



Abbott

Bioline[®] Syphilis 3.0

Syphilis anti-TP Test
Test anti-TP de la syphilis
Prueba anti-TP de la sífilis
Teste anti-TP da sífilis

ENGLISH

About the test

[Introduction] Treponema pallidum (TP) is the causative agent of the venereal disease syphilis. Syphilis is a disease caused by the spirochete bacterium Treponema pallidum. Clinical diagnostic tests related to syphilis are the detection of syphilis antibodies in human blood by immunoassay. Among the existing immunological method, the confirmatory treponemal tests are the agglutination format such as the T. pallidum hemagglutination assay (TPHA) and the immunostaining analysis by fluorescent treponemal antibody absorption test (FTA-ABS). Recently, the ELISA format and immunochromatographic format to detect antibody of T. pallidum are available. Since very highly purified antigens from inoculated TP may contain a certain amount of contaminating materials such as flagella of TP, native TP antigen may cause a non-specific reaction in the assay for test serum specimens, and thus may lead to false positive results. To avoid this problem, some potential problems in immunoassays, researchers have constructed TP genes for the expression of recombinant antigens in bacterium systems such as E. coli and focused on TP membrane protein, which are definitely immunogenic. The major immunoreactive antigens of these membrane proteins have been reported to have a MW 47, 42, 17 and 15kDa, and 15kDa based on western blot analysis.

[Test principle] The Bioline[®] Syphilis 3.0 contains a membrane strip, which is precoated with recombinant Treponema pallidum antigens (17, 15kDa) on test band region. The recombinant Treponema pallidum antigens-coated gold conjugate (17, 15kDa), patient specimen and specific diluent moves along the immunochromatographic path to the test band and forms an antigen-antibody-antigen gold particle complex. Therefore, the formation of a visible line in the test region (T) indicates a positive result for the detection of Treponema pallidum specific antibodies (IgG, IgM, IgA) against Treponema pallidum. The Syphilis 3.0 is a solid phase immunochromatographic assay for the qualitative detection of antibody of all isotypes (IgG, IgM, IgA) against Treponema pallidum. This test is intended for professional use as an aid on the diagnosis of syphilis. This test may not be suitable for diagnosis of early infection or blood donation screening.

Materials provided and active ingredients of main components

The Bioline[®] Syphilis 3.0 test kit contains the following items to perform the assay:

- 30 Test devices with desiccant in individual foil pouches
- Assay diluent (1 L x 4 ml/vial)
- 30 Capillary pipettes (20 µl) (Option), 30 Sterile lancets (Option), 30 Alcohol swabs (Option)
- 1 Alcohol swab
- Active ingredients of main components:

- 1 test strip includes:
 - Gold Conjugates: Recombinant Treponema pallidum antigens (17, 15kDa)-gold colloid (1.0±0.2 µg)
 - Test Line: Recombinant Treponema pallidum antigens (17, 15kDa) (0.7±0.14 µg)
 - Control Line: Goat anti-Treponema pallidum serum (0.75±0.15 µg)
 - Assay diluent: Tris-HCl Buffer (4 ml), Sodium azide (0.02w/w%)

Materials required but not provided

- Microscope, Protective gloves, Timer, Biohazard container

Kit storage and stability

1. The Bioline[®] Syphilis 3.0 test kit or its components should be stored at a temperature between 2°C and 30°C. Do not freeze the kit or its components. If assay diluent is kept at 2 - 30 °C, it is stable until the expiration date after the opening of the bottle.

2. The test device is sensitive to both heat and humidity. Perform the test immediately after removing the test device from the foil pouch.

4. Do not use the kit or its components beyond the expiration date. The shelf life of the kit is indicated on the outer package.

5. Do not use the test kit if the pouch is damaged or the seal is broken.

Warnings

- The test devices are for in vitro diagnostic use only. Do not reuse the test device.
- The instructions must be followed exactly to achieve accurate results. Any individual performing an assay with this product must be trained in its use and must be experienced in laboratory procedures.
- Do not pipet by mouth, drink, or eat in areas where specimens or test results may be handled.
- Wear protective gloves while handling specimens and wash hands thoroughly afterwards.
- Avoid spilling or allowing specimen and assay diluent into aerosol formation.
- Clean up spills thoroughly using an appropriate disinfectant.
- Decontaminate and dispose of all specimens, reagent kits and potentially contaminated materials in a biohazard container as if they were infectious waste.
- Do not mix or interchange different specimens.
- Do not eat the desiccant in the foil pouch.
- Care should be taken to avoid contamination of the end of the bottle when adding assay diluent into a specimen well.
- 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.

Specimen collection and handling

- Whole blood**
- [Collection by venipuncture] Using venipuncture, collect whole blood into the collection tube (containing anticoagulants including heparin, EDTA and sodium citrate). If the blood specimen is not immediately tested, it should be refrigerated at 2 - 8 °C.
- If stored at 2 - 8 °C, the blood specimen should be tested within 3 days of refrigeration.
- Do not use a blood specimen stored for more than 3 days; it can cause a non-specific reaction.
- Bring blood specimens to room temperature (15 - 30 °C) prior to use.
- Clean the area to be lanced with an alcohol swab.
- Squeeze the end of the finger and prick with a sterile lancet.
- Immerse the open end of a 20 µl capillary pipette provided in the blood drop and release the pressure to draw blood into the capillary pipette to the black line.

Collection using a lancet

- Clean the area to be lanced with an alcohol swab.
- Squeeze the end of the finger and prick with a sterile lancet.
- Immerse the open end of a 20 µl capillary pipette provided in the blood drop and release the pressure to draw blood into the capillary pipette to the black line.

Performance characteristics

- A total of 263 serum specimens collected from Korea were tested on the Bioline[®] Syphilis 3.0 in Korea. The serum specimens were comprised of 153 anti-TP positive and 210 anti-TP negative. The results showed that the Bioline[®] Syphilis 3.0 test is very accurate to TPHA.

Reference

	Bioline [®] Syphilis 3.0	Total Results		
Method	Results	Positive	Negative	
TPHA	Positive	152	1	153
Results	Negative	1	209	210
Sensitivity (95% CI)		99.3% (96.4 - 99.9%)		
Specificity (95% CI)		99.5% (97.4 - 99.9%)		

Expected values

The Bioline[®] Syphilis 3.0 has been demonstrated by a leading commercial TPHA syphilis test. The overall accuracy is greater or equal to 99.0%.

Analytical specificity

4. Reproducibility of Bioline[®] Syphilis 3.0 has been demonstrated by within-run, between-run and batch-to-batch studies using in-house reference panels. All values were identical to reference panel acceptance criteria.

5. Expected values

The Bioline[®] Syphilis 3.0 has been compared with a leading commercial TPHA syphilis test. The overall accuracy is greater or equal to 99.0%.

Analytical specificity

3. Analytical specificity

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Bioline®
Syphilis 3.0Syphilis anti-TP Test
Test anti-TP de la syphilis
Prueba anti-TP de la sífilis
Teste anti-TP da sífilisPREPARATION / PRÉPARATION / PREPARACIÓN /
PREPARAÇÃO /

1

Now, open the package and look for the following:

1. Test device with desiccant in individual foil pouch
2. Assay diluent
3. Instructions for use

FR Ouvrez l'emballage et vérifiez que les éléments suivants sont présents :

1. Dispositif de test avec agent déshydratant conditionné dans un emballage en aluminium individuel
 2. Diluant du test
 3. Mode d'emploi
- ES Abra el paquete y busque la siguiente:
1. Dispositivo de prueba con desecante en la bolsa de papel de aluminio individual
 2. Diluyente del ensayo
 3. Instrucciones de uso
- PT Abra a embalagem e procure o seguinte:
1. Dispositivo de teste com dessecante em bolsa de alumínio individual
 2. Diluente de ensaio
 3. Instruções de utilização

Option / En option / Opcional

- EN 1. Capillary Pipette (20 µl)
2. Sterile lancet
3. Alcohol swab
- ES 1. Pipeta capilar (20 µl)
2. Lanceta estéril
3. Hisopo con alcohol
- PT 1. Pipette capillaire (20 µl)
2. Lancette stérile
3. Compresse d'alcool

2

FIRST, read carefully the instruction on how to use the Bioline™ Syphilis 3.0 test kit.

FR TOUT D'ABORD, lisez attentivement les instructions d'utilisation du kit de test Bioline™ Syphilis 3.0.

PT PRIMEIRO, leia atentamente as instruções de utilização do kit de teste Bioline™ Syphilis 3.0.

3

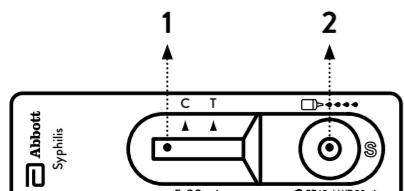
EN Next, look at the expiry date at the back of the foil pouch. Use another kit, if expiry date has passed.

FR Vérifiez ensuite la date de péremption au dos de la pochette en aluminium. Si la date de péremption est dépassée, utilisez un autre kit.

ES A continuación, compruebe la fecha de caducidad indicada en la parte posterior de la bolsa de aluminio. Utilice otro kit de prueba si se ha alcanzado la fecha de caducidad.

PT Em seguida, verifique a data de validade na parte posterior da bolsa de alumínio. Utilize outro kit se a data de validade tiver expirado.

4

EN Open the foil pouch and check the following points:
1. Result window
2. Specimen & Assay diluent well
Then, label the device with the patient identifier.FR Ouvrez la pochette en aluminium et vérifiez les éléments suivants :
1. Fenêtre de résultat
2. Puits d'échantillonnage et de diluant de dosage
Apposez ensuite sur le dispositif une étiquette comportant l'identifiant du patient.ES Abra la bolsa de aluminio y compruebe lo siguiente:
1. Ventana de resultados
2. Pocillo de diluyente del ensayo y muestras
A continuación, etiquete el dispositivo con el identificador del paciente.PT Abra a bolsa de alumínio e verifique os seguintes pontos:
1. Janela de resultados
2. Poço de amostra e do diluente de ensaio
Em seguida, coloque uma etiqueta no dispositivo com o identificador do paciente.

SP 10µl / WB 20µl : Serum 10 µl or Plasma 10 µl or Whole blood 20 µl / 10 µl de plasma ou de sérum ou 20 µl de sang / 10 µl de plasma ou soro ou 20 µl de sangre / 10 µl de plasma ou soro ou 20 µl de sange

Assay diluent 4 drops / Diluant de dosage 4 gouttes / Diluyentes del ensayo 4 gotas / Diluente de ensaio 4 gotas

REF 06FK10

TEST PROCEDURE / DÉROULEMENT DU TEST / PROCEDIMIENTO / PROCEDIMENTO DO TESTE

I. Blood (by venipuncture), Plasma or Serum specimen / Échantillon de sang (par ponction veineuse), de plasma ou de sérum / Muestra de sangre (por punción venosa), plasma o suero / Amostra de sangue (por punção venosa), de plasma ou de soro

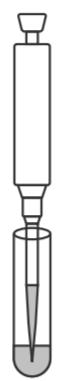
Specimen collection / Prélèvement d'un échantillon / Obtención de muestras / Colheita de amostras

1 EN Take 10 µl of plasma or serum specimen (20 µl of whole blood) using a micropipette.

FR Prélevez 10 µl de plasma ou de sérum (20 µl de sang total) à l'aide d'une micropipette.

ES Obtenga 10 µl de muestra de suero o plasma (20 µl de sangre total) con una micropipeta.

PT Utilizando uma micropipa, colha 10 µl de amostra de plasma ou de soro (20 µl de sangue total).

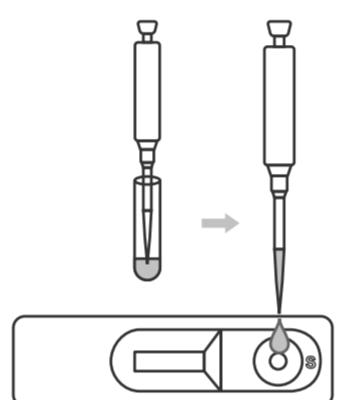


1 EN Dispense 10 µl of plasma or serum (20 µl of blood) into the specimen well (S).

FR Versez 10 µl de plasma ou de sérum (20 µl de sang) dans le puits d'échantillonnage (S).

ES Añada 10 µl de plasma o suero (20 µl de sangre) en el pocillo para muestras (S).

PT Coloque 10 µl de plasma ou de soro (20 µl de sangue) no poço da amostra (S).

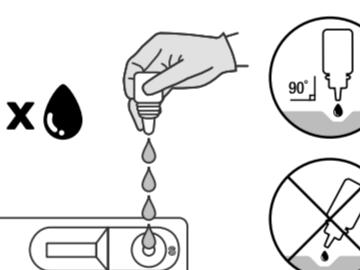


2 EN Dispense 4 drops of assay diluent into the assay diluent well.

FR Versez 4 gouttes de diluant de dosage dans le puits de diluant de dosage.

ES Añada 4 gotas de diluyente del ensayo en el pocillo para diluyente del ensayo.

PT Coloque 4 gotas de diluente de ensaio no poço do diluente de ensaio.



3 EN Interpret test results in 5 - 20 minutes after adding assay diluent. Do not read the test results after 20 minutes; late readings can yield false results.

FR Interprétez les résultats du test au bout de 5 à 20 minutes après l'ajout du diluant de dosage. Ne lisez pas les résultats après 20 minutes ; passé ce délai, les résultats peuvent être erronés.

ES Interprete los resultados transcurridos entre 5 y 20 minutos tras añadir el diluyente del ensayo. No efectúe la lectura de los resultados de la prueba transcurridos 20 minutos ya que se podrían producir resultados falsos.

PT Interprete os resultados do teste no espaço de 5 a 20 minutos depois de adicionar o diluente de ensaio. Não leia os resultados do teste após 20 minutos; as leituras tardias podem produzir resultados falsos.



5 - 20 MIN

II. Blood specimen (with a lancet) / Échantillon de sang (prélevé à l'aide d'une lancette) / Muestra de sangre (con una lanceta) / Amostra de sangue (com uma lanceta)

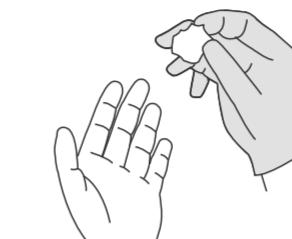
Specimen collection / Prélèvement d'un échantillon / Obtención de muestras / Colheita de amostras

1 EN Clean the area to be lanced with an alcohol swab.

FR Nettoyez la zone de prélèvement avec un tampon imbibe d'alcool.

ES Limpie la zona donde se va a realizar la punción con un hisopo con alcohol.

PT Limpe a área a lancetar usando uma zaragatoa com álcool.

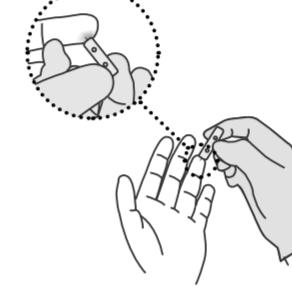


2 EN Prick the lateral side of the finger with the sterile lancet.

FR Piquez sur le côté du doigt avec la lancette stérile.

ES Pinche el lateral del dedo con la lanceta estéril.

PT Pique a parte lateral do dedo com a lanceta estéril.

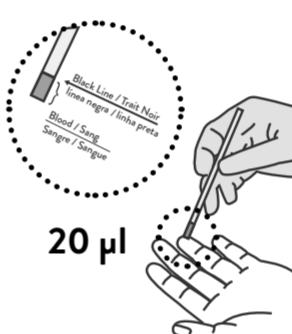


3 EN Immerse the open end of a 20 µl capillary pipette provided in the blood drop and release the pressure to draw blood into the capillary pipette to the black line.

FR Plongez l'extrémité ouverte d'une pipette capillaire de 20 µl fournie dans la goutte de sang et relâchez la pression pour que la pipette capillaire aspire le sang jusqu'à atteindre la ligne noire.

ES Introduzca el extremo abierto de la pipeta capilar de 20 µl suministrada en la gota de sangre y libere la presión para que entre sangre en ella hasta la línea negra.

PT Mergulhe a extremidade aberta de uma pipeta capilar de 20 µl fornecida na gota de sangue e liberte a pressão de modo a colher o sangue para a pipeta capilar até à linha preta.

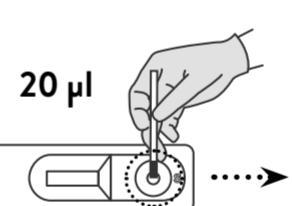


1 EN Dispense 20 µl of drawn blood into the specimen well(S).

FR Versez 20 µl de sang prélevé dans le puits d'échantillonnage (S).

ES Añada 20 µl de la sangre extraída en el pocillo para muestras (S).

PT Coloque 20 µl de sangue colhido no poço da amostra (S).

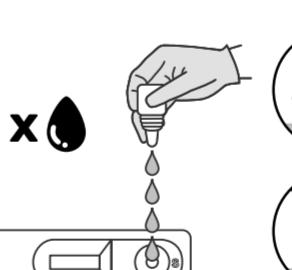


2 EN Dispense 4 drops of assay diluent into the assay diluent well.

FR Versez 4 gouttes de diluant de dosage dans le puits de diluant de dosage.

ES Añada 4 gotas de diluyente del ensayo en el pocillo para diluyente del ensayo.

PT Coloque 4 gotas de diluente de ensaio no poço do diluente de ensaio.



3 EN Interpret test results in 5 - 20 minutes after adding assay diluent. Do not read the test results after 20 minutes; late readings can yield false results.

FR Interprétez les résultats du test au bout de 5 à 20 minutes après l'ajout du diluant de dosage. Ne lisez pas les résultats après 20 minutes ; passé ce délai, les résultats peuvent être erronés.

ES Interprete los resultados transcurridos entre 5 y 20 minutos tras añadir el diluyente del ensayo. No efectúe la lectura de los resultados de la prueba transcurridos 20 minutos ya que se podrían producir resultados falsos.

PT Interprete os resultados do teste no espaço de 5 a 20 minutos depois de adicionar o diluente de ensaio. Não leia os resultados do teste após 20 minutos; as leituras tardias podem produzir resultados falsos.

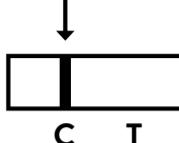
INTERPRETATION / INTERPRÉTATION / INTERPRETACIÓN /
INTERPRETAÇÃO /NEGATIVE / NÉGATIF / NEGATIVO /
NEGATIVO /

EN One line "C" in the result window.

FR Une ligne de contrôle « C » dans la fenêtre de résultat.

ES Una línea "C" en la ventana de resultados.

PT Uma linha "C" na janela de resultados.

POSITIVE / POSITIF / POSTIVO /
POSITIVO /

EN Two lines "C" and "T" in the result window.

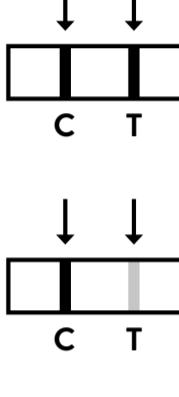
FR Deux lignes « C » et « T » dans la fenêtre de résultat.
Attention : si la ligne de test est présente, même très pâle, le résultat est considéré comme positif.

ES Dos líneas "C" y "T" en la ventana de resultados.

Attention: La presencia de cualquier línea de prueba, aunque sea de un color débil, indica que el resultado es positivo.

PT Duas linhas, "C" e "T", na janela de resultados.

Atenção: A presença de qualquer linha de teste, mesmo sendo muito tênue, significa que o resultado é considerado positivo.



INVALID / NON VALIDÉ / NO VÁLIDO / INVÁLIDO

EN • No "C" line in the result window.

• It is recommended that the specimen be retested.

FR • Aucune ligne « C » dans la fenêtre de résultat.

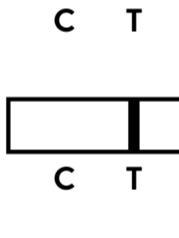
• Il est recommandé de tester à nouveau l'échantillon.

ES • No hay línea "C" en la ventana de resultados.

• Se recomienda repetir la prueba con esa muestra.

PT • Sem linha "C" na janela de resultados.

• Recomenda-se que a amostra seja novamente testada.



GLOSSARY OF SYMBOLS / GLOSSAIRE DES SYMBOLES / GLOSARIO DE SÍMBOLOS / GLOSSÁRIO DE SÍMBOLOS

	Temperature limitation Limites de température Limitaciones de temperatura Limites de temperatura		Lot Number No. de lot Número de lote Número de lote
	For in vitro diagnostic use only Pour diagnostic in vitro uniquement Sómente para uso de diagnóstico in vitro		Catalog Number Code produit Número de Referencia Número de Catálogo
	Do not reuse Usage unique No reutilizar Não reutilizar		Authorized Representative Représentant autorisé Representante autorizado Representante autorizado
	Use By Date de péremption Fecha de caducidad Utilizar até		Instructions for use Voir mode d'emploi Añcion, ver Instrucciones de uso Atenção, ver Instruções de uso
	Contains sufficient for X tests Permet de réaliser X tests Contenido suficiente para X pruebas Contém o suficiente para X testes		Keep away from sunlight Conserver à l'abri de la lumière du soleil Manténgase fuera de la luz del sol Mantener afastado de la luz solar
	Caution Attention Atenção		CE marking according to IVD Medical Devices Directive 98/79/EC Marquage CE conformément à la directive sur les dispositifs médicaux de diagnostic in vitro 98/79/CE Marcado CE conforme a la Directiva 98/79/CE relativa a los productos sanitarios para diagnóstico in vitro Marcção CE de acordo com a Diretiva 98/79/CE relativa aos dispositivos médicos de diagnóstico in vitro