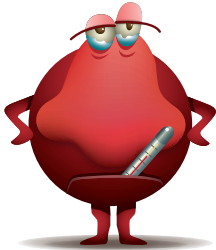
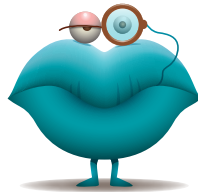


osom[®]

rapid diagnostics



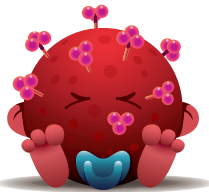
Sniff



Smooch



Streppy



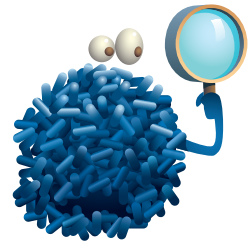
Ruvee



Henry P. Lori



Tribie



Beverly

Meet Our Awesome Family.

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

OSOM[®] 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[®]

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OSOM[®]

Tests / Service / Outcomes

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



MADE IN THE USA



QC Inside[®] A select number of OSOM[®] rapid tests now include something special inside; two extra tests in each kit for external QC. This added value, which only

Sekisui Diagnostics offers, removes the added expense of performing quality control testing.

SDX Academy 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.sdxacademy.com.



osom[®] products

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- 3 Strep A
- 4 Influenza A&B
- 5 RSV/Adeno
- 6 Mononucleosis
- 7 H. pylori
- 8 iFOBT
- 9 Trichomonas
- 9 Bacterial Vaginosis
- 10 hCG
- 11 Controls/Accessories

Family Health

Strep A



SEKISUI CAT. #	Strep A 141/141E	Ultra Strep A 147	Ultra Strep A 149
TEST FORMAT	Dipstick	Dipstick	Dipstick
QC INSIDE*	Yes	No	Yes
QUANTITY/KIT	50	25	50
SAMPLE TYPE	Throat Swab	Throat Swab	Throat Swab
CLIA	Waived	Waived	Waived
CPT CODE	87880 QW	87880 QW	87880 QW
# OF STEPS	4	3	4
TIME TO RESULT	5 minute + 1 minute extraction	5 minute + 2 minute extraction	5 minute + 2 minute extraction
PERFORMANCE SENSITIVITY SPECIFICITY	96.0% 97.8%	95.7% 100%	95.7% 100%
KIT STORAGE	Room Temp	Room Temp	Room Temp
SHELF LIFE	17 months	15 months	15 months
TRANSPORT MEDIA	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
SAMPLE STORAGE	Room Temp up to 72 hours	Room Temp up to 48 hours	Room Temp up to 48 hours
REAGENT DELIVERY	1 and 2 reagent bottles	Single Reagent Bottle	A and B reagent bottles

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Refer to Instructions For Use for detailed product information.
Please note that some products listed may not be available in all markets.
For in-vitro diagnostic use only.

*Two extra tests for external QC testing

Family Health

Influenza A&B



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SEKISUI CAT. #	Influenza A&B 190E	Ultra Flu A&B 1006/1006E																								
TEST FORMAT	Dipstick	Cassette																								
QC INSIDE*	Yes	Yes																								
QUANTITY/KIT	25	25																								
SAMPLE TYPE	Nasal Swab	Nasal Swab, NP** Swab, Nasal Aspirate/Wash																								
CLIA	N/A	Waived-Swab Moderate-Nasal Aspirate/ Wash																								
CPT CODE (IF BOTH ARE ORDERED)	N/A	87804QW (A or individual) 87804QW-59 (B)																								
# OF STEPS	3	6																								
TIME TO RESULT	10 minutes	10-15 minutes																								
PERFORMANCE	<table border="1"> <thead> <tr> <th colspan="2">PERFORMANCE VS. CULTURE</th> </tr> <tr> <th>Sensitivity</th> <th>Specificity</th> </tr> </thead> <tbody> <tr> <td>NASAL SWAB-INFLUENZA A</td> <td>73.8%</td> </tr> <tr> <td>NASAL SWAB-INFLUENZA B</td> <td>60.0%</td> </tr> <tr> <td>NASAL/NP** SWAB-INFLUENZA A</td> <td>-</td> </tr> <tr> <td>NASAL/NP SWAB-INFLUENZA B</td> <td>-</td> </tr> </tbody> </table>	PERFORMANCE VS. CULTURE		Sensitivity	Specificity	NASAL SWAB-INFLUENZA A	73.8%	NASAL SWAB-INFLUENZA B	60.0%	NASAL/NP** SWAB-INFLUENZA A	-	NASAL/NP SWAB-INFLUENZA B	-	<table border="1"> <thead> <tr> <th colspan="2">CLIA WAIVER PERFORMANCE VS. PCR</th> </tr> <tr> <th>Sensitivity</th> <th>Specificity</th> </tr> </thead> <tbody> <tr> <td>-</td> <td>-</td> </tr> <tr> <td>-</td> <td>-</td> </tr> <tr> <td>89.2%</td> <td>99.4%</td> </tr> <tr> <td>86.4%</td> <td>99.0%</td> </tr> </tbody> </table>	CLIA WAIVER PERFORMANCE VS. PCR		Sensitivity	Specificity	-	-	-	-	89.2%	99.4%	86.4%	99.0%
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86.4%	99.0%																									
KIT STORAGE	Room Temp	Refrigerate/Room Temp																								
SHELF LIFE	15 months	24 months																								
TRANSPORT MEDIA	No	Yes																								
SAMPLE STORAGE																										
ROOM TEMP-SWAB	8 hours	4 hours																								
REFRIGERATE-SWAB	24 hours	8 hours																								
FROZEN-ASPIRATE		7 days																								

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For in-vitro diagnostic use only.

*Two extra tests for external QC testing **Nasopharyngeal

Family Health

RSV/Adeno



SEKISUI CAT. #	RSV/Adeno 197E	
TEST FORMAT	Dipstick	
QC INSIDE*	No	
QUANTITY/KIT	25	
SAMPLE TYPE	Nasal Swab, Nasal Suction, Throat Swab (Adeno)	
CLIA	N/A	
CPT CODE	N/A	
# OF STEPS	4	
TIME TO RESULT	10 minutes	
PERFORMANCE (VS. PCR)	Sensitivity	Specificity
NASAL SWAB/SUCTION-RSV	90.4%	99.0%
NASAL SWAB/SUCTION-ADENO	85.0%	98.4%
THROAT SWAB-ADENO	91.5%	95.5%
KIT STORAGE	Room Temp	
SHELF LIFE	24 months	
SAMPLE TRANSPORT	Dry transport tube	
SAMPLE STORAGE	Refrigerate up to 24 hours	

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Family Health

Mononucleosis



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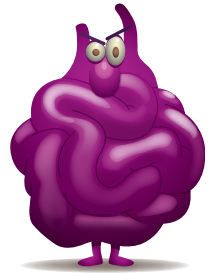
SEKISUI CAT. #	Mono 145
TEST FORMAT	Dipstick
QC INSIDE*	Yes
QUANTITY/KIT	25
SAMPLE TYPE	Whole Blood, Serum, Plasma
CLIA	Waived (Whole Blood) Moderate (Serum/Plasma)
CPT CODE	86308 QW
# OF STEPS	3
TIME TO RESULT	5 minutes
PERFORMANCE SENSITIVITY SPECIFICITY	RECONCILED W/EBV SEROLOGY 99.0% 95.9%
KIT STORAGE	Room Temp
SHELF LIFE	12 months
SAMPLE TRANSPORT	Blood collection tube
SAMPLE STORAGE ROOM TEMP-WHOLE BLOOD REFRIGERATE-SERUM/PLASMA	24 hours 48 hours

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*Two extra tests for external QC testing

Family Health

H. pylori



SEKISUI CAT. #	H. pylori 175
TEST FORMAT	Cassette
QC INSIDE*	No
QUANTITY/KIT	25
SAMPLE TYPE	Whole Blood, Serum, Plasma
CLIA	Waived (Whole Blood) Moderate (Serum/Plasma)
CPT CODE	86318QW (Whole Blood) 86677 (Serum/Plasma)
# OF STEPS	2
TIME TO RESULT	10 minutes
PERFORMANCE SENSITIVITY SPECIFICITY	VS. BIOPSY 96.0% 89.0%
KIT STORAGE	Room Temp
SHELF LIFE	18 months
SAMPLE TRANSPORT	Collection Tube
SAMPLE STORAGE REFRIGERATE-SERUM/PLASMA	48 hours

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Family Health

iFOBT



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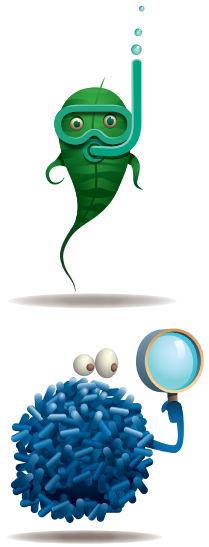
SEKISUI CAT. #	iFOB 1002
TEST FORMAT	Cassette
QC INSIDE*	Yes
QUANTITY/KIT	25
SAMPLE TYPE	Stool
CLIA	Waived
CPT CODE	G0328QW Diagnosis 82274QW Screening
# OF STEPS	3
PERFORMANCE SENSITIVITY SPECIFICITY	50 ng hHb/mL specific for human hemoglobin
TIME TO RESULT	5 to 10 minutes
KIT STORAGE	Refrigerate/Room Temp
SHELF LIFE	12 months
SAMPLE TRANSPORT	Stool Collection Tube with Mailer
SAMPLE STORAGE	Room Temp for up to 10 days (extracted sample)

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*Two extra tests for external QC testing

Women's Health

Trichomonas Bacterial Vaginosis



SEKISUI CAT. #	Trichomonas Rapid 181/181E	BVBLUE® 183
TEST FORMAT	Dipstick	Colorimetric enzyme activity
QC INSIDE*	No	Yes
QUANTITY/KIT	25	25
SAMPLE TYPE	Vaginal Swab or Saline solution from wet mount	Vaginal Swab
CLIA	Waived	Waived
CPT CODE	87808QW	87905QW
# OF STEPS	3	2
PERFORMANCE SENSITIVITY SPECIFICITY	CULTURE & WET MOUNT (COMBINED) 83% 99%	GRAM'S STAIN 92.8% 98%
TIME TO RESULT	10 minute	10 minute
KIT STORAGE	Room Temp	Refrigerated
SHELF LIFE	16 months	11 months
SAMPLE TRANSPORT	Kit Swabs in clean dry container	Kit Swabs in clean dry container
SAMPLE STORAGE ROOM TEMP-SWAB REFRIGERATE-SWAB	24 hours 36 hours	48 hours 7 days

Refer to Instructions For Use for detailed product information.
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*Two extra tests for external QC testing

Women's Health

hCG



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SEKISUI CAT. #	hCG Urine 101	Card Pregnancy 102	hCG Combo 124	Ultra hCG Combo 1004
TEST FORMAT	Dipstick	Cassette	Cassette	Cassette
QC INSIDE*	No	No	No	Yes
QUANTITY/KIT	50	25	25	25
SAMPLE TYPE	Urine	Urine	Urine/Serum	Urine/Serum
CLIA	Waived	Waived	Waived (Urine)	Waived (Urine)
CPT CODE	81025	81025	81025-Urine 84703-Serum	81025-Urine 84703-Serum
# OF STEPS	1	1	1	1
PERFORMANCE SENSITIVITY SPECIFICITY	25 mIU/ml	20 mIU/ml	20 mIU/ml (Urine) 10 mIU/ml (Serum)	25 mIU/ml
TIME TO RESULT	5 minutes	3 minutes	3 minutes (Urine) 5 minutes (Serum)	3 to 5 minutes
KIT STORAGE	Room Temp	Room Temp	Room Temp	Refrigerate/ Room Temp
SHELF LIFE	18 months	24 months	24 months	24 months
SAMPLE TRANSPORT URINE SERUM/PLASMA	Dry Container	Dry Container	Dry Container Collection Tube	Dry Container Collection Tube
SAMPLE STORAGE ROOM TEMP-URINE REFRIGERATE-URINE REFRIGERATE-SERUM/PLASMA	48 hours	8 hours 72 hours	8 hours 72 hours 48 hours	48 hours 48 hours

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 *Two extra tests for external QC testing

OSOM® Rapid Tests

Controls/Accessories

PRODUCT AND RELATED CONTROL/ACCESSORIES	CATALOG #
OSOM® Strep A/Ultra Strep A Rayon Swabs Dual Rayon Swab in Transport Tube	7628 7784
OSOM® Influenza A&B Control Kit	191
OSOM® Ultra Flu A&B Control Kit Nasal Wash Kit	1005 1007
OSOM® RSV/Adeno Control Kit Throat Swabs	198E 7703
OSOM® H.pylori Control Kit	176
OSOM® iFOBT Controls Stool Collection Tubes Patient Mailers	1000 1001 1003
OSOM® Trichomonas Control Kit Vaginitis Transport Set Rayon Swabs Dual Rayon Swab in Transport Tube	182 185 7628 7784
OSOM® BVBLUE® Control Kit Vaginitis Transport Set Transport Swab	184 185 186
OSOM® hCG Urine Control Set	134
OSOM® hCG Serum Control Set	138

Refer to Instructions For Use for detailed product information.
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SEKISUI

DIAGNOSTICS

Because every result matters™

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