Validation Kit for BactoSense User Manual

English

Document ID: UM_0003-01

Compiled on 16 November 2026

https://manual.bnovate.net/other-manuals/validation-kit

Validation Kit for BactoSense

General information

The Validation Kit is a reagent kit used to validate the proper functioning of BactoSense. Its reagents have been developed for use after measuring drinking water samples. The kit may not be effective if stored under inadequate conditions, if expired, or if samples other than drinking water have been measured.

Store the kit refrigerated at **2–8 °C (35–47 °F)**, away from light. Under these conditions, the shelf-life is **one year**. The kit provides **10 validations**.

Safety information



WEAR PROTECTIVE GLOVES

In case of skin contact, rinse immediately and abundantly with fresh water. In case of pain or irritation, consult a doctor.



WEAR PROTECTIVE SAFETY GLASSES

In case of eye contact, flush eyes immediately with flowing water for 10–15 minutes, holding eyelids apart, and consult a doctor.



READ THE INSTRUCTIONS BEFORE USE

Carefully follow this manual and the BactoSense user manual.

Contents

Item	Quantity	SDS document number	Use
Alcohol Wipes	10	—	Single use
Beads Solution	10	50106	Single use
Reference Solution	10	—	Single use
Sterile Solution	10	—	Single use
Tube Holder	1	—	Multiple uses

Discard single-use items according to local waste disposal regulations. Safety data sheets (SDS) are available from bNovate or your local distribution partner upon request.

When to use the Validation Kit

Perform an instrument validation:

- After shipping or other long-distance transport with vibration or shock.
- After storing the instrument for more than one month.
- If there are indications that measurement results could be erroneous.

The full validation consists of three parts, performed in order: Optical Validation, Reference Validation and Sterile Validation. All acceptance criteria must be met. A full validation takes approximately **3 hours**.

In specific cases, a partial validation can be performed. Complete the preparations first, then follow the relevant part.

Preparations

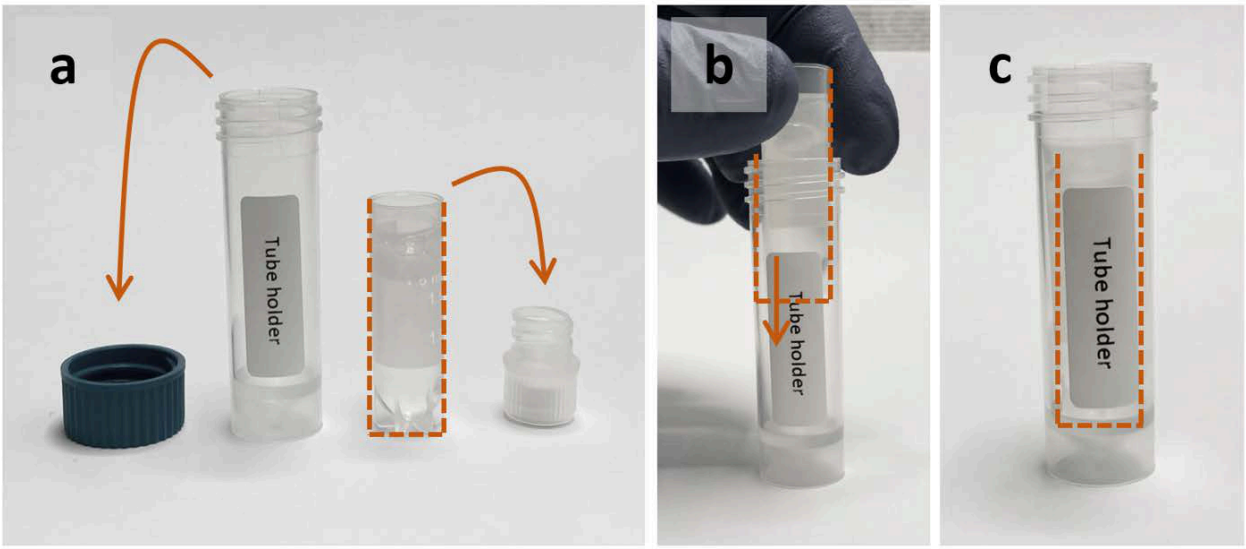
1. Verify that the kit has not expired and has been stored under the specified conditions.
2. For a full validation, remove one alcohol wipe, one Beads Solution, one Reference Solution, one Sterile Solution and the Tube Holder. For a partial validation, take only the wipe, Tube Holder and relevant solution.
3. Make sure the manual sampling device is tightly installed on BactoSense.
4. Unpack the alcohol wipe. Wipe the sampling needle from top to bottom to remove contaminants. Let it dry for **30 seconds**.
5. Log in as **Admin**. From **Home → Maintenance → Self-check**, press **Rerun**. Verify that every test displays a green **PASS**.
6. Open **Home → Maintenance → Instrument validation**. Check **Activate Instrument validation** and press **Save**.
7. For a full validation, continue with Part A. For a partial validation, continue with the corresponding part.

Part A: Optical Validation

This tests the optical system by measuring a solution containing fluorescent particles.

1. Complete the preparations if not already done.
2. Attach the wash station to the manual sampling device. If none is available, attach an empty, clean 5 mL screw-cap tube.
3. As **Admin**, open **Home → Manual mode → Start**. Select **Clean Sampling Device with Washstation**, with **one replication**. Without a wash station, select **Clean Sampling Device**, with **two replications**. Press **Next** and start the protocol.
4. After completion, shake the Beads Solution tube vigorously for **10 seconds**, by hand or using a vortex mixer.
5. Remove the caps from the Beads Solution tube and Tube Holder. Insert the opened tube into the holder. Remove the wash station and attach the holder containing the Beads Solution to the manual sampling device.

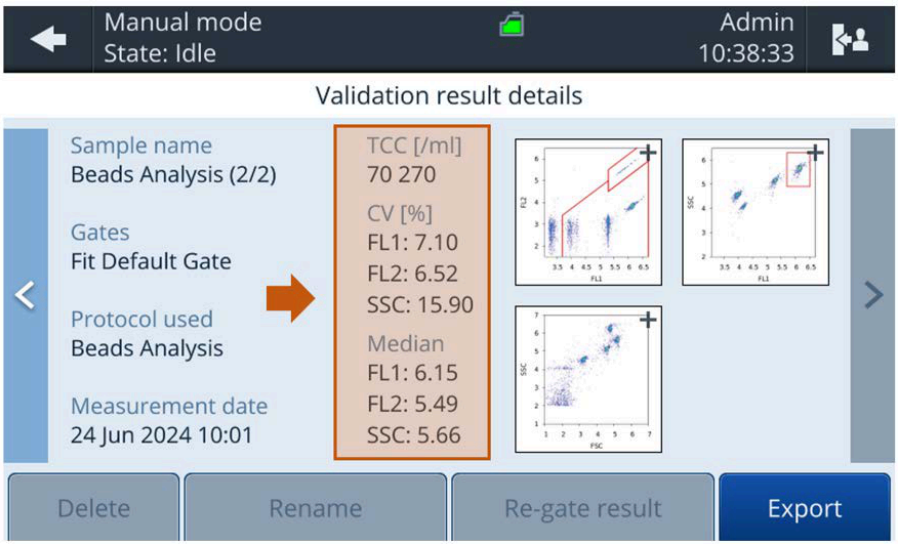
> ⚠ **USE THE WHOLE REAGENT TUBE**
> Insert the entire reagent tube into the Tube Holder, rather than pouring its contents into the holder.



6. Open **Home → Manual mode → Start**. Select **Prime**, with **one replication**. Press **Next** and start.
7. Return to the protocol overview. Select **Beads Analysis**, with **two replications**. Press **Next** and start.
8. Review the results. All the following criteria must be met:

   TCC: 50,000–75,000/mL

Channel	CV (%)	Median
FL1	Less than 15	5.7–6.5
FL2	Less than 20	5.1–5.7
SSC	Less than 25	4.7–6.3



9. If the test passes, remove the Tube Holder, remove the Beads Solution tube, close its cap and discard it. Continue with Part B.

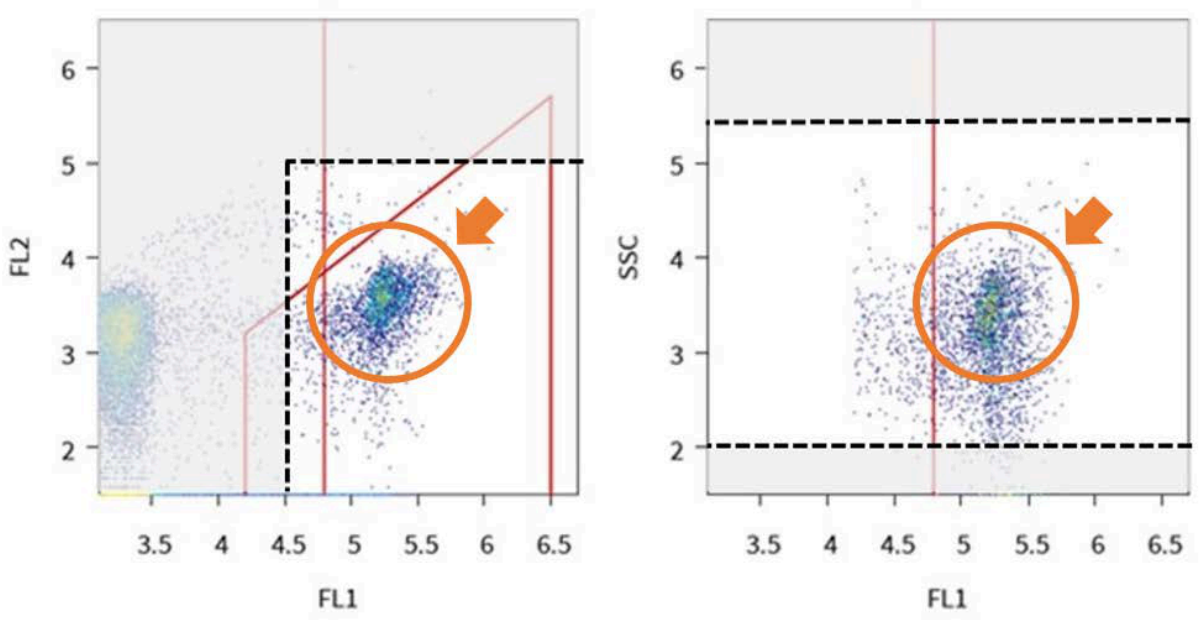
   If it fails, check the kit's expiry and storage conditions, then repeat, making sure the Beads Solution is well mixed. If failures persist, contact bNovate support or your local service representative.

Part B: Reference Validation

This validates the automated staining process.

1. Complete the preparations if performing this part alone.
2. Attach the wash station, or an empty, clean 5 mL screw-cap tube if no wash station is available.
3. As **Admin**, open **Home → Manual mode → Start**. Run **Clean Sampling Device with Washstation**, with **one replication**. Without a wash station, run **Clean Sampling Device**, with **two replications**. Press **Next** and start.
4. Uncap the Reference Solution tube and insert the entire tube into the Tube Holder, as shown in Part A. Remove the wash station and attach the holder containing the Reference Solution.
5. Open **Home → Manual mode → Start**. Run **Prime**, with **one replication**.
6. Return to the protocol overview. Select **Water Analysis**, with **two replications**. In **Gates**, select the default gate for the cartridge type, for example **ICC Default Gate** or **TCC Default Gate**. Press **Next** and start.
7. Compare the main bacteria clouds to the reference criteria:

Dotplot	Acceptance criterion
FL1 / FL2	Main cloud above 4.5 on the FL1 axis and below 5 on the FL2 axis
FL1 / SSC	Main cloud above 2 and below 5.5 on the SSC axis



APPEARANCE OF THE CLOUDS

Depending on the cartridge and storage conditions, the clouds may differ from the example.

8. If the test passes, remove the Tube Holder, remove the Reference Solution tube, close its cap and discard it. Continue with Part C.

   If it fails, check the kit's expiry and storage conditions. Repeat with a fresh Reference Solution. If failures persist, contact bNovate support or your local service representative.

Part C: Sterile Validation

This validates the cleanliness of BactoSense by measuring cell-free water.

1. Complete the preparations if performing this part alone.
2. Attach the wash station, or an empty, clean 5 mL screw-cap tube if no wash station is available.
3. As **Admin**, open **Home → Manual mode → Start**. Run **Clean Sampling Device with Washstation**, with **one replication**. Without a wash station, run **Clean Sampling Device**, with **two replications**. Press **Next** and start.
4. Uncap the Sterile Solution tube and insert the entire tube into the Tube Holder, as shown in Part A. Remove the wash station and attach the holder containing the Sterile Solution.
5. Open **Home → Manual mode → Start**. Run **Prime**, with **one replication**.
6. Return to the protocol overview. Select **Water Analysis**, with **two replications**. In **Gates**, select **ICC Default Gate** or **TCC Default Gate**, according to the cartridge. Press **Next** and start.
7. Review the results. The applicable criterion must be met:

Cartridge	Acceptance criterion
TCC	TCC less than 300/mL
ICC	ICC less than 100/mL

8. If the test passes, remove the Tube Holder, remove the Sterile Solution tube, close its cap and discard it. Return the holder to the Validation Kit and attach the wash station to the manual sampling device.

   If it fails, check the kit's expiry and storage conditions. Perform biological decontamination, then repeat with a fresh Sterile Solution. If failures persist, contact bNovate support or your local service representative.

9. Open **Home → Maintenance → Instrument validation**. Uncheck **Activate Instrument validation** and press **Save**.

You have successfully validated your instrument when all required parts have passed.