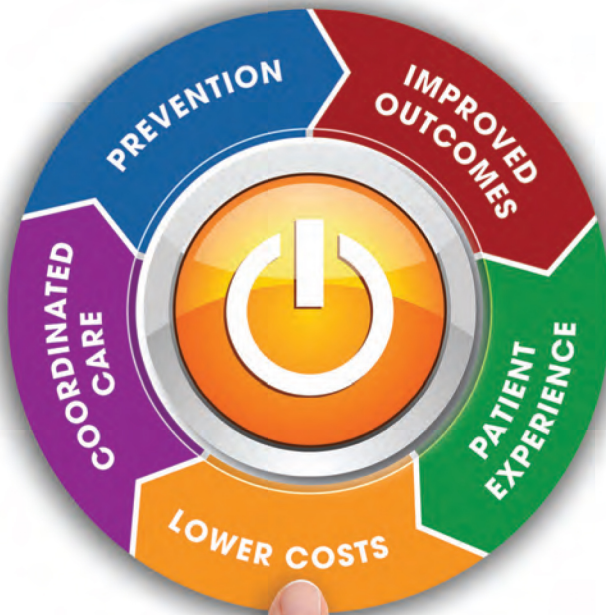


# osom<sup>®</sup>

answers for healthcare start here



Diagnostic Products  
for Health Systems







**Isn't it time we measure the value of a product by the outcomes rather than simply by the cost?**

OSOM<sup>®</sup> rapid diagnostics offers you a variety of family and women's health products and our services deliver unparalleled value. Fast, point-of-care results help reduce follow-up visits, promote education/prevention and allow for more precise treatment.

Together we can improve patient care and lower healthcare costs.

Awesome...yes, OSOM<sup>®</sup>

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## Our tests are awesome... yes, OSOM®

**Made In The USA** Our tests are manufactured in the U.S.A. using the highest quality standards.

**OSOM® Custom Care** Sekisui Diagnostics' Customer Support Team works with you to provide customized assistance to meet your needs. Our highly-trained Technical Support Specialists, all medical technologists with extensive clinical laboratory backgrounds, are available to assist you with:

- **C**oncerns or questions about any of our products
- **A**ssay use, adoption and staff training
- **R**ecord keeping, regulations and reimbursement
- **E**valuation of new methods: remote or onsite assay verification program

For more information or for assistance call us at 800-332-1032 (U.S. only) or email us at [osomrapidtests@sekisui-dx.com](mailto:osomrapidtests@sekisui-dx.com).

**QC® Inside** A select number of OSOM® rapid tests now include something special inside; two extra test sticks in each kit for external QC. This added value, which only Sekisui Diagnostics offers, removes the added expense of performing quality control testing.

**Online Product Training** View a simple animation of the test procedure, take a quiz and print a training certificate, anytime! Our multi-lingual training module can help to train clinical staff. Go to [www.osomtraining.com](http://www.osomtraining.com).

# osom<sup>®</sup> products

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# Family Health

## Strep A



SEKISUI CAT. #	141	147	149
TEST FORMAT	Dipstick	Dipstick	Dipstick
QC INSIDE*	Yes	No	Yes
QUANTITY/KIT	50	25	50
CLIA	Waived	Waived	Waived
CPT CODE	87880 QW	87880 QW	87880 QW
# OF STEPS	4	3	4
SENSITIVITY VS. SINGLE-SWAB CULTURE	96%	95.7%	95.7%
SPECIFICITY VS. SINGLE-SWAB CULTURE	97.8%	100%	100%
TIME TO RESULT	5 min. + 1 min. extraction	5 min. + 2 min. extraction	5 min. + 2 min. extraction
KIT STORAGE	Room Temp.	Room Temp.	Room Temp.
SHELF LIFE	17 mos.	15 mos.	15 mos.
SAMPLE STORAGE	Room Temp. up to 72 hrs.	Room Temp. up to 72 hrs.	Room Temp. up to 72 hrs.
SAMPLE TRANSPORT	Stuart's or Amies media or in dry transport tube	Stuart's or Amies media or in dry transport tube	Stuart's or Amies media or in dry transport tube
REAGENT DELIVERY	A and B reagent bottles	Single reagent bottle	A and B reagent bottles

\*Two extra tests for external QC testing

BENEFIT	OSOM® FEATURES	REFERENCES
IMPROVED OUTCOMES	Clinical comparison to Rigorous Gold Standard and statistically equivalent to culture.*	"The Ultra Strep A test has sensitivity (even when compared to Rigorous Gold Standard) within a range that would consider sufficient to eliminate the need for culture back-up." <sup>1</sup>
PATIENT EXPERIENCE	Results in 5 minutes while the patient waits.	Once treatment begins, patient should start to feel better after 24 to 48 hours. <sup>4</sup>
PREVENTION	Highly sensitive; accurate diagnosis is important to avoid over prescribing of antibiotics.	Studies have shown antibiotics were prescribed in 68% of pediatric acute respiratory tract visits—and of those, 80% were unnecessary according to CDC guidelines. In addition, unnecessary prescriptions for adult upper respiratory infections cost \$1.1 billion annually. <sup>2</sup>
COORDINATED CARE	Easy-to-use with minimal waste	"The OSOM color immunochromatographic dipstick Strep A performed at least as well as the best of the many rapid strep A antigen detection tests that we evaluated in our office laboratory during the past 12 years. There are few reagent steps, the color endpoint is distinct, the 50 test strips are contained in a small easy-to-store cylinder and there is much less plastic for our biodegradable trash. Our nurses appreciate the simplicity and rapidity." <sup>3</sup>
LOWER COSTS	Two additional tests for external QC testing ensures there are 50 dipsticks for patient testing. Ask your customer how much "net" value their current rapid test provides rather than simply focusing on the total cost per kit.	

## Family Health

# Mononucleosis



SEKISUI CAT. #	145
TEST FORMAT	Dipstick
QC INSIDE*	Yes
QUANTITY/KIT	25
CLIA	Waived (Whole Blood); Moderate (Serum/Plasma)
CPT CODE	86308 QW
# OF STEPS	3
SENSITIVITY	99%
SPECIFICITY (RECONCILED W/EBV SEROLOGY)	95.9%
TIME TO RESULT	5 min.
KIT STORAGE	Room Temp.
SHELF LIFE	12 mos.
SAMPLE STORAGE	Serum/Plasma: refrigerated up to 48 hrs. or frozen up to 3 mos. Whole Blood: room temp. up to 24 hrs.
SAMPLE TRANSPORT	In blood collection tube
SAMPLE TYPE	Serum, Plasma. or Whole Blood

\*Two extra tests for external QC testing



BENEFIT	OSOM® FEATURES	REFERENCES
IMPROVED OUTCOMES	To rule out other more severe infections such as cytomegalovirus (CMV) or toxoplasmosis.	
PATIENT EXPERIENCE	Results in 5 minutes while the patient waits.	
PREVENTION	Rest, recommended with positive diagnosis of mono, can help to reduce spread of infection.	
COORDINATED CARE	Can be used on children <18 years old.	Package insert
LOWER COSTS	Two additional tests for external QC testing ensures there are 25 dipsticks for patient testing. Ask your customer how much "net" value their current rapid test provides rather than simply focusing on the total cost per kit.	

**Results in 5 minutes while the patient waits.**

answers for healthcare start here



## Family Health

# Influenza A&B



SEKISUI CAT. #	190
TEST FORMAT	Dipstick
QC INSIDE*	Yes
QUANTITY/KIT	25
CLIA	Non-waived
CPT CODE	If A or B alone is ordered, use 87804; If both A and B are ordered, use 87804 (A) & 87804-59 (B)
# OF STEPS	3
SENSITIVITY (VS. CULTURE)	A= 73.8% (CI: 64-82%) B= 60% (CI: 45-74%)
SPECIFICITY (VS. CULTURE)	A= 96.4% (CI: 93-98%) B= 96.4% (CI: 94-98%)
TIME TO RESULT	10 min.
KIT STORAGE	Room Temp.
SHELF LIFE	15 mos.
SAMPLE STORAGE	Refrigerate for 24 hrs. or store at room temp. for 8 hrs; once extracted, can be stored for 24 hrs. at room temp. or refrigerated
SAMPLE TRANSPORT	Clean, dry container; plastic or glass tube

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\*Two extra tests for external QC testing

BENEFIT	OSOM® FEATURES	REFERENCES
IMPROVED OUTCOMES	Highly sensitive and specific	Studies have shown antibiotics were prescribed in 68% of pediatric acute respiratory tract visits — and of those, 80% were unnecessary according to CDC guidelines. <sup>2</sup>
PATIENT EXPERIENCE	Results in 10 minutes while patient waits.	
PREVENTION	Accurate diagnosis is important to avoid over-prescribing of antibiotics.	<p>“A rapid test that enables the early recognition of patients with influenza has many advantages.”<sup>5</sup></p> <ul style="list-style-type: none"> <li>• Prevent unnecessary antibiotic prescriptions, hospitalizations and Influenza transmission</li> <li>• Contribute to the reduction of the economic burden of influenza</li> <li>• Enable the proper use of antiviral agents</li> </ul>
COORDINATED CARE	Specific diagnosis eliminates more serious health consequences.	“The clinical symptoms of influenza tend to overlap with the symptoms of other respiratory infections in both pediatric and adult patients. This makes the clinical diagnosis of influenza problematic.” <sup>5</sup>
LOWER COSTS	<p>Diagnose and properly treat in one visit.</p> <p>Two additional tests for external QC testing ensures there are 25 dipsticks for patient testing. Ask your customer how much “net” value their current rapid test provides rather than simply focusing on the total cost per kit.</p>	\$1.1 billion is spent annually on unnecessary prescriptions for adult upper respiratory infections. <sup>2</sup>

## Family Health

# H. pylori



SEKISUI CAT. #	175
TEST FORMAT	Cassette
QC INSIDE	No
QUANTITY/KIT	25
CLIA	Waived (Whole Blood) Moderate (Serum/Plasma)
CPT CODE	86318QW (Whole Blood) 86677 (Serum/Plasma)
# OF STEPS	2
SENSITIVITY	96% vs. biopsy
SPECIFICITY	89% vs. biopsy
TIME TO RESULT	10 min.
KIT STORAGE	Room Temp.
SHELF LIFE	18 mos.
SAMPLE STORAGE	Refrigerate up to 48 hrs.
SAMPLE TRANSPORT	Collection tube

BENEFIT	OSOM® FEATURES	REFERENCES
IMPROVED OUTCOMES	Highly sensitive.	Accurate diagnosis reduces the need for antisecretory medications as well as the number of endoscopies. <sup>6</sup>
PATIENT EXPERIENCE	Non-invasive testing	Eradication of H. pylori improves healing and reduces the risk of recurrence or rebleeding in patients with duodenal or gastric ulcers. <sup>6</sup>
PREVENTION	Reduces the risk of developing more serious ulcers and other health issues.	
COORDINATED CARE	Front line test to aid in the diagnosis and to promote treatment prior to involving specialists.	
LOWER COSTS	Early diagnosis leads to more economical therapy prior to expensive procedures like endoscopy.	

**Early diagnosis leads to more economical therapy without expensive procedures.**

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## Women's Health

# Trichomonas Bacterial Vaginosis



SEKISUI CAT. #	181	183
TEST FORMAT	Dipstick	Colorimetric enzyme activity test
QC INSIDE*	No	No
QUANTITY/KIT	25	25
CLIA	Waived	Waived
CPT CODE	87808QW	87905QW
# OF STEPS	3	2
SENSITIVITY	83%	92.8%
SPECIFICITY	99%	98%
REFERENCE METHOD	Culture and Wet Mount (combined)	Gram's Stain
TIME TO RESULT	10 min.	10 min.
KIT STORAGE	Room Temp.	Refrigerated
SHELF LIFE	16 mos.	11 mos.
SAMPLE TYPE	Vaginal swab or saline solution from wet mount	Vaginal swab
SAMPLE STORAGE	Room Temp. up to 24 hrs. Refrigerated up to 36 hrs.	Room Temp. up to 48 hrs.; Refrigerated up to 7 days
SAMPLE TRANSPORT	<ul style="list-style-type: none"> <li>• Clean dry container</li> <li>• #7628 rayon swabs only</li> <li>• #7760 plastic transport tubes</li> <li>• #7754 dual rayon swab in transport tube</li> <li>• #185 OSOM® Vaginitis Transport Set (for use with BVBLUE® and OSOM® Trichomonas)</li> </ul>	Clean dry container; options include: <ul style="list-style-type: none"> <li>• #7760 plastic transport tubes</li> <li>• #185 OSOM® Vaginitis Transport Set (for use with BVBLUE® and OSOM® Trichomonas)</li> <li>• #186 OSOM® BVBLUE® transport swab</li> </ul>

\*Two extra tests for external QC testing

BENEFIT	OSOM® FEATURES	REFERENCES
IMPROVED OUTCOMES	Better sensitivity than traditional methods	<p>Elevated sialidase level that is measured at 12 weeks of gestation is associated strongly with early spontaneous preterm births and miscarriage. As the amount of vaginal sialidase activity increases, the likelihood of adverse outcomes also increases.<sup>8</sup></p> <p>Rapid Trichomonas antigen testing is equivalent to culture and it compares favorably with the sensitivity of TMA for the detection of TV.<sup>9</sup></p>
PATIENT EXPERIENCE	Results in 10 min. while the patient waits.	The majority of women at the greatest risk for the sequelae of BV are not in settings where the conventional diagnostic methods are either practical or possible, and they greatly benefit from access to rapid reliable point-of-care tests to improve the diagnosis and management of BV. <sup>10</sup>
PREVENTION	There are a number of complications associated with a Trichomonas and BV infection; each of which carries significant health and economic costs.	MINIMIZE SERIOUS HEALTH CONSEQUENCES <sup>10</sup> ; susceptibility to HIV and other STD's (HSV, Chlamydia, Gonorrhea); increased chance of post-operative infections; increased risk of pre-term birth; pelvic inflammatory disease
COORDINATED CARE	Therapy can be implemented to integrate the efforts of medical and social service.	The OSOM®Trichomonas Rapid Test will be an important addition to the repertoire of techniques available for T. vaginalis detection... in settings where difficult patient follow-up makes point-of-care testing attractive. <sup>11</sup>
LOWER COSTS	Reduce labor costs and overall expense to the system by avoiding long term serious health consequences.	The decreased hands-on time of performing the OSOM® test significantly decreased the amount of MLA/MLT time devoted to microscopy. The projected labor savings can be utilized to perform other laboratory procedures. <sup>12</sup>

## Women's Health

# Trichomonas and BV Method Comparison

BACTERIAL VAGINITIS (VS. GRAM STAIN)					
METHOD	SENSITIVITY	SPECIFICITY	# IN STUDY	CPT CODE	REIMBURSEMENT*
OSOM® BVBLUE® <sup>13, 14</sup>	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 <sup>14</sup>		
Amsel criteria	58.1%	95.4%	118		
Culture	55.6%	86.5%	55	87075	\$ 13.01

TRICHOMONAS					
METHOD	SENSITIVITY	SPECIFICITY	# IN STUDY	CPT CODE	REIMBURSEMENT*
OSOM® Trichomonas	83.3%	99%	437	87808QW	\$ 16.49
Wet mount <sup>15</sup>	58%	100%		87210	\$ 5.87

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

The OSOM® tests are more sensitive than traditional diagnostic methods.

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# Women's Health

# Standards for Training & Assessment

## WET MOUNT VS. CLIA-WAIVED TESTS

PROVIDER PERFORMED MICROSCOPY PROCEDURES	CLIA-WAIVED TESTS
<p><b>WET MOUNT</b></p> <p>CLIA &amp; Joint Commission:</p> <ul style="list-style-type: none"><li>✓ Competency assessment, observation, and documentation of <b>6 elements</b> (below)</li><li>✓ <b>Yearly</b> for all testing personnel and twice annually for new staff</li></ul> <hr/> <ol style="list-style-type: none"><li>1. Direct observation of testing and process</li><li>2. Monitoring, recording, reporting of test results</li><li>3. Review of intermediate test results, Quality Control, proficiency testing, etc.</li><li>4. Assess test performance using previously analyzed samples, blind samples, or proficiency testing</li><li>5. Direct observation of instrument maintenance</li><li>6. Assessment of problem solving skills</li></ol>	<p><b>OSOM® TRICHOMONAS / OSOM® BVBLUE®</b></p> <p>CLIA: Follow manufacturer instructions*</p> <hr/> <p>Joint Commission:</p> <ol style="list-style-type: none"><li>1. Staff training is performed and documented</li><li>2. Plus <b>two</b> of the following (annually):<ul style="list-style-type: none"><li>• Testing an “unknown” sample</li><li>• Direct observation of testing</li><li>• Review External QC</li><li>• Written competency exam</li></ul></li></ol>

\*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.

# Women's Health

## hCG



<b>SEKISUI CAT. #</b>	101	102	124
<b>TEST FORMAT</b>	Dipstick	Cassette	Cassette
<b>QC INSIDE</b>	No	No	No
<b>QUANTITY/KIT</b>	50	25	25
<b>CLIA</b>	Waived	Waived	Waived (Urine)
<b>CPT CODE</b>	81025	81025	81025; 84703
<b># OF STEPS</b>	1	1	1
<b>SENSITIVITY</b>	25 mIU/ml	20 mIU/ml (urine)	20 mIU/ml (urine) 10 mIU/ml (serum)
<b>TIME TO RESULT</b>	5 min.	3 min.	3 minutes (urine), 5 minutes (serum)
<b>KIT STORAGE</b>	Room Temp.	Room Temp.	Room Temp.
<b>SHELF LIFE</b>	18 mos.	24 mos.	24 mos.
<b>SAMPLE</b>	Urine	Urine	Urine or Serum
<b>SAMPLE STORAGE</b>	Refrigerated up to 48 hrs.	Room Temp. up to 8 hrs. or refrigerated up to 72 hrs.	Urine: room temp. up to 8 hrs. or refrigerated up to 72 hrs.  Serum: refrigerated 48 hrs. or frozen up to 1 yr.

BENEFIT	OSOM® FEATURES	REFERENCES
IMPROVED OUTCOMES	Highly sensitive and specific.	
PATIENT EXPERIENCE	Fast	
PREVENTION	Avoid complications from drugs or medical procedures.	
COORDINATED CARE	Easy to perform, in the office.	
LOWER COSTS	Economical	

**Avoid complications from drugs or medical procedures.**

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## Footnotes

\*See package insert for study details

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