Bauer - Karlsruhe

VIRUS-SAMMLUNG UND TRANSPORTKITS

ENTWICKELT FÜR VIRALE PROBENSAMMLUNG, TRANSPORT UND KONSERVIERUNG, WIE GRIPPE, VOGELGRIPPE UND HFMK, USW.

Handelsname: Virus Collection and Transport Kit
Hersteller: CITOTEST Labware Manufacturing Co., Ltd.

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Bauer-Karlsruhe

VIRUS-SAMMLUNG UND TRANSPORTKITS

Konformitätserklärung

COMMERCIAL CENTER&R-D Center
#1002, Building 3, 89 Shengli Rd, Jiangning
District, Nanjing 211106, China
Tel.: 0086 25 86216803
Fax: 0086 25 86214463
E-mail: info@citotest.com

PRODUCTION
339 Beihai West Road, Haimen, Jiangsu, China
Tel.: 0086 513 82259348
Fax: 0086 513 82110195
E-mail: info@citotest.com.cn

CITOTEST®
LABWARE MANUFACTURING CO.,LTD

CITOTEST LABWARE MANUFACTURING CO.,LTD www.citotest.com

CE

Declaration of Conformity

According to annex III of the Council Directive 98/79/EC on in vitro diagnostic medical device
We,

Manufacturer: CITOTEST LABWARE MANUFACTURING CO., LTD

Registered Address : 339 Beihai West Road, Haimen, Jiangsu, China

Declare under our sole responsibility that the following in vitro diagnostic medical devices other than those covered by annex II and devices for performance evaluation

Name: Collection and Transport Kit

Type or model: VTM；VTM-N；ITM；PBS；NSS

Meet the provisions of the Council Directive 98/79/EC concerning medical devices which apply to them.

Undersigned declares to fulfill the obligations imposed by Annex III section 2 to 5:

- availability of the technical documentation set in Annex III (section 3), allowing the assessment of conformity of the product with the requirements of the Directive.
- the manufacturer shall take necessary measures to ensure that the manufacturing process follows the principles of quality assurance as appropriate for the products manufactured (Annex III section 4).
- the manufacturer shall institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase and to implement appropriate means to apply any necessary corrective actions (Annex III section 5).

Conformity assessment was performed according to Article 9 (7) and Annex III, section 3.

Our current Quality System is formatted to international standards:

EN ISO 13485:2016 N ISO15223-1:2016 EN 1041:2008 EN ISO14971:2012
EN ISO 18113:1-2011 EN ISO 18113:2-2011 EN 13612:2002 EN ISO 23640:2015

Corporate Contact Information

Bauer-Karlsruhe

Gebrauchsanweisung

CITOSWAB® VIRUS COLLECTION AND TRANSPORT KIT

Intended Use
CITOSWAB® Virus Collection and Transport kit is a ready-to-use system, which are confirmed to be used for the collection and transport clinical specimens containing virus, chlamydiae, mycoplasma or ureaplasma.

Summary and Explanation
CITOSWAB® Virus Collection and Transport Kit provides a safe and convenient way to collection and transport clinical specimens. Each Collection and Transport Kit comprises a sterile peel pouch containing a swab used to collect the sample, a transport tube containing medium into which the swab is placed after sampling, and a biohazard bag used to place the transport tube for transportation. Once a swab sample is collected, it should be placed immediately into the transport tube, and submitted to the laboratory as quickly as possible. Although VTM can maintain organisms for long periods of time at room temperature, it is recommended that specimens be frigerated at 2-8℃ cool kept on wet ice while in transit. If there will be a long delay before processing, specimens should be frozen at -70℃.

Principle
The kit is available with VTM, VTM-N, ITM, PBS and NNS media. VTM medium consists of modified Hank's-HEPES buffer solution supplemented with bovine serum albumin, gelatin, antibiotic and etc. It is osmotically balanced and buffered to maintain the viability of virus specimens during transportation to laboratory. VTM-Nand ITM media consists of Tris-HCl buffers, EDTA and guanidine salt. The presence of guanidine salts acts as the protein deformers and nuclease inhibitors which makes the virus inactive, but does not affect the integrity of the viral nucleic acid. Phosphate buffered saline (PBS) and Normal saline solution (NSS) can be also used to collect and transport samples for molecular RT-PCR SARS-CoV-2 assays.

Precautions
1. Single-use device for professional in-vitro diagnostic use only.
2. To be used only by adequately trained and qualified personnel.
3. Use aseptic technique and biohazard precautions when collecting and handling specimen.
4. All specimens and materials used to process them should be considered potentially infectious and handled in a manner which prevents infection of laboratory personnel. Sterilize all biohazard waste including specimens, containers and media after their use.
5. Delays in transportation and lack of refrigeration may reduce recovery of the organisms.
6. Don't use after expiry date, and don't use if there is evidence of leakage, the color of the medium has changed color or appears turbid.
7. Don't reuse. Risks include simply contamination, cross-contamination, and infection etc.
8. Directions should be read and followed carefully.

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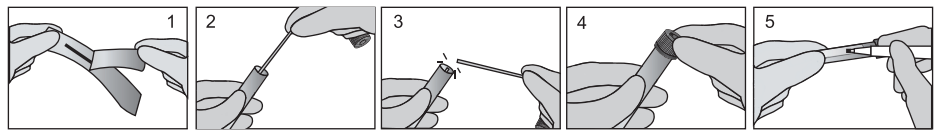
Storage
Room temperature, optimum storage temperature is 5℃to 25℃. The shelf life is 12 months. Do not overheat, incubate, or freeze prior to use. Improper storage will result in a loss of efficacy. Don't use after expiration date, which is clearly printed on the outer box and on each individual sterile pouch unit and the specimen transport tube label.

Material Provided
CITOSWAB®Collection and Transport System contains a plastic transport tube with 1ml or 3ml medium which is supplied alone or in a kit with one or more sterile swabs. All used sterile swabs in kits are manufactured by CITOTEST Labware Manufacturing Co., LTD and certified as a Class IIa device (CE 0197) under the classification terms of the European Medical Device Directive EC 93/42.

Material Not Provided
Other materials required for culturing, identification and extracting purposes.

Directions for Use


1.Peel off the pouch and collection; 2.Put the swab into the medium; 3.Snap the stick of swab; 4.Screw the tube cap tightly; 5.Label the specimen information.

Quality Control
All raw materials and batches of finished product are subjected to rigorous quality control by CITOTEST. Certificates of sterility and quality assurance are available on request.

Results
Results obtained will largely depend on proper and adequate specimen collection, as well as timely transport and processing in the laboratory.

Limitations
This product is not intended to be used for the collection and transportation of bacterial cultures. Repeated freezing and thawing of specimens may reduce the recovery of viable organisms.

CITOTEST LABWARE MANUFACTURING CO.,LTD
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Contact: Tel.: 0513-82259348; Fax: 0513-82110195
Web: www.citotest.com

CE IVD MEDICAL DIAGNOSTIC IN VITRO DEVICE

EC REP **Obelis s.a.**
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1030 Brussels, Belgium

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CITOTEST®
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MANU
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Phone: 0086 513 82259348
Fax: 0086 513 82110195
Mail：zhangdechao@citotest.com.cn
Representative：Zhang Dechao
Position：Manager
Signature：Zhang Dechao
Date：2020.12.8
Stamp：

European Authorized Representative:
Registered Address:
Obelis s.a.
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B-1030 Brussels, Belgium
Phone: 32.2.732.59.54
Fax: 32.2.732.60.03
E-mail: mail@obelis.net
Representative: Mr. Gideon ELKAYAM (CEO)

Amies:

*2118-0406	*2118-0407	*2118-0018	*2118-0007
2118-0045			

Stuart:

*2118-0408	*2118-0409		

VTM:

*2118-0412	*2118-0413	*2118-0413-99	*2118-0419-88
*2118-0419-99	*2118-0420	*2118-0420-99	*2118-0421
*2118-0421-88	*2118-0421-99	*2118-0422	*2118-0422-88
*2118-0422-99	2118-0010	2118-0019	2118-0012
2118-0013	*2118-1501	*2118-1502	*2118-1503
*2118-1504	*2118-1504-99	*2118-1509	*2118-1509-99
*2118-1511	*2118-1513-99	*2118-1521	*2118-1521-99
*2118-1522	*2118-1522-99	*2118-1523	*2118-1524
*2118-1531	*2118-1532	*2118-1533	*2118-1534
*2118-1541	*2118-1541-99	*2118-1542	*2118-1542-99
2118-0011	2118-0412-99	2118-1524-99	2118-1534-88
2118-1504-88	2118-1534-99	2118-0044	2118-1514-99
2118-1542-88	2118-0050	2118-1578-99	

VTM-N:

*2118-0414	*2118-0415	*2118-0416	*2118-0417
*2118-0417-88	*2118-0417-99	*2118-0423	*2118-0423-88
*2118-0424	*2118-0424-88	2118-0014	2118-0015
2118-0016	2118-0017	*2118-1505	*2118-1506
*2118-1507	*2118-1508	*2118-1510	*2118-1512
*2118-1525	*2118-1526	*2118-1527	*2118-1528
*2118-1528-99	*2118-1535	*2118-1536	*2118-1537
*2118-1538	2118-1508-99	2118-0042	2118-1538-88
*2118-1507-99			

Note: the model with * in which the transport medium is applicable to the declaration of conformity

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VIRUS-SAMMLUNG UND TRANSPORTKITS

EAR Zertifikat

Obelis SA
EUROPEAN AUTHORIZED REPRESENTATIVE CENTER

EUROPEAN RESPONSIBLE PERSON CENTER – Obelis – SINCE 1988

E.A.R.-CERTIFICATE

(ART 10.3 of the Directive 98/79/EC on In Vitro Diagnostic)

ref. no. : TMV 1147-2021

order no. : GR 0234- 2020

date: 31/03/2021

Manufacturer:	CITOTEST Labware Manufacturing Co., Ltd. 339 Beihai West Road, Haimen, Jiangsu, China	Facilities:	CITOTEST Labware Manufacturing Co., Ltd., 339 Beihai West Road, Haimen, Jiangsu, China No. 48, Xinxiu Road, Haimen City, Jiangsu 226100, PR China
Product Categories:	Please See Annex A - List of Devices (11 Devices, 2 Pages)		
Models:	Please See Annex A - List of Devices (11 Devices, 2 Pages)		

The European Authorized Representative Center Obelis s.a. declares that the aforementioned manufacturer has fulfilled the essential requirement of appointing a European Authorized Representative in accordance with article 10.3 of the Directive 98/79/EC and to the terms and conditions set out in the agreement entered into force on 01/09/2020.*

G. ELKAYAM C.E.O.

Obelis s.a. - O.E.A.R.C.
Registered Address :
Bld Général Wahis 53
1030 Bruxelles
Tél. +32 2 732 59 54 - fax +32 2 732 60 03

Mr. G. Elkayam CEO
Obelis sa

Obelis European Authorized Representative Center is a member of the European Association of Authorized Representatives (E.A.A.R.), ISO 9001 : 2015 and ISO 13485 : 2016 certified in accordance to the profession of a European Authorized Representative.

*This certificate is not a confirmation of product notification nor an approval to place products on the market.
**This certificate will become void automatically upon termination of the EAR agreement.

* This is not a CE mark and is only provided as a template for informational purposes.

CE

Registered Address: Bd. Général Wahis 53 - 1030 Brussels I Registered Office Address: Bd Brand Whitlock 30, B–1200 Brussels - Belgium
T: + 32 (0) 2 732 5954 I F: + 32 (0) 2 732 6003 I Email: mail@obelis.net I Website: www.obelis.net
V3 – ID: 00453116 – 22/02/2019

Bauer - Karlsruhe

Order No.: GR 0234- 2020
Ref No.: TMV 1147-2021

Annex A - List of Devices

(Recital 29 of the Directive 98/79/EC on In Vitro Diagnostic Medical Devices)

#	Catalogue reference number	Commercial Name	Generic Device Term	Short description and intended use	GMDN / GIVD Code	Class
1.	Amies; Stuart; Cary-Blair; Amies gel; Amies with charcoal gel; Stuart gel; Stuart with charcoal gel; Clary-Blair gel; VTM; VTM-N; ITM	Microbiology Transport System	Amies; Stuart; Cary-Blair; Amies gel; Amies with charcoal gel; Stuart gel; Stuart with charcoal gel; Clary-Blair gel; VTM; VTM-N; ITM	For the transport and preservation of clinical samples	14.01.02.01	IVDD 98/79/EC Others
2.	VTM; VTM-N; ITM; PBS; NSS; UTM	Virus Collection and Transport Kit	VTM; VTM-N; ITM; PBS; NSS; UTM	For clinical specimen collection and transport.	14.01.02.01	IVDD 98/79/EC Others
3.	LTM-01 (Amies); LTM-02 (Stuart); LTM-03 (Cary-Blair); LTM-04 (PBS); LTM-05 (NSS); GTM-01 (Amies gel); GTM-02 (Stuart gel); GTM-03 (Cary-Blair gel); GTM-04 (Amies with charcoal gel); GTM-05 (Stuart with charcoal gel)	Universal Collection and Transport Kit	LTM-01 (Amies); LTM-02 (Stuart); LTM-03 (Cary-Blair); LTM-04 (PBS); LTM-05 (NSS); GTM-01 (Amies gel); GTM-02 (Stuart gel); GTM-03 (Cary-Blair gel); GTM-04 (Amies with charcoal gel); GTM-05 (Stuart with charcoal gel)	For clinical specimen collection and transport.	14.01.02.01	IVDD 98/79/EC Others

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4.	SCK-01 (NPBS); SCK-02 (NNSS); SCK-03 (BPW); SCK-04 (Letheen Broth); SCK-05 (D/E Neutralizing Broth); SCK-06 (Butterfield's Buffer); SCK-07 (NBPW)	Surface Collection Kit	SCK-01 (NPBS); SCK-02 (NNSS); SCK-03 (BPW); SCK-04 (Letheen Broth); SCK-05 (D/E Neutralizing Broth); SCK-06 (Butterfield's Buffer); SCK-07 (NBPW)	For environmental sampling applied in the food, pharmaceutical, biotechnology and cosmetic industries.	14.01.02.01	IVDD 98/79/EC Others
5.	SC-1; SC-2	Saliva Collection Kit	SC-1; SC-2	For saliva specimen collection, transport and storage.	51.09.10.01	IVDD 98/79/EC Others
6.	Nucleic Acid Extraction Kit (Magnetic Beads)	Nucleic Acid Extraction Kit	Nucleic Acid Extraction Kit (Magnetic Beads)	For nucleic acid extraction and preparation.	15.90.40.01	IVDD 98/79/EC Others
7.	Nucleic Acid Extraction Kit (Spin Column)	Nucleic Acid Extraction Kit	Nucleic Acid Extraction Kit (Spin Column)			IVDD 98/79/EC Others
8.	5ml; 10ml; 12ml	Transport Tube	5ml; 10ml; 12ml	For preparing, transporting and storing specimens.	29.01.10.01	IVDD 98/79/EC Others
9.	10% NBF; 13% NBF	Tissue Fixative	10% NBF; 13% NBF	For fixation of fresh tissue samples.	13.07.01.05	IVDD 98/79/EC Others
10.	Harris; Mayer's; Eosin Y (Aqueous); Eosin Y (Alcoholic)	HE Staining Kit	Harris; Mayer's; Eosin Y (Aqueous); Eosin Y (Alcoholic)	For staining before observing the histological morphology of various tissue sections.	13.07.01.08	IVDD 98/79/EC Others
11.	PBS; NSS; Butterfield 's Buffer; NPBS; NNSS	Buffer Solution	PBS; NSS; Butterfield's Buffer; NPBS; NNSS	For biological specimen dilution, washing and storage	14.01.08.02	IVDD 98/79/EC Others

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VIRUS-SAMMLUNG UND TRANSPORTKITS

IVD Notification Zertifikat

Obelis SA
EUROPEAN AUTHORIZED REPRESENTATIVE CENTER

EUROPEAN RESPONSIBLE PERSON CENTER – Obelis – SINCE 1988

CERTIFICATE OF IVD NOTIFICATION

Ref. No.: TMV 1146-2021

Order No.: GR 0234- 2020

Belgium

Date: 31/03/2021

This is to certify that, according to the Council Directive 98/79/EC, Obelis s.a. (O.E.A.R.C.) performed all notification duties and responsibilities as the European Authorized Representative (EC REP) of:

name: CITOTEST Labware Manufacturing Co., Ltd.

Address: 339 Beihai West Road, Haimen, Jiangsu, China

as stipulated and demanded by the aforementioned directive.

The Manufacturer declares that the IVD devices comply with the Directive including all essential requirements.

The Manufacturer has provided Obelis s.a. (O.E.A.R.C.) with all the appropriate declarations according to the 98/79/EC Directive – article 10 requirements including the EC Declaration of Conformity confirming that his In-Vitro Diagnostics medical devices, as stipulated here above, are fulfilling the applicable requirements of the European Council Directive 98/79/EC

The notification of the following In-Vitro Diagnostic medical devices has been completed by Obelis s.a. (O.E.A.R.C.) on the 22/12/2020 in compliance with the European Council Directive 98/79/EC - article 10 requirements.

In-vitro diagnostic medical devices: Please See Annex A - List of Devices (2 pages, 11 Devices)

As of the 23/12/2020, and as long as the manufacturer will continue complying with the hereabove mentioned requirements* he therefore:

- Is required to affix the CE marking on these devices;

- Place these devices in the Territory of Belgium and/or the other EEA Member States (excluding territories not in alignment with Decision 2010/227/EU).

Mr. G. Elkayam CEO
Obelis sa

Obelis European Authorized Representative Center is a member of the European Association of Authorized Representatives (E.A.A.R.), ISO 9001 : 2015 and ISO 13485 : 2016 certified in accordance to the profession of a European Authorized Representative.

* This is not a CE mark and is only provided as a template for informational purposes.

** This Certificate will be automatically void if the notification is rejected by the EU Authorities or upon termination of the EAR agreement.

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V3 – ID: 00454716 – 22/02/2019

Order No.: GR 0234- 2020
Ref No.: TMV 1146-2021

Annex A - List of Devices

(Recital 29 of the Directive 98/79/EC on In Vitro Diagnostic Medical Devices)

#	Catalogue reference number	Commercial Name	Generic Device Term	Short description and intended use	GMDN / GIVD Code	Class
1.	Amies; Stuart; Cary-Blair; Amies gel; Amies with charcoal gel; Stuart gel; Stuart with charcoal gel; Clary-Blair gel; VTM; VTM-N; ITM	Microbiology Transport System	Amies; Stuart; Cary-Blair; Amies gel; Amies with charcoal gel; Stuart gel; Stuart with charcoal gel; Clary-Blair gel; VTM; VTM-N; ITM	For the transport and preservation of clinical samples	14.01.02.01	IVDD 98/79/EC Others
2.	VTM; VTM-N; ITM; PBS; NSS; UTM	Virus Collection and Transport Kit	VTM; VTM-N; ITM; PBS; NSS; UTM	For clinical specimen collection and transport.	14.01.02.01	IVDD 98/79/EC Others
3.	LTM-01 (Amies); LTM-02 (Stuart); LTM-03 (Cary-Blair); LTM-04 (PBS); LTM-05 (NSS); GTM-01 (Amies gel); GTM-02 (Stuart gel); GTM-03 (Cary-Blair gel); GTM-04 (Amies with charcoal gel); GTM-05 (Stuart with charcoal gel)	Universal Collection and Transport Kit	LTM-01 (Amies); LTM-02 (Stuart); LTM-03 (Cary-Blair); LTM-04 (PBS); LTM-05 (NSS); GTM-01 (Amies gel); GTM-02 (Stuart gel); GTM-03 (Cary-Blair gel); GTM-04 (Amies with charcoal gel); GTM-05 (Stuart with charcoal gel)	For clinical specimen collection and transport.	14.01.02.01	IVDD 98/79/EC Others

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4.	SCK-01 (NPBS); SCK-02 (NNSS); SCK-03 (BPW); SCK-04 (Letheen Broth); SCK-05 (D/E Neutralizing Broth); SCK-06 (Butterfield's Buffer); SCK-07 (NBPW)	Surface Collection Kit	SCK-01 (NPBS); SCK-02 (NNSS); SCK-03 (BPW); SCK-04 (Letheen Broth); SCK-05 (D/E Neutralizing Broth); SCK-06 (Butterfield's Buffer); SCK-07 (NBPW)	For environmental sampling applied in the food, pharmaceutical, biotechnology and cosmetic industries.	14.01.02.01	IVDD 98/79/EC Others
5.	SC-1; SC-2	Saliva Collection Kit	SC-1; SC-2	For saliva specimen collection, transport and storage.	51.09.10.01	IVDD 98/79/EC Others
6.	Nucleic Acid Extraction Kit (Magnetic Beads)	Nucleic Acid Extraction Kit	Nucleic Acid Extraction Kit (Magnetic Beads)	For nucleic acid extraction and preparation.	15.90.40.01	IVDD 98/79/EC Others
7.	Nucleic Acid Extraction Kit (Spin Column)	Nucleic Acid Extraction Kit	Nucleic Acid Extraction Kit (Spin Column)			IVDD 98/79/EC Others
8.	5ml; 10ml; 12ml	Transport Tube	5ml; 10ml; 12ml	For preparing, transporting and storing specimens.	29.01.10.01	IVDD 98/79/EC Others
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10.	Harris; Mayer's; Eosin Y (Aqueous); Eosin Y (Alcoholic)	HE Staining Kit	Harris; Mayer's; Eosin Y (Aqueous); Eosin Y (Alcoholic)	For staining before observing the histological morphology of various tissue sections.	13.07.01.08	IVDD 98/79/EC Others
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