

osom[®]

Trichomonas and BV Method Comparison

PROCEDURE	PROVIDER PERFORMED MICROSCOPY PROCEDURES	CLIA-WAIVED TESTS	
METHOD	WET MOUNT	OSOM [®] TRICHOMONAS	OSOM [®] BVBLUE [®]
<p>Regulations/standards for training & assessment of testing personnel</p> <p><small>*Under GLP (Good Laboratory Practices for Waived Sites (CDC/MMWR)) staff should be trained before reporting patient results; periodic evaluation of competency recommended.</small></p> <p><small>This information is provided for informational use only; please refer to your local, state, federal and accreditation regulations for specific requirements.</small></p>	<p>CLIA & Joint Commission:</p> <ul style="list-style-type: none"> ✓ Competency assessment, observation, and documentation of 6 elements (below) ✓ Yearly for all testing personnel and twice annually for new staff <hr/> <ol style="list-style-type: none"> 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 	<p>CLIA: Follow manufacturer instructions*</p> <p>Joint Commission:</p> <ol style="list-style-type: none"> 1. Staff training is performed and documented 2. Plus two of the following (annually): <ul style="list-style-type: none"> • Testing an "unknown" sample • Direct observation of testing • Review External QC • Written competency exam 	<p>CLIA: Follow manufacturer instructions*</p> <p>Joint Commission:</p> <ol style="list-style-type: none"> 1. Staff training is performed and documented 2. Plus two of the following (annually): <ul style="list-style-type: none"> • Testing an "unknown" sample • Direct observation of testing • Review External QC • Written competency exam





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THE AMERICAS

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METHOD	SENSITIVITY	SPECIFICITY	# IN STUDY	CPT CODE	REIMBURSEMENT (CMS NAT'L LIMIT)*
BACTERIAL VAGINITIS (VS. GRAM STAIN)					
OSOM® BVBLUE® ^{1,2}	92.8%	98%	220	87905QW	\$ 16.80
Vaginal fluid pH >4.5	90.3%	65.1%	117	83986QW	\$ 4.92
Clue cells (>20%)	71%	89.5%	117	87210	\$ 5.87
Vaginal fluid amines	67.7%	93%	117	82120QW	\$ 5.17
Abnormal discharge	58.3%	46.7%	31 ²		
Amsel criteria	58.1%	95.4%	118		
Culture	55.6%	86.5%	55	87075	\$ 13.01

TRICHOMONAS

OSOM® Trichomonas	83.3%	99%	437	87808QW	\$ 16.49
Wet mount ³	58%	100%		87210	\$ 5.87

1. OSOM® BVBLUE® package insert

2. Myziuk, L., Romanowski, B. and S. Johnson; BVBLUE® Test for Diagnosis of Bacterial Vaginosis. Jnl. of Clin. Microbiology, May 2003;41(5):1925-1928

3. Wiese, Wilhelmine, 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