

Date: 01st January 2021**TO WHOMSOEVER IT MAY CONCERN**

We hereby certify that,

Sanmedico SRL
Str. Corobceanu 7A, Apt.9,
MD-2012, CITY CHISINAU
Republic of Moldova,
Tel:-00-373-231 31515 / 00-373-222 60595
Fax:-00-373-22 62 30 32
E-mail: sanmedico.office@gmail.com

have been appointed by us as our **Exclusive Authorized Distributor** for selling our Products in **MOLDOVA**

This certificate is valid upto 31st December 2022.

This Authorization Letter shall stand effective from the date of signing and can be terminated by either party with two months advance notice.

For **HIMEDIA LABORATORIES PVT. LTD.,**

V.M.WARKE.

DIRECTOR – SALES & MARKETING



Certificate of CE-Registration

This is to certify that, in accordance with the *In Vitro* Diagnostic Medical Device Directive 98/79/EC, **CEpartner4U BV** agrees to perform all duties and responsibilities as the Authorized Representative for

Himedia Laboratories PVT. LTD

23 Vadhani Industrial Estate,
LBS Marg, Mumbai - 86, MS,
India

as stipulated and demanded by the aforementioned Directive. The Dutch Competent Authorities have accepted the manufacturer's medical device registrations by CEpartner4U as listed on the product list attached to the manufacturer's Declaration of Conformity:

IVD devices are registered under number:

Cell Culture Media	Registration No: NL-CA002-26448
Viral Transport Medium	Registration No: NL-CA002-26449
Diagnostic products	Registration No: NL-CA002-53715

see appendix

**consequently these IVD devices were entered in EUDAMED by the Dutch
Competent Authority.**

The manufacturer has provided CEpartner4U with all necessary documentation, together with an appropriate Declaration of Conformity that the IVD medical devices fulfil the essential requirements of Directive 98/79/EC.

Issue date: 2020-12-09



Olga Teirlinck
Consultant CEpartner4U BV

cepartner4U

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tel: +31 (0)343 442 524
www.cepartner4u.nl

Appendix

List of devices:

Product group	Type/ Model / Ref number	Device Name	Risk Class	Date of CE compliance
Cell Culture Media				
CCM- Karyotyping Media	AL165A	HiKaryoXL™ RPMI Medium w/ L-Glutamine, FBS, PHA-M, Penicillin, Streptomycin and Sodium bicarbonate	Low risk	20/12/2012
CCM- Karyotyping Media	AL169A	HiKaryoXL™ Nutrient Mixture F10 Medium w/ L-Glutamine, FBS, PHA-M, Penicillin, Streptomycin and Sodium bicarbonate	Low risk	20/12/2012
CCM- Karyotyping Media	AL173A	HiKaryoXL™ RPMI Medium w/ L-Glutamine, FBS, Penicillin, Streptomycin and Sodium bicarbonate 1X Liquid Karyotyping Medium	Low risk	20/12/2012
CCM- Karyotyping Media	AL185A	HiKaryoXL™ Nutrient Mixture F-10 Ham Medium w/ L-Glutamine, FBS, Penicillin, Streptomycin and Sodium bicarbonate 1X Liquid Cell Culture Medium	Low risk	20/12/2012
CCM- Karyotyping Media	AL249A	HiKaryoXL™ RPMI Medium w/ L-Glutamine, FBS, PHA-P, Penicillin, Streptomycin and Sodium bicarbonate	Low risk	20/12/2012
CCM- Stem Cell Differentiation Media	AL512	HiMesoXL™ Mesenchymal Stem Cell Expansion Medium	Low risk	28/04/2017
CCM- Stem Cell Differentiation Media	AL519	HiMesoXL™ Mesenchymal Stem Cell Expansion Medium, Reduced Serum	Low risk	28/04/2017
CCM- Stem Cell Differentiation Media	AL250A	HiPer [®] Dulbecco's Modified Eagle Medium, High Glucose	Low risk	28/04/2017
CCM- Stem Cell Differentiation Media	AL250	HiPer [®] Dulbecco's Modified Eagle Medium, High Glucose	Low risk	28/04/2017
CCM- Viral Transport Media	AL296	HiViral™ Transport Medium	Low risk	22/04/2019
CCM- Viral Transport Media	AL297	HiViral™ Transport Medium	Low risk	22/04/2019
CCM- Stem Cell Differentiation Media	AL521	HiAdipoXL™ Adipocyte Differentiation Medium	Low risk	28/04/2017
CCM- Stem Cell Differentiation Media	AL522	HiOsteoXL™ Osteocyte Differentiation Medium	Low risk	28/04/2017
CCM- Stem Cell Differentiation Media	AL523	HiChondroXL™ Chondrocyte Differentiation Medium	Low risk	28/04/2017
CCM- Stem Cell Differentiation Media Supplement	TCL167	HiAdipoXL™ Adipocyte Differentiation Supplement	Low risk	28/04/2017
CCM- Stem Cell Differentiation Media Supplement	TCL168	HiOsteoXL™ Osteocyte Differentiation Supplement	Low risk	28/04/2017
CCM- Stem Cell Differentiation Media Supplement	TCL169	HiChondroXL™ Chondrocyte Differentiation Supplement	Low risk	28/04/2017
CCM- Stem Cell Freezing Medium	TCL107	CryoXL™ Stem Cell Freezing Medium	Low risk	28/04/2017
CCM- Stem Cell Freezing Medium	TC450U	CryoXL™ DMSO, Sterile Sterile Filtered, Cell Culture Tested, Meets USP specifications	Low risk	08/12/2017
CCM- Stem Cell Differentiation Staining Kits	CCK013	EZstain™ Adipocyte Staining Kit	Low risk	28/04/2017
CCM- Stem Cell Differentiation Staining Kits	CCK029	EZstain™ Chondrocyte Staining Kit	Low risk	28/04/2017
CCM- Stem Cell Differentiation Staining Kits	CCK030	EZstain™ Osteocyte Staining Kit	Low risk	28/04/2017
CCM- Balanced Salt Solutions	TL1006	Dulbecco's Phosphate Buffered Saline 1X w/o Phenol red, Calcium and Magnesium w/o Phenol red, Calcium and Magnesium	Low risk	16/12/2017
CCM- Balanced Salt Solutions	TL1098	Hanks' Balanced Salt Solution 1X w/ Sodium bicarbonate w/o Calcium, Magnesium and Phenol red w/o Calcium, Magnesium and Phenol red	Low risk	16/12/2017
CCM- Antibiotic Solutions	A033	Amphotericin B 250microgram per ml with 250 microgram per ml amphotericin B in normal saline	Low risk	16/12/2017
CCM- Antibiotic Solutions	A002	Antibiotic Antimycotic Solution 100X Liquid w/10,000 U Penicillin, 10mg Streptomycin and 25µg Amphotericin B per ml in 0.9% normal saline	Low risk	16/12/2017

Product group	Type/ Model / Ref number	Device Name	Risk Class	Date of CE compliance
CCM- Animal Cell Culture Medium Liquid	AL183	Dulbecco's Modified Eagle Medium (DMEM), Low glucose w/ 1gm Glucose per litre, Sodium bicarbonate and Sodium pyruvate w/o L- Glutamine and Phenol red	Low risk	16/12/2017
RPM -Viral Transport Medium w/ swabs	AL167	HiViral Transport Medium	Low risk	20/12/2012
RPM -Viral Transport Medium w/ swabs	MS2760	HiViral™ Transport Kit	Low risk	20/12/2012
RPM -Viral Transport Medium w/ swabs	MS2760A	HiViral™ Transport Kit (A)	Low risk	20/12/2012
RPM -Viral Transport Medium w/ swabs	MS2760B	HiViral™ Transport Kit (B)	Low risk	20/12/2012
RPM -Viral Transport Medium w/ swabs	MS2760C	HiViral™ Transport Kit (C)	Low risk	20/12/2012
RPM -Viral Transport Medium w/ swabs	MS2760D	HiViral™ Transport Kit (D)	Low risk	20/12/2012
RPM -Viral Transport Medium w/ swabs	MS2760E	HiViral™ Transport Kit (E)	Low risk	20/12/2012
RPM -Viral Transport Medium w/ swabs	MS2760F	HiViral™ Transport Kit (F)	Low risk	20/12/2012
RPM -Viral Transport Medium w/ swabs	MS2760G	HiViral™ Transport Kit (G)	Low risk	20/12/2012
RPM -Viral Transport Medium w/ swabs	MS2760H	HiViral™ Transport Kit (H)	Low risk	28/04/2017
RPM-Viral Transport Medium	AL304	Universal Liquid Medium	Low risk	25/08/2020
RPM -Viral Transport Medium	AL305	Universal Liquid Medium	Low risk	25/08/2020
RPM -Viral Transport Medium	AL306	Universal Liquid Medium	Low risk	25/08/2020
RPM -Viral Transport Medium	AL307	Universal Liquid Medium CS	Low risk	25/08/2020
RPM -Viral Transport Medium	AL167T3	HiViral™ Transport Medium	Low risk	01/09/2020
RPM -Viral Transport Medium	AL167T5	HiViral™ Transport Medium	Low risk	01/09/2020
RPM -Viral Transport Medium	MS4760L1	HiViral™ Transport Kit (L1)	Low risk	01/09/2020
RPM -Viral Transport Medium	MS2760S1	HiViral™ Transport Kit (S1)	Low risk	01/09/2020
RPM -Viral Transport Medium	AL167R	HiViral™ Transport Medium	Low risk	11/09/2020
RPM -Viral Transport Medium	MS2760R	HiViral™ Transport Kit (R)	Low risk	11/09/2020
RPM -Viral Transport Medium	MS2760S	HiViral™ Transport Kit (S)	Low risk	11/09/2020
RPM -Viral Transport Medium	MS2760L	HiViral™ Transport Kit (L)	Low risk	11/09/2020
RPM -Viral Transport Medium	MS2760M	HiViral™ Transport Kit (M)	Low risk	11/09/2020
RPM -Viral Transport Medium	MS2760N	HiViral™ Transport Kit (N)	Low risk	11/09/2020
RPM -Viral Transport Medium	MS2760P	HiViral™ Transport Kit (P)	Low risk	11/09/2020
RPM -Viral Transport Medium	MS2760Q	HiViral™ Transport Kit (Q)	Low risk	11/09/2020
RPM -Viral Transport Medium	MS4760	HiViral™ Transport Kit	Low risk	11/09/2020
RPM -Viral Transport Medium	MS4760A	HiViral™ Transport Kit (A)	Low risk	11/09/2020
RPM -Viral Transport Medium	MS4760H	HiViral™ Transport Kit (H)	Low risk	11/09/2020
RPM -Viral Transport Medium	MS4760R	HiViral™ Transport Kit (R)	Low risk	11/09/2020
RPM -Viral Transport Medium	MS4760L	HiViral™ Transport Kit (L)	Low risk	11/09/2020
RPM -Viral Transport Medium	AL304M	Universal Liquid Medium and accessories kit	Low risk	11/09/2020
RPM -Viral Transport Medium	AL304A	Universal Liquid Medium and accessories kit (A)	Low risk	11/09/2020
RPM -Viral Transport Medium	AL304H	Universal Liquid Medium and accessories kit (H)	Low risk	11/09/2020
RPM -Viral Transport Medium	AL304R	Universal Liquid Medium and accessories kit (R)	Low risk	11/09/2020
RPM -Viral Transport Medium	AL304S	Universal Liquid Medium and accessories kit (S)	Low risk	11/09/2020
RPM -Viral Transport Medium	AL305L	Universal Liquid Medium and accessories kit (L)	Low risk	11/09/2020
RPM -Viral Transport Medium	AL305M	Universal Liquid Medium and accessories kit (M)	Low risk	11/09/2020
RPM -Viral Transport Medium	AL305N	Universal Liquid Medium and accessories kit (N)	Low risk	11/09/2020
RPM -Viral Transport Medium	AL305P	Universal Liquid Medium and accessories kit (P)	Low risk	11/09/2020
RPM -Viral Transport Medium	AL305Q	Universal Liquid Medium and accessories kit (Q)	Low risk	11/09/2020
RPM -Viral Transport Medium	AL306M	Universal Liquid Medium and accessories kit (M)	Low risk	11/09/2020
RPM -Viral Transport Medium	AL306A	Universal Liquid Medium and accessories kit (A)	Low risk	11/09/2020
RPM -Viral Transport Medium	AL306H	Universal Liquid Medium and accessories kit (H)	Low risk	11/09/2020
RPM -Viral Transport Medium	AL306R	Universal Liquid Medium and accessories kit (R)	Low risk	11/09/2020
RPM -Viral Transport Medium	AL306L	Universal Liquid Medium and accessories kit (L)	Low risk	11/09/2020
RPM -Viral Transport Medium	MS2760M1	HiViral™ Transport Kit (M1)	Low risk	13/10/2020

Product group	Type/ Model / Ref number	Device Name	Risk Class	Date of CE compliance
RPM -Viral Transport Medium	MS276001	HiViral™ Transport Kit (O1)	Low risk	13/10/2020
RPM -Viral Transport Medium	MS2760L3	HiViral™ Transport Kit (L3)	Low risk	13/10/2020
RPM -Viral Transport Medium	MS2760T3	HiViral™ Transport Kit	Low risk	13/10/2020
RPM -Viral Transport Medium	MS2760T5	HiViral™ Transport Kit	Low risk	13/10/2020
RPM -Viral Transport Medium	MS2760D1	HiViral™ Transport Kit (D1)	Low risk	13/10/2020

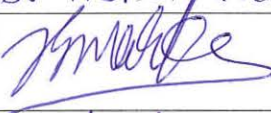
Product group	Type/ Model / Ref number	Device Name	Risk Class	Date of CE compliance
RPM -Viral Transport Medium	AL167CS	COVIDSafe™ Virus Inactivation Medium	Low risk	07/07/2020
RPM -Viral Transport Medium	MS5760T3	COVIDSafe™ Virus Inactivation Kit	Low risk	01/09/2020
RPM -Viral Transport Medium	MS5760T5	COVIDSafe™ Virus Inactivation Kit	Low risk	01/09/2020
RPM -Viral Transport Medium	AL167CST3	COVIDSafe™ Virus Inactivation Medium	Low risk	01/09/2020
RPM -Viral Transport Medium	AL167CST5	COVIDSafe™ Virus Inactivation Medium	Low risk	01/09/2020
RPM -Viral Transport Medium	MS5760	COVIDSafe™ Virus Inactivation Kit	Low risk	08/09/2020
RPM -Viral Transport Medium	MS5760A	COVIDSafe™ Virus Inactivation Kit (A)	Low risk	08/09/2020
RPM -Viral Transport Medium	MS5760Q	COVIDSafe™ Virus Inactivation Kit (A)	Low risk	08/09/2020
RPM -Viral Transport Medium	MS5760L	COVIDSafe™ Virus Inactivation Kit (A)	Low risk	08/09/2020
RPM -Viral Transport Medium	MS5760H	COVIDSafe™ Virus Inactivation Kit (A)	Low risk	08/09/2020
RPM -Viral Transport Medium	MSC2X1	COVIDSafe™ Virus Inactivation Kit	Low risk	01/10/2020
RPM -Viral Transport Medium	MSC4X1	COVIDSafe™ Virus Inactivation Kit	Low risk	01/10/2020
RPM -Viral Transport Medium	MSC2X2	COVIDSafe™ Virus Inactivation Kit	Low risk	01/10/2020
RPM -Viral Transport Medium	MSC4X2	COVIDSafe™ Virus Inactivation Kit	Low risk	01/10/2020

Product group	Type/ Model / Ref number	Device Name	Risk Class	Date of CE compliance
Diagnostic products – In vitro Diagnostic device	EL001	ELISafe 19 (Elisa kit)	Low risk	20/10/2020
	EL001 Kit Contents			
	EL001A	S1 spike protein SARS-Cov-2 coated 96 well microplate		
	EL001B	Plate Sealer		
	EL001C	Wash Buffer Concentrate 10X		
	EL001D	Sample Dilution Buffer 1X		
	EL001E	Sample Diluent Powder		
	EL001F	Secondary Antibody Dilution Buffer 1X		
	EL001G	HRP Conjugate Secondary Ab		
	EL001H	TMB		
	EL001I	Stop Solution		
	EL001J	Negative Control		
EL001K	Positive Control			

Date of issue: 08th September 2020**DECLARATION OF CONFORMITY**

Manufacturer	<p>Himedia Laboratories Private Limited, Reg. Office: 23, Vadhani Industrial Estate, LBS Marg Ghatkopar (west), Mumbai-400086 State: Maharashtra Country :INDIA www.himedialabs.com</p> <p>Manufacturing site: B-4-5-6 / MIDC, Palkhed, Dindori, Nashik – 422202, Maharashtra, India</p>
Authorized representative	<p>CE Partner 4U BV, ESDOORNLAAN 13, 3951 DB MAARN, THE NETHERLANDS www.cepartner4u.eu</p>
Conforms	<p>Annex III In vitro Diagnostic Medical Devices Directive 98/79/EC</p>
Product (s)	<p>AL167R: HiViral™ Transport Medium MS2760R: HiViral™ Transport Kit (R) MS2760S: HiViral™ Transport Kit (S) MS2760L: HiViral™ Transport Kit (L) MS2760M: HiViral™ Transport Kit (M) MS2760N: HiViral™ Transport Kit (N) MS2760P: HiViral™ Transport Kit (P) MS2760Q: HiViral™ Transport Kit (Q) MS4760 : HiViral™ Transport Kit MS4760A : HiViral™ Transport Kit (A) MS4760H : HiViral™ Transport Kit (H) MS4760R : HiViral™ Transport Kit (R) MS4760L : HiViral™ Transport Kit (L) AL304M : Universal Liquid Medium and accessories kit AL304A : Universal Liquid Medium and accessories kit (A) AL304H : Universal Liquid Medium and accessories kit (H) AL304R : Universal Liquid Medium and accessories kit (R) AL304S : Universal Liquid Medium and accessories kit (S) AL305L : Universal Liquid Medium and accessories kit (L) AL305M : Universal Liquid Medium and accessories kit (M)</p>

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	AL305N : Universal Liquid Medium and accessories kit (N) AL305P : Universal Liquid Medium and accessories kit (P) AL305Q : Universal Liquid Medium and accessories kit (Q) AL306M : Universal Liquid Medium and accessories kit (M) AL306A : Universal Liquid Medium and accessories kit (A) AL306H : Universal Liquid Medium and accessories kit (H) AL306R : Universal Liquid Medium and accessories kit (R) AL306L : Universal Liquid Medium and accessories kit (L)
We hereby declare that the above mentioned product complies with European In vitro Diagnostic Directive and its relevant transposition into national laws of the member states into which we place the devices.	
Name and Authority	Director Dr. Vishal Warke
Signature	
Date	08/09/2020

CERTIFICATE

Quality Austria - Trainings, Zertifizierungs und Begutachtungs GmbH awards this **qualityaustria** certificate to the following organisation:

This **qualityaustria** certificate confirms the application and further development of an effective

HIMEDIA

HiMedia Laboratories Private Limited

Unit-1 : B-4-5-6 / MIDC, Palkhed, Dindori,
Nashik – 422 202 Maharashtra, India

Registered Office : 23, Vadhani Industrial Estate,
LBS Marg, Ghatkopar (West) Maharashtra, India

Design and Development, Manufacturing and Supply
of Biosciences Products for application in Microbiology
(including Dehydrated culture Media, Antimicrobial
Susceptibility Systems, Culture Media Bases and
Bacteriological Differentiation Aids), Animal Tissue
Culture, Plant Tissue Culture and Molecular Biology

The validity of the **qualityaustria** certificate will be
maintained by annual surveillance audits and one
renewal audit after three years.

QUALITY MANAGEMENT SYSTEM

complying with the requirements of standard
ISO 9001:2015

Registration No.: 17285/0

Date of initial issue: 29 December 2015

Valid until: 31 March 2022

Vienna, 08 April 2019

Quality Austria - Trainings, Zertifizierungs und Begutachtungs GmbH,
AT-1010 Vienna, Zelinkagasse 10/3



Konrad Scheiber
General Manager



Dr. Mag. Anni Koubek
Specialist representative

Quality Austria - Trainings,
Zertifizierungs und
Begutachtungs GmbH is
accredited according to
the Austrian Accreditation
Act by the BMWFVW
(Federal Ministry of
Science, Research and
Economy).

Quality Austria is
accredited as an
organisation for
environmental verification
by the BMLFUW (Federal
Ministry of Agriculture,
Forestry, Environment and
Water Management).

Quality Austria is
authorized by the VDA
(Association of the
Automotive Industry).

For accreditation
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Quality Austria is the
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Dok. Nr. FO_24_028

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The current validity of the certificate is documented exclusively on the Internet under
<http://www.qualityaustria.com/en/cert> EAC: 19.2

CERTIFICATE

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HIMEDIA

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Susceptibility Systems, Culture Media Bases and
Bacteriological Differentiation Aids), Animal Tissue
Culture, Plant Tissue Culture and Molecular Biology

The validity of the **qualityaustria** certificate will be
maintained by annual surveillance audits and one
renewal audit after three years.

QUALITY MANAGEMENT SYSTEM

complying with the requirements of standard

EN ISO 13485:2016

Medical devices - Quality management systems -
Requirements for regulatory purposes

Registration No.: 00275/0


Date of initial issue: 21 November 2017

Valid until: 31 March 2022

Vienna, 08 April 2019

Quality Austria - Trainings, Zertifizierungs und Begutachtungs GmbH,
AT-1010 Vienna, Zelinkagasse 10/3



 **qualityaustria**



Quality Austria - Trainings,
Zertifizierungs und
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accredited according to
the Austrian Accreditation
Act by the BMWFW
(Federal Ministry of
Science, Research and
Economy).

Quality Austria is
accredited as an
organisation for
environmental verification
by the BMLFUW (Federal
Ministry of Agriculture,
Forestry, Environment and
Water Management).

Quality Austria is
authorized by the VDA
(Association of the
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Dok. Nr. FO_24_028

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The current validity of the certificate is documented exclusively on the Internet under
<http://www.qualityaustria.com/en/cert> EAC: 19.2



Konrad Scheiber
General Manager



Ing. Andreas Aichinger, MSc
Specialist representative

HiViral™ Transport Kit (S)

With Viral Transport Medium in self-standing / conical bottom tube, One Sterile Nasopharyngeal Nylon Flocked Swab with Breakpoint and One Sterile Oropharyngeal Viscose Swab with Breakpoint

Product Code: MS2760S

Intended Use: For collection and transportation of potentially infectious samples containing Viruses, Mycoplasma and Ureaplasma (other than Cytomegalovirus and Chlamydia) from the collection site to the laboratory.

Introduction:

HiMedia's HiViral™ Transport Kit (S) is a specially designed transport system to collect and transport viruses in an active form to the laboratory for isolation. It is designed to maintain the viability and the virulence of the viral sample. It contains 3.0ml viral transport medium in self-standing or conical bottom tube.

HiViral™ Transport Medium is made of Hanks Balanced Salt Solution and contains a protective protein, antibiotics to control microbial and fungal contamination and buffers to control the pH. Phenol red is used as a pH indicator. The medium also contains a cryoprotectant which helps in preserving the viruses if specimens are frozen for prolonged storage.

The nasopharyngeal nylon flocked swab has a short perpendicular ultra-flexible plastic shaft that is designed for better patient comfort. This plastic shaft is attached with soft nylon strands that results in efficient collection and release of particulate matter. It yields significantly more sample which helps in maximizing the sensitivity of serological and molecular detection assays. This swab has a molded breakpoint which allows the swab to be broken in to the tube. The oropharyngeal viscose swab is a tipped swab on a polypropylene shaft, which can be used for collecting throat samples. It has a breakpoint.

Kit Contents:

1. HiViral™ Transport Medium in self-standing or conical bottom tubes (AL167) - 1No.
2. Sterile nasopharyngeal nylon flocked swab with breakpoint (PW1172) - 1No
3. Sterile oropharyngeal viscose swab with breakpoint (PW043B) - 1No

Procedure:

A. Collection of Samples

For a complete diagnostic analysis of viral diseases, it is important that the infectivity of the viruses is preserved after sample collection. The infectivity of viruses' decreases over time and the decay rate is generally a function of temperature. Stability of samples is enhanced by cooling therefore samples should be kept at 2-8°C. The probability of a successful isolation is more if the samples are processed immediately after collection and the viral load in the sample is more. Viral load is maximum if the samples are collected immediately after the onset of clinical symptoms and before the administration of antiviral medications.

B. Directions:

1. Cut open the pouch to remove the swab.
2. Specimen can be collected with the swab in the following manner.

Nasopharyngeal swab

Insert dry swab in to nostril and back to the nasopharynx. Leave in place for a few seconds. Slowly withdraw the swab with a rotating motion.

Oropharyngeal swab

Ask patient to open his/her mouth. Swab the back of the throat near the tonsils thoroughly.

3. Break the swab near the break point and insert swab into the tube containing viral transport medium and close the cap tightly.
4. Label the sample correctly with the name of the patient and time and date of collection.
5. Transport the samples immediately to the laboratory for processing.

Transportation of the Samples:

Samples should be transported to the laboratory as soon as possible.

Samples can be refrigerated at 2-8°C after collection or can be transported at 2-8°C on wet ice within 48 hours. If a long delay is expected in transit and processing, samples should be transported on dry ice and should be frozen at -70°C.

Precautions:

1. Isolation of viruses will largely depend on proper specimen collection, timing of sample collection and processing of samples.
2. Specimen collection should be done in the acute phase of illness.
3. Do not use the product if (1) there is change in the color of the medium,(2) there is evidence of leakage,(3) there are other signs of deterioration.
4. To maintain infectivity of viruses it is important that temperature be properly maintained for sample collection to processing.
5. Avoid repeated freeze-thaw of collected samples.
6. It is recommended to refer to standard procedures and published protocols for sample collection and processing.

Quality control:

Appearance

Orange coloured clear solution

pH at 25°C

7.00-7.60

Osmolality in mOsm/Kg H₂O

600mOsm* - 700mOsm*

Sterility

No bacterial or fungal growth is observed after 14 days of incubation as per USP specification.

Storage and shelf life:

Store at 15-30°C.

Use before expiry date given on the product label.



In vitro diagnostic medical device



CE Marking



Consult instructions for use



Do not use if package is damaged



Reg. Off : 23, Vadhani Ind Est.,
LBS Marg, Mumbai-400086, India.
Works : B-4-5-6 / MIDC, Palkhed,
Dindori, Nashik- 422202
Maharashtra, India
www.himedialabs.com



CE Partner 4U, Esdoornlaan 13, 3951
DB Maarn The Netherlands,
www.cepartner4u.eu



Single use.
Not intended to be reprocessed and/
or used on another patient

Revision 01/2021

Disclaimer :

User must ensure suitability of the product(s) in their application prior to use. Products conform solely to the information contained in this and other related HiMedia™ Publications. The information contained in this publication is based on our research and development work and is to the best of our knowledge true and accurate. HiMedia™ Laboratories Pvt Ltd reserves the right to make changes to specifications and information related to the products at any time. Products are not intended for human or animal diagnostic or therapeutic use but for laboratory, research or further manufacturing use only, unless otherwise specified. Statements contained herein should not be considered as a warranty of any kind, expressed or implied, and no liability is accepted for infringement of any patents.

HIVIRAL™ TRANSPORT KITS

Introducing Round Bottom Tube Format



Better Availability • Enhanced Throughput

Considering COVID-19 pandemic and increasing global demand of Viral Transport Media (VTM), HiMedia has introduced a new configuration that contains viral transport medium in round bottom vacutainer tubes.

These are the same tubes that are used for blood collection and transportation, and hence, are **leak-proof**.

These round bottom tubes are available in two capacities, **75mm and 100mm**.

HiMedia has designed autoclavable and reusable **adapters** to make these tubes self-standing and make centrifugation easy.

These kits are available in different configurations depending on type of tube and swab.

Manufactured in
GMP, ISO 13485 and
ISO 9001 Certified
facility

CE Marked for IVD
(98/79/EC)

Guaranteed
Functionality,
Sensitivity and
Specificity

Designed according
to WHO Directive
(Annex 8) and ICMR
guidelines

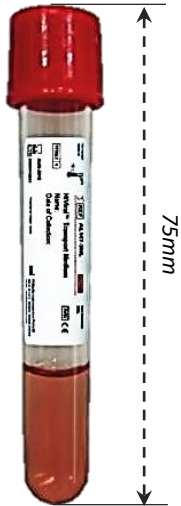
Validated by
reputed Indian
Institutes such as NIV
and ICMR

Validated by
European, Middle
Eastern and Hong
Kong authorities

Ordering Information

Kits with 1.3ml medium in 75mm tubes

Tube Dimensions (Diameter x Height): 12.4 x 75mm



Code	Product Name
MS2760L-50NO MS2760L-100NO	HiViral™ Transport Kit (L) With Viral Transport Medium in round bottom tube, one Sterile Nasopharyngeal Nylon Flocked Swab with Breakpoint and One Sterile Oropharyngeal Viscose Swab with Breakpoint
MS2760M-50NO MS2760M-100NO	HiViral™ Transport Kit (M) With Viral Transport Medium in round bottom tube and One Sterile Nasopharyngeal Nylon Flocked Swab with Breakpoint
MS2760N-50NO MS2760N-100NO	HiViral™ Transport Kit (N) With Viral Transport Medium in round bottom tube, One Sterile Nasopharyngeal Nylon Flocked Swab with Breakpoint and One Sterile Oropharyngeal Viscose Swab without Breakpoint
MS2760P-50NO MS2760P-100NO	HiViral™ Transport Kit (P) With Viral Transport Medium in round bottom tube and two Sterile Nasopharyngeal Nylon Flocked Swabs with Breakpoint
MS2760Q-50NO MS2760Q-100NO	HiViral™ Transport Kit (Q) With Viral Transport Medium in round bottom tube, one Sterile Nasopharyngeal Nylon Flocked Swab with Breakpoint and one Sterile Oropharyngeal Nylon Flocked Swab with Breakpoint

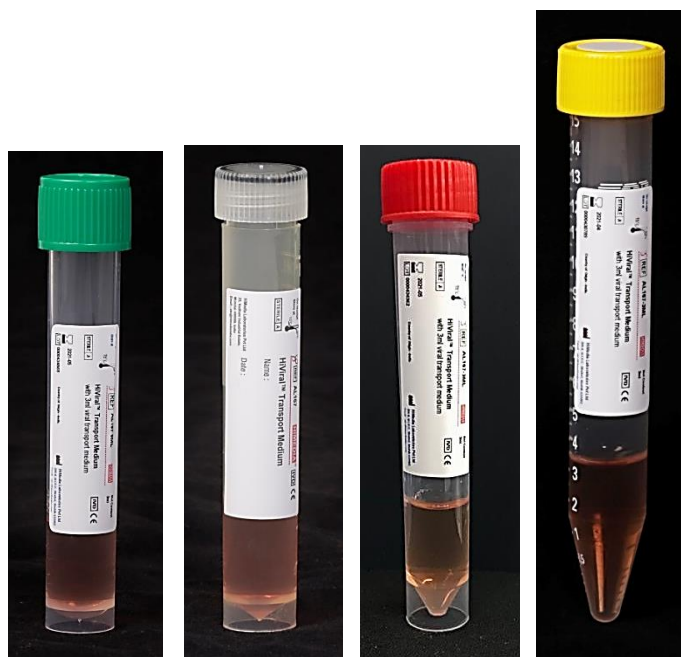
Kits with 3ml medium in 100mm tubes

Tube Dimensions (Diameter x Height): 12.4 x 100mm



Code	Product Name
MS4760-50NO MS4760-100NO	HiViral™ Transport Kit With Viral Transport Medium in round bottom tube and One Sterile Nasopharyngeal Nylon Flocked Swab with Breakpoint
MS4760A-50NO MS4760A-100NO	HiViral™ Transport Kit (A) With Viral Transport Medium in round bottom tube, One Sterile Nasopharyngeal Nylon Flocked Swab with Breakpoint and One Sterile Oropharyngeal Viscose Swab without Breakpoint
MS4760H-50NO MS4760H-100NO	HiViral™ Transport Kit (H) With Viral Transport Medium in round bottom tube and two Sterile Nasopharyngeal Nylon Flocked Swabs with Breakpoint
MS4760R-50NO MS4760R-100NO	HiViral™ Transport Kit (R) With Viral Transport Medium in round bottom tube, one Sterile Nasopharyngeal Nylon Flocked Swab with Breakpoint and one Sterile Oropharyngeal Nylon Flocked Swab with Breakpoint
MS4760L-50NO MS4760L-100NO	HiViral™ Transport Kit (L) With Viral Transport Medium in round bottom tube, one Sterile Nasopharyngeal Nylon Flocked Swab with Breakpoint and One Sterile Oropharyngeal Viscose Swab with Breakpoint

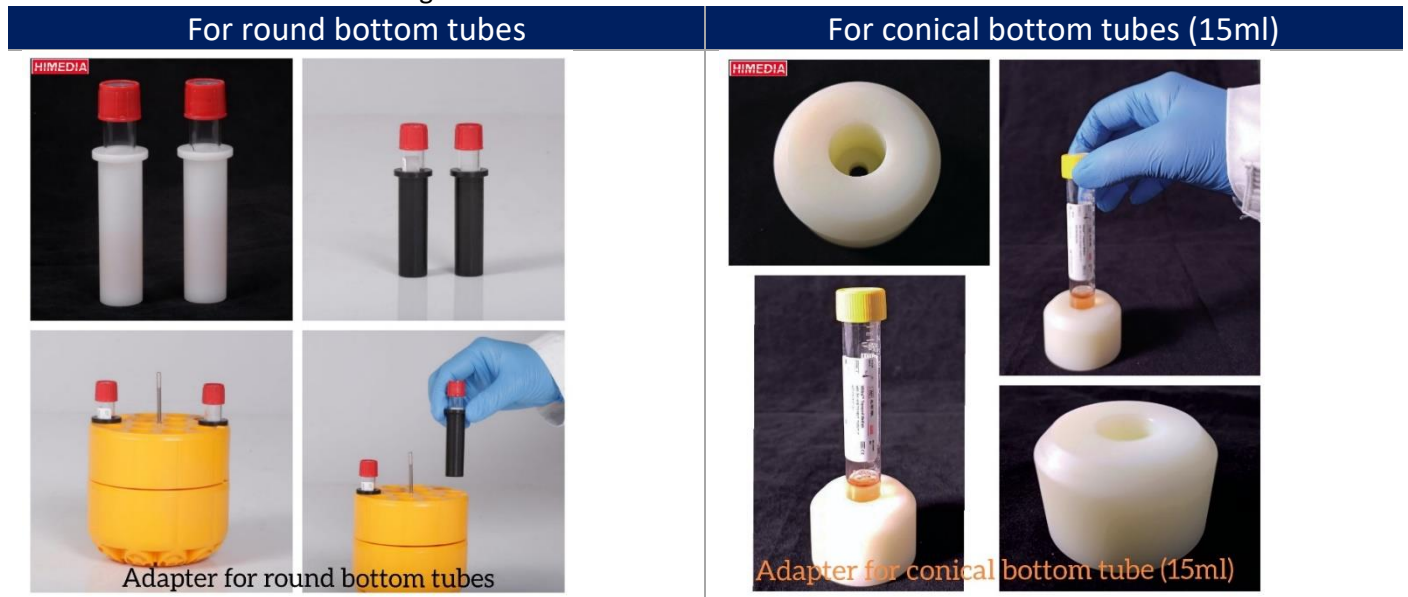
Kits with 3ml medium in self-standing / conical bottom centrifuge tubes



Code	Product Name
MS2760-50NO	HiViral™ Transport Kit With Viral Transport Medium in self-standing / conical bottom tube and one Sterile Nasopharyngeal Nylon Flocked Swab with Breakpoint
MS2760A-50NO	HiViral™ Transport Kit (A) With Viral Transport Medium in self-standing / conical bottom tube, One Sterile Nasopharyngeal Nylon Flocked Swab with Breakpoint and One Sterile Oropharyngeal Viscose Swab without Breakpoint
MS2760H-50NO	HiViral™ Transport Kit (H) With Viral Transport Medium in self-standing / conical bottom tube and two Sterile Nasopharyngeal Nylon Flocked Swabs with Breakpoint
MS2760R-50NO	HiViral™ Transport Kit (R) With Viral Transport Medium in self-standing / conical bottom tube, one Sterile Nasopharyngeal Nylon Flocked Swab with Breakpoint and one Sterile Oropharyngeal Nylon Flocked Swab with Breakpoint
MS2760S-50NO	HiViral™ Transport Kit (S) With Viral Transport Medium in self-standing / conical bottom tube, One Sterile Nasopharyngeal Nylon Flocked Swab with Breakpoint and One Sterile Oropharyngeal Viscose Swab with Breakpoint

Tube Holders/ Adapters







- Made up of high quality Nylon / Delrin
- Reusable and autoclavable
- Fit into standard 15ml centrifuge tube rotor



Ready reckoner for easy selection

Code	Tube	Media volume (ml)	Nasopharyngeal nylon flocked w/ breakpoint	Oropharyngeal viscose w/o breakpoint	Oropharyngeal viscose w/ breakpoint	Oropharyngeal nylon flocked w/ breakpoint
MS2760L	75mm round bottom	1.3ml	•		•	
MS2760M	75mm round bottom	1.3ml	•			
MS2760N	75mm round bottom	1.3ml	•	•		
MS2760P	75mm round bottom	1.3ml	• (2 swabs)			
MS2760Q	75mm round bottom	1.3ml	•			•
MS4760	100mm round bottom	3ml	•			
MS4760A	100mm round bottom	3ml	•	•		
MS4760H	100mm round bottom	3ml	• (2 swabs)			
MS4760R	100mm round bottom	3ml	•			•
MS4760L	100mm round bottom	3ml	•		•	
MS2760	Self-standing / conical bottom	3ml	•			
MS2760A	Self-standing / conical bottom	3ml	•	•		
MS2760H	Self-standing / conical bottom	3ml	• (2 swabs)			
MS2760R	Self-standing / conical bottom	3ml	•			•
MS2760S	Self-standing / conical bottom	3ml	•		•	

Swabs

Code	Name	Breakpoint (mm) from tip	Tube			
			75mm round bottom	100mm round bottom	120mm self-standing / conical bottom centrifuge tube	
PW1172	HiViral™ Nasopharyngeal Nylon Flocked swab with breakpoint 	89mm	X	MS4760 MS4760A MS4760H MS4760R MS4760L	MS2760 MS2760A MS2760H MS2760R	
PW043	HiViral™ Oropharyngeal Viscose swab without breakpoint 	No breakpoint	X	MS4760 MS4760A MS4760H MS4760R MS4760L	MS2760 MS2760A MS2760H MS2760R	
PW043B	HiViral™ Oropharyngeal Viscose swab with breakpoint 	80mm	X	MS4760 MS4760A MS4760H MS4760R MS4760L	MS2760 MS2760A MS2760H MS2760R	
PW043C	HiViral™ Oropharyngeal Viscose swab with breakpoint 	65mm		MS2760L MS2760M MS2760N MS2760P MS2760Q	MS4760 MS4760A MS4760H MS4760R MS4760L	MS2760 MS2760A MS2760H MS2760R
PW043D	HiViral™ Oropharyngeal Viscose swab with breakpoint 	30mm		MS2760L MS2760M MS2760N MS2760P MS2760Q	MS4760 MS4760A MS4760H MS4760R MS4760L	MS2760 MS2760A MS2760H MS2760R
PW1374	HiViral™ Oropharyngeal Nylon flocked swab with breakpoint 	30mm		MS2760L MS2760M MS2760N MS2760P MS2760Q	MS4760 MS4760A MS4760H MS4760R MS4760L	MS2760 MS2760A MS2760H MS2760R