

WHO Prequalification of In Vitro Diagnostics PUBLIC REPORT

Product: MERISCREEN HIV 1-2 WB
WHO reference number: PQDx 0464-074-00

MERISCREEN HIV 1-2 WB with product codes **HVWRPD-01, HVWRPD-02, HVWRPD-06, HVWRPD-07, HVWRPD-08** manufactured by **Meril Diagnostics Pvt. Ltd.**, CE-Mark – Annex **IV.4**, was accepted for the WHO list of prequalified in vitro diagnostics and was listed on 24 September 2020

Summary of WHO prequalification assessment for MERISCREEN HIV 1-2 WB

	Date	Outcome
Prequalification listing	24 September 2020	listed
Dossier review	Abridged	N/A
Site inspection(s) of the quality management system	17 June 2020	MR
Product performance evaluation	Quarter (Q) 4-2019 to Q 2-2020	MR

MR: Meet Requirements

N/A: Not Applicable

This public report has since been amended. Amendments may have arisen because of changes to the prequalified product for which the WHO has been notified and has undertaken a review. Amendments to the report are summarized in the following table, and details of each amendment are provided below.

Version	Summary of amendment	Date of report amendment
2.0	Extension of shelf life from 18 months to 24 months.	17 March 2022
3.0	Addition of three pack sizes with new product codes to the existing pack sizes, i.e., 50 tests, 10 tests & 100 tests. Product codes for these new pack sizes are HVWRPD-06 (50T), HVWRPD-07 (10T), and HVWRPD-08 (100T). Amended time to test results from 22 to 20 minutes in the public report's operational characteristics and ease of use section.	11 April 2023

Intended use:

According to the claim of intended use from Meril Diagnostics Pvt. Ltd, “*MERISCREEN HIV 1-2 WB Test is a single use, qualitative, screening, in-vitro diagnostic immunochromatography assay and used for detection of antibodies (IgG, IgA and IgM) specific to HIV-1 and HIV-2 in human fingerstick whole blood, venous whole blood, serum or plasma specimens. The test is intended for trained users (either in laboratory or in point-of-care setting) to aid in the diagnosis of infection with HIV-1 and HIV-2 and for the diagnosis of HIV infection in symptomatic, asymptomatic and persons at risk of HIV infections. It is not intended for testing children below 2 years. The assay is manual and does not require additional instrument.*”

Assay Description:

According to the claim of assay description from Meril Diagnostics Pvt. Ltd, “*the MERISCREEN HIV 1-2 WB rapid test kit contains a membrane strip, which is pre-coated with HIV-1 & HIV-2 antigens on test region ‘1’ and test region ‘2’ respectively. Recombinant antigen gold conjugate will form a coloured band in the test region ‘1’ and test region ‘2’ of result window. As the test sample flows through the membrane after addition of Assay buffer, the antigen gold conjugate complexes with anti-HIV antibodies. The complex moves further on the membrane towards the test region, where HIV antigens are coated and leads to formation of reddish purple band(s) at test region(s). Absence of test bands indicates a negative test results. The control band is used for procedural control and should always appear if the test procedure is performed correctly. The intensity of control band has nothing to do with intensity of test band(s).*”

Test kit contents:

Component	30 tests (product code HVWRPD- 01)	40 tests (product code HVWRPD- 02)	50 tests (product code HVWRPD- 06)	10 tests (product code HVWRPD- 07	100 tests (product code HVWRPD- 08
Pouches; each contains a Test device with one desiccant	30	40	50	10	100
Assay Buffer bottle	2 X 3.0 ml vials	2 X 3.0 ml vials	3 X 3.0 ml vials	1 X 3.0 ml vials	5 X 3.0 ml vials
Specimen transfer device- capillary tubes- 10 µl)	30	40	50	10	100
Sterile lancets	30	40	50	10	100
Alcohol swabs	30	40	50	10	100
Pack insert	1	1	1	1	1

Items required but not provided:

- Timer
- New pair of disposable gloves
- Pen
- Sterile gauze (for fingerstick whole blood specimens)
- Plaster
- Centrifuge (for serum/plasma specimens only)
- Biohazard Sharp Box
- Non-sharp disposal container
- Venous blood collection materials and precision pipette plus tips

Storage:

The test kit should be stored at 2-30 °C.

Shelf-life upon manufacture:

24 months.

Warnings/limitations:

Please refer to the instructions for use.

Prioritization for prequalification

Based on the established eligibility criteria, MERISCREEN HIV 1-2 WB was given priority for the WHO prequalification assessment.

Product dossier assessment

In accordance with the WHO procedure for abridged prequalification assessment, Meril Diagnostics Pvt. Ltd. was not required to submit a product dossier for MERISCREEN HIV 1-2 WB as per the *“Instructions for compilation of a product dossier”* (PQDx_018 version 3). Notwithstanding, certain aspects of the product dossier previously submitted for stringent regulatory review were reviewed by an assessor during the desk assessment of the site of manufacture.

Manufacturing site inspection

Due to the current outbreak of COVID-19 caused by the 2019 novel coronavirus (SARS-CoV-2) that has constituted a Public Health Emergency of International Concern, an onsite inspection of this facility was not possible. In lieu of an onsite inspection, WHO performed a desk assessment of the site of manufacture (Second Floor, D1-D3, Meril Park, Survey No 135/2/B & 174/2, Muktanand Marg, Chala, Vapi, 396191, India) of MERISCREEN HIV 1-2 WB

in June 2020 as per the “*Information for manufacturers on prequalification inspection procedures for the sites of manufacture of diagnostics*” (PQDx_014 version 4).

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 desk assessment performed at a manufacturing site for *in vitro* diagnostic products and gives a summary of the desk assessment findings.

Information on the most current desk assessment can be found at:

https://www.who.int/diagnostics_laboratory/evaluations/PQDxSiteInspection/en/

All published WHOPIRs are with the agreement of the manufacturer.

The manufacturer's responses to the questions identified at the time of the desk assessment were accepted on 15 July 2020.

Product performance evaluation

MERISCREEN HIV 1-2 WB was evaluated by the National AIDS Research Institute, Pune, India, on behalf of WHO in the 4th quarter of 2019 and 1st quarter of 2020, according to protocol PQDx_030, version 10.

Clinical performance evaluation

In this limited laboratory-based evaluation of clinical performance characteristics, a panel of 1200 clinically-derived serum specimens (455 HIV-1 positive, 15 HIV-2 positive and 730 HIV negative) was used. The specimens were characterized using the following reference algorithm: Genscreen ULTRA HIV Ag-Ab (Bio-Rad) and AiD anti-HIV 1+2 ELISA (Beijing Wantai Biological Pharmacy Enterprise Co., Ltd) in parallel, followed by INNO-LIA HIV I/II Score (Fujirebio) on initially reactive specimens.

Clinical performance characteristics in comparison with an agreed reference standard		
	Initial (95% CI)	Final (95% CI)
Sensitivity % (N=470)	99.1 (97.8-99.8)	99.4 (98.1-99.9)
Specificity % (N= 730)	99.9 (99.2-100)	99.9 (99.2-100)
Invalid rate % (N= 1200)	0	
Inter-reader variability % (N= 1200)	0.1	

453/455 HIV-1 positive specimens were detected as HIV-1 by MERISCREEN HIV 1-2 WB. None of the HIV-1-positive specimens showed a reactive HIV-2 line.

14/15 HIV-2 positive specimens were detected as HIV-2 by MERISCREEN HIV 1-2 WB, with weak lines for 12 of these specimens. Of 15 HIV-2 positive specimens, MERISCREEN HIV 1-2 WB showed both HIV-1 and HIV-2 reactive lines in 1 (6.7%) specimen.

Analytical performance evaluation

Analytical performance characteristics	
Sensitivity during seroconversion on 5 seroconversion panels in comparison with a benchmark assay (AiD anti-HIV 1+2 ELISA)	Of a total of 34 specimens, 9 were detected by the assay under evaluation; versus 10 specimens detected by the benchmark assay. Seroconversion sensitivity index of 0.2; therefore, detection is 0.2 specimens later than the benchmark assay.
Analytical sensitivity on a mixed titer panel (PRB205)	All 25 specimens were correctly classified.
Analytical sensitivity on WHO reference preparation panel(s) (NIBSC code 02/210)	5 of 6 HIV types/subtypes were detected. HIV-1 subtype O contained in the panel was not detected.
Lot to lot variation on a dilution panel	Lot to lot variation was within +/- 1 two-fold dilutions for 9 of 10 dilution series. For one dilution series, a difference of two 2-fold dilution was observed between the two lots.

Operational characteristics and ease of use

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

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

Key operational characteristics	
Number of steps*	3 steps for whole blood 2 steps for serum/plasma
Time to result	20 minutes
Endpoint stability (interval)	10 minutes (the test can be read between 20 and 30 minutes after the 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 MERISCREEN HIV 1-2 WB meets the WHO prequalification requirements.









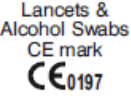


Labelling

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





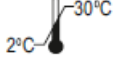




1. Labels

1.1 Product code HVWRPD-01






Product Box Label

REF	HVWRPD-01 30T	 Diagnostics
IVD	One Step Rapid Test for detection of Anti-HIV in Human Serum/Plasma/Whole Blood	
	MERISCREEN HIV 1-2 WB	
	KIT CONTAINS	
	1. 30 Test Devices, pouched with desiccant	
	2. 2 X 3.0 ml Assay Buffer Bottles	
	3. 01 No. Pack Insert	
	4. 30 Capillary Tube (10 µl)	
	5. 30 Alcohol Swabs	LOT XXXXXX
	6. 30 Sterile Lancets	 YYYY-MM
		 YYYY-MM
		
	 Lancets & Alcohol Swabs CE mark CE 0197	 1434
	Meril Diagnostics Pvt. Ltd. Second Floor, D1-D3, Meril Park, Survey No. 135/2/B & 174/2, Muktanand Marg, Chala, Vapi-396191, Gujarat, India. Tel.: +91-260-2408000, Fax: +91-260-2408025, E-mail: diagnostics@merillife.com, Web: www.merillife.com, Mfg.Lic.No.: MFG/MD/2018/000029	
EC REP	OBELIS S.A., Bd General Wahis 53, 1030, Brussels, Belgium. T +32.2.732.5954, F +32.2.732.6003, E mail@obelis.net	

Aluminum Pouch Label


REF	HVWRPD-01 30T	 Diagnostics
IVD	One Step Rapid Test for detection of Anti-HIV in Human Serum/Plasma/Whole Blood	
	MERISCREEN HIV 1-2 WB	
	For <i>in-Vitro</i> diagnostics use only	
	Do not open the foil pouch until it attains room temperature	
		LOT XXXXXX
		 YYYY-MM
		 YYYY-MM
	 1434	
	Meril Diagnostics Pvt. Ltd. Second Floor, D1-D3, Meril Park, Survey No. 135/2/B & 174/2, Muktanand Marg, Chala, Vapi-396191, Gujarat, India. Tel.: +91-260-2408000, Fax: +91-260-2408025, E-mail: diagnostics@merillife.com, Web: www.merillife.com, Mfg.Lic.No.: MFG/MD/2018/000029	
EC REP	OBELIS S.A., Bd General Wahis 53, 1030, Brussels, Belgium. T +32.2.732.5954, F +32.2.732.6003, E mail@obelis.net	


Assay Buffer Bottle Label


REF	HVWRPD-01 30T	
IVD	One Step Rapid Test for detection of Anti-HIV in Human Serum/Plasma/Whole Blood	
	MERISCREEN HIV 1-2 WB	
	Assy Buffer (Vol. 3.0ml)	LOT XXXXXX  YYYY-MM
 Meril Diagnostics Pvt. Ltd. Second Floor, D1-D3, Meril Park, Survey No. 135/2/B & 174/2, Muktanand Marg, Chala, Vapi-396191, Gujarat, India. Tel.: +91-260-2408000, Fax: +91-260-2408025, E-mail: diagnostics@merillife.com, Web: www.merillife.com, Mfg.Lic.No.: MFG/MD/2018/000029		
EC REP OBELIS S.A., Bd General Wahis 53, 1030, Brussels, Belgium. T +32.2.732.5954, F +32.2.732.6003, E mail@obelis.net		

Lancet

Product Name: Lancet

LOT	XXXX
	YYYY-MM
Qty.:	30 Nos.
<div style="display: inline-block; border: 1px solid black; padding: 2px 5px;">STERILE</div> <div style="display: inline-block; border: 1px solid black; padding: 2px 5px;">R</div>	


Meril Diagnostics Pvt. Ltd.
 Second Floor, D1-D3, Meril Park, Survey No.135/2/B &174/2, Muktanand Marg, Chala, Vapi-396191, Gujarat, India.
 T +91 260 2408000, F +91 260 2408025,
 E diagnostics@merillife.com, W www.merillife.com



Alcohol Swab


Product Name: Alcohol Swab	
(70% Isopropyl Alcohol)	
LOT	XXXX
	YYYY-MM
Qty.:	30 Nos.
	Meril Diagnostics Pvt. Ltd.
Second Floor, D1-D3, Meril Park, Survey No.135/2/B & 174/2, Muktanand Marg, Chala, Vapi-396191, Gujarat, India.	
T +91 260 2408000, F +91 260 2408025, E diagnostics@merillife.com, W www.merillife.com	









Specimen Transfer Device – Capillary Tube (10µl)


Specimen Transfer Device: Capillary Tube (10 µl)	
LOT	XXXXXX
Qty.:	30 Nos.
 	
	Meril Diagnostics Pvt. Ltd.
Second Floor, D1-D3, Meril Park, Survey No. 135/2/B & 174/2, Muktanand Marg, Chala, Vapi - 396 191, Gujarat, India.	
Tel.: +91-260-2408000, Fax: +91-260-2408025, E-mail: diagnostics@merillife.com, Web: www.merillife.com	

1.2 Product code HVWRPD-02


Product Box Label




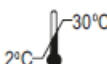



REF	HVWRPD-02 40T	 Diagnostics
IVD	One Step Rapid Test for detection of Anti-HIV in Human Serum/Plasma/Whole Blood	
	MERISCREEN HIV 1-2 WB	
	KIT CONTAINS	


 40   	1. 40 Test Devices, pouched with desiccant 2. 2 X 3.0 ml Assay Buffer Bottles 3. 01 No. Pack Insert 4. 40 Capillary Tube (10 µl) 5. 40 Alcohol Swabs 6. 40 Sterile Lancets	Lancets & Alcohol Swabs CE mark 		LOT XXXXXX  YYYY-MM  YYYY-MM
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 Meril Diagnostics Pvt. Ltd.
 Second Floor, D1-D3, Meril Park, Survey No. 135/2/B & 174/2, Muktanand Marg, Chala, Vapi-396191,
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 Web: www.merillife.com, Mfg.Lic.No.: MFG/MD/2018/000029
EC/REF OBELIS S.A., Bd General Wahis 53, 1030, Brussels, Belgium.
 T +32.2.732.5954, F +32.2.732.6003, E mail@obelis.net


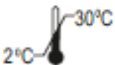


Aluminum Pouch Label

REF	HVWRPD-02 40T	 Diagnostics
IVD	One Step Rapid Test for detection of Anti-HIV in Human Serum/Plasma/Whole Blood	
	MERISCREEN HIV 1-2 WB	
	For <i>in-Vitro</i> diagnostics use only	

 1   	Do not open the foil pouch until it attains room temperature		LOT XXXXXX  YYYY-MM  YYYY-MM
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 Meril Diagnostics Pvt. Ltd.
 Second Floor, D1-D3, Meril Park, Survey No. 135/2/B & 174/2, Muktanand Marg, Chala, Vapi-396191,
 Gujarat, India. Tel.: +91-260-2408000, Fax: +91-260-2408025, E-mail: diagnostics@merillife.com,
 Web: www.merillife.com, Mfg.Lic.No.: MFG/MD/2018/000029
EC/REF OBELIS S.A., Bd General Wahis 53, 1030, Brussels, Belgium.
 T +32.2.732.5954, F +32.2.732.6003, E mail@obelis.net


Assay Buffer Bottle Label

REF	HVWRPD-02 40T	
IVD	One Step Rapid Test for detection of Anti-HIV in Human Serum/Plasma/Whole Blood	
CE 1434	MERISCREEN HIV 1-2 WB	
	Assy Buffer (Vol. 3.0ml)	LOT XXXXXX  YYYY-MM
 Meril Diagnostics Pvt. Ltd. Second Floor, D1-D3, Meril Park, Survey No. 135/2/B & 174/2, Muktanand Marg, Chala, Vapi-396191, Gujarat, India. Tel.: +91-260-2408000, Fax: +91-260-2408025, E-mail: diagnostics@merillife.com, Web: www.merillife.com, Mfg.Lic.No.: MFG/MD/2018/000029		
EC/REP	OBELIS S.A. , Bd General Wahis 53, 1030, Brussels, Belgium. T +32.2.732.5954, F +32.2.732.6003, E mail@obelis.net	



Lancet

Product Name: Lancet


LOT	XXXX	
	YYYY-MM	
Qty.:	40 Nos.	
	STERILE R	


Meril Diagnostics Pvt. Ltd.
 Second Floor, D1-D3, Meril Park, Survey No. 135/2/B & 174/2, Muktanand Marg, Chala, Vapi-396191, Gujarat, India.
 T +91 260 2408000, F +91 260 2408025,
 E diagnostics@merillife.com, W www.merillife.com

Alcohol Swab

Product Name: Alcohol Swab	
(70% Isopropyl Alcohol)	
LOT	XXXX
	YYYY-MM
Qty.:	40 Nos.
	Meril Diagnostics Pvt. Ltd.
Second Floor, D1-D3, Meril Park, Survey No.135/2/B &174/2, Muktanand Marg, Chala, Vapi-396191, Gujarat, India.	
T +91 260 2408000, F +91 260 2408025, E diagnostics@merillife.com, W www.merillife.com	

Specimen Transfer Device- Capillary Tube (10µl)

Specimen Transfer Device:	
Capillary Tube (10 µl)	
LOT	XXXXXX
Qty.:	40 Nos.
 	
	Meril Diagnostics Pvt. Ltd.
Second Floor, D1-D3, Meril Park, Survey No. 135/2/B & 174/2, Muktanand Marg, Chala, Vapi - 396 191, Gujarat, India.	
Tel.: +91-260-2408000, Fax: +91-260-2408025, E-mail: diagnostics@merillife.com, Web: www.merillife.com	

1.3 Product code HVWRPD-06

Product box label

REF HVWRPD-06 50T

IVD

50

KIT CONTAIN

1. 50 Test devices pouched with dessiccant
2. 3x3.0ml Assay Buffer Bottles
3. 01 No. Pack Insert
4. 50 capillary Tube (10 µL)
5. 50 Alcohol swabs
6. 50 Sterile Lancets

One Step Rapid Test for detection of Anti-HIV in Human serum/plasma/whole blood

MERISCREEN HIV 1-2 WB

Meril
Diagnostics

LOT :XXXX

EXP :YYYY/MM

EXP :YYYY/MM

Lancet & Alcohol swab CE mark

2°C 30°C

CE 1434 CE 0197

Mfg.Lic.No : MFG/MD/2018/000029

Meril Diagnostics Pvt.Ltd.Second Floor, D1-D3,Meril Park, Survey No. 135/2/B & 174/2, Muktanand Marg,Chala,Vapi-396191,Gujrat,India. Tel: +91-260-2408000, Fax: +91-260-2408025
Email: diagnostics@merillife.com, web: www.merillife.com

EC REP Obelis S.A., Bd General wahis 53,1030,Brussels,Belgium. T: +32.2.732.5954, F: +32.2.732.6003
E: mail@obelis.net

Aluminium Pouch label

REF HVWRPD-06 50T

IVD

1

One step Rapid Test for detection of Anti-HIV in Human Serum/Plasma/Whole blood

MERISCREEN HIV 1-2 WB

For in-vitro diagnostics use only

Do not open the foil pouch untill it attains room temperature

Meril
Diagnostics

LOT :XXXX

EXP :YYYY-MM

EXP :YYYY-MM

2°C 30°C







CE 1434

Mfg.Lic.No:MFG/MD/2018/000029

Meril Diagnostics Pvt.Ltd.,
Second Floor D1-D3,Meril Park,Survey no.135/b & 174/2, Muktanand Marg,Chala,Vapi-396191,Gujrat,India. Tel:+91-260-24080000, Fax + 91-260-2408025
Email:diagnostics@merillife.com


EC REP Obelis s.a.,Bd General wahis 53,1030,Brussels Belgium.T: +3227326003,
F: +3227326003, E:mail@obelis.net


Buffer label


REF	HVWRPD-06 50T		
IVD	One step Rapid Test for detection of Anti-HIV in Human Serum/Plasma/Whole blood		
 2°C - 30°C	MERISCREEN HIV 1-2 WB Assay Buffer (vol. 3ml)		LOT :XXXX
 1434			 :YYYY-MM  :YYYY-MM
 Meril Diagnostics Pvt.Ltd., Second Floor D1-D3,Meril Park,Survey no.135/b & 174/2, Muktanand Marg,Chala,Vapi-396191,Gujrat,India. Tel:+91-260-24080000, Fax + 91-260-2408025 Email:diagnostics@merillife.com			
EC REP	Obelis s.a.,Bd General wahis 53,1030,Brussels Belgium.T: +3227326003, F: +3227326003, E:mail@obelis.net		

Lancet label

Product Name: Lancet

LOT	XXXX
	YYYY-MM
Qty.:	50 Nos.
STERILE	R




Meril Diagnostics Pvt. Ltd.
 Second Floor, D1-D3, Meril Park, Survey No.135/2/B &174/2, Muktanand Marg, Chala, Vapi-396191, Gujarat, India.
 T +91 260 2408000, F +91 260 2408025,
 E diagnostics@merillife.com, W www.merillife.com

Alcohol swab label

Product Name: Alcohol Swab	
(70% Isopropyl Alcohol)	
LOT	XXXX
	YYYY-MM
Qty.:	50 Nos.
	Meril Diagnostics Pvt. Ltd.
Second Floor, D1-D3, Meril Park, Survey No.135/2/B & 174/2, Muktanand Marg, Chala, Vapi-396191, Gujarat, India.	
T +91 260 2408000, F +91 260 2408025,	
E diagnostics@merillife.com , W www.merillife.com	

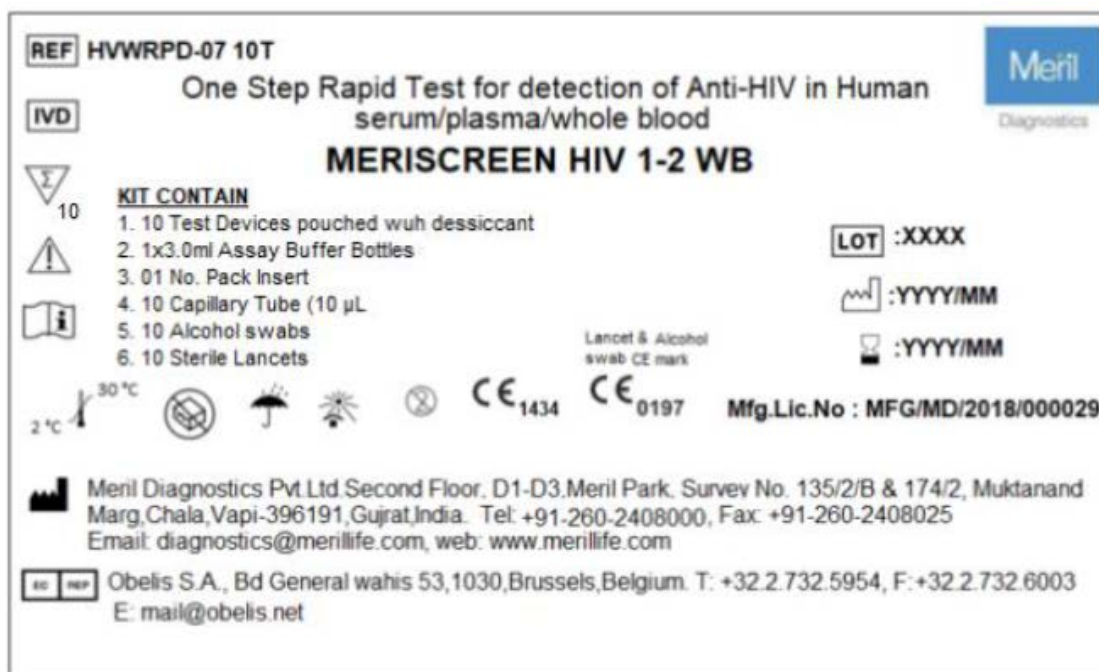


Specimen Transfer Device – Capillary Tube (10µl)

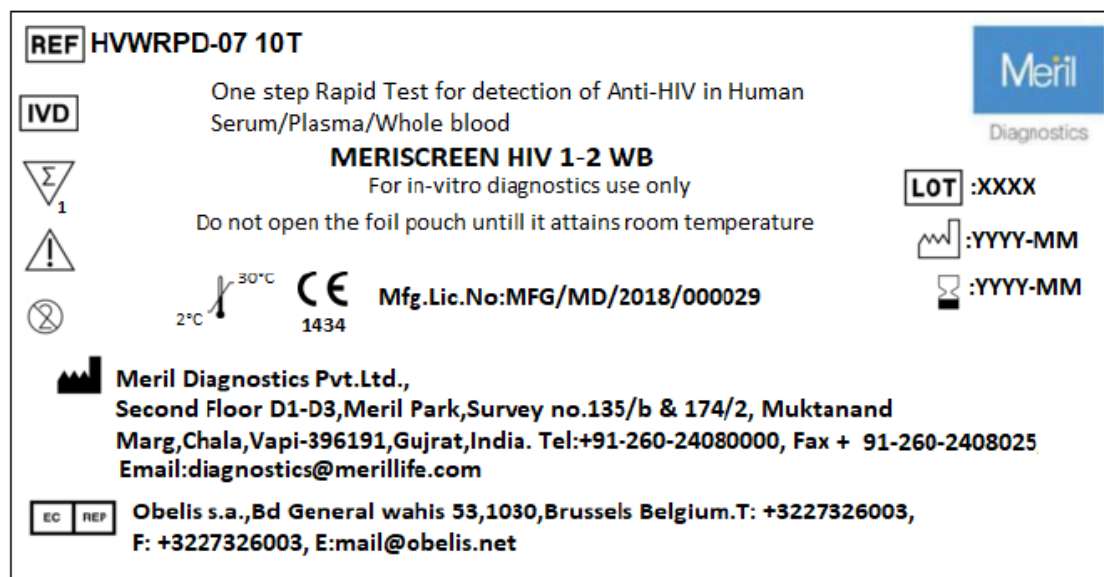
Specimen Transfer Device: Capillary Tube (10 µl)	
LOT	XXXXXX
Qty.:	50 Nos.
 	
 Meril Diagnostics Pvt. Ltd.	
Second Floor, D1-D3, Meril Park, Survey No. 135/2/B & 174/2, Muktanand Marg, Chala, Vapi - 396 191, Gujarat, India.	
Tel.: +91-260-2408000, Fax: +91-260-2408025,	
E-mail: diagnostics@merillife.com ,	
Web: www.merillife.com	

1.4 Product code HVWRPD-07







Product box label



Aluminium Pouch label






Buffer label

REF HVWRPD-07 10T	
IVD One step Rapid Test for detection of Anti-HIV in Human Serum/Plasma/Whole blood	
 30°C  1434	LOT :XXXX  :YYYY-MM  :YYYY-MM
MERISCREEN HIV 1-2 WB Assay Buffer (vol. 3ml)	
 Meril Diagnostics Pvt.Ltd., Second Floor D1-D3,Meril Park,Survey no.135/b & 174/2, Muktanand Marg,Chala,Vapi-396191,Gujrat,India. Tel:+91-260-24080000, Fax + 91-260-2408025 Email:diagnostics@merillife.com	
EC REP Obelis s.a.,Bd General wahis 53,1030,Brussels Belgium.T: +3227326003, F: +3227326003, E:mail@obelis.net	



Lancet label


Product Name: Lancet

LOT	XXXX
	YYYY-MM
Qty.:	10 Nos.
<div style="border: 1px solid black; display: inline-block; padding: 2px 5px;">STERILE R</div>	
	

 **Meril Diagnostics Pvt. Ltd.**
 Second Floor, D1-D3, Meril Park, Survey No.135/2/B &174/2, Muktanand Marg, Chala, Vapi-396191, Gujarat, India.
 T +91 260 2408000, F +91 260 2408025,
 E diagnostics@merillife.com, W www.merillife.com

Alcohol swab label














Product Name: Alcohol Swab	
(70% Isopropyl Alcohol)	
LOT	XXXX
	YYYY-MM
Qty.:	10 Nos.
	Meril Diagnostics Pvt. Ltd.
Second Floor, D1-D3, Meril Park, Survey No.135/2/B &174/2, Muktanand Marg, Chala, Vapi-396191, Gujarat, India.	
T +91 260 2408000, F +91 260 2408025, E diagnostics@merillife.com, W www.merillife.com	

**Specimen Transfer Device – Capillary Tube (10µl)**






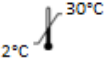



Specimen Transfer Device: Capillary Tube (10 µl)	
LOT	XXXXXX
Qty.:	10 Nos.
 	
 Meril Diagnostics Pvt. Ltd.	
Second Floor, D1-D3, Meril Park, Survey No. 135/2/B & 174/2, Muktanand Marg, Chala, Vapi - 396 191, Gujarat, India.	
Tel.: +91-260-2408000, Fax: +91-260-2408025, E-mail: diagnostics@merillife.com, Web: www.merillife.com	

1.5 Product code HVWRPD-08


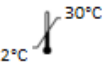



Product box label

REF	HVWRPD- 08 100T			
IVD	One Step Rapid Test for detection of Anti-HIV in Human serum/plasma/whole blood MERISCREEN HIV 1-2 WB			
	100	KIT CONTAIN		
		1. 100 Test Devices, pouched with desiccant	LOT	:XXXX
		2. 5x3.0ml Assay Buffer Bottles		:YYYY/MM
		3. 01 No. Pack Insert		:YYYY/MM
		4. 100 Capillary Tube (10µL)		
		5. 100 Alcohol swabs		
		6. 100 Sterile Lancets		
		Lancet & Alcohol swab CE mark		
	2 °C			1434
				0197
			Mfg.Lic.No : MFG/MD/2018/000029	
 Meril Diagnostics Pvt.Ltd.Second Floor, D1-D3,Meril Park, Survey No. 135/2/B & 174/2, Muktanand Marg,Chala,Vapi-396191,Gujrat,India. Tel: +91-260-2408000, Fax: +91-260-2408025 Email: diagnostics@merillife.com , web: www.merillife.com				
EC REP	Obelis S.A., Bd General wahis 53,1030,Brussels,Belgium. T: +32.2.732.5954, F:+32.2.732.6003 E: mail@obelis.net			



Aluminium Pouch label

REF HVWRPD-08 100T			
IVD	One step Rapid Test for detection of Anti-HIV in Human Serum/Plasma/Whole blood		
	MERISCREEN HIV 1-2 WB		
1	For in-vitro diagnostics use only		LOT :XXXX
	Do not open the foil pouch until it attains room temperature		 :YYYY-MM
	 2°C 30°C	 1434	 :YYYY-MM
 Meril Diagnostics Pvt.Ltd., Second Floor D1-D3,Meril Park,Survey no.135/b & 174/2, Muktanand Marg,Chala,Vapi-396191,Gujrat,India. Tel:+91-260-24080000, Fax + 91-260-2408025 Email:diagnostics@merillife.com			
EC REP	Obelis s.a.,Bd General wahis 53,1030,Brussels Belgium.T: +3227326003, F: +3227326003, E:mail@obelis.net		


Buffer label

REF HVWRPD-08 100T			
IVD	One step Rapid Test for detection of Anti-HIV in Human Serum/Plasma/Whole blood		
 2°C 30°C	MERISCREEN HIV 1-2 WB		LOT :XXXX
 1434	Assay Buffer (vol. 3ml)		 :YYYY-MM
 Meril Diagnostics Pvt.Ltd., Second Floor D1-D3,Meril Park,Survey no.135/b & 174/2, Muktanand Marg,Chala,Vapi-396191,Gujrat,India. Tel:+91-260-24080000, Fax + 91-260-2408025 Email:diagnostics@merillife.com			
EC REP	Obelis s.a.,Bd General wahis 53,1030,Brussels Belgium.T: +3227326003, F: +3227326003, E:mail@obelis.net		

Lancet label

Product Name: Lancet	
LOT	XXXX
	YYYY-MM
Qty.:	100 Nos.
STERILE	R
	Meril Diagnostics Pvt. Ltd.
Second Floor, D1-D3, Meril Park, Survey No.135/2/B &174/2, Muktanand Marg, Chala, Vapi-396191, Gujarat, India. T +91 260 2408000, F +91 260 2408025, E diagnostics@merillife.com, W www.merillife.com	

Alcohol swab label

Product Name: Alcohol Swab	
(70% Isopropyl Alcohol)	
LOT	XXXX
	YYYY-MM
Qty.:	100 Nos.
STERILE	R
	Meril Diagnostics Pvt. Ltd.
Second Floor, D1-D3, Meril Park, Survey No.135/2/B &174/2, Muktanand Marg, Chala, Vapi-396191, Gujarat, India. T +91 260 2408000, F +91 260 2408025, E diagnostics@merillife.com, W www.merillife.com	

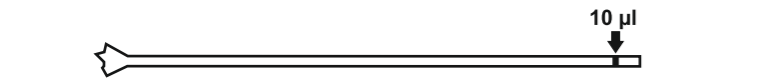
Specimen Transfer Device – Capillary Tube (10µl)**2. Instructions for use¹**

¹ English version of the IFU was the one that was assessed by WHO. It is the responsibility of the manufacturer to ensure correct translation into other languages.

Product Disclaimer:
Every precaution has been taken to ensure the diagnostic ability and accuracy of this product. The product is used outside of the control of the Manufacturer and Distributor and the result may accordingly be affected by environmental factors and/or user error. A person who is the subject of the diagnosis should consult a doctor for further confirmation of the result.

Warning:
The manufacturers and Distributors of this product shall not be liable for any losses, liability, claims, costs or damages whether direct or indirect or consequential arising out of or related to an incorrect diagnosis, whether positive or negative, in the use of this product.

Disposable Capillary tube



10 µl



10 µl

One Step Rapid Test for detection of anti-HIV
in Human Serum/Plasma/ Whole blood
MERISCREEN HIV 1-2 WB

Product code	Pack Size
HVWRPD-01	30Tests
HVWRPD-02	40Tests
HVWRPD-06	50Tests
HVWRPD-07	10Tests
HVWRPD-08	100 Tests

INTENDED USE:

MERISCREEN HIV 1-2 WB Test is a single use, qualitative, screening, in-vitro diagnostic immunochromatography assay and used for detection of antibodies (IgG, IgA and IgM) specific to HIV-1 and HIV-2 in human fingerstick whole blood, venous whole blood, serum or plasma specimens. The test is intended for trained users (either in laboratory or in point-of-care setting) to aid in the diagnosis of infection with HIV-1 and HIV-2 and for the diagnosis of HIV infection in symptomatic, asymptomatic and persons at risk of HIV infections. It is not intended for testing children below 2 years. The assay is manual and does not require additional instrument.

INTRODUCTION:

Acquired Immunodeficiency Syndrome (AIDS) is caused by two types of Human Immunodeficiency Virus, HIV-1 and HIV-2. Transmission of infection is mainly by exposure to certain infected body fluids e.g., blood and blood products, genital secretions etc. and by transplacental route. Infection by HIV-1 has been reported worldwide; HIV-2 infection has been reported as occurring mainly in West Africa and some European countries. Both these viruses show substantial antigenic cross reactivity in their core proteins, but the envelope glycoproteins are least cross reactive. Detection of antibodies against envelope proteins of both viruses ensures detection of antibodies against both types of viruses following infection. The earliest specific antibody response following infection by HIV may be of immunoglobulin M (IgM) followed by a response in immunoglobulin G (IgG). Maximum sensitivity for detection of anti-HIV sero-conversion is achieved by assays which respond to both IgM and IgG.

PRINCIPLE:

The MERISCREEN HIV 1-2 WB rapid test kit contains a membrane strip, which is pre-coated with HIV-1 & HIV-2 antigens on test region '1' and test region '2' respectively. Recombinant antigen gold conjugate will form a coloured band in the test region '1' and test region '2' of result window. As the test specimen flows through the membrane after addition of Assay buffer, the antigen gold conjugate complexes with anti-HIV antibodies. The complex moves further on the membrane towards the test region, where HIV antigens are coated and leads to formation of reddish purple band(s) at test region(s). Absence of test bands indicates a negative test results. The control band is used for procedural control and should always appear if the test procedure is performed correctly. The intensity of control band has nothing to do with intensity of test band(s).

REAGENTS AND MATERIALS PROVIDED:

Each kit contains:

Kit Contents	HVWRPD-01	HVWRPD-02	HVWRPD-06	HVWRPD-07	HVWRPD-08
Test device pouched with desiccant	30	40	50	10	100
Assay Buffer Bottle	2 X 3.0 ml	2 X 3.0 ml	3 X 3.0 ml	1 X 3.0 ml	5 X 3.0 ml
Specimen transfer device capillary tube (10µL)	30	40	50	10	100
Sterile lancets	30	40	50	10	100
Alcohol swabs	30	40	50	10	100
Pack Insert	1	1	1	1	1



Diagnostics

 For in vitro diagnostic use
Read this pack insert thoroughly before use

- MATERIALS REQUIRED BUT NOT PROVIDED:**
- 1.Timer
 - 2.New pair of disposable gloves
 - 3.Pen
 - 4.Sterile gauze/Plaster (for fingerstick whole blood specimens)
 - 5.Centrifuge (for serum/plasma specimens only)
 - 6.Biohazard Sharp Box
 - 7.Non-sharp disposal biohazard container
 - 8.Venous blood collection materials and precision pipette plus tips

STORAGE AND STABILITY:
All reagents are ready to use as supplied. Store unopened test devices at 2-30°C. If stored at 2-8°C, allow test device to attain room temperature before opening. The test device is stable up to the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit over 30°C. Once test device foil is opened, it gives accurate result till 24 hours. But, it is recommended that test device should be used immediately after opening the foil. After opening the Assay buffer bottle, the buffer is stable until the expiration date if kept at 2-30°C.

- WARNINGS AND PRECAUTIONS:**
1. For in-vitro diagnostics use only.
 2. Read the instructions carefully before performing the test. The instruction must be followed exactly to get accurate results.
 3. Do not use any other buffer than the buffer supplied within this kit.
 4. The buffer contains sodium azide as a preservative which may be toxic if ingested. When disposed of through a sink, flush with large quantities.
 5. Do not use any other specimens than prick whole blood, venous whole blood, serum or plasma.
 6. Do not use any other anticoagulants other than EDTA, heparin and citrate.
 7. Allow all reagents and specimen(s) to attain room temperature (18°C to 30°C) before use.
 8. Once test device foil is opened, it gives accurate result till 24 hours. But, it is recommended that test device should be used immediately. Though performance of test device is not affected by the different range of humidity i.e., 40% RH, 60% RH and 75% RH, it is recommended that the test device should be used in ambient humidity i.e., between 40% RH and 60% RH.
 9. Do not use the kit contents beyond the expiry date.
 10. Do not use test device if pouch is lack of desiccant.
 11. Do not use the lancet if the seal is broken.
 12. Do not touch the nitrocellulose part of the device. prick or scratch on nitrocellulose membrane may give erroneous results.
 13. Test Devices and assay buffers of different lot must not be mixed and used.
 14. Do not re-use accessories like capillary tubes, alcohol swabs or lancets for testing purpose.
 15. Perform the test by using kit's assay buffers. Performing the test with any other buffer is not valid.
 16. Follow the assay procedure and storage instructions strictly. Deviation will lead to erroneous results.
 17. Do not use haemolysed or lipemic specimen for testing.
 18. Use sufficient volume of specimen for testing.
 19. Do not re-use the Test Devices and pipette tips from the procedure; this may lead to inaccurate results.
 20. Do not pipette reagents nor specimens by mouth and do not smoke, eat or drink while handling specimens and performing a test.
 21. Avoid contact of reagents with eyes and skin. If either of the reagents come into contact with skin or eyes, wash thoroughly with water.
 22. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed. Do not re-use used gloves or washed gloves.
 23. Handle specimens(s) and used materials as if it is capable of transmitting infection.

24. Follow standard Lab procedure and biosafety guidelines for handling and disposal of potentially infective materials/expired kit/used kits. All remnants of specimen(s), used materials, expired materials/kits, pipette tips etc. should be disposed in suitable biohazard container. Materials should be autoclaved at 121°C for 30 minutes or dipped in 10% hypochlorite solution for 30 minutes prior to disposal.
25. Clean up spills thoroughly using an appropriate disinfectant.
26. The test device should remain in its original sealed pouch until usage. Do not use the test device if the seal is broken or the pouch is damaged. In case desiccant pouch changes colour from blue to light pink colour or test device pouch is lack of desiccant then test device should not be used.
27. In case of performance changes or product malfunction, stop using the kit immediately and contact your local distributor.

SPECIMEN COLLECTION AND PREPARATION OF FINGERSTICK WHOLE BLOOD:

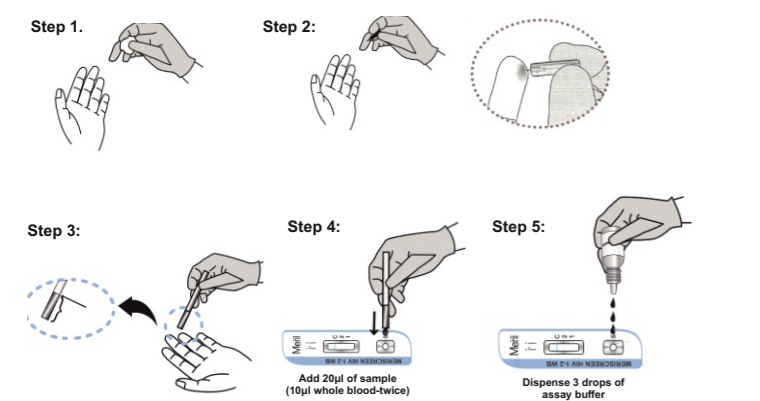
Consider any materials of human origin as infectious and handle them using standard bio-safety procedures.

Specimen Collection and Test Procedure for Fingerstick Whole Blood:

1. Bring test components and reagents to room temperature.
2. Choose a finger for the prick:
 - Do not choose a finger that is swollen, bruised or scarred.
 - Preferably choose the 3rd or 4th finger of the hand the patient does not use to write. Alternatively choose the heel or the earlobe for neonates.
3. Open the packaging of the alcohol swab. Take out the alcohol swab. Do not throw away the empty packaging (wrapper) but keep it aside.
4. Wipe the complete fingertip with the alcohol swab. Wait until the finger has completely dried (minimum 30 seconds).
5. Place the alcohol swab in the wrapper and set it aside (you will use it again to stop the bleeding after you collected the patient's blood).
6. Take the safety-seal lancet.
7. Detach the cap of the lancet. Puncture the side of the pulp (ball) of the finger with the lancet, perpendicular to the lines of the prick. Dispose the lancet immediately into the sharps box.
8. Make sure a well-formed drop of blood is present on the tip of the finger.
9. If there is no well-formed drop of blood, repeat the prick. Use a new lancet and choose a different puncture site.
10. Take the Capillary tube and suck blood up to 10µl mark from the whole blood drop. Place the circular end of the Capillary tube in the circle well (marked "S") so that it touches the strip (pad at the bottom of the well) Press down lightly to transfer the whole blood to the strip. (Repeat this step again to make specimen volume as 20 µl).
11. Put the used capillary tube into the non-sharps disposal container.
12. Add three drops of the Assay Buffer to the Specimen well (S). Buffer bottle should be held perpendicular to the test.

Interpret the test results at 20 minutes. Do not read the results after 30 minutes.

PICTORIAL REPRESENTATION OF FINGER-STICK TEST PROCEDURE:



SPECIMEN COLLECTION AND PREPARATION OF VENOUS WHOLE BLOOD/PLASMA/SERUM/

Consider any materials of human origin as infectious and handle them using standard bio-safety procedures.

VENOUS WHOLE BLOOD COLLECTION:

Collect venous whole blood specimen into collection tube containing EDTA,

Citrate or Heparin by following laboratory procedure. Be sure that blood is well mixed before sampling.

PLASMA COLLECTION:

Collect blood specimen into collection tube containing EDTA, Citrate or Heparin by following laboratory procedure.

1. Separate the plasma by centrifugation (Centrifugation time & speed: 2350-3150 x g for ~ 10 minutes).
2. Carefully withdraw the plasma into new pre-labelled tube.

SERUM COLLECTION:

1. Collect blood specimen into a collection tube containing no anticoagulants.
2. Allow the blood to clot.
3. Separate the serum by centrifugation. (Centrifugation time & speed: 2350-3150 x g for ~ 10 minutes).
4. Carefully withdraw the serum into a new pre-labelled tube. Test the specimens as soon as possible after collection.

Stored serum/plasma/whole blood specimens at 2-8°C up to 3 days can be used for testing. For longer-term storage, Serum/Plasma specimens should be frozen at -20°C and these specimens should not be frozen and thawed repeatedly (Not more than 3 times). Capillary whole blood shall be used/tested immediately after collection.

Test Procedure for Serum/Plasma/Venous Whole Blood

1. Bring the specimen and test components to room temperature if refrigerated or frozen. Mix the specimen well prior to assay once thawed.
2. When ready to test, open the pouch at the notch and remove device. Place the test device on a clean, flat surface.
3. Take specimen up to the marking (of 10 µl) on Capillary tube. For serum/plasma, take 10 µl one time and for whole blood take 10 µl of specimen two times.
4. Add specimen (10 µl serum/plasma or 20 µl of whole blood) to the specimen well (S) using capillary tube. Dispose of fused capillary tube as a bio-hazard waste in biohazard sharp bin. Alternately, a calibrated pipette and tips can be used in place of the capillary tube to dispense 10 µl of serum/plasma or 20 µl of venous whole blood specimen.
5. Add three drops of the Assay Buffer to the specimen well (S). **Interpret the test results at 20 minutes. Do not read the results after 30 minutes.**

INTERPRETATION OF RESULTS:

Note: The faint blue line at "Control" position is always visible before testing. This faint blue line should not be interpreted as Control line during result interpretation. A reddish purple band is expected at the control band if the test has been conducted properly. Expected results are as follows:

NEGATIVE RESULT: If only the Control (C) band is developed, the test indicates that no detectable HIV antibodies are present in the specimen. The result is negative.

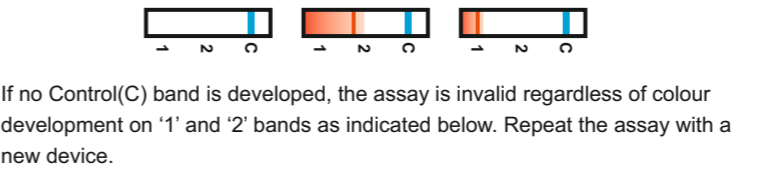
POSITIVE RESULT: If Control(C), HIV-1(1) and/or HIV-2(2) bands are developed, the test indicates for the presence of antibodies to HIV-1 and/or HIV-2 in the specimen. The result is HIV positive.

	Reactive for anti-HIV-1 and anti-HIV-2 antibodies (Mix infection with HIV-1 and HIV-2).
	Reactive for anti-HIV-1 antibodies (Infection with HIV-1)
	Reactive for anti-HIV-2 antibodies (Infection with HIV-2).

INVALID RESULT:

Failure of a reddish purple line to appear over the faint blue line at the control band even after the addition of specimens and assay buffer and no color development at control band, the assay is invalid as indicated below. Sometimes, color development due to red blood cells/their lysed components

may cover the reading area which can affect the interpretation of results. Repeat the assay with a new device.



If no Control(C) band is developed, the assay is invalid regardless of colour development on '1' and '2' bands as indicated below. Repeat the assay with a new device.

PERFORMANCE CHARACTERISTICS:

The performance of MERISCREEN HIV 1-2 WB has been determined by testing specimens of anti-HIV positive specimens and HIV negative specimens. In addition, its performance on commercially available seroconversion panels has been evaluated.

Diagnostic Sensitivity:

Diagnostic sensitivity of MERISCREEN HIV 1-2 WB was evaluated using 555 anti-HIV positive specimens including 400 HIV-1 positive specimens, 112 HIV-2 positive specimens, and 43 HIV-1 subtypes. All specimens were identified as positive when tested with MERISCREEN HIV 1-2 WB assay kit. Entire study included testing of 412 EDTA plasma, 24 citrate plasma and 119 serum specimens. Diagnostic sensitivity of MERISCREEN HIV 1-2 WB assay kit was calculated for these specimen types are given in below table:

Specimen Type	Calculated diagnostic sensitivity	95% CI
EDTA Plasma	100%	99.08% to 100.00%
Citrate Plasma	100%	85.75% to 100.00%
Serum	100%	96.95% to 100.00%

Overall, diagnostic sensitivity of MERISCREEN HIV 1-2 WB assay kit was calculated as 100% (95% CI: 99.34% to 100.00%) and positive predicted value was calculated as 100%.

Diagnostic Specificity:

Diagnostic specificity of MERISCREEN HIV 1-2 WB was evaluated using 1961 HIV negative specimens including 1450 healthy blood donor specimens, 204 pregnant women specimens, 207 hospitalized (clinical) specimens and 100 Interfering substances. All specimens were identified as negative when tested with MERISCREEN HIV 1-2 WB assay kit. Entire study included testing of 509 EDTA plasma, 1210 citrate plasma, 31 Heparin plasma and 211 serum specimens. Diagnostic specificity of MERISCREEN HIV 1-2 WB assay kit was calculated for these specimen types are given in below table:

Specimen Type	Calculated diagnostic specificity	95% CI
EDTA Plasma	100%	99.28% to 100.00%
Citrate Plasma	100%	99.70% to 100.00%
Heparin Plasma	100%	88.78% to 100.00%
Serum	100%	98.27% to 100.00%

Overall, diagnostic specificity of MERISCREEN HIV 1-2 WB assay kit was calculated as 100% (95% CI: 99.81% to 100%) and negative predicted value was calculated as 100%.

Sensitivity in Seroconversion Panels:

MERISCREEN HIV 1-2 WB assay kit was tested with 30 HIV seroconversion panels including early sero-conversion HIV specimens to evaluate the sensitivity in seroconversion panels. From the results, it can be concluded that MERISCREEN HIV 1-2 WB has relatively comparable sensitivity when

compared with CE marked comparator assay kit i.e., Turklab's Rapidan® Tester Anti-HIV ½ Test, WB/S/P.

Repeatability & Reproducibility:

Inter-day, inter-lot, inter-operator, within-run variability were assessed by testing specimens in replicates of 3 by three operators over the five days. Study includes testing of plasma EDTA and Serum specimens. The results have shown 100% agreement with the specimen status when tested with anti-HIV positive specimens and HIV negative specimens. The results and data analysis showed 100% sensitivity for anti-HIV positive specimens and 100% specificity for HIV negative specimens.

Hook effect:

30 anti-HIV high-titer positive specimens were diluted to generate moderate titer and weak titer anti-HIV positive specimens and these specimens were tested in replicates of three (03) with MERISCREEN HIV 1-2 WB assay kit to check whether MERISCREEN HIV 1-2 WB assay kit exhibit hook effect or not. There was no intensity drop observed anywhere with high-titer anti-HIV positive specimens. So, it is concluded that MERISCREEN HIV 1-2 WB does not exhibit hook effect.

Specimen matrix equivalency:

25 anti-HIV positive and 25 HIV negative specimens were collected in eight specimen matrices: capillary whole blood by prick, venous whole blood (EDTA, Citrate, Heparin), Plasma (EDTA, Citrate, Heparin) and serum. Specimens were "same day" fresh specimens (≤1 day after sampling) and tested with MERISCREEN HIV 1-2 WB assay kit. The data obtained during this study showed 100% agreement among matrices. There was no statistical difference observed among matrices.

LIMITATIONS OF THE TEST:

1. As with all diagnostic tests, the test result must always be co-related with clinical findings.
2. Presence of heterophile antibodies in patient's specimen with Rheumatic diseases and autoimmune disorder may lead to false results.
3. A negative result can occur if the quantity of the analyte of interest present in the specimen is below the detection limits of the assay or the analyte of interest that are detected are not present during the stage of disease in which a specimen is collected.
4. A negative result at any time does not preclude the possibility of exposure or infection.
5. Repeat the test in case of very faint band or if have any doubt for test band.
6. Other clinically available tests should be used if questionable results are obtained.
7. This test should not be used on specimens from immunosuppressed individuals.
8. Reactive specimens should always be confirmed by EIA and RNA HIV test or Western Blot in agreement with local regulations/national or international recommendation.
9. MERISCREEN HIV 1-2 WB assay kit is tested with following interfering and cross reacting specimens: Hepatitis, Anti-Chromatine, RF Factors. Anti-TPO, Influenza virus, Herpes virus, Bilirubin, Lipid, Hemoglobin, Ascorbic acid, Acetaminophen, Ethanol, Gamma Globulin, Hepatitis C, Hepatitis B, Syphilis and the performance of the kit was not affected by these interfering and cross-reacting factors. Interfering and cross reacting factors other than these may affect the performance of the kit.

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