KinisiForo
SYSTEM OF ELLIPTICAL TRAINING

CovBELD
For Rapid Detection of SARS-COV-2
For Professional Use Only
For In Vitro Diagnostic Use Only

CovBELD:

CovBELD (Coronavirus BELD) comprises a screen-printed electrode, biosensor and BELD measuring instrument. Screen-printed electrodes and biosensor are to be used with the BELD instrument for the required test. The BELD instrument is a point of care system for professional use which is used for in vitro diagnostic tests. This test is for **HEALTHCARE PROFESSIONAL USE ONLY** and allows users to perform tests using small sample volumes and to view results quickly. CovBELD displays the test results (Positive or Negative) on a mobile application (Android and iOS) irrespective of the test subject's location based on EU regulations on the Instrument touchscreen.

Intended Use:

The CovBELD (Coronavirus BELD) test is a cell-based assay that is used with the BELD instrument intended for the qualitative detection of the S1 spike protein antigen from SARS-CoV-2 in nasopharyngeal (NP) and nasal (NS) swab specimens after the swabs have been added to viral transport media from individuals who are suspected of COVID-19 by their healthcare provider.
Results are related with the identification of SARS-CoV-2 S1 spike protein antigen. Antigen is generally detectable in upper respiratory specimens during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease.
Negative results should be treated as presumptive and confirmed with a molecular assay, if necessary, for patient management. Negative results do not rule out COVID-19 and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be considered in the context of a patient's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19.
The CovBELD test is intended for use by trained clinical laboratory personnel and individuals trained in point of care settings, and proficient in performing tests using the BELD Instrument.
Caution: For in Vitro diagnostic Use.

	Before you start testing, if you are new to the CovBELD, BELD device and software, you must read this entire Product Insert and BELD device user manual. In addition, please watch the Training Video. All these materials are available at EMBIO Diagnostics website.

Summary and explanation of the test:

The World Health Organisation (WHO) have named the disease caused by SARS-CoV-2 virus as coronavirus 2019 or COVID-19. The most common symptoms of COVID-19 are fever, tiredness, and dry cough. Some patients may have aches and pains, nasal congestion, headache, conjunctivitis, sore throat, diarrhoea, loss of taste or smell, or a rash on skin or discoloration of fingers or toes. These symptoms are usually mild and begin gradually. Some people become infected but do not develop any symptoms and do not feel unwell. However, the disease can develop rapidly and have high morbidity in certain populations, especially those with underlying health conditions. The disease can spread from person to person through small droplets from the nose or mouth which are spread when a person with COVID-19 coughs or exhales. Most estimates of the incubation period for COVID-19 range from 2-14 days.
The use of a CovBELD Test will enable the physician to verify infection quickly, begin proper treatment and to initiate isolation precautions helping prevent further spread of infection.

Principle of the test:

The CovBELD is used to monitor the response on cells that are modified to target SARS CoV-2 antigen detection. The antibodies of S1 protein are insert on the cells and the detection is read on the online application, which receives the analysis from cloud.

Materials Provided:

- BELD Device.
- Disposable electrodes.
- Biosensors.
- CovBELD Test product insert.
- BELD device quick reference instructions.

Materials required but not provided

- Viral Transport Medium (VTM). According to CDC PREPARATION OF VIRAL TRANSPORT MEDIUM.
- Micropipettes (20 µL or 200 µL).
- Standard nasal swab and nasopharyngeal swab collection equipment.

Warnings and precautions

- For in vitro diagnostic use.
- Do not use the biosensors beyond the expiration date.
- Use appropriate precautions in the collection, handling, storage, and disposal of patient samples.
- Use of Nitrile, Latex (or equivalent) gloves is recommended when handling patient samples.
- Do not reuse the used Test electrode.
- The user should never open the biosensors tube exposing it to the ambient environment until is ready for immediate use.
- If the biosensor solution contacts the skin or eye, flush with copious amounts of water.
- To obtain accurate results, the Package Insert instructions must be followed.
- Inadequate or inappropriate sample collection, storage, and transport may yield false test results.
- Sample collection and handling procedures require specific training and guidance.
- To obtain accurate results, use the Viral Transport Media (VTM).
- Use the appropriate Fixed Volume Pipette in accordance with test procedures.
- To obtain accurate results, do not use visually bloody or overly viscous samples.
- To obtain accurate results, the test should not be used inside a laminar flow hood or in a heavily ventilated area.
- Testing should be performed in an area with adequate ventilation.
- Dispose of containers and unused contents in accordance with Local regulatory requirements.
- Wear suitable protective clothing, gloves, and eye/face protection when handling the contents of this kit.
- Wash hands thoroughly after handling.

Kit storage and stability

Store the kit at 4 ^{o}C temperature. On the day of the test let the biosensors and samples warmed to room temperature. Cold samples can lead to erroneous or invalid results.

Handling the Disposable electrodes:

When you are ready to perform a test, open the carton, take out a electrode, do not use the electrode if there are any visible signs of damage.

Sample material:

The following samples can be used with the CovBELD:

- Nasal Swab Sample (NS).
- Nasopharyngeal Swab Sample (NP).

Preparing to perform a Test:

Sample collection and handling

SAMPLE COLLECTION

Nasal Swab Sample

To collect a nasal swab sample, carefully insert the swab into the nostril that presents the most secretion under visual inspection. Using gentle rotation, push the swab until resistance is met at the level of the turbinates {less than one inch into the nostril). Rotate the swab several times against the nasal wall then remove it from the nostril.

Nasopharyngeal Swab Sample

To collect a nasopharyngeal swab sample, carefully insert the swab into the nostril that presents the most secretion under visual inspection. Keep the swab near the septum floor of the nose while gently.

Pushing the swab into the posterior nasopharynx. Rotate the swab several times then remove it from the nasopharynx.

Sample Transport and Storage

Samples should be tested as soon as possible after collection. Based on data generated with influenza virus, nasal or nasopharyngeal swabs are stable for up to 24-hours at room temperature or 2° to 8°C.

If transport of samples with viral transport medium {VTM) is required, minimal dilution of the sample is recommended, as dilution may result in decreased test sensitivity. Whenever possible, 1 milliliter or less is best to avoid excessive dilution of the patient sample. While holding the swab, remove the cap from the tube. Insert the swab into the tube until the breakpoint is level with the tube opening. Bend the swab shaft at a 180 degrees angle to break it off at the breaking point. You may need to gently rotate the

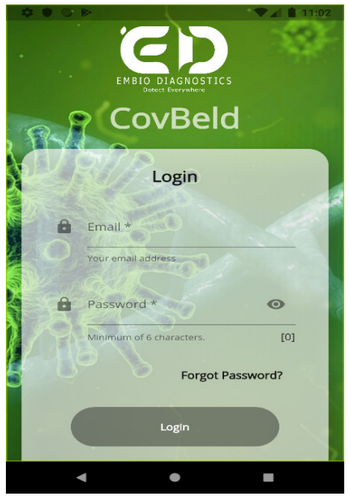
swab shaft to complete the breakage. Based on data generated with influenza virus, nasal or nasopharyngeal swabs in VTM are stable for up to 72-hours at 2° to 8C.

Note: When using viral transport medium {VTM), it is important to ensure that the VTM containing the sample is warmed to room temperature. Cold samples can lead to erroneous or invalid results. Several minutes will be required to bring a cold sample to room temperature.

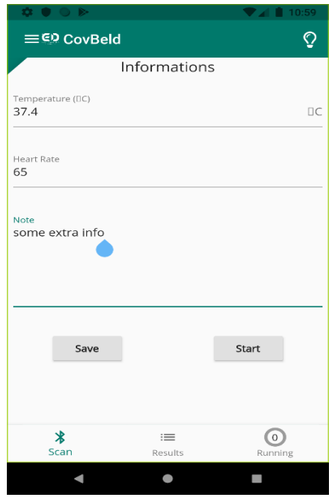
Performing Test

A. Connect the screen-printed electrode with the device and turn on the device

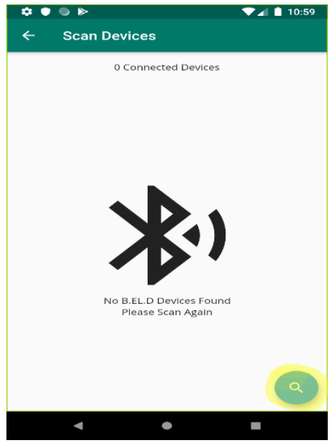
B. Turn on Bluetooth, open the application and login

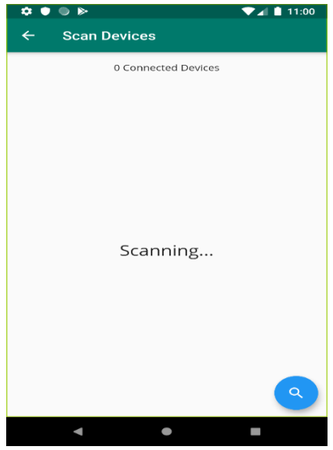


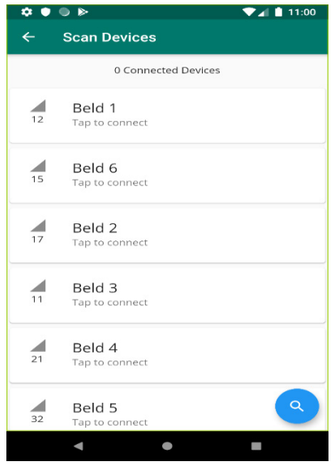
C. Complete the informations and press Start



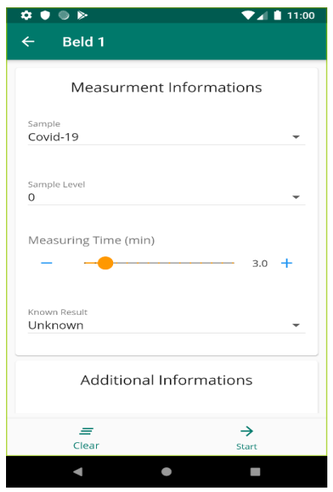
D. From the search command, connect the application with the device





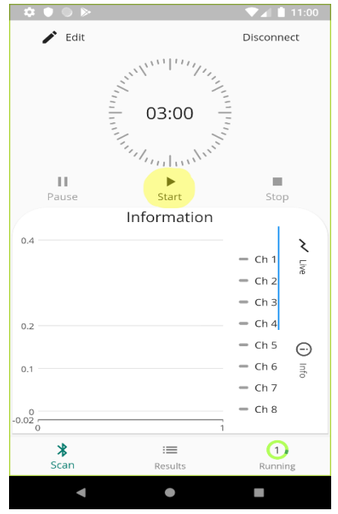


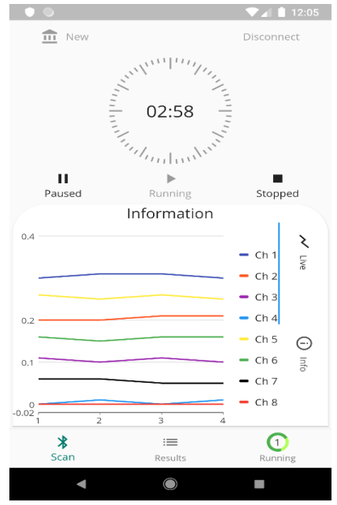
E. Fill the appropriate fields and press Start

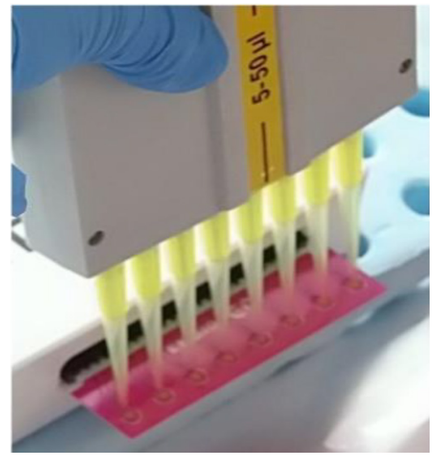


F. START the measurement and then add 20µl of the sample in channels

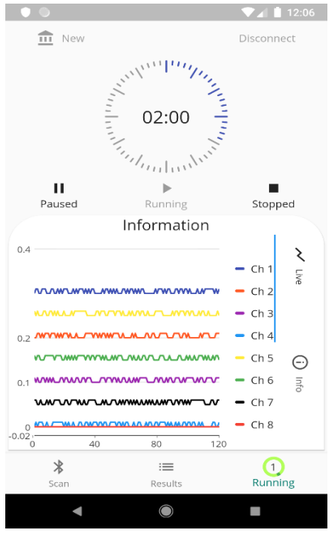
ATTENTION, if the lines on the chart do not appear after pressing the start button do not add the sample. Stop the measurement and start it again. Ensure that the lines are visible in the chart and then add the sample



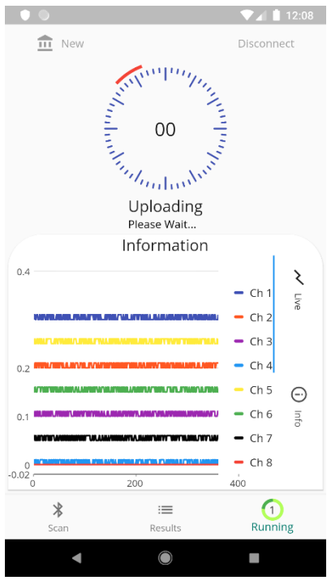




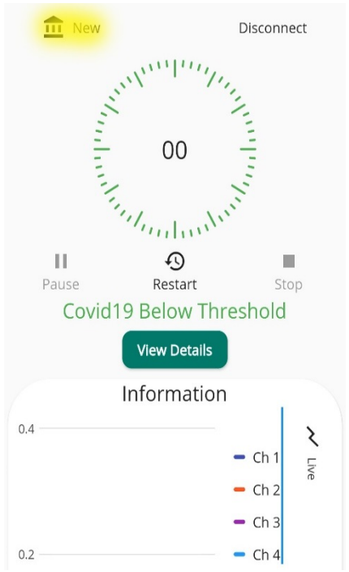
G. The duration of the measurement is 3 minutes, after the pass of the first minute add 20µl of the biosensors in the same channels as previously (final volume in each channel is 40µl).

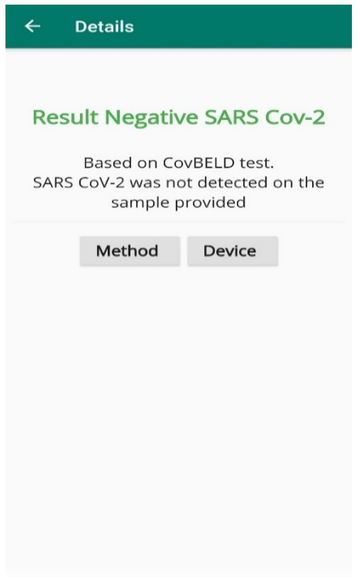


H. After the END of the measurement, the data are uploading automatically.



I. By pressing the "View Details" command a new slide is opening with the details for the result. For a new measurement press NEW and then EDIT the new information for the next sample in order to be ready for a new measurement.





Note: Additional functions may be become available for sharing the information of each test.

Limitations

- The contents of this kit are to be used for the qualitative detection of SARS-CoV-2 S1 spike protein antigen from nasal swab and nasopharyngeal swab.
- Test performance depends on the amount of virus (antigen) in the sample and may or may not correlate with viral culture results performed on the same sample.
- A negative test result may occur if the level of antigen in a sample is below the detection limit of the test or if the sample was collected or transported improperly.
- Failure to follow the Test Procedure may adversely affect test performance and/or invalidate the test result.
- Test results must be evaluated in conjunction with other clinical data available to the physician.
- Positive test results do not rule out co-infections with other pathogens.
- Negative test results are not intended to rule in other non-SARS viral or bacterial infections.
- Negative results should be treated as presumptive and confirmed with an authorized molecular assay based in Directive 98/79/EC, if necessary, for clinical management, including infection control.
- Clinical performance was evaluated with frozen samples, and performance may be different with fresh samples.
- Specimen stability recommendations are based upon stability data from influenza testing and performance may be different with SARS-CoV-2. Users should test specimens as quickly as possible after specimen collection.

Clinical performance

THIRD PARTY VALIDATION

The third-party validation was handled on Faculty of Medicine of University of Thessaly. Since its foundation it has earned a distinguished reputation, nationally and internationally, for its quality of teaching and research. It has been the first faculty established since the opening of the School of Health Sciences at the University of Thessalia, it has been autonomous since 1995 and operating in the city of Larissa.

Due to the limited availability of direct swabs, the clinical performance of the CoVBELD was established with a study using two hundred seven (246) previously characterized frozen NP swabs originally collected in 3-mL viral transport media.

Final data analysis is presented below:

Reference RT-PCR Assay				
CoVBELD		POS	NEG	Total
	POS	102	8	110
	NEG	3	133	136
	TOTAL	105	141	246

Performance Characteristics	**Values**
Accuracy	95,52%
Sensitivity	92,73%
Specificity	97,79%
Positive Predictive Value (PPV)	97,14%
Negative Predictive Value (NPV)	94,32%

Limit of Detection (LoD)

LoD studies determine the lowest detectable concentration of SARS-CoV-2 at which approximately 95% of all (true positive) replicates test positive. To define the lower LOD of the system we used a positive sample that displayed Ct for the E gene when tested with the R-Biofarm kit. The approximate LoD was identified by extracting and testing 10-fold serial dilutions of a characterized positive sample.

The biosensor, based on Vero/anti-S1 cells membrane-engineered was able to give a positive signal when a positive sample with Ct 37 was analyzed which corresponds to a viral concentration of approximately 4 copies / μL or 4 X 10^3 copies / mL.

Symbols glossary

	Temperature limitation
	Manufacturer
	In vitro diagnostic medical device
	Catalogue Number
	Contains sufficient for 12 or 24 or 48 Tests
	"CE Mark ". This product fulfils the requirements of the European Directive 98/79/EC on in vitro diagnostic medical devices.

	Lot Number
	Use-by Date – indicates the date after which the unopened IVD/Quality Control Material cannot be used
	Do not re-use
	Refer to instructions for use

Kinisiforo Ltd customer services:

For product enquiries please contact Kinisiforo Ltd Customer Services at onisiforos@kinisiforoltd.com. Any adverse results experienced with the use of this product, and/or quality problems should also be reported to Kinisiforo Ltd Customer Services by email: onisiforos@kinisiforoltd.com.

For return policy:

Please contact Kinisiforo Ltd Customer Services for terms and conditions.

Limited warranty:

Please contact Kinisiforo Ltd Customer Services for terms and conditions.

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“CE Mark” applies to BELD device, Disposable electrodes and Biosensors.