



BELD USER MANUAL

For *Listeria monocytogenes* detection

USR-01

Issue 2

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Pages: 11

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Materials Supplied in kit

- BELD Device
- Disposable electrodes
- Biosensors

Equipment required (not provided)

- Incubator (30-37°C)
- Micropipettes (20-200 µL, 100-1000 µL)
- Stomacher bags
- LX broth (225 mL / sample) [Biomerieux, ref. 42626]
- Agar Listeria according to Ottaviani and Agosti – Api Listeria Rapid Kit

Sample preparation and handling

SAMPLE TRANSPORT AND STORAGE

For sample transport please store samples in a cool box between 1 and 8°C. Samples should be tested as soon as possible after collection, preferably no later than 24 h after arrival at the laboratory and no later than 36 h after sampling (EN ISO 7218 Standard). The time duration before analysis should be recorded and written in the analysis report.

TEST PROCEDURE

1. Add a test portion of 25 g or 25 mL to 225 mL of selective enrichment broth (LX broth) to obtain a tenfold dilution.
2. Homogenize.
3. Incubate the suspensions at 30°C for 22-24h (**Figure 1**).
4. Test the samples mixing 20 µL of the suspensions with 20 µL of the biosensors (see [Realization of BRaD LMO Test](#) below).
5. In case of **Positive** result, proceed to confirmation tests (**Figure 2**).

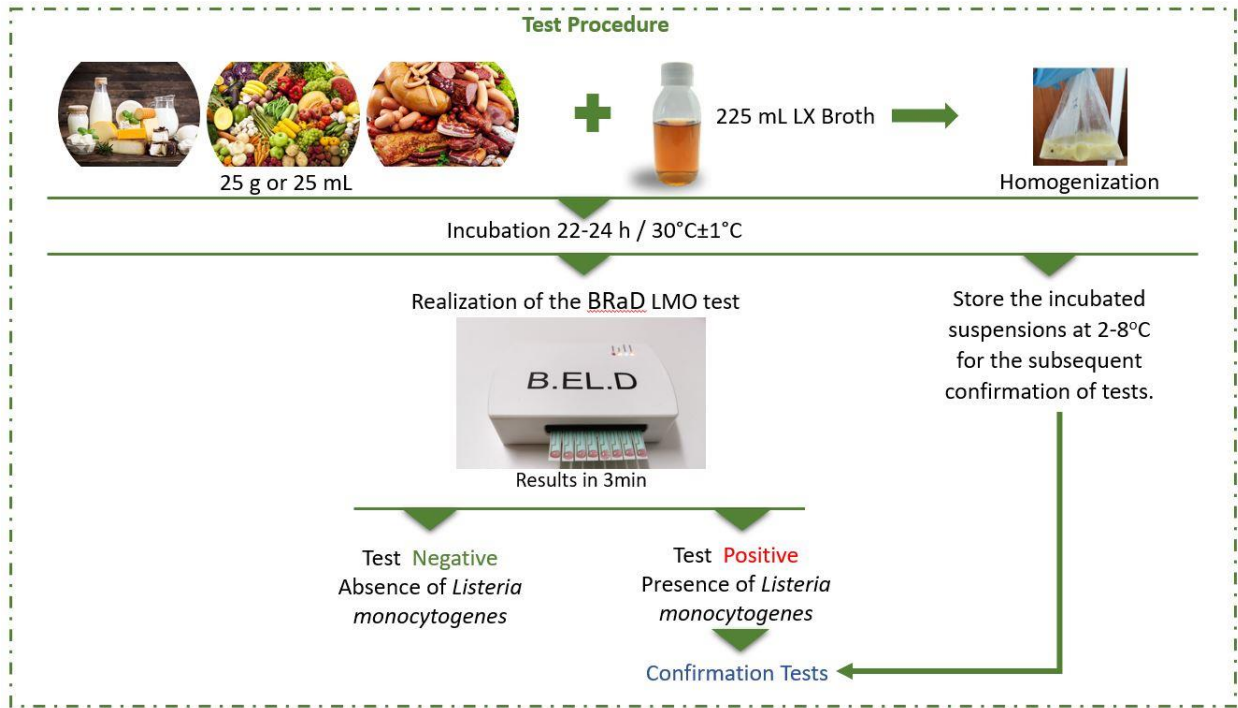


FIGURE 1 TEST PROCEDURE

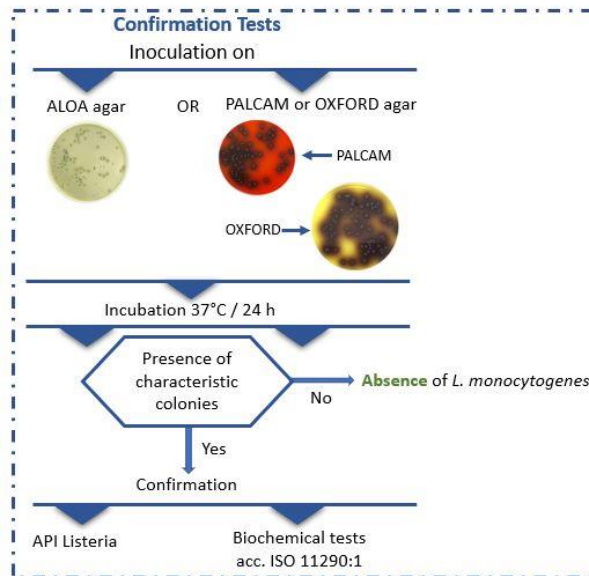
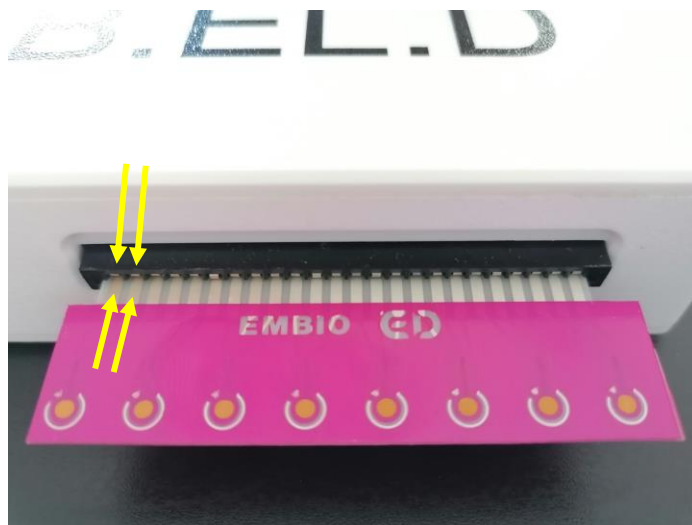


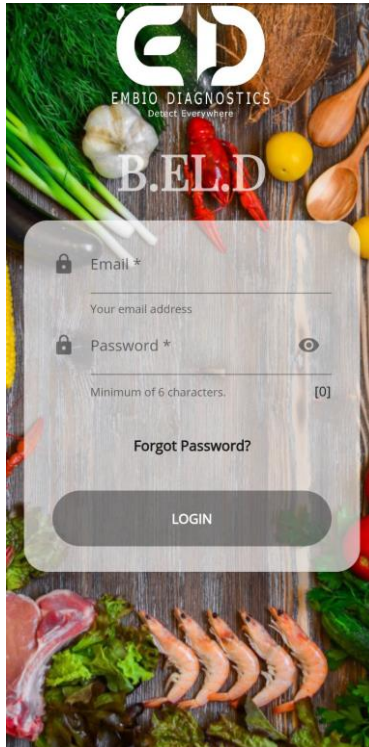
FIGURE 2 CONFIRMATION TEST PROCEDURE

Realization of BRaD LMO test

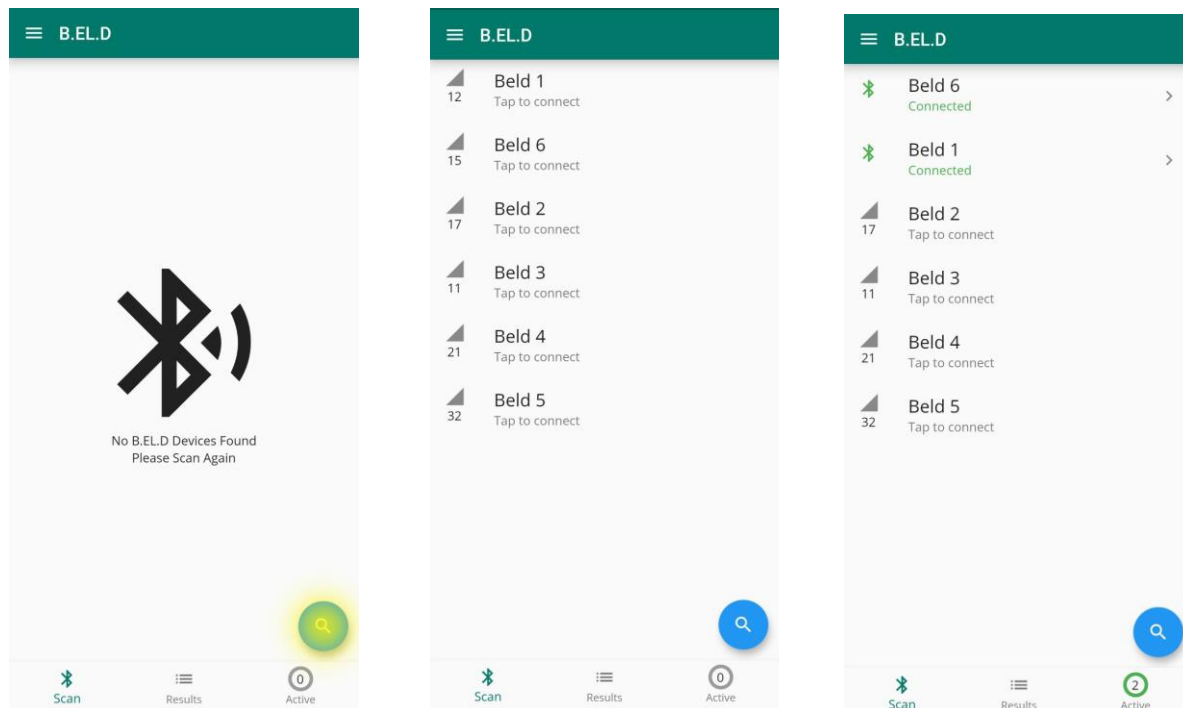
- A. Connect the screen-printed electrode with the device and turn on the device. Be sure that the electrodes are aligned with the connectors.



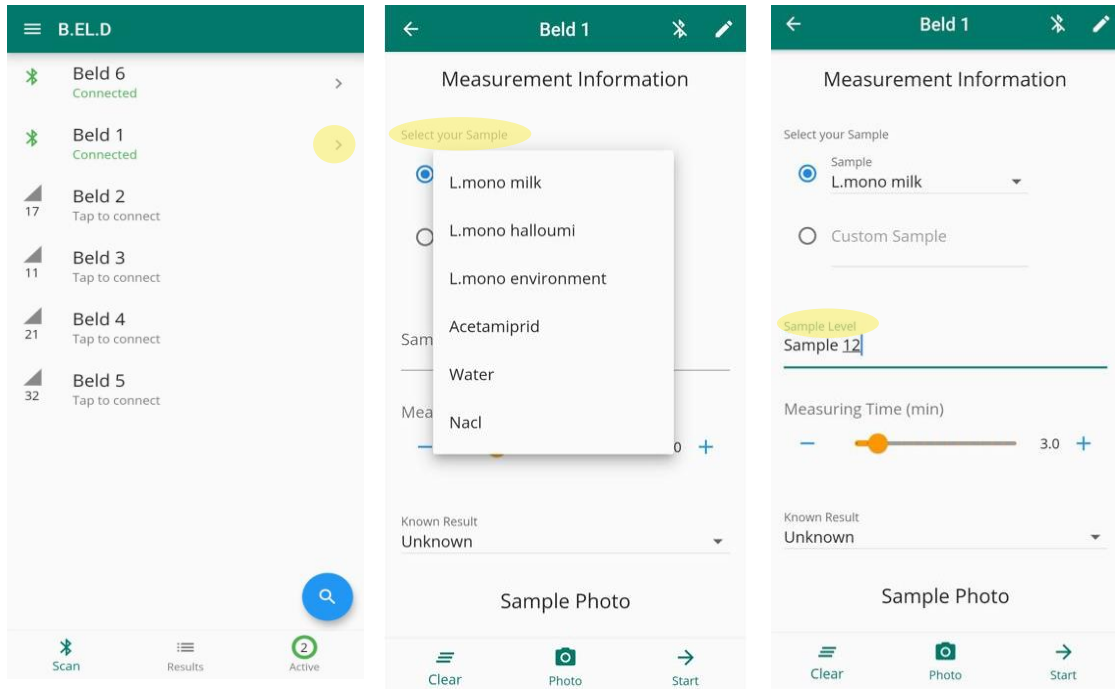
B. Turn on the bluetooth functionality and location services on your mobile phone, open the application and login



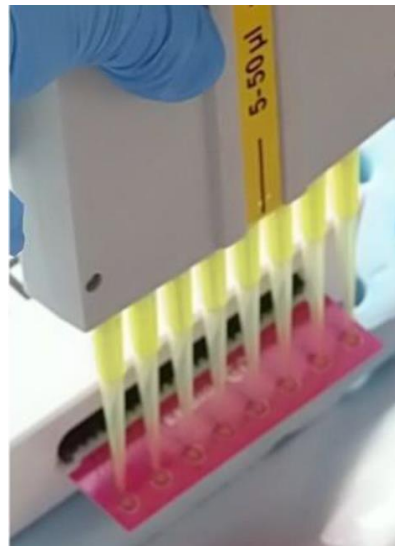
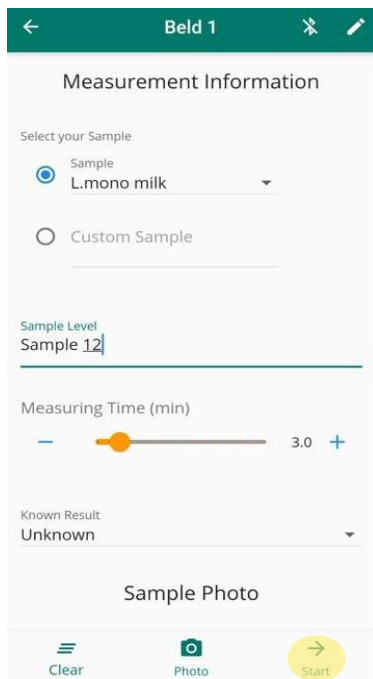
C. Press the search command and connect the application to the device.



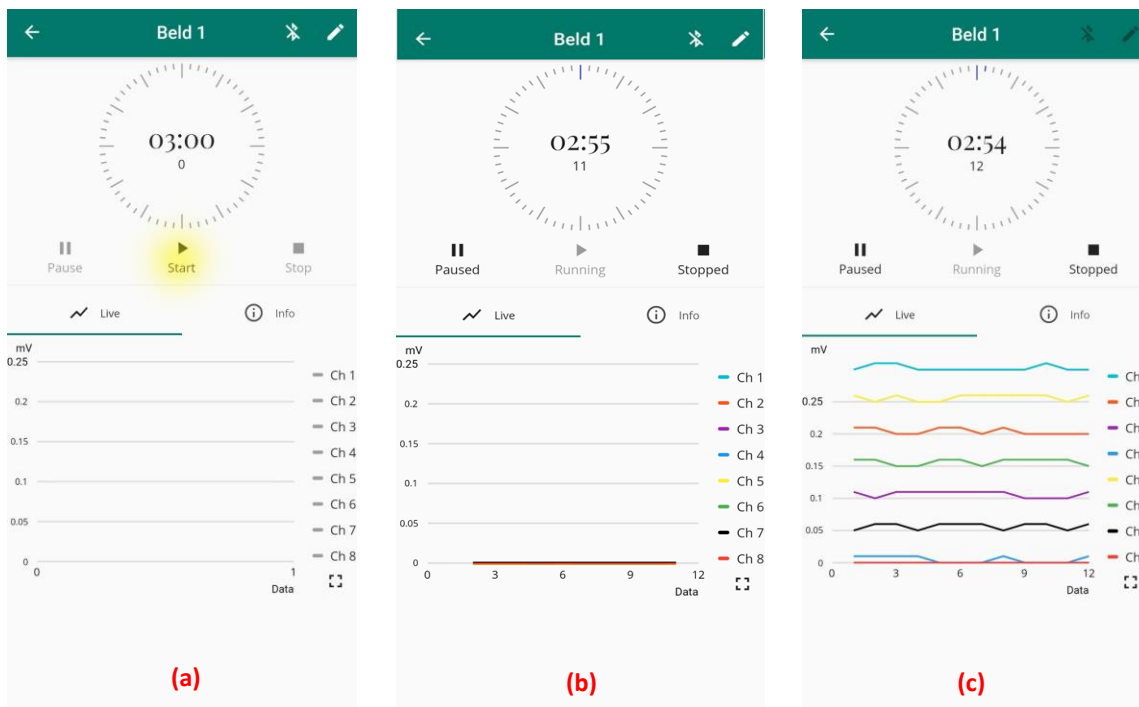
D. Tap the connected device and fill in the appropriate fields (select your Sample and Sample level).



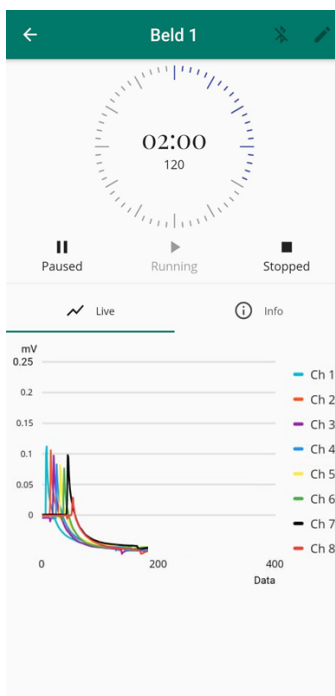
E. START the measurement and then add 20 μ L (volume can be adjusted according to the application) of the sample onto channels 1-8 with a multichannel or single-channel automatic pipette.



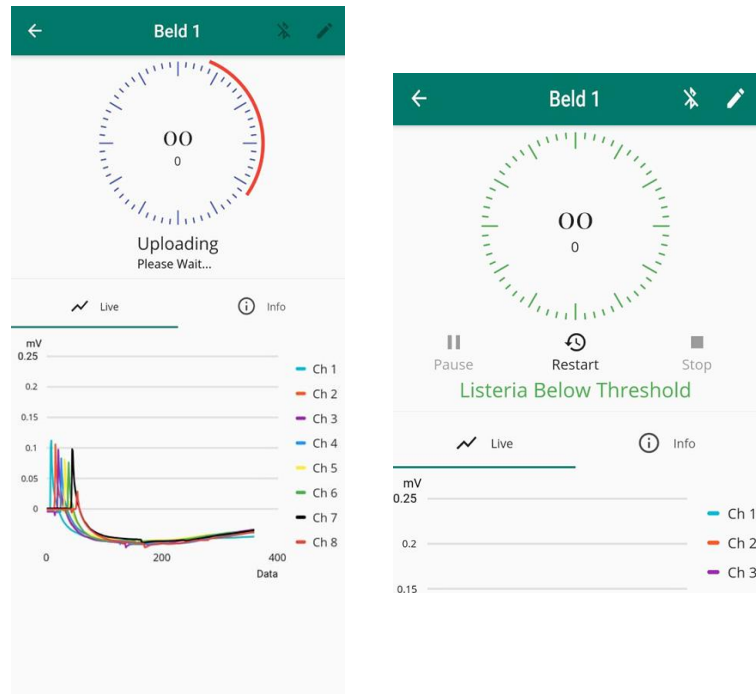
ATTENTION, if the lines on the chart do not appear after pressing the start button do not add the sample. Stop the measurement and start it again (a). Ensure that the lines are visible in the chart and they all start at 0 mV before adding the sample (b). In case lines do not start at 0 mV (c) stop the measurement and start it again.



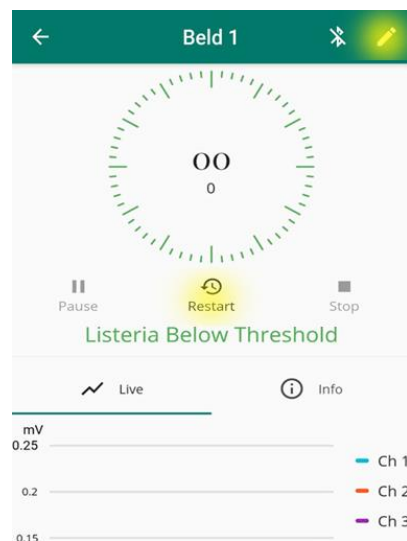
F. Once the first minute has passed, immediately start adding 20 μ L of the biosensors onto the same channels as above hence the final volume in each channel will be 40 μ L.



- G. After the END of the measurement, the result will appear on your mobile screen and the data will be uploaded automatically.



- H. For each new measurement press Restart and then press EDIT (pencil icon found in the top right hand corner of the screen) to add new information for the next sample. You will now be ready to start the next measurement.



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 samples.
- Use of Nitrile, Latex (or equivalent) gloves is recommended when handling samples.
- Test electrodes are for one use only.
- The user should not open the tube containing the biosensors 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.
- Use the appropriate Fixed Volume Pipette in accordance with test procedures.
- 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.

Troubleshooting

Faults	Actions
User enters false Credentials	Error message appears. User must enter the right credentials.
User forgot his password	Can press “Forgot Password?” button to restore the password.
User (email) already exists	Error message appears. Must use a different password.
Wrong password. a) Password does not meet the requirements (e.g. short length) b) Confirm password does not match.	Error message appears. Must enter Password that meets the requirements.

Wrong information accidentally entered	Completed measurements can be found in the results tab. Edit is available.
Bluetooth is off	Turn on Bluetooth
Location Permission disabled	User must navigate to app permissions and enable Location.
No results found	Check if there are active BELD devices nearby. Beld device must not be connected to another mobile app.
Cannot connect to BELD device	a) BELD Must not run on low battery b) BELD device must be in close proximity (<2m) to the mobile phone and no obstacles located between them c) If a and b does not fix the problem then restart both the BELD and mobile app.
Accidentally wrong parameters	a) Sample code and Sample Level can be edited after the measurement has finished. b) If the sample is incorrect, the measurement must run again (each sample corresponds to a different algorithm) c) Measurement time must be >3 minutes.
The chart remains empty after the start button is pressed	a) Stop measurement and check if BELD is still connected. If it is connected press start again. If it is disconnected or pressing start does not fix the problem then start again with a new measurement.
Result is stuck in "Uploading"	a) Check your internet connection b) If no result appears in 2 minutes, the measurement must be taken from the beginning.
User enters wrong email data	If "share via email screen" is still open a new email can be sent, otherwise the measurement must be taken from the beginning.
User enters wrong phone number	If "share via email screen" is still open a new sms can be sent, otherwise the measurement must be taken from the beginning.
Email or SMS has not arrived	Email and phone must be in the correct form.
Possibility of accessing the user's data	Only non-sensitive data is stored and encrypted in the database. Communication via the application is also encrypted via SSL.











Kit storage and stability

Store the kit at 4°C temperature. On the day of the test let the biosensors and samples warm up to room temperature. Cold samples can lead to erroneous or invalid results.



Symbols glossary

	Temperature limitation
	Manufacturer
	Catalogue Number
	Contains sufficient for 12 or 24 or 48 Tests
	Refer to instructions for use
	Lot Number
	Use-by Date – indicates the date after which the unopened IVD/Quality Control Material cannot be used
	Do not re-use

EMBIO Diagnostics Ltd customer services:

For product enquiries please contact **EMBIO Diagnostics Ltd** Customer Services at info@embiodiagnostics.eu or for further contact details please visit embiodiagnostics.eu. Any adverse results experienced with the use of this product and/or quality problems should also be reported to **EMBIO Diagnostics Ltd** Customer Services by email: k.loizou@embiodiagnostics.eu.

Return policy:

Please contact **EMBIO Diagnostics Ltd** Customer Services for terms and conditions.

Limited warranty:

Please contact **EMBIO Diagnostics Ltd** Customer Services for terms and conditions.

Manufacturer Information:

EMBIO Diagnostics Ltd, Athalassas Avenue 8B, Nicosia, Cyprus.

