**Regulations/standards for training & assessment of testing personnel**

**CLIA & Joint Commission:**
- ✔ Competency assessment, observation, and documentation of 6 elements (below)
- ✔ Yearly for all testing personnel and twice annually for new staff
- 1. Direct observation of testing and process
- 2. Monitoring, recording, reporting of test results
- 3. Review of intermediate test results, Quality Control, proficiency testing, etc.
- 4. Assess test performance using previously analyzed samples, blind samples, or proficiency testing
- 5. Direct observation of instrument maintenance
- 6. Assessment of problem solving skills

**CLIA-WAIVED TESTS**

**OSOM® TRICHOMONAS**

- CLIA: Follow manufacturer instructions*
- Joint Commission:
  1. Staff training is performed and documented
  2. Plus **two** of the following (annually):
     - Testing an “unknown” sample
     - Direct observation of testing
     - Review External QC
     - Written competency exam

**OSOM® BVBLUE®**

- CLIA: Follow manufacturer instructions*
- Joint Commission:
  1. Staff training is performed and documented
  2. Plus **two** of the following (annually):
     - Testing an “unknown” sample
     - Direct observation of testing
     - Review External QC
     - Written competency exam

*Under GLP (Good Laboratory Practices for Waived Sites (CDC/MMWR) staff should be trained before reporting patient results; periodic evaluation of competency recommended.

This information is provided for informational use only; please refer to your local, state, federal and accreditation regulations for specific requirements.
# Trichomonas and BV Method Comparison

<table>
<thead>
<tr>
<th>Method</th>
<th>Sensitivity</th>
<th>Specificity</th>
<th># in Study</th>
<th>CPT Code</th>
<th>Reimbursement (CMS Nat'L Limit)*</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Bacterial Vaginitis (vs. Gram Stain)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>OSOM® BVBLUE®</td>
<td>92.8%</td>
<td>98%</td>
<td>220</td>
<td>87905QW</td>
<td>$16.80</td>
</tr>
<tr>
<td>Vaginal fluid pH &gt;4.5</td>
<td>90.3%</td>
<td>65.1%</td>
<td>117</td>
<td>83986QW</td>
<td>$4.92</td>
</tr>
<tr>
<td>Clue cells (&gt;20%)</td>
<td>71%</td>
<td>89.5%</td>
<td>117</td>
<td>87210</td>
<td>$5.87</td>
</tr>
<tr>
<td>Vaginal fluid amines</td>
<td>67.7%</td>
<td>93%</td>
<td>117</td>
<td>82120QW</td>
<td>$5.17</td>
</tr>
<tr>
<td>Abnormal discharge</td>
<td>58.3%</td>
<td>46.7%</td>
<td>312</td>
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</tr>
<tr>
<td>Amsel criteria</td>
<td>58.1%</td>
<td>95.4%</td>
<td>118</td>
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<td></td>
</tr>
<tr>
<td>Culture</td>
<td>55.6%</td>
<td>86.5%</td>
<td>55</td>
<td>87075</td>
<td>$13.01</td>
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<tr>
<td><strong>Trichomonas</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>OSOM® Trichomonas</td>
<td>83.3%</td>
<td>99%</td>
<td>437</td>
<td>87808QW</td>
<td>$16.49</td>
</tr>
<tr>
<td>Wet mount</td>
<td>58%</td>
<td>100%</td>
<td></td>
<td>87210</td>
<td>$5.87</td>
</tr>
</tbody>
</table>

1. OSOM® BVBLUE® package insert
3. Wiese, Wilhelmin, MD; Patel, Sangya R., MD et al; A Meta-Analysis of the Papanicolaou Smear and Wet Mount for the Diagnosis of Vaginal Trichomoniasis, American Journal of Medicine, 2000; 108:301-308

* Codes and reimbursement are from 2013 CMS Clinical Diagnostic Fee Schedule and are provided as suggestions and estimates only.

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**OSOM® TRANSPORT SYSTEMS**

Now you can easily transport specimens for OSOM® Trichomonas and OSOM® BVBLUE® to an alternate site for testing.

**OSOM® VAGINITIS TRANSPORT SYSTEM (TRICH & BV) #185**

**OSOM® BVBLUE® TRANSPORT SWAB #186**