

STANDARD F Legionella Ag FIA

STANDARD™ F Legionella Ag FIA



EXPLANATION AND SUMMARY

[Introdução]
The genus Legionella is a pathogenic group of gram-negative bacteria. The genus Legionella contains more than 50 species, of which at least 24 have been associated with human infections. The best characterized member of the genus, Legionella pneumophila, is the major causative agent of Legionellosis. Legionella pneumophila is commonly found in lakes, rivers, creeks, hot springs and other bodies of water where it is symbiotically present in aquatic amoebae. Most people become infected when they inhale microscopic water droplets containing the bacteria. Legionellosis is a generic term describing the pneumonic and non-pneumonic forms of infection with Legionella. The non-pneumonic form, Pontiac disease fever, is an acute self-limiting influenza-like illness usually lasting 2-5 days. No deaths are associated with this type of infection. The pneumonic form, Legionnaires' disease, has an incubation period of 2-10 days. The severity of disease ranges from a mild cough to a rapidly fatal pneumonia. Death occurs through progressive pneumonia with respiratory failure or shock, and in many cases Legionnaires' disease is important as the rate of mortality from untreated Legionnaires' disease ranges from 10 to 50%. STANDARD F Legionella Ag FIA, containing a highly specific and sensitive antibody, provides significant fast, easy and accurate system to identify the Legionella Ag from human urine specimen.

[Intended use]
STANDARD F Legionella Ag FIA is a fluorescence immunosassay for the qualitative detection of Legionella pneumophila Serogroup 1 antigen present in urine samples from patients with symptoms of pneumonia. This test is for in vitro diagnostic use and intended for professional use, only for an initial screening test. STANDARD F Legionella Ag FIA should be used with the appropriate analyzer, STANDARD F Analyzers, manufactured by SD BIOSENSOR.

[Test principle]
STANDARD F Legionella Ag FIA is based on immunofluorescence technology with STANDARD F Analyzer to detect Legionella pneumophila serogroup 1 antigen. STANDARD Legionella Ag FIA has control and test line which is marked with monoclonal anti-PPR and rabbit anti-Legionelle each. The patient's sample is applied into the sample well of the test device and the sample migrates through the membrane. If Legionella antigen is present, it will react with europium conjugated monoclonal anti-Legionella on the conjugation pad and form antibody-antigen-fluorescence particle complexes. These complexes move along to the membrane to be captured by the anti-Legionella on the test line and make fluorescent signal. The intensity of the fluorescence light generated on the membrane is scanned by the STANDARD F Analyzer manufactured by SD BIOSENSOR. STANDARD F Analyzer can analyze the presence of the antigen in the clinical specimen by processing the results using pre-programmed algorithms and display the test result on the screen.

[Kit contents]
• Test device • Fixed volume pipette (100µl) • Positive control • Negative control
• Control extraction buffer • Instruction manual for use

[Materials required but not provided]
STANDARD F Analyzer
• Timer

KIT STORAGE AND STABILITY

Store the kit at 2-30°C / 36-86°F, out of direct sunlight. Kit materials are stable until expiration date printed on the outer box. Do not freeze the kit.

WARNINGS AND PRECAUTIONS

1. Do not re-use the test kit.
2. Use the STANDARD F Legionella Ag FIA at 15-32°C / 59-90°F and 10-90%RH.
3. Do not use the test kit if the pouch is damaged or the seal is broken.
4. Do not smoke, drink or eat while handling specimen.
5. Wear personal protection, gloves and lab coats when handling kit reagents. Wash hands thoroughly when afterwards.
6. Clean up spills thoroughly using an appropriate disinfectant.
7. Handle all specimens as though they contain infectious agents.
8. Observe established precautions against microbiological hazards throughout testing procedures.
9. Dispose of all specimens and materials used to perform the test as bio-hazard waste. Laboratory chemical and bio-hazard waste must be handled and discarded in accordance with all local, state, and national regulations.
10. Silica gel foil pouch is used to absorb moisture and keep humidity from affecting products. If the moisture indicating silica gel beads change from yellow to green, the test device in the pouch should be discarded.
11. Immediately use the test device after taking out of a foil pouch.
12. If the test result with positive/negative control is abnormal, do not use the kit.
13. The bar code of the test device is used by analyzer to identify the type of test being run and to identify the individual test device so as to prevent to a second read of the test device by the same analyzer.
14. Once a test device has been successfully scanned by analyzer, do not attempt to scan the test device again in the same analyzer.
15. As the detection reagent is a fluorescent compound, no visible results will form on the test device.
16. Improper specimen collection, handling or transport may yield inaccurate results.
17. Do not write on the bar code or damage the bar code of the test device.
18. Do not use unclassified specimens in this instructions for use.

SPECIMEN COLLECTION AND PREPARATION

1. Urine specimens should be collected in a clean and dry container and collected at any time of the day may be used.
2. Urine specimen may be stored at room temperature (15-30°C/59-86°F) for up to 3 days or at 2-8°C/ 36-40°F for up to 2 weeks prior to testing.
3. For prolonged storage, specimens may be frozen and stored at -40°C/-40°F. The frozen specimens are stable up to 3 months at -40°C/-40°F.
4. Frozen urine specimens should be thawed and fully mixed before testing.
5. If the urine specimen contains visible precipitates, it should be centrifuged, filtered, or allowed to settle to obtain a clear supernatant for testing.
6. Boric acid can be used as a preservative.

TEST PROCEDURE

1. Allow kit components and collected urine sample to room temperature (15-30°C/59-86°F) a minimum of 30 minutes before using.
2. Carefully read instructions for the STANDARD F Legionella Ag FIA.
3. Check the expiry date at the back of the foil pouch. Use another lot, if expiry date has passed.

4. Open the foil pouch, and check the test device and the silica gel pack in the foil pouch.



• If there is no violet colored Check Band on membrane of test device, do not use kit.

• Do not write on the bar code or damage the bar code of the test device.

• Preparation of the positive/negative control sample

1. Insert the positive/negative control swab in the kit into the control extraction buffer tube. Swirl the swab at least five times.
2. Remove the swab and dispose the used swab in accordance with your biohazard waste disposal protocol.
3. To analyze of the external quality control sample, follow instructions for 'Analysis of sample' stated below.

[Analysis of sample]
• Using a STANDARD Test™ mode

1. Prepare a STANDARD F100, F200 and F2400 analyzer
2. In case of STANDARD F200 and F2400 analyzer, input patient ID and/or operator ID on the analyzer.
3. Take the test device out of the foil pouch.

[Internal procedural control]
1. The internal procedural control zones is on the membrane of the test device. STANDARD F Analyzers read the fluorescence signal of the internal procedural control zone and decide whether the result is valid or invalid.

2. The invalid result means that the fluorescence signal is not within the pre-set range.

4. Insert the test device to the test slot of the analyzer. When inserting the test device to the analyzer, the analyzer will read the barcode data, and check the test device is valid.



5. Compress the top bulb of a fixed volume pipette (100µl) and place the tip of the pipette into the prepared sample.

6. Slowly release the top bulb of the pipette dipping the tip of the pipette into the sample.

7. Completely squeeze the sample into the sample well of the test device pressing hard the top bulb of the pipette.

8. After applying the sample, immediately press the **TEST START** button.

9. The analyzer will automatically display the test result within 15 minutes. Strong positive result can be detected early at 5 minutes by F100 and F200 analyzers.

• Using a **READ ONLY** mode

- Applying of STANDARD F100 and F200 analyzer
1. Take the test device out of the foil pouch and place on a flat and dry surface. Write a sample information on the label of test device.

2. Compress the top bulb of a fixed volume pipette (100µl) and place the tip of the pipette into the prepared sample.

3. Slowly release the top bulb of the pipette dipping the tip of the pipette into the sample.

4. Completely squeeze the sample into the sample well of the test device pressing hard the top bulb of the pipette.

5. Incubate the test device for 15 minutes outside of the analyzer. Incubation must not be more than 30 minutes.

6. Prepare a STANDARD F Analyzer and select the 'Read Only' mode according to the analyzer's manual.

7. Insert the test device to the test slot of the analyzer.

8. When inserting the test device to the analyzer, the analyzer will automatically scan and display the test results.

* The information written on the label which is sticked between the sample well and the test result window is scanned and displayed on the screen by the STANDARD F200 analyzer and the STANDARD F2400 analyzer.

INTERPRETATION OF TEST RESULTS

Result	COI (Cutoff Index) value	Interpretation
Positive	COI > 1.0	Positive for Legionella antigen
Negative	COI < 1.0	Negative for Legionella antigen
Invalid	COI value is not displayed	Retest should be performed with a new test device and a new patient sample.

QUALITY CONTROL

[Calibration Set Test]
The calibration set test of STANDARD F Analyzers should be conducted according to the analyzer's manual.

When to use calibration set
1. Before using the analyzer for the first time
2. When you drop the analyzer
3. Whenever you do not agree with your result

How to use calibration set
Calibration set test is a required function that ensures optimal performance by checking the internal analyzer optics and functions.

1. Select the 'Calibration' menu.
2. The specific calibration set is included with the analyzer.
3. Insert the CAL-1 first, and then insert the CAL-2 for UV-LED testing and the CAL-3 for RGB-LED testing in order.

* The STANDARD F Analyzer automatically calibrate and identify the optical performance through measuring the membrane of the test device whenever the test is conducted in 'Standard Test' mode. If 'EEF' message displays on the screen, it means that the analyzer has a problem, so check with CAL devices. Contact the SD BIOSENSOR local distributor if the 'EEF' message still appears.

[Internal procedural control]
1. The internal procedural control zones is on the membrane of the test device. STANDARD F Analyzers read the fluorescence signal of the internal procedural control zone and decide whether the result is valid or invalid.

2. The invalid result means that the fluorescence signal is not within the pre-set range.

If the screen of STANDARD F Analyzer shows 'Invalid Device', turn off and turn of the analyzer again and re-test with a new test device.

External quality control

1. Positive and negative controls are supplied with each kit and these controls are provided as a means of additional quality control to demonstrate a positive or negative reaction.
2. It is recommended that positive and negative controls be run:
- once for each new lot.
- once for each untrained operator.
- as required by test procedures in this instruction and in accordance with local, state and federal regulations or accreditation requirements.

LIMITATION OF THE TEST

1. The test procedure, precautions and interpretation of results for this test must be followed strictly when testing.
2. This test detects the presence of Legionella pneumophila serogroup 1 antigen in the specimen and should not be used as the sole criteria for the diagnosis of Legionella infection.
3. Test results must be considered with other clinical data available to the physician.
4. For more accuracy of immune status, additional followup testing using other laboratory methods is recommended.
5. Neither the quantitative value nor the rate of Legionella pneumophila serogroup 1 antigen concentration can be determined by this qualitative test.
6. Failure to follow the test procedure and interpretation of test results may adversely affect test performance and/or produce invalid results.
7. Rheumatoid Factor does not interfere at concentrations ≤14.84 IU/mL with the STANDARD F Legionella Ag FIA test.

PERFORMANCE CHARACTERISTICS

1. Analytical Reactivity: The strains of Legionella pneumophila serogroup 1, 3, 5, 6 and 8 were tested by STANDARD F Legionella Ag FIA. All of the strains were detected at the concentrations listed in the below table.

No.	Strain	Limit of Detection (CFU/mL)*
1	<i>L. pneumophila</i> serogroup 1 Knoxville	4.0 x 10 ³
2	<i>L. pneumophila</i> Serogroup 1 Camperdown	8.5 x 10 ³
3	<i>L. pneumophila</i> Serogroup 1 Philadelphia	4.5 x 10 ³
4	<i>L. pneumophila</i> Serogroup 3 ESC1	9.0 x 10 ³
5	<i>L. pneumophila</i> Serogroup 5 Dallas 1E	8.5 x 10 ³
6	<i>L. pneumophila</i> Serogroup 6 Chicago 2	9.5 x 10 ³
7	<i>L. pneumophila</i> Serogroup 8 Concord 3	8.0 x 10 ³

* Colony forming unit (CFU) is a unit used to estimate the number of viable bacteria in a sample.

2. Clinical sensitivity: Total 39 samples were evaluated for sensitivity. The STANDARD F Legionella Ag FIA Test got a high correlation with other FIA test.

Reference	STANDARD F Legionella Ag FIA	Total Result		
	Positive	Negative		
FIA	Positive	37	39	
	Negative	0	0	
	Total Result	37	0	39
	Sensitivity		37/39 (94.9%)	

3. Clinical specificity: Total 40 samples were evaluated for specificity. The STANDARD F Legionella Ag FIA Test got a high correlation with other FIA test.

Reference	STANDARD F Legionella Ag FIA	Total Result		
	Positive	Negative		
FIA	Positive	0	0	
	Negative	0	40	40
	Total Result	0	40	40
	Specificity		40/40 (100%)	

ANALYTICAL SPECIFICITY

1. Cross reactivity: The STANDARD F Legionella Ag FIA and STANDARD F were evaluated with a total 9 microorganism and 10 viruses. STANDARD F Legionella Ag FIA did not show any sign of cross reactivity with microorganism or viruses listed below table.

No.	Type	Microorganism/Virus	Concentration
1	Bacteria	<i>E. coli</i>	2.0x10 ⁸ cfu/mL
2		<i>Haemophilus influenzae</i>	2.0x10 ⁸ cfu/mL
3		<i>Klebsiella pneumoniae</i>	2.0x10 ⁸ cfu/mL
4		<i>Pseudomonas aeruginosa</i>	2.0x10 ⁸ cfu/mL
5		<i>Serratiamarcescens</i>	2.0x10 ⁸ cfu/mL
6		<i>Staphylococcus epidermidis</i>	2.0x10 ⁸ cfu/mL
7		<i>Staphylococcus aureus</i>	1.0x10 ⁹ cfu/mL
8		<i>Streptococcus pneumoniae</i>	2.0x10 ⁸ cfu/mL
9		<i>Streptococcus pyogenes</i>	2.0x10 ⁸ cfu/mL
10		Adenovirus Type 1	1.0x10 ⁷ TCID ₅₀ /mL
11		Adenovirus Type 11	2.0x10 ⁷ TCID ₅₀ /mL
12		Adenovirus Type 23	2.0x10 ⁷ TCID ₅₀ /mL
13	Adenovirus Type 3	2.0x10 ⁷ TCID ₅₀ /mL	
14	Adenovirus Type 5	2.0x10 ⁷ TCID ₅₀ /mL	
15	Viruses	Cosackievirus A3	2.0x10 ⁷ TCID ₅₀ /mL
16		Cosackievirus B2	2.0x10 ⁷ TCID ₅₀ /mL
17		Parainfluenza virus 1 KBPV-VR-64	2.0x10 ⁷ TCID ₅₀ /mL
18		Parainfluenza virus 2 KBPV-VR-65	1.0x10 ⁷ TCID ₅₀ /mL
19		Parainfluenza virus KBPV-VR-69	2.0x10 ⁷ TCID ₅₀ /mL

2. Interfering Substances: Several over-the-counter substances, chemicals and body fluid were evaluated with STANDARD F Legionella Ag FIA and STANDARD F analyzer. There are no interfering reactions with substances below Table.

No.	Potential interfering substances	Concentration of substances
1	Amphotericin B	0.05mg/mL
2	Ascorbic acid	0.5mg/mL
3	Bilirubin	0.25mg/mL
4	Caffeine (anhydrous)	4mg/mL
5	Erythromycin	0.1mg/mL
6	Glucose	20mg/mL
7	Oxalic acid	1.6mg/mL
8	Protein (HSA)	0.5mg/mL
9	Rifampicin	0.2mg/mL
10	Urea	20mg/mL
11	Whole Blood	0.5% v/v
12	Normal Human Serum	0.5% v/v
13	Hemoglobin	2mg/mL
14	Geworin Tab.	7.5mg/mL
15	Povidone-iodine	1% v/v

BIBLIOGRAPHY

1. Berdall B, Farshy C E, Feely J C. Detection of Legionella pneumophila antigen in urine by enzyme-linked immunospecific assay. J Clin Microbiol. 1979;20:575-578.
2. Köhler R B, Zimmerman S E, Wilson E, Allen S D, Edelstein P H, Wheat L J, White A. Rapid radioimmunoassay diagnosis of Legionnaires' disease: detection and partial characterization of urinary antigen. Ann Intern Med. 1981;94:601-605.
3. Tang P W, Tomá S. Broad-spectrum enzyme-linked immunosorbent assay for detection of Legionella soluble antigens. J Clin Microbiol. 1986;24:556-558.
4. Tilton R C. Legionnaires' disease antigen detected by enzyme-linked immunosorbent assay. Ann Intern Med. 1979;90:697-698.

5. Bibb, W.F., P.M. Arrow, L. Thacker, and R.M. McKinney. Detection of soluble Legionella pneumophila antigens in serum and urine specimens by enzyme-linked immunosorbent assay with monoclonal and polyclonal antibodies. J. Clin. Microbiol. 1984;20:478-482.

Product Disclaimer
While every precaution has been taken to ensure the diagnostic ability and accuracy of this product, the product is used outside of the control of the SD BIOSENSOR and distributor and the result may accordingly be affected by environmental factors and/or user error. A person who is the subject of the diagnosis should consult a doctor for further confirmation of the result.

Warning
The SD BIOSENSOR and distributors of this product shall not be liable for any losses, liability, claims, costs, damages, whether direct or indirect, or consequential arising out of or related to an incorrect diagnosis, whether positive or negative, in the use of this product.

Authorized Representative:
MT Promedi Consulting GmbH
Altenhofstrasse 80 66286 St. Ingbert Germany
Phone: +49 6994 5811023, Fax: +49 6994 5811221

Any inquiries regarding instructions provided should be addressed to:
SD BIOSENSOR, Inc. Sales & Marketing Department, 15660beon-gil, Yeongtong-gu, Suwon-si, Gyeonggi-do, 16690, REPUBLIC OF KOREA
or you can also contact us through sales@sdbiosensor.com

• The information written on the label which is sticked between the sample well and the test result window is scanned and displayed on the screen by the STANDARD F200 analyzer and the STANDARD F2400 analyzer.

STANDARD F Legionella Ag FIA

STANDARD™ F Legionella Ag FIA



EXPLICAÇÃO E RESUMO

[Introdução]
O gênero Legionella é um grupo de bactérias Gram-negativas patogênicas. O gênero Legionella contém mais de 50 espécies, das quais, no mínimo, 24 têm sido associadas a infecções humanas. O membro mais característico do gênero é a Legionella pneumophila, o principal agente causador de Legionelose. A Legionella pneumophila é normalmente encontrada em lagos, rios, riachos, termas e outros corpos d'água onde ela está presente simbioticamente em amebas aquáticas. A maioria das pessoas se infecta quando inalam gotículas de água microscópicas que contêm a bactéria. Legionelose é um termo genérico que descreve as formas pneumônicas e não pneumônicas de infecção com Legionella. A forma não pneumônica, a Febre Pontiac, é uma doença do tipo influenza autolimitante que dura, normalmente, de 2 a 5 dias. Este tipo de infecção não é associada com morte. A forma pneumônica, nomeadamente, a doença dos legionários tem um período de incubação de 2-10 dias. A severidade da doença varia de uma tosse leve a uma pneumonia rapidamente fatal. A morte ocorre através da progressão da pneumonia, com falência respiratória ou choque e falência múltipla dos órgãos. É importante fazer o diagnóstico precoce da doença do legionário, pois a taxa de mortalidade da doença do legionário não tratado varia de 10 a 50%. O STANDARD F Legionella Ag FIA, que contém um anticorpo altamente específico e sensível, oferece um sistema rápido, fácil e exato para identificar o Legionella Ag em espécime de urina humana.

[Uso pretendido]
O STANDARD F Legionella Ag FIA é um imunoensaio fluorescente para a detecção qualitativa do antigênio de Legionella pneumophila serogruppo 1 presente em amostras de pacientes com sintomas de pneumonia. Este teste se destina ao uso diagnóstico in vitro, para o uso profissional, somente para um teste de rastreamento inicial. O STANDARD F Legionella Ag FIA deve ser usado com o analisador apropriado, os analisadores STANDARD F, fabricados pela SD BIOSENSOR.

[Princípio do teste]
O STANDARD F Legionella Ag FIA se baseia na tecnologia da imunofluorescência, no qual o analisador STANDARD F para o teste do antigênio de Legionella pneumophila serogruppo 1, O STANDARD F Legionella Ag FIA tem uma linha de controle e linha de teste, revestida cada uma com anticorpos monoclonais anti-PPR e anti-Legionella de coelho. A amostra do paciente é colocada no poço da amostra do dispositivo de teste e a amostra migra através membrana. Se houver o antigênio Legionella, ele irá reagir com os anticorpos monoclonais anti-Legionella conjugados no pad de conjugação e formar complexos de partícula fluorescente anticorpo-antígeno. Esses complexos se movem ao longo da membrana para serem capturados pelos anti-Legionella na linha de teste e formam um sinal fluorescente. A intensidade da luz fluorescente gerada na membrana é lida pelo analisador STANDARD F fabricado pela SD BIOSENSOR. O analisador STANDARD F pode analisar a presença do analito no espécime clínico processando os resultados, usando algoritmos pré-programados e exibir o resultado do teste no monitor.

[Conteúdo do kit]
• Dispositivo buffer • Pipeta de volume fixo (100µl) • Controle positivo • Controle negativo • Buffer de extração de controle • Instruções de uso

[Materiais necessários, mas não fornecidos]
• Analisador STANDARD F
• Cronômetro

ARMAZENAGEM E ESTABILIDADE DO KIT

Armazene o kit na temperatura de 2-30°C / 36-86°F, longe da luz direta do sol. Os materiais do kit são estáveis até a data de validade impressa na embalagem externa. Não congele o kit.

AVISOS E PRECAUÇÕES

1. Não realize o kit e teste.
2. Use o STANDARD F Legionella Ag FIA a temperatura de 15-32°C / 59-90°F e 10-90%RH.
3. Não use o kit de teste se a embalagem estiver danificada ou o selo estiver rompido.
4. Não fume, beba ou ingira alimentos ao manusear o espécime.
5. Ao manusear os reagentes do kit, vista equipamento de proteção pessoal, como luvas e aventais de laboratório, lave cuidadosamente as mãos ao finalizar o teste.
6. Limpe completamente os salpicos usando um desinfetante apropriado.
7. Manuseie todos os espécimes como se contivessem agentes infecciosos.
8. Observe as precauções determinadas contra os perigos microbiológicos em todos os procedimentos de teste.
9. Descarte todos os espécimes e materiais usados na realização do teste como resíduo de patologia perigosa em resíduos laboratoriais e biológicos apropriados, não reutilize, manuseie e descartados conforme todas as regulamentações locais, estaduais e federais.
10. O saco de sílica gel dentro da embalagem metalizada serve para absorver umidade e evitar que ela afete os produtos. Se a cor da sílica gel perolada indicar de umidade ruim dentro da embalagem, o teste, o dispositivo de teste dentro da embalagem tipo saco deve ser descartado.
11. Teste o dispositivo de teste imediatamente após tê-lo retirado da embalagem de alumínio para garantir resultados precisos e confiáveis.
12. Se o resultado do teste com controle positivo/negativo for anormal, não use o kit.
13. O código de barras do dispositivo de teste é usado pelo analisador para identificar o tipo de teste que está sendo realizado e para identificar o dispositivo de teste individual, para evitar que haja uma segunda leitura do dispositivo de teste pelo mesmo analisador.
14. Depois de lido o dispositivo de teste com o analisador, não tente escanê-lo novamente no mesmo analisador.
15. Como o reagente de detecção é um composto fluorescente, não se formam resultados imprecisos.
16. A coleta, o manuseio e o transporte inapropriados do material podem levar a resultados imprecisos.
17. Não escreva sobre o código de barras ou danifique o código de barras do dispositivo de teste.
18. Não use espécimes não especificados nestas instruções de uso.

COLETA E PREPARAÇÃO DO ESPÉCIME

1. Devem ser coletadas espécimes de urina em um recipiente limpo e seco, a qualquer hora do dia.
2. O espécime de urina deve ser armazenado na temperatura ambiente (15-30°C/59-86°F) por até 3 dias ou a 2-8°C/ 36-46°F por até 2 semanas antes de ser testado.
3. Para armazenamento prolongada, os espécimes devem ser congelados e armazenados a -40°C/-40°F. Os espécimes congelados são estáveis até 3 meses a -40°C/-40°F.
4. Os espécimes de urina congelada devem ser derretidos e inteiramente misturados antes de efetuar o teste.
5. Se um espécime de urina apresentar precipitações visíveis, ele deve ser centrifugado, filtrado ou permitir que ele asente para obter um sobrenadante claro para efetuar o teste.
6. O ácido bórico pode ser usado como conservante.

PROCEDIMENTO DO TESTE

1. Deixe os componentes do kit e a amostra de urina coletada à temperatura ambiente (15-30°C/59-86°F) por no mínimo 30 minutos antes de realizar o teste.
2. Cuidadosamente, leia as instruções de uso do STANDARD F Legionella Ag FIA.
3. Confira a data de validade no verso da embalagem metalizada. Se a data de validade estiver vencida, use outro lote.

4. Abra o saco metalizado e verifique o dispositivo de teste e o saco de sílica gel dentro do saco metalizado.

• Se não houver uma linha de controle violeta na membrana do dispositivo de teste, não use o dispositivo.
• Linha de controle

• Não escreva sobre o código de barras ou danifique o código de barras do dispositivo de teste.

• A informação escrita no rótulo que está colado entre o poço da amostra e a janela de resultado do teste é digitalizada e mostrada no ecran pelo analisador STANDARD 200 e pelo analisador STANDARD 2400.

• Preparação da amostra de controle positivo/negativo

1. Insira o swab de controle positivo/negativo no kit no tubo Buffer de extração de controle. Agite o swab no mínimo cinco vezes.
2. Remova o swab e descarte o swab usado conforme seu protocolo de descarte de resíduos biológicos perigosos.
3. Para analisar a amostra de controle de qualidade externa, siga as instruções para 'Análise de amostra' detalhadas abaixo.

STANDARD F Legionella Ag FIA

STANDARD™ F Legionella Ag FIA



EXPLICAÇÃO E RESUMO

[Introdução]
O gênero Legionella é um grupo de bactérias Gram-negativas patogênicas. O gênero Legionella contém mais de 50 espécies, das quais, no mínimo, 24 têm sido associadas a infecções humanas. O

