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"DIAQUICK"
Malaria P.f./Pan Cassette

for the detection of P. falciparum (HRP II) and pLDH (P. falciparum, P. vivax, P. ovale, P. malariae) in human whole blood

Cat.No.	Content
Z11200CE	- 25 tests individually packed (25 x Ref. No: Z11200B) - 1 buffer tube; assay diluent sufficient for 25 tests - 25 disposable sample applicators (5 µl) - 1 package insert

For professional in vitro diagnostic use only.

GENERAL INFORMATION

Method	sandwich type immunochromatographic assay
Shelf life	24 months from date of production
Storage	1-30°C
Sample	human whole blood samples
Results	after 15-30 minutes

SUMMARY

Malaria is one of the worldwide diseases, which are known as mosquito-borne infections. It is accompanied by symptoms such as high fever, shivering, arthralgia (joint pain), vomiting, etc. Other typical symptoms of malaria are a cyclical occurrence of sudden coldness followed by rigor, fever and sweating. The seriousness depends on the infection type, the most serious form being caused by *Plasmodium falciparum*. A *P.falciparum* infection needs a very fast treatment, as it may be fatal otherwise. Four species of the Plasmodium parasites are responsible for malaria infections in human – *P. falciparum*, *P. vivax*, *P. ovale* and *P. malariae*.
In humans, the parasites (called sporozoites) migrate to the liver, where they mature and release another form, the merozoites. The disease now occurs in more than 90 countries worldwide and it is estimated that there are over 500 million clinical cases and maybe 2 million malaria-caused deaths per year.

TEST PRINCIPLE

The DIAQUICK Malaria P.f./Pan Cassette is an immunochromatographic assay. As the test sample flows through the membrane assembly after the addition of the clearing buffer, the coloured colloidal gold conjugates of monoclonal anti-*P. falciparum* (HRP II specific) and monoclonal anti-Pan (pLDH specific) bind to the HRP II/pLDH in the lysed sample. This complex moves further on the membrane to the test region, where it is immobilised by the monoclonal anti-HRP II and monoclonal anti-pLDH specific antibody coated on the membrane, leading to a formation of pink-purple bands, which confirm a positive test result. Absence of coloured bands in the test region indicates a negative test result.

ACTIVE INGREDIENTS OF MAIN COMPONENTS

The DIAQUICK Malaria P.f./Pan Cassette contains following items to perform the assay:

- Test device individually foil pouched with a desiccant
- Assay diluent
- Specimen collection loop
- Instructions for use

Active ingredients of main component:

- Mouse monoclonal antibodies to P.f. HRPII-1 (0,13 ± 0,023 µg)
- Mouse monoclonal antibodies to Pan pLDH-1 (0,13 ± 0,026 µg)
- Mouse monoclonal antibody to P.f. HRPII-2 (0,96 ± 0,192 µg)
- Mouse monoclonal antibody to Pan pLDH-2 (0,64 ± 0,128 µg)
- Goat anti-mouse immunoglobulin G (0,8 ± 0,16 µg)

STORAGE AND STABILITY

- Store the test device packaged in the sealed foil pouch at 1-30°C. Do not freeze.
- Shelf-life: 24 months from manufacturing date.

PRECAUTIONS

- For in vitro diagnostic use only.
- Do not use the test device beyond the expiration date.
- Do not use the test device if the pouch is damaged or the seal is broken.
- The test result should be used in conjunction with other clinical information such as clinical signs and symptoms and other test results to diagnose *P. falciparum* and *P. vivax*, *P. ovale*, *P. malariae*.
- Keep it sealed until usage and once opened use it quickly.
- Do not re-use a device that has already been used.
- The result of the Pan (pLDH) region should be diagnosed with other clinical results or other test results, because there is a possibility of false negatives caused by *P. malariae* and *P. ovale*.

SPECIMEN COLLECTION AND STORAGE

Specimen Storage

- Test the whole blood specimen within an hour after sampling.
- Handle all specimens as potentially infectious.
- Specimens showing high levels of haemolysis should be avoided, as this can give inaccurate results.
- If the specimen was kept in the fridge before, it should be left at room temperature for 15 min. before testing it.

Whole blood specimen

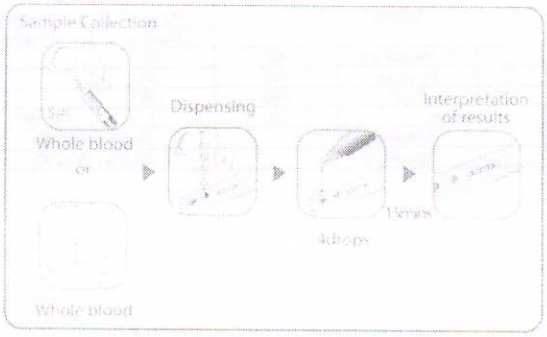
1. Use a tube with EDTA or heparin anticoagulant. Gathered blood from syringe can cause faster haemolysis and should be avoided.
2. Operate the test within an hour after collecting.

Finger puncture whole blood

1. Clean fingertip with an alcohol pad and let dry.
2. Take a lancet and make a quick deep stab on the side of the finger.
3. Avoid squeezing the fingertip to accelerate bleeding as this tends to dilute the blood with excess tissue fluid.

TEST PROCECURE

1. Pull out the specimen and device, and leave it on room temperature for 15 min. before the test
2. Open the sealed pouch and take out the test device.
3. Take 5 µL of whole blood by loop and drop the specimen in the specimen insertion hole.
4. Add 4 drops of buffer (approx. 120 µL) and start the timer.
5. Wait for 15-30 min. and then read the results. Do not interpret the test results after 30 minutes.

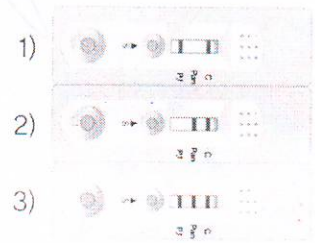


INTERPRETATION OF TEST RESULTS

Negative Result

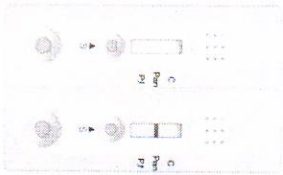
A coloured band is visible only in the control region (C).

Positive Result



1) Positive for P.f.: two coloured bands are visible in the P.f. region and control region (C).
2) Positive for Pan: Two coloured bands are visible in the Pan region and control region (C).
3) Positive for P.f. and Pan: Three coloured bands are visible in the P.f. region, the Pan region and control region (C).

Invalid Result



If there is no coloured line in the control line region (C), the result is invalid. This is due to deterioration of the test device or improper test procedure. Repeat the test with a new test strip.

QUALITY CONTROL

The appearance of the control line indicates that sufficient sample fluid was added for capillary flow to occur and all of the reagents in the test device are working properly. The absence of the control line may indicate that insufficient sample was added or the test device is inactivated.

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LIMITATIONS

- The DIAQUICK Malaria P.f./Pan Cassette is designed for primary screening of *P. falciparum* (HRPII) and pLDH (*P. falciparum, P.vivax, P. ovale, P.malariae*) in human blood.
- This test can provide a fast and easy way to get a result, but does not completely exclude the possibility of false positive or false negative results caused by various factors. So, the test results must be evaluated in conjunction with other clinical data available to the physician.
- The device and buffer of different lots must not be mixed and used.
- In a few cases, where the P.f. (HRPII) band is positive and the Pan malaria band is negative, it may indicate a case of post treatment malaria. However, such a reaction pattern may also be obtained in a few cases of untreated malaria. Re-testing after 2 days is advised in such cases.
- Most blood samples clear within the running time of the test. However, in a few fresh samples and especially in stored samples, the background clearance may be delayed for 15-20 min. longer.

PERFORMANCE CHARACTERISTICS

Sample			DIAQUICK Malaria P.f./Pan Cassette	
			Positive	Negative
Positive	P. falciparum	50	50	0
	P. vivax	150	149	1
	Total	200	199	1
Negative		200	1	199
Sensitivity			99,5% (199/200)	
Specificity			99,5% (199/200)	

LITERATURE

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