



FalciVax™

RAPID TEST FOR MALARIA

Pv/Pf

DEVICE

INTENDED USE

FalciVax™ is a rapid, qualitative, two site sandwich immunoassay utilizing whole blood for the detection of *P.falciparum* specific histidine rich protein-2 (Pf. HRP-2) and *P.vivax* specific pLDH. The test can also be used for specific detection and differentiation of *P.vivax* malaria and *P.falciparum* malaria in areas with high rates of mixed infections.

The test is intended for professional use at clinical and point of care sites in suspected cases of malaria infection.

SUMMARY

Four species of the Plasmodium parasites are responsible for malarial infections in human viz. *P. falciparum*, *P.vivax*, *P. ovale* and *P. malariae*. Of these *P. falciparum* and *P. vivax* are considered the "Big Two" due to incidence of cerebral malaria and drug resistance associated with *P. falciparum* malaria, and high rate of infectivity and relapse associated with *P.vivax*. As the course of treatment is dependent on the species, differentiation between *P.falciparum* and *P.vivax* is of utmost importance for better patient management and speedy recovery.

In **FalciVax™**, the detection system for *P.falciparum* malaria is based on the detection of *P.falciparum* specific histidine rich protein-2 (Pf. HRP-2), which is a water soluble protein that is released from parasitised erythrocytes of infected individuals. The detection system for *P.vivax* malaria is based on presence of *P.vivax* specific pLDH.

PRINCIPLE

FalciVax™ utilizes the principle of agglutination of antibodies/ antisera with respective antigen in immuno-chromatography format along with use of nano gold particles as agglutination revealing agent. As the test sample flows through the membrane assembly of the device after addition of the clearing buffer, the colored colloidal gold conjugates of the Agglutinating Sera for HRP-2 and the Agglutinating Sera for *P. vivax* specific pLDH complexes the HRP-2/ pLDH in the lysed sample. This complex moves further on the membrane to the test region where it is immobilized by the Agglutinating Sera for Pan Malaria specific pLDH and / or Agglutinating Sera for HRP-2 coated on the membrane leading to formation of pink-purple colored band/s which confirms a positive test result. A band will appear under Pf at the test region in falciparum positive samples, while a band will appear under Pv in vivax malaria positive samples. Appearance of band under Pf as well as Pv in the test region suggests a mixed infection.

Absence of colored band/s in the test region indicates a negative test result. The unreacted conjugate and unbound complex if any, move further on the membrane and are subsequently immobilized by Agglutinating Sera for Rabbit globulin coated on the membrane at the control region, forming a pink-purple band. The control band formation is based on the 'Rabbit globulin / Agglutinating Sera for Rabbit globulin' system. Since it is completely independent of the analyte detection system, it facilitates formation of consistent control band signal independent of the analyte concentration. This control band serves to validate the test performance.

REAGENTS AND MATERIALS SUPPLIED

FalciVax™ kit contains:

A. Individual pouches, each containing:

1. **DEVICE** Membrane assembly pre-dispensed with Agglutinating Sera for HRP-2 - colloidal gold conjugate, Agglutinating Sera for *P. vivax* specific pLDH - colloidal gold conjugate, rabbit globulin colloidal gold conjugate, Agglutinating Sera for HRP-2, Agglutinating Sera for Pan Malaria specific pLDH and Agglutinating Sera for Rabbit globulin at the respective regions.
2. Desiccant pouch.
3. **PIPETTE** Disposable Plastic Sample Applicator.

B. **BUF** Clearing buffer in a dropper bottle.

C. Package Insert.

D. Pictorial representation.

Product codes	REF	503150001	503150005	503150010	503150025	503150050	503150100
Pouch sealed tests	▽	01	05	10	25	50	100
Clearing buffer bottles		01 x 1.25ml	01 x 2.0ml	01 x 3.0ml	01 x 4.0ml	02 x 4.0ml	04 x 4.0ml
Instructions for use		01	01	01	01	01	01

OPTIONAL MATERIAL REQUIRED

Calibrated micropipette capable of delivering 5µl sample accurately.

STORAGE AND STABILITY

The sealed pouches in the test kit & the kit components may be stored between 1°C to 40°C till the duration of the shelf life as indicated on the pouch/ carton. DO NOT FREEZE. After first opening of the clearing buffer bottle, it can be stored between 1°C to 40°C for the remaining duration of its shelf life.

NOTES

Read the instructions carefully before performing the test.

For in vitro diagnostic use only. NOT FOR MEDICINAL USE. For professional use.

The test is not intended for use in screening of asymptomatic population.

Do not use beyond expiry date.

Do not intermix components of different lots.

The device and sample applicator are for single use only.

Contact with the contents of desiccant pouch containing, among other substances, cobalt chloride (CAS# 7646-79-9) should be kept to a minimum. Inhalation / swallowing may cause harm.

Handle all specimens as potentially infectious.

Follow standard biosafety guidelines for handling and disposal of potentially infective material.

Clearing buffer contains Sodium Azide(0.1%), avoid skin contact with this reagent. Azide may react with lead and copper in the plumbing and form highly explosive metal oxides. Flush with large volumes of water to prevent azide build up in the plumbing.

SPECIMEN COLLECTION AND PREPARATION

Fresh blood from finger prick / puncture should be used as a test specimen. However, fresh anti coagulated whole blood may also be used as a test sample. EDTA or CPDA or Heparin or Oxalate or Tri-sodium Citrate can be used as suitable anticoagulants. The specimen should be collected in a clean glass or plastic container. If immediate testing is not possible then the specimen may be stored at 2°C to 8°C for upto 72 hours before testing. Clotted or contaminated blood samples should not be used for performing the test.

TESTING PROCEDURE AND INTERPRETATION OF RESULTS

1. Bring the **FalciVax™** kit components to room temperature before testing.
2. Open the pouch and retrieve the device, sample applicator and desiccant pouch. Check the color of the desiccant. It should be blue, if it has turned colorless or pink, discard the device and use another device. **Once opened, the device must be used immediately.**
3. Label the test device with patient's identity.
4. Place the testing device on a flat horizontal surface.
5. Tighten the cap of the clearing buffer bottle provided with the kit in the clockwise direction to pierce the buffer bottle nozzle.
6. Evenly mix the anti coagulated blood sample by gentle swirling. Dip the sample applicator into the sample. Ensuring that an applicator full of blood is retrieved, blot the blood so collected in the sample port 'A'. (This delivers approximately 5µl of the whole blood specimen).

OR

In case finger prick blood is being used, touch the sample applicator to the blood on the finger prick. Ensuring that an applicator full of blood is retrieved, immediately blot the specimen in the sample port 'A'. (Care should be taken that the blood sample has not clotted and the transfer to the sample port is immediate).

OR

Alternatively, 5µl of the anti coagulated or finger prick specimen may be delivered in the sample port 'A' using a micro pipette.

NOTE : Ensure that the blood from the sample applicator has been completely taken up at the sample port 'A'.

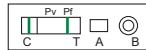
7. Immediately dispense **two drops** of clearing buffer into buffer port 'B', by holding the buffer bottle vertically.
8. Read the results at the end of **20 minutes** as follows:



NEGATIVE for malaria : Only one pink-purple band appears in the control window 'C'.



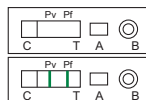
POSITIVE for *P.vivax* malaria : In addition to the control band, a pink-purple band also appears under the region marked 'Pv' in the test window 'T'.



POSITIVE for *P.falciparum* malaria : In addition to the control band, a pink-purple band also appears under the region marked 'Pf' in the test window 'T'.



POSITIVE for *P.falciparum* and *P.vivax* malaria : In addition to the control band, two pink-purple bands appear under the regions marked 'Pf' and 'Pv' in the test window 'T'.



INVALID RESULT: The test should be considered invalid if no bands appear on the device. The test should also be considered invalid if only test bands (Pv and/or Pf) appear and no control band appears. Repeat the test with a new device ensuring that the test procedure has been followed accurately.

PERFORMANCE CHARACTERISTICS

In an in-house study, a panel of 200 samples whose results were earlier confirmed with microscopy were tested with **FalciVax™**. The results obtained are as follows:

Sample	Total No. of samples tested	FalciVax™		Sensitivity (%)	Specificity (%)
		Positive	Negative		
<i>P.falciparum</i> positive	20	20	0	100	-
<i>P.vivax</i> positive	25	25	0	100	-
Malaria negative	155	0	155	-	100

LIMITATIONS OF THE TEST

1. As with all diagnostic tests, the results must always be correlated with clinical findings.
2. The results of test are to be interpreted within the epidemiological, clinical and therapeutic context. When it seems indicated, the parasitological techniques of reference should be considered (microscopic examination of the thick smear and thin blood films).
3. Any modification to the above procedure and / or use of other reagents will invalidate the test procedure.
4. Interference due to presence of heterophile antibodies in patient's sample can lead to erroneous analyte detection in immunoassay, has been reported in various studies. **FalciVax™** uses HETEROPHILIC BLOCKING REAGENT (HBR) to inhibit majority of these interferences.
5. **FalciVax™** is 100% sensitive to *P. falciparum* and *P. vivax* malaria. However, a negative test result does not rule out the possibility of infection with *P. ovale* and *P. malariae*.
6. In case of infection with *P. vivax* usually, the 'Pv' bands can be employed for monitoring success of anti-malarial therapy. However, since treatment duration and medication used affect the clearance of parasites, the test should be repeated after 5-10 days of start of treatment.
7. If the reaction of the test remains positive with the same intensity after 5-10 days, post treatment, the possibility of a resistant strain of malaria has to be considered.
8. In *P. falciparum* malaria infection, Pf. HRP-2 is not secreted in gametogony stage. Hence in "Carriers", the 'Pf' band may be absent.
9. Since Pf. HRP-2 persists for upto a fortnight even after successful therapy, a positive test result does not indicate a failed therapeutic response. If the reaction of the test remains positive with the same intensity after 5-10 days, post treatment, the possibility of a resistant strain of malaria has to be considered.
10. The 'Pv' band can be used for monitoring success of anti malarial therapy, in case of stand alone *P. vivax* infection. For monitoring success of anti malarial therapy in case of stand alone *P. falciparum* infection or mixed infection, employing a Pan specific pLDH based system is recommended (available as **Parabank**) after 5-10 days of initiation of the chemotherapeutic agent.
11. Do not interpret the test results beyond 30 minutes.
















WARRANTY

This product is designed to perform as described on the label and package insert. The manufacturer disclaims any implied warranty of use and sale for any other purpose.

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9. Data on file: Viola Diagnostic Systems.

SYMBOL KEYS

	Temperature Limitation		Consult Instructions for use		Date of Manufacture		Do not reuse
	Manufacturer		<i>In vitro</i> Diagnostic Medical Device		This side up		Clearing Buffer
	Use by		Catalogue Number		Device		
	Contains sufficient for <n> tests		Batch Number / Lot Number		Disposable Plastic Sample Applicator		



Manufactured by:

Viola Diagnostic Systems

A Division of Tulip Diagnostics (P) Ltd.

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EC REP

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