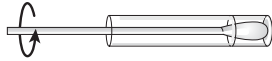


Warning: Read the Directional Insert prior to performing the test.

1



Collect a vaginal fluid sample with a swab. Contact the swab with the lower one-third of the vaginal wall. Collect as much fluid as possible. Put the swab into the BV Test Vessel.

Gently swirl the mixture.

2

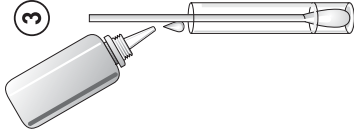


Let the BV Test Vessel containing the swab stand for 10 minutes between 17° and 37°C.



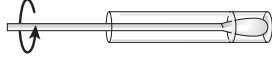
10 min.
17°– 37°C
(62.6°– 98.6°F)

3



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

4



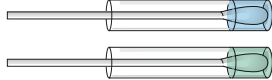
Gently swirl the mixture.

Read the results immediately.

CAUTION: The Developer

Solution is a dilute alkaline solution. This may cause skin and eye irritation. If the solution comes in contact with the skin or eyes, flush with large volumes of water.

5



Positive Result:
A blue or green color in the BV Test Vessel or on the head of the swab.

POSITIVE

NEGATIVE

Negative Result:
A yellow color in the BV Test Vessel.

INTERPRETATION OF TEST RESULTS

There are two possible results:

(a) positive result or (b) negative result

NOTE: You may need to remove the swab to read the test results.

A Positive Result shows a high level of sialidase activity. A Negative Result shows a normal level of sialidase activity.

For facilities in the US: A CLIA Certificate of Waiver is needed to perform testing in waived settings. Read all instructions carefully before use. If a laboratory modifies the following test instructions including Quality Control, the test will be considered High Complexity and no longer considered Waived.

WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use only.
- Do not use after the expiration date printed on the kit.
- Do not store the kit at temperatures above 8°C (46°F).
- Do not store the kit in strong light.
- Follow your laboratory safety guidelines in the collection, handling, storage and disposal of patient specimens and all items exposed to patient specimens.
- Used tests should never be re-used.
- This product is intended for vaginal fluid use only.
- Do not use samples from patients who have used vaginal cream products within 72 hours before testing.
- Do not touch or collect fluid near the cervix.
- Developer solution contains an sodium hydroxide solution. The use of nitrile or latex gloves, wearing protective eye wear, and clothing is recommended when handling the reagent within this kit. Wash hands thoroughly after handling material.

STORAGE AND STABILITY

Store the kit refrigerated, 2° –8°C (36°–46°F), out of direct sunlight. Store vessels inside the box. Kit contents are stable until the expiration date printed on the outer box.

NOTE: Allow the kit to come to room temperature before running the test.

LIMITATIONS OF THE PROCEDURE

- Do not use samples from the cervix.
 - Patients may have mixed infections. The OSOM BVBLUE Test shows that sialidase enzyme is active in the sample. The OSOM BVBLUE Test does not show if other organisms such as yeast and parasitic organisms are present in the sample.
 - Test results should be considered in conjunction with other clinical and patient information.
 - Test operators must follow all instructions to
 - a) collect the sample
 - b) store the sample and
 - c) use the test procedure properly
- If the instructions are not followed, the OSOM BVBLUE Test may not give correct results.

QUALITY CONTROL

1. Internal Quality Controls

The OSOM BVBLUE Test contains two types of internal quality control with each test run. For daily quality control, the manufacturer recommends documenting these controls on each day of testing:

- Type 1 Control: Before adding a patient specimen, inspect the 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 Test Vessel.

- Type 2 Control: The OSOM BVBLUE Test has a two-color result format: blue/green is positive, yellow is negative. After running the test according to the instructions for use, the appearance of either a uniform yellow, blue, or green color in the testing vessel or a blue or green color on the swab assures proper mixing of the reagent and sample has occurred.

If the test fails to provide either a blue, green, or a yellow color result, the test is invalid.

- Do not report patient results if either of the Internal Quality Controls does not produce expected results.

2. External Quality Controls

External Controls are used to test that the reagents are working properly. Also use the Controls to test that you are able to correctly perform the test procedure.

- A Control Kit that contains a positive control and a negative control may be purchased separately from SEKISUI Diagnostics, Catalog No. 184.
- Refer to the Control Kit Directional Insert for instructions on how to interpret the results of the controls.

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 Only) or +1-781-652-7800.

You should follow the manufacturer's guidelines for QC testing. These guidelines state that external controls be run with each new lot, each new shipment and with each new untrained operator.

SEKISUI
DIAGNOSTICS

osom[®]



BVBLUE[®] Test

CLIA Complexity: Waived

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

For facilities in the US: A CLIA Certificate of Waiver is needed to perform testing in waived settings. Read all instructions carefully before use. If a laboratory modifies the following test instructions including Quality Control, the test will be considered High Complexity and no longer considered Waived.

INTENDED USE

The OSOM BVBLUE Test is an enzyme activity test for use in the detection of vaginal fluid specimens for sialidase activity, an enzyme produced by bacterial pathogens such as *Gardnerella vaginalis*, *Bacteroides spp.*, *Prevotella spp.*, and *Mobiluncus spp.*

The OSOM BVBLUE Test is indicated for use in women suspected of having Bacterial Vaginosis (BV) infection, e.g., women with vaginal discharge typical of BV and/or women with previous history of BV, as an aid in the diagnosis of BV infection. Test results should be considered in conjunction with other clinical and patient information (see Limitations of the Procedure).

For *in vitro* Diagnostic Use Only. The OSOM BVBLUE Test is indicated for professional use only and may be used at the point of care and/or in physician's offices. It is not intended for home use.

SUMMARY AND EXPLANATION OF THE TEST

Vaginitis is one of the most common reasons that women visit obstetricians or gynecologists.⁽¹⁻³⁾ BV is the most common form of infectious vaginitis. The causative agents of the infection are bacterial pathogens such as *Gardnerella vaginalis*, *Bacteroides spp.*, *Prevotella spp.* and *Mobiluncus spp.*

Complications associated with BV include salpingitis, endometritis, post-hysterectomy infections, recurrent UTI's, and an increased risk of PID and HIV.⁽⁵⁻⁷⁾ BV presents a serious danger in women, due to its significant association with placental infection, premature rupture of membranes, and preterm birth.⁽⁸⁻¹⁰⁾

Studies have shown elevated sialidase activity in women with BV and an increased risk for preterm birth and low birth weight infants in patients exhibiting elevated sialidase activity.^(4, 11-15)

The OSOM BVBLUE Test is designed to provide a clear, simple indication of elevated sialidase activity in patient vaginal fluid samples. The generation of a blue or green color indicates a positive test result; a yellow color indicates a negative test result.

PRINCIPLES OF BVBLUE

The OSOM BVBLUE Test includes a chromogenic substrate of bacterial sialidase. In the test procedure, a vaginal fluid sample is placed in the BV Test Vessel. The sample then reacts with the chromogenic substrate. A Developer Solution is added after the reaction.

If the sample has a high level of sialidase, a blue or green color will be seen in the BV Test Vessel or on the head of the swab. If the sample has no sialidase, or has very low levels, a yellow color will be seen in the BV Test Vessel.

REAGENTS / MATERIALS

- IBX-4041 component (0.25 mg/test).
- potassium acetate (24.5 mg/test).
- sodium hydroxide (1.0 mg/test).

MATERIALS PROVIDED

- 25 Test Vessels each containing 0.25 mg IBX-4041 component in 0.5 mL of an aqueous potassium acetate buffer solution (49mg/mL; 0.5 M; pH 5.5-6.0).
- 1 Developer Solution Bottle containing 10.0 mL of an aqueous sodium hydroxide solution (40mg/mL; 1.0 M; pH>11.0).
- Sterile Swabs.
- 1 Directional Insert.


Note: Extra reagents have been provided for external QC testing.

MATERIALS REQUIRED BUT NOT PROVIDED

- OSOM BVBLUE Control Kit.
- Timer.

WARNINGS AND PRECAUTIONS

Hazard and Precaution Symbol and Statements only apply to the Developer Solution.

Component (s)	Pictogram	Signal Word	Hazardous Ingredients
OSOM® BVBLUE® Developer Solution		Danger	sodium hydroxide, caustic soda (CAS No) 1310-73-2
Hazard statements	H314 - Causes severe skin burns and eye damage H318 - Causes serious eye damage		
Precautionary statements	P260 - Do not breathe dust/fume/gas/mist/vapors/spray. P264 - Wash hands, forearms and face thoroughly after handling. P280 - Wear protective gloves/protective clothing/eye protection/face protection. P301+P330+P331 - If swallowed: rinse mouth. Do NOT induce vomiting. P303+P361+P353 - If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower. P304+P340 - If inhaled: Remove person to fresh air and keep comfortable for breathing. P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310 - Immediately call a poison center or doctor. P321 - Specific treatment (see supplemental first aid instruction on this label). P363 - Wash contaminated clothing before reuse. P405 - Store locked up. 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 only.
- Caution: Federal Law restricts this device to sale by or on the order of a licensed practitioner.
- Do not use after the expiration date printed on the kit.
- Do not store the kit at temperatures above 8°C (46°F).
- Do not store the kit in strong light.
- Follow your laboratory safety guidelines in the collection, handling, storage and disposal of patient specimens and all items exposed to patient specimens.
- Used tests should never be re-used.
- This product is intended for vaginal fluid use only.
- Developer solution contains an sodium hydroxide solution. The use of nitrile or latex gloves, wearing protective eye wear, and clothing is recommended when handling the reagent within this kit. Wash hands thoroughly after handling material.

SPECIMEN COLLECTION AND STORAGE

- Using a swab provided in the kit, collect specimens from the lower one-third of the vaginal wall. Collecting specimens from the cervix should be avoided because (a) it might increase risk to OB patients, and (b) cervical sialidase activity is usually higher than vaginal sialidase activity.
- Do not use specimens from patients who have (a) used a vaginal cream or ointment product, (b) douched, or (c) used spermicides, vaginal lubricants or feminine sprays within 72 hours of testing.
- Test the patient specimen as soon as possible after collection.
- If you do not perform the OSOM BVBLUE test immediately, store the swabs either at room temperature for up to 48 hours or refrigerated for up to 7 days. To transport patient specimens, place each swab in a clean, dry container such as a plastic or glass tube. Do not use any transport media.
- If you do not collect enough sample or collect from a patient undergoing antimicrobial therapy the test may give a false negative result.

STORAGE AND STABILITY

Store the kit refrigerated, 2-8°C (36-46°F), out of direct sunlight. Store vessels inside the box. Kit contents are stable until the expiration date printed on the outer box.

NOTE: Allow the kit to come to room temperature before running the test.

INDICATIONS OF INSTABILITY

Signs of possible product instability include:

- A blue color in a BV Test Vessel when one drop of Developer Solution is added to the BV Test Vessel in the absence of a patient specimen.

- Positive control does not give expected results.
- Negative control does not give expected results.

QUALITY CONTROL

1. Internal Quality Controls

The OSOM BVBLUE Test contains two types of internal quality control with each test run. For daily quality control, the manufacturer recommends documenting these controls on each day of testing:

- Type 1 Control: 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.

- Type 2 Control: The OSOM BVBLUE Test has a two-color result format: blue/green is positive, yellow is negative. After running the test according to the instructions for use, the appearance of either a uniform yellow, blue, or green color in the testing vessel or a blue or green color on the swab assures proper mixing of the reagent and sample has occurred.

If the test fails to provide either a blue, green, or a yellow color result the test is invalid.

Do not report patient results if either the Type 1 Control or the Type 2 Control does not produce expected results.

2. External Quality Controls

External Controls (available from SEKISUI Diagnostics), are used to test that the reagents are working properly. Also use the Controls to test that you are able to correctly perform the test procedure.

- A Control Kit that contains a positive control and a negative control is available from SEKISUI Diagnostics and may be purchased separately, Catalog No. 184.
- Refer to the Control Kit Directional Insert for instructions on how to interpret the results of the controls.

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 (800)-332-1042 (US Only) or +1-781-652-7800.

2a. For CLIA Waived Labs

You should follow the guidelines below for QC testing. The manufacturer recommends that external controls be run with each new lot, each new shipment and with each new untrained operator.

2b. For CLIA Non-Waived Labs

Quality Control requirements should be established in accordance with local, state and federal regulations or accreditation requirements. Minimally, the manufacturer recommends that external controls be run with each new lot, each new shipment and with each new untrained operator.

LIMITATIONS OF THE PROCEDURE

- Do not use samples from the cervix.
- Patients may have mixed infections. The OSOM BVBLUE Test shows that sialidase enzyme is active in the sample. The OSOM BVBLUE Test does not show if other organisms such as yeast and parasitic organisms are present in the sample.
- Test results should be considered in conjunction with other clinical and patient information.
- Test operators must follow all instructions to a) collect the sample, b) store the sample, and c) use the test procedure properly. If the instructions are not followed, the OSOM BVBLUE test may not give correct results.

EXPECTED VALUES

The OSOM BVBLUE Test can show sialidase activity in vaginal fluid at levels of $\geq 7.64U$. There are two possible results; positive or negative. If the test fails to provide a blue, green, or yellow color result, the test is invalid.

INSTRUCTIONS FOR USE

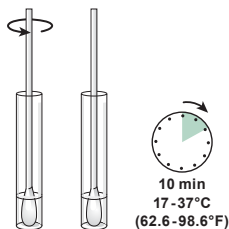
Allow the kit to come to room temperature before running the test.

STEP 1

Remove one BV Test Vessel and the Developer Solution Bottle from the kit prior to use. Remove the cap from the BV Test Vessel.

STEP 2

Collect a vaginal fluid sample with a swab. Contact the swab with the lower one-third of the vaginal wall. Collect as much fluid as possible.



NOTE: Do not use samples from patients who have used vaginal cream products within 72 hours before testing. Do not touch or collect fluid near the cervix.

STEP 3

Put the swab into the BV Test Vessel. Gently swirl the mixture.

STEP 4

Let the BV Test Vessel containing the swab stand for 10 minutes between 17° and 37° C, (62.6–98.6°F).

STEP 5

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

Read the results immediately.

CAUTION: The Developer Solution is a dilute alkaline solution. This may cause skin and eye irritation. If the solution comes in contact with the skin or eyes, flush with large volumes of water.

INTERPRETATION OF TEST RESULTS

There are two possible results: (a) positive result or (b) negative result.

a) Positive Result: A blue or green color in the BV Test Vessel or on the head of the swab.

b) Negative Result: A yellow color in the BV Test Vessel.

NOTE: You may need to remove the swab to read the test results.

A Positive Result shows a high level of sialidase activity.

A Negative Result shows a normal level of sialidase activity.

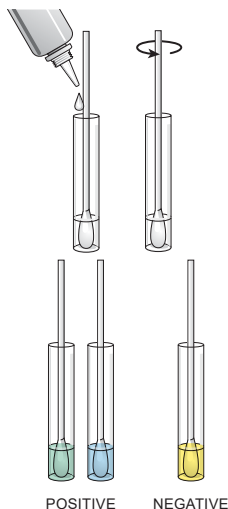


TABLE 1. RESULTS OF A STUDY OF 113 WOMEN

Patient Type	Mean Vaginal Fluid Sialidase Activity
Patients with BV (n=28)	12.3 U (95% CI 8.1–16.6 U)
Healthy Controls (n=65)	2.7 U (95% CI 2.2–3.2 U)
Patients with Candidiasis (n=17)	3.7 U (95% CI 2.6–4.8 U)
Patients with Trichomoniasis (n=3)	1.99 U (95% CI 0.6–3.4 U)

PERFORMANCE CHARACTERISTICS MINIMUM DETECTION LIMIT (MDL)

The OSOM BVBLUE Test was evaluated by different users using control samples to demonstrate the MDL of 0.25 µg (7.64 U). A total of 72 samples with sialidase levels above the MDL were evaluated. Complete agreement of results was obtained on every sample. A total of 141 samples with sialidase levels below the MDL were evaluated. Complete agreement of results was obtained on every sample.

REPRODUCIBILITY STUDIES

The OSOM BVBLUE Test was evaluated at three clinics by three different users (MLTs and RNs) for reproducibility within and between runs and clinics. Each site evaluated 5 coded control samples in triplicate on each of 3 days. A total of 45 samples were evaluated by each clinic. Three of the 5 samples were positive samples and 2 were negative samples. Complete agreement of results was obtained on every sample by each of the three sites, demonstrating the inter-operator, inter-site, intra-site, and inter-day reproducibility of the test.

The OSOM BVBLUE Test was evaluated at three clinics by three different users (MLTs and RNs) for reproducibility within and between runs and clinics. Each site evaluated 10 coded clinical samples over 3 days. Six of the 10 samples were positive samples and 4 were negative samples. Complete agreement of results was obtained on every sample by each of the three sites, demonstrating the inter-operator, inter-site, intra-site, and inter-day reproducibility of the test.

INTERFERENCE STUDIES

In all clinical studies, no evidence of interference was observed for menses (n=118); blood (n=620); semen (n=620); birth control methods (n=36) including birth control pills, Depo-Provera, Norplant, IUDs, condoms, or tubal ligation; or microorganisms (n=118) including Staphylococcus, Streptococcus, E. coli, Candida albicans, Lactobacillus, among others.

METHOD COMPARISON

The OSOM BVBLUE Test was evaluated at five clinics by different users (MDs, MLTs, and RNs) in the US. A total of 620 women were evaluated. Patients treated with a vaginal cream or ointment product within 72 hours prior to testing were excluded.

Independent investigators evaluated the performance of the OSOM BVBLUE Test compared to Amsel Criteria in 620 women (TABLE 2). A clinical diagnosis of BV required the following three symptoms: vaginal fluid pH > 4.5, the presence of vaginal fluid amines, and the presence of clue cells (>20%). Of the 164 symptomatic women, 65% were diagnosed with BV. Of the 456 asymptomatic women, <1% were diagnosed with BV. The sensitivity and specificity of OSOM BVBLUE compared to Amsel .Criteria was found to be 85.2% and 89.6% respectively.

Independent investigators evaluated the performance of OSOM BVBLUE compared to Gram's stain in 118 women (TABLES 3 and 5). A clinical diagnosis of BV required a Gram's stain score of 7–10.⁽¹⁶⁾ Of the 27 symptomatic women, 78% were diagnosed with BV. Of the 91 asymptomatic women, 11% were diagnosed with BV. The sensitivity and specificity of OSOM BVBLUE compared to Gram's stain was found to be 90.3% and 96.6% respectively.

Independent investigators evaluated the performance of OSOM BVBLUE compared to Gram's stain in 220 women (TABLE 6). The sensitivity and specificity of OSOM BVBLUE compared to Gram's stain was found to be 92.8% and 98.0%, respectively.

TABLE 2. UNRECONCILED PERFORMANCE OF OSOM BVBLUE COMPARED TO AMSEL CRITERIA

	BVBLUE Positive
All patients tested (n = 620) (P < 0.0001)	145 (23.4%)
Results in patients with BV by Amsel Criteria (n = 108)	92 (85.2%)
Results in patients without BV by Amsel Criteria (n = 512)	53 (10.4%)

TABLE 3. UNRECONCILED PERFORMANCE OF OSOM BVBLUE COMPARED TO GRAM'S STAIN

	BVBLUE Positive
All patients tested (n = 118) (P < 0.0001)	31 (26.3%)
Results in patients with BV by Gram's Stain (n = 31)	28 (90.3%)
Results in patients without BV by Gram's Stain (n = 87)	3 (3.4%)

MIXED INFECTIONS

The OSOM BVBLUE Test was investigated in 255 patients stratified by clinical diagnosis. The results of this study are presented in TABLE 4.

TABLE 4. RESULTS OF OSOM BVBLUE IN PATIENTS STRATIFIED BY CLINICAL DIAGNOSES

No. of Patients	Clinical Diagnosis			BVBLUE Positive
	Amsel Criteria	Wet Mount		
	BV	Yeast	Trich	
5	+	+	-	4
2	+	-	+	2
4	-	-	+	0
41	-	+	-	0
50	+	-	-	48
153	-	-	-	9
Total (255)	57	46	6	63

TABLE 5. PERFORMANCE OF OSOM BVBLUE AND EIGHT OTHER CLINICAL METHODS COMPARED TO GRAM'S STAIN RESULTS IN 118 PATIENTS

Test vs. Gram's Stain	Sensitivity (%)	Specificity (%)	Overall Accuracy (%)
All patients (n=118)			
OSOM BVBLUE	90.3	96.6	94.9
Amsel Criteria	58.1	95.4	85.6
Vaginal Fluid pH ^a (n=117)	90.3	65.1	71.8
Vaginal Fluid Amines (n=117)	67.7	93.0	86.3
Vaginal Fluid pH and Vaginal Fluid Amines ^b (n=117)	67.7	94.2	87.2
Wet Prep (>20% clue cells) (n=117)	71.0	89.5	84.6

Wet Prep (any clue cells) (n=117)	77.4	84.9	82.9
Semiquantitative Identification of Morphotypes Associated with BV ^c	100	86.2	89.8
Clinically Significant Culture of Microorganisms Associated with BV ^d (n=55)	55.6	86.5	76.4

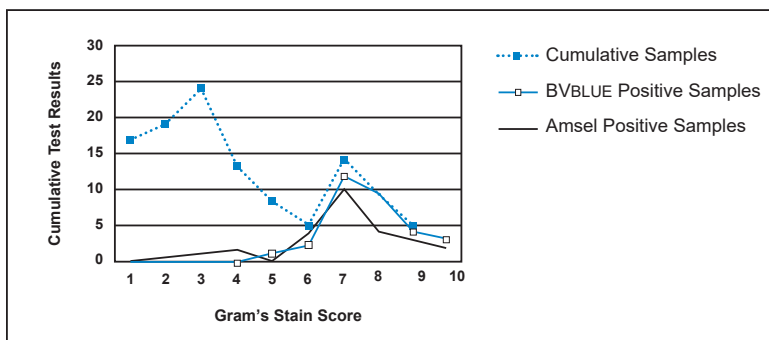
^a Vaginal fluid pH > 4.5 considered positive result.

^b Vaginal fluid pH > 4.5 and presence of vaginal fluid amines considered positive result. All other combinations considered negative result.

^c Includes identification and scoring of *Gardnerella vaginalis*, *Bacteroides* spp., *Prevotella* spp., and/or *Mobiluncus* spp. using Gram's stain. Score of 1+ considered positive result for *Mobiluncus* spp. All other morphotypes required score of 3+.

^d Includes typing and scoring of *Gardnerella vaginalis*, *Bacteroides* spp., and/or *Prevotella* spp. Score of 2+ for each microorganism considered positive result.

FIGURE 1. ASSOCIATION BETWEEN GRAM'S STAIN SCORE AND TEST RESULTS FROM OSOM BVBLUE AND AMSEL CRITERIA^a



^a Gram's stains scored using Nugent method.⁽¹³⁾

TABLE 6. PERFORMANCE OF OSOM BVBLUE COMPARED TO GRAM'S STAIN

Sample Type	Correct	Incorrect	Agreement (95% CI)
All patients tested (n=220) (P<0.0001)	212	8	96.4% (93.9–98.8%)
Results in patients with BV by Gram's Stain (n=69)	64	5	92.8% (86.6–98.9%)
Results in patients without BV Gram's Stain (n=151)	148	3	98.0% (95.8–100%)

CLIA WAIVER PERFORMANCE

The OSOM BVBLUE Test was evaluated by seventy-five non-trained operators at three non-clinical lab sites. Each operator at each site tested four samples from a randomly coded panel of strong negative (25), weak negative (25), weak positive (25), and strong positive samples (25). Three trained lab operators at one lab site ran all 300 samples. Agreement among non-trained operators and known sample distribution was as follows:

TABLE 7. CLIA WAIVER PERFORMANCE OF OSOM BVBLUE

Sample (sialidase activity)	Agreement
Strong Negative (0.15 U)	98.7%
Weak Negative (6.08 U)	100%
Weak Positive (9.15 U)	100%
Strong Positive (20.1 U)	100%

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ASSISTANCE

For assistance call SEKISUI Diagnostics Technical Assistance at 800-332-1042 (US Only) or +1-781-652-7800.

RE-ORDER

No. 183 OSOM® BVBLUE® (25 Tests)

No. 184 OSOM® BVBLUE® Control Kit

OSOM® is a registered U.S. trademark of SEKISUI Diagnostics, LLC.

BVBLUE® is a registered trademark of Gryphus Diagnostics, LLC.

U.S. Patent nos 6,512,100;6,667,161;6,812,332. Other patents pending.



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DIAGNOSTICS

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SYMBOLS

EC **REP** Authorised representative in the EC

LOT Batch code

REF Catalog number

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

CE CE Mark


i Consult instructions for use


Σ n Contains sufficient for $\langle n \rangle$ tests

 Corrosive

IVD *In vitro* diagnostic medical device

 Manufacturer

 Temperature limit

 Use by date

MADE IN THE USA