PRODUCT CATALOG



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.

OSOM® rapid diagnostics

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.

QC® inside

aptitude® Metrix® | Provided by SEKISUI DIAGNOSTICS

The Metrix® molecular platform is a novel molecular testing technology that combines speed and reliability to meet the urgent needs of today's healthcare landscape. Get results quickly and efficiently in a few simple steps and without the need for maintenance or calibration.

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

FAMILY HEALTH



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



OSOM Mono Test

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



HENRY P. LORI



SMOOCH

ORDERING INFORMATION	CONFIGURATION	CATALOG NUMBER	CPT CODE
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	
OSOM Mono Test	25 Tests	145	86308QW

WOMENS HEALTH



OSOM BVBLUE® Test

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



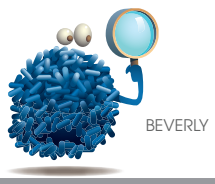
OSOM Trichomonas Rapid Test

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



OSOM Ultra hCG Combo Test

- Detects β-core fragments
- 25 mIU/mL sensitivity



BEVERLY



TRIXIE

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 Ultra hCG Combo Test	25 Tests	1004	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	

RESPIRATORY HEALTH



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



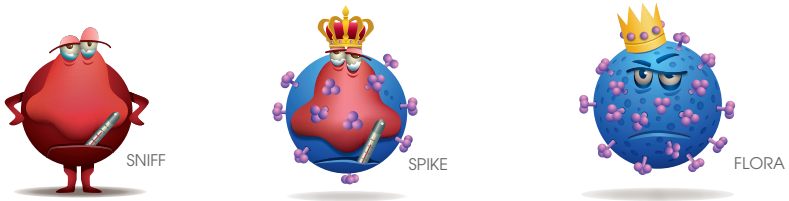
OSOM COVID-19/Flu A&B Combo Test

- High performance sensitivity and specificity
  COVID-19: 87.6% sensitivity; 99.8% specificity
  Influenza A: 86.9% sensitivity; 99.6% specificity
  Influenza B: 86.8% sensitivity; 99.7% specificity



OSOM COVID-19 Test

- 84.78% sensitivity
  99.69% specificity
- Results in 15 minutes



ORDERING INFORMATION	CONFIGURATION	CATALOG NUMBER	CPT CODE
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 Flu SARS-CoV-2 Combo Control Kit	5 Positive Control Swabs 5 Negative Control Swabs	1079	
OSOM COVID-19/Flu A&B Combo Test	27 Tests	1099	87812QW
OSOM COVID-19 Test	25 Tests	1092	87811QW

RESPIRATORY HEALTH



OSOM RSV Test

- Can be used on both younger children and elderly adults
- Results in 15 minutes or less



OSOM Ultra Strep A Test

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



OSOM Strep A Test

- 96% Sensitivity
- 98% Specificity
- Results in 5 minutes



RUVEE



STREPPY

ORDERING INFORMATION	CONFIGURATION	CATALOG NUMBER	CPT CODE
OSOM RSV Test	25 Tests	1091	87807QW
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

1. Refer to package insert for details.

MOLECULAR READER

aptitude Metrix® | Provided by SEKISUI DIAGNOSTICS



Metrix System

- Maintenance free with no calibration required
- Display results within 20-30 minutes
- Compact device



Metrix COVID/Flu Test

- Rapid and Accurate
- COVID-19: 96% sensitivity 99% specificity
- Flu A: 96% sensitivity 99% specificity
- Flu B: 95% sensitivity 99% specificity



Metrix COVID-19 Test

- Asymptomatic and Symptomatic testing
- Saliva or Nasal Swab sample types
- Saliva: 90% sensitivity 99% specificity[2]
- Nasal Swab: 97% sensitivity 99% specificity[2]

ORDERING INFORMATION	CONFIGURATION	CATALOG NUMBER	CPT CODE
Metrix Reader	Reader Power Adapter USB-C Power Cord	MTRX-RDR-Gen2	
Metrix COVID/Flu Test	25 Caps & Sample Collectors 25 Swabs 25 Sensors	MTRX-C19+FLU-25PK	87636QW
Metrix COVID/Flu Molecular Test Bundle	50 Caps & Sample Collectors 50 Swabs 50 Sensors Reader Power Adapter USB-C Power Cord	MTRX-C19+Flu-B1	87636QW
Microbix RVP4(H3) Control Panel	1 SARS-CoV-2 / Flu A&B Positive Swab 1 SARS-CoV-2 / Flu A&B Negative Swab	CPK-S-00008	
Metrix COVID-19 Test	25 Caps & Sample Collectors 25 Swabs 25 Sensors	MTRX-C19-25PK	87635QW
Metrix COVID-19 Molecular Test 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	

2. Rounded numbers compared to RT-PCR. See IFU.

These products have not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA. The Metrix COVID/Flu Test has been authorized only for the detection and differentiation of nucleic acid from SARS-CoV-2, Influenza A, and Influenza B, not for any other viruses or pathogens. The Metrix COVID-19 Test 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 these products 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 just COVID-19 or COVID-19, Flu A, and Flu B 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.

NOTES



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SEKISUI DIAGNOSTICS
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