lifeSign

EARLY DETECTION • RAPID DIAGNOSIS • BETTER OUTCOMES



lifeSign

A PBM Group Company

85 Orchard Road • Skillman • New Jersey • 08558 800.526.2125 • 732.246.3366 • Fax: 732.246.0570 www.lifesignmed.com

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PRODUCT CATALOG

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LifeSign is a medical diagnostics company delivering high quality rapid point of care testing products to the healthcare industry.

Lifesign's extensive line of innovative products is used by clinicians worldwide to aid in the detection of medical conditions which include Infectious Disease, Women's Health, Drugs of Abuse and Cardiac Markers.

Our products are developed and manufactured in the USA under ISO, FDA, cGMP, and CE mark guidelines. Lifesign's team of sales, technical and customer service professionals deliver the highest quality of service and support to our customers.

INFECTIOUS DISEASE

Status™ COVID-19/Flu A&B

A rapid immunoassay for the simultaneous direct detection and differential diagnosis of SAR-CoV-2, Influenza Type A and Type B antigens from anterior nasal and nasopharyngeal swab specimens.



- COVID-19 Anterior nasal swab specimens Sensitivity of 93.8%, & Specificity of 100%
- COVID-19 Nasopharyngeal swab specimens Sensitivity of 93.1%, & Specificity of 100%
- Flu A Sensitivity 91.4%, Specificity 95.7%
- Flu B Sensitivity 87.6%, Specificity 95.9%
- FDA emergency use authorization (EUA)
- Results in 15 minutes
- Flocked nasopharyngeal swab improving specimen collection and ease of use

| ORDERING INFORMATION | | |
|--------------------------|-----------|-------|
| PRODUCT | #OF TESTS | ITEM# |
| Status™ Covid-19/Flu A&B | 25 | 33225 |

Status™ Covid-19 Antigen

- CLIA waived
- OTC and professional use
- FDA emergency use authorization (EUA)
- Results in 15 minutes
- Nasal swab providing comfortable and easy collection

| ORDERING INFORMATION | | |
|--------------------------|-----------|-------|
| PRODUCT | #OF TESTS | ITEM# |
| Status™ Covid-19 Antigen | 1 | 33301 |
| Status™ Covid-19 Antigen | 2 | 33302 |
| Status™ Covid-19 Antigen | 25 | 33325 |





INFECTIOUS DISEASE

Status™ Flu A and B

For the qualitative detection of Influenza Type A and Type B antigens directly from nasal swab, nasopharyngeal swab and nasal aspirate/wash specimens.

36052

- CLIA Waived
- Flu A Sensitivity of 91.4%, & Specificity of 95.7%
- Flu B Sensitivity of 87.6%, & Specificity of 95.9%
- Flexible, flocked nasal swab improving manageablity of specimen collection
- Innovative flip test design with on board sample extraction
- Positive and negative control swabs included
- Differentiates between Influenza Type A and Type B
- Individual pre-measured extraction reagent capsules

| marviadar pre medsared extracti | on reagent ear | 554165 |
|---|----------------|---------|
| ORDERING INFORMATION | | |
| PRODUCT | #OF TESTS | ITEM# |
| Status™ Flu A&B | 25 | 36025 |
| Status™ Nasal Aspirate kit (44 Pipettes, 1 Reagent) | 22 | 510AS |
| Status™ Flu A&B Controls | 5 sets | 36022CS |



Status[™] Strep A Products

For the detection of Group A Streptococcal antigens directly from throat swabs specimens.

Status™ Strep A Flip

Status™ A&B Nasal Swab Refills

- CLIA Waived
- Sensitivity of 96.2%, Specificity of 98.7%
- Results in 5-10 minutes
- External positive and negative controls included
- Innovative flip test device with on board sample extraction
- Individual, pre-measured sample extraction capsules



Status™ Strep A Strip

- CLIA Waived
- Sensitivity of 96.2%
- Specificity of 98.7%
- Results in 5-10 minutes
- External positive and negative controls included



INFECTIOUS DISEASE

Status™ Strep A Plus

- CLIA Waived
- Sensitivity of 96.2%, Specificity of 98.7%
- Results in 5-10 minutes
- External positive and negative controls included





| ORDERING INFORMATION | | |
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| PRODUCT | #OF TESTS | ITEM# |
| Status™ Strep A Flip (Cassettes) | 25 | 34125 |
| Status™ Strep A Strip (Pouch) | 30 | 34130 |
| Status™ Strep A Plus (Canister-strips) | 50 | 34250 |

Status™ Mono

For the qualitative detection of infectious Mononucleosis Heterophile antibodies in whole blood, serum or plasma.

- CLIA Waived for whole blood
- FDA cleared with no age restrictions
- Results in 8 minutes
- Requires only 25uL of whole blood or 10uL serum/plasma
- Sensitivity of 99% SUPERIOR
- Specificity of 98.8%
- External positive and negative controls included
- Safe pipettes for accurate sample collection



| ORDERING INFORMATION | | |
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| PRODUCT | #OF TESTS | ITEM# |
| Status™ Mono (WB/Serum/Plasma) | 25 | 68364 |
| Status™ Mono (WB/Serum/Plasma) | 30 | 84M30 |
| Status™ Mono Control Set | 2 x 1 mL | 200014 |

GI DISORDER

Status™ H. pylori

For the qualitative detection of Anti-Helicobacter pylori antibodies in human whole blood, serum and plasma.

- CLIA Waived for whole blood
- Requires only 25uL of whole blood or 10uL of serum/plasma
- Results in 10 minutes
- Sensitivity of 95.9% with overall agreement to biopsy histology



| ORDERING INFORMATION | | |
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| PRODUCT | #OF TESTS | ITEM# |
| Status™ H. pylori | 30 | 37030 |
| Status™ H. pylori Control Set | 2 x 1 mL | 200013 |

Status™ iFOBT

Rapid immunoassay for the qualitative detection of Immunochemical Fecal Occult Blood (human hemoglobin in human fecal specimens).

• CLIA Waived

- No dietary or medication restrictions
- Increased patient compliance
- Results in 5 minutes
- Contains 30 test devices,
 50 collection tubes,
 & 50 mailing envelopes



| ORDERING INFORMATION | | |
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| PRODUCT | #OF TESTS | ITEM# |
| Status™ iFOBT (Complete Kit) | 30 | 38030 -DTM |
| Status™ iFOBT Sample Collection Tubes Only | 50 | 38050 -T |
| Status™ iFOBT Mailing Envelopes Only | 50 | 38050-M |
| Status™ iFOBT Mailers & Collection Tubes | 25 | 38025-TM |
| Status™ iFOBT Device & Tubes | 50 | 38050-DT |
| Status™ iFOBT Control Set | 2 x 1 mL | 200020 |

UROLOGY

Uricult®

The preferred in-office urine culture system.

- Easy to perform; Dip Incubate Read Results
- Results within 18-24 hours
- Positive culture can be sent to reference lab for additional studies if needed
- Trademark of Orion Diagnostica



| ORDERING INFORMATION | | |
|-----------------------------------|-----------|-------|
| PRODUCT | #OF TESTS | ITEM# |
| Uricult® CLED/EMB | 10 | 1000 |
| Uricult® CLED/Polymixin/MacConkey | 10 | 1003 |



Uricult® Control Kit

Quality control for Uricult[®] urine culture paddles. Each contains positive and negative control diluents.

| ORDERING INFORMATION | | |
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| PRODUCT | #OF TESTS | ITEM# |
| Uricult® Control Kit | 2 x 99 mL | 200030 |

Status[™] BTA

A rapid test for the qualitative detection of bladder tumor associated antigens in human urine.

CLIA Waived

- Indicated for use as an aid in monitoring bladder cancer patients in conjunction with cystoscopy
- Superior sensitivity & specificity providing a more accurate diagnosis
- Results in 5 minutes



| ORDERING INFORMATION | | |
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| PRODUCT | #OF TESTS | ITEM# |
| Status™ BTA | 25 | 39025 |
| Status™ BTA Control Kit | 2 x 2 mL | 200019 |

CARDIAC CARE



LifeSign™ MI

For the rapid qualitative detection of cardiac markers in human whole blood, serum, and plasma to aid in the diagnosis of acute myocardial infarction.

- Qualitative CK-MB, Myoglobin, Troponin I
- Enables prompt detection of emergency room decisions
- Easy to use procedure
- Results in 15 minutes
- Reduces unnecessary testing and hospital admissions

| ORDERING INFORMATION | | |
|---|-----------|------------|
| PRODUCT | #OF TESTS | ITEM# |
| LifeSign™ MI Troponin I | 20 | 60101 |
| LifeSign™ MI Myoglobin (CK-MB)/Troponin I | 20 | 60201 |
| LifeSign™ MI Cardiac Control Kit | 2 x 1 mL | LSC-301(a) |

WOMEN'S HEALTH



Status[™] hCG

For the detection of hCG in serum or urine.

- CLIA Waived for urine
- Serum and urine 25mlU/mL sensitivity
- Results in 3-5 minutes
- Minimal susceptibility to the hook effect hCG β core fragment

Status[™] hCG Strip

For the detection of hCG in urine.

- CLIA Waived for urine
- Simple "dip and read" procedure
- 25mlU/mL sensitivity
- Results in 3-5 minutes
- \bullet Minimal susceptibility to the hook effect hCG β core fragment



| ORDERING INFORMATION | | |
|------------------------------------|------------|----------|
| PRODUCT | #OF TESTS | ITEM# |
| Status™ hCG Urine/Serum (Cassette) | 35 | 35035 |
| Status™ Urine (Cassette) | 35 | 35135 |
| Status™ hCG Strip | 35 | 35235 |
| Status™ hCG Control Set | 2 x 2.5 mL | 135-100A |

DRUGS OF ABUSE

Status[™] DS

One step immunoassay for the qualitative detection of drugs of abuse and their metabolites in urine.

- Simple one-step procedure
- Manageable results with 97-99% correlation to GC/MS
- Results in as little as 5 minutes



| ORDERING INFORMATION | | | |
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| PRODUCT | #OF TESTS | ITEM# | |
| Status™ DS TCA | 35 | 20935 | |
| Status [™] DS Control Set | 2 x 5 mL | 21000 | |
| Status [™] DS 10 panel MET/THC/OPI/COC/AMP/ BZO/BAR/TCA/PCP/MTD | 25 | 21025 | |

NICOTINE

Status™ Nicotine

Rapid immunoassay for the detection of cotinine and nicotine metabolites in urine.

- Simple one-step procedure
- Accurate results with 97-99% correlation to GC/MS
- Results in 10 minutes
- 500mg/mL cut-off



| ORDERING INFORMATION | | | |
|------------------------|-----------|-------|--|
| PRODUCT | #OF TESTS | ITEM# | |
| Status™ DS Nicotine | 35 | 21735 | |
| Status™ DS Control Set | 2 x 5 mL | 21000 | |

INDUSTRIAL



Hygicult[®]

Rapid hygiene culture system.

- Ready to use for on site hygiene monitoring
- Store at room temperature
- Hinged slide for convenient surface sampling
- AOAC approved
- Incubate at 36°C for 24 hours

| ORDERING INFORMATION | | | |
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| PRODUCT | #OF TESTS | ITEM# | |
| Hygicult ™TPC | 10 | 68010 | |
| Hygicult ™Y&F | 10 | 68013 | |

Easicult®

Convenient industrial culture system identifying bacteria & fungi in oils, water, fuels and other applications.

- Ready to use on site testing
- Monitors microbial contamination
- Easy result interpretation
- Incubate at 36°C for up to 24 hours
- Option to incubate at room temperature for up to 5 days





| ORDERING INFORMATION | | | |
|----------------------|-----------|-------|--|
| PRODUCT | #OF TESTS | ITEM# | |
| Easicult ™TTC | 10 | 4030 | |
| Easicult ™ Combi | 10 | 4060 | |

INCUBATOR



Cultura® M Incubator

Small, durable and reliable incubator. Suitable for the incubation of dip paddles.

- Lightweight and portable
- Temperature range from 25°C to 48°C
- Holds up to 18 dip paddles

| ORDERING INFORMATION | | |
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| PRODUCT | #OF TESTS | ITEM# |
| Cultura® M Incubator | NA | 05866 |