

# SD BIO Malaria Ag P.f/Pan (05FK60)

Test de détection rapide en une étape des antigènes HRP-II(P.f) et pLDH (Pan) du paludisme  
Prueba Rápida de un paso para la detección de los antígenos de Malaria HRP-II(P.f) y pLDH(Pan)  
Test rápido de paso único para detecção dos抗原os HRP-II (P.f) e pLDH (Pan) da Malária

## English

## About the test

Infectious malaria is a serious and sometimes fatal parasitic disease characterized by fever, chills and anemia. The disease is caused by a parasite that is transmitted from one human to another through the bite of infected Anopheles mosquitoes. There are four types of malaria that can infect humans: Plasmodium falciparum, P. vivax, P. ovale and P. malariae. In humans, the parasites (called sporozoites) migrate to the liver where they mature and are released in another form, merozoites. The disease now occurs in more than 90 countries worldwide, and it is estimated that there are over 300 million clinical cases and 2.7 million malaria-caused deaths yearly.

**[Test principle]** The SD BIOLINE Malaria Ag P.f/Pan test device contains a membrane strip, which is pre-coated with mouse monoclonal antibodies specific to P. falciparum on test line P.f region and with mouse monoclonal antibodies specific to P. falciparum on control line C. It also contains mouse monoclonal antibodies specific to pLDH or P.f and mouse monoclonal antibodies specific to pLDH or P.f on control line C. The test device contains a membrane strip with a circular end of inverted cup which is used to collect blood sample. The specimen, Or, take a disposable inverted cup (Syl) provided, dip the circular end of inverted cup into the specimen. Or, take a disposable inverted cup (Syl) provided, dip the circular end of inverted cup into the specimen.

1. Anticoagulants including heparin, EDTA and citrate do not affect the test results.  
2. Use separate disposable capillary pipettes or pipette tips for each specimen in order to avoid cross-contamination of specimens which could produce erroneous results.  
3. Discard the lancet or alcohol swab if it is pricked or damaged. The use of damaged lancet may cause any infection at the puncture skin due to cease to existing its sterility.

**[Test procedure (Refer to figure)]**

- Allow all test components and specimen to room temperature prior to testing.
- The test device should be from foil pack and place it on a flat, dry surface. Label the test device with a patient identifier.
- Clean the fingertip and prick the lateral side of the finger with the sterile lancet provided.
- With a capillary pipette (Syl) provided, draw white blood specimen to the pLDH or - or colloidal gold conjugate wells with the specimen well. Or, with a disposable inverted cup (Syl) provided, dip the circular end of a loop of the inverted blood specimen well. Or, with a disposable inverted cup (Syl) provided, dip the circular end of a loop of the inverted blood specimen well and then transfer chromatographically to the test region (P.f) and form a visible line as the antibody-antigen antibody complex with the specimen well. Or, with a disposable inverted cup (Syl) provided, dip the circular end of a loop of the inverted blood specimen well and then transfer chromatographically to the test region (P.f) and form a visible line as the antibody-antigen antibody complex with the specimen well.
- [Intended Use] SD BIOLINE Malaria Ag P.f/Pan test kit intended for the detection of Malaria infection in human blood specimens, indicating qualitative and differential diagnosis between HRP-II(Histidine-rich protein) II to Plasmodium falciparum and pLDH(Plasmodium lactate dehydrogenase) specific to Plasmodium species (Pan) in human blood. SD BIOLINE Malaria Ag P.f/Pan test is intended for professionals only for an initial screening test, and reactive specimens should be confirmed by a supplemental assay such as microscopic examination of the blood smear.
- Attention: If you do not hold the bottle vertically, it can lead to inaccurate results.
- Wait a minimum of 15 minutes (up to 30 minutes) and read result.

**[Materials provided and active ingredients of main component]**

- The SD BIOLINE Malaria Ag P.f/Pan test kit contains the following items to perform the assay:  
• 25 Test devices with desiccator in individual foil pouch  
• 25 Disposable specimen applicators (Syl), 25 Sterile lancets (option), 25 Alcohol swabs (option)  
• 1 Instructions for use
- Active ingredients of main component:  
• 1 test strip includes: Gold conjugate : Mouse monoclonal antibodies specific to P.f HRP-II gold colloid (0.18±0.03ug/g). Mouse monoclonal antibodies specific to pLDH - gold colloid (0.06±0.02ug/g).  
• 2 Test lines (P.f and control line "C") within the result window, regardless of which lines appear first. It is positive even if "P.f" and "control line ("C)" are faint.  
• Other plasmodium species (P.v or P.o or P.m or P.o) : Presence of two colored lines (test line "P.f" and control line "C") within the result window, regardless of which lines appear first. It is positive even if "P.f" and "control line ("C)" are faint.  
• Assay dilution includes: Triton X-100 (q.s.), 200 mM Phosphate Saline Buffer (q.s.), 200 mM (q.s.), Triton X-100 (q.s.), azotocine de sodium (q.s.)
- Materials required but not provided

• Micropette, protective gloves, Timer, Biobazard container  
**[Kit storage and stability]**  
1. The test kit should be stored at a temperature between 1 °C and 40 °C. Do not freeze the kit or its components.  
2. The test kit should be stored at a temperature between 15 °C and 40 °C for up to 30 months from the date to the test. Do not open the pouch whilst components come to room temperature.  
3. After first opening of the assay diluent bottle, assay diluent is stable until the expiration date, if kept at 1 °C - 40 °C.  
4. The test device is sensitive to both heat and humidity.  
5. Check the humidity indicator on the desiccator for color change and throw the pouch if the color indicates saturation (yellow KODAK. If green).  
6. Perform the test immediately after removing the test device from the foil pouch.  
7. Do not use the test kit beyond its expiration date.  
8. Do not use the test kit if the pouch is damaged or if the seal is broken.  
9. When transporting or storing the kit, avoid exposure to high temperature (above 45 °C) for a period longer than a week.

## Warnings

1. For in vitro diagnostic use only. Do not reuse the test device and kit components.  
2. 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.  
3. Never store at refrigerator, all kit components must be brought to room temperature (15 - 40 °C) for at least 30 mins prior to the test. Do not open the pouch whilst components come to room temperature.  
4. After first opening of the assay diluent bottle, assay diluent is stable until the expiration date, if kept at 1 °C - 40 °C.  
5. The test device is sensitive to both heat and humidity.  
6. Check the humidity indicator on the desiccator for color change and throw the pouch if the color indicates saturation (yellow KODAK. If green).  
7. Perform the test immediately after removing the test device from the foil pouch.  
8. Do not use the test kit beyond its expiration date.  
9. Do not use the test kit if the pouch is damaged or if the seal is broken.  
10. Do not use the test kit if the seal is indicated on the outer package.  
11. Do not eat the desiccant in the foil pouch.

## Specimen collection and storage

[Collection by venipuncture]  
1. Using venipuncture, collect whole blood into the collection tube (containing anticoagulants including heparin, EDTA and sodium citrate).  
2. If the blood specimen is not immediately tested, it should be refrigerated at 2 - 8 °C.  
3. If stored at 2 - 8 °C, the blood specimen should be tested within 3 days.  
4. Do not use a blood specimen more than 3 days; it can cause a non-specific reaction.

[Collection using a lancet]  
1. Clean the area around the site to be tested with an alcohol swab.

2. Soak the tip of the finger with a sterile lancet provided.

3. Wipe away the first drop of blood with sterile swab or cotton.

4. Take a fingertip (Syl) provided, while gently squeezing the tube, immerse the open end in the blood drop and then gently release the pressure to draw blood into the capillary pipette to black line. Or, take a disposable inverted cup (Syl) provided, dip the circular end of a loop into the blood drop.

5. Analyze for the detection of malaria based on the level of parasitemia.

6. Plasmodium falciparum : Sensitivity with > 50 parasite/jul of blood is 100%.

7. Non-Plasmodium falciparum : Sensitivity with > 50 parasite/jul of blood is greater than 98%.

8. Assay for the detection of malaria according to the level of parasitemia.

9. Plasmodium falciparum : Sensitivity with > 50 parasite/jul of blood is 100%.

10. Non-Plasmodium falciparum : Sensitivity with > 50 parasite/jul of blood is greater than 98%.

11. Do not eat the desiccant in the foil pouch.

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104.

# SD BIO Malaria Ag P.f/Pan (05FK60)

## Preparation / Préparation / Preparación / Preparação

**1**

- EN** 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** Ouvrir le kit et vérifier les éléments suivants:  
 1. Dispositif de test avec agent déshydratant emballé dans des pochettes individuelles en aluminium  
 2. Diluant de dosage  
 3. Mode d'emploi

- ES** Abra el empaque y busque lo siguiente:  
 1. Dispositivo de prueba con desecante en bolsa de papel de aluminio individuales  
 2. Diluyente del ensayo  
 3. Instrucciones de uso

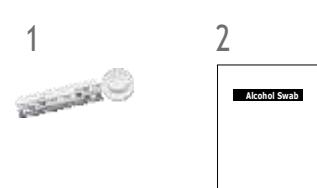
- PT** Abra a embalagem e observe abaixo:  
 1. Dispositivo de teste com dessecante em bolsa de folha de alumínio individuais  
 2. Diluente de ensaio  
 3. Instruções de utilização



- 4** Disposable specimen applicator (5µl) / Applicateur d'échantillon à usage unique (5µl) / APLICADOR DE MUESTRA DESCHABLE (5µl) / Aplicadores de amostras descartáveis (5µl)

Or / Ou	O bien	Or / Ou	O bien
Capillary pipette Pipette capillaire Pipa capilar Pipa capilar	Disposable specimen loop Anse de prélevement à usage unique Asta de muestras deschable Ansa de inoculación descartável	Disposable inverted cup Une cupe de prélevement à usage unique Pipa invertida desechable Ventosa invertida descartável	

## Option / Opción / Opcão



- 2** First, carefully read the instructions for using the SD BIOLINE Malaria Ag P.f/Pan test kit.

- FR** Commencer par lire attentivement le mode d'emploi du kit de SD BIOLINE Malaria Ag P.f/Pan.

- ES** Primero, lea detenidamente las instrucciones de uso del kit de análisis SD BIOLINE Malaria Ag P.f/Pan.

- PT** Primeiro, leia cuidadosamente as instruções para utilizar o kit de teste SD BIOLINE Malaria Ag P.f/Pan.

## For example / Par exemple / Por ejemplo / Por exemplo

- EN** Next, look at the expiration date on the back of the foil pouch. If the expiration date has passed, use another lot. To avoid false results, ensure that the assay diluent used is from the same kit as the new test device.

- FR** Vérifier ensuite la date d'expiration à l'arrière de l'emballage en aluminium. Si la date d'expiration est dépassée, utiliser un autre lot. Pour éviter tout faux résultat, s'assurer que le diluant du test utilisé provient du même kit que le nouveau dispositif de test.

- ES** A continuación, compruebe la fecha de caducidad en la parte posterior de la bolsa de papel de aluminio. Si la fecha de caducidad ha vencido, utilice otro lote. Para evitar resultados falsos, asegúrese de que el diluyente del ensayo utilizado es del mismo kit que el dispositivo de prueba nuevo.

- PT** A seguir, verifique o prazo de validade na parte posterior da bolsa de folha de alumínio. Se o prazo de validade tiver sido ultrapassado, utilize outro lote. Para evitar resultados falsos, certifique-se de que o diluente do ensaio utilizado é do mesmo kit que o novo dispositivo do teste.

- 4** Open the foil pouch and look for the following:  
 1. Result window  
 2. Specimen well (●)  
 3. Assay diluent well (○)

Then, label the device with the patient identifier.

- ES** Abra la bolsa de aluminio y busque lo siguiente:  
 1. Ventana de resultados  
 2. Poco de muestra (●)  
 3. Poco de diluyente de prueba (○)

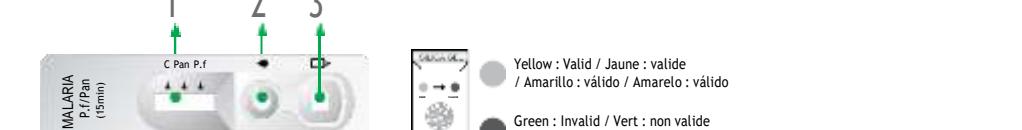
A continuación, etiquete el dispositivo de prueba con la identificación del paciente.

- FR** Ouvrir l'enveloppe et vérifier les éléments suivants:  
 1. Fenêtre de résultat  
 2. Puits d'échantillon (●)  
 3. Puits pour le diluant (○)

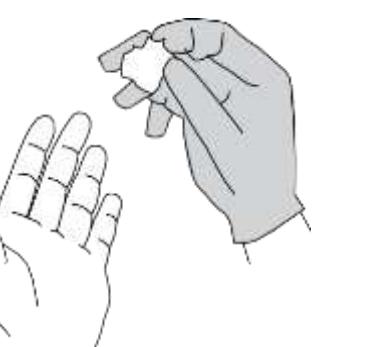
Étiqueter ensuite le dispositif avec l'identifiant patient.

- PT** Abra a bolsa de folha de alumínio e verifique se contém os seguintes itens:  
 1. Janela de resultados  
 2. Poço da amostra (●)  
 3. Poço para o diluente de ensaio (○)

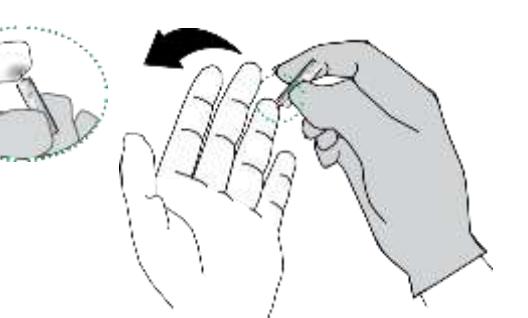
Em seguida, coloque uma etiqueta no dispositivo com o identificador do paciente.



## Test procedure / Procédure de test / Procedimiento de la prueba / Procedimento do teste

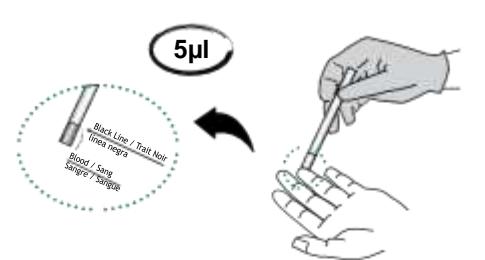
**1**

- EN** Clean the area to be lanced with an alcohol swab.  
**FR** Nettoyer la surface à prélever à l'aide d'un tampon imbibé d'alcool.  
**ES** Limpie el área a ser pinchada con un copo de algodón humedecido con alcohol.  
**PT** Limpe a área a ser lancelada com swab de álcool.

**2**

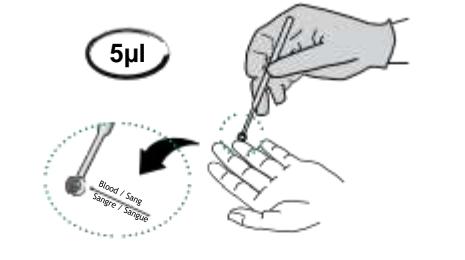
- EN** Prick the lateral side of the finger with the sterile lancet provided. Then, safely dispose of the lancet immediately after.  
**FR** Piquer le côté latéral du doigt avec la lancette stérile fournie. Jeter la lancette immédiatement après conformément aux règles de sécurité.  
**ES** Pinche el lado del dedo con la lanceta estéril suministrada. Deseche de forma segura la lanceta inmediatamente después.  
**PT** Pique a lateral do dedo com a lanceta esterilizada fornecida. Em seguida, elimine a lanceta em segurança imediatamente após a utilização.

## Capillary pipette / Pipette capillaire / Pipeta capilar / Pipeta capilar

**3**

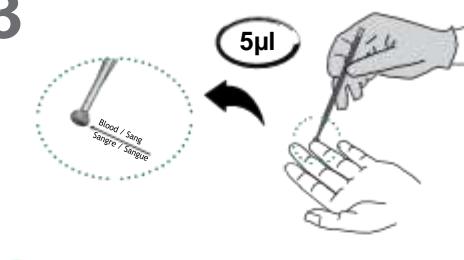
- EN** With a 5µl capillary pipette, draw blood to black line.  
**FR** Avec une pipette capillaire de 5µl, aspirer le sang jusqu'au trait noir.  
**ES** Con una pipeta capilar de 5µl, extraiga sangre hasta la línea negra.  
**PT** Com uma pipeta capilar de 5µl, desloque o sangue para a linha preta.

## Disposable specimen loop / Anse de prélevement à usage unique / Asa de muestras deschable / Ansa de inoculación descartável

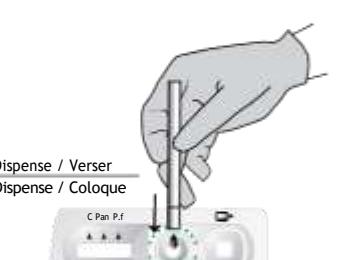
**3**

- EN** Take a disposable specimen loop (5µl) provided, dip the circular end of a loop into the blood specimen.  
**FR** Prendre une anse de prélevement à usage unique (5µl) fournie, immerger son extrémité circulaire dans l'échantillon de sang.  
**ES** Tome un asa de muestras deschable (5µl) suministrado y sumérja el extremo circular de la asa en la muestra de sangre.  
**PT** Pegue uma ansa de inoculação descartável (5µl) fornecida, coloque a extremidade circular numa amostra de sangue.

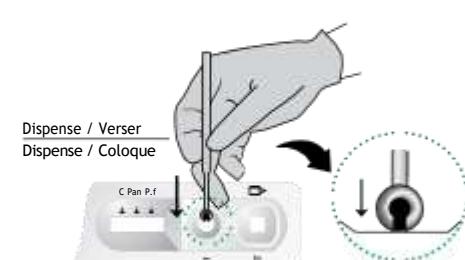
## Disposable inverted cup / Une cupe de prélevement à usage unique / Pipeta invertida desechable / Ventosa invertida descartável

**3**

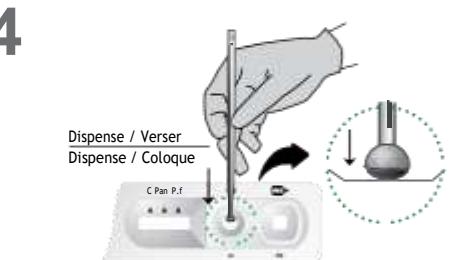
- EN** Take a disposable inverted cup (5µl) provided, dip the circular end of a inverted cup into the blood specimen.  
**FR** Prendre une cupe de prélevement à usage unique (5µl) fournie, immerger son extrémité circulaire dans l'échantillon de sang.  
**ES** Tome una pipeta invertida desechable (5µl) suministrada y sumérja el extremo circular de la pipeta invertida en la muestra de sangre.  
**PT** Pegue numa ansa de inoculação descartável (5µl) fornecida, coloque a extremidade circular numa ventosa na amostra de sangue.

Or / Ou  
O bien**4**

- EN** Dispense 5µl of drawn blood into round specimen well touching pad (●).  
**FR** Verser 5µl de sang prélevé dans le puits d'échantillon rond qui touche le tampon (●).  
**ES** Dispense 5 µl de la sang extraída en el pocillo para muestras redondo tocando la almohadilla (●).  
**PT** Coloque 5 µl de sangue recolhido no poço redondo da amostra tocando no espaço (●).

**4**

- EN** Dispense 5µl of drawn blood into round specimen well touching pad (●).  
**FR** Verser 5µl de sang prélevé dans le puits d'échantillon rond qui touche le tampon (●).  
**ES** Dispense 5 µl de la sang extraída en el pocillo para muestras redondo tocando la almohadilla (●).  
**PT** Coloque 5 µl de sangue recolhido no poço redondo da amostra tocando no espaço (●).

Or / Ou  
O bien**4**

- EN** Dispense 5µl of drawn blood into round specimen well touching pad (●).  
**FR** Verser 5µl de sang prélevé dans le puits d'échantillon rond qui touche le tampon (●).  
**ES** Dispense 5 µl de la sang extraída en el pocillo para muestras redondo tocando la almohadilla (●).  
**PT** Coloque 5 µl de sangue recolhido no poço redondo da amostra tocando no espaço (●).

## Use Loop : Let the circular end of the loop touch the pad, then press down lightly.

- EN** Use Loop : Let the circular end of the loop touch the pad, then press down lightly.  
**FR** Avec l'anse : Laisser l'extrémité circulaire de l'anse toucher le tampon, puis appuyer légèrement.

- ES** Uso del asa : Deje que el extremo circular de la asa entre en contacto con la almohadilla y presione ligeramente.

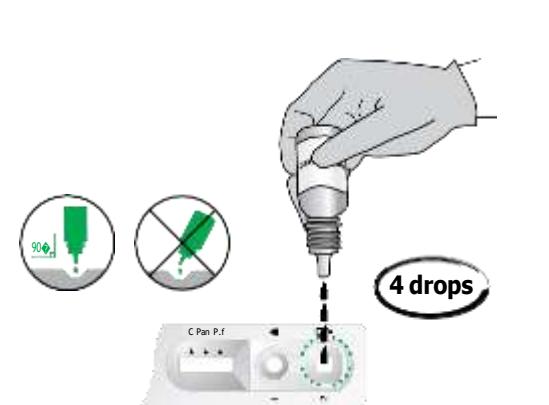
- PT** Utilização da asa : Deixe que a extremidade circular da asa tocar no espaço e, em seguida, faça uma leve pressão para baixo.

## Use Inverted cup : Let the circular end of the inverted cup touch the pad, then press down lightly.

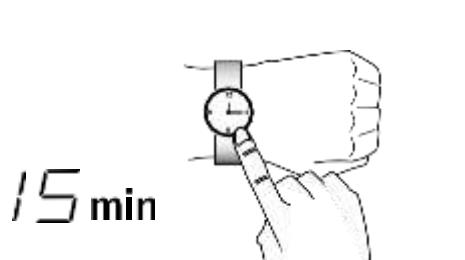
- EN** Use Inverted cup : Let the circular end of the inverted cup touch the pad, then press down lightly.  
**FR** Avec la cupe de prélevement : Laisser l'extrémité circulaire de la cupe de prélevement toucher le tampon, puis appuyer légèrement.

- ES** Uso de la pipeta invertida : Deje que el extremo circular de la pipeta invertida entre en contacto con la almohadilla y presione ligeramente.

- PT** Uso o copo invertido : Deixe que a extremidade circular da asa tocar no espaço e, em seguida, faça uma leve pressão para baixo.

**5**

- EN** Dispense 4 drops of assay diluent vertically into the square assay diluent well (●).  
**FR** Ajouter 4 gouttes de diluant verticalement dans le puits carré du test (●).  
**ES** Agregue 4 gotas de diluyente verticalmente para prueba en el pocillo para diluyente de prueba cuadrado (●).  
**PT** Adicione 4 gotas de diluente para ensaio verticalmente no orifício quadrado para o diluente de ensaio (●).

**6**

- EN** Wait a minimum of 15 minutes (up to 30 minutes) and read results.  
**FR** Interpréter les résultats dans les 15 minutes suivantes minimum (dans les 30 minutes suivantes maximum).

- ES** Espere como mínimo 15 minutos (como máximo 30 minutos) y lea el resultado.

- PT** Aguarde no mínimo 15 minutos (até 30 minutos) e leia o resultado.

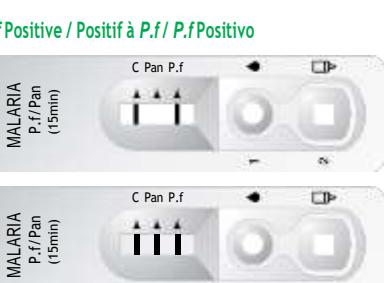
## Interpretation / Interprétation / Interpretación / Interpretação

## Negative / Negatif / Negativo / Negativo

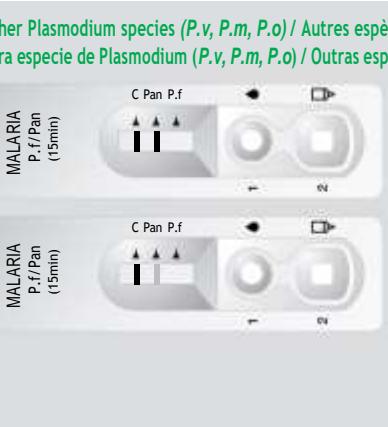


- EN** No malaria P.f/Pan antigen  
One line "C" in the result window  
**FR** Pas d'antigène P.f/Pan dans la fenêtre de résultats  
**ES** Ningún antígeno de malaria P.f/Pan  
Una linea "C" en la ventana de resultados.  
**PT** Sem antígeno da Malária P.f/Pan  
Uma linha "C" na janela de resultados

## Positive / Positif / Positivo / Positivo



- EN** The presence of two colored bands ("P" test line and "C" control line) or three colored bands  
("P," "P" + "C" and "C" control line) within the result window indicate P.f positive result.  
Caution : It is positive even if "Pan" and/or "P.f" lines are faint.  
**FR** La présence de deux bandes colorées (ligne de test "P" et ligne de contrôle "C") ou trois bandes colorées (lignes de test "P" et "P" + "C" et ligne de contrôle "C") dans la fenêtre de résultats, quelle que soit la bande qui apparaît en premier, indique un résultat positif pour P.f.  
Mise en garde : Le test est positif même si les lignes "Pan" et/ou "P.f" sont très faibles.  
**ES** La presencia de dos bandas de color (líneas de prueba "P" y "P" + "C" y línea de control "C") o tres bandas de color (líneas de prueba "P", "P" + "C" y línea de control "C") dentro de los resultados, independientemente de qué banda aparece primero, indica un resultado positivo para P.f.  
Precaución : Es positivo incluso si las líneas "Pan" y/o "P.f" son débiles.  
**PT** A presença de duas bandas coloridas (linhas de teste "P" e "P" + "C" e linha de controlo "C") dentro da janela de resultados, independentemente da banda que aparecer primeiro, indica um resultado positivo para outras espécies de Plasmodium, tais como Plasmodium vivax, Plasmodium malariae ou Plasmodium ovale.  
Mise en garde : Le test est positif même si la ligne "Pan" est faible.  
**ES** La presencia de dos bandas de color (línea de prueba "P" y línea de control "C") en la ventana de resultados, independientemente de que banda aparece primero, indica un resultado positivo de otra especie de Plasmodium (P.v, P.m o P.o).  
Precaución : Es positivo incluso si la línea "Pan" o "P.f" es débil.  
**PT** A presença de duas bandas coloridas (linhas de teste "P" e "P" + "C" e linha de controlo "C") dentro da janela de resultados, independentemente da banda que aparecer primeiro, indica uma infecção combinada de P.f y P.v o P.m o P.o.  
Atenção : É positivo mesmo se a linha "Pan" for tênue.



- EN** The presence of three colored bands ("P," "P" + "C" and "C" control line) within the result window, regardless of which band appears first, indicate P.f positive or mixed infection of P.f and P.v or P.m or P.o.  
Caution : It is positive even if "Pan" and/or "P.f" lines are faint.  
**FR** La présence de trois bandes colorées ("P", "P + C" et "C" ligne de contrôle) dans la fenêtre de résultat, quelle que soit la bande qui apparaît en premier, indique un résultat positif ou mixte de P.f et/ou P.v ou P.m ou P.o.  
Mise en garde : Le test est positif même si les lignes "Pan" et/ou "P.f" sont très faibles.  
**ES** La presencia de tres bandas de color (líneas de prueba "P", "P + C" y línea de control "C") en la ventana de resultados, independientemente de que banda aparece primero, indica un resultado positivo o mixto de P.f y/o P.v o P.m o P.o.  
Precaución : Es positivo incluso si las líneas "Pan" y/o "P.f" son débiles.  
**PT** A presença de três bandas coloridas (linhas de teste "P", "P + C" e linha de controlo "C") dentro da janela de resultados, independentemente da banda que aparecer primeiro, indicar uma infecção misturada de P.f e de P.v ou P.m ou P.o.  
Atenção : É positivo mesmo se as linhas "Pan" ou "P.f" forem tênues.



- EN** No "C" line in the result window.  
It is recommended that the specimen be retested using a new test kit.  
**FR** Aucune ligne "C" dans la fenêtre de résultats.  
Il est recommandé dans ce cas de tester à nouveau l'échantillon à l'aide d'un nouveau kit de test.  
**ES** Ninguna línea "C" en la ventana de resultados.  
Se recomienda volver a analizar la muestra usando un nuevo kit de análisis.  
**PT** Sem linha "C" na janela de resultados.<