Sapid diagnostics



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®





Tests / Service / Outcomes

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



QC Inside® A select number of OSOM® rapid tests now include some-



MADE IN THE USA

thing 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 multilingual training module can help to train clinical staff. Go to www.sdxacademy.com.



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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

Family Health Influenza A&B







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 NASAL SWAB-INFLUENZA A NASAL SWAB-INFLUENZA B NASAL/NP** SWAB-INFLUENZA A NASAL/NP SWAB-INFLUENZA B	PERFORMANCE VS. CULTURE Sensitivity Specificity 73.8% 96.4% 60.0% 96.4%	CLIA WAIVER PERFORMANCE VS. PCR Sensitivity Specificity	
KIT STORAGE	Room Temp	Refrigerate/Room Temp	
SHELF LIFE	15 months	24 months	
TRANSPORT MEDIA	No	Yes	
SAMPLE STORAGE ROOM TEMP-SWAB REFRIGERATE-SWAB FROZEN-ASPIRATE	8 hours 24 hours	4 hours 8 hours 7 days	

^{*}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) NASAL SWAB/SUCTION-RSV NASAL SWAB/SUCTION-ADENO THROAT SWAB-ADENO	Sensitvity Specificity 90.4% 99.0% 85.0% 98.4% 91.5% 95.5%	
KIT STORAGE	Room Temp	
SHELF LIFE	24 months	
SAMPLE TRANSPORT	Dry transport tube	
SAMPLE STORAGE	Refrigerate up to 24 hours	

Family Health Mononucleosis





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

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	15 months
SAMPLE TRANSPORT	Collection Tube
SAMPLE STORAGE REFRIGERATE-SERUM/PLASMA	48 hours

Family Health iFOBT



SEKISUI CAT. #	iFOB 1002
TEST FORMAT	Cassette
QC INSIDE*	Yes
QUANTITY/KIT	25
SAMPLE TYPE	Stool
CLIA	Waived
CPT CODE	GO328QW 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)

Women's Health

Trichomonas Bacterial Vaginosis









Trichomonas Rapid 181/181E TEST FORMAT Dipstick Colorimetric enzyme activity QC INSIDE* No Yes QUANTITY/KIT 25 SAMPLE TYPE Vaginal Swab or Saline solution from wet mount CLIA Waived Waived CPT CODE 87808QW 87905QW # OF STEPS 3 2 PERFORMANCE SENSITIVITY SPECIFICITY 99% TIME TO RESULT 10 minute KIT STORAGE Room Temp Refrigerated SHELF LIFE 16 months SAMPLE TRANSPORT Kit Swabs in clean dry container SAMPLE STORAGE ROOM TEMP-SWAB REFRIGERATE-SWAB REFRIGERATE-SWAB REFRIGERATE-SWAB TEST FORMAN CCIOrimetric enzyme activity 128 Reginal BVBLUE® 183 BVBLUE® 183 Colorimetric enzyme activity 25 25 Vaginal Swab Vaginal Sw			
QC INSIDE* No Yes QUANTITY/KIT 25 SAMPLE TYPE Vaginal Swab or Saline solution from wet mount CLIA Waived Waived CPT CODE 87808QW # OF STEPS 3 2 PERFORMANCE SENSITIVITY SPECIFICITY 99% GRAM'S STAIN 92.8% 92.8% 98% TIME TO RESULT 10 minute KIT STORAGE ROOM TEMP SAMPLE TRANSPORT Kit Swabs in clean dry container SAMPLE STORAGE ROOM TEMP-SWAB 24 hours 48 hours	SEKISUI CAT. #		
QUANTITY/KIT 25 SAMPLE TYPE Vaginal Swab or Saline solution from wet mount CLIA Waived Waived Waived CPT CODE 87808QW # OF STEPS 3 2 PERFORMANCE SENSITIVITY SPECIFICITY 99% TIME TO RESULT 10 minute KIT STORAGE Room Temp Refrigerated SHELF LIFE 16 months SAMPLE TRANSPORT Kit Swabs in clean dry container SAMPLE STORAGE ROOM TEMP-SWAB 25 Vaginal Swab Vaginal Swab Vaginal Swab Vaginal Swab Vaginal Swab Vaginal Swab SRPOSQW # OF STEPS 3 2 CULTURE & WET MOUNT (COMBINED) 92.8% 92.8% 98% TIME TO RESULT 10 minute 10 minute Kit STORAGE Room Temp Refrigerated SHELF LIFE 16 months 11 months SAMPLE STORAGE ROOM TEMP-SWAB 24 hours 48 hours	TEST FORMAT	Dipstick	
SAMPLE TYPE Vaginal Swab or Saline solution from wet mount CLIA Waived Waived Waived Waived EPT CODE 87808QW # OF STEPS 3 2 PERFORMANCE SENSITIVITY SENSITIVITY SPECIFICITY 99% TIME TO RESULT 10 minute Note To make the strength of the stre	QC INSIDE*	No	Yes
solution from wet mount CLIA Waived Waived CPT CODE 87808QW 87905QW # OF STEPS 3 2 PERFORMANCE SENSITIVITY 83% 92.8% 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 SAMPLE STORAGE ROOM TEMP-SWAB 24 hours 48 hours	QUANTITY/KIT	25	25
# OF STEPS 3 2 PERFORMANCE CULTURE & WET MOUNT (COMBINED) SENSITIVITY 83% 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 SAMPLE STORAGE ROOM TEMP-SWAB 24 hours 48 hours	SAMPLE TYPE		Vaginal Swab
# OF STEPS 3 2 PERFORMANCE SENSITIVITY 83% 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 SAMPLE STORAGE ROOM TEMP-SWAB 24 hours 48 hours	CLIA	Waived	Waived
PERFORMANCE SENSITIVITY SPECIFICITY 99% 10 minute 10 minute KIT STORAGE ROOM TEMP SAMPLE TRANSPORT Kit Swabs in clean dry container SAMPLE STORAGE ROOM TEMP-SWAB 24 hours REFAM'S STAIN 92.8% 98% 10 minute 10 minute 11 minute 11 months 11 months 11 months 12 SAMPLE STORAGE ROOM TEMP-SWAB 48 hours	CPT CODE	87808QW	87905QW
SENSITIVITY SPECIFICITY 99% 72.8% 98% TIME TO RESULT 10 minute 10 minute 11 minute KIT STORAGE Room Temp Refrigerated SHELF LIFE 16 months 11 months SAMPLE TRANSPORT Kit Swabs in clean dry container SAMPLE STORAGE ROOM TEMP-SWAB 24 hours 48 hours	# OF STEPS	3	2
KIT STORAGE Room Temp Refrigerated SHELF LIFE 16 months 11 months SAMPLE TRANSPORT Kit Swabs in clean dry container SAMPLE STORAGE ROOM TEMP-SWAB 24 hours 48 hours	SENSITIVITY	83%	92.8%
SHELF LIFE 16 months 11 months SAMPLE TRANSPORT Kit Swabs in clean dry container SAMPLE STORAGE ROOM TEMP-SWAB 24 hours 48 hours	TIME TO RESULT	10 minute	10 minute
SAMPLE TRANSPORT Kit Swabs in clean dry container SAMPLE STORAGE ROOM TEMP-SWAB 24 hours Kit Swabs in clean dry container Kit Swabs in clean dry container	KIT STORAGE	Room Temp	Refrigerated
container container SAMPLE STORAGE ROOM TEMP-SWAB 24 hours 48 hours	SHELF LIFE	16 months	11 months
ROOM TEMP-SWAB 24 hours 48 hours	SAMPLE TRANSPORT		
	ROOM TEMP-SWAB	2	

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Women's Health

hCG









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/mI	20 mlU/ml	20 mIU/mI (Urine) 10 mIU/mI (Serum)	25 mlU/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

^{*}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

Notes





Because every result matters

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