

SD BIO Malaria Ag P.f/Pan (05FK63)

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)

Teste rápido de passo único para detecção dos抗原os HRP-II(P.f) e pLDH (Pan) da Malaria

English

About the test

[Introduction] 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 per year. At present, malaria is diagnosed by looking for parasites in a drop of blood. Blood is placed on a microscope slide and stained so that the parasites will be visible under a microscope.

[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 lactate dehydrogenase of Plasmodium species Pan (P.v., P.o., P.m.) on control line C. The membrane strip is coated with rabbit anti-mouse IgG antibody. This antibody reacts with the mouse monoclonal antibodies specific to P. falciparum and mouse monoclonal antibodies specific to pLDH on pan-colloid gold conjugate wells with the malaria antigen in the specimen. They react along the membrane chromatographically to the test region P.f and form a visible line as the antibody-antigen antibody gold particle complex with a high degree of specificity.

[Intended Use] SD BIOLINE Ag P.f/Pan test intended for the detection of Malaria infection in human blood specimens. Indicating qualitative and differential diagnosis of Malaria (Histo-anti-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 professional use only for initial screening test. and reactive specimens should be confirmed by a supplemental assay such as microscopic examination of the blood smear.

Materials provided and active ingredients of main component

- 1. One Step Malaria Ag P.f/Pan test kit containing the following items to perform the assay:
 - 25 Test devices for descendant in individual foil pouch
 - 25 Assay diluent
 - 25 Disposable specimen applicators (Syl), 25 Sterile lancets, 25 Alcohol swabs
 - 25 Summarized Instructions for use
 - 1 Instruction for use
 - 1 Test strip

Materials required but not provided

- Microscope, protective gloves, Time, Biohazard 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. 25 Test devices descendant in individual foil pouch
- 3. 25 Assay diluent
- 4. 25 Disposable specimen applicators (Syl), 25 Sterile lancets, 25 Alcohol swabs
- 5. 25 Summarized Instructions for use
- 6. 1 Instruction for use
- 7. 1 Test strip
- 8. 25 Positive controls
- 9. 25 Negative controls
- 10. 25 Control lines (test line "P.f", "Pan" and control line "C") within the result window, regardless of the date of manufacture. It is recommended to store the controls in a separate bag.
- 11. 25 Assay diluent
- 12. 25 Alcohol swabs
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SD BIO LINE Malaria Ag P.f/Pan (05FK63)

Preparation / Préparation / Preparación / Preparação

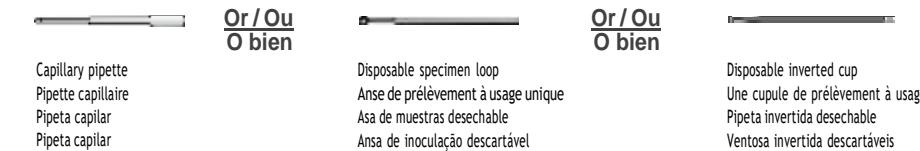
1

- EN** Open the package and look for the following:
1. Test device with desiccant in individual foil pouch
 2. Assay diluent
 3. Sterile lancet
 4. Alcohol swab
 5. Summarized instructions for use
 6. 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. Lancette stérile
 4. Compresse d'alcool
 5. Résumé des instructions d'utilisation
 6. Instructions d'utilisation

- ES** Abra el paquete y busque lo siguiente:
1. Dispositivo de prueba con desecante en bolsa de papel de aluminio individuales
 2. Diluyente del ensayo
 3. Lanceta estéril
 4. Hisopo con alcohol
 5. Instrucciones resumida de uso
 6. Instrucciones de uso



- PT** Dispenser de amostras (5µl) / Applicateur d'échantillon à usage unique (5µl) / APLICADOR DE MUESTRA DISECHABLE (5µl) / Aplicadores de amostras descartáveis (5µl)



- EN** 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.

- EN** [For example / Par exemple / Por ejemplo / Por exemplo]
- FR** 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.
- ES** Vérfique 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.
- PT** 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.
- EN** 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.

- EN** Open the foil pouch and look for the following:
1. Result window
 2. Specimen well (●)
 3. Assay diluent well (●)
- FR** Ouvrir l'enveloppe et vérifier les éléments suivants:
1. Fenêtre de résultat
 2. Puits d'échantillon (●)
 3. Puits pour le diluant (●)
- ES** Abra la bolsa de aluminio y busque lo siguiente:
1. Ventana de resultados
 2. Pocillo de muestras redondo (●)
 3. Pocillo para diluyente de prueba (●)
- PT** Abra a bolsa de aluminio e busque lo siguiente:
1. Janela de resultados
 2. Poco da amostra (●)
 3. Poco para o diluente do ensaio (●)

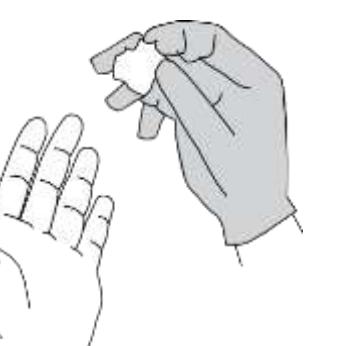
- A continuación, etiquete el dispositivo de prueba con la identificación del paciente.
- EN** Then, label the device with the patient identifier.
- FR** Étiqueter ensuite le dispositif avec l'identifiant patient.
- ES** Luego, etiquete el dispositivo con el identificador del paciente.
- PT** Em seguida, coloque uma etiqueta no dispositivo com o identificador do paciente.



Yellow : Valid / Javne : valide / Amarillo : válido / Amarelo : válido
Green : Invalid / Vert : non valide / Verde : não válido / Verde : inválido

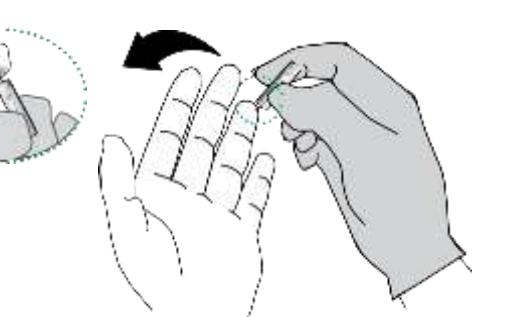
Test procedure / Procédure de test / Procedimiento de la prueba / Procedimento do teste

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.

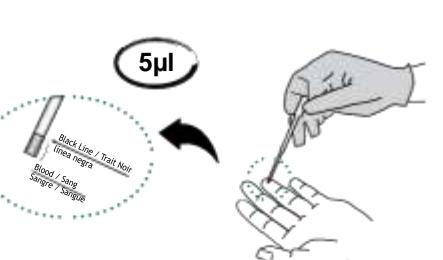
2



- 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.

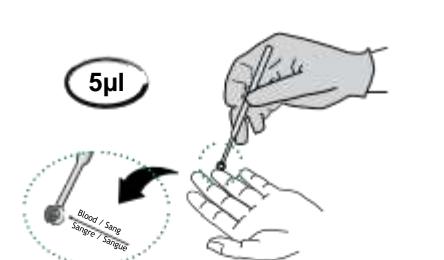
3

Capillary pipette / Pipette capillaire / Pipeta capilar / Pipeta capilar



- 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.

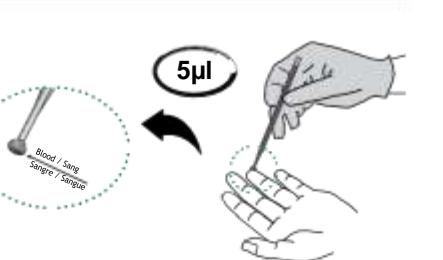
Disposable specimen loop / Anse de prélevement à usage unique / Ansa de muestras desecharable / Ansa de inoculação descartável



- 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 ansa de muestras desecharable (5µl) suministrado y sumerja el extremo circular de la ansa en la muestra de sangre.
- PT** Pegue numa ansa de inoculação descartável (5µl) fornecida, coloque a extremidade circular numa amostra de sangue.

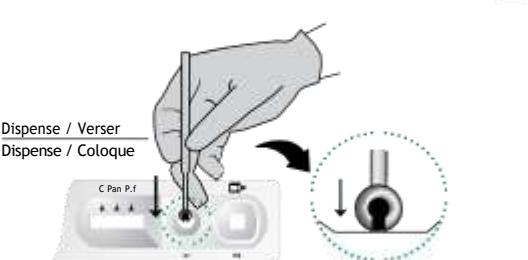
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Disposable inverted cup / Une cuve de prélevement à usage unique / Pipeta invertida desecharable / Ventosa invertida descartável



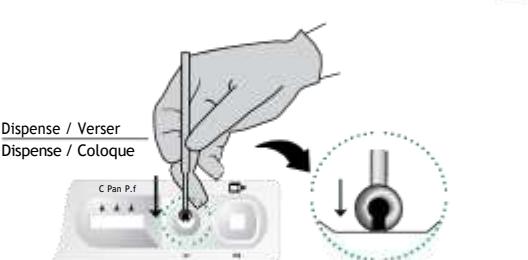
- EN** Take a disposable inverted cup (5µl) provided, dip the circular end of an inverted cup into the blood specimen.
- FR** Prendre une cuve de prélevement à usage unique (5µl) fournie, immerger son extrémité circulaire dans l'échantillon de sang.
- ES** Tome una pipeta invertida desecharable (5µl)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

3

Or / Ou
O bien

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

4

Or / Ou
O bien

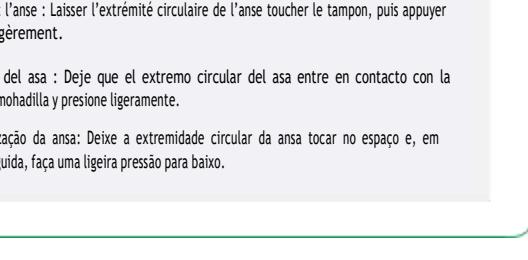
- EN** Dispense 5µl of drawn blood into round specimen well touching pad (●).
- FR** Verser 5 µl de sang prélevé dans le puits d'échantillon rond qui touche le tampon (●).
- ES** Distribuir 5µl de sang extraído en el pocillo de muestra redondo tocando la almohadilla (●).
- PT** Coloque 5µl de sangue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

4

Or / Ou
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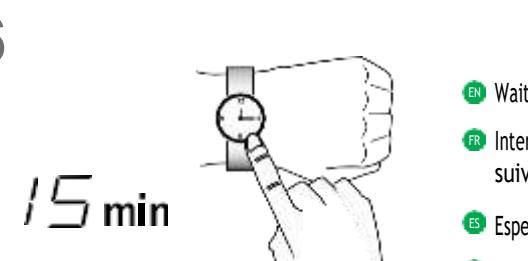
- EN** Use Loop : Let the circular end of the loop touch the pad, then press down lightly.
- FR** Avec l'anse : Laisser l'extrémité circulaire de l'anse toucher le tampon, puis appuyer légèrement.
- ES** Uso del asa : Deje que el extremo circular del asa entre en contacto con la almohadilla y presione ligeramente.
- PT** Utilização da ansa : Deixe que a extremidade circular da ansa tocar no espaço e, em seguida, faça uma leve pressão para baixo.

5

Or / Ou
O bien

- EN** Use Inverted cup : Let the circular end of the inverted cup touch the pad, then press down lightly.
- FR** Avec la cuve de prélevement : Laisser l'extrémité circulaire de la cuve de prélevement toucher le tampon, puis appuyer légèrement.
- ES** Uso del asa : Deje que el extremo circular de la pipeta invertida entre en contacto con la almohadilla y presione ligeramente.
- PT** Utilização da ansa : Deixe que a extremidade circular da ansa tocar no espaço e, em seguida, faça uma leve pressão para baixo.

5

Or / Ou
O bien

- 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.

6



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
- PT** Sem antígeno da Malária P.f/Pan

Positive / Positif / Positivo / Positivo



- EN** The presence of two colored bands ("P" test line and "C" control line) or three colored bands ("P", "P" test lines 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") dans la fenêtre de résultats, quelle que soit la bande qui apparaît en premier, indique un résultat positif pour P.f.



- EN** The presence of two bands of color (lines of prueba "P" y líneas de control "C") en la ventana de resultados, independientemente de qué banda aparece primero, indica un resultado P.f positivo.
- FR** La présence de deux bandes colorées (lignes de test "P" et "P" et ligne de contrôle "C") dans la fenêtre de résultats, quelle que soit la bande qui apparaît en premier, indique un résultat positif P.f.



- EN** A presence of two bands color (lines of test "P" and "P" and line of control "C") within the result window, regardless of which band appears first, indicate Pan positive result.
Caution : It is positive even if "Pan" line is faint.
- FR** La présence de deux bandes colorées (lignes de test "P" et "P" et ligne de contrôle "C") dans la fenêtre de résultats, quelle que soit la bande qui apparaît en premier, indique un résultat positif pour autre espèces de Plasmodium telle que Plasmodium vivax, Plasmodium malariae ou Plasmodium ovale.



- EN** The presence of two bands of color (lines of prueba "P" y líneas de control "C") en la ventana de resultados, independientemente de qué banda aparece primero, indica un resultado positivo de otra especie de Plasmodium (P.v, P.m o P.o).
- FR** La présence de deux bandes colorées (lignes de test "P" et "P" et ligne de contrôle "C") dans la fenêtre de resultados, independientemente de qué banda que aparecer primero, indica un resultado positivo de otras especies de Plasmodium (P.v, P.m o P.o).



- EN** A presence of two bands color (lines of test "P" and "P" and line of control "C") dentro de janelas de resultados, independientemente de que banda que aparecer primero, indica resultado positivo de outras espécies de Plasmodium (P.v, P.m o P.o).
- FR** La présence de deux bandes colorées (lignes de test "P" et "P" et ligne de contrôle "C") dentro de janelas de resultados, independientemente de que banda que aparecer primero, indica resultado positivo de outras espécies de Plasmodium (P.v, P.m o P.o).



- EN** Mixed infection : P.f and P.v (or P.m, P.o) / Positif pour une infection mixte P.f et P.v (ou P.m, P.o) / Infección combinada P.f y P.v (o P.m, P.o) / Infecção misturada de P.f e P.v (ou P.m e P.o)
- FR** La présence de trois bandes colorées ("P", "P" et "C" dans la fenêtre de résultats, quelle que soit la bande qui apparaît en premier, indique un résultat positif pour mélange d'infection P.f et P.v ou P.m ou P.o.



- EN** Caution : It is positive even if "Pan" line is faint.
- FR** La présence de trois bandes colorées ("P", "P" et "C" dans la fenêtre de résultats, quelle que soit la bande qui apparaît en premier, indique un résultat positif à Plasmodium falciparum ou une infection mixte à P.f avec P.v ou P.m ou P.o.



- EN** The presence of three colored bands ("P", "P" test lines and "C" control line) within the result window, regardless of which band appears first, indicate P.f, P.m or P.o positive result.
- FR** La présence de trois bandes colorées ("P", "P" et "C" dans la fenêtre de résultats, quelle que soit la bande qui apparaît en premier, indique un résultat positif à Plasmodium falciparum ou à Plasmodium vivax ou à Plasmodium malariae.



- EN** A presence of three bands color (lines of prueba "P", "P" and line of control "C") dentro de janelas de resultados, independientemente de que banda que aparecer primero, indicar una infección combinada de P.f y/o P.v o P.m o P.o.
- FR** La présence de trois bandes colorées (lignes de test "P", "P" et ligne de contrôle "C") dans la fenêtre de résultats, indiquant une infection combinée de P.f et de P.v ou de P.m ou de P.o.



- EN** Caution: Es positivo incluso si las líneas "Pan" y/o "P.f" son débiles.
- FR** Attention: Es positivo incluso si las líneas "Pan" y/o "P.f" son débiles.



- EN** A presence of three bands color (lines of prueba "P", "P" and line of control "C") dentro de janelas de resultados, independientemente de que banda que aparecer primero, indicar una infección misturada de P.f, de P.v ou de P