STUDY TITLE

Summary of Safety and Performance

DOCUMENT NUMBER

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STUDY ARTICLE

MERISCREEN HBsAg Kit

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

1.1 Device trade name(s)

MERISCREEN HBsAg Kit

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:

8905459MHBSAGRTG4

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

W0105020201 / 48322

1.6 Risk class of device:

MERISCREEN HBsAg Kit 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:

This section is not applicable as MERISCREEN HBsAg Kit is neither a near-patient testing nor a companion diagnostic.

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

The 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 HBsAg

Sr. No.	Details of Certificate	Date of Issue	Description
1	EU Technical Documentation Assessment Certificate No.: 2023-IVDR/TD-004	09/09/2023	Initial Issue
2	EU Quality Management System Certificate No.: 2023-IVDR/QS-004	09/09/2023	
3	EU Technical Documentation Assessment Certificate No.: 2023-IVDR/TD-004/A	28/06/2024	Added product code: RPDHBV-03, 30 Tests
4	EU Quality Management System Certificate No.: 2023-IVDR/QS-004/A	28/06/2024	

1.9 Authorised representative if applicable; name and the SRN:

Authorized Representative: Obelis s.a., Belgium

Authorized Representative: BE-AR-000000106

1.10 NB's name (the NB that will validate the SSP) and the NB's single identification number:

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

NB Single Identification Number: CE 2265

2. Intended use of the device

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

MERISCREEN HBsAg is a qualitative, In-Vitro diagnostic immuno-chromatography assay based on lateral flow technology for the detection of Hepatitis-B surface antigen (HBsAg), a marker of hepatitis-B virus in human serum or plasma. This kit is designed for screening & diagnosis of Hepatitis B virus infection and intended to be used by healthcare professionals as an aid to diagnosis. The assay is manual and does not require additional instruments.

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

The test is intended for Healthcare Professionals for primary screening of Hepatitis B virus.

2.3 Limitations and/or contra-indications (e.g. relevant interferences, cross-reactions):

- This is only a screening test. All reactive test samples should be confirmed by confirmatory test like EIA.
- The test is not intended for blood and organ donors.
- As with all diagnostic tests, the test result must always be co-related with clinical findings.
- Presence of heterophile antibodies in patients sample 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 sample 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 is only intended for human serum and plasma samples with anticoagulants EDTA, Heparin and Citrate.
- This is the qualitative test and should not be used for measurement of HBsAg concentration.

- False negative HBsAg results are associated with lower HBsAg levels, early window period of sero-conversion, low viral load, HBsAg mutants, in addition to ART exposure where lamivudine and tenofovir are used.
- Several authors have reported in the literature cases of viral hepatitis B (acute or chronic) wherein viral DNA is detectable in the absence of the surface antigen (HBsAg negative patients). These abnormal profiles, though rare, are the consequence of possible genetic mutations, either at the S and pre-S gene level (preventing recognition of the Ag by some immunological reagents) or, usually, at the X and polygene level, inducing weak viral replication. Testing additional markers (HBsAg-specific antibody or, if possible, amplified viral DNA) is recommended for the final diagnosis of the infection, in those very particular cases.
- False positive results may occur in vaccinate patients.
- Test results should be interpreted in conjunction with clinical findings.

3. Device Description

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

MERISCREEN HBsAg Kit contains:

1. Individually Packed Test Devices
2. Sample droppers
3. IFU

MERISCREEN HBsAg Kit consists of two analyte specific reagents which are “Capture: Polyclonal Anti-HBsAg Antibody” and “Conjugate: Monoclonal Anti-HBsAg Antibody”. The test format of MERISCREEN HBsAg Kit is Immunochromatography.

MERISCREEN HBsAg Kit is a rapid, qualitative, sand-witch immunoassay for the detection of Hepatitis B surface antigen (HBsAg) a marker for Hepatitis B infection in human serum or plasma by Healthcare Professionals. This kit is designed for primary screening of Hepatitis B virus.

MERISCREEN HBsAg Kit is intended to be used in population with high HBV prevalence and clinical symptoms of HBsAg infection. It is not an automated assay.

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 1: Components of MERISCREEN HBsAg Kit:

Sr. No.	Product Name: MERISCREEN HBsAg	Product Code : RPDHBV-01	Product Code : RPDHBV-03	Active Ingredients
		Pack Size : 50 Tests	Pack Size : 30 Tests	
1.	Test Device	50 Nos.	30 Nos.	Anti-HBsAg antibody immobilized onto nitrocellulose membrane as transparent line and colloidal gold conjugated impregnated onto conjugate pad which act as a detector.
2.	Sample droppers	50 Nos.	30 Nos.	-
3.	IFU	01 No.	01 No.	-

Table 2: Details of Basic UDI-DI and Product Code:

Product Code	Basic UDI DI
RPDHBV-01	8905459MHBSAGRTG4
RPDHBV-03	

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

Table 3: Differences of MERISCREEN HBsAg Kit and previous generation/variants:

#	Parameter/ Specification	Subjective Device	Comparative Device	Equivalence
1	Device Name	MERISCREEN HBsAg Kit	Rapidan Tester, HBsAg Test, WB/S/P	-
2	Manufacturer	Meril Diagnostic Pvt. Ltd., India	TURKLAB, Turkey	-
3	Regulatory Status	CE approved (CE2265)	CE approved (CE 1434)	-
Clinical Equivalence				
4	Intended Use	MERISCREEN HBsAg Kit is a rapid, qualitative, sand-witch immunoassay for the detection of Hepatitis B	HBsAg Test is a rapid chromatographic immunoassay for the qualitative detection of	Equivalent

		surface antigen (HBsAg) a marker for Hepatitis B infection in human serum or plasma by Healthcare Professionals. This kit is designed for primary screening of Hepatitis B virus.	Hepatitis B surface antigen (HBsAg) in human whole blood/ serum / plasma.	
5	Principle of operation	Immunochromatography	Immunochromatography	Similar
6	Specimens can be used	Serum and Plasma (Heparin, EDTA and Citrate)	Whole blood (Heparin, EDTA and Citrate), Serum and Plasma (Heparin, EDTA and Citrate)	Equivalent
Analytical & Technical Equivalence				
7	Kit components	Individually Packed Test Devices, Sample Droppers, IFU	Test cassettes, droppers and IFU	Equivalent
8	Result should be read at	20 minutes	15 minutes	Comparable
9	Storage condition	2-30°C	4-30°C	Comparable
10	Specificity	100.00% (95% CI: 99.89% to 100%)	100%	Comparable
11	Sensitivity	100% (95% CI: 99.47% to 100.00%)	100%	Equivalent

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:

- Sample Dropper as specimen transfer device

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 HBsAg Kit.

4. Reference to any harmonized standards and CS applied

Table 4: List of Standards:

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.	BS EN 1041:2008+A1:2013	Information supplied by the manufacturer of medical devices
9.	EN ISO 13485:2016	Medical Devices – Quality Management System Requirements for Regulatory Purpose (ISO 13485:2016)
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-	In vitro diagnostic medical devices - Information supplied by the manufacturer (labeling) - Part 2: In vitro diagnostic reagents for

	2:2011	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.01: Guidance on Classification Rule for in vitro Diagnostics Medical Device under Regulation (EU) 2017/746, January 2022
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 those are judged acceptable using the above 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 HBsAg Kit

give 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 understand ability
- 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 are provided in Pack Insert so that the laboratory or other user can:

- Verify that the MERISCREEN HBsAg kit 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 HBsAg Kit are disclosed in IFU which describes the situations in which the MERISCREEN HBsAg Kit 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 studies;

5.2 Warnings and precautions:

- For in vitro diagnostics and professional use only.

- Allow all reagents and sample(s) to attain room temperature (18ºC to 30ºC) before use.
- Once test device foil is opened, it gives accurate results 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 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 touch the nitrocellulose part of the device. Finger print or scratch on nitrocellulose membrane may give erroneous results.
- Follow the assay procedure and storage instructions strictly. Deviation will lead to erroneous results.
- Do not use haemolysed specimen for testing.
- Use sufficient volume of sample for testing.
- Do not re-use the Test Devices; sample dropper from the procedure may lead to aberrant results.
- Do not pipette reagents 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 any reagents come into contact with the 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 gloves or use of washed gloves.
- Handle sample(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 material. All remnants of sample(s), used materials, pipette tips etc. should be disposed in suitable biohazard container. Materials should be autoclaved at 121½C 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 color from blue to light pink color or test device pouch is lack of desiccant, then test device should not be used.

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 HBsAg Kit 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 36 literatures related to HBsAg Rapid were downloaded. From these, 7 duplicate literatures and 9 irrelevant were deleted. Selected literatures were appraised as per the appraisal suitability criteria and as per the criteria for data contribution. Out of 20 literatures, 4 were excluded as they were of different devices, or with different intended use or intended users. Other 16 literatures included study on devices those are similar to that of the MERISCREEN HBsAg Kit and it address 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 5: Summary of performance data of MERISCREEN HBsAg Kit**:**

Sr. No.	Name of the Performance Study	Results of the Performance Studies
Analytical Performance Study		
1	Specimen Type	25 HBsAg positive EDTA plasma, 25 HBsAg positive heparin plasma, 25 HBsAg positive citrate plasma and 25 HBsAg positive serum samples were tested with MERISCREEN HBsAg Kit and CE marked Turklab's Rapidan® Tester HBsAg Test, WB/S/P kit at North City Diagnostics Centre (Pvt.) Ltd., Kolkata. All positive samples have shown accurate result as per sample status. MERISCREEN HBsAg Kit has shown 100% agreement with HBsAg positive serum samples and plasma samples along with different types of anticoagulants (EDTA, Heparin and Citrate). 25 HBsAg negative EDTA plasma, 25 HBsAg negative heparin plasma, 25 HBsAg negative citrate plasma and 25 HBsAg negative serum samples were tested with MERISCREEN HBsAg Kit and CE marked Turklab's Rapidan® Tester HBsAg Test, WB/S/P kit at Meril Diagnostics Pvt. Ltd., Vapi (in-house). All negative samples have shown accurate result as per sample status. MERISCREEN HBsAg Kit has shown 100% agreement with HBsAg negative serum samples and plasma samples along with different types of anticoagulants (EDTA, Heparin and Citrate).
2	Specimen Stability	Based on the results and data analysis, it is concluded that "stored serum/plasma specimens at 2-8°C up to 5 days can be used for testing".
3	Diagnostic Sensitivity	Diagnostic sensitivity of MERISCREEN HBsAg Kit was calculated as 100% (95% CI: 99.18% to 100.00%) and positive predicted value was calculated as 100%.
4	Diagnostic Specificity	Diagnostic specificity of MERISCREEN HBsAg Kit 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 HBsAg positive samples and HBsAg negative samples.

		The results and data analysis showed 100% sensitivity for HBsAg positive samples and 100% specificity for HBsAg negative samples.
6	Sensitivity in seroconversion panels	Results of MERISCREEN HBsAg Kit were compared with the results of CE marked Turklab's Rapidan® Tester HBsAg Test, WB/S/P kit. From the results, it can be concluded that MERISCREEN HBsAg Kit meets the acceptance criteria as it has relatively comparable sensitivity when compared with CE marked comparator assay kit i.e., Turklab's Rapidan® Tester HBsAg Test, WB/S/P.
7	Analytical Specificity (Interference and Cross Reactivity)	Analytical specificity (Interference and Cross Reactivity) of MERISCREEN HBsAg Kit was evaluated for the qualitative detection of Hepatitis B surface antigen (HBsAg), a marker for Hepatitis B infection in human serum or plasma samples by using 100 Interfering substances. All samples were identified as negative when tested with MERISCREEN HBsAg Kit. The test results of MERISCREEN HBsAg Kit were compared with the results of CE marked comparator assay kit i.e., Turklab's Rapidan® Tester HBsAg Test, WB/S/P. Analytical specificity (Interference and Cross Reactivity) of MERISCREEN HBsAg Kit was calculated as 100% (95% CI: 99.81% to 100%) and negative predicted value was calculated as 100%. Hence from the results of the tested samples, it is concluded that interfering substances/cross reactive specimens do not affect the performance of MERISCREEN HBsAg Kit.
8	Measuring range of assay	30 high-titer HBsAg positive samples were serially diluted to moderate titer, weak titer and tested in replicates of three (03) with MERISCREEN HBsAg Kit to check whether MERISCREEN HBsAg Kit exhibit hook effect or not. There was no intensity drop observed anywhere with high-titer HBsAg positive samples. Thus, results have met the acceptance criteria i.e., MERISCREEN HBsAg Kit does not exhibit hook effect.
9	Validation of Assay Procedure - Reading Time	MERISCREEN HBsAg Kit showed clear and accurate results at the end of the 20 minutes and till 60 minutes. Also, the background clearance was checked for all the tested samples and test results showed the background clearance within 20 minutes. No false positive or false negative results were observed throughout the study. But sometimes after 30 minutes, back-flow

		could be possible which may lead to false positive result and unclear background. So from the safer side, it is claimed that the result should be read at the 20 minutes and not later than 30 minutes.
10	Comparison Study between European and Non-European Population	Equivalence of the performance of MERISCREEN HBsAg Kit to be used for qualitative detection of HBsAg in human serum and plasma samples has been established when tested with HBsAg positive and HBsAg negative samples from European population and Non-European population. There is no significant difference observed in the performance of MERISCREEN HBsAg Kit 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 HBsAg Kit by using HBsAg positive and HBsAg negative samples. All positive samples were identified as positive and all negative samples were identified as negative when tested with MERISCREEN HBsAg Kit when results were read at the end of 20 minutes under 40% RH, 60% RH and 75% RH. Sensitivity and Specificity of MERISCREEN HBsAg Kit was calculated as 100% when calculated for the test results of test devices which were exposed to 40% RH, 60% RH and 75% RH. Thus, from the results and data analysis, it is concluded that the performance of test device of MERISCREEN HBsAg Kit 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 Study of MERISCREEN HBsAg Kit		
12		Clinical performance study of MERISCREEN HBsAg Kit by manufacturer is conducted to derive diagnostic sensitivity and specificity in comparison with reference kits using positive and negative samples. Diagnostic sensitivity of MERISCREEN HBsAg Kit was evaluated for the qualitative detection of Hepatitis B surface antigen (HBsAg), a marker for Hepatitis B infection in human serum or plasma samples by using 450 HBsAg positive samples. All samples were identified as positive when tested with MERISCREEN HBsAg Kit. The test results of MERISCREEN HBsAg Kit were compared with the results of CE marked

		comparator assay kit i.e., Turklab's Rapidan® Tester HBsAg Test, WB/S/P. Diagnostic sensitivity of MERISCREEN HBsAg Kit was calculated as 100% (95% CI: 99.18% to 100.00%) and positive predicted value was calculated as 100%. So, from the results and data analysis, it is concluded that MERISCREEN HBsAg Kit meets the acceptance criteria of Diagnostic Sensitivity study. Same samples were tested with CE marked comparator assay kit i.e., Turklab's Rapidan® Tester HBsAg Test, WB/S/P and all samples were found as positive. Thus, it is also concluded that MERISCREEN HBsAg Kit is comparable with that of the CE marked comparator assay kit i.e., Turklab's Rapidan® Tester HBsAg Test, WB/S/P kit. Diagnostic specificity of MERISCREEN HBsAg Kit was evaluated for the qualitative detection of Hepatitis B surface antigen (HBsAg), a marker for Hepatitis B infection in human serum or plasma samples by using 1961 HBsAg 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 HBsAg Kit. The test results of MERISCREEN HBsAg Kit were compared with the results of CE marked comparator assay kit i.e., Turklab's Rapidan® Tester HBsAg Test, WB/S/P. Diagnostic specificity of MERISCREEN HBsAg Kit was calculated as 100% (95% CI: 99.81% to 100%) and negative predicted value was calculated as 100%. So, from the results and data analysis, it is concluded that MERISCREEN HBsAg Kit meets the acceptance criteria of Diagnostic Specificity study. Same samples were tested with CE marked comparator assay kit i.e., Turklab's Rapidan® Tester HBsAg Test, WB/S/P and all samples were found as negative. Thus, it is also concluded that MERISCREEN HBsAg Kit is comparable with that of the CE marked comparator assay kit i.e., Turklab's Rapidan® Tester HBsAg Test, WB/S/P kit. Thus, it can be concluded that MERISCREEN HBsAg Kit is safe and reliable for its intended use when tested with positive and negative clinical specimens.

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 HBsAg Kit is a rapid, qualitative, sand-witch immunoassay for the detection of Hepatitis B surface antigen (HBsAg) a marker for Hepatitis B infection in human serum or plasma by Healthcare Professionals. This kit is designed for primary screening of Hepatitis B virus.

MERISCREEN HBsAg Kit is intended to be used in population with high HBV prevalence and clinical symptoms of HBsAg infection. It is not an automated assay.

The conducted analytical and clinical performance study conducted by Meril and on independent sites (where applicable) demonstrates the performance of the MERISCREEN HBsAg Kit 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 HBsAg Kit. 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 HBsAg kit 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 HBsAg Kit is safe for use by Healthcare Professionals for primary screening of Hepatitis B virus.

6.6 Ongoing or planned Post-Market Performance Follow-Up

Post-market performance follow-up of MERISCREEN HBsAg Kit is planned and on-going.

Meril Diagnostics has gathered the information on performance of MERISCREEN HBsAg Kit through various sources viz., performance evaluation of MERISCREEN HBsAg Kit, feedbacks collected from users, literature search related to performance evaluation of MERISCREEN

HBsAg Kit, 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 HBsAg Kit is within the acceptable criteria and no negative findings have been reported.
- There is no complaint received for the period up to November 2022, thus there is no requirement to update the risk-benefit assessment and risk management report and hence CAPA is not being required.
- From the analysis of gathered clinical evidences of MERISCREEN HBsAg, no new clinical concern is emerged.

There is no requirement to update the performance evaluation report of MERISCREEN HBsAg Kit 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 HBsAg Kit. Hence, it is concluded that the post-market performance follow-up of MERISCREEN HBsAg Kit supports the safety and performance of the device MERISCREEN HBsAg Kit 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 HBsAg Kit shall be a trained healthcare professional who shall have prior experience of testing samples using HBsAg Rapid Detection Tests (RDTs).

The MERISCREEN HBsAg Kit is suitable to be used by Healthcare Professionals. 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 6: 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	30/05/2024	Section 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) is updated	☑ Yes Validation language: English ☐ No
02	As on approval date	Table 1: Certificate of MERISCREEN HBsAg is updated.	☑Yes Validation language: English ☐ No