STANDARD F

Respiratory Disease

- Influenza A/B FIA
- RSV Ag FIA
- S.pneumoniae Ag FIA
- Strep A Ag FIA
- Legionella Ag FIA

Supplied by:

Oxford BioSystems

Tel: +44(0)1235 431390
sales@oxfordbiosystems.com
www.oxfordbiosystems.com
STANDARD F | Fluorescent immunoassay

- Rapid, Easy-to-use and Respiratory disease Diagnostics Platform for Point of Care Use

- Excellent sensitivity and specificity with Fluorescent immunoassay
  - Proven lateral flow design enhanced with fluorescent immunoassay technology featuring Europium
  - Specific antibodies selected to optimize performance in concert with fluorescence

- Objective test results
  - Eliminate ambiguous test results as the analyzer interprets and determines the results

- Cut of Index (COI)
  - Great reference value for medical decision-making

- Rapid test results
  - Provides accurate, objective and automated results in just 90 seconds in case of strong positive specimen (Influenza Test)

- 2D barcode technology
  - Auto coding procedure by recognizing 2D barcode
  - Reduce time and errors associated with manually recording LOT specific information

- Expandable parameters
  - Adenovirus test for respiratory infection is coming soon

User friendly interface
- 7" Color Touch Screen

Minimized risk of contamination
- Keep the entrance shut unless the testing is in progress. The dust cover protects against contamination.

Convenient report
- Built-in Printer

Compact desktop
- 200 x 240 x 205
- 2.5 kg

Graphic LCD
- Result is presented clearly and concisely

Portable system
- Battery (AA x 4) or AC/DC adapter

Hand held size
- 105 x 135 x 100
- 700 g
STANDARD F Influenza A/B FIA

Quick-test with reliable performance

STANDARD F Influenza A/B FIA test system (Analyzer + Test device) can be used as a commercially available rapid diagnostic tests. Moreover, it performs higher accuracy and faster test results within 1.5 – 10 minutes with the STANDARD FIA Analyzer.

Benefits
- Fast result (1.5 - 10 minutes)
- More than 200 times higher sensitive than RDTs
- Filter cap for mucoidal samples
- Great detectability
  - A type(H1N1, H1N1/2009, H3N2, H4N6, H5N1, H5N3, H6N5, H7N1, H7N2, H8N4, H9N2)
  - B type

Clinical evaluation data

<table>
<thead>
<tr>
<th>Reference</th>
<th>Strain</th>
<th>Sensitivity</th>
<th>Specificity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anyplex™ II RV16 Detection</td>
<td>A</td>
<td>84.48% (49/58)</td>
<td>100% (197/197)</td>
</tr>
<tr>
<td>Anyplex™ II RV16 Detection</td>
<td>B</td>
<td>72.06% (49/68)</td>
<td>96.57% (197/204)</td>
</tr>
</tbody>
</table>

Reference : Guro, Korea University Hospital Clinical laboratory medicine.
* Sample : Nasopharyngeal swab diluted in VTM

STANDARD F RSV Ag FIA

Quick-test with reliable performance

STANDARD F RSV Ag FIA test system (Analyzer + Test device) can aid in treatment decisions in clinical settings such as prescribing medications and further diagnosis.

Benefits
- Fast results in 5 - 15 minutes.
- High sensitivity and specificity
- Filter cap for mucoidal samples.

Clinical evaluation data

<table>
<thead>
<tr>
<th>Reference</th>
<th>Strain</th>
<th>Sensitivity</th>
<th>Specificity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anyplex™ II RV16 Detection + FIA</td>
<td>A</td>
<td>90.57% (48/53)</td>
<td>92.19% (118/128)</td>
</tr>
</tbody>
</table>

Reference : Guro, Korea University Hospital Clinical laboratory medicine.
* Sample : Nasopharyngeal swab diluted in VTM
STANDARD F

**Legionella Ag FIA**

Quick-test with reliable performance

STANDARD F *Legionella Ag FIA* test system (Analyzer + Test device) detects *Legionella pneumophila* serogroup 1 antigen via easily collectible urine sample. Without further sample processing, *STANDARD F Legionella Ag FIA* performs high sensitivity, and the test is not affected by Rheumatoid factor.

**Benefits**

- Fast results in 5 - 15 minutes.
- Urine sample, One step test
- Test not affected by Rheumatoid factor (spiked below 14.84IU/mL)

<table>
<thead>
<tr>
<th>Rheumatoid Factor (IU/mL)</th>
<th>STANDARD F Legionella Ag FIA</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Test with normal urine spiked with RF serum.</td>
</tr>
<tr>
<td>14.84</td>
<td>Negative</td>
</tr>
<tr>
<td>7.42</td>
<td>Negative</td>
</tr>
<tr>
<td>3.71</td>
<td>Negative</td>
</tr>
<tr>
<td>1.86</td>
<td>Negative</td>
</tr>
<tr>
<td>0.93</td>
<td>Negative</td>
</tr>
<tr>
<td>0.46</td>
<td>Negative</td>
</tr>
<tr>
<td>0.23</td>
<td>Negative</td>
</tr>
</tbody>
</table>

**Clinical evaluation data**

<table>
<thead>
<tr>
<th>Reference</th>
<th>Sensitivity</th>
<th>Specificity</th>
</tr>
</thead>
<tbody>
<tr>
<td>FIA</td>
<td>94.9% (37/39)</td>
<td>100% (40/40)</td>
</tr>
</tbody>
</table>

Reference : Internal evaluation

---

STANDARD F

**S.pneumoniae Ag FIA**

Quick-test with reliable performance

STANDARD F *S.pneumoniae Ag FIA* test system (Analyzer + Test device) detects *S. pneumoniae* antigen in urine sample for the patients with pneumonia and in cerebral spinal fluid sample for the patients with meningitis.

**Benefits**

- Fast results in 5 - 10 minutes.
- Urine sample for pneumonia.
- CSF sample for meningitis.
- One step test.

**Clinical evaluation data**

<table>
<thead>
<tr>
<th>Reference</th>
<th>Sensitivity</th>
<th>Specificity</th>
</tr>
</thead>
<tbody>
<tr>
<td>FIA</td>
<td>96.2% (25/26)</td>
<td>100% (40/40)</td>
</tr>
</tbody>
</table>

Reference : Internal evaluation
STANDARD F Strep Ag FIA

Quick-test with reliable performance

STANDARD F Strep Ag FIA test system (Analyzer + Test device) detects group A streptococcal (Strep A) antigen directly from throat swabs of symptomatic patients or confirmation of presumptive Group A Streptococcal colonies recovered from culture.

**Benefits**
- Fast results in 5 minutes.
- Collects and dispenses correct amount of sample via the fixed volume dropper.
- Eliminates the subjectivity of a visual result.
- Room temperature storage.

**Clinical evaluation data**

<table>
<thead>
<tr>
<th>Reference</th>
<th>Sensitivity</th>
<th>Specificity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bacterial culture</td>
<td>93.3%(28/30)</td>
<td>95%(38/40)</td>
</tr>
</tbody>
</table>

Reference : Internal evaluation

### Ordering Information

**STANDARD F Analyzers**

<table>
<thead>
<tr>
<th>Products</th>
<th>Cat. No.</th>
<th>Printer</th>
<th>Unit</th>
<th>Weight</th>
<th>Carton size(W/L/H)</th>
</tr>
</thead>
<tbody>
<tr>
<td>F100</td>
<td>10FA10</td>
<td>External</td>
<td>1 unit</td>
<td>0.7 kg</td>
<td>105 x 135 x 100</td>
</tr>
<tr>
<td>F200</td>
<td>10FA20</td>
<td>Built-in</td>
<td>1 unit</td>
<td>2.5 kg</td>
<td>200 x 240 x 205</td>
</tr>
</tbody>
</table>

**STANDARD F Tests**

<table>
<thead>
<tr>
<th>Products</th>
<th>Cat. No.</th>
<th>Storage temperature</th>
<th>Shelf life</th>
<th>Pack size</th>
<th>Qty/Carton</th>
<th>Carton size(W/L/H)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Influenza A/B FIA</td>
<td>10INF10D</td>
<td>2–30°C/36–86°F</td>
<td>18M</td>
<td>25T/Kit</td>
<td>15</td>
<td>525 x 325 x 420</td>
</tr>
<tr>
<td>RSV Ag FIA</td>
<td>10RSV10D</td>
<td>2–30°C/36–86°F</td>
<td>18M</td>
<td>25T/Kit</td>
<td>15</td>
<td>525 x 325 x 420</td>
</tr>
<tr>
<td>S. pneumoniae Ag FIA</td>
<td>10SPN10D</td>
<td>2–30°C/36–86°F</td>
<td>18M</td>
<td>25T/Kit</td>
<td>45</td>
<td>515 x 465 x 420</td>
</tr>
<tr>
<td>Legionella Ag FIA</td>
<td>10LEG10D</td>
<td>2–30°C/36–86°F</td>
<td>18M</td>
<td>25T/Kit</td>
<td>45</td>
<td>515 x 465 x 420</td>
</tr>
<tr>
<td>Strep A Ag FIA</td>
<td>10STR10D</td>
<td>2–30°C/36–86°F</td>
<td>18M</td>
<td>25T/Kit</td>
<td>30</td>
<td>515 x 465 x 420</td>
</tr>
</tbody>
</table>
How to use the STANDARD F respiratory test kits

**STANDARD F Influenza A/B FIA & RSV FIA**

**STANDARD Test Mode**

Select the STANDARD TEST mode

Insert Test device into the F Analyzer

Press START button after apply sample

Check the test result.

**Ready Only Test Mode**

Select the READ ONLY mode and insert test device into the F Analyzer.

Check the test result.

- Influenza **10 min.**
- RSV **15 min.**

**STANDARD F S.pneumoniae Ag FIA & Legionella Ag FIA**

**STANDARD Test Mode**

Select the STANDARD TEST mode

Insert Test device into the F Analyzer

Press START button after apply sample

Check the test result.

**Ready Only Test Mode**

Select the READ ONLY mode and insert test device into the F Analyzer.

Check the test result.

**STANDARD F Strep A Ag FIA**

**STANDARD Test Mode**

Select the STANDARD TEST mode

Insert Test device into the F Analyzer

Press START button after apply sample

Check the test result.

**Ready Only Test Mode**

Select the READ ONLY mode and insert test device into the F Analyzer.

Check the test result.

**SD BIOSENSOR**

Head Office  C-4th & 5th Floor, 16, Deogyeong-daero 1556beon-gil, Yeongtong-gu, Suwon-si, Gyeonggi-do, 16690, REPUBLIC OF KOREA

Factory  74, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, 28161, REPUBLIC OF KOREA

Tel  +82-31-300-0400  Fax  +82-31-300-0499  E-mail  sales@sdbiosensor.com  Website  www.sdbiosensor.com

LEF-RESP6EN / SDC.1710 © 2017 SD BIOSENSOR. All rights reserved.  
SD BIOSENSOR is not related to Alere Inc. or Standard Diagnostics, Inc.