

FACT SHEET FOR RECIPIENTS

Emergency Use of Tiger Tech COVID Plus Monitor During the COVID-19 Pandemic

March 19, 2021

Coronavirus
Disease 2019
(COVID-19)

You are being given this Fact Sheet because your screener is using the Tiger Tech COVID Plus Monitor ("Tiger Tech Monitor," in short) to help prevent exposure to and spread of SARS-CoV-2, the virus that causes COVID-19. Tiger Tech Monitor checks if you have certain biological markers (that is, biomarkers) in your blood flow. It is another screening step that is conducted after your temperature check showed that you did not have a fever because not all SARS-CoV-2 infected individuals have a fever. Like thermometers, the Tiger Tech Monitor is **not** a diagnostic test. So, it will not diagnose if you are infected with the SARS-CoV-2. Rather, it will only indicate if you are demonstrating certain biomarkers. These biomarkers may be indicative of SARS-CoV-2 infection or other conditions (such as severe allergic reactions).

This Fact Sheet contains information to help you understand the risks and benefits of using the Tiger Tech Monitor to screen you for certain biomarkers.

For the most up to date information on COVID-19, please visit the CDC Coronavirus Disease 2019 (COVID-19) webpage:

<https://www.cdc.gov/COVID19>

What is COVID-19?

COVID-19 is a disease caused by the SARS-CoV-2 virus. The virus, which can cause mild to severe respiratory illness, was first identified in Wuhan, China, and has now spread globally, including the United States. The current information available to characterize the spectrum of clinical illness associated with COVID-19 suggests that symptoms include cough, shortness of breath or difficulty breathing, fever, chills, muscle pain, headache, sore throat, or loss of taste or smell.

What is the Tiger Tech Monitor?

The Tiger Tech Monitor is an armband with light sensors and a tiny computer processor inside. The sensors obtain signals from the blood flow. The computer then

analyzes the signals (waveforms) and predicts if you are exhibiting certain biomarkers.

How does the Tiger Tech Monitor work?

During use, the Tiger Tech Monitor is wrapped around your bare left arm above the elbow, with the sensors facing the outer side of your upper arm. You must sit still for 3-5 minutes. Once the measurement is completed, a "red light," "green light," or "blue light" will light up, telling you the screening result. The meanings of these lights are explained below.

What does a "red light" mean?

A "red light" means that you are exhibiting certain biomarkers. Like when you are having a fever or other COVID-19 symptoms, you should self-isolate and/or go to a COVID-19 testing site for diagnostic testing, if needed. You should also consult with your healthcare provider.

If you have an underlying condition (such as disseminated intravascular coagulation, sepsis, or cancer) that makes your blood at increased risk of clotting, or another type of hyper-inflammatory state (such as severe allergic reactions), your condition may also lead the Tiger Tech Monitor to display a "red light." If you receive a "red light" indicator from the Tiger Tech Monitor, you might consider consulting with your healthcare provider about your health conditions. When you talk to your healthcare provider, show him/her this fact sheet so that they can better understand how this device works and what the "red light" indicator means. Your healthcare provider may decide to refer you for diagnostic testing.

What does a "green light" mean?

A "green light" means you are not exhibiting certain biomarkers. However, a "green light" does not mean that you are not infected with the SARS-CoV-2 virus. You should continue to wash your hands often, wear a face covering in public, and practice social distancing.

How can I learn more? The most up-to-date information on COVID-19 is available at the CDC General

Webpage: <https://www.cdc.gov/COVID19>. In addition, please also contact your healthcare provider with any questions/concerns.

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What does a “blue light” mean?

A “blue light” means the measurement is inconclusive and that you will need to be measured a second time. If the second measurement still gives a “blue light,” you should treat the blue light as a green light, and continue to wash your hands often, wear a face covering in public, and practice social distancing.

You have the option to refuse this product.

What are the known and potential risks and benefits of the Tiger Tech Monitor?

Known and potential benefits of the Tiger Tech Monitor include:

- Improving ability to potentially identify asymptomatic cases of COVID-19 compared to temperature check alone

Known and potential risks of the Tiger Tech Monitor include:

- Giving an incorrect “red light” in individuals without current SARS-CoV-2 infection (about 6 out of 100 times in one study) or an incorrect “green light” in individuals with current SARS-CoV-2 infection (about 2 out of 100 times in one study)

When used in accordance with the Instructions for Use, the potential benefits of using the Tiger Tech Monitor are expected to outweigh the potential risks during the COVID-19 pandemic.

Warning statements for the Tiger Tech Monitor

- The Tiger Tech COVID Plus Monitor is **NOT** a diagnostic device, and must not be used to diagnose or exclude SARS-CoV-2 infection.
- Use of the Tiger Tech COVID Plus Monitor in an asymptomatic population is intended to be part of an infection control plan that includes uses of a

thermometer. A “red light” indicator from the Tiger Tech COVID Plus Monitor does not necessarily indicate current SARS-CoV-2 infection. Instead, it is only an indication – like a fever – that a person is demonstrating certain biomarkers of certain conditions, such as hypercoagulation, that may be associated with SARS-CoV-2 infection. As such, this device is only for use as a preventative screening tool.

Is the Tiger Tech Monitor FDA-approved or cleared for screening for possible SARS-CoV-2 infection?

No. The Tiger Tech Monitor is not approved or cleared by the FDA for screening asymptomatic individuals for certain biomarkers. FDA has authorized the use of the Tiger Tech Monitor through an emergency access mechanism called an Emergency Use Authorization (EUA).

What is an EUA?

This EUA is supported by the Secretary of Health and Human Service’s (HHS’s) declaration that circumstances exist to justify the emergency use of medical devices during the COVID-19 pandemic. The Tiger Tech Monitor available under this EUA has not undergone the same type of review as an FDA-approved or cleared device. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, or available alternatives. In addition, the FDA decision is based on the totality of scientific evidence available demonstrating that it is reasonable to believe that the Tiger Tech Monitor, when used by trained personnel, may be effective at preventing exposure to and spread of SARS-CoV-2 by identifying certain biomarkers in asymptomatic individuals over the age of 5, when performed following a temperature reading that does not meet the criteria for fever in settings where temperature check is being conducted in accordance with CDC and local institutional infection prevention and control guidelines.

The EUA for the Tiger Tech Monitor is in effect for the duration of the COVID-19 declaration justifying

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emergency use of the product, unless terminated or revoked (after which the product may no longer be used for the emergency use).

How can I learn more?

CDC websites:

General: <https://www.cdc.gov/COVID19>

FDA websites:

General: www.fda.gov/novelcoronavirus

EUAs: <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations>

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www.tigertech.solutions

www.covidplusmonitor.com

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Phone: (800) 557-5138

Email: support@covidplusmonitor.com

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