

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.

Acucy is a registered trademark of Sekisui Diagnostics, Inc. © 2014 Sekisui Diagnostics, Inc. All rights reserved.

OSOM is a registered trademark of Sekisui Diagnostics, Inc. © 2014 Sekisui Diagnostics, Inc. All rights reserved.

QC Inside is a registered trademark of Sekisui Diagnostics, Inc. © 2014 Sekisui Diagnostics, Inc. All rights reserved.

Read Now and Walk Away are registered trademarks of Sekisui Diagnostics, Inc. © 2014 Sekisui Diagnostics, Inc. All rights reserved.

Acucy is a registered trademark of Sekisui Diagnostics, Inc. © 2014 Sekisui Diagnostics, Inc. All rights reserved.

OSOM is a registered trademark of Sekisui Diagnostics, Inc. © 2014 Sekisui Diagnostics, Inc. All rights reserved.

QC Inside is a registered trademark of Sekisui Diagnostics, Inc. © 2014 Sekisui Diagnostics, Inc. All rights reserved.

Read Now and Walk Away are registered trademarks of Sekisui Diagnostics, Inc. © 2014 Sekisui Diagnostics, Inc. All rights reserved.

Acucy is a registered trademark of Sekisui Diagnostics, Inc. © 2014 Sekisui Diagnostics, Inc. All rights reserved.

OSOM is a registered trademark of Sekisui Diagnostics, Inc. © 2014 Sekisui Diagnostics, Inc. All rights reserved.

QC Inside is a registered trademark of Sekisui Diagnostics, Inc. © 2014 Sekisui Diagnostics, Inc. All rights reserved.

Read Now and Walk Away are registered trademarks of Sekisui Diagnostics, Inc. © 2014 Sekisui Diagnostics, Inc. All rights reserved.

Acucy is a registered trademark of Sekisui Diagnostics, Inc. © 2014 Sekisui Diagnostics, Inc. All rights reserved.

OSOM is a registered trademark of Sekisui Diagnostics, Inc. © 2014 Sekisui Diagnostics, Inc. All rights reserved.

QC Inside is a registered trademark of Sekisui Diagnostics, Inc. © 2014 Sekisui Diagnostics, Inc. All rights reserved.

Read Now and Walk Away are registered trademarks of Sekisui Diagnostics, Inc. © 2014 Sekisui Diagnostics, Inc. All rights reserved.

SEKISUI Diagnostics, Your Point-of-Care Testing Partner



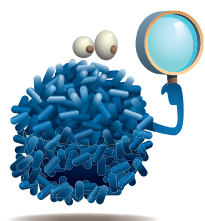
POINT-OF-CARE READER



RAPID DIAGNOSTICS

TABLE OF CONTENTS

OSOM Rapid Tests	
OSOM Rapid Tests Women’s Health.....	3
OSOM Rapid Tests Family Health.....	4,5
Acucy Reader System	
Acucy Reader and Influenza A&B Test.....	6



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 β -core fragments¹
- ✓ 25 mIU/mL sensitivity

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

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 culture¹
- ✓ 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 COVID-19 Antigen Rapid Test

- ✓ 95.1% Positive Percent Agreement; 97.0% Negative Percent Agreement
- ✓ Results in 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)	Influenza A: 87804QW Influenza B: 87804QW If both Influenza A and Influenza B are ordered: 87804QW, 87804QW-59
OSOM Ultra Plus Flu A&B Control Kit	5 A+/B- Control Swabs 5 A-/B+ Control Swabs	1034	
OSOM COVID-19 Antigen Rapid Test	40 Tests	1066-40	87811QW
OSOM COVID-19 Antigen Control Kit	5 x SARS-CoV-2 Positive Control Swabs and 5 x SARS-CoV-2 Negative Control Swabs	1068	

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

1. Refer to package insert for details.

The OSOM COVID-19 Antigen Rapid Test has not been FDA cleared or approved. It is authorized by FDA under an EUA for use by authorized laboratories. It has been authorized only for the detection of SARS-CoV-2 antigen, not for any other viruses or pathogens and is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C 336bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

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	Not available in the U.S.
OSOM RSV/Adeno Control Kit	5-RSV Positive Swabs 5-Adenovirus Positive Swabs	198E	
OSOM iFOB Test	25 Tests	1002	G0328QW (Screening) 82274QW (Diagnostic)
OSOM iFOB Control Kit	1-1mL Bottle Positive 1-1mL Bottle Negative	1000	
OSOM H. pylori Test	25 Tests	175	86318QW (Whole Blood) 86677 (Serum/ Plasma)
OSOM H. pylori Control Kit	1-1mL Bottle Positive 1-1mL Bottle Negative	176	

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



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	Influenza A: 87804QW Influenza B: 87804QW If both Influenza A and Influenza B are ordered: 87804QW, 87804QW-59
Acucy Influenza A&B Control Kit	5 Influenza A+/B- Swabs 5 Influenza A-/B+ Swabs	1011	

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



Locations

Worldwide HQ
SEKISUI Diagnostics, LLC
Burlington, MA, USA
+1 781-652-7800

SEKISUI Diagnostics, LLC
San Diego, CA, USA
+1 858-777-2600

SEKISUI Diagnostics, LLC
Exton, PA, USA
+1 610-594-8590

SEKISUI Diagnostics P.E.I. Inc.
Charlottetown, PEI, Canada
+1 902-566-1396

SEKISUI Diagnostics (UK) Ltd.
Maidstone, Kent, UK
+44-1622-607800

SEKISUI Diagnostics GmbH
Darmstadt, Germany
+49-6151-3598520

SEKISUI Medical Co., Ltd.
Tokyo, Japan
+81-3-3272-0671

SEKISUI Medical Technology (China) Ltd.
Shunyi District, Beijing, China
+86-10-8048-6325

SEKISUI Medical Technology (China) Ltd.
Chaoyang District, Beijing, China
+86-10-6269-2662

Veredus Laboratories
Singapore
+65 6496 8600

SEKISUI
DIAGNOSTICS
Because every result matters™

sekisuidiagnostics.com