

osom[®] BVBLUE[®] CONTROL KIT

For the directional insert in additional languages, visit www.osomtests.com under Product Documentation on the OSOM BVBLUE Test product page.

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 ≥250U/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 (≥10U/40μL)
- 1 bottle (5mL) BVBLUE Negative Control (2-3.5U/40μL)
- Directional Insert

Materials Required But Not Provided

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

WARNINGS AND PRECAUTIONS

Component(s)	Pictogram	Signal Word	Hazardous Ingredients
OSOM [®] BVBLUE [®] Negative Control/ OSOM [®] BVBLUE [®] Positive Control		Danger	Neuraminidase (CAS No) 9001-67-6
Hazard statements	H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled.		
Precautionary statements	P261 - Avoid breathing dust/fumes/gas/mist/vapors/spray. P284 - [In case of inadequate ventilation] wear respiratory protection. P304+P341 - If inhaled: If breathing is difficult, remove person to fresh air and keep comfortable for breathing. P342+P311 - If experiencing respiratory symptoms: Call a poison center or doctor. P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.		

- For *in vitro* diagnostic use.
- Do not use control beyond the expiration date shown on the label.
- Wear disposable gloves while performing 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.

Remove the OSOM BVBLUE Test Kit from the refrigerator prior to use.

Allow the test kit to warm to room temperature before use.

Before adding a patient specimen, inspect the BV Test Vessel. It should contain a colorless liquid without precipitates (sediment). If the testing vessel contains a precipitate, the test is invalid. Do not use the BV Test Vessel.

R_XONLY **CE**

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.

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 SEKISUI Diagnostics Technical Service at 1-800-332-1042 (US) or +1-781-652-7800 (outside US).

REFERENCES

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

ASSISTANCE

For technical assistance, call SEKISUI Diagnostics Technical Service at 1-800-332-1042 (US) or techservices@sekisuidiagnostics.com

RE-ORDER

No. 183 OSOM[®] BVBLUE[®] Test (25 Tests)

No. 184 OSOM[®] BVBLUE[®] Control Kit



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EC REP

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Bergerweg 18
6085 AT Horn
The Netherlands

MANUFACTURED FOR
SEKISUI Diagnostics, LLC
6659 Top Gun Street
San Diego, CA 92121 USA

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.

SYMBOLS

EC REP

Authorised representative in the EC

LOT

Batch code

REF

Catalog Number

R_XONLY

Caution: Federal law restricts this device to sale by or on the order of a physician

CE

CE Mark



Health Hazard

IVD

In vitro diagnostic medical device



Manufacturer



Temperature limit



Use-by date

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