

Bioline® Influenza Antigen

Influenza Virus Type A & B Antigen Test

Test en une étape de détection d'antigène du virus de la grippe de type A & B

Prueba de un solo paso de antígenos del virus de la gripe tipo A y B

Teste do Antígeno do Vírus da Influenza Tipo A & B em Um Passo

ENGLISH

About the test

[Intended Use] Bioline® Influenza Antigen test is a chromatographic immunoassay for the differential and qualitative detection of influenza virus type A and type B antigens directly from nasal /or throat / nasopharyngeal swabs or nasal/nasopharyngeal aspirate specimens. The assay is not intended to detect influenza virus type C antigens. Bioline® Influenza Antigen rapid test is intended for professional use. This kit is for in vitro diagnostic use only.

[Test principle] Bioline® Influenza Antigen test involves (1) the extraction of influenza A and B viral antigens from the specimen and (2) the insertion of the test strip in the extraction reagent tube. Bioline® Influenza Antigen test strips are immobilized with mouse monoclonal anti-influenza A and anti-influenza B antibodies, respectively. And the directly sensitive antibodies are used as detector materials. These enable the Bioline® Influenza Antigen test strips to identify influenza type A and type B antigens directly from nasal swab, throat swab or nasal / nasopharyngeal aspirate specimens, with a high degree of accuracy.

Materials provided and active ingredients of main components

- Bioline® Influenza Antigen test kit contains the following items to perform the assay.
 - Bioline® Influenza Antigen [10 Tests/kit] Cat. No. 19FK11 :
 - 10 Test strips individually foil pouched with a desiccant
 - 10 Disposable test tubes
 - Assay diluent (1 x 5 ml/vial)
 - 10 Disposable droppers
 - 10 Sterilized swabs for specimen Collection
 - Control swabs : 1 Influenza A Positive Control swab, 1 Influenza B Positive Control swab, 1 Influenza Negative Control swab
 - 1 Instructions for use
 - Bioline® Influenza Antigen [25 Tests/kit] Cat. No. 19FK12 :
 - 25 Test strips individually foil pouched with a desiccant
 - 25 Disposable test tubes
 - Assay diluent (1 x 10 ml/vial)
 - 25 Disposable droppers
 - 25 Sterilized swabs for specimen Collection
 - Control swabs : 1 Influenza A Positive Control swab, 1 Influenza B Positive Control swab, 1 Influenza Negative Control swab
 - 1 Instructions for use
- Active ingredients of main components
 - 1 Test strip includes : Gold Conjugates B : Mouse monoclonal anti - influenza A - gold colloidal (0.06±0.02 µg), Gold Conjugates B : Mouse monoclonal anti-influenza B gold colloidal (0.06±0.01 µg), Test Line "A", Mouse monoclonal anti-influenza A antibody (0.80±0.16 µg), Test Line "B", Mouse monoclonal anti-influenza B antibody (0.80±0.16 µg), Control Line : Goat anti-mouse immunoglobulin G (0.70±0.14 µg)
 - Assay diluent : Tricine (0.4M), NaCl (q.s.), Triton-X-100 (q.s.), Sodium azide (0.02%)
 - Control Swabs : Influenza A Positive Control swab : Inactivated human influenza virus type A/H1N1 (0.1x2⁷ HAU), Inactivated human influenza virus type A/H3N2 (0.1x2⁷ HAU), Influenza B Positive Control swab : Inactivated human influenza virus B (0.1x2⁷ HAU), Influenza Negative Control swab : Formalin-inactivated Streptococcus pyogenes (5x10⁷ Org.)

Kit storage and stability

- The test kit should be stored at 1 - 30°C. Do not freeze the kit or components.
- Do not use it beyond the expiration.
- The shelf-life of the kit is indicated on the outer package. This product is stable during 24 months from the date of manufacture.
- Do not use the test kit if the pouch is damaged or the seal is broken.
- The test strip is sensitive to both heat and humidity. Perform the test immediately after removing the test strip from the foil pouch.

Specimen collection and storage

- Specimen collection
 - Nasal swab specimens**
 - To collect a nasal swab specimen, insert the sterile swab into the nostril that presents the most secretion under inspection. Using gentle rotation, push the swab until resistance is met at the level of the turbinate (less than one inch into the nostril). Rotate the swab a few times against the nasal wall.
 - Throat swab specimens**
 - To collect a throat swab specimen, vigorously rub a rayon throat swab on both tonsillar surfaces and the posterior pharynx. Remove swab from mouth and insert, tip down, into paper wrapper.
 - [Nasopharyngeal swab specimens]**
 - To collect a nasopharyngeal swab specimen, insert swab into nostril parallel to the palate and leave in place for a few seconds to absorb secretions.
- [Nasal /Nasopharyngeal aspirate specimens]**
 - The proper volume of Nasal / Nasopharyngeal aspirate specimens is 2 - 2.5 ml. Transfer the specimen into a clean, dry specimen container.
 - Excessive volume of Nasal /Nasopharyngeal aspirate specimen may result in incorrect test result.
 - Process specimen as described in "Procedure of the test"
- Specimen transport and storage
 - Specimen should be tested as soon as possible after collection.
 - Transport fresh specimens to the laboratory as rapidly as possible in a suitable liquid transport system maintained on ice or refrigerated at 2-8 °C up to 3 days.
 - If not use of transport media, specimens may be stored refrigerated (2-8 °C), or at room temperature (15-30 °C), in a clean, dry, closed container for up to 8 hours prior to testing.
 - If the specimen should be tested later, swab specimens should be placed into 1 - 2 ml of transport media or saline by direct extraction.
 - Transport media : Use of the following transport media has been tested and found to be compatible with Bioline® Influenza Antigen test.
 - Saline
 - EDEM+0.5%BSA
 - PBS
 - PBS+0.5%BSA
 - PBS+0.5%Gelatin

Warnings

- For in vitro diagnostic use only. Do not reuse test strip.
- The instruction must be followed exactly to get accurate results. Anyone performing an assay with this product must be trained in its use and must be experienced in laboratory procedures.
- Do not eat or smoke while handling specimens.
- Wear protective gloves while handling specimens and wash hands thoroughly afterwards.
- Avoid splashing or aerosol formation of specimen and assay diluent.
- Clean up spills thoroughly using an appropriate disinfectant.
- Decontaminate and dispose of all specimens, reaction kits and potentially contaminated materials in a biohazard container as if they were infectious waste.
- Do not mix and interchange different specimens.
- Components must not be used after the expiration date printed on the labels. Do not mix or interchange different batches/lots of reagents.
- Do not drink assay diluent.
- The assay diluent contains a proprietary anti-microbial agent, sodium azide, which presents no hazard to the user if normal laboratory safety precautions are followed. If contact with assay diluent to the eyes and/or skin, wash affected area with soap and water immediately. If irritation or signs of toxicity occur, seek medical attention.

REF 19FK11/19FK12

FRANÇAIS

À propos du test

[Utilisation prévue] Le test Bioline® Influenza Antigen est un test immuno-chromatographique permettant la détection différentielle et qualitative d'antigènes des virus A et B de la grippe à partir d'un prélèvement direct nasal/à la gorge/ rhino-pharyngé ou par aspiration nasale/rhino-pharyngée. Le test n'est pas conçu pour détecter les antigènes du virus de la grippe C. Le test rapide Bioline® Influenza Antigen est destiné à l'usage professionnel et, uniquement, pour un diagnostic in vitro.

[Principe du test] Le test Bioline® Influenza Antigen implique (1) l'extraction des antigènes A et B en isolant et exposant à un réactif les nucléoprotéines internes du virus du prélèvement du patient et (2) l'insertion de bandelettes de test dans le tube contenant l'extrait. Les bandelettes du test Bioline® Influenza Antigen sont immobilisées respectivement par des anticorps antigrippe A et antigrippe B monoclonaux de souris. Ces anticorps spécialement sélectionnés sont utilisés comme détecteurs. Ces derniers permettent au test Bioline® Influenza Antigen d'identifier les antigènes de type A et de type B directement à partir d'un prélèvement nasal/à la gorge ou d'un prélèvement par aspiration nasale/rhino-pharyngée, avec un haut degré de précision.

Matériel fourni et principes actifs des principaux composants

- Le kit de test Bioline® Influenza Antigen contient les éléments suivants :
 - Bioline® Influenza Antigen [10 Tests/kit] Cat. No. 19FK11 :
 - 10 bandelettes du test emballées individuellement avec agent déshydratant
 - 10 tubes de collecte
 - Diluant de dosage (1 x 5 ml/flacon)
 - 10 compte-gouttes
 - 10 écouvillons stériles pour prélèvements
 - Écouvillons de contrôle ; écouvillon de contrôle positif à la grippe A, 1 écouvillon de contrôle positif à la grippe B, 1 écouvillon de contrôle négatif de la grippe
 - 1 mode d'emploi
 - Bioline® Influenza Antigen [25 Tests/kit] Cat. No. 19FK12 :
 - 25 bandelettes du test emballées individuellement avec agent déshydratant
 - 25 tubes de collecte
 - Diluant de dosage (1 x 10 ml/flacon)
 - 25 compte-gouttes
 - 25 écouvillons stériles pour prélèvements
 - Écouvillons de contrôle ; écouvillon de contrôle positif à la grippe A, 1 écouvillon de contrôle positif à la grippe B, 1 écouvillon de contrôle négatif de la grippe
 - 1 mode d'emploi
- Principes actifs des principaux composants
 - Une bandelette de test contient : Or conjugué A : Anticorps antigrippe A monoclonal de souris – or colloïdal (0,11±0,02 µg). Or conjugué B : Anticorps antigrippe B monoclonal de souris – or colloïdal (0,06±0,01 µg).
 - Ligne de test « A » : Anticorps antigrippe A monoclonal de souris (0,80±0,16 µg). Ligne de test « B » : Anticorps antigrippe B monoclonal de souris (0,80±0,16 µg).
 - Ligne de contrôle : Anticorps de chèvre anti-Immunglobuline de souris (0,70±0,14 µg)
 - Diluants : Tricine (0,4M), NaCl (q.s.)+ Triton X-100 (q.s.), Azide de sodium (0,02%)
 - Écouvillons de contrôle ; Écouvillon de contrôle positif à la grippe A : Virus humain de la grippe de type A/H1N1 inactivé (0,1 X 2⁷ HAU), Virus humain de la grippe de type A/H3N2 inactivé (0,1 X 2⁷ HAU), Écouvillon de contrôle positif à la grippe B : Virus humain de la grippe de type B inactivé (0,1 X 2⁷ HAU), Écouvillon de contrôle négatif à la grippe : Streptococcus pyogenes inactivés par une solution de formaldéhyde (5 X 10⁷ Org.)

[Reaction with Test Strip]

- Remove the test strip from the foil pouch prior to use.
- Place the test strip into the tube with the arrows on the test strip pointing down. Do not handle or move the test strip until the test is complete and ready for reading.
- Read result at 10 - 15 minutes. Some positive results may appear soon.

Test interpretation (Refer to figure)

- Negative result : Only one control line appears.
- Positive result.
 - ⚠ Caution:** The presence of any line, no matter how faint, the result is considered positive.
 - Positive for Influenza virus type A: Two lines appears : Dividing membrane into quadrisection, one purple color line adjacent to specimen pad and control line appears.
 - Positive for Influenza virus type B: Two lines appears : Dividing membrane into quadrisection, one purple color line in the center of the membrane and control line appears.
 - Positive for Influenza virus type A&B (Co-infection suspected) : Three lines appear : Two purple color lines ("B" & "A" line) and control line appear.
- Invalid result : Control line fails to appear. If the purple color line (C) is not visible within the result window after performing the test, the result is considered invalid. Some causes of invalid results are : not following the directions correctly or the test may have deteriorated beyond the expiration date. It is recommended that the specimen be re-tested using a new test kit.

Test limitations

- The contents of this kit are to be used for the differential and qualitative detection of influenza A and B antigen from nasal / throat / nasopharyngeal swab or nasal/nasopharyngeal aspirate specimens. This test can differentiate between influenza virus type A and B.
- Failure to follow the test procedure and interpretations of test results may adversely affect test performance and / or invalidate the test results.
- Test results must be evaluated in conjunction with other clinical data available to the physician.
- A negative test result may occur if the level of antigen in a specimen is below the detection limit of the test or from improper specimen collection. Negative test results are not intended to rule-out other non-influenza viral infection.

Internal quality control

- Internal quality control : The test strip has "Test Line" and "Control Line" on the surface of the test strip. Both the Test Line and Control Line in result window are not visible before applying any specimens. The Control Line is used for procedural control. The control line of the RDT only shows that the diluents has been applied successfully, and that the active ingredients of main components on the strip was still functional, but it is not a guarantee that the specimen has been properly applied and does not represent a positive specimen control.
- External quality control : Good laboratory practice suggests the use of positive and negative controls to ensure that:
 - Test reagents are working, and
 - The test is correctly performed.
- Run the external controls under the following circumstances:
 - With each new operator prior to performing testing on patient specimens,
 - When receiving a new test shipment,
 - At periodic intervals as dictated by local, state and country requirements, and/or by the user's Quality Control procedures.
- Is the responsibility of each site using the Bioline® Influenza Antigen to establish an adequate quality assurance program to ensure test strip performance under its specific location and conditions of use.
- Control Procedures : Positive and Negative control swabs should be tested according to the test procedure (Specimen extraction + Reaction with test strip).
- Specification
 - Influenza A Positive control swab should be interpreted as test line A positive.
 - Influenza B Positive control swab should be interpreted as test line B positive.
 - Influenza Negative control swab should be interpreted as negative.
- When interpreting positive control results, if any line appears, no matter how faint, the result is considered positive. If the expected control results are not obtained, repeat the procedure with a new test strip. If the repeated control result is incorrect, do not run the test with patient specimens. Contact the technical support advice line during normal business hours.

	Temperature limitation Limites de température Limitaciones de temperatura Limitações de temperatura		Lot Number No. de lote Número de lote
	For in vitro diagnostic use only Pour diagnostic in vitro uniquement Solo para uso de diagnóstico in vitro Somente para uso de diagnóstico in vitro		Catalog Number Code produit Número de Referência Número de Catálogo
	Do not reuse Ne réutiliser Nio reutilizar		Authorized Representative Représentant autorisé Representante autorizado

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Warning:
The manufacturers and distributors of this product shall not be liable for any damages, direct, indirect, or consequential losses, liability, claims, costs or damages arising from or related to an incorrect positive or negative diagnosis using this product.

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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 manufacturer and distributor

Performance characteristics

1.

Sensitivity and specificity
A total of 134 positive and 287 negative specimens for Influenza virus type A and/or type B collected from Korea and Vietnam were tested on the Bioline™ Influenza Antigen kit. Clinical specimens determined to be positive or negative using Viral culture and/or RT-PCR were tested using the Bioline™ Influenza Antigen test to determine sensitivity and specificity of the test.

2.

Analytical specificity and cross reactivity : Bioline™ Influenza Antigen rapid test was evaluated with a total 32 bacterial and viral isolates. Bacterial isolates were evaluated at a concentration of 1x10⁸ c.u./ml. Viral isolates were evaluated at a various concentration. These studies had been performed to demonstrate that there have been no cross reactivity test with 32 bacterial panels and virus panels on Bioline™ Influenza Antigen rapid test. Analytical sensitivity : Analytical sensitivity was established using a total of 14 human epidemic strains of influenza viruses : 9 influenza A and 5 influenza B.

3.

Reproducibility of Bioline™ Influenza antigen has been demonstrated by studies (within-run, between-run and batch-to-batch) with in-house reference panels. All values were identical to reference panel acceptance criteria.

4.

Used Methods for detection of influenza virus and results

Viral Culture and / or RT-PCR	Bioline™ Influenza Antigen	Commercial Influenza test
	Positive	Negative
Positive		
Type A H3	81	77
Type A H5	12	10
Type B	41	36
Sub Total	134	123
Negative	287	3
TOTAL	421	126
Sensitivity (95% CI)	91.8 % (85.9 - 95.4 %)	89.6 % (83.2 - 93.7%)
Specificity (95% CI)	99.0 % (97.0 - 99.6 %)	98.3 % (96.0 - 99.3%)

In a comparison of Bioline™ Influenza Antigen versus a leading commercial Influenza test, results gave sensitivity of 91.8 % (123/134), specificity of 99.0 % (284/287). Bioline™ Influenza Antigen Rapid test showed good correlation with viral culture and/or RT-PCR (total agreement = 96.6 %) and clinical performance was superior to competitor's one.

Analytical specificity and cross reactivity : Bioline™ Influenza Antigen rapid test was evaluated with a total 32 bacterial and viral isolates. Bacterial isolates were evaluated at a concentration of 1x10⁸ c.u./ml. Viral isolates were evaluated at a various concentration. These studies had been performed to demonstrate that there have been no cross reactivity test with 32 bacterial panels and virus panels on Bioline™ Influenza Antigen rapid test. Analytical sensitivity : Analytical sensitivity was established using a total of 14 human epidemic strains of influenza viruses : 9 influenza A and 5 influenza B.

Reproducibility of Bioline™ Influenza antigen has been demonstrated by studies (within-run, between-run and batch-to-batch) with in-house reference panels. All values were identical to reference panel acceptance criteria.

Caractéristiques des performances

1.

Sensibilité et spécificité
Au total 134 échantillons positifs et 287 échantillons négatifs pour le virus influenza A et/ou B collectés en Corée ont été testés à l'aide du test Bioline™ Influenza Antigen kit. Des échantillons cliniques qui se sont avérés positifs ou négatifs par culture virale et/ou RT-PCR ont été analysés à l'aide du test Bioline™ Influenza Antigen afin de déterminer la sensibilité et la spécificité du test.

2.

Spécificité analytique et réactivité croisée : Le test Bioline™ Influenza Antigen a été évalué avec un total de 32 isolats bactériens et viraux. Les isolats bactériens ont été évalués à une concentration de 1 x 10⁸ cellules/ml. Les isolats viraux ont été évalués à différentes concentrations. Ces études ont été réalisées afin de démontrer qu'il n'existe aucune réactivité croisée entre les 32 panels bactériens et viraux et le test rapide Bioline™ Influenza Antigen.

3.

Sensibilité analytique : La sensibilité analytique a été établie à l'aide d'un total de 14 souches épidémiques humaines du virus de la grippe : 9 souches de type A et 5 souches de type B.

4.

La reproductibilité (intra-cycle, inter-cycle et cycle à cycle) de la Bioline™ Influenza Antigen a été démontrée par des études associées à des panels de référence internes. Toutes les valeurs étaient identiques aux critères d'acceptation du panel de référence.

Méthodes utilisées pour la détection du virus de la grippe et résultats

Culture virale et/ou RT-PCR	Bioline™ Influenza Antigen	Test commercial de la grippe
	Positifs	Négatifs
Positif		
Type A H3	81	77
Type A H5	12	10
Type B	41	36
Sous-total	134	123
Négatif	287	3
TOTAL	421	126
Sensibilité (IC à 95 %)	91,8 % (85,9 - 95,4 %)	89,6 % (83,2 - 93,7%)
Spécificité (IC à 95 %)	99,0 % (97,0 - 99,6 %)	98,3 % (96,0 - 99,3%)

Características de rendimiento

1. Sensibilidad y especificidad
Se analizaron con el kit Bioline™ Influenza Antigen un total de 134 muestras positivas y 287 negativas del virus de la gripe tipo A o B recogidas en Corea y Vietnam. Para determinar la sensibilidad y especificidad de la prueba, se analizaron con Bioline™ Influenza Antigen muestras clínicas determinadas como positivas o negativas usando cultivo viral o PCR en tiempo real.

Métodos utilizados para la detección de la gripe y resultados					
Cultivo de virus y/o RT-PCR	Bioline™ Influenza Antigen		Prueba comercial de la gripe		
	Positivo	Negativo	Positivo	Negativo	
Positivo					
Tipo A H3	81	77	4	73	8
Tipo A H5	12	10	2	9	3
Tipo B	41	36	5	38	3
Subtotal	134	123	11	120	14
Negativo	287	3	284	5	282
TOTAL	421	126	295	125	296
Sensibilidad (IC 95 %)	91,8 % (85,9 - 95,4 %)		89,6 % (83,2 - 93,7%)		
Especificidad (IC 95 %)	99,0 % (97,0 - 99,6 %)		98,3 % (96,0 - 99,3%)		

En una comparación de la prueba Bioline™ Influenza Antigen con una prueba de la gripe comercialmente líder en el mercado, los resultados fueron los siguientes: sensibilidad 91,8 % (123/134), especificidad 99,0 % (284/287). La prueba rápida Bioline™ Influenza Antigen mostró una buena correlación con el cultivo viral y/o el RT-PCR (coincidencia total = 96,6 %) y el rendimiento clínico fue superior al de la competencia.

2. Especificidad analítica y reactividad cruzada: La prueba rápida Bioline™ Influenza Antigen fue evaluada con un total de 32 aislamientos bacterianos y virales. Las bacterias aisladas se evaluaron a una concentración de 1 X 10⁸ células/ml. Los virus aislados se evaluaron a diferentes concentraciones. Estos estudios fueron realizados para demostrar que no hubo reactividad cruzada con 32 paneles bacterianos y virales.

3. Sensibilidad analítica: Se estableció la sensibilidad analítica utilizando un total de 14 cepas epidémicas humanas de virus de la gripe: 9 de gripe tipo A y 5 de gripe tipo B. Se concluyó que la prueba Bioline™ Influenza Antigen es igual o mejor que otras pruebas comercialmente disponibles para la detección de bajas concentraciones de virus de la gripe.

4. La reproductibilidad de la prueba Bioline™ Influenza Antigen ha sido demostrada mediante estudios (intra-ensayo, inter-ensayo y lote a lote) con paneles de referencia internos. Todos los valores fueron idénticos a los criterios de aceptación de los paneles de referencia.

Métodos usados para a detecção do da influenza e seus resultados					
Cultura Viral e / ou RT-PCR	Bioline™ Influenza Antigen		Teste comercial da Influenza		
	Positivo	Negativo	Positivo	Negativo	
Positivo					
Tipo A H3	81	77	4	73	8
Tipo A H5	12	10	2	9	3
Tipo B	41	36	5	38	3
Subtotal	134	123	11	120	14
Negativo	287	3	284	5	282
TOTAL	421	126	295	125	296
Sensibilidade (IC de 95%)	91,8 % (85,9 - 95,4 %)		89,6 % (83,2 - 93,7%)		
Especificidade (IC de 95%)	99,0 % (97,0 - 99,6 %)		98,3 % (96,0 - 99,3%)		

Na comparação de Bioline™ Influenza Antigen versus o líder comercial de teste de influenza demonstrou um resultado de sensibilidade de 91,8 % (123/134), especificidade de 99,0 % (284/287).

O Teste Rápido Bioline™ Influenza Antigen demonstrou ter uma boa correlação com a cultura viral e / ou RT-PCR (concordância total = 96,6 %) e o desempenho clínico foi superior àquele apresentado pelo concorrente.

3. Especificidade Analítica e reatividade cruzada: O teste Bioline™ Influenza Antigen foi avaliado com um total de 32 isolados bacterianos e virais. Os isolados bacterianos foram avaliados em uma concentração de 1 X 10⁸ células/ml. Os isolados virais foram avaliados em várias concentrações. Estes estudos foram feitos para demonstrar que não houve reatividade cruzada no teste de 32 painéis de bactérias e vírus no teste rápido de Bioline™ Influenza Antigen.

4. A reprodutibilidade da Bioline™ Influenza Antigen foi demonstrada por estudos (intra-ensaio, entre ensaios e lote-para-lote) com painéis de referência internos. Todos os valores foram idênticos aos critérios de aceitação dos painéis de referência.

PREPARATION / PRÉPARATION / PREPARACIÓN / PREPARAÇÃO

1

EN

Now, open the package and look for the following:

1.

Test strips individually foil pouched with a desiccant

2.

Assay diluent

3.

Disposable droppers

4.

Sterilized swabs for specimen Collection

5.

Disposable test tubes

6.

Control swabs

7.

Instructions for use

ES

Ahora, abra el paquete y busque lo siguiente:

1.

Tiras reactivas envasadas individualmente en una bolsa de aluminio con un desecante

2.

Diluyente de ensayo

3.

Goteros desechables

4.

Hisopos para recogida de muestras

5.

Tubos de prueba desechables

6.

Hisopos de control

7.

Instrucciones de uso

FR

Ouvrir le kit et vérifier les éléments suivants:

1.

Bandelettes du test emballées individuellement avec desiccant

2.

Diluant de dosage

3.

Compte-gouttes

4.

Ecouvillons stériles pour prélèvements

5.

Tubes de collecte

6.

Ecouvillons de contrôle

7.

Mode d'emploi

PT

Abra a embalagem e encontre o seguinte:

1.

Tiras de teste individualmente embalada com dessecante

2.

Diluyente do ensaio

3.

Conta-gotas descartáveis

4.

Hastes para esfregaços esterilizados para coleta de amostras

5.

Tubos de ensaio descartáveis

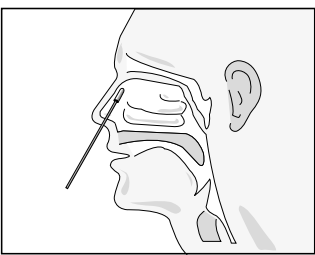
6.

Hastes para esfregaço de controle

7.

Instruções de uso

METHODS OF SPECIMEN COLLECTION / MÉTHODES DE PRÉLÈVEMENT / MÉTODOS DE RECOGIDA DE MUESTRAS / MÉTODOS DE COLETA DE AMOSTRA



EN

Nasal Swab

ES

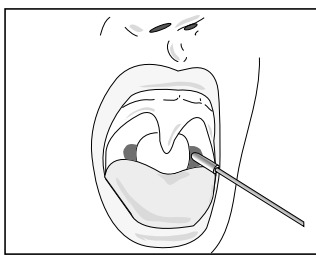
Hisopo nasal

FR

Prélèvement nasal

PT

Esfregaço Nasal



EN

Throat Swab

ES

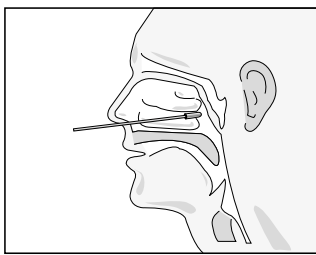
Hisopo de garganta

FR

Prélèvement de la gorge

PT

Esfregaço de Garganta



EN

Nasopharyngeal Swab

ES

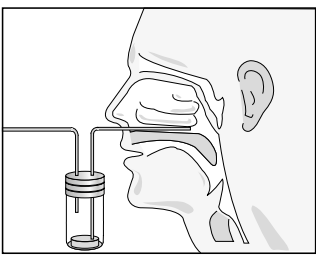
Hisopo nasofaríngeo

FR

Prélèvement rhino-pharyngien

PT

Esfregaço Nasofaríngeo



EN

Nasal Aspirate

ES

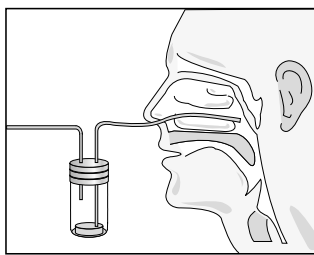
Aspiración nasal

FR

Aspirat nasal

PT

Aspiração Nasal



EN

Nasopharyngeal Aspirate

ES

Aspiración nasofaríngea

FR

Aspirat rhino-pharyngien

PT

Aspiração Nasal

TEST PROCEDURE / PROCÉDURE DU TEST / PROCEDIMIENTO DE LA PRUEBA / PROCEDIMENTO DO TESTE

All swab specimens / Tous les prélèvements / Todas las muestras de hisopos / Todas amostras de esfregaços

1

EN

Up to Fill Line (approximately 300 µl)

FR

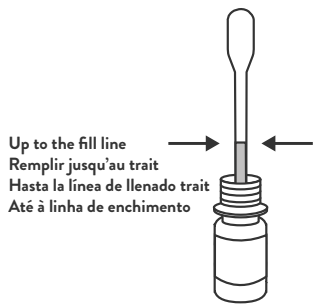
Jusqu'à la ligne (environ 300 µl)

ES

Hasta la línea de llenado (aproximadamente 300 µl)

PT

Até a linha do preenchimento (aproximadamente 300 µl)



Up to the fill line

Remplir jusqu'au trait

Hasta la línea de llenado

Até à linha de enchimento

2

EN

Transfer 300 µl of Assay diluent drawn from bottle to a test tube.

FR

Transférer 300 µl du diluant dans un tube de test.

ES

Transfiera 300 µl de diluyente para ensayo a un tubo de ensayo.

PT

Transfira de 300 µl do diluente do ensaio extraídos do frasco para um tubo de ensaio.



3

EN

Insert the swab specimen, swirl the swab at least five times.

FR

Insérer l'échantillon, le tourner au moins cinq fois.

ES

Inserte la muestra del hisopo, gire el hisopo al menos cinco veces.

PT

Inserir a amostra do esfregaço, gire-o pelo menos cinco vezes.



4

EN

Remove the swab while squeezing.

FR

Retirer l'échantillon tout en appuyant l'écouvillon contre la paroi du tube .

ES

Retire el hisopo presionándolo.

PT

Remova a haste para esfregaço enquanto a aperta.



5

EN

Place the test strip into the test tube.

FR

Placer la bandelette dans le tube de test.

ES

Coloque la tira reactiva en el tubo de ensayo.

PT

Coloque a tira do teste dentro do tubo de ensaio.



2

EN

FIRST, read carefully the instruction on how to use the Bioline™ Influenza Antigen test kit.

ES

PRIMERO, lea detenidamente las instrucciones sobre cómo usar el kit de prueba Bioline™ Influenza Antigen.

FR

Lire TOUT D'ABORD attentivement le mode d'emploi du kit de Bioline™ Influenza Antigen.

PT

PRIMEIRAMENTE leia cuidadosamente as instruções de como usar o kit de teste Bioline™ Influenza Antigen.

Nasal aspirate, nasopharyngeal aspirate specimen or Extracted specimen into transport media / Aspirat nasal, aspirat rhino-pharyngien ou prélèvement extrait dans le milieu de transport

Muestra nasal y nasofaríngea por aspiración o muestra extraída en un medio de transporte / Amostra por aspiração nasal, nasofaríngea ou amostra extraída em meio de transporte

3

EN

Next, look at the expiry date at the back of the foil pouch. Use another kit, if expiry date has passed.

ES

Luego, verifique la fecha de caducidad en la parte posterior de la bolsa de aluminio. Use otro kit, si la fecha ha expirado.

FR

Vérifier la date de péremption au verso de l'enveloppe protectrice. Utiliser un autre kit si la date de péremption est dépassée.

PT

Depois, observe a data de validade no verso da bolsa de alumínio. Use outro kit caso a data de validade já tenha vencido.

1

EN

Dispense 100 µl of Assay diluent into a test tube.

FR

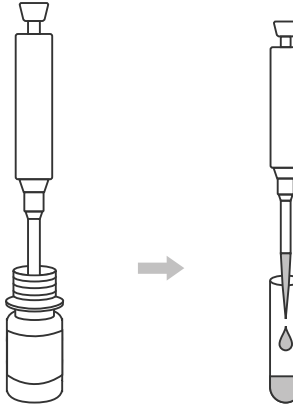
Transférer 100 µl du diluant dans un tube de test.

ES

Dispense 100 µl del diluyente de ensayo en un tubo de ensayo.

PT

Dispense 100 µl de diluente do ensaio em um tubo de ensaio.



2

EN

Directly pipet 100 µl of extracted specimen, or aspirates, transfer specimen into the same test tube.

FR

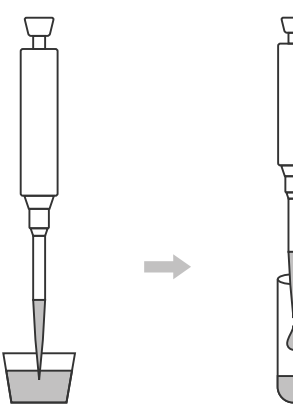
Prendredirectement, à l'aide d'une pipette, 100 µl de l'échantillon extrait, ou des aspirats et transférer l'échantillon dans le même tube de test.

ES

Pipetee directamente 100 µl de la muestra extraída, o de las aspiraciones, y transfiera la muestra al mismo tubo de ensayo.

PT

Coloque diretamente com uma pipeta 100 µl da amostra extraída ou aspirada, transfira a para amostra no mesmo tubo de ensaio.



3

EN

Mix well.

FR

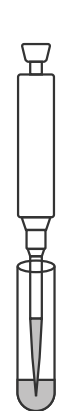
Bien mélanger.

ES

Mezcle bien.

PT

Misture bem.



4

EN

Place the test strip into the test tube.

FR

Placer la bandelette dans le tube de test.

ES

Coloque la tira reactiva en el tubo de ensayo.

PT

Coloque a tira de teste dentro do tubo de ensaio.



INTERPRETATION / INTERPRÉTATION / INTERPRETACIÓN / INTERPRETAÇÃO

EN

Read the result at 10 - 15 minutes. Don't read test results after 15 minutes.

FR

Attendre 10 -15 minutes avant de lire les résultats. Ne pas interpréter après 15 minutes.

ES

Lea el resultado en 10 - 15 minutos. No lea los resultados de la prueba pasados 15 minutos.

PT

Leia o resultado entre 10 e 15 minutos. Não leia resultados de testes após 15 minutos.

HOW TO INTERPRET TEST RESULTS / POUR INTERPRÉTER LES RÉSULTATS DU TEST / CÓMO INTERPRETAR LOS RESULTADOS / COMO INTERPRETAR OS RESULTADOS DOS TESTES

Positive / Positif / Positivo

A type / tipo

B type / tipo

Type A&B Co-infection / Tipo A&B co-infection

Invalid / Non valide / No valido / Inválido

Negative / Négatif / Negativo