

BVBLUE[®] CONTROL Kit

INTENDED USE:

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

SUMMARY:

The controls are for use with the BVBLUE Test. The 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 limit of detection in a dropper bottle that 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:

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

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:

- 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.

STORAGE AND STABILITY:

Store the BVBLUE Control Kit refrigerated at 36-46°F (2-8°C). 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 BVBLUE Control Kit from the refrigerator prior to use. Allow the BVBLUE Control Kit to warm to room temperature before use. If stored in a refrigerator, remove the BVBLUE Test Kit from the refrigerator prior to use. Allow the BVBLUE Test Kit to warm to room temperature before use.

POSITIVE CONTROL

STEP 1

Remove one BV Test Vessel and the Developer Solution from the 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 into the solution in the BV Test Vessel. Let the BV Test Vessel containing the swab stand for **10 minutes** between 62.6 and 98.6° F (17 and 37 °C).

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 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 into the solution in the BV Test Vessel. Let the BV Test Vessel containing the swab stand for **10 minutes** between 62.6 and 98.6° F (17 and 37 °C).

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 cotton swab.

b) **Negative Control Result:** The negative control will produce a yellow color in the Test Vessel and on the head of the cotton swab.

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. Call Gryphus Diagnostics Technical Support for further information.

REFERENCES:

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

ASSISTANCE:

For technical assistance, call Gryphus Diagnostics Technical Service at 800-924-4195.

RE-ORDER:

No. BVB25 BVBLUE[®] Test (25Tests)

No. S750 BVBLUE[®] Control Kit

Manufactured by:

GryphusDiagnostics

Knoxville, TN 37919 USA

Phone: 865-251-0101

Toll-free: 800-924-4195

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BVBLUE[®] is a registered trademark of Gryphus Diagnostics, LLC

KEY TO COMPONENT LABELING

 In vitro diagnostic medical device

 Batch code

 Use by YYYY-MM

 Temperature Limitation

 Catalog Number

A25 Rev2
Effective: 11/07/05