STUDY TITLE

Summary of Safety and Performance

DOCUMENT NUMBER

CE-SSP/IM/CLD/012

Revision No. 02

STUDY ARTICLE

MERISCREEN HIV 1-2 WB

Summary of Safety and Performance Approvals:
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1. Device identification and general information

1.1. Device trade name(s)

MERISCREEN HIV 1-2 WB

1.2. Manufacturer's name and address

Manufacturer's Name: Meril Diagnostics Pvt. Ltd.

Manufacturer's Address:

Meril Diagnostics Private Limited

Second Floor, D1-D3, Meril Park, Survey No. 135/2/B & 174/2,

Muktanand Marg, Chala, Vapi - 396191, Gujarat, India.

1.3. Manufacturer's single registration number (SRN):

IN-MF-000028158

1.4. Basic UDI-DI:

8905459MHVWRPDJX

1.5. European Medical Device Nomenclature (EMDN) description / text:

W0105090302

1.6. Risk class of device:

MERISCREEN HIV 1-2 WB is classified as Class D, Rule 1 first indent as per Annex VIII of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on In Vitro Diagnostic Medical Devices and Repealing Directive 98/79/EC and Commission Decision 2010/227/EU.

1.7. Indication whether it is a device for near-patient testing and/or a companion diagnostic:

MERISCREEN HIV 1-2 WB is intended for healthcare professionals (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.

1.8. Year when the first certificate was issued under Regulation (EU) 2017/746 covering the device:

First Certificate was issued under Regulation (EU) 2017/746 by 3 EC International a.s., Slovak Republic to Meril Diagnostics Pvt. Ltd. on 09/09/2023. Certificate details are given as below:

Table 1: Certificate of MERISCREEN HIV 1-2 WB

Sr. No.	Details of Certificate	Date of Issue	Description
1	EU Technical Documentation Assessment Certificate No.: 2023-IVDR/TD-002	09/09/2023	Initial Issue
2	EU Quality Management System Certificate No.: 2023-IVDR/QS-002	09/09/2023	
3	EU Technical Documentation Assessment Certificate No.: 2023-IVDR/TD-002/A	08/01/2024	Added product code: HVWRPD-09 (25T), added product codes with autosafety lancet: HVWRPD-10 (30T), HVWRPD-11 (60T), HVWRPD-12 (40T).
4	EU Quality Management System Certificate No.: 2023-IVDR/QS-002/A	08/01/2024	

1.9. Authorised representative if applicable; name and the SRN:

Name of Authorized Representative: Obelis S.A., Belgium

Authorized Representative's SRN: BE-AR-000000106

1.10. NB's name and the NB's single identification number:

NB Name: 3EC International a.s., Slovak Republic

NB Single Identification Number: 2265

2. Intended use of the device

2.1. Intended purpose (elements in Annex II 1.1 (c)):

MERISCREEN HIV 1-2 WB 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 healthcare professionals (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.

2.2. Indication(s) and target population(s):

The test is intended for healthcare professionals (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.

2.3. Limitations and/or contra-indications:

- As with all diagnostics tests, the test result must always be co-related with clinical findings.
- Presence of heterophile antibodies in patient's specimen with Rheumatic diseases and autoimmune disorder may lead to false results.
- 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.
- A negative result at any time does not preclude the possibility of exposure or infection.
- Repeat the test in case of very faint band or if have any doubt for test band.
- Other clinically available tests should be used if questionable results are obtained.
- This test should not be used on specimens from immunosuppressed individuals.
- Reactive specimens should always be confirmed by EIA and RNA HIV test or Western Blot in agreement with local regulations/national or international recommendation.
- MERISCREEN HIV 1-2 WB 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, Syphillis 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.

3. Device description

3.1. Description of the device, including the conditions to use the device (e.g. laboratory, near-patient testing):

MERISCREEN HIV 1-2 WB contains:

1. Pouches; each contains Test device with one desiccant
2. Assay Buffer bottle
3. Capillary tubes
4. IFU
5. Alcohol Swabs
6. Lancets/Auto Safety Lancets

The MERISCREEN HIV 1-2 WB is One-step rapid test for detection of anti-HIV in Human Serum/plasma/fingerstick capillary & venous whole blood. It consists of two analyte specific reagents which are “Capture: HIV-1 and HIV-2 specific antigen” and “Conjugate: HIV-1 and HIV-2 recombinant antigen”. The test format of MERISCREEN HIV 1-2 WB is immunochromatography.

The test is intended for healthcare professionals (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.

3.2. In case the device is a kit, description of the components (including regulatory status of components, for example, IVDs, medical devices and any Basic UDI-DIs):

Table 2: Components of MERISCREEN HIV 1-2 WB

Contents of the kit including accessories	Number of tests per kit: 30 Product code: HVWRPD-01	Number of tests per kit: 40 Product code: HVWRPD-02	Number of tests per kit: 50 Product Code: HVWRPD-06	Number of tests per kit: 10 Product Code: HVWRPD-07	Number of tests per kit: 100 Product Code: HVWRPD-08	Number of tests per kit: 25 Product Code: HVWRPD-09	Number of tests per kit: Product Code: 30 HVWRPD-10	Number of tests per kit: 60 Product Code: HVWRPD-11	Number of tests per kit: 40 Product Code: HVWRPD-12
Test devices, pouched with desiccant	30	40	50	10	100	25	30	60	40
Assay buffer bottles	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	2 X 3.0 ml	2 X 3.0 ml	3 X 3.0 ml	2 X 3.0 ml
Specimen transfer bottles - capillary tubes (10 µl)	30	40	50	10	100	25	30	60	40
Sterile lancets	30	40	50	10	100	25	30 (Auto Safety Lancets)	60 (Auto Safety Lancets)	40 (Auto Safety Lancets)
Alcohol	30	40	50	10	100	25	30	60	40

swabs									
Pack Insert	1	1	1	1	1	1	1	1	1

Table 3: Details of Basic UDI-DI and Product Code

Product Code	Basic UDI DI	UDI-DI
HVWRPD-01	8905459MHVWRPDJX	18906074564327
HVWRPD-02		18906074563733
HVWRPD-06		08905459001696
HVWRPD-07		08905459001191
HVWRPD-08		08905459001702
HVWRPD-09		08905459006639
HVWRPD-10		08905459006646
HVWRPD-11		08905459006653
HVWRPD-12		08905459006660

3.3. A reference to previous generation(s) or variants if such exists, and a description of the differences:

Table 4: Differences of MERISCREEN HIV 1-2 WB and previous generation/variants

#	Parameter/ Specification	Subjective Device	Previous version of MERISCREEN HIV 1-2 WB (CE approved)	Comparative Device			Equivalence
1	Device Name	MERISCREEN HIV 1-2 WB	MERISCREEN HIV 1-2 WB	Rapidan Tester, Anti-HIV 1/2 Test, WB/S/P	HIV 1/2 STAT-PAK® ASSAY	ABON HIV 1/2/O Tri-Line Human Immunodeficiency Virus Rapid Test Device	-
2	Manufacturer	Meril Diagnostic Pvt. Ltd., India	Meril Diagnostic Pvt. Ltd., India	TURKLAB, Turkey	CHEMBIO DIAGNOSTIC SYSTEM, INC, USA	Abon Biopharm (Hangzhou) Co. Ltd, China	-
3	Regulatory Status	CE approved (CE2265)	CE approved (CE 1434)	CE approved (CE 1434)	CE approved (CE 0459)	CE Approved (CE 0459)	-
Clinical Equivalence							
4	Intended Use	MERISCREEN HIV 1-2 WB is a single use, qualitative, screening, *in-vitro* diagnostic immunochromatography	MERISCREEN HIV 1-2 WB is qualitative, screening, in-vitro diagnostic immunochromatography assay for	Anti-HIV 1/2 Test is a rapid qualitative immunoassay for the detection of antibodies (IgG, IgA and IgM) generated against all	The Chembio HIV 1/2 STAT-PAK is a single-use immunochromatographic, rapid screening test for the detection of antibodies to	The HIV 1/2/O Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum /Plasma) is a	Equivalent

		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 healthcare professionals (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.	detection of antibodies (IGG, IgA and IgM) specific to HIV-1 and HIV-2 in human serum, plasma and venous whole blood. The test is intended for use by trained competent person.	subtypes of Human Immunodeficiency Virus Type 1 (HIV-1) (including Group O) and Type 2 (HIV-2) in human whole blood / serum / plasma.	Human Immunodeficiency Virus Types 1 and 2 (HIV 1/2) in fingerstick whole blood, venous whole blood, serum or plasma specimens. The Chembio HIV 1/2 STAT-PAK is intended for use as a point-of-care test to aid in the diagnosis of infection with HIV-1 and HIV-2. This test is suitable for use in multi-test algorithms designed for the statistical validation of rapid HIV test results. When multiple rapid HIV tests are available, this test should be used in appropriate multi-test algorithms.	rapid chromatographic immunoassay for the qualitative detection of antibodies to HIV-1, HIV-2 and Subtype O in whole blood, serum or plasma to aid in the diagnosis of HIV infection. This product should not be used for the screening of blood donations.	
5	Principle of operation	Immunochromatography	Immunochromatography	Immunochromatography	Lateral flow (Immunochromatography)	Rapid chromatographic immunoassay	Similar
6	Specim	Fingerstick	Venous Whole	Whole blood	Fingerstick	Fingerstick	Equiva

	ens can be used	whole blood, Venous Whole blood (Heparin, EDTA and Citrate), Serum and Plasma (Heparin, EDTA and Citrate)	blood (Heparin, EDTA and Citrate), Serum and Plasma (Heparin, EDTA and Citrate)	(Heparin, EDTA and Citrate), Serum and Plasma (Heparin, EDTA and Citrate)	whole blood, venous whole blood, serum or plasma	whole blood, venous whole blood, serum or plasma	lent
Analytical & Technical Equivalence							
7	Kit comp onents	Test device sealed in a foil pouch with desiccant, Assay buffer bottle, IFU, Capillary tubes, alcohol swabs and lancets	Test device sealed in a foil pouch with desiccant, Assay buffer bottle, IFU, Capillary tubes	Test cassettes, droppers, diluents (for whole blood samples only) and instructions for use	Individually pouched test devices with desiccant, disposable 5µL sample loops, HIV running buffer and 1 Product Insert	Test Devices, Buffer, Droppers, Package insert, Desiccant	Equiva lent
8	Result should be read at	20 minutes	20 minutes	15 minutes	15 minutes	10 minutes	Compa rable
9	Storag e condit ion	2-30°C	2-30°C	4-30°C	8-30°C	2-30°C	Compa rable
10	Specif icity	100% (95% CI: 99.81% to 100%)	99.97% (95% CI: 99.83% to 100%)	100%	99.9% with the lower 95% confidence interval of 99.6%	>99% (95% CI: 99.4-100%)	Compa rable
11	Sensit ivity	100% (95% CI: 99.34% to 100.00%)	100% (95% CI: 99.57% to 100.00%)	100%	100% (95% CI: 99.1 to 100%)	99% (95%CI: 98.0-99.2%)	Equiva lent

3.4. Description of any accessories which are intended to be used in combination with the device:

The following list of the accessories which are supplied with the kit:

- Capillary tube as specimen transfer device
- Alcohol Swab
- Lancet/Auto Safety Lancet

3.5. Description of any other devices and products which are intended to be used in combination with the device:

This section is not applicable as there are no other devices and products which are intended to be used in combination with MERISCREEN HIV 1-2 WB.

4. Reference to any harmonized standards and CS applied

Table 5: List of Standards applied

Sr. No.	Document Number/Title	Title of Document
List of Reference Standards		
1.	Schedule M – IV	Good Manufacturing Practices & Requirements of Premises, Plant & Equipment for IVD Reagents & Kits
2.	EU IVDR 2017/746	Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on In Vitro Diagnostic Medical Devices and Repealing Directive 98/79/EC and Commission Decision 2010/227/EU
3.	EU 2022/1107	COMMISSION IMPLEMENTING REGULATION (EU) 2022/1107 of 4 July 2022 laying down common specifications for certain class D in vitro diagnostic medical devices in accordance with Regulation (EU) 2017/746 of the European Parliament and of the Council
List of Applicable Standards		
4.	EN 13975:2003	Sampling procedures used for acceptance testing of in vitro diagnostic medical devices - Statistical aspects
5.	EN 13641:2002	Elimination Or Reduction Of Risk Of Infection Related To In Vitro Diagnostic Reagents
6.	EN 13612: 2002	Performance evaluation of in vitro diagnostic medical devices
7.	EN 14136:2004	Use of external quality assessment schemes in the assessment of the performance of in vitro diagnostic examination procedures
8.	EN ISO 13485:2016	Medical Devices – Quality Management System Requirements for Regulatory Purpose (ISO 13485:2016)
9.	EN ISO 13485:2016+A11:2021	Medical Devices – Quality Management systems. Requirements for regulatory purposes
10.	ISO 14971:2019 (E)	Medical devices - Application of risk management to

		medical devices
11.	BS EN ISO 14971:2019+A11:2021	Medical devices - Application of risk management to medical devices
12.	EN ISO 18113-1:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labeling) - Part 1: Terms, definitions and general requirements (ISO 18113-1:2009)
13.	EN ISO 18113-2:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labeling) - Part 2: In vitro diagnostic reagents for professional use (ISO 18113-2:2009)
14.	EN ISO 15193:2009	In vitro diagnostic medical devices - Measurement of quantities in samples of biological origin - Requirements for content and presentation of reference measurement procedures (ISO 15193:2009)
15.	EN ISO 15194:2009	In vitro diagnostic medical device – Measurement of quantities in samples of biological origin – Requirements for certified reference materials and the content of supporting documentation (ISO 15194:2009)
16.	EN ISO 15223-1:2021	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements
17.	EN ISO 17511:2021	In vitro diagnostic medical devices — Requirements for establishing metrological traceability of values assigned to calibrators, trueness control materials and human samples
18.	EN ISO 23640:2015	In vitro diagnostic medical devices – Evaluation of stability on in vitro diagnostic reagents (ISO 23640:2011)
19.	ISO 9001:2015	Quality Management System Requirement
20.	EN ISO 14644-1:2015 (E)	Clean rooms and associated controlled environments- Part 1: Classification of Air Cleanliness
21.	EN ISO 14644-2:2015 (E)	Clean rooms and associated controlled environments- Part 2: Specifications for testing and monitoring to prove continued compliance with ISO 14644-1
22.	BS EN ISO 14644-3:2019	Clean rooms and associated controlled environments- Part 3: Test Methods
23.	ISO 14644-4:2001	Clean rooms and associated controlled environments -- Part 4: Design, construction and start-up
24.	EN 62366-1:2015	Medical Devices - Part 1: Application of Usability Engineering to Medical Devices
25.	EN ISO 20916:2019	In vitro diagnostic medical devices — Clinical

		performance studies using specimens from human subjects — Good study practice
Sr. No.	**Guidance**	
1.	Clinical and laboratory standard institute" and established the Stability Testing Guideline, EP25-A , Volume 29, number 20	
2.	MDCG 2022-2 - Guidance on general principles of clinical evidence for In Vitro Diagnostic medical devices (IVDs), January 2022	
3.	MDCG 2020-7 - Post-market clinical follow-up (PMCF) Plan Template: A guide for manufactures and notified bodies, April 2020	
4.	MDCG 2020-8 - Post-market clinical follow-up (PMCF) Evaluation Report Template: A guide for manufacturers and notified bodies, April 2020	
5.	MDCG 2018-1 Rev.4 - Guidance on BASIC UDI-DI and changes to UDI-DI, April 2021	
6.	MDCG 2021-19 - Guidance note integration of the UDI within an organisation's quality management system, July 2021	
7.	NCCLS-EP15 A - User demonstration of performance for precision and accuracy; Approved guidelines	
8.	ASTM D 4169-08 - Standard practice for performance testing of shipping containers and systems	
9.	MDCG 2022-9 - Summary of safety and performance Template, May 2022	
10.	MDCG 2020-16 Rev.02: Guidance on Classification Rule for in vitro Diagnostics Medical Device under Regulation (EU) 2017/746, February 2023	
11.	User Protocol for Evaluation of Qualitative Test Performance; Approved Guideline, EP12-A, Volume 22, number 14	
12.	Interference Testing in Clinical Chemistry; Approved Guideline – Second Edition, EP 7A-2, Volume 25, Number 27	
13.	Protocols for Determination of Limits of Detection and Limits of Quantitation; Approved Guideline, EP17-A, Volume 24, Number 34	
14.	Evaluation of Precision Performance of Clinical Chemistry Devices; Approved Guideline, EP5-A, Volume 19, Number 2	
15.	User Verification of Performance for Precision and Trueness; Approved Guideline – Second Edition , EP 15-A2, Volume 25, Number 17	
16.	GHTF/SG2-N54R8:2006 Medical Devices Post Market Surveillance: Global Guidance for Adverse Event Reporting for Medical Devices	
17.	GHTF/SG2-N57R8:2006 Medical Devices Post Market Surveillance: Content of Field Safety Notices	
18.	SG5//N1R8:2007 – Clinical Evidence – Key Definitions and Concepts, May 2007	
19.	SG5/N2R8:2007 – Clinical Evaluation, May 2007	
20.	GHTF/SG5/N3:2010 - Clinical Investigations, February 2010	
21.	Guidance for post-market surveillance and market surveillance of medical devices, including in vitro diagnostics, ISBN: 978-92-4-001531-9	

5. Risks and Warnings

5.1. Residual risks and undesirable effects:

After applying the risk control measures, residual risks related to user error is evaluated using the risk acceptability criteria described in the Probability and Risk Matrix. For residual risks that are judged acceptable using the risk acceptability criteria, information necessary to include in the IFU and other accompanying documents in order to disclose those residual risks. Information for safety gives instructions on action(s) to take or not to take to avoid a risk. Disclosure of individual and overall residual risks related to user error in case of MERISCREEN HIV 1-2 WB gives background and relevant information necessary to explain the residual risks to users so that users can proactively take appropriate actions to minimize exposure to the residual risks.

Information for safety is developed by considering the following points:

- The level of priority appropriate to classify an action (warning and precaution, note,
- etc.)
- The level of detail of information needed
- The location for the information for safety
- The wording or pictures to be used to ensure clarity and understandability
- The appropriate media for providing the information (e.g., IFU, labels)
- Regulatory requirements

Description of the relevant analytical performance characteristics and the results of clinical performance studies is provided in IFU so that the laboratory or other user can:

- Verify that the MERISCREEN HIV 1-2 WB is performing as intended
- Determine the measurement uncertainty associated with the examination results
- Know that the examination results will meet the medical needs of the clinicians.

Limitations of the MERISCREEN HIV 1-2 WB are disclosed in IFU which describes the situations in which the MERISCREEN HIV 1-2 WB might not perform as intended and can therefore be a means of disclosing residual risks such as:

- Interfering substances not detectable by the user (e.g., drugs, biological metabolites);
- Specific patient’s populations in which the performance characteristics might not
- apply;

- Values outside he measuring interval (where performance characteristics are not
- validated);
- Patient populations where reference intervals or medical decision points might not
- apply;
- Primary sample typed that have not been validated for the intended use;
- Circumstances and factors that might affect examination results, but have not been studied.

5.2. Warnings and precautions:

- For in-vitro diagnostics use only.
- Read the instructions carefully before performing the test. The instruction must be followed exactly to get accurate results.
- Do not use any other buffer than the buffer supplied within this kit.
- The buffer contains sodium azide as a preservative which may be toxic if ingested. When disposed of through a sink, flush with large quantities.
- Do not use any other specimens than prick whole blood, venous whole blood, serum or plasma.
- Do not use any other anticoagulants other than EDTA, heparin and citrate.
- Allow all reagents and specimen(s) to attain room temperature (18ºC to 30ºC) before use.
- 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.
- Do not use the kit contents beyond the expiry date.
- Do not use test device if pouch is lack of desiccant.
- Do not use the lancet if the seal is broken.

- Do not touch the nitrocellulose part of the device. prick or scratch on nitrocellulose membrane may give erroneous results.
- Test Devices and assay buffers of different lot must not be mixed and used.
- Do not re-use accessories like capillary tubes, alcohol swabs or lancets for testing purpose.
- Perform the test by using kit's assay buffers. Performing the test with any other buffer is not valid.
- Follow the assay procedure and storage instructions strictly. Deviation will lead to erroneous results.
- Do not use haemolysed or lipemic specimen for testing.
- Use sufficient volume of specimen for testing.
- Do not re-use the Test Devices and pipette tips from the procedure; this may lead to inaccurate results.
- Do not pipette reagents nor specimens by mouth and do not smoke, eat or drink while handling specimens and performing a test.
- Avoid contact of reagents with eyes and skin. If either of the reagents come into contact with skin or eyes, wash thoroughly with water.
- 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.
- Handle specimens(s) and used materials as if it is capable of transmitting infection.
- 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 121ºC for 30 minutes or dipped in 10% hypochlorite solution for 30 minutes prior to disposal.
- Clean up spills thoroughly using an appropriate disinfectant.
- 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.

- In case of performance changes or product malfunction, stop using the kit immediately and contact your local distributor.

5.3. Other relevant aspects of safety, including a summary of any field safety corrective action (FSCA including FSN), if applicable

There were no field safety corrective actions initiated for MERISCREEN HIV 1-2 WB as there was no reportable/unexpected serious incident reported till date.

6. Summary of performance evaluation and post-market performance follow-up (PMPF)

6.1. Summary of scientific validity of the device

Scientific validity of the device was determined by performing literature search using different keywords on different search database viz. MEDLINE, ScienceDirect, Google Search Engine, etc. Total of 35 relevant literatures were downloaded. From these, three duplicate literatures were deleted, one literature was not peer-reviewed and four articles were not relevant as per the appraisal suitability criteria, hence, these were not included in the literature appraisal study. Selected literatures were appraised as per the appraisal suitability criteria and as per the criteria for data contribution. Out of 27 literatures, 10 were excluded as they were of different devices, or with different intended use or intended users. Other 17 literatures included study on devices those are similar to that of the MERISCREEN HIV 1-2 WB and it addresses the safety and performance aspects of the device.

6.2. Summary of performance data from the equivalent device, if applicable

Refer Table 3 for Summary of performance data from the equivalent device.

6.3. Summary of performance data from conducted studies of the device prior to CE-marking

Table 6: Summary of performance data of MERISCREEN HIV 1-2 WB

Sr. no.	Name of the Performance Study	Results of the Performance Studies
Analytical Performance Study:		
1	Specimen Type	MERISCREEN HIV 1-2 WB has shown 100% agreement with anti-HIV positive capillary whole blood samples, serum samples, plasma (EDTA, Citrate, Heparin) samples and venous whole blood (EDTA, Citrate, Heparin) samples. Furthermore, the test results of MERISCREEN HIV 1-2 WB are comparable with the test results of CE marked Turklab's Rapidan® Tester Anti-HIV ½ Test, WB/S/P kit. MERISCREEN HIV 1-2 WB has shown 100% agreement with HIV negative capillary whole blood samples, serum samples, plasma (EDTA, Citrate, Heparin) samples and whole blood (EDTA, Citrate, Heparin) samples. Furthermore, the test results of MERISCREEN HIV 1-2 WB are comparable with the test results of CE marked Turklab's Rapidan® Tester Anti-HIV ½ Test, WB/S/P kit.
2	Specimen Stability	Based on the results and data analysis, it is concluded that "stored serum/plasma/venous whole blood specimens at 2-8°C up to 3 days can be used for testing
3	Diagnostic Sensitivity	Diagnostic sensitivity of MERISCREEN HIV 1-2 WB was calculated as 100% (95% CI: 99.34% to 100.00%) and positive predicted value was calculated as 100%.
4	Diagnostic Specificity	Diagnostic specificity of MERISCREEN HIV 1-2 WB was calculated as 100% (95% CI: 99.81% to 100%) and negative predicted value was calculated as 100%.
5	Repeatability & Reproducibility	The results have shown 100% agreement with the sample status when tested with anti-HIV positive samples and HIV negative samples. The results and data analysis showed 100% sensitivity for anti-HIV positive samples and 100% specificity for HIV negative samples.
6	Sensitivity in seroconversion panels	Results of MERISCREEN HIV 1-2 WB were compared with the results of CE marked Turklab's Rapidan® Tester Anti-HIV ½ Test, WB/S/P kit. From the results, it can be concluded that MERISCREEN HIV 1-2 WB meets the acceptance criteria as it 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.
7	Analytical	Diagnostic specificity of MERISCREEN HIV 1-2 WB was

	Specificity	evaluated for qualitative determination of antibodies of all classes specific to HIV-1 and HIV-2 in human serum, plasma and whole blood by using 100 Interfering substances. All samples were identified as negative when tested with MERISCREEN HIV 1-2 WB. The test results of MERISCREEN HIV 1-2 WB were compared with the results of CE marked comparator assay kit i.e., Turklab's Rapidan® Tester Anti-HIV ½ Test, WB/S/P. Diagnostic specificity of MERISCREEN HIV 1-2 WB was calculated as 100% (95% CI: 99.81% to 100%) and negative predicted value was calculated as 100%.
8	Measuring range of assay	35 anti-HIV positive samples including high-titer, moderate titer and weak anti-HIV positive samples were tested in replicates of three with MERISCREEN HIV 1-2 WB to check whether MERISCREEN HIV 1-2 WB exhibit hook effect or not. There was no intensity drop observed anywhere with high-titer anti-HIV positive samples. Thus, the study results have met acceptance criteria i.e., MERISCREEN HIV 1-2 WB does not exhibit hook effect.
9	Validation of reading time	MERISCREEN HIV 1-2 WB showed clear and accurate results at the end of the 20 minutes and till 50 minutes when tested with anti-HIV positive samples including weak titer positive samples and with HIV negative samples. Also, the background clearance was checked for all the tested samples and test results showed the background clearance within 20 minutes. After 50 minutes, few of the MERISCREEN HIV 1-2 WB devices showed unclear background, but no false positive or false negative results were observed throughout the study. From the results and data analysis, it is claimed that the result should be read at the end of the 20 minutes and not later than 30 minutes
10	Comparison Study between European and Non-European Population	Equivalence of the performance of MERISCREEN HIV 1-2 WB to be used for qualitative determination of antibodies of all classes specific to HIV-1 and HIV-2 in human serum, plasma and whole blood samples has been established when tested with anti-HIV positive and HIV negative samples from European population and Non-European population. There is no statistically significant difference observed in the performance of MERISCREEN HIV 1-2 WB when tested with the samples from different population i.e., European and Non-European population.
11	Evaluation of effect of humidity on performance of test device	The effect of different range of humidity i.e., 40% RH, 60% RH and 75% RH was evaluated on the performance of Test Device of MERISCREEN HIV 1-2 WB by using Anti-HIV positive and HIV negative samples. All positive samples

		were identified as positive and all negative samples were identified as negative when tested with MERISCREEN HIV 1-2 WB when results were read at the end of the 20 minutes under 40% RH, 60% RH and 75% RH. Sensitivity and Specificity of MERISCREEN HIV 1-2 WB was calculated as 100% when calculated for the test results of test devices which were exposed to 40% RH, 60% RH and 75% RH. It is concluded that the performance of test device of MERISCREEN HIV 1-2 WB is not affected by the different range of humidity i.e., 40% RH, 60% RH and 75% RH. But, it is recommended that the test device should be used in ambient humidity i.e., between 40 to 60% RH.
Clinical Performance of MERISCREEN HIV 1-2 WB:		
12		Clinical performance study by manufacturer is conducted to derive diagnostic sensitivity and specificity in comparison with reference kits using positive and negative samples. Diagnostic sensitivity of MERISCREEN HIV 1-2 WB was evaluated for qualitative determination of antibodies specific to HIV-1 and HIV-2 in human serum, plasma and whole blood by using 555 anti-HIV positive samples including 400 HIV-1 positive samples, 112 HIV-2 positive samples, and 43 HIV-1 subtypes. All samples were identified as positive when tested with MERISCREEN HIV 1-2 WB. The test results of MERISCREEN HIV 1-2 WB were compared with the results of CE marked comparator assay kit i.e., Turklab's Rapidan® Tester Anti-HIV ½ Test, WB/S/P. Diagnostic sensitivity of MERISCREEN HIV 1-2 WB was calculated as 100% (95% CI: 99.34% to 100.00%) and positive predicted value was calculated as 100%. There are no false negative results obtained in the study and sensitivity is 100%, it means that the true positive rate is 100 and false positive rate is 0, the positive likelihood ratio is calculated as infinite. For the expected values in affected population, it is concluded that antibodies against HIV infection is present in all affected/tested population, depends on individual's immune state as well as on exposure of infection based on this qualitative analysis. Diagnostic specificity of MERISCREEN HIV 1-2 WB was evaluated for qualitative determination of antibodies of all classes specific to HIV-1 and HIV-2 in human serum, plasma and whole blood by using 1961 HIV negative samples including 1450 healthy blood donor samples, 204 pregnant women samples, 207 hospitalized (clinical) samples and 100 Interfering substances. All samples were

		identified as negative when tested with MERISCREEN HIV 1-2 WB. The test results of MERISCREEN HIV 1-2 WB were compared with the results of CE marked comparator assay kit i.e., Turklab's Rapidan® Tester Anti-HIV ½ Test, WB/S/P. Diagnostic specificity of MERISCREEN HIV 1-2 WB was calculated as 100% (95% CI: 99.81% to 100%) and negative predicted value was calculated as 100%. There are no false positive results obtained in the study, and specificity is 100%, it means that the false negative rate is zero and true negative rate is 100, the negative likelihood ratio is calculated as zero. For the expected values in normal population, it is concluded that antibodies against HIV infection is absent in all normal/tested population based on this qualitative analysis. Thus, it is also concluded that MERISCREEN HIV 1-2 WB is comparable with that of the CE marked comparator assay kit i.e., Turklab's Rapidan® Tester Anti-HIV ½ Test, WB/S/P kit.

6.4. Summary of performance data from other sources, if applicable

This section is not applicable as there is no performance data from any other sources.

6.5. An overall summary of the performance and safety

MERISCREEN HIV 1-2 WB 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 healthcare professionals (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 conducted analytical and clinical performance studies conducted by Meril and on independent sites demonstrate the performance of the MERISCREEN HIV 1-2 WB to be used as intended. The scientific validity of the kit was determined by appraising relevant scientific literatures that addressed the safety and performance of MERISCREEN HIV 1-2 WB. Also, no field safety corrective actions have been initiated as no reportable/unexpected serious incidents were reported till date. All risk control measures have been implemented

and the overall residual risk wherever present is acceptable using the defined criteria. On the basis of risk analysis, it can be concluded that MERISCREEN HIV 1-2 WB is considered as safe and reliable for its intended use. The Risk-Control measures are being constantly reviewed to identify if any other hazards are introduced based on the production and post-production information.

Thus, from the aforementioned information on summary and safety aspects of the kit, it is concluded that the MERISCREEN HIV 1-2 WB is safe for use by healthcare professionals (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.

6.6. Ongoing or planned post-market performance follow-up

Post-market performance follow-up of MERISCREEN HIV 1-2 WB is planned and on-going.

Meril Diagnostics has gathered the information on performance of MERISCREEN HIV 1-2 WB through various sources viz., performance evaluation of MERISCREEN HIV 1-2 WB, feedbacks collected from users, literature search related to performance evaluation of MERISCREEN HIV 1-2 WB, review of data on adverse event reporting and analysis of information on scientific data of similar devices available on the market.

From the analysis of the post market performance follow up data collected from different sources the following interpretations have been made:

- The analytical performance of MERISCREEN HIV 1-2 WB is within the acceptable criteria and no negative findings have been reported.
- There is no complaint received for the period up to August 2022, thus there is no requirement to update the risk-benefit assessment and risk management report and hence CAPA is not be required.
- From the analysis of gathered clinical evidences of MERISCREEN HIV 1-2 WB, no new clinical concern is emerged.

There is no requirement to update the performance evaluation report of MERISCREEN HIV 1-2 WB as no new conclusions have been derived from the PMPF data.

The PMPF data gathered from different sources indicate no new derivations on the performance of MERISCREEN HIV 1-2 WB. Hence, it is concluded that the post-market performance follow-up of MERISCREEN HIV 1-2 WB supports the safety and performance of the device MERISCREEN HIV 1-2 WB for its intended use.

7. Metrological traceability of assigned values

7.1. Explanation of the unit of measurement, if applicable

This section is not applicable as no calibrators and control materials are supplied with the kit. Also, the test is qualitative and only reports the presence or absence of the test target hence this section is not applicable.

7.2. Identification of applied reference materials and/or reference measurement procedures of higher order used by the manufacturer for the calibration of the device

This section is not applicable as no calibrators and control materials are supplied with the kit. Also, the test is qualitative and only reports the presence or absence of the test target hence this section is not applicable.

8. Suggested profile and training for users

The user for MERISCREEN HIV 1-2 WB shall be a trained healthcare professional who shall have prior experience of testing samples using HIV Rapid Detection Tests (RDTs).

The MERISCREEN HIV 1-2 WB is suitable to be used by healthcare professionals (either in laboratory or in point-of-care setting). The healthcare professional is required to read the provided Instructions for use (IFU) carefully before using the kit. Upon following the step-wise procedure for testing as mentioned in the IFU, the healthcare professional shall be able to interpret the correct testing results.

9. Revision history

Table 7: Revision history

SSP revision number	Date issued	Change Description	Revision validated by the Notified Body
00	22/06/2023	Initial Issue	☑Yes Validation language: English ☐ No
01	22/06/2023	Information on new pack size and new pack sizes with auto safety lancets was added.	☑Yes Validation language: English ☐ No
02	As on approval date	Table 1: Certificate of MERISCREEN HIV 1-2 WB Is updated.	☑Yes Validation language: English ☐ No