

Operating instructions

Food & Beverage Kit

Type Spoilage Bacteria Ident v2



REF: BKB00-B02A2

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1 About this document

1.1 Document function

These operating instructions contain all information about the Food & Beverage Kit, Type Spoilage Bacteria Ident v2, in the following operating instructions mainly referred to as “Kit”. Great care has been taken to ensure that all information contained in the operating instructions is correct and complete at the time of publication.

This document describes the state at the time of publishing. It needs not necessarily to agree with future versions. These operating instructions as well as the Endress+Hauser BioSense Analysis System are subject to change without notice.

1.2 Warnings

The structure of the information and their meaning are shown in [Table 1](#).

Structure of Information	Meaning
⚠ CAUTION Causes (/consequences) ▶ Corrective action	This symbol alerts to a dangerous situation. Failure to avoid this situation can result in minor or more serious injuries.
NOTICE Cause/situation ▶ Action/note	This symbol alerts to situations which may result in loss of function or damage to property.

Table 1: The structure of information symbols and their meaning.

1.3 List of abbreviations

In [Table 2](#) all abbreviations and their description used in this document are listed in alphabetical order.

Term	Description
°C	Degree Celsius
Ct	Cycle threshold for PCR amplification
EXP	Expiry date
LOT	Lot number
PCR	Polymerase chain reaction
REF	Reference number
STOR	Storage conditions

Table 2: All abbreviations and their description used in this document.

1.4 Documentation

The operating instructions Device + Control software complement these operating instructions and are available on demand (see chapter [7 Support](#)).

1.5 Registered trademarks

Registered names, trademarks, etc. mentioned in this document should not be assumed to be unprotected by law, even if they are not explicitly marked as registered names or trademarks.

2 Basic safety instructions

2.1 Requirements for the personnel

- Read these operating instructions before use and take care that the document was understood.
- Keep the operating instructions in a safe but easily accessible place.

2.2 Intended use

- Any use for other purposes is not permitted. Liability for improper use as well as resulting consequences is excluded.
- Do not use the Kit for anything other than its intended use.
- Use one Concentration Module and one Detection Module per sample.

2.3 Workplace and operational safety

- A visual inspection must always be carried out before use (see chapter [4.1 Incoming acceptance](#)).
- Do not operate damaged reagents or products and protect them against unintentional operation.
- Label damaged products as defective. Defects must be reported to Endress+Hauser BioSense GmbH (see chapter [7 Support](#)).
- Operation of the Kit is possible on any table or flat surface.

2.4 Product safety

The Kit is designed to meet state-of-the-art safety requirements. The Kit complies with relevant product safety regulations and meets international safety standards.

NOTICE

Risk of false results

- Each component of the Concentration Module and Detection Module is made for single use only!
- The Detection Module must not be exposed to direct sunlight for an extended amount of time in order not to influence the integrity of the measurement results.

NOTICE

Risk of false disposal

- Please comply to the federal, state, and local safety and environmental regulations. All waste should be considered as potentially infectious and must be handled and discarded according to the federal, state, and local safety regulations.

2.5 Important safeguards

NOTICE

Risk of false results

- All due care and attention should be exercised in handling the materials and reagents contained in the Concentration Module and Detection Module.

CAUTION

Risk of personal injury

- Never eat or drink any components of the Kit! Seek medical advice if swallowed.

3 Product description

3.1 Endress+Hauser BioSense Analysis System

The Endress+Hauser BioSense Analysis System consists of the Device with accompanying Control Software and an application specific Kit. The following operating instructions describe the operation of the Kit. Information about the Device can be found in the separate operating instructions for the Device. Information about an optional laptop can be found in the separate operating instructions for the Device + Control software.

3.2 Food & Beverage Kit, Type Spoilage Bacteria Ident v2

The Kit is designed for the detection of spoilage bacteria in the Food & Beverage industry. The Kit is part of the BioSense Analysis System.

The Kit includes Concentration Modules and Detection Modules (see chapter 4.2 *Scope of delivery*).

The Concentration Module contain all reagents and means for sample preparation.

The Detection Module enables automated lysis and Real-Time PCR based detection of defined quality parameters by utilizing a microfluidic cartridge. The Detection Module serves as a disposable component and contains the sample-specific and the application-specific biochemistry for the analysis. Sophisticated microfluidic structures enable precise and repeatable automation of complex biochemical processes. All necessary reagents for processing are pre-stored on the Detection Module. The Kit, Type Spoilage Bacteria Ident v2 detects the following quality parameters (see [Table 3](#)). The Detection Module is designed for use in the Device only. All main components of the Kit are displayed in [Figure 1](#).

Quality Parameter	Description
Lactobacillus brevis (<i>L.brevis</i>)	Can cause high turbidity, slime formation, off-flavors, and a high level of diacetyl in beer
horA gene	General gene markers for detection of spoilage bacteria
horC gene	

Table 3: List of quality parameters detected in the Kit, Type Spoilage Bacteria Ident v2.



Figure 1: Picture of the Detection Module (left) and Concentration Module (right) of the Food & Beverage Kit, Type Spoilage Bacteria Ident v2.

4 Incoming product acceptance and product identification

4.1 Incoming acceptance

1. Verify that the packaging is undamaged. Notify the support (see chapter [7 Support](#)) of any damage to the packaging. Keep the damaged goods until the issue has been resolved.
2. Verify that the contents are undamaged. Notify the support (see chapter [7 Support](#)) of any damage to the delivery contents. Keep the damaged goods until the issue has been resolved.
3. Do not operate damaged products and protect them against unintentional operation. Label damaged products as defective.
4. Check that the delivery is complete, and nothing is missing. It is recommended to compare the shipping documents with the purchase order.

4.1.1 Identifying the product

The REF Number and LOT number of the product can be found in the following locations:

- On the Kit labels
- In the delivery papers

If there are any questions, please contact the Endress+Hauser BioSense support (see chapter [7 Support](#)).

4.1.2 Manufacturer address

Endress+Hauser BioSense GmbH, Georges-Köhler-Allee 302, 79110 Freiburg, Germany

4.2 Scope of delivery

[Table 4](#) lists all the components included in the Kit and their reference numbers for ordering. [Table 5](#) lists all the components of the Concentration Module.

Part	Quantity	REF
Concentration Module, Type A5	10 x	BCB00-B00A3
Detection Module, Type Spoilage Bacteria Ident v2	10 x	BDB00-B02A2
Kit operating instructions, Type Spoilage Bacteria Ident v2	1 x	B-2010
Certificate of analysis	1 x	B-2011

Table 4: List of all components included in the Food & Beverage Kit, Type Spoilage Bacteria Ident v2 including the quantity and the reference number for orders.

Concentration Module, Type A5	Quantity
Sample container	1 x
TCT Bead container including TCT Beads	1 x 2 g (pre-filled)
Buffer container including "Concentration Buffer"	1 x 3 ml (pre-filled)
Transfer pipette	1 x
Swab	1 x
Buffer container including "Buffer A"	1 x 1 ml (pre-filled)

Table 5: Quantity of components of the Concentration Module, Type A5.

4.3 Transport and storage

The Kit is shipped at ambient temperatures. Store the Kit dry and at room temperature (15 °C to 25 °C). All sealed Modules are stable until the expiration date printed on the label on the box or bag. Avoid storage in direct sunlight.

Before each use, ensure that all components included in the Kit are at room temperature.

4.4 Product use and warranty

The Kit is to be used exactly as described in these operating instructions. It is forbidden to carry out any modifications to the Kit. Endress+Hauser BioSense GmbH does not give any warranty for the functionality or reliability of the Kit if any modifications are carried out on the Kit, or the Kit is not used according to the operating instructions. Endress+Hauser BioSense GmbH is not liable for damages caused by improper use of the Kit.

The Kit is not designed for the usage of other starting materials or other amounts of starting materials/samples than those, referred to in these operating instructions (see chapter [5.1 Sample preparation and workflow](#)).

The Detection Module is not functional, if any part of the Detection Module is loose.

If there are any questions, please contact the Endress+Hauser BioSense support (see chapter [7 Support](#)).

5 Operation

5.1 Sample preparation and workflow

Depending on the characteristics of the sample, different handling is necessary. Hence different material needs to be used. The possible sample types are swab samples, liquids, and colonies. The Concentration Modules are equipped for each available sample type.

NOTICE

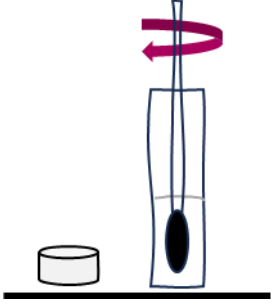
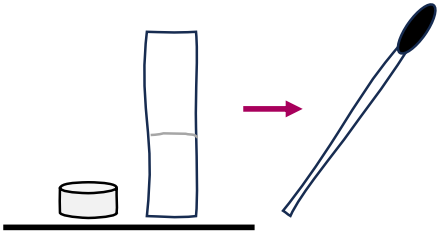

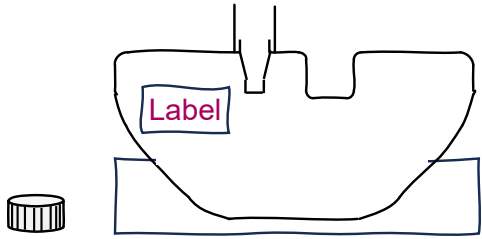
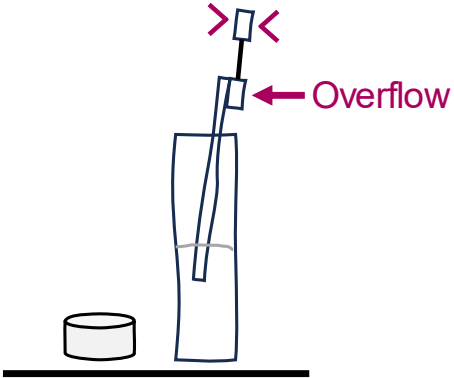
Risk of contamination and false results

- Read this chapter carefully before starting with the workflow. For information on the components see chapter [3 Product description](#).

To avoid unintentional contamination, it is recommended to wear disposable gloves.

5.1.1 Sample preparation – Swab sample

Step	Description	Depiction
1	Remove the swab from the Concentration Module. NOTICE Risk of contamination <ul style="list-style-type: none"> ▪ Do not touch the tip of the swab nor touch other surfaces with the tip of the swab while unpackaging to avoid unintentional contamination. 	
2	Remove the Buffer Tube labelled “Buffer A” from the Concentration Module. Open the Lid of the Buffer Tube and place the swab into the Buffer Tube. Rotate it for 5 seconds.	
3	Wipe with firm pressure an area of 10 cm x 10 cm using side to side movements, rotate the swab to make sure that the full tip has had contact to the surface. Follow the pattern as depicted.	

<p>4</p>	<p>Place the swab back into the Buffer Tube, rotate it for ten seconds and leave the swab inside for one minute.</p>	
<p>5</p>	<p>Remove the swab by first wiping it off at the inside of the tube. Put the swab back in the pouch. It serves as a waste bag.</p>	
<p>6</p>	<p>Close the Buffer Tube and shake the Buffer Tube vigorously for 15 seconds, then wait for one minute.</p>	
<p>7</p>	<p>Put the Detection Module into the stand and open the lid of the Detection Module.</p>	
<p>8</p>	<p>Open the lid of the Buffer Tube. Take out the sample with the provided pipette. Afterwards, squeeze the upper bulb of the pipette in the air. Hold the pipette squeezed while putting it in the liquid in the Buffer Tube. Slowly release the bulb to aspirate the liquid into the pipette.</p> <p>NOTICE</p> <p>Risk of false results</p> <ul style="list-style-type: none"> Make sure that the pipette is filled completely without air bubbles and a droplet is in the overflow chamber. 	

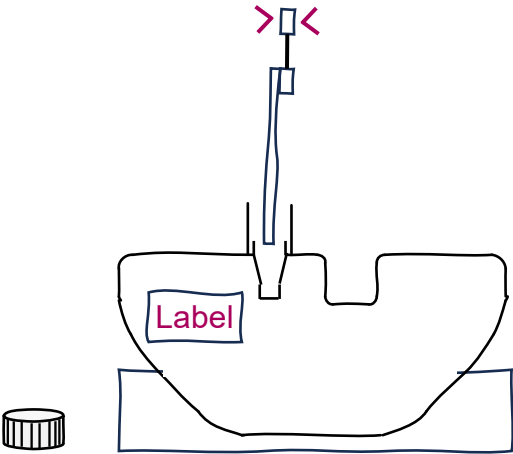


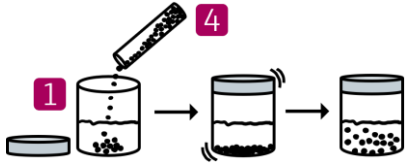

<p>9</p> <p>Transfer the sample into the Detection Module by placing the pipette centered and squeezing the upper bulb of the pipette. This ensures that the liquid accumulates in the white inlay.</p> <p>Put the pipette and the Buffer Tube back in the pouch and dispose it according to chapter 5.2. Disposal of the used Modules.</p> <p>Close the Detection Module carefully.</p> <p>NOTICE</p> <p>Risk of damaging the Detection Module</p> <ul style="list-style-type: none"> ▪ If you label the Detection Module, label on the area as depicted on the right-hand side and do not cover the transparent areas on both sides and the QR-code on the white cover side. 	<p>Close the Detection Module carefully.</p> <p>NOTICE</p> <p>Risk of damaging the Detection Module</p> <ul style="list-style-type: none"> ▪ If you label the Detection Module, label on the area as depicted on the right-hand side and do not cover the transparent areas on both sides and the QR-code on the white cover side. 	
<p>10</p> <p>Start the analysis by proceeding to the chapter “Operation” in the operating instructions of the Device + Control Software.</p>		

Table 6: Description of the sample preparation steps for a swab sample.

5.1.2 Sample preparation – Beer sample

Step	Description	Depiction
<p>1</p>	<p>The beer sample should be at room temperature. Open the sample container (1) and pour in 30 ml of the beer sample.</p>	
<p>2</p>	<p>Add the TCT beads (4) to the sample and close the lid of the sample container (1). Immediately invert and shake the sample container for five seconds.</p> <p>NOTICE</p> <p>Risk of losing the sample</p> <ul style="list-style-type: none"> ▪ If the beads stick together or to the sample container, continue shaking. 	
<p>3</p>	<p>Let the sample container (1) sit for 60 minutes at room temperature to allow the TCT beads to concentrate the sample.</p>	

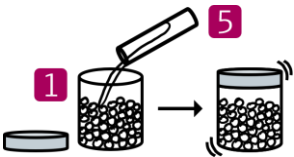
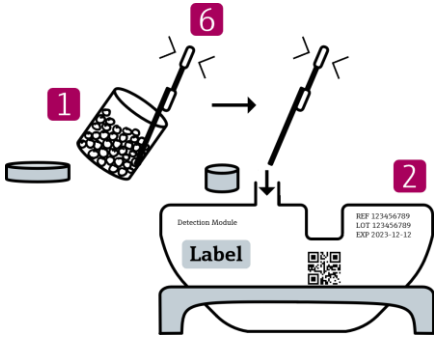
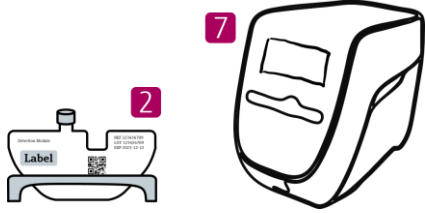
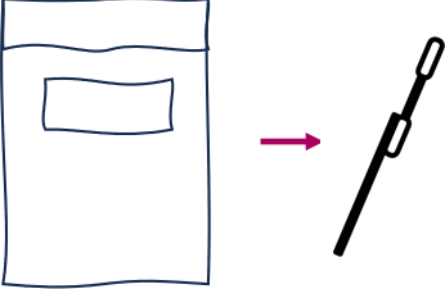
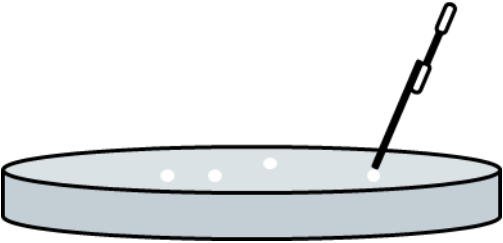
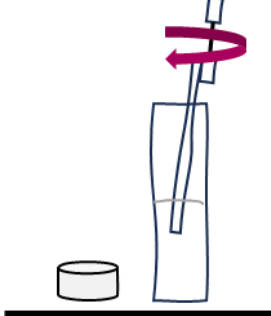
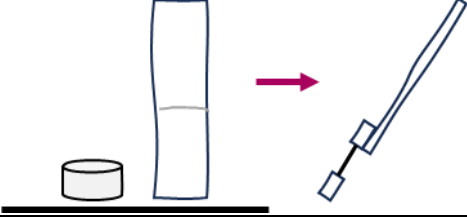

	<p>NOTICE</p> <p>Risk of losing the sample</p> <ul style="list-style-type: none"> ▪ If the beer is not at room temperature when the TCT beads are added, the time required for concentration may vary. ▪ Different types of beer may react differently. 	
<p>4</p>	<p>After 60 minutes, open the lid of the sample container (1) and pour in the concentration buffer from the buffer container labelled “Concentration Buffer” (5).</p> <p>Close the lid of the sample container tightly and shake the sample container for five seconds.</p> <p>NOTICE</p> <p>Risk of losing the sample</p> <ul style="list-style-type: none"> ▪ Immediately start step 5. 	
<p>5</p>	<p>Open the lid of the Detection Module (2). Hold the sample container (1) at a slight angle and take out the concentrated sample with the provided pipette (6) by inserting it into the liquid, squeezing and then releasing the upper bulb of the pipette. Make sure that the pipette is filled completely without air bubbles. Transfer the sample into the Detection Module by squeezing the upper bulb of the pipette. Close the Detection Module.</p> <p>NOTICE</p> <p>Risk of losing the sample</p> <ul style="list-style-type: none"> ▪ The pipette must be filled completely. This is visible by the lower bulb overflowing. There must be no air bubbles in the filled pipette (see chapter 6.1 General Troubleshooting). ▪ Do not turn the Detection Module upside down at any time after being filled with the sample. 	
<p>6</p>	<p>For operation of the Endress+Hauser BioSense Device (7), please refer to the operating instructions of the Endress+Hauser BioSense Device.</p> <p>Proceed to the chapter “Operation” in the operating instructions of the Endress+Hauser BioSense Device to start the analysis of the Detection Module (2).</p>	

Table 7: Description of the sample preparation steps for a liquid sample.

5.1.3 Sample preparation – Colonies on culture plate

Step	Description	Depiction
1	<p>Remove the pipette from the Concentration Module.</p> <p>NOTICE</p> <p>Risk of contamination</p> <ul style="list-style-type: none"> Do not touch the tip of the pipette nor touch other surfaces with the tip of the pipette while unpackaging to avoid unintentional contamination. 	
2	<p>Pick up the colony from the culture plate, holding the pipette at a slight angle.</p> <p>NOTICE</p> <p>Risk of losing a sample</p> <ul style="list-style-type: none"> Do not squeeze the upper bulb of the pipette to prevent the colony from being aspirated. <p>NOTICE</p> <p>Risk of false results</p> <ul style="list-style-type: none"> Please pick only one culture, not multiple cultures. 	
3	<p>Insert the pipette into the Buffer Tube labelled “Buffer A”, rotate it for ten seconds and leave the pipette inside for one minute.</p>	
4	<p>Remove the pipette after making sure the colony is inside the buffer. Keep the pipette to be used a second time in step 7.</p>	
5	<p>Close the Buffer Tube and shake the Buffer Tube vigorously for 15 seconds, then wait for one minute.</p>	

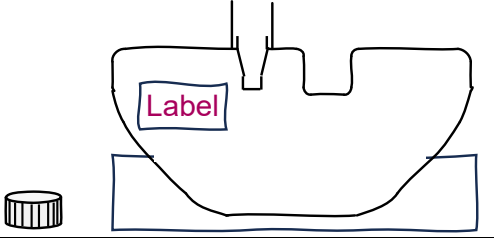
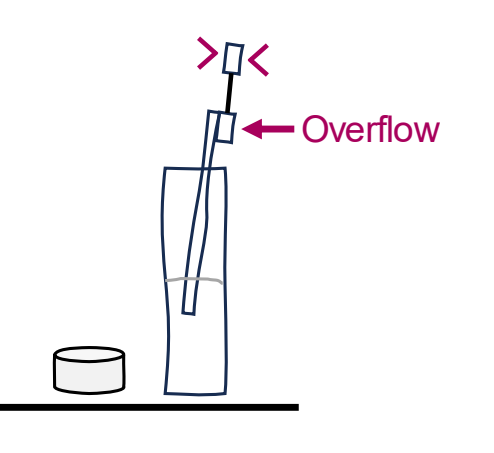
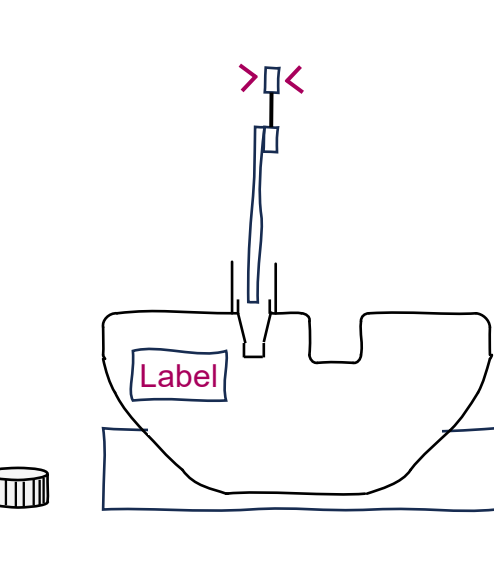
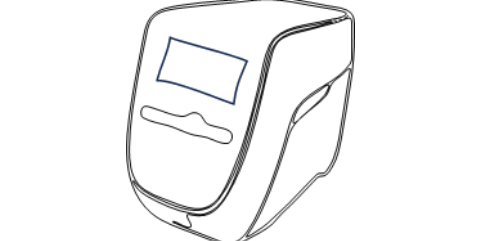
<p>6</p>	<p>Put the Detection Module into the stand and open the lid of the Detection Module.</p>	
<p>7</p>	<p>Open the lid of the Buffer Tube. Take out the sample with the pipette. Afterwards, squeeze the upper bulb of the pipette in the air. Hold the pipette squeezed while putting it in the liquid in the Buffer Tube. Slowly release the bulb to aspirate the liquid into the pipette.</p> <p>NOTICE</p> <p>Risk of false results</p> <p>Make sure that the pipette is filled completely without air bubbles and a droplet is in the overflow chamber.</p>	
<p>8</p>	<p>Transfer the sample into the Detection Module by placing the pipette centered and squeezing the upper bulb of the pipette. This ensures that the liquid accumulates in the white inlay. Put the pipette and the Buffer Tube back in the pouch and dispose it according to chapter 5.2. Disposal of the used Modules.</p> <p>Close the Detection Module carefully.</p> <p>NOTICE</p> <p>Risk of damaging the Detection Module</p> <p>If you label the Detection Module, label on the area as depicted on the right-hand side and do not cover the transparent areas on both sides and the QR-code on the white cover side.</p>	
<p>9</p>	<p>Start the analysis by proceeding to the chapter "Operation" in the operating instructions of the Device + Control Software.</p>	

Table 8: Description of the sample preparation steps for colonies from culture plate.

5.2 Disposal of the used Modules

After completion of the sample preparation, all components of the Concentration Module must be disposed of in a waste container. The concentrated liquid must be disposed of in a waste container together with the storage container after 24 hours.

The Detection Module must be disposed immediately after ejection from the Device. Do not open the Detection Module.

⚠ CAUTION

Risk of contamination

- The Detection Module must be considered potentially contaminated with nucleic acids.

5.3 Results

5.3.1 Display results

After the ejection of the Detection Modules, the Device Control Software displays the test results. For further information please refer to the operating instructions for the Device + Control Software.

⚠ CAUTION

Risk of incorrect results

- The results are only applicable to samples analyzed exactly according to the operating instructions. Changes in the procedure may lead to altered or even false results.

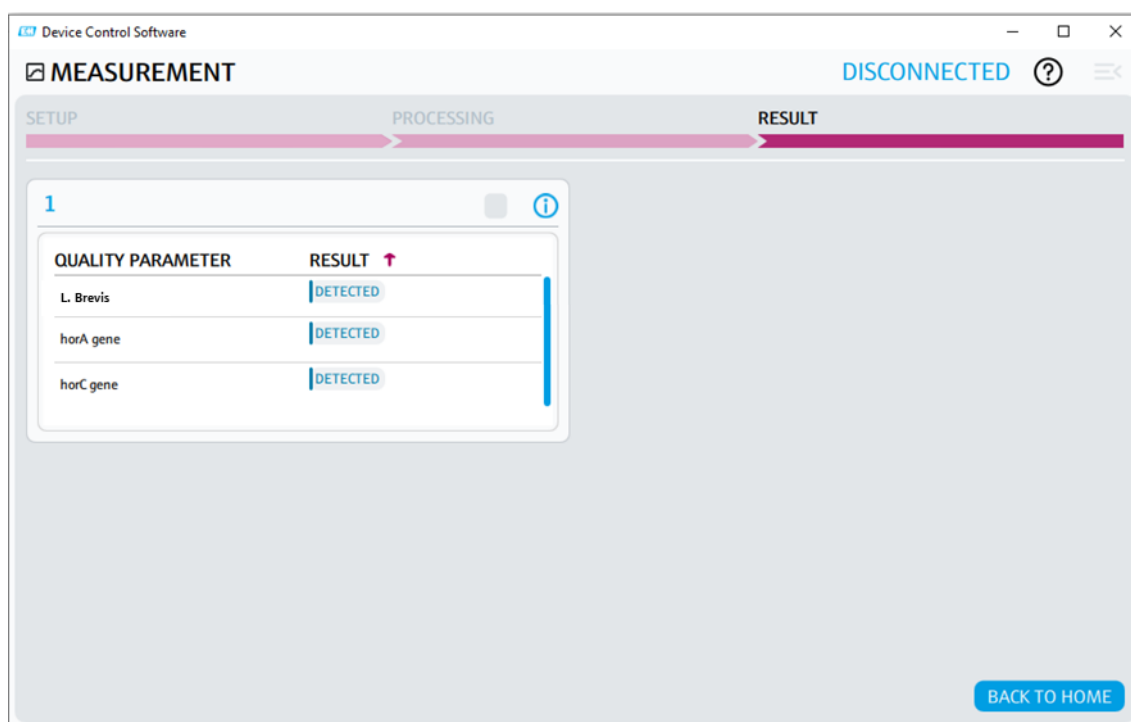


Figure 2: Exemplary result screen for one sample result.

6 Diagnostics and troubleshooting

In case of questions or errors, please contact Endress+Hauser BioSense support (see chapter [7 Support](#)).

6.1 General troubleshooting

In some error cases it is possible to fix errors by following the actions in [Table 7](#). In all other cases, please contact Endress+Hauser BioSense support (see chapter [7 Support](#)).

Error description	Action
Residual liquid in the sample container is above the 10 ml marker after the incubation time of 30 minutes at room temperature.	Let the sample sit at room temperature until the residual liquid level is below the 10 ml marker.
<p>In the chapters:</p> <p>5.1.1 Sample preparation – Swab sample step 9</p> <p>5.1.2 Sample preparation – Beer sample step 5</p> <p>5.1.3 Sample preparation – Colonies on culture plate step 7</p> <p>The pipette cannot be filled completely due to air bubbles in the pipette, or there is no visible overflow in the lower bulb of the pipette.</p>	Tap the bottom of the sample container on a table or wait for 10 seconds to allow the liquid to flow to the bottom of the sample container. If there is no overflow in the adjoining chamber but the pipette seems full and without air bubbles, keep following the operation.

Table 9: Troubleshooting. The action can be carried out in specific cases of errors.

7 Support

7.1 Contact information

Please contact Endress+Hauser BioSense support (support.ehbs@endress.com) concerning all support tasks.

ehbs.endress.com
