PRODUCT CATALOG

POINT-OF-CARE

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.

aptitude Metrix® COVID-19 Test | Provided by SEKISUI DIAGNOSTICS

A novel molecular technology with a similar principle as PCR, the Metrix® platform helps improve clinical outcomes by administering immediate treatment in just 30 minutes.

SEKISUI Diagnostics, Your Point-of-Care Testing Partner

POINT-OF-CARE READER

RAPID DIAGNOSTICS

MOLECULAR READER

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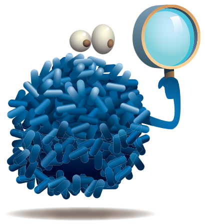
OSOM® Rapid Tests

Acucy® Reader System

Metrix® Molecular System



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 fragments[1]
- ✔ 25 mIU/mL sensitivity

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

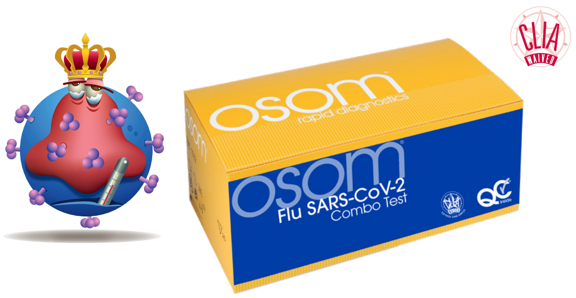
Please note that some products listed may not be available in all markets.

1. Data on file.

Family Health

OSOM Ultra Strep A Test

- ✔ Sensitivity not statistically different than single swab culture[1]
- ✔ Two-color results in 5 minutes



OSOM Flu SARS-CoV-2 Combo Test

- ✔ High performance sensitivity and specificity
  COVID-19: 87.0%[2] sensitivity; 99.1% specificity
  Influenza A: 93.1% sensitivity; 99.5% specificity
  Influenza B: 89.1% sensitivity; 99.7% specificity

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

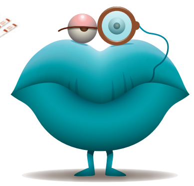
- ✔ 95.1% Positive Percent Agreement;
  97.0% Negative Percent Agreement
- ✔ Results in 15 minutes

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 5 x Sterile Nasal Swabs (Negative Control)	1068	
OSOM Flu SARS-CoV-2 Combo Test	25 Tests	1080	87428QW
OSOM Flu SARS-CoV-2 Combo Control Kit	5 x Positive Control Swabs 5 x Negative Control Swabs	1079	

Please note that some products listed may not be available in all markets.
1. Refer to package insert for details.
2. Determined by a controlled analysis; data shown is inclusion of 10% low positive samples by PCR. For all study cohort and additional controlled analysis and performance refer to IFU.

The OSOM COVID-19 Antigen Rapid Test and OSOM Flu SARS-CoV-2 Combo Test have not been FDA cleared or approved. They are authorized by FDA under an EUA for use by authorized laboratories. The OSOM COVID-19 Antigen Rapid Test has been authorized only for the detection of SARS-CoV-2 antigen, not for any other viruses or pathogens. OSOM Flu SARS-CoV-2 Combo Test has been authorized only for the detection of proteins from SARS-CoV-2, influenza A and influenza B, not for any other viruses or pathogens. The use of these products 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 S360bbb-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.

PRODUCT CATALOG - ACUCY READER SYSTEM

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	

PRODUCT CATALOG - METRIX MOLECULAR SYSTEM

Metrix COVID-19 Test

- ✔ Asymptomatic and Symptomatic testing
- ✔ Saliva or Nasal Swab sample types
- ✔ Saliva: Sensitivity 90% Specificity 99%*
- ✔ Nasal Swab: Sensitivity 97% Specificity 99%*

Metrix System

- ✔ Maintenance free with no calibration required
- ✔ Displays results within 30 Minutes
- ✔ Compact device

ORDERING INFORMATION	CONFIGURATION	CATALOG NUMBER	CPT CODE
Metrix Reader	Reader Power Adapter USB-C Power Cord	MTRX-RDR	
Metrix COVID-19 Test	25 Caps & Sample Collectors 25 Swabs 25 Sensors	MTRX-C19-25PK	87635QW
Metrix Molecular Bundle	50 Caps & Sample Collectors 50 Swabs 50 Sensors Reader Power Adapter USB-C Power Cord	MTRX-C19-B1	87635QW
Microbix COVID-19 Control Kit (for use with Metrix COVID-19 Test)	1 SARS-CoV-2 Positive Swab 1 SARS-CoV-2 Negative Swab	RED-S-19/99-P-01	

Please note that some products listed may not be available in all markets.
*Rounded numbers compared to RT-PCR. See IFU.

Th Metrix COVID-19 Test has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA; This product has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens. The emergency use of this product 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. § 360bbb 3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

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