red** – Interviewer instructions (not to be read aloud)

**Green** – Research questions (for interviewer's information, not to be read aloud)

## Introduction

Hello, my name is **[INSERT INTERVIEWER NAME]**. I work for Westat, a research company in Rockville, Maryland. Thank you for taking the time to be a part of this study.

Westat is conducting this study, which is sponsored by the U.S. Food and Drug Administration (or FDA), to see what people think about health information related to medical products.

In a moment, I will give control of the screen to you so you can look at a website. After you look at the website, I will ask you some questions on your thoughts and feelings about the information. Any ideas you have are okay.

**IF PARTICIPANT CANNOT ACCESS WEBSITE OR USE SCREENSHARING, RESCHEDULE INTERVIEW.**

# Informed Consent

Before we get started, there are a few things I want to go over. Your participation in this interview is voluntary, and you don't have to answer any questions you prefer not to. It is also okay if you want to stop after we start. Just let me know.

All of your answers and everything you say will be kept secure to the extent permitted by law. This means we will not share your name or contact information. The interview will take about 45 minutes and you will receive \$50 as a token of appreciation.

We would like to record this conversation to make sure we hear everything you say correctly. Please speak clearly and loudly. Also, please minimize background noise by finding a quiet location away from other people and distractions. If you haven't already, please silence your cell phone and other devices.

Only the research team working on this project will be able to listen to the recording and see our notes. Your name will not be linked to any of your responses, though we may include quotes that you provide in our reports. The recordings and our notes will be destroyed after we finish the project.

**IF FDA STAFF ARE ON THE PHONE:** I also want you to know that a couple members of the FDA research team are listening to this interview so they can hear directly from you.

Any questions? Is it okay if I record the interview? **IF NO, TERMINATE.**

**TURN ON RECORDER.** The date and time is \_\_\_\_\_. Now that I am recording, I want to ask again, is it okay if I record this interview?

# Research Questions

1. What are the main message(s) that participants get from the materials?
2. What do participants recognize as the call to action?
3. How clear and understandable is the text to participants? What words or phrases are confusing and what suggestions do participants offer for replacing them?
4. Do participants understand which tests are appropriate for their children and whether help from an adult is needed?
5. What information do participants find useful? Not useful?
6. What information do participants say is missing or would be helpful to add?
7. Are the questions listed in the FAQ the ones that participants want answered?
8. How well do participants think the content is organized?
9. What suggestions do participants offer for improving the materials?

# Background Questions

To start, I have a few general questions.

## FOR THOSE WHO USED ANY AT-HOME COVID-19 TEST IS PAST 6 MONTHS

You told us when you volunteered for this interview that you had used an at-home COVID-19 test in the past 6 months. Is this correct? **IF NO, TERMINATE.**

- Where did you get your at-home COVID-19 tests? **IF NEEDED**, Did you get free tests in the mail or from your library, buy your tests, get them some other way, or any combination of these?
  - o **IF BOUGHT**, How did you decide which brand of at-home COVID-19 tests to buy? **IF NEEDED**, Did you consider the brand, the price, or any other factors?
- Have you always used the same brand of at-home COVID-19 tests, or have you used different brands? Why is that?
- **IF PARENT (FROM SCREENER)**, You told us when you volunteered for this interview that you had children ages **[INSERT FROM SCREENER]** living in your home, is that correct? Have they used any of your at-home COVID-19 tests in the past 6 months?
  - o **IF YES**, Did you help your children with using any tests, or did they use the tests on their own? Why is that?

## FOR THOSE WHO HAVE NOT USED AN AT-HOME COVID-19 TEST IS PAST 6 MONTHS

You told us when you volunteered for this interview that you had not used an at-home COVID-19 test in the past 6 months. Is this correct? **IF NO, TERMINATE.**

- Can you tell me more about that? **IF NEEDED**, Have you not used an at-home COVID-19 test because you haven't had symptoms, because you aren't sure where to get them, or some other reason?
- **[IF KNOWS WHERE TO GET THEM]** Do you have any at-home COVID-19 tests currently in your household?
  - o **IF YES**, Where did you get your at-home COVID-19 tests? **IF NEEDED**, Did you get free tests in the mail or from your library, did you buy your tests, get them some other way, or any combination of these?
    - **IF BOUGHT**, How did you decide which brand of at-home COVID-19 tests to buy? **IF NEEDED**, Did you consider the brand, the price, or any other factors?

## FOR ALL PARTICIPANTS

What questions do you have about at-home COVID-19 tests?

If there was a website that listed the various at-home COVID-19 tests available on the market, what information about each test would you want to find on that website?

Have you heard anything about at-home COVID-19 tests expiring? **IF NEEDED**, What have you heard?

Now I am going to share my screen with you. Do you see a page titled “[At-Home OTC COVID-19 Diagnostic Tests](#)?” This is a page on FDA’s website. Please take a few minutes to read it now **without clicking on anything**. I will give you control of the screen so you can review at your own pace. **[HAND CONTROL TO PARTICIPANT]** When you finish, I will ask you some questions about the information.

**CHECK IN AFTER 2 MINUTES. ALLOW 1 MORE MINUTE IF NEEDED.**

**IF RESPONDENTS NAVIGATE AWAY, DIRECT THEM BACK TO THE PAGE FOR NOW AND INFORM THEM THAT THEY MIGHT LOOK AT OTHER PAGES LATER.**

### **CONCURRENT OBSERVATIONS/INSTRUCTIONS.**

**NOTE ANY OF THE FOLLOWING BEHAVIORS TO RECORD IN NOTES OR PROBE ON RETROSPECTIVELY:**

- Any verbal reaction to statements in the information.
- Any verbal expressions of confusion, surprise, discomfort, offense. Note which statements evoked any of these reactions.

## List of Diagnostic Tests Page

**TO BE ADMINISTERED AFTER RESPONDENT COMPLETES HIS/HER REVIEW.**

In your own words, what is the overall, main message of what you’ve just read?

- What is it asking you to do?
- Why do you think FDA is telling you this information?

What are your overall thoughts about this webpage?

What do you like about it and why?

What don’t you like and why?

Is there too little or too much information and why?

- **IF TOO LITTLE**, What other information would you have liked to see? Where on the page should that information go?
- **IF TOO MUCH**, What information seems unnecessary?

How easy or difficult is it to understand the information?

- Are there any words or phrases that confuse you or that you aren’t sure of? **IF NEEDED**, How could that be stated more clearly?

Overall, what are your thoughts on the way this webpage is organized?

- **IF NEEDED**, More specifically, what are your thoughts on the way the table is organized?

Let's take a closer look at each column of the table.

- For the first column:
  - o How helpful are the images and why?
  - o **IF NEEDED**, What would you do if you wanted to learn more about any of these tests?
  - o Some tests have an alternate brand listed. What does that mean to you?
- Looking at the second column, what questions do you have about the information for who can use this test? **IF NEEDED**, What questions do you have about the tests being used by people both with or without symptoms?
- In the middle column, "Who can use this test: Age", how useful is the information?
  - o **FOR PARENTS OF CHILD(REN) (FROM SCREENER)** How old are your children, and how many of these tests does it look like they can use?
    - **IF PARENT OF CHILD UNDER 2 WOULD USE ANY TEST**: What makes you say that? **IF NEEDED**, The table indicates that most tests should only be used for children 2 years and older. How could that be stated more clearly?
    - **IF PARENT OF CHILD 2 TO 17**: Would you help your child use the test? Why is that?
- What questions do you have about the information in the column titled "Other Details"?
  - o It indicates that some tests are antigen tests and others are molecular tests. What does this mean to you? **IF NEEDED**, What additional information about this difference would be helpful to add?
  - o **IF NEEDED**, Are there any words or phrases that confuse you or that you aren't sure of in this column?
- The column to the far right "Expiration Date" mentions the shelf life and expiration dates of each test. What questions do you have about this information?
  - o If you had a BinaxNOW Ag Card Home Test [**the first one listed**] and the package indicated it expired on November 6, 2022, what would you do? **LISTEN FOR: throw it away, look to see if the expiration date had been updated, etc.**
    - If I told you the lot number of your test was 174292A, can you show me how you would look to see if the expiration date had been extended?
- If you wanted to search this table, how would you do that? **IF NEEDED**, Each of the column headers in the table has little arrows beside them. How useful are those arrows?
  - o How else could this table be made easier to search or scan?

After reading this webpage, what new information have you learned about at-home COVID-19 tests?

Does anything you've read on this webpage concern you? Why is that?

How useful is this webpage to you?

- Which parts are most useful to you?
- Which parts are the least useful to you?

What additional questions do you have after reading this webpage?

After reading this webpage, what would you do? **IF NEEDED**, Ignore it, share it, buy certain tests but not others, etc.

Now I am going to share a different page with you from FDA's website. Do you see a page titled "[At-Home COVID-19 Diagnostic Tests: Frequently Asked Questions?](#)" Please take a couple minutes to read it now. I will give you control of the screen so you can review at your own pace. **[HAND CONTROL TO PARTICIPANT]** When you finish, I will ask you some questions about the information.

**CHECK IN AFTER 2 MINUTES. ALLOW 1 MORE MINUTE IF NEEDED.**

**IF RESPONDENTS NAVIGATE AWAY, DIRECT THEM BACK TO THE PAGE.**

## FAQ Page (As Time Allows)

**TO BE ADMINISTERED AFTER RESPONDENT COMPLETES HIS/HER REVIEW.**

What are your overall thoughts about this webpage?

What are your thoughts on the way this webpage is organized?

Are these the questions you would want answers to if you were thinking about using an at-home COVID-19 test? **IF NO**, What questions would you want answered?

- Which question would you click on first? Why?
- Were there any answers that did not address the question as completely as you would have expected or that raised additional questions or concerns?
- Are there any questions that you think are NOT needed or can be removed? **IF YES**, Which questions and why do you think they are unnecessary?

How easy or difficult is it to understand the information?

- Are there any words or phrases that confuse you or that you aren't sure of? **IF NEEDED**, How could that be stated more clearly?

After reading this webpage, what new information have you learned about at-home COVID-19 tests?

## **WRAP-UP**

Do you have any other suggestions for improving either webpage I shared with you today?

**PROBE ON ANY OUTSTANDING ISSUES FROM OBSERVATION (INFORMATION THAT RESPONDENT SEEMED CONFUSED ABOUT).**

## **CLOSING**

**IF OBSERVERS ARE PRESENT, CHECK TO SEE IF THEY HAVE FURTHER QUESTIONS.**

Those are all the questions I have for you. Is there anything else you would like the FDA to know about these webpages or communicating about at-home COVID-19 tests?

**DISCUSS ANY RESPONDENT COMMENTS.**

Thank you for your time.

**STOP TAPE RECORDER.**