

**ASSENT FORM  
FOR CHILD PARTICIPANTS AGES 7 TO 13 YEARS**

**Sponsor / Study Title:** MP Biomedicals, LLC / "Over the counter Rapid Antigen Test for detection of SARS-CoV-2 virus: Clinical Evaluation"

**Protocol Number:** EDP-SOP-TNC-014

**Principal Investigator:  
(Study Doctor)** «PiFullName»

**Telephone:** «lcfPhoneNumber»

**Address:** «PiLocations»

You are being asked to be in this research study to help determine the usability of a study test. This form explains the study. After reading this form, you can decide to be in the study, or you can decide not to be in the study. Either choice is okay. If you decide to start the study and then change your mind, you can stop being in the study at any time.

Please ask the study doctor or study staff to explain anything you do not understand. They will answer all the questions you have. You can ask questions about the study at any time.

If you want to talk to the study doctor alone please ask.

**WHAT IS THIS RESEARCH STUDY ABOUT?**

The study doctor is studying a study test for COVID-19, called the Rapid SARS-CoV-2 Antigen Test. The study doctor wants to learn more about this study test and to see if it is safe and helpful for children who might have COVID-19.

About 30 children will be asked to be in this study.

**WHAT WILL HAPPEN TO ME IN THIS RESEARCH STUDY?**

If you want to be in the study, here is a list of things that will happen:

- You will have one visit for the study.
- You will be in the study and you will use the study COVID-19 test for one visit.
- Your parent(s)/legal guardian(s) will collect one shallow swab about half an inch into each nostril for 15 seconds each.
- The study staff will collect one deeper nasopharyngeal swab to obtain a sample from the back of your nose.

- Your sample will be stored for future research unless your parent(s)/legal guardian(s) ask for it be thrown away.

### **WHAT SIDE EFFECTS WILL THERE BE?**

This study COVID-19 test may cause unwanted things to happen. These unwanted things are called “side effects.” Some side effects could be uncomfortable, make you feel sick, or hurt. Some side effects are not known yet. Here are some side effects that you might have while you are in the study:

- The swab may irritate (bother) the inside of your nose and make your eyes water.
- Swabbing too deep may cause nose bleeds.
- You may feel a small amount of pain if your nose is already sore or irritated when swabbing your nose.

Tell your parent(s)/legal guardian right away if you do not feel well or think you might have a side effect.

### **WILL YOU GET BETTER IF YOU ARE IN THE STUDY?**

We do not know if you will get better if you are in the study. The study COVID-19 test being studied may or may not detect COVID-19. Other children who have COVID-19 may be helped in the future.

### **WILL WHAT I SAY BE KEPT PRIVATE?**

What you tell the study doctor or anything else about you may be written down. What is written down about you will be seen by the study doctor, and other people who run and manage the study. People who make sure that the study is being done the right way may also see it. If the information about the study is sent anywhere else, it will not have your name on it.

What the study doctor learns about you may also be shared with your parents or legal guardian.

### **WHAT IF I DON'T WANT TO BE IN THIS STUDY?**

You do not have to be in the study if you do not want to. You can also decide to start the study now and then stop being in it at any time. No one will be mad at you if you decide not to be in the study or decide to stop being in it later. Your regular doctor will still take care of you.

## STATEMENT OF ASSENT

I would like to be in this study.

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Printed Name of Child Participant (required if 7-13 years or older)

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Child Assent Signature (required if 7-13 years or older)

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Date

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Age

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Printed Name of Person Obtaining Assent

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Signature of Person Obtaining Assent

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Date

Study ID #: MPB-014-\_\_\_\_\_

(same study ID # assigned to all forms associated with a single Rapid SARS-CoV-2 Antigen Test)