

WHO Prequalification of In Vitro Diagnostics PUBLIC REPORT

Product: ONE STEP Malaria (Pf/Pv) Tri-line Test WHO reference number: PQDx 0627-017-00

ONE STEP Malaria (Pf/Pv) Tri-line Test with product codes ITPW11009-TC25 and ITPW11009-TC40 manufactured by InTec Products, Inc., Rest of World regulatory, was accepted for the WHO list of prequalified in vitro diagnostics and was listed on 28 May 2024.

Summary of WHO Prequalification Assessment for One Step Malaria (Pf/Pv) Tri-Line Test

	Date	Outcome
Prequalification listing	28 May 2024	listed
Dossier assessment	12 April 2024	MR
Site inspection of quality management system	11 to 13 October 2023	MR
Product performance evaluation	Quarter 3 2021	MR

MR: Meets Requirements

Intended use

According to the intended use claim from InTec Products, Inc., *“One Step Malaria (Pf/Pv) Tri-line Test is a colloidal gold, two site sandwich immunoassay utilizing whole blood (venous and fingerstick) for the detection of Pf specific histidine rich protein-II (Pf HRP-II) and Pv specific pLDH. This rapid test can be used as an aid in the diagnosis and differentiation of malaria infections caused by P.falciparum and P.vivax for symptomatic patients¹, including adults (including pregnant women) and children. This test is intended for professional use by laboratory professionals, trained healthcare workers or trained lay providers in laboratory and non-laboratory settings.”*

Assay description

According to the claim of assay description from InTec Products, Inc, *“Colloid gold conjugated-Anti-HRP-II(a) and colloid gold conjugated-Anti-pLDH(a) are pre-applied in the reaction pad. Anti-HRP-II(b) is pre-coated in the Pf band region of the membrane. Anti-pLDH(b) is pre-coated in the Pv band region of the membrane. After the buffer is added, red blood cells will be lysed.*

For Pf positive specimens, colloid gold conjugated-Anti-HRP-II(a) will react with HRP-II released from red blood cells and form a colloid gold conjugated-Anti-HRP-II(a)-HRP-II

complex. The complex will migrate through the test strip and be captured by Anti-HRP-II(b) pre-coated in the Pf band region, forming a Pf band.

For Pv-positive specimens, colloid gold conjugated-Anti-pLDH(a) will react with pLDH released from red blood cells and form a colloid gold conjugated-Anti-pLDH(a)-pLDH complex. The complex will migrate through the test strip and be captured by Anti-pLDH(b) pre-coated in the Pv band region, forming a Pv band.

For Pf and Pv co-infected specimens, two kinds of complexes above will form. The complexes will migrate through the test strip and be captured by correlated antibodies pre-coated in the Pf band region and Pv band region, forming a Pf band and a Pv band.

A negative specimen will not produce a Pf band or Pv due to the absence of a colloidal gold conjugate/plasmodium antigen complex. To ensure assay validity, a control band in the control band region will appear at the end of the test procedure regardless of the test result. Only when the control band appears the assay is valid.”

Test kit contents

Component	25 Tests/Kit (T/K) (ITPW11009-TC25)	40 T/K (ITPW11009-TC40)
Cassette	1 x 25 pieces	1 x 40 pieces
Dropper	1 x 25 pieces	1 x 40 pieces
Buffer bottle	2mL x 3 bottles	2mL x 4 bottles
Lancet	1 x 25 pieces	1 x 40 pieces
Alcohol swab	1 x 25 pieces	1 x 40 pieces
Instructions for use	1 x 1 piece	1 x 1 piece

Items required but not provided:

- Timer or stopwatch.
- Blood sampling tools (sterile gauze pad, venous puncture device, collection tube with EDTA/heparin sodium/sodium citrate for whole blood or plasma, collection tube with no anticoagulant for serum.)
- Biohazard waste bin and sharps bin.
- Disposable gloves.
- A calibrated precision pipette and applicable pipette tips.

Storage

The test kit should be stored at 2-40 °C.

Shelf-life upon manufacture

24 months.

Warnings/limitations

Please refer to the current version of the manufacturer's instructions for use attached to this public report.

Prioritization for Prequalification Assessment

Based on the established criteria, the One Step Malaria (Pf/Pv) Tri-Line Test was given priority for WHO prequalification assessment.

Dossier assessment

InTec Products, Inc. submitted a product dossier for One Step Malaria (Pf/Pv) Tri-Line Test as per the "Instructions for compilation of a product dossier" (PQDx_018). The information (data and documentation) submitted in the product dossier was reviewed by WHO staff and external technical experts (assessors) appointed by WHO. The manufacturer's responses to the nonconformities found during dossier screening and assessment findings were accepted on 12 April 2024.

Commitments for prequalification

1. The manufacturer must submit additional information regarding the formulation and composition. At the time of publication of this Public Report, the information was provided and is under review.
2. The manufacturer must submit additional information regarding the specimen type. At the time of publication of this Public Report, the information was provided and is under review.
3. The manufacturer must submit additional information regarding analytical specificity. At the time of publication of this Public Report, the information was provided and is under review.
4. The manufacturer must submit additional information regarding the clinical evaluation. At the time of publication of this Public Report, the information was provided and is under review.

Based on the product dossier screening and assessment findings, the product dossier for the ONE STEP Malaria (Pf/Pv) Tri-line Test meets WHO prequalification requirements.

Manufacturing site inspection

An onsite inspection of InTec Products, Inc. at 332 Xinguang Rd, Xinyang IND AREA, Haicang, Xiamen 361011, China, was conducted from 11 to 13 October 2023. At the time of considering the product application for Prequalification, the Manufacturer of the product had a well-established quality management system and manufacturing practices in place

that would support the manufacture of a product of consistent quality. Routine inspections of the Manufacturing site will be conducted with copies of the WHO Public Inspection Report (WHOPIR) published on the WHO Prequalification web page as per Resolution WHA57.14 of the World Health Assembly. Note that a WHOPIR reflects the information on the most current assessment performed at a manufacturing site for in vitro diagnostic products and summarises the assessment findings.

<https://extranet.who.int/pqweb/vitro-diagnostics/who-public-inspection-reports>

All published WHOPIRs are with the agreement of the manufacturer. Based on the site inspection and corrective action plan review, the quality management system for the ONE STEP Malaria (Pf/Pv) Tri-line Test meets WHO prequalification requirements.

Product performance evaluation

ONE STEP Malaria (Pf/Pv) Tri-line Test was evaluated in the 3rd quarter of 2021 at Centers of Disease Control and Prevention on behalf of WHO according to protocol PQDx_317, version 2.1. From this evaluation, we drew the following conclusions.

ONE STEP Malaria (Pf/Pv) Tri-line Test was evaluated against a *Plasmodium falciparum* cultured line panel, *P. falciparum* wild-type parasite panel, *P. vivax* wild-type parasite panel and a *P. falciparum* and *P. vivax* negative panel.

Performance characteristics		
	<i>P. falciparum</i>	<i>P. vivax</i>
Panel detection score at 200 parasites/ μ L (N _{Pf} =100) (N _{Pv} =35)	93/100, 93.0%	35/35, 100%
False positive results %	Negative specimens: 0/200, 0% Of which, clean negative specimens: 0/104, 0.0%	
Invalid rate % (N= 1010)	0/1010, 0.0%	
Inter-reader variability % (N= 1010)	HRP-2 test line: 1.0% (10/1010) Pv-pLDH test line: 0.3% (3/1010)	
The lowest concentration of HRP-2 was detected using the 1 st WHO International standard for Pf antigens (NIBSC code: 16/376)	HRP-2 test line: 31.3 IU/mL for both lots Pv-pLDH test line: N/A	

Operational characteristics and ease of use

This assay does not require laboratory equipment and can be performed in laboratories with limited facilities or in non-laboratory settings.

The assay was found easy to use by the operators performing the evaluation.

Key operational characteristics	
Specimen types and volume	5 µL of capillary or venous whole blood
Number of steps*	2 steps in total 1 step with specimen transfer device (precision pipette was used during the evaluation)
Time to result	15 minutes
Endpoint stability (interval)	5 minutes (the test can be read between 15 and 20 minutes after addition of diluent)
Internal QC	Yes, reagent addition control

* *Definition: each action required to obtain a result (excluding specimen collection, device preparation – opening the pouch), e.g. for RDTs: add specimen, add buffer (2 steps).*

Based on these results, the performance evaluation for ONE STEP Malaria (Pf/Pv) Tri-line Test meets the WHO prequalification requirements.

Labelling

- 1. Labels**
- 2. Instructions for use**

1. Labels

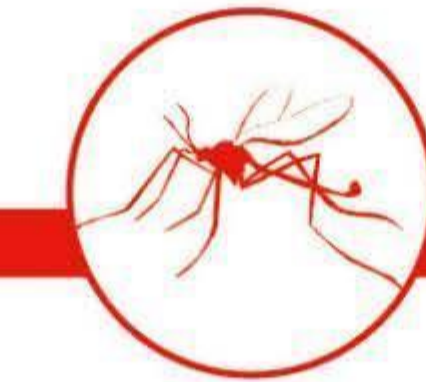
1.1. 25 T/K, product code ITPW11009-TC25



ONE STEP Malaria (Pf/Pv) Tri-lineTest

Malaria Antigen Pf/Pv (HRP2/pLDH) RDT

Malaria



- Content**
25 Cassettes
25 Droppers
3 Buffer bottles
25 Lancets
25 Alcohol swabs
1 Instructions for use

- Required but not provided**
Timer or stopwatch
Blood sampling tools
Biohazard waste bin
Sharps bin
Disposable gloves

REF ITPW11009-TC25

InTec PRODUCTS, INC.
332 Xinguang Road, Xinyang Industrial Area,
Haicang, 361022, Xiamen, Fujian, P.R.China
Tel: +86 592 6807188
Website: www.intecasi.com
Email: intecproducts@asintec.com



- Required but not provided**
Timer or stopwatch
Blood sampling tools
Biohazard waste bin
Sharps bin
Disposable gloves



InTec PRODUCTS, INC.

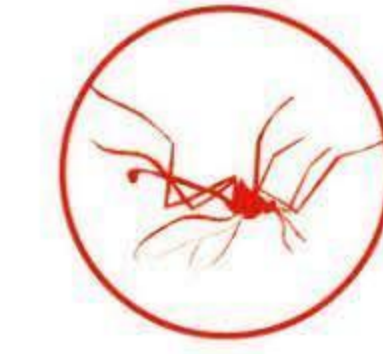
InTec PRODUCTS, INC.
332 Xinguang Road, Xinyang Industrial Area,
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Website: www.intecasi.com
Email: intecproducts@asintec.com



ONE STEP Malaria (Pf/Pv) Tri-lineTest

Malaria Antigen Pf/Pv (HRP2/pLDH) RDT



Rapid test for the antigen detection of malaria (Plasmodium falciparum and Plasmodium vivax)

REF ITPW11009-TC25





One Step Malaria (Pf/Pv) Tri-line Test *Malaria*



Malaria Antigen Pf/Pv (HRP2/pLDH) RDT

 **ADVANCED QUALITY
IN MEDICAL DIAGNOSTICS**

One Step Malaria (Pf/Pv) Tri-line Test

REF

LOT



Contents

- 1 Cassette
- 1 Dropper
- 1 Desiccant



InTec PRODUCTS, INC.

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Haicang, 361022, Xiamen, Fujian, P.R.China

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Website: www.intecasi.com

Email: intecproducts@asintec.com





Buffer bottle

For One Step Malaria (Pf/Pv) Tri-line Test



IVD



REF

ITPW11009-TC25

Vol: 2mL


LOT

Storage: 2-40°C



Alcohol Swabs

Produce Code : 06-023060
Specifications of Blade : 30mm × 60mm
Qty: 25Pcs/Bag

 Manufacturer:
SteriLance Medical (Suzhou) Inc .
No.168 PuTuoShan Road, New District,
215153 Suzhou, Jiangsu, P.R.China



REF 06-023060

LOT XXXXX

 YYYY-MM-DD

 YYYY-MM-DD

Intended use : It's used for skin disinfection before blood sampling, injection and infusion.

Instructions for Use :

1. Open the package and take out the alcohol swab;
2. Use the alcohol swab to wipe the skin;
3. After the alcohol on the surface is dried, the disinfection is completed;
4. Discard the used alcohol swab in the special container.

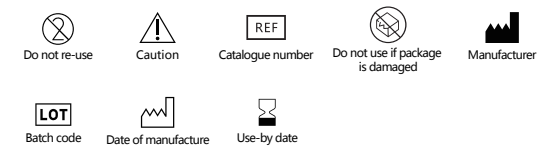
Contraindications :

1. Do not use if there is skin infection or skin damage on the wiping part.
2. It should be used with caution or follow the doctor's advice for the user allergic to alcohol.

Caution :

- This product is not suitable for trauma or burns. Stop the use and consult your doctor if you have symptoms of redness, allergies, swelling, pain or inflammation.
- Do not use the product if the package of alcohol swab is damaged.
- Alcohol swab is for external use only, not for eyes or mucous membrane. Please consult your doctor if it touches the wound.
- Do not use if there is skin infection or skin damage on the wiping part.
- The alcohol swab is for single use and shall be kept away from naked fire.
- Keep the alcohol swab away from children.
- Do not use beyond the use-by date.

Symbolic interpretation:








PANTONE Reflex Blue C

Size:50*40mm



Blood Lancets





Model / Specification : 1 / 28G


	LOT NO.	: 240607001
	EXP. DATE	: 2029-06-06
	MFG. DATE	: 2024-06-07
	QTY	: 25pcs




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(112406060710240607001

 **STERILE**  **MD**

 **STERILE R**  **40°C** **80%**  **UDI**  **0197**

 **EC REP** **Linkfar Healthcare GmbH**
Neederthorstraße 71, 40474 Düsseldorf, Germany
TEL: +49 211 33026618

 **Shandong Lianfa Medical Plastic Products Co., Ltd.**
No.15Shuangshan Sanjian Road, Zhangjiu, Jinan City, 250200, Shandong P. R. China

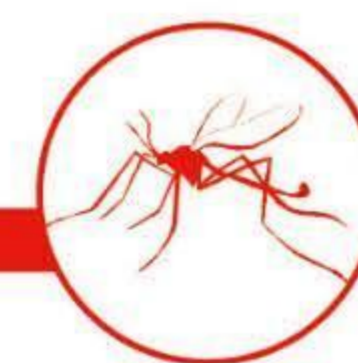
1.2. 40 T/K, product code ITPW11009-TC40



ONE STEP Malaria (Pf/Pv) Tri-lineTest

Malaria Antigen Pf/Pv (HRP2/pLDH) RDT

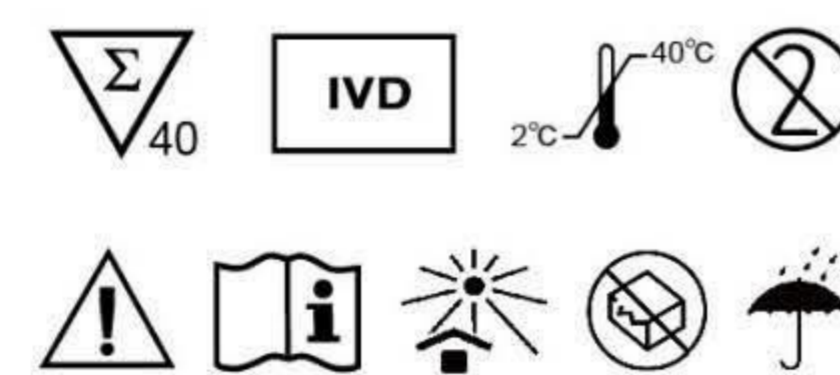
Malaria



Content
 40 Cassettes
 40 Droppers
 4 Buffer bottles
 40 Lancets
 40 Alcohol swabs
 1 Instructions for use

Required but not provided
 Timer or stopwatch
 Blood sampling tools
 Biohazard waste bin
 Sharps bin
 Disposable gloves

REF ITPW11009-TC40



REF ITPW11009-TC40

Content
 40 Cassettes
 40 Droppers
 4 Buffer bottles
 40 Lancets
 40 Alcohol swabs
 1 Instructions for use

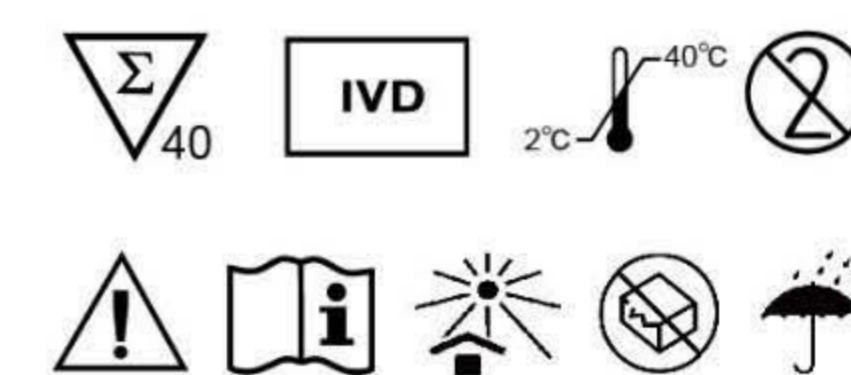


Required but not provided
 Timer or stopwatch
 Blood sampling tools
 Biohazard waste bin
 Sharps bin
 Disposable gloves

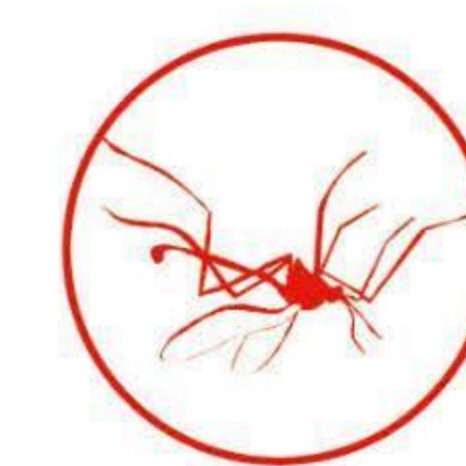
ONE STEP Malaria (Pf/Pv) Tri-lineTest

Malaria Antigen Pf/Pv (HRP2/pLDH) RDT

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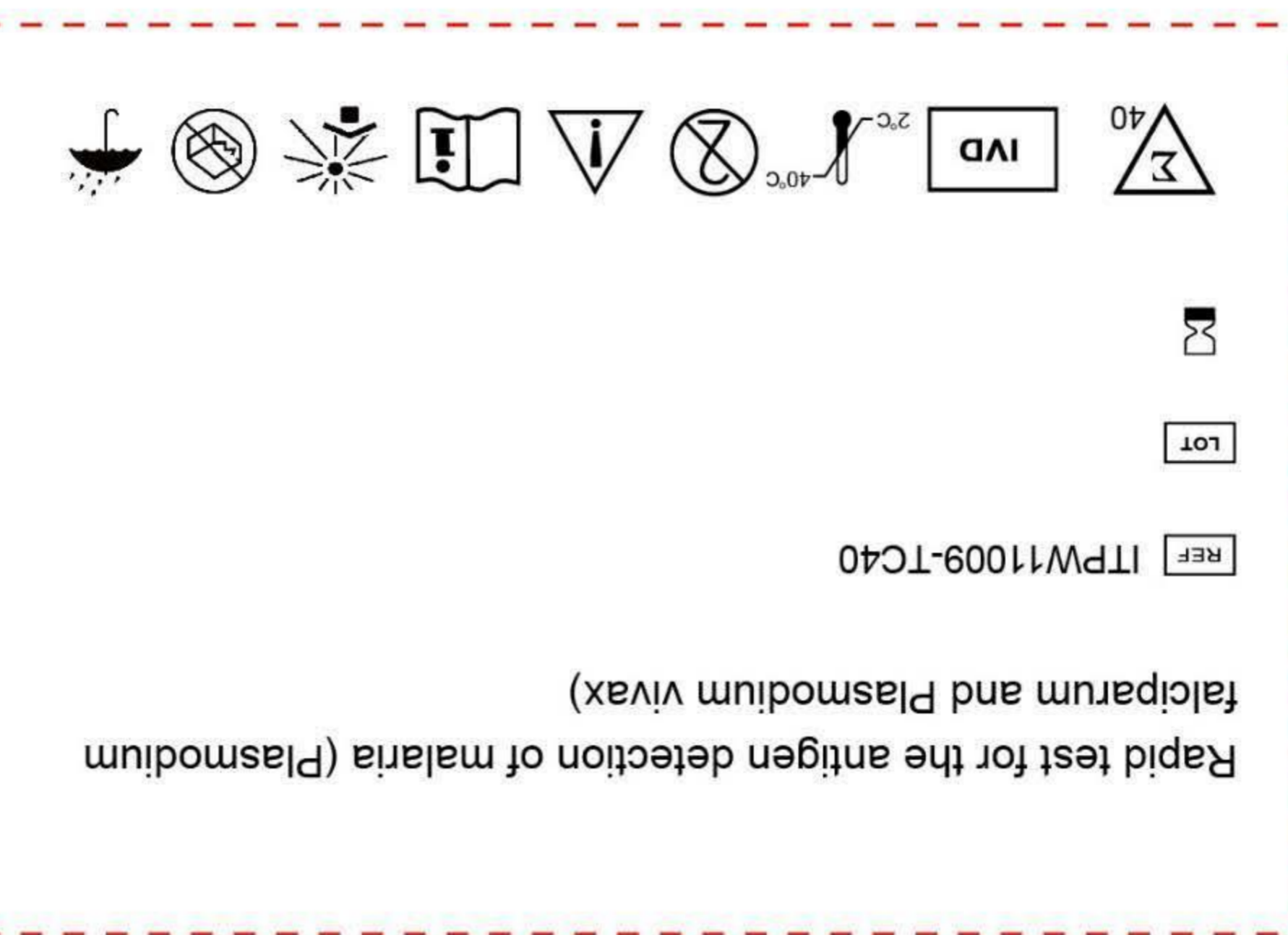


InTec PRODUCTS, INC.



ONE STEP Malaria (Pf/Pv) Tri-lineTest

Malaria Antigen Pf/Pv (HRP2/pLDH) RDT



**ADVANCED QUALITY
 IN MEDICAL DIAGNOSTICS**



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 Haicang, 361022, Xiamen, Fujian, P.R.China

Tel: +86 592 6807188
 Website: www.intecasi.com
 Email: intecproducts@asintec.com



One Step Malaria (Pf/Pv) Tri-line Test *Malaria*



Malaria Antigen Pf/Pv (HRP2/pLDH) RDT

 **ADVANCED QUALITY
IN MEDICAL DIAGNOSTICS**

One Step Malaria (Pf/Pv) Tri-line Test

REF

LOT



Contents

- 1 Cassette
- 1 Dropper
- 1 Desiccant



InTec PRODUCTS, INC.

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Haicang, 361022, Xiamen, Fujian, P.R.China

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Website: www.intecasi.com

Email: intecproducts@asintec.com





Buffer bottle

For One Step Malaria (Pf/Pv) Tri-line Test



IVD



REF

ITPW11009-TC40

Vol: 2mL


LOT

Storage: 2-40°C



Alcohol Swabs

Produce Code : 06-023060
Specifications of Blade : 30mm × 60mm
Qty: 40Pcs/Bag


 Manufacturer:
SteriLance Medical (Suzhou) Inc .
No.168 PuTuoShan Road, New District,
215153 Suzhou,Jiangsu, P.R.China



REF 06-023060

LOT XXXXX

 YYYY-MM-DD

 YYYY-MM-DD

Intended use : It's used for skin disinfection before blood sampling, injection and infusion.

Instructions for Use :

1. Open the package and take out the alcohol swab;
2. Use the alcohol swab to wipe the skin;
3. After the alcohol on the surface is dried, the disinfection is completed;
4. Discard the used alcohol swab in the special container.

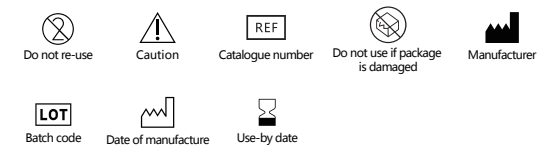
Contraindications :

1. Do not use if there is skin infection or skin damage on the wiping part.
2. It should be used with caution or follow the doctor's advice for the user allergic to alcohol.

Caution :

- This product is not suitable for trauma or burns. Stop the use and consult your doctor if you have symptoms of redness, allergies, swelling, pain or inflammation.
- Do not use the product if the package of alcohol swab is damaged.
- Alcohol swab is for external use only, not for eyes or mucous membrane. Please consult your doctor if it touches the wound.
- Do not use if there is skin infection or skin damage on the wiping part.
- The alcohol swab is for single use and shall be kept away from naked fire.
- Keep the alcohol swab away from children.
- Do not use beyond the use-by date.

Symbolic interpretation:








PANTONE Reflex Blue C

Size:50*40mm









Blood Lancets











Model / Specification : 1 / 28G


	LOT NO.	: 240607002
	EXP. DATE	: 2029-06-06
	MFG. DATE	: 2024-06-07
	QTY	: 40pcs




01206049517007000171290606
(1120606071)03240607002

  40°C  80%        0197

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Neanderthustraße 71, 40474 Düsseldorf, Germany
TEL: +49 211 33026618

 **Shandong Lianfa Medical Plastic Products Co., Ltd.**
No.15Shuangshan Sanjian Road, Zhangjiu, Jinan City, 250200, Shandong P. R. China

2. Instructions for use¹

¹ English version of the IFU was the one that was assessed by WHO. The manufacturer is responsible for ensuring correct translation into other languages.



REF ITPW11009-TC25
ITPW11009-TC40
01.05.14.079-240507

One Step Malaria (Pf/Pv) Tri-line Test

FOR IN VITRO DIAGNOSTIC USE ONLY. **IVD**

Please read this instructions for use carefully prior to use and strictly follow the instructions. Reliability of the assay cannot be guaranteed if there are any deviations from the instructions for use.

Clinical significance

Malaria is a serious, sometimes fatal, parasitic disease, widespread in the tropical and subtropical regions (mainly Africa, South America, and Southeast Asia). It is characterized by fever with chills, anemia and is caused by Plasmodium parasite that is transmitted to people through the bites of infected female Anopheles mosquitoes.

Among several parasitic Plasmodium species that cause malaria in humans (i.e., P. falciparum, P. vivax, P. malariae, P. ovale, and P. knowlesi), P. falciparum (Pf) and P. vivax (Pv) are two pathogens posing the greatest threat as they are the deadliest or most prevalent.

Intended use

One Step Malaria (Pf/Pv) Tri-line Test is a colloidal gold, two site sandwich immunoassay utilizing whole blood (venous and fingerstick) for the detection of Pf specific histidine rich protein-II (Pf HRP-II) and Pv specific pLDH. This rapid test can be used as an aid in the diagnosis and differentiation of malaria infections caused by P.falciparum and P.vivax for symptomatic patients¹, including adult (including pregnant women) and children. This test is intended for professional use by laboratory professionals, trained healthcare workers or trained lay providers in laboratory and non-laboratory settings.

Summary

One Step Malaria (Pf/Pv) Tri-line Test is based on immunochromatography, and used for HRP-II/pLDH detection in human whole blood (venous and fingerstick)^{2,3}. It is a simple, visual qualitative test that detects Pf HRP-II and Pv pLDH in human whole blood, and presents the result within 20 minutes³.

Test principle⁴

Colloid gold conjugated-Anti-HRP-II(a) and colloid gold conjugated-Anti-pLDH(a) are pre-applied in the reaction pad. Anti-HRP-II(b) is pre-coated in the Pf band region of the membrane. Anti-pLDH(b) is pre-coated in the Pv band region of the membrane. After the buffer is added, red blood cells will be lysed.

For Pf positive specimens, colloid gold conjugated-Anti-HRP-II(a) will react with HRP-II released from red blood cells and form a colloid gold conjugated-Anti-HRP-II(a)-HRP-II complex. The complex will migrate through the test strip and be captured by Anti-HRP-II(b) pre-coated in the Pf band region, forming a Pf band.

For Pv positive specimens, colloid gold conjugated-Anti-pLDH(a) will react with pLDH released from red blood cells and form a colloid gold conjugated-Anti-pLDH(a)-pLDH complex. The complex will migrate through the test strip and be captured by Anti-pLDH(b) pre-coated in the Pv band region, forming a Pv band.

For Pf and Pv co-infected specimens, two kinds of complexes above will form. The complexes will migrate through the test strip and be captured by correlated antibodies pre-coated in the Pf band region and Pv band region, forming a Pf band and a Pv band.

A negative specimen will not produce a Pf band or Pv due to the absence of a colloidal gold conjugate/plasmodium antigen complex. To ensure assay validity, a control band in the control band region will appear at the end of the test procedure regardless of the test result.

Only when the control band appears the assay is valid.

Storage conditions and stability

One Step Malaria (Pf/Pv) Tri-line Test shall be stored at 2-40°C. Test cassette should be used immediately upon opening the foil pouch. Buffer should be and used within 8 weeks after opening.

Warnings and precautions

The warnings and precautions are included, but not limited to the following:

- This product is for in vitro diagnosis of the infection of Pf and/or Pv only, and other diseases cannot be analyzed with any component of this kit.
- Wear gloves during the entire testing process.
- Do not use expired reagents or test cassettes.
- Do not use accessories if the seal or package is broken.
- Do not use test cassette if the foil pouch is damaged or the seal is broken.
- Do not use the provided lancet if the cap is already pulled off before use.
- Do not reuse the accessories. All the accessories are for single use.
- Do not reuse the test cassette. Each cassette enclosed in a foil pouch is only for single use.
- Do not suck buffer or specimen by mouth.
- Do not eat or smoke while handling specimens.
- Do not store specimen in dropper, it is only used for specimen collection.
- Do not use pooled specimens or specimens other than specified (i.e. saliva, urine).
- Do not interchange reagents among kits of different batch number or even products.
- Do not perform the test under environment which leads to rapid evaporation (e.g. close to a running fan or air conditioner).
- Ensure the specimen is added correctly prior to the addition of buffer.
- Avoid contact between the "S" well of cassette and buffer bottle to prevent contamination of buffer.

- Clean and disinfect all the areas that may be contaminated by spills of specimens or reagents with appropriate disinfectant.
- Decontaminate and dispose of all specimens, reagents, accessories and other potentially contaminated materials as infectious wastes in a biohazard container. Used lancet should be disposed of in a sharps bin.
- Operate the test at conditions that are both >40°C and >70% relative humidity (RH) might lead to incorrect results.
- Sample buffer contains 0.3% Triton X-100 and 0.01% sodium azide. If contact with buffer to the eyes and/or skin, wash affected area with soap and water immediately. Do not dispose buffer enter drains, and offer surplus solutions to a licensed disposal company (dispose of contents/container to an approved waste disposal plant).

Reagents and materials provided

Table 1 Reagents and materials provided

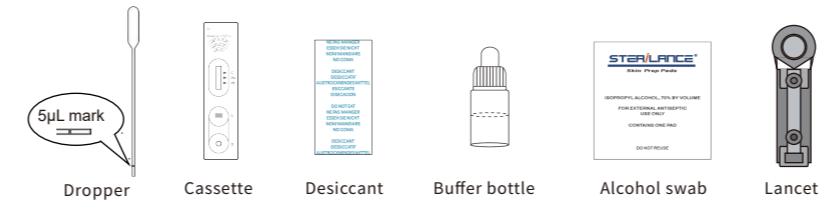
Components	25 tests (ITPW11009-TC25)	40 tests (ITPW11009-TC40)
Cassette	1 x 25 pieces	1 x 40 pieces
Dropper	1 x 25 pieces	1 x 40 pieces
Buffer bottle	2mL x 3 bottles	2mL x 4 bottles
Lancet	1 x 25 pieces	1 x 40 pieces
Alcohol swab	1 x 25 pieces	1 x 40 pieces
Instructions for use	1 x 1 piece	1 x 1 piece

Materials required but not provided

- Timer or stopwatch
- Blood sampling tools (sterile gauze pad, venous puncture device, collection tube with EDTA/heparin sodium/sodium citrate for whole blood or plasma, collection tube with no anticoagulant for serum.)
- Biohazard waste bin and sharps bin
- Disposable gloves
- A calibrated precision pipette and applicable pipette tips

Preparation

1. Unseal the foil pouches. The components are as below:



2. Wear gloves.



3. Mark the sample ID number.



I. Fingerstick whole blood

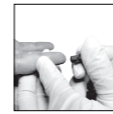
4. Clean the finger with alcohol swab and leave it to dry.



5. Twist the lancet cap for over 180° and remove it.



6. Place the lancet firmly on side of finger (avoid callus) to trigger it



7. Gently press around the bleeding point. Wipe away the first drop of blood.



8. Gently squeeze and release the bulb of the dropper to collect blood until reaching 5µL mark.



9. Touch the dropper tip on the pad of "S" well, to add all the blood collected.



10. Add 3 drops of buffer into "D" well immediately.

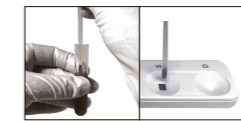


11. Wait and interpret the result between 15-20 minutes.

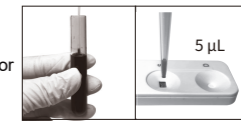


II. Venous whole blood

4. Gently squeeze and release the bulb of the dropper to collect blood until reaching 5µL mark. Touch the dropper tip on the pad of "S" well to add all the blood collected.



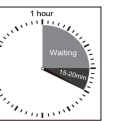
Or, if using transfer pipette add 5 µL whole blood into "S" well.



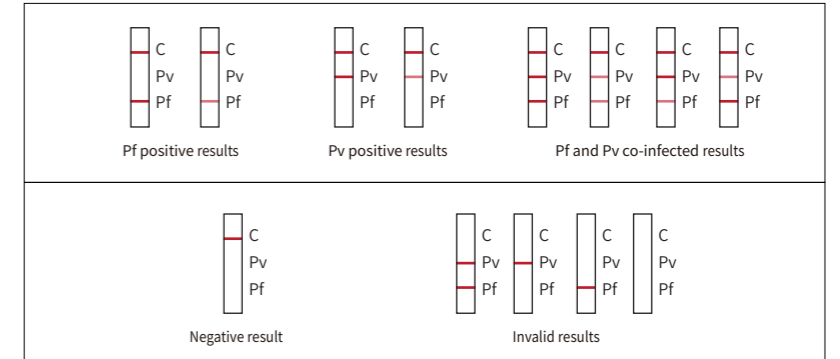
5. Add 3 drops of buffer into "D" well immediately.



6. Wait and interpret the result between 15-20 minutes.



Test results



Specimen collection and storage

Fingerstick whole blood

- 1) Rub the target finger (middle or ring finger) to stimulate blood flow, and avoid calloused areas of the finger. Clean the finger with an alcohol swab (Figure I.4) and leave it to dry.
- 2) Prick the finger with the provided lancet: (a) Twist clockwise the protective cap and remove it, see Figure I.5 for details. (b) Place the lancet firmly on the finger to trigger it, see Figure I.6 for details.
- 3) Gently press the bleeding point (avoid excessive bleeding). Wipe away the first drop of blood with a sterile gauze pad (Figure I.7). Allow a new drop of blood to form.
- 4) Transfer the blood specimen with the dropper provided. Gently squeeze the bulb of the dropper, touch the blood, and gently release the bulb to draw up the blood (Figure I.8).

Note: The fingerstick blood should be tested immediately after collection.

Venous whole blood

Collect whole blood specimen into a collection tube (with specified anticoagulant, namely EDTA, heparin sodium or sodium citrate) according to standard venous blood sampling process. Then gently mix the venous blood collection tube by inverting the specimen to make it homogenous for sampling. Other anticoagulants may lead to incorrect results.

Notes:

- Venous whole blood specimens can be stored at 2-8°C for up to 7 days if not tested immediately. Store at -18°C or below for 30 months. Frozen specimens shall be equilibrated to room temperature (10-30°C) before testing. Multiple freeze-thaw cycles should be avoided (3 times at most).
- Avoid using hyperlipidemia or excessively aged specimens.

Test procedure

1. Do not open the pouch until ready to perform a test. Use the test under low environment humidity (RH ≤ 70%) within 1 hour.
2. Equilibrate all reagents and specimens to room temperature (10-30°C) before use.
3. Unseal the foil pouch and put the cassette on a flat, clean and dry surface.
4. Mark the sample ID number on test cassette.
5. Gently squeeze and release the bulb of the dropper to collect blood until reaching 5µL mark (or 5µL by the transfer pipette) and touch the dropper tip on the pad of "S" well.
6. Then add 3 drops of lysis buffer into "D" well and start the timer immediately.
7. Wait for at least 15 minutes (and 20 minutes at most) to interpret the result.

Caution:

- Always apply specimen with a new and clean dropper or pipette tip to avoid cross contamination.
- Negative results cannot rule out the possibility of the exposure to or the infection with of Pf and/or Pv.

Result interpretation

Pf positive: Purplish red bands appear at both the Pf band area (even though very faint) and the control band area indicates a positive result.

Pv positive: Purplish red bands appear at both the Pv band area (even though very faint) and the control band area indicates a positive result.

Pf and Pv co-infected: Purplish red bands appear at Pf band area (even though very faint), Pv band area (even though very faint) and the control band area indicates a positive result.

Negative: Purplish red band only appears on control band area indicates a negative result.

Invalid 1: A purplish red band appears only at the Pf band area of the cassette. Repeat the test. Contact the supplier if the control band remains invisible.

