

OSOM[®] BVBLUE[®] CONTROL Kit

INTENDED USE:

The OSOM[®] BVBLUE[®] Control Kit is intended for *in vitro* diagnostic use with the OSOM BVBLUE Test as unassayed control material to monitor test performance.

SUMMARY:

The controls are for use with the OSOM BVBLUE Test. The OSOM BVBLUE Positive Control is a solution of sialidase that is supplied in a dropper bottle and will produce a green or blue color when used with the test. The BVBLUE Negative Control is a solution of sialidase at a level below the test's limit of detection. It is supplied in a dropper bottle and will produce a yellow color when used with the test. These controls may be used to confirm the integrity of the reagents in the test vessel.

REAGENTS:

OSOM BVBLUE Positive Control is a solution of ≥ 250 U/mL of bacterial sialidase.

OSOM BVBLUE Negative Control is a solution of 50 – 87.5U/mL of bacterial sialidase.

Materials Provided:

- 1 bottle (5mL) BVBLUE Positive Control (≥ 10 U/40 μ L)
- 1 bottle (5mL) BVBLUE Negative Control (2–3.5U/40 μ L)
- Directional Insert

Materials Required But Not Provided:

- OSOM BVBLUE Test Kit and Instructions For Use
- Timer or watch
- Swabs

WARNINGS AND PRECAUTIONS:

- For *In Vitro* Diagnostic Use
- Do not use control beyond the expiration date shown on the label.
- Use disposable gloves while you perform the test.
- Used tests, swabs, and other associated materials should be discarded into appropriate waste containers.
- Allow controls to come to room temperature before use.

- Use the amount of control as described in the Instructions for Use (i.e. one drop). Using an excess amount may result in a false result.

STORAGE AND STABILITY:

Store the OSOM BVBLUE Control Kit refrigerated at 2-8°C (36-46°F). Do not freeze. The kit is stable until the expiration date shown on the label.

LIMITATIONS OF THE PROCEDURE:

Do not use control beyond the expiration date on the label.

INSTRUCTIONS FOR USE:

Remove the OSOM BVBLUE Control Kit from the refrigerator prior to use. Allow the Control Kit to warm to room temperature before use.

If the OSOM BVBLUE Test Kit is stored in a refrigerator, remove it prior to use. Allow the test kit to warm to room temperature before use.

POSITIVE CONTROL

STEP 1

Remove one BV Test Vessel and the Developer Solution from the OSOM BVBLUE Test Kit prior to use. Remove the cap from the BV Test Vessel.

STEP 2

Add one drop of BVBLUE Positive Control to the BV Test Vessel.

STEP 3

Put the head of a swab from the test kit into the solution in the BV Test Vessel. Let the BV Test Vessel containing the swab stand for **10 minutes** between 17 and 37 °C (62.6 and 98.6° F).

STEP 4

Add one drop of Developer Solution to the BV Test Vessel containing the swab. Gently swirl the mixture.

STEP 5

Read the results immediately after the addition of Developer Solution. See EXPECTED RESULTS Section.

NEGATIVE CONTROL

STEP 1

Remove one BV Test Vessel and the Developer Solution from the OSOM BVBLUE Test Kit prior to use. Remove the cap from the BV Test Vessel.

STEP 2

Add one drop of BVBLUE Negative Control to the BV Test Vessel.

STEP 3

Put the head of a swab from the test kit into the solution in the BV Test Vessel. Let the BV Test Vessel containing the swab stand for **10 minutes** between 17 and 37 °C (62.6 and 98.6° F).

STEP 4

Add one drop of Developer Solution to the BV Test Vessel containing the swab. Gently swirl the mixture.

STEP 5

Read the results immediately after the addition of Developer Solution. See EXPECTED RESULTS Section.

EXPECTED RESULTS:

- a) **Positive Control Result:** The positive control will produce a blue or green color in the test vessel and/or on the head of the swab.
- b) **Negative Control Result:** The negative control will produce a yellow color in the test vessel.

Note: In the case of weak positive results, take the swab out of the vessel to determine if a blue or green color is present on the swab.

Do not report patient results if either of the two quality control tests does not produce the expected results.

If QC testing fails:

- Check expiration dates of the test kit and controls
- Ensure the instructions for testing were followed
- Repeat the test

If the controls still do not perform as expected contact Genzyme Technical Service at 1-800-332-1042.

REFERENCES:

Read the directional insert for the OSOM BVBLUE Test Kit for more information.

ASSISTANCE:

For technical assistance, call Genzyme Diagnostics Technical Service at 800-332-1042.

RE-ORDER:

- No. 183 OSOM® BVBLUE® Test (25Tests)
No. 184 OSOM® BVBLUE® Control Kit

Manufactured for:



Cambridge, MA 02139

Tel: 800-332-1042 (US only)

617-252-7760

Fax: 617-252-7759


www.genzymediagnosics.com


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Manufactured by Gryphus Diagnostics, LLC

KEY TO COMPONENT LABELING

 In vitro diagnostic medical device

 Batch code

 Use by YYYY-MM

 Temperature Limitation

 Catalog Number