TruQuick™ Malaria P.f./Pan 25T

A rapid test for the qualitative detection of circulating antigens of *P. falciparum* (P.f.), *P. vivax* (P.v.), *P. ovale* (P.o.), and *P. malariae* (P.m.) in whole blood.

REF **TQ2125** IVD **Rx Only**

INTENDED USE
TruQuick Malaria P.f./Pan is a rapid immunoassay for the qualitative detection of *Plasmodium falciparum* ((P.f.), *P. vivax* (P.v.), *P. ovale* (P.o.), and *P. malariae* (P.m.) in whole blood.

SUMMARY AND EXPLANATION OF THE TEST
Malaria is caused by a protozoan which invades human red blood cells.[1] Malaria is one of the world's most prevalent diseases. According to the WHO, the worldwide prevalence of the disease is estimated to be 300-500 million cases and over 1 million deaths each year. Most of these victims are infants, young children. Over half of the world's population lives in malarious areas. Microscopic analysis of appropriately stained thick and thin blood smears has been the standard diagnostic technique for identifying malaria infections for more than a century.[2] The technique is capable of accurate and reliable diagnosis when performed by skilled microscopists using defined protocols. The skill of the microscopist and use of proven and defined procedures, frequently present the greatest obstacles to fully achieving the potential accuracy of microscopic diagnosis. Although there is a logistical burden associated with performing a time-intensive, labor-intensive, and equipment-intensive procedure such as diagnostic microscopy, it is the training required to establish and sustain competent performance of microscopy that poses the greatest difficulty in employing this diagnostic technology.

TruQuick Malaria P.f./Pan is a rapid test to qualitatively detect the presence of *P. falciparum* -specific HRP-II and four kinds of circulating *plasmodia* P.f., P.v., P.o., and P.m.). The test utilizes colloidal gold conjugate to selectively detect P.f-specific and Pan-malarial antigens (P.f., P.v., P.o. and P.m. in whole blood.

BIOLOGICAL PRINCIPLES
The membrane is precoated with anti-HRP-II antibodies and anti-Aldolase antibodies. During testing, the whole blood specimen reacts with the dye conjugate, which has been precoated on the Test Cassette. The mixture then migrates along the membrane by capillary action, reacts with anti-Histidine-Rich Protein II (HRP-II) antibodies on the membrane at the P.f. Test Line region and with anti-Aldolase antibodies on the membrane at the Pan Line region. If the specimen contains HRP-II or Plasmodium-specific Aldolase or both, a colored line will appear in P.f. line region or Pan line region or two colored lines will appear in P.f. line region and Pan line region. The absence of the colored lines in P.f. line region or Pan line region indicates that the specimen does not contain HRP-II and/or Plasmodium-specific Aldolase. To serve as a procedure control, a colored line will always appear in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS/MATERIALS PROVIDED
The maximum number of tests obtained from this test kit is listed on the outer box.
- Test Cassettes: TruQuick Malaria P.f./Pan contains anti-HRP-II conjugated to gold and anti-Aldolase antibodies conjugated to gold and anti-HRP-II antibodies and anti-Aldolase antibodies coated on the membrane.
- Buffer: A buffered solution containing Proclin 300 as a preservative. The Buffer is supplied in a dropper vial ready for use.
- Disposable specimen droppers
- Package insert

MATERIALS NOT PROVIDED
- Pipette and disposable tips (optional)
- Specimen collection containers
- Lancets (for fingerstick whole blood only)
- Timer

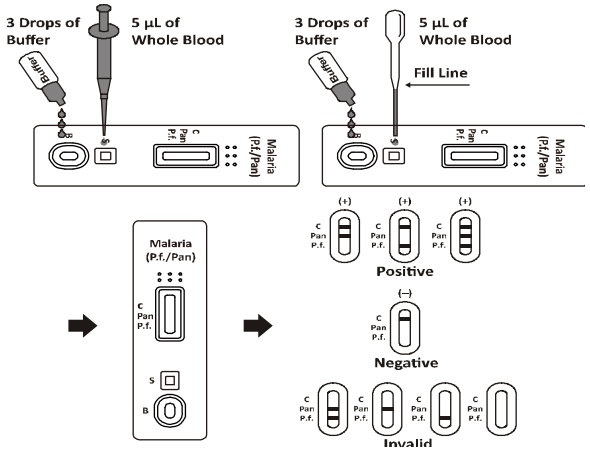
PRECAUTIONS
1. For in vitro diagnostic use only. Do not use after expiration date.
2. For whole blood specimen use only. Do not use other specimens.
3. Do not eat, drink or smoke in the area where the specimens or kits are handled.
4. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of specimens.
5. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
6. The used test should be discarded according to local regulations.
7. Humidity and temperature can adversely affect results.
8. Do not exchange or mix Buffer and Test Cassettes from kits of different lot numbers.
9. Caution must be taken at the time of specimen collection. Inadequate volume of specimen may lead to lower sensitivity.
10. Be sure to add sufficient Buffer to the cassette's sample well. Invalid result may occur if inadequate Buffer is added.

HAZARD and PRECAUTIONARY STATEMENTS
Refer to the SDS, available at www.meridianbioscience.com for Hazard and Precautionary Statements.

SHELF LIFE AND STORAGE
The kit can be stored at room temperature or refrigerated (2-30 C). The Test Cassette is stable through the expiration date printed on the sealed pouch. The Test Cassette must remain in the sealed pouch until use. **DO NOT FREEZE**. Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION
1. TruQuick Malaria P.f./Pan can be performed with whole blood only.
2. Both Fingerstick Whole Blood and Venipuncture Whole Blood can be used.
3. To collect Fingerstick Whole Blood specimens:
   - Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.
   - Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger
   - Puncture the skin with a sterile lancet. Wipe away the first sign of blood.
   - Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
4. Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Whole blood collected by venipuncture should be stored at 2-8 C if the test is to be run within two days of collection. For long term storage, specimens should be kept below -20 C. Whole blood collected by fingerstick should be tested immediately.
5. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly for more than three times.
6. If specimens are to be shipped, they should be packed in compliance with federal regulations covering the transportation of etiologic agents.

TEST PROCEDURE
Allow the test, specimen, Buffer and/or controls to reach room temperature (15-30 C) prior to testing.
1. Bring the pouch to room temperature before opening it. Remove the Test Cassette from the sealed pouch and use it as soon as possible.
2. Place the cassette on a clean and level surface.
   For Whole Blood specimen:
   - Use a pipette: Transfer 5 µL of well mixed whole blood to the specimen well, then add 3 drops of Buffer (approximately 180 µL).
   - Use a disposable specimen dropper: Hold the dropper vertically, draw the specimen up to the Fill Line as shown in illustration below (approximately 5 µL). Transfer the specimen to the specimen well, then add 3 drops of Buffer (approximately 180 µL) and start the timer.
3. Wait for the colored line(s) to appear. Read results at **10 minutes**. Do not interpret the result after **20 minutes.**



INTERPRETATION OF RESULTS
(Please refer to the illustration above.)
POSITIVE:* Two or Three distinct colored lines appear.
***P. falciparum* or mixed malaria infection:** one line appears in the control region, one line appears in Pan line region and one line appears in P.f. line region.
***P. falciparum* infection:** one line appears in the control region, and one line appears in P.f .line region.
Non-*falciparum Plasmodium* species infection: one line appears in the control region and one line appears in Pan line region.
***NOTE:** The color intensity of P.f. or Pan test lines may vary depending on the concentration of antigens, viz., HRP-II or Aldolase present in the specimen.
NEGATIVE: Only one colored line appears in the control region.
INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test device. If the problem persists, discontinue using the test kit immediately and contact Meridian's Technical Services Department 1-800-343-3858 or your local distributor.

QUALITY CONTROL
This test should be performed per applicable local, state, or federal regulations or accrediting agencies.
Internal procedural controls are included in the test. A colored line appearing in the control region (C) is an internal procedural control. It confirms sufficient specimen volume and correct procedural technique.

External controls are not supplied with this kit; however, it is recommended that positive and negative external controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

If the expected control reactions are not observed, repeat the control tests as the first step in determining the root cause of the failure. If control failures are repeated please contact Meridian's Technical Services Department at 1-800-343-3858 (US) or your local distributor.

EXPECTED VALUES
TruQuick Malaria P.f./Pan was compared with traditional thick and thin blood films microscopic analysis. The correlation between the two systems is over 99.0%.

LIMITATIONS OF THE PROCEDURE
1. TruQuick Malaria P.f./Pan is for in vitro diagnostic use only. This test should be used for the detection of P.f., P.v., P.o., P.m. antigens in whole blood specimens only. Neither the quantitative value nor the rate of increase in P.f., P.v., P.o., and P.m. concentration can be determined by this qualitative test.
2. TruQuick Malaria P.f./Pan will only indicate the presence of antigens of *Plasmodium* spp. (P.f., P.v., P.o., P.m.) in the specimen and should not be used as the sole criterion for the diagnosis of malaria infection.
3. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
4. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of malaria infection.

SPECIFIC PERFORMANCE CHARACTERISTICS
Sensitivity
TruQuick Malaria P.f./Pan was compared with microscopy on clinical samples. The results show that the sensitivity of TruQuick Malaria P.f./Pan is > 99.9% when compared to results obtained with microscopy.
Specificity
TruQuick Malaria P.f./Pan uses antibodies that are highly specific to Malaria P.f.-specific and Pan-malarial antigens in whole blood. The results show that the specificity of TruQuick Malaria P.f./Pan is > 99.9%, when compared to results obtained with microscopy.

Method		Microscopy			Total Results
TruQuick Malaria P.f./ Pan	Results	Positive		Negative	
		P. v.	P. f.		
	Positive	54*	85**	0	139
	Negative	1	0	500	501
Total Results		55	85	500	640

Comment: Blood Samples infected by *Plasmodium falciparum* (n = 85), *Plasmodium vivax* (n = 54) were included, as well as 500 malaria negative samples to be confirmed with microscopy.
Note: *There was one *P. vivax* sample to show a P.v. line and a P.f. line.
** There were two *P. falciparum* samples that both showed a P.v. line and a P.f. line.
Sensitivity for P.f.-specific antigens: 85/85 > 99.9 %(95% CI***: 96.5%~100.0%)
Sensitivity for P.v. antigens: 54/55 = 98.2% (95% CI***: 90.3%~100.0%)
Specificity: 500/500 > 99.9% (95% CI***: 99.4%-100.0%)
Correlation: (54+85+500)/(54+85+1+500) = 99.8% (95% CI***: 99.1%-100.0%)
*** Confidence Intervals

Minimum Detection Level

Type	Parasites/µL
P. falciparum	200
Plasmodimum non-*falciparum* species (*P. vivax*)	1500

REPRODUCIBILITY
Intra-Assay Precision
Within-run precision was determined by using 15 replicates of four specimens: a negative, a P.f. positive, a Pan positive and an P.f./Pan dual positive. The specimens were correctly identified > 99% of the time.
Inter-Assay Precision
Between-run precision was determined by 15 independent assays on the same four specimens: negative, a P.f. positive, a Pan positive and an P.f./Pan dual positive. Three different lots of TruQuick Malaria P.f./Pan were tested using these specimens. The specimens were correctly identified > 99% of the time.

CROSSREACTIVITY
Specimens containing the following were tested with TruQuick Malaria P.f./Pan and were nonreactive: RF (10), HBsAg (10), HBsAb (10), HBeAg (5), HBeAb (5), HBcAb (5), HCV (5), HIV (10), Syphilis (10), HAMA (3), *H. pylori* (3), MONO (3), anti-CMV (3), anti-Rubella (2), anti-TOXO (2).

TESTS FOR INTERFERING SUBSTANCES

The following potentially interfering substances were added to negative and low positive samples:

Ascorbic Acid 2 g/mL	Acetaminophen 20 mg/dL
Gentisic Acid 20 mg/dL	Acetylsalicylic Acid 20 mg/dL
Oxalic Acid 60 mg/dL	Creatin 200 mg/dL
Bilirubin 1 g/dL	Caffeine 20 mg/dL
Albumin 2 g/dL	

REFERENCES

1. MaConell B. Malaria Laboratory Diagnosis. January 2001.
2. Cooke AH, Chiodini PL, Doherty T. et al. Comparison of a parasite lactate dehydrogenase-base immunochromatographic antigen detection assay with microscopy for the detection of malaria parasite in human blood samples. Am J Trop Med Hyp.1999, Feb:60(2):173-2.

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SYMBOL USAGE

You may see one or more of these symbols on the labeling/packaging of this product:

Key guide to symbols

	Use By	CONTROL +	Positive control
LOT	Batch Code	CONTROL −	Negative control
IVD	In vitro diagnostic medical device	EC REP	Authorized Representative in the European Community
CE	This product fulfills the requirements of Directive 98/79/EC on in vitro diagnostic medical devices	SMP PREP DIL SPE	Sample Preparation Apparatus containing Sample Diluent
REF	Catalogue number		Do not freeze
	Consult Instructions for Use	BUF RXN	Reaction Buffer
	Manufacturer		For IVD Performance Evaluation Only
Σ	Contains sufficient for <n> tests	SOLN STOP	Stopping Solution
	Temperature limitation	CONJ ENZ	Enzyme Conjugate
SN	Serial number	CONTROL	Assay Control
TEST	Test Device	REAG	Reagent
	Date of manufacture	BUF WASH	Wash Buffer
BUF	Buffer		Warning
CONJ	Conjugate	DIL SPE	Specimen Diluent (or Sample Diluent)
SUBS	Substrate	BUF WASH 20X	Wash Buffer Concentration: 20X
RUO	Research Use Only	DET REAG	Detection Reagent
IUO	Investigational Use Only	Rx Only	Prescription Use Only
	Do not use if package is damaged		

For technical assistance, call Technical Support Services at 800-343-3858 between the hours of 8AM and 6PM, USA Eastern Standard Time. To place an order, call Customer Service Department at 800-543-1980.