MALARIA P.f/P.v 3 Line card test

For Professional Use

MALERISCAN®

IVD

Qualitative Detection of Antibodies of all isotypes specific to Malaria P.f. & P.v. in human Serum or plasma

Read the pack Insert before use provided along with the kit

REF MAL

INTENDED USE : MALARIA P.f/P.v 3 Line Card MALERISCAN® TEST is an immunochromato-graphy based assay for the qualitative detection of antibodies of all isotypes specific to P.f. & P.v in human serum or plasma.

INTRODUCTION : Malaria is a serious, sometimes fatal, parasitic disease characterized by the fever, chills and anemia and is caused by a parasite that is transmitted from one human to another by the bite of infected Anopheles mosquitoes. There are four kinds 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 release another form, the merozoites. The Malaria P.f./P.v. test is a immunochromatographic (rapid) test for the qualitative detection of antibodies of all isotypes (IgA, IgG and IgM) specific to Plasmodium falciparum and Plasmodium vivax in human serum or plasma.

TEST PRINCIPLES : Malaria P.f./P.v. 3 line test device consists of a sample window containing an absorbant pad where the serum/plasma is to be added. It contains a Membrane strip, which is pre-coated with recombinant malaria P.f. capture antigen (MSP, CSP) on test band P.f.region and with recombinant malaria P.v. capture antigen (MSP, CSP) on test band P.v. region. The recombinant malaria P.f/P.v. antigen (MSP, CSP)-colloidal gold conjugate and serum sample moves along the membrane chromatographically to the test region (P.f, P.v.) and forms a visible line as the antigen-antibody-antigen gold particle complex forms with high degree of sensitivity and specificity. The control line is used for procedural control. Control line should always appear if the procedure is performed properly and the reagents are working.

STORAGE AND STABILITY : Kit should be stored between 2-30°C in the sealed pouch. The kit is stable until the expiry date mentioned on the pouch when stored under the above conditions. **The opened diluent bottle is stable for 18 months**

PACK SIZE : Available in Packs of 10's, 25's & 50's

CONTENTS OF THE KIT :

PACK SIZE	10 Tests	25 Tests	50 Tests
Test Device	10 Nos.	25 Nos.	50 Nos.
Diluent	1.4 ml	3.5 ml	7.0 ml
10 µl Dropper	10 Nos.	25 Nos.	50 Nos.
Silicagel	10 Nos.	25 Nos.	50 Nos.
Pack Insert	1 No.	1 No.	1 No.

MATERIAL REQUIRED BUT NOT PROVIDED :

a) Sterilized vial
b) Disposable gloves
c) Precission pipette
d) Sodium hypochlorite solution (Free available chlorine 50-500mg/L)
e) Autoclaved Tips.

WARNINGS & PRECAUTIONS :

In order to obtain reproducible results, the following rules must be observed:

a). Read this Pack Insert carefully.
b). DO NOT FREEZE THE KITS. If refrigerated the kits should be brought to room temperature before testing. Assay should be conducted at room temperature (15-30°C).
c). Do not use the kits beyond their expiry date.
d). Use only serum or plasma.
e). Carefully observe the prescribed number of drops to be added, 10µl or 1 drop of serum or plasma and 2 drops of diluent only
f). Use the test device soon after it is removed from the pouch.
g). Do not use the test device, if the pouch seal is broken.
h). Avoid any contamination among samples; for this purpose, disposable tips and sterilized vial should be used for each sample and reagent.
i). Read the Positive result in 10 minutes and Negative result in 20 minutes. Do not interpret the result after 20 minutes.
j). Do not smoke, eat drink or apply cosmetics during the assay.
k). For In vitro Diagnostic Use only.
l). For single use only.
m). Avoid using hemolytic, lipemic, icteric or bacterially contaminated specimens. Otherwise they may give erroneous results.

All human serum and plasma samples should be considered potentially infectious. It is recommended that all specimens of human origin should be handled as recommended for any potentially infectious human serum or blood specimen in the Centers for Disease Control / National Institute of Health manual "Biosafety in Microbiological and Biomedical Laboratories",1984.
Never pipette by mouth.
Do not smoke, eat or drink in areas in which specimens or kitreagents are handled. Afterwards wash hands carefully.
Avoid splashing or forming aerosols.
Discard all materials and specimens as if capable of transmitting infection The preferred method of disposal is autoclaving for a minimum of one hour at 121°C. Liquid wasted not containing acid may be mixed with sodium hypochlorite so that the final mixture contains 50-500 mg/l available chlorine. Allow 30 minutes for decontamination.
Note : Liquid waste containing acid must be neutralized with a proportional amount of base prior to the addition of sodium hypochlorite.
Spills should be wiped up throughly using either an iodophor disinfectant or sodium hypochlorite solution. Materials used to wipe up spills should be added to biohazardous waste matter for proper disposal.
Reagents are stored between 2-30°C. Avoid unnecessary exposure to light. Do not use reagents after expiration date.
Do not mix or interchange reagents from different kits or kit batches. Cross contamination of reagents or samples can cause erroneous results.
Use a new pipette tip for each sample.
Optimal results are obtained by strictly adhering to the test protocol. Accurate and precise pipetting, as well as following the exact time and temperature requirements, is essential.

Once the assay has been started, all steps should be performed without interruption.

SPECIMEN : Fresh Serum or Plasma.

SPECIMEN COLLECTION AND PREPARATION :

a). Collect blood in a clean, dry, Sterilized vial and allow it to clot.Seperate the serum by centrifugation at 5000 r.p.m for 15 minutes at room temperature.
b). If serum is not to be assayed immediately it should be stored at 2-8°C or if storing more than 3 days then freeze the specimen at -20 °C or below.

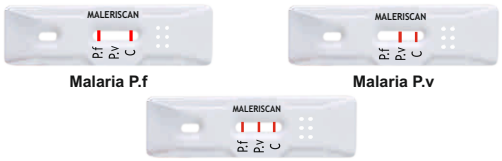
ASSAY PROCEDURE:

a). Bring the pouch to room temperature.
b). Remove the device from the pouch just prior to testing.
c). Place the device on a flat surface.
d). Add 10 µl or 1 drop or serum or plasma into the sample window and allow to soak in.
e). Add 2 drops of diluent provided in the dropper bottle into the same sample window.
f). Read the Positive results in 10 minutes & Negative results in 20 minutes.
DO NOT READ ANY RESULT BEYOND TWENTY MINUTES.
g). Any line appearing after 20 minutes would be of no diagnostic value

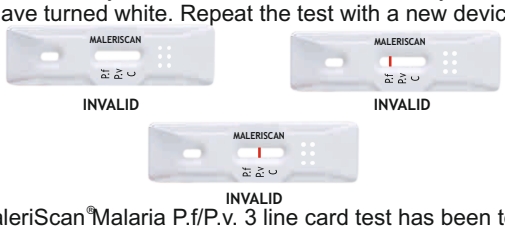
INTERPRETATIONS OF THE TEST

Negative : The Presence of only One Band at "C"
with in the result window indicates a Negative Results.

Positive : The Presence of a Band at "C" and bands at "P.f." and/or "P.v." within the results window indicates the Positive Result for "P.f." and / or "P.v." respectively.



Invalid : If no lines appear or line appears at "P.f." and / or "P.v." within theResult Window after performing the test, the result considered invalid.
The directions may not have been followed correctly or the silicagel might have turned white. Repeat the test with a new device.



The MaleriScan® Malaria P.f/P.v. 3 line card test has been tested with positive and negative clinical samples tested by microscopic examinationof whole blood.

PERFORMANCE CHARACTERISTICS :

A. Malaria P.f Sensitivity and Specificity

No. of positive Samples tested	No. of positive by Malaria P.f/P.v.3 line Antibody Card	Sensitivity	No. of negative Samples tested	No. of negative by Malaria P.f/P.v.3 line Antibody Card	Specificity
170	150	88.2%	200	197	98.5%

B. Malaria P.v Sensitivity and Specificity

No. of positive Samples tested	No. of positive by Malaria P.f/P.v.3 line Antibody Card	Sensitivity	No. of negative Samples tested	No. of negative by Malaria P.f/P.v.3 line Antibody Card	Specificity
173	158	91.3%	208	205	98.5%

R-16, 2013-05-03

LIMITATIONS OF THE TEST :

The test is limited to the detection of antibodies to Malaria both Plasmodium falciparum and Plasmodium vivax simultaneously. Although the test is very accurate in detecting antibodies to Malaria P.f/P.v a low incidence of false results can occur. Other clinically available tests are required if questionable results are obtained. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

REFERENCES :

1. Alon Warburg and Imogene Schneider. In vitro Culture of the Mosquito Stages ofplasmodium falciparam. Experimental Parasitology 76,12 126(1993).
2. Arthur E.Brown, H.Kyle Webster : characteristics of Natural Antibody Response to the Circumsporozoite protein of Plasmodium vivax Am..J.
Trop. Med.Hyg., 44(1), 1991,p.21-27 (90-173) date Issued : 03/05/2001 05FK30-02-1
3. David R and et.al A. Longitudinal Study of Type-Specific Antibody Response to Plasmodium faciparum Merozoite Surface Protein - 1 in an Area of Unstable Malaria in Sudan. Journal of Immunology. 161:347-359 (1998).
4. Helen L. Gibson, Jeffrey E. Tucker : Structure and expression of the gene for Pv200 a major blood-stage surface antigen of Plasmodium vivax. Molecular and Biochemical Parasitology. 50 (1992) 325-334.

NOTE:: Even after the best effort is made to supply the product as per the sample submitted but due to continuous R & D, the company reserves the right to improve/change any specifications/components without prior information/notice to the buyer

LIMITED EXPRESSED WARRANTY OF MANUFACTURER

The manufacturer limits the warranty to this test kit, as much as that the test kit will function as an in vitro diagnostic assay within the Nature of Sample, Procedure limitations and specifications as described in the product instruction manual, when used strictly in accordance with the instructions contained. The manufacturer disclaims any warranty expressed or implied including such expressed or implied warranty with respect to merchantability, fitness for use or implied utility for any purpose. The manufacturer's liability is limited to either replacement of the product or refund of the purchase price of the product and in no case liable to claim of any kind for an amount greater than the purchase price of the goods in respect of which damages are likely to be claimed. The manufacturer shall not be liable to the purchaser or third parties for any injury, damage or economic loss, howsoever caused by the product in the use or in the application there of.

BS ISO-15223-1:2012(E) MEDICAL DEVICES SYMBOL					
2°C 30°C	Temperature Limitation	2001-06	Date of Manufacture	IVD	In vitro Diagnostic Device
LOT	Batch Code		Company name & address		Consult Instructions For Use
	Use by	Company	Company Name	EC REP	Authorised Representative in European Community
	Do Not Reuse	Σ	Sufficient for		KEEP AWAY FROM SUNLIGHT
	KEEP DRY	NON STERILE	NON-STERILE	CONTROL −	NEGATIVE CONTROL
CONTROL +	POSITIVE CONTROL				

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