Version 1

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ThEA Direct Swab V.1

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Ram Global XPRIZE Rapid Covid Testing

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ABSTRACT

RAM Group has developed ThEA™ - an optical, reagent free / chemical free detection system for rapid diagnosis for SARS-Cov-2. The system consists of a THz spectrometer, a low-cost disposable sensor cartridge and a set of classification algorithms. ThEA's < 60s detection time allows rapid screening at the point of sample collection or quick-turnaround batch processing from a central location. The primary goal of the current study is to clinically validate the ThEA classification algorithm. This can be accomplished by testing several patient samples at the point of collection in a controlled environment. The key learning outcomes of this study will be determining how well the ThEA classification algorithm is able to identify SARS-Cov-2 features from the THz data collected from patient. The classification accuracy will in turn be evaluated by cross checking versus PCR control tests done by the institution for the same patient cohort.
The test includes taking an oropharyngeal swab from the patient and directly smearing it on the sensor surface followed by reading out the THz response in a THz time domain spectrometer. ThEA analysis software with classification algorithm will then be able to classify whether the sample is infectious with Sars-Cov-2 virus or not.

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GUIDELINES

Temperature and humidity can affect the sample THz measurements. A temperature and humidity logger will be connected to the PC, and a reference measurement will be taken before every sample measurement to record the external conditions. Hourly measurement of Air and Substrate spectrum will help track environmental variability in the measurements. Swab collection can have an effect of creating variability in the direct smear pattern as well and must only be done by a trained medical professional.

a. Both positive and negative samples should be treated equally during sample preparation procedure. For e.g. if the negative samples are collected from healthy volunteers and positive samples are collected from people already known to have infection, there should not be any bias during sample collection, preparation or during measurement. The exact protocol must be followed for all participants.

b. The order for measurement for positive and negative should be fully randomized. For e.g. if all positive measurements are done in one session and negatives in another session this can create a bias. Similarly, where possible, it is also important to randomize the positive patient selection and not to take measurements in continuously increasing or decreasing order of CT values.

MATERIALS TEXT

MATERIALS

KleenGuard™ A20 Breathable Particle Protection Lab Coats **Thermo**

Fisher Catalog #01349C

Advanced Protection Disposable Facemasks, Advanced protection; Blue; Ear loops **Thermo**

Fisher Catalog #17100897

Comfort Nitrile Gloves, Small **Thermo**

Fisher Catalog #19041171B

COPAN ESwab™, Regular Flocked Collection Kit **Thermo**

Fisher Catalog #R723480

Deionized Water **Contributed by users**

SAFETY WARNINGS

Personnel risk – safety, working with infectious substances and waste. These risks will be managed according to local rules by the qualified medical professionals at the testing institution/ Lab.

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BEFORE STARTING

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Make sure that the THz analyzer is placed on a sturdy table or fumehood. Make sure that all local safety guidelines are followed. Start the analyzer according to the instruction manual. Make sure that the temperature and humidity logger is connected to the system.

Initialization 3m

1 Start the temperature, humidity logger and bar code scanner. 1m

Room temperature **The entire experiment runs at room temperature**

2 Initialize measurement, data logging software (ThEA measurement) and analysis (ThEA Analysis) software. 1m

Calibration 2m

3 Take a measurement of air and save to DB, i.e. no sample in beam optical path (once per hour) **– Air spectrum.** 40s

4 Scan the barcode and take a measurement of the calibration cartridge provided - **Substrate spectrum**, once per hour just after Air measurement in previous step and save to DB. 40s

4.1 Insert the calibration cartridge in the cartridge holder and press 'Substrate'

4.2 Keep the calibration cartridge in its original packaging for future use.

Measurement 2m 30s

5 Enter the metadata of the patient sample under test in the ThEA measurement software. Enter details about sourcing pts, traceability, agree to follow up etc without compromising personal information. Scan the barcode of the 'ThEA Rapid' cartridge to be used. 40s

6 Take a measurement of the bare sensor – **Reference spectrum,** for *every* patient sample to be performed. 40s

6.1 Insert the cartridge in the cartridge holder and press 'Reference'

7 Take an oropharyngeal swab and smear on the sensor surface two times in an 'x' pattern. 30s

8 Take a measurement of the sensors and save to DB– **Measurement spectrum**. 40s

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8.1 Insert the cartridge in the cartridge holder and press 'Measurement'

9 Open 'ThEA' analysis software and load 'Reference' file followed by 'Measurement' file and press 'Analyze' 20s

9.1 Result is displayed on the screen. Possible outcomes are: 'Positive', 'Negative', 'Inconclusive'.

10 Dispose of the one-time use sensor and the swab.

Follow local rules for disposal

If Inconclusive 4m

11 Take a new oropharyngeal swab

12 Repeat step 5 to 10 using 'ThEA Advanced' cartridge. **go to step #5**

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