Traditional Laboratory Method

• For detection of Candida, Gardnerella and Trichomonas
• Technologist Required
• Handle Sample/Preparation Multiple Times
• Turn-around Time up to 15 Days

BD Affirm™ Microbial Identification Test

• With detection of Candida, Gardnerella and Trichomonas
• Easy-to-use
• 2 Minutes Hands-On Time
• 1 Hour Turn-around Time for 18 Results (6 patients x 3 results)
• Walkaway Technology

Comparative Workflow For Detection of Bacterial Vaginosis

Traditional Laboratory Method

•_physician collects 1 (one) specimen (swab) that tests for Trichomonas, Gardnerella and Candida
• Label, package, transport to the lab.

BD Affirm™ VPIII Microbial Identification Test

• Since adapting the BD Affirm™ VPIII our laboratory has increased productivity and turn-around time of our vaginal specimens. Results are objective and can be run by any technician.

Physician’s Office or Clinic

Sutter Health Care Workflow Analysis with BD Affirm™ VPIII for Detection of Bacterial Vaginosis

Physician collects 1 (one) specimen (swab) that tests for Trichomonas, Gardnerella and Candida. Label, package, transport to the lab.

Laboratory Procedures: N = 10

<table>
<thead>
<tr>
<th>Time (as of 8 a.m.)</th>
<th>PHYSICIAN’s OFFICE OR CLINIC</th>
<th>Total Time to Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>8 a.m.</td>
<td>affirm processing</td>
<td>1 hour 55 minutes</td>
</tr>
<tr>
<td>9 a.m.</td>
<td>affirm processing</td>
<td>1 hour 55 minutes</td>
</tr>
<tr>
<td>10 a.m.</td>
<td>affirm processing</td>
<td>1 hour 55 minutes</td>
</tr>
</tbody>
</table>

*Since adopting the BD Affirm™ VPIII our laboratory has increased productivity and turn-around time of our vaginal specimens. Results are objective and can be run by any technician.*
Comparative Workflow For Detection of Bacterial Vaginosis

Traditional Laboratory Method
- **Technologist Required**
- Handle Sample Preparation Multiple Times
- Turn-around Time: Up to 5 Days

BD Affirm™ Microbial Identification
- RNA detection of Candida, Gardnerella, and Trichomonas
- **Easy-to-Use**
- **2 Minutes Hands-On Time**
- 1 Hour Turn-around Time for 18 Results (6 patients x 3 results)
- **Walkaway Technology**

**Sutter Health Care Workflow Analysis with BD Affirm™ VPIII for Detection of Bacterial Vaginosis**

**Traditional Laboratory Method**

**BD Affirm™ VPIII Microbial Identification Test**

PHYSICIAN’S OFFICE OR CLINIC
- Physician collects 1 (one) specimen (swab) that tests for Trichomonas, Gardnerella, and Candida.
- Label, package, transport to the lab.

LABORATORY PROCEDURES: N = 10

**Total Time to Results**
- 1 hour 55 minutes

**Day 1**

**8 a.m.**
- Batch 1: Open sample bags, check ID
- Enter patient info into data management system
- Set up 6 samples
- Incubate samples 10 minutes

**9 a.m.**
- **BD Affirm™ Automated Sample Processing**
- (6 samples) 32 minutes

**10 a.m.**
- Batch 2: Set up 4 samples
- Set up instrument, reagents

**Original of EES-EEF IF intermingled on strip with sample set up by the Affirm processor**

**Legend**
- **BD**
- **BD Affirm™**
- **EES-EEF IF strip**
- **Intermittent vaginal discharge**
- **Vaginal Vaginosis**
- **Rapid test kit**
- **Vaginal swab**
- **Data Entry**
- **Sample Bag**
- **Reagents**
- **Sample Set up**
- **Sample Preparation**
- **Data Entry**
- **Data Entry**
- **Data Entry**
- **Data Entry**
- **Medical Record**

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Traditional Laboratory Workflow
For Detection of Bacterial Vaginosis

PHYSICIAN’S OFFICE OR CLINIC

Physicians collect multiple specimens for
Trichomonas, Gardnerella and Candida.
Identify 3 to 4 acids, 5 pH, landscape,
Gram stain, and culture. In "Hot" Target devices may be
necessary for suspected Trichomonas.

LABORATORY PROCEDURES

Specimens are in lab for bacterial isolation.
Rapid test results and culture set up
Culture evaluated depending on negative outcome of rapid tests.
Adequate to multiple batch.

Maintenance Criteria:
Candida: Refrigerate
Trichomonas: No Refrigerate need

Speed Criteria:
Candida: 1 to 2 hours
Trichomonas: Rapid delivery necessary

RESULTS FOR GRAM STAIN

ORGANISM    RESULTS    PROCEDURE

Candida
Trichomonas vaginalis

18 - 24 Hours Incubation

Prepare Preliminary Report: Negative for
by Gram Stain. (Culture Pending)

Prepare Preliminary Report: Negative for
on Wet Mount (Culture Pending).

Prepare Final Report: Positive for

Perform Germ Tube Test:

Re-examine Culture

FROM DAY 1

10 a.m.

FROM DAY 2

8 a.m.

FROM DAY 4

8 a.m.

FROM DAY 5

9 a.m.

FROM DAY 3

10 a.m.

LEGEND

Lab Assistant

Technician

Culture Processing

Culture Media Options: Diamond’s, Trichosel™, Hollander’s

MIXED CULTURE SET-UP, MEDIA OPTIONS

Culture Set-up: BAP, Sab Dex, Mycosel, Potato Dextrose

18 - 24 Hours Incubation

RESULTS FOR CALCOFLUOR WHITE STAIN

ORGANISM    RESULTS    PROCEDURE

Candida
Trichomonas vaginalis

Prepare Final Report: Positive for

Perform Germ Tube Test:

Re-examine Culture

FROM DAY 1

10 a.m.

FROM DAY 2

8 a.m.

FROM DAY 4

8 a.m.

FROM DAY 5

9 a.m.

FROM DAY 3

10 a.m.

RESULTS FOR pH

ORGANISM    RESULTS    PROCEDURE

Candida
Trichomonas vaginalis

Prepare Final Report: Positive for

Perform Germ Tube Test:

Re-examine Culture

FROM DAY 1

10 a.m.

FROM DAY 2

8 a.m.

FROM DAY 4

8 a.m.

FROM DAY 5

9 a.m.

FROM DAY 3

10 a.m.

RESULTS FOR ACID STAIN

ORGANISM    RESULTS    PROCEDURE

Candida
Trichomonas vaginalis

Prepare Final Report: Positive for

Perform Germ Tube Test:

Re-examine Culture

FROM DAY 1

10 a.m.

FROM DAY 2

8 a.m.

FROM DAY 4

8 a.m.

FROM DAY 5

9 a.m.

FROM DAY 3

10 a.m.

RESULTS FOR IN HARMONY STAIN

ORGANISM    RESULTS    PROCEDURE

Candida
Trichomonas vaginalis

Prepare Final Report: Positive for

Perform Germ Tube Test:

Re-examine Culture

FROM DAY 1

10 a.m.

FROM DAY 2

8 a.m.

FROM DAY 4

8 a.m.

FROM DAY 5

9 a.m.

FROM DAY 3

10 a.m.

Total Time to Results
4 - 5 Days

Yeasts of medical importance, pp. 1694-1695.
Comparative Workflow
For Detection of Bacterial Vaginosis

Traditional Laboratory Method

- Technologist Required
- Handle Sample/Preparation Multiple Times
- Turn-around Time Up to 5 Days

BD Affirm™ Microbial Identification

- Easy-to-Use
- 2 Minutes Hands-On Time
- 1 Hour Turn-around Time for 18 Results (6 patients x 3 results)
- Walkaway Technology

"Since adapting the BD Affirm™ VPIII our laboratory has increased productivity and turn-around time of our vaginal specimens. Results are objective and can be run by any technician."

Barbara Schwindt
Microbiology Technical Specialist
Marin General Hospital
Member of the Sutter Health Group

For more information, contact your local BD Representative or call BD Diagnostics at 800-553-3470 today.

Total Time to Results
1 hour 55 minutes

Day 1
8 a.m.
9 a.m.
10 a.m.

BATCH 1:
Open sample bags, check ID
Enter patient info into data management system
Set up 6 samples
Incubate sample 10 minutes
BD Affirm Automated Sample Processing 32 minutes (6 samples)
BD Affirm Automated Sample Processing 32 minutes (4 samples)
Incubate sample 10 minutes
Set up instrument, reagents

BATCH 2:
Set up 4 samples
Set up instrument, reagents
Prepare Final Report

Physician’s Office or Clinic

Physician collects 1 (one) specimen (swab) that tests for Trichomonas, Gardnerella and Candida.
Label, package, transport to the lab.

Legend

BD Affirm Automated Sample Processing
Lab Assistant Affirm Processing
Preparation of Specimen
Physician’s Office or Clinic
Physician collects 1 (one) specimen (swab) that tests for Trichomonas, Gardnerella and Candida.
Label, package, transport to the lab.

Support Health Care Provider

For more information, contact your local BD Representative or call BD Diagnostics at 800-553-3470 today.
BD Affirm™ VPIII Test Procedure for Candida, Gardnerella and Trichomonas

Always label Sample Collection Tube, Probe Analysis Card, and Reagent Cassette with correct sample ID.

Sample Preparation
Start Sample Preparation within 1 hour of collection or store up to 4 hours at 2 - 8°C.

1. Add 12 drops (0.4 mL) Lysis Solution and vigorously swirl swab for 10 seconds.

2. Incubate 10 min. at 85°C.

3. Add 12 drops (0.6 mL) Buffer Solution. Flick tube 10 times and then dispose of swab/cap.

Note: Prepared samples may be stored up to 24 hours at room temperature before processing.

Automated Processing

1. Add 4 drops (0.1 mL) Substrate Solution to Well 7.

2. Place Filter Tip on tube. Place tube in Reservoir and dispense entire sample into Well 1.


Controls
Test is VALID if POSITIVE Control = BLUE
NEGATIVE Control = COLORLESS

For result interpretation of trivalent control see package insert.

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