FACT SHEET FOR USERS

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

March 19, 2021

This Fact Sheet informs you of the significant known and potential risks and benefits of the emergency use of the Tiger Tech COVID Plus Monitor ("Tiger Tech Monitor," in short). The Tiger Tech Monitor is authorized for emergency use by trained personnel to help prevent exposure to and spread of SARS-CoV-2, the virus that causes COVID-19, 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 Centers for Disease Control and Prevention (CDC) and local institutional infection prevention and control guidelines.

The Tiger Tech Monitor is **not a diagnostic screening tool**. Diagnostic tests should be used instead to detect the SARS-CoV-2 virus. Please refer to CDC's COVID-19 testing recommendations on when individuals should receive a diagnostic test at the CDC website listed at the end of this document.

All recipients who are screened with the Tiger Tech Monitor should receive the Fact Sheet for Recipients regarding this device.

Where is the Tiger Tech Monitor authorized to be used for COVID-19 screening?

The Tiger Tech Monitor is only authorized to be used in settings where temperature checks are being performed to screen asymptomatic individuals for potential SARS-CoV-2 infection in accordance with CDC and local institutional infection prevention and control guidelines. See CDC's website for example:

- https://www.cdc.gov/coronavirus/2019-ncov/community/guidance-business-response.html#anchor_1609683211941
- https://www.cdc.gov/coronavirus/2019-ncov/community/schools-childcare/symptom-screening.html

What do I need to know about COVID-19 and COVID-19 screening?

Current information on COVID-19 for healthcare providers, including case definitions and information about clinical signs and symptoms and/or epidemiological criteria is available on the CDC website listed at the end of this document.

COVID-19 non-diagnostic screening, such as through temperature checks, is an important tactic that can help proactively identify individuals who may be infected with the SARS-CoV-2 virus, which may help control the exposure to and spread of the virus. Non-diagnostic screening is commonly performed at places such as schools, workplaces, healthcare facilities, theme parks, stadiums, and airports.

What is the Tiger Tech Monitor?

The Tiger Tech Monitor is an armband with embedded optical sensors and a processor. During use, the armband is wrapped around the recipient's bare left arm above the elbow. The sensors acquire biosignals from the recipient's left outer bicep over a period of 3-5 minutes. The processor first extracts a series of morphological features ("biomarkers") from the pulsatile signals, which have been correlated with certain biomarkers of certain conditions, such as hypercoagulation (i.e., a condition where a person's blood clots more easily than normal), that may be associated with SARS-CoV-2 infection. The processor then predicts whether the recipient is showing certain signals, such as hypercoagulation in blood. The prediction requires roughly 2 minutes of motionless (artifact-free) data. The prediction result is shown in the form of a "red light," "green light," or "blue light." The meanings of these lights are explained later in this fact sheet.

A head-to-head comparison between the Tiger Tech Monitor predictions and reverse transcription polymerase chain reaction (RT-PCR) diagnosis results in asymptomatic individuals in two different studies are summarized below:

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Study #1: A Hospital Setting

Tiger Tech Results / RT-PCR Results	Positive	Negative
Positive	68	1
Negative	22	376

The results of Study #1, which was considered a validation stdy, demonstrated that the Tiger Tech Monitor could achieve a point estimate of the positive percent agreement (PPA; proportion of the COVID-19 positive individuals identified correctly by the Tiger Tech Monitor to demonstrate certain biomarkers) of 98.6% and the negative percent agreement (NPA; proportion of the COVID-19 negative individuals identified correctly by the Tiger Tech Monitor to not demonstrate certain biomarkers) of 94.5%.

Study #2: A K-12 School Setting

Tiger Tech Results / RT-PCR results	Positive	Negative
Positive	7	0
Negative	0	412

Study #2 was a confirmatory study. The results of Study #2 demonstrated that a point estimate of the PPA and NPA of 100%, respectively, of the Tiger Tech Monitor.

What does a "red light" mean?

A "red light" indicates that the recipient is exhibiting certain biomarkers of certain conditions, such as hypercoagulation in blood. The recipient should be directed per established CDC and local institutional infection prevention and control guidelines for individuals having a fever (e.g., quarantine, COVID-19 testing). The recipient should also consult with their healthcare provider.

Note that an individual's underlying hypercoagulable condition (such as disseminated intravascular coagulation, sepsis, or cancer) or other hyper-inflammatory states (such as severe allergic reactions)

may also lead the Tiger Tech Monitor to display a "red light." Direct the recipient to consult with their healthcare provider.

What does a "green light" mean?

A "green light" indicates that the recipient is not exhibiting certain biomarkers of certain conditions, such as hypercoagulation in blood. The recipient should be directed per established CDC and local institutional infection prevention and control guidelines for individuals having a temperature reading that does not meet the criteria for fever (e.g., mask wearing, social distancing).

What does a "blue light" mean?

A "blue light" indicates that the measurement is inconclusive due to indeterminate features. The user should turn the device off, remove it from the recipient, wait 5 minutes, and try a second time. If the second attempt is still a "blue light," the recipient should be directed per established institutional infection control and protection guidelines for individuals having a temperature reading that does not meet the criteria for fever (e.g., mask wearing, social distancing).

How is the Tiger Tech Monitor used in the screening process at a point of admittance?

The Tiger Tech Monitor is only authorized to be used by trained personnel following a temperature reading that does not meet the criteria for fever when performed in accordance with CDC and local institution infection prevention and control guidelines. It should **NOT** be used to replace temperature checks; rather it should only be used on asymptomatic individuals over the age of 5 who had a temperature reading that does not meet the criteria for fever (less than 100.4 °F, or 38 °C).

What are the known and potential benefits and risks 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

The Tiger Tech Monitor has been designed to minimize risks of false predictions with its use. However, 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.

How should the Tiger Tech Monitor be cleaned between uses?

The Tiger Tech Monitor should be sanitized after each use using at least 70% alcohol wipes.

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.

What is an Emergency Use Authorization (**EUA)?**

The United States FDA has authorized the emergency use of the Tiger Tech Monitor to be used by trained personnel to help prevent exposure to and spread of SARS-CoV-2 by identifying certain biomarkers in asymptomatic individuals over the age of 5 under an emergency access mechanism called an EUA. The 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 use of the Tiger Tech Monitor 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, 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 emergency use of these devices, unless terminated or revoked (after which the products 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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