Brochure
Professional and Only in IVD Products
Company Profile

Laihe Biotech specializes in IVD industry. As the international supplier and manufacturer, Laihe Biotech for the purpose of good faith, practicability, efficiency and innovation, it always provides customers with fast, accurate, reliable health detection products and services as our business philosophy. Furthermore, Laihe has attained CE and ISO13485 certification. Our future is expecting your participation.

- Drug of abuse tests
- Cardiac marker tests
- Tumor marker tests
- Fertility tests
- Infectious diseases tests
- TORCH tests
- POCT(real time) analyzer
<table>
<thead>
<tr>
<th>Product Name</th>
<th>Format</th>
<th>Specimen</th>
<th>Certification</th>
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<tbody>
<tr>
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<tr>
<td><strong>Qualitative Test Kit</strong></td>
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<td>MET (methamphetamine)</td>
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<td>MET 300 (methamphetamine)</td>
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<tr>
<td>POC Reader/Analyzer</td>
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</tbody>
</table>
Multi-Drug Screen Test Integrated Cup

A rapid, one step screening test for the simultaneous, qualitative detection of multiple drugs and drug metabolites in human urine.

General Information
- Materials: cup, insert paper
- Reading Time: 5~15 minutes
- Storage: 4~30°C

<table>
<thead>
<tr>
<th>Test</th>
<th>Calibrator</th>
<th>Cut-off</th>
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<tbody>
<tr>
<td>Amphetamine (AMP 1,000)</td>
<td>d-Amphetamine</td>
<td>1,000 ng/mL</td>
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<tr>
<td>Amphetamine (AMP 300)</td>
<td>d-Amphetamine</td>
<td>300 ng/mL</td>
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<tr>
<td>Barbiturates (BAR)</td>
<td>Secobarbital</td>
<td>300 ng/mL</td>
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<tr>
<td>Benzodiazepines (BZO)</td>
<td>Oxazepam</td>
<td>300 ng/mL</td>
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<tr>
<td>Cocaine (COC)</td>
<td>Benzoylcegonine</td>
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<tr>
<td>Marijuana (THC)</td>
<td>11-nor-Δ^2^-THC-9 COOH</td>
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<td>Methadone (MTD)</td>
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<td>Methamphetamine (mAMP)</td>
<td>d-Methamphetamine</td>
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<td>Methylenedioxyethamphetamine (MDMA)</td>
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<td>Opiates (OPI 2,000)</td>
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<td>Phencyclidine (PCP)</td>
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<td>Propoxyphene (PPX)</td>
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<td>Tricyclic Antidepressants (TCA)</td>
<td>Nortriptyline</td>
<td>1,000 ng/mL</td>
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</table>

NEGATIVE:* Two lines appear. One colored line should be in the control region (C), and another apparent colored line adjacent should be in the test region (T). This negative result indicates that the drug concentration is below the detectable level.

POSITIVE: One colored line appears in the control region C. No line appears in the test region (T). This positive result indicates that the drug concentration is above the detectable level.

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test using a new test panel. If the problem persists, discontinue using the lot immediately and contact your manufacturer.
Myoglobin/CK-MB/Troponin I Combo Test (Cassette)(Whole Blood/Serum/Plasma)

A rapid test for the qualitative detection of Myoglobin, CK-MB, and Troponin I in whole blood, serum or plasma. For professional in vitro diagnostic use only.

General Information
- Reading time: Read results at 10 minutes

Performance

<table>
<thead>
<tr>
<th>Method</th>
<th>Results</th>
<th>EIA</th>
<th>Total Results</th>
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<tbody>
<tr>
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<td>Negative</td>
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<tr>
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<td>69</td>
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<td>Negative</td>
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<tr>
<td>Total Results</td>
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<td>CK-MB test</td>
<td>Results</td>
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<td>Troponin I test</td>
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<td>505</td>
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<td>513</td>
<td>741</td>
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</tbody>
</table>

Test Procedure

Test Results
- **POSITIVE**: A colored line in the control line region (C) and the presence of one or more colored lines in the test line regions indicates a positive result. This indicates that the concentration of Myoglobin, CK-MB and/or Troponin I is above the minimum detection level.
- **NEGATIVE**: One colored line appears in the control line region ©. No apparent colored lines appear in any of the test line region(s). This indicates that the concentration of Myoglobin, CK-MB and Troponin I are below the minimum detection levels.
Typhoid IgG/IgM Rapid Test Cassette

The Typhoid IgG/IgM Rapid Test Cassette is a rapid, qualitative and differential test for the detection of IgG and IgM antibodies to Salmonella typhi (S. typhi) and paratyphi in human serum or plasma.

General Information
- Materials: Test devices /Droppers/Paper Insert
- Sensitivity: 91.8%
- Specificity: 98.7%
- Reading Time: 20~30 minutes
- Storage: 4~30°C

Performance

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<td>230</td>
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</tbody>
</table>

Test Procedure

1. POSITIVE
1.1 IgM Positive: Only IgM band is developed, the test indicates for the presence of anti-S. typhi or paratyphi IgM in the specimen. The result is IgM positive.
1.2 P.v Positive: Only IgG band is developed, the test indicates for the presence of anti-S. typhi or paratyphi IgG in the specimen. The result is IgG positive.
1.3 IgG and IgM Positive: Both IgG and IgM band are developed, the test indicates for the presence of anti-S. typhi or paratyphi IgG and IgM in the specimen. The result is both IgG and IgM are positive.
2. Negative: Only one colored line appears in the control region.
3. Invalid: Control line fails to appear. Insufficient specimen column or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.
Malaria Pf/pv Ag Rapid Test (Whole Blood)

The Malaria Pf/Pv Ag Test is a rapid lateral flow chromatographic immunoassay for the simultaneous detection and differentiation of Malaria P.falciparum specific histidine rich protein-2 (PFHRP-II) and Malaria P.vivax specific lactate dehydrogenase (Pv-LDH) in human blood specimen as a aid in the diagnosis of Malaria infection. It is for In-Vitro Diagnostic use only.

General Information
- Materials: Test devices /Droppers/Pepper Insert
- Cut-off: 750 ng/ml
- Sensitivity: 100%
- Specificity: 98.7%
- Reading Time: 20~30 minutes
- Storage: 4~30°C

Performance

<table>
<thead>
<tr>
<th>Method</th>
<th>GC/MS</th>
<th>Total Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Malaria Pf/Pv Ag Rapid Test</td>
<td>Results</td>
<td></td>
</tr>
<tr>
<td>Positive</td>
<td>Positive</td>
<td>50</td>
</tr>
<tr>
<td></td>
<td>Negative</td>
<td>4</td>
</tr>
<tr>
<td>Total Results</td>
<td></td>
<td>54</td>
</tr>
<tr>
<td>Negative</td>
<td></td>
<td>298</td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>298</td>
</tr>
</tbody>
</table>

Test Procedure

POSITIVE:

P.f Positive: One line appears in the control region, and one line appears in Pf(T2) line region.
P.v Positive: One line appears in the control region and one line appears in Pv(T1) line region.
P.f and P.v Positive: One line appears in the control region, one line appears in Pv(T1) line region and one line appears in Pf(T2) line region.
Negative: Only one colored line appears in the control region.
Invalid: Control line fails to appear. Insufficient specimen column or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.
Dengue IgG/IgM Rapid Test Device

A rapid test for the qualitative detection of antibodies (IgG and IgM) to Dengue virus in whole blood, serum, or plasma.

General Information
- Materials: Test devices/Droppers/Buffer/insert
- Sensitivity: 95.8%
- Specificity: 99.0%
- Reading Time: 5~15 minutes
- Storage: 2~30°C

Performance

<table>
<thead>
<tr>
<th>Dengue Infection</th>
<th>Result</th>
<th>IgM</th>
<th>IgG</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary Infection</td>
<td>Positive</td>
<td>14</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Negative</td>
<td>3</td>
<td>17</td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>17</td>
<td>17</td>
</tr>
<tr>
<td></td>
<td>Relative Sensitivity</td>
<td>82.4%</td>
<td>0%</td>
</tr>
<tr>
<td>Secondary Infection</td>
<td>Positive</td>
<td>39</td>
<td>55</td>
</tr>
<tr>
<td></td>
<td>Negative</td>
<td>16</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>55</td>
<td>55</td>
</tr>
<tr>
<td></td>
<td>Relative Sensitivity</td>
<td>70.9%</td>
<td>&gt;99.0%</td>
</tr>
<tr>
<td>Non-Dengue Infection</td>
<td>Positive</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Negative</td>
<td>378</td>
<td>378</td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>378</td>
<td>378</td>
</tr>
<tr>
<td></td>
<td>Relative Sensitivity</td>
<td>&gt;99.0%</td>
<td>&gt;99.0%</td>
</tr>
</tbody>
</table>

Test Procedure

(15-30°C) prior to testing.

Note: IgG Positive detects secondary dengue infection, IgM Positive detects primary dengue infection. Both IgG and IgM Positive detect indicative of secondary dengue infection.
POCT Immunofluorescence Analyzer

The analyzer is used in the immunofluorescence analysis of human samples, based on immunochromatographic dry reagent. It is used for professional in-vitro diagnostic test in medical institution only. It can be used in central laboratory, clinic laboratory, clinical department or other medical service center (community healthcare center, etc.), diagnostic center, research laboratory and so on.

Features

- Software version: Version 1
- Operating system: Linux
- Light: LED or diode laser
- Port: a. USB *4
  b. Ethernet *1
  c. Double serial ports
    Port 1: LIS system self-uploading
    Port 2: connecting PC with deploying reagent
- Display: 24-color LCD
- Sample: whole blood, serum/plasma and urine
- Power: host input: DC 24V 3A
  Adapter input: 100-240VAC, 50-60Hz
- Repeatability: CV≤10%
- Stability: σ≤±8%
- Linear dependence: r≥0.97
- Accuracy: Δn≤±15

General Information

- Close system with barcode and ID card
- 10.1 inch LCD touch screen
- Portable design
- Link with LIS system
- Auto-check when power on
- Result in 3-15 min

Parts list

<table>
<thead>
<tr>
<th>No.</th>
<th>Part name</th>
<th>Quantity</th>
<th>Note</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Power adapter</td>
<td>1</td>
<td>Standard part</td>
</tr>
<tr>
<td>2</td>
<td>Instruction</td>
<td>1</td>
<td>Standard part</td>
</tr>
<tr>
<td>3</td>
<td>Qualification certification</td>
<td>1</td>
<td>Standard part</td>
</tr>
<tr>
<td>4</td>
<td>Guarantee card</td>
<td>1</td>
<td>Standard part</td>
</tr>
<tr>
<td>5</td>
<td>Cable</td>
<td>1</td>
<td>Standard part</td>
</tr>
</tbody>
</table>
## POCT Immunofluorescence Analyzer

### Current Corollary Test

<table>
<thead>
<tr>
<th>Test</th>
<th>Sample</th>
<th>Range</th>
<th>Clinical application</th>
</tr>
</thead>
<tbody>
<tr>
<td>PCT</td>
<td>Whole blood/Serum/Plasma</td>
<td>0.1-100ng/ml</td>
<td>Best Indicator of Infection &amp; Sepsis</td>
</tr>
<tr>
<td>CRP</td>
<td>Whole blood/Serum/Plasma</td>
<td>5-200mg/L</td>
<td>Differential diagnosis virus infection and bacterial infection</td>
</tr>
<tr>
<td>hsCRP</td>
<td>Whole blood/Serum/Plasma</td>
<td>0.5-5 mg/L</td>
<td>Cardiovascular disease risk</td>
</tr>
<tr>
<td>CTnl</td>
<td>Whole blood/Serum/Plasma</td>
<td>0.1-50ng/ml</td>
<td>Myocardial infarction risk signal: &gt;0.3ng/ml</td>
</tr>
<tr>
<td>CK-MB</td>
<td>Whole blood/Serum/Plasma</td>
<td>3~100 ng/mL</td>
<td>Myocardial infarction risk signal: 5ng/ml</td>
</tr>
<tr>
<td>MYO</td>
<td>Whole blood/Serum/Plasma</td>
<td>5~500 ng/mL</td>
<td>Myocardial infarction risk signal: 50ng/ml</td>
</tr>
<tr>
<td>NT-pro BNP</td>
<td>Whole blood/Serum/Plasma</td>
<td>100~32000 pg/mL</td>
<td>Heart failure risk signal: &gt;300pg/ml</td>
</tr>
<tr>
<td>PSA</td>
<td>Serum/Plasma</td>
<td>0.5~100 ng/mL</td>
<td>Prostate cancer risk: PSA&gt;4.0ng/mL</td>
</tr>
<tr>
<td>AFP</td>
<td>Serum/Plasma</td>
<td>5~350 ng/mL</td>
<td>Primary liver cancer risk:AFP&gt;20ng/mL</td>
</tr>
<tr>
<td>CEA</td>
<td>Serum/Plasma</td>
<td>3~500 ng/mL</td>
<td>Colorectal cancer, stomach cancer, lung cancer, liver cancer, pancreatic cancer risk: CEA&gt;5.0ng/mL</td>
</tr>
</tbody>
</table>
TORCH Rubella/CMV/Toxo/HSV IgM Combo
Rapid Test

A rapid test for the qualitative detection of IgM antibodies to Rubella virus (Rubella), Cytomegalovirus (CMV), Toxoplasma gondii (Toxo), and Herpes simplex virus (HSV) in serum or plasma. For in vitro diagnostic use only.

General Information
- Materials: Test devices /Droppers/Paper Insert
- Reading Time: 20~30 minutes
- Storage: 4~30°C

Performance

<table>
<thead>
<tr>
<th></th>
<th>Rubella</th>
<th>CMV</th>
<th>TOXO</th>
<th>HSV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Relative Sensitivity</td>
<td>95.0%</td>
<td>96.2%</td>
<td>94.1%</td>
<td>94.7%</td>
</tr>
<tr>
<td>Relative Specificity</td>
<td>99.3%</td>
<td>&gt;99.9%</td>
<td>98.0%</td>
<td>94.1%</td>
</tr>
</tbody>
</table>

Test Procedure

1. POSITIVE:
   1.1 Rubella Positive: Two colored lines appear in the “Rubella”
   1.2 CMV Positive: Two colored lines appear in the “CMV”
   1.3 Toxo Positive: Two colored lines appear in the “Toxo”
   1.4 HSV Positive: Two colored lines appear in the “HSV”

2. Negative: Only one colored line appears in the control region.

3. Invalid: Control line fails to appear. Insufficient specimen column or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.