

PRODUCT CATALOG

# POINT- OF-CARE



POINT-OF-CARE

**SEKISUI**  
DIAGNOSTICS  
*Because every result matters™*

SEKISUI Diagnostics delivers differentiated products, instrument systems, and services that support the improvement of patient care worldwide.



The OSOM® portfolio of rapid diagnostics offers a variety of family and women's health products, and our services deliver unparalleled value.

Many of the OSOM tests include the QC Inside® feature which provides extra tests at no charge for external QC testing.



The Acucy® System provides clinicians flexibility in workflow and accurate, standardized results for improved patient care. With Read Now and

Walk Away modes, clinicians can easily adjust their workflow based on patient volume to provide an optimal patient experience.

## FastPack<sup>®</sup> IP System

The FastPack® IP System is a fully automated quantitative immunoassay analyzer designed for use in any size physician office laboratory.

Utilizing sophisticated chemiluminescence technology, the FastPack IP System allows you to produce complex immunoassay results in 12 minutes or less with the push of a button.

# SEKISUI, Your Point-of-Care Testing Partner



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## Women's Health



### OSOM BVBLUE® Test

- ✓ Aids in the diagnosis of bacterial vaginosis
- ✓ Sensitivity: 92.8% vs. Gram stain
- ✓ Results in 10 minutes



### OSOM Trichomonas Rapid Test

- ✓ Only CLIA-waived rapid test available
- ✓ Detects antigen in 10 minutes  
(does not require live trichomonas organisms)



### OSOM hCG Urine Test

- ✓ One-step simple: dip and read
- ✓ 25 mIU/mL sensitivity



### OSOM Card Pregnancy and hCG Combo Test

- ✓ Sensitivity: 10 mIU/mL serum;  
20 mIU/mL urine
- ✓ No drop counting pipette



### OSOM Ultra hCG Combo Test

- ✓ Detects  $\beta$ -core fragments<sup>1</sup>
- ✓ 25 mIU/mL sensitivity

ORDERING INFORMATION	CONFIGURATION	CATALOG NUMBER	CPT CODE
OSOM BVBLUE Test	25 Tests	183	87905QW
BVBLUE Control Kit	1-5 mL Bottle Positive	184	
	1-5 mL Bottle Negative		
OSOM Trichomonas Rapid Test	25 Tests	181 or 181E (CE marked)	87808QW
Trichomonas Positive Control Kit	10 Positive Swabs	182	
OSOM hCG Urine Test	50 Tests	101	81025QW 81025QW 81025QW-Urine 84703-Serum 81025QW-Urine 84703-Serum
OSOM Card Pregnancy Test	25 Tests	102	
OSOM hCG Combo Test	25 Tests	124	
OSOM Ultra hCG Combo Test	25 Tests	1004	
hCG Urine Control Set	1-10 mL Bottle Positive	134	
	1-10 mL Bottle Negative		
hCG Serum Control Set	1-5 mL Bottle Positive	138	
	1-5 mL Bottle Negative		

Please note that some products listed may not be available in all markets.

1. Data on file.



## Family Health



### OSOM Ultra Strep A Test

- ✓ Sensitivity not statistically different than single swab culture<sup>1</sup>
- ✓ Two-color results in 5 minutes



### OSOM Strep A Test

- ✓ 96.0% sensitivity; 97.8% specificity
- ✓ Two-color results in 5 minutes



### OSOM Ultra Plus Flu A&B Test

- ✓ High performance sensitivity and specificity  
Influenza A: 90.3% sensitivity; 96.7% specificity  
Influenza B: 88.0% sensitivity; 99.2% specificity
- ✓ Results in 10 minutes



### OSOM Ultra Flu A&B Test

- ✓ PPA & NPA\* compared to molecular testing:  
Influenza A: 89.2% sensitivity; 99.4% specificity  
Influenza B: 86.4% sensitivity; 99.0% specificity
- ✓ Results in 10-15 minutes

ORDERING INFORMATION	CONFIGURATION	CATALOG NUMBER	CPT CODE
OSOM Ultra Strep A Test	25 Tests 50 Tests	147 149	87880QW
OSOM Strep A Test	50 Tests 20 Tests	141 or 141E (CE marked) 141E-20 (CE marked)	87880QW 87880QW
OSOM Ultra Plus Flu A&B	25 Tests	1032 or 1032E (CE marked)	87804QW 87804QW-59
OSOM Ultra Plus Flu A&B Control Kit	5 A+/B- Control Swabs 5 A-/B+ Control Swabs	1034	
OSOM Ultra Flu A&B Test	25 Tests	1006	87804QW 87804QW-59
OSOM Ultra Flu A&B Test Control Kit	5-Influenza A&B Positive Swabs 5-Influenza A&B Negative Swabs	1006	

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1. Refer to package insert for details.

\*PPA: positive percent agreement; NPA: negative percent agreement

## Family Health



### OSOM Mono Test

- ✓ >99% sensitivity; 95.9% specificity
- ✓ Two-color results in 5 minutes



### OSOM RSV/Adeno Test

- ✓ Sensitivity and specificity compared to molecular testing:  
RSV: 90.4% and 99.0%, respectively  
Adeno: 85.0% and 98.4%, respectively



### OSOM iFOB Test

- ✓ Analytical sensitivity: 50 ng hHb/mL
- ✓ No dietary or drug restrictions
- ✓ Results in 5-10 minutes



### OSOM H. pylori Test

- ✓ 95.9% sensitivity; 89.1% specificity vs. biopsy
- ✓ Results in 10 minutes

ORDERING INFORMATION	CONFIGURATION	CATALOG NUMBER	CPT CODE
OSOM Mono Test	25 Tests	145	86308QW
OSOM RSV/Adeno Test	25 Tests	197E	86308QW (Whole Blood) 86308 (Serum/ Plasma)
OSOM RSV/Adeno Control Kit	5-RSV Positive Swabs	198	
OSOM iFOB Test	25 Tests	1002	G0328QW (Screening) 82274QW (Diagnostics)
OSOM iFOB Control Kit	1-2 mL Bottle Positive 1-2 mL Bottle Negative	1000	
OSOM H. pylori Test	25 Tests	175	86318QW (Whole Blood) 86677 (Serum/ Plasma)
OSOM H. pylori Control Kit	1-2 mL Bottle Positive 1-2 mL Bottle Negative	176	

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The Acucy Influenza A&B Test for the rapid qualitative detection of influenza A&B is composed of a rapid chromatographic immunoassay for the direct and qualitative detection of influenza A and B viral nucleoprotein antigens from nasal and nasopharyngeal swabs of symptomatic patients that is automatically analyzed on the Acucy Reader.



Acucy Influenza A&B Test Kit

- ✓ Best-In-Class Influenza A performance
  - ✓ Results in 15 minutes
  - ✓ CLIA Waived
- Influenza A: Sensitivity 96.4% Specificity 96.0%
- Influenza B: Sensitivity 82.3% Specificity 98.1%



Acucy System

- ✓ Definitive and standardized results
- ✓ Read Now and Walk Away modes
- ✓ Available connectivity

ORDERING INFORMATION	CONFIGURATION	CATALOG NUMBER	CPT CODE
Acucy System	Acucy Reader Printer with Paper Roll Power Adapter USB Stick	1039	
Acucy Influenza A&B Test Kit	25 Test Cassettes (plus 2 extra for QC) 1 Influenza A+/B- Swab 1 Influenza A-/B+ Swab	1010	87804QW
Acucy Influenza A&B Control Kit	5 Influenza A+/B- Swabs 5 Influenza A-/B+ Swabs	1011	

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# FastPack<sup>®</sup> IP System

The FastPack IP System is a fully automated quantitative immunoassay analyzer designed for use in any physician office laboratory. Using sophisticated chemiluminescence technology, the FastPack IP System allows you to produce complex immunoassay results in 12 minutes or less with the push of a button. The FastPack IP System is versatile and requires minimal space while offering a test menu that will make a clinical impact on patient care. Assays include Vitamin D, Testosterone, PSA, Free PSA, TSH, Free T4, and hCG.



### SIMPLE

- ✓ No specialized training required
- ✓ The system’s “One Touch” operation provides an easy to use format not offered by any other lab quality analyzers
- ✓ Innovative reagent pack contains all assay reagents for no chemical exposure and minimal hands on time
- ✓ No system maintenance required

### FAST

- ✓ Results in 12 minutes or less
- ✓ On-demand results improve office efficiency by decreasing patient call-backs
- ✓ Quick answers allow for the adjustment of treatment on the spot

### ACCURATE

- ✓ The system requires minimal space, yet provides laboratory accuracy and precision at the simple push of a button
- ✓ Uses monoclonal antibody technology coupled with a patented chemiluminescence substrate for true laboratory performance

ORDERING INFORMATION	CONFIGURATION	CATALOG NUMBER
FastPack IP System FastPack IP Analyzer FastPack IP System Printer FastPack IP Pipette	Each	SYSTEM 08000043 20000034 20000049
Replacement Printer Ribbon	Each	17000378
100 µL Pipette	Each	20000049
25 µL Pipette (Use with FastPack IP hCG)	Each	20000048
Pipette Tips	Box of 96	17000474
FastPack Control (US Only)	Kit	25000056
FastPack <sup>®</sup> Control (International Only)	Kit	25000065

Please note that some products listed may not be available in all markets.





### FastPack IP Vitamin D Immunoassay

- ✓ Quantitative measurement of 25-hydroxyvitamin D
- ✓ Lower limit: 12.9 ng/mL
- ✓ Upper limit: 150 ng/mL
- ✓ Results in 12 minutes



### FastPack IP Prostate Specific Antigen (PSA) Immunoassay

- ✓ Quantitative measurement of total PSA
- ✓ Lower limit: 0.04 ng/mL
- ✓ Upper limit: 50 ng/mL
- ✓ Results in 12 minutes



### FastPack IP Free PSA Immunoassay Not Available in US

- ✓ Quantitative measurement of free PSA
- ✓ Lower limit: 0.05 ng/mL
- ✓ Upper limit: 20 ng/mL
- ✓ Results in 12 minutes



### FastPack IP Testosterone Immunoassay

- ✓ Quantitative measurement of total testosterone
- ✓ Lower limit: 23 ng/dL
- ✓ Upper limit: 1600 ng/dL
- ✓ Results in 12 minutes



### FastPack IP Sex Hormone Binding Globulin (SHBG) Immunoassay

- ✓ Quantitative measurement of SHBG
- ✓ Lower limit: 0.80 nmol/L
- ✓ Upper limit: 174 nmol/L
- ✓ Results in 8 minutes

ORDERING INFORMATION	CONFIGURATION	CATALOG NUMBER	CPT CODE
FastPack IP Vitamin D Complete Includes Calibrator, Controls, and Pre-treatment Buffer	30 Tests	25000068	82306
FastPack Vitamin D Verification	Kit	25000064	
FastPack IP Prostate Specific Antigen (PSA) <small>Not Available in the US</small>	30 Tests	25000040	84153
FastPack IP Free Prostate Specific Antigen (free PSA)	30 Tests	25000045	
FastPack Vitamin D Verification	Kit	25000003	
FastPack PSA Calibration	Kit	25000002	
FastPack PSA Verification	Kit	25000017	
FastPack Free PSA Calibration	Kit	25000008	
FastPack IP Testosterone	30 Tests	25000041	84403
FastPack Testosterone Calibration	Kit	25000014	
FastPack Testosterone Verification	Kit	25000029	
FastPack IP SHBG Complete Includes Calibrator, Controls, and Diluent	30 Tests	25000081	84270
FastPack IP SHBG Verification	Kit	25000083	

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FastPack IP Thyroid Stimulating Hormone (TSH) Immunoassay

- ✓ Quantitative measurement of TSH
- ✓ Lower limit: 0.13 µIU/mL
- ✓ Upper limit: 100 µIU/mL
- ✓ Results in 12 minutes



FastPack IP Free Thyroxine (fT4) Immunoassay

- ✓ Quantitative measurement of free T4
- ✓ Lower limit: 0.4 ng/dL
- ✓ Upper limit: 6.0 ng/dL
- ✓ Results in 7 minutes



FastPack IP Human Chorionic Gonadotropin (hCG) Immunoassay

- ✓ Quantitative measurement of hCG
- ✓ Lower limit: 1.8 mIU/mL
- ✓ Upper limit: 1000 mIU/mL; up to 10 million with dilution
- ✓ Results in 12 minutes

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ORDERING INFORMATION	CONFIGURATION	CATALOG NUMBER	CPT CODE
FastPack IP Thyroid Stimulating Hormone (TSH)	30 Tests	25000042	84443
FastPack TSH Calibration	Kit	25000024	
FastPack TSH Verification	Kit	25000030	
FastPack IP Free Thyroxine (fT4)	30 Tests	25000043	84439
FastPack fT4 Calibration	Kit	25000016	
FastPack fT4 Verification	Kit	25000031	
FastPack IP Human Chorionic Gonadotropin (hCG)	30 Tests	25000044	84702
FastPack hCG Calibration	Kit	25000035	
FastPack hCG Verification	Kit	25000033	
FastPack hCG Diluent	Kit/25	25000036	

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## Locations

### Worldwide HQ

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[sekisuidiagnostics.com](http://sekisuidiagnostics.com)