

BEAVER Sample Collection Kit

1. Illustration



Sample Collection Kit (Inactivated, Colorless)

Individual packaging (Left 1), Stand-up packaging (Left 2) and box for stand-up inactivated kits (Left 3)



Sample Collection Kit (Inactivated, Pink)



Sample Collection Kit (Non-inactivated, Hanks medium) and its box for stand-up packaging



Case packaging



Swab

Length: 15cm

Break Point to Top Distance: 8cm
for Nasal Sampling and 3cm for
Oral Sampling

Tubes Vol.: 10ml

Preservatives: 3mL

The pink color is led by phenol red, pH indicator. There are two types of inactivated kits. One of them contains guanidine salt and the other does not. All types of kits now are containing 10 mL tubes with 3 mL preservative.

2. Label Size

Outside labels: 5.2x7.7 (cm)

Labels on the cases: 10x9 (cm)

3. Packing Specification

A: individual packing, 500pcs/carton, 50*40*34 (cm), 9kg

B: stand-up packing, 500pcs/carton, 50*40*34 (cm), 9kg

4. User Manual

User Manual

【PRODUCT INFORMATION】

Sample Collection Kit (Cat. # 43903)

【DESCRIPTION】

The Sample Collection Kit (Inactivated) is designed for collection, transportation and short-time storage of clinical specimen.

【COMPONENTS OF THE KIT】

Sample Collection Kit	The Components of each kit: 1 collection tube with inactivated preservatives 1 individually packaged Swab 1 biohazard bag
-----------------------	--

【STORAGE】

Before use, the product can be stored at 15-35 °C for 24 months. After use, the sample can be stored at room temperature for 1 week. For longer time storage, please place it at -20 °C or below.

【CAUTION】

1. Single use only, don't reuse.
2. Before starting, read the user manual and make sure all the operations are followed as indicated.
3. Make sure the collection tube is sealed well. If not, do not use and discard. Do not use the product if precipitate occurs.
4. All specimens and materials used in the process 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 using them.
5. Results obtained will largely depend on proper and adequate specimen collection, as well as timely transport and processing in the laboratory. Nucleic acid extraction is beneficial to improving the sensitivity of detection.

【PROTOCOLS】

Label relevant sample information on the tube and follow the protocols below:

1. Take out of the swab from the package, and swab deep into the oral or nasal cavity or other part of the body for sampling. The specific sampling methods as follows:
 - a) Nasal swab: Gently insert the swab head into the nasal condyle of the nasal passage, and then slowly turn it out after staying for a while. Wipe the other nostril with another swab if necessary.
 - b) Pharyngeal swab: Wipe the bilateral pharyngeal tonsils and posterior pharyngeal wall with the swab.
2. Open the collection tube and immerse the swab head in the preservatives. Then break the plastic stick at lower place to make the swab head sealed in the tube. Discard the tail.
3. Screw up the tube cap, and shake it up-and-down several times.
4. Place the sampling tube in a biohazard bag and seal it for transportation



Name : BEAVER Biomedical Engineering Co., Ltd

Add : 1 Huayun Rd., Bldg. B4, Suzhou Industrial Park, China









Tel : +86 512-85187639 Postal code : 215123 web: www.beaverbio.com

Name: Luxus Lebenswelt GmbH

Add: Kochstr. 1, 47877, Willich, Germany
DIMDI Code: DE/0000047791

Contact Person: Lin Sun Tel/Fax: 0049-1715605732

E-mail: Info.m@luxuslw.de

							
Date of manufacture	Use-by date	Batch code	Catalogue number	Temperature limit	Do not use if package is damaged	Keep dry	Do not re-use

Limited use of trademark license

Beaver Biomedical Engineering Co., Ltd. disclaims all intellectual property rights owned or co-owned by the developer and all the contents and services developed or cooperated with other units and is protected by intellectual property laws such as trademark, patent and copyright. The rights of the purchaser of this product are limited to the use of the purchased quantity of the product for internal research and the right is not transferable and is not available for any commercial application and the purchaser is not entitled to re-sell the product or any part thereof. Such as for commercial use (including but not limited to sales of the agent), must be approved by Beaver Biomedical Engineering Co., Ltd., and when used to indicate the source and intellectual property rights, copyright, etc. Beaver Biomedical Engineering Limited Company all the mark. For more information, please contact Beaver@beaverbio.com or Beaver Biomedical Engineering Co., Ltd. Address: 1 Huayun Rd., Bldg. B4, Suzhou Industrial Park. This product is produced by Beaver Biomedical Engineering Co., Ltd.

Copyright Notice:

© 2013 BEAVER Biomedical Engineering Co., Ltd. All rights reserved. Any of the contents of this User's Guide, regardless of trademark, design, text, images and any other information without special instructions, are copyrighted by Beaver Biomedical Engineering Co., Ltd.. The Company reserves the right to take legal action and to hold its duties in violation of the relevant laws and regulations of the State and does not respect the statement, without the consent and unauthorized use of the contents of this User Manual. For support, please visit: www.beaverbio.com/support or email: Service@beaverbio.com.

User Manual

【PRODUCT INFORMATION】

Sample Collection Kit (Cat. # 43904)

【DESCRIPTION】

The Sample Collection Kit is designed for collection, transportation and short-time storage of clinical specimen.

【COMPONENTS OF THE KIT】

Sample Collection Kit (VTM)	# 43904
	Components of kit: 1、 collection tube with Viral Transport Medium (Orange-red) 2、 individually packed Swab (Customizable) 3、 biohazard bag

【STORAGE】

Before use, the product can be stored at 15-35 °C for 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. Once swab sample is collected, it should be placed immediately into the collection tube, and submitted to the laboratory as quickly as possible. Although Viral Transport Medium can maintain organisms for long periods of time at room temperature, it is recommended that specimens be refrigerated at 2-8°C cool kept on wet ice while in transit. If there will be a long delay before processing, specimens should be frozen at -70°C.

【CAUTION】

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

【PROTOCOLS】

Label relevant sample information on the tube and follow the below protocols:

1. Take out of the swab from the package, and swab deep into the oral or nasal cavity or other part of the body for sampling. The specific sampling methods are as follows:
 1. Nasal swab: Gently insert the swab head into the nasal condyle of the nasal passage, wait for a while and slowly turn then turn it out . Wipe the other nostril with another swab if necessary.
 2. Pharyngeal swab: Wipe the bilateral pharyngeal tonsils and posterior pharyngeal wall with the swab.
2. Open the collection tube and immerse the swab head in the Viral Transport Medium, and then break the plastic stick at lower part of the swab to make the swab head sealed in the tube, discard the tail of the swab.
3. Screw up the tube cap, and shake it up-and-down several times.

4. Place the sampling tube in a biohazard bag and seal it for transportation.



EC	REP
----	-----

Name : BEAVER Biomedical Engineering Co., Ltd

Add : 1 Huayun Rd., Bldg. B4, Suzhou Industrial Park, China









Tel : +86 512-85187639 Postal code : 215123 web: www.beaverbio.com

Name: Luxus Lebenswelt GmbH

Add: Kochstr. 1, 47877, Willich, Germany
DIMDI Code: DE/0000047791

Contact Person: Lin Sun Tel/Fax: 0049-1715605732

E-mail: Info.m@luxuslw.de

							
Date of manufacture	Use-by date	Batch code	Catalogue number	Temperature limit	Do not use if package is damaged	Keep dry	Do not re-use

Limited use of trademark license

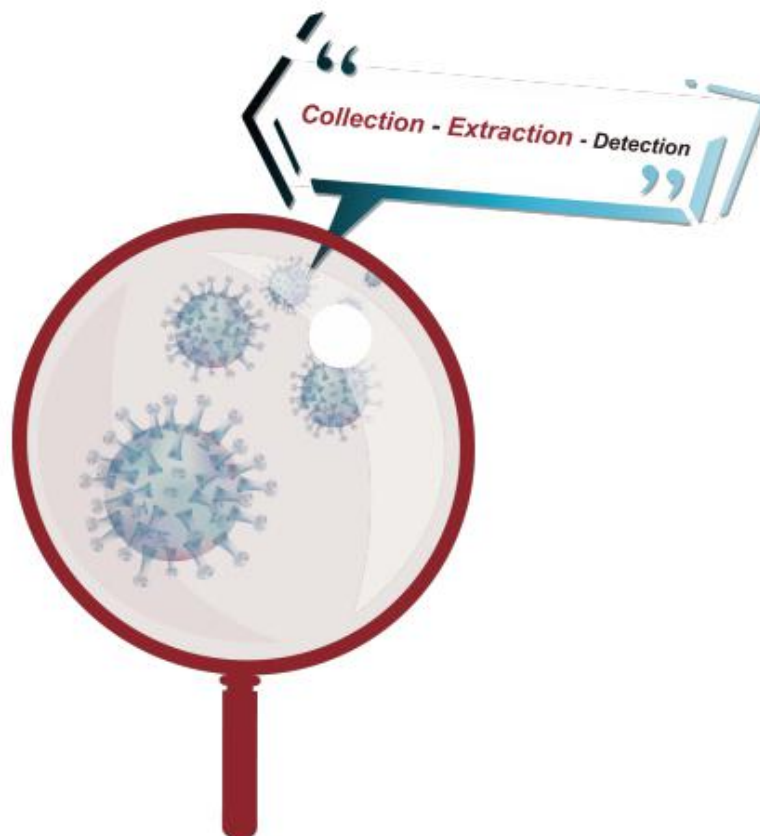
Beaver Biomedical Engineering Co., Ltd. disclaims all intellectual property rights owned or co-owned by the developer and all the contents and services developed or cooperated with other units and is protected by intellectual property laws such as trademark, patent and copyright. The rights of the purchaser of this product are limited to the use of the purchased quantity of the product for internal research and the right is not transferable and is not available for any commercial application and the purchaser is not entitled to re-sell the product or any part thereof. Such as for commercial use (including but not limited to sales of the agent), must be approved by Beaver Biomedical Engineering Co., Ltd., and when used to indicate the source and intellectual property rights, copyright, etc. Beaver Biomedical Engineering Limited Company all the mark. For more information, please contact Beaver@beaverbio.com or Beaver Biomedical Engineering Co., Ltd. Address: 1 Huayun Rd., Bldg. B4, Suzhou Industrial Park. This product is produced by Beaver Biomedical Engineering Co., Ltd.

Copyright Notice:

© 2013 BEAVER Biomedical Engineering Co., Ltd. All rights reserved. Any of the contents of this User's Guide, regardless of trademark, design, text, images and any other information without special instructions, are copyrighted by Beaver Biomedical Engineering Co., Ltd.. The Company reserves the right to take legal action and to hold its duties in violation of the relevant laws and regulations of the State and does not respect the statement, without the consent and unauthorized use of the contents of this User Manual. For support, please visit: www.beaverbio.com/support or email: Service@beaverbio.com.

5. Flyer

www.beaverbio.com



**Viral Nucleic Acid Test
Sample Processing Solution**

BEAVER Biomedical Engineering Co., Ltd.



Sample Collection and Storage

Sample Collection Kit

The Sample Collection Kit is designed for collection, transportation and short-time storage of virus specimen. Typically, samples are taken by a swab from Throat or Nasal. The stored samples can be used in subsequent molecular experiments such as DNA/RNA extraction, PCR testing or sequencing.

This product has been qualified as Class One of Medical instrument and registered in the United States FDA. It also has European Union CE certificate.



Sample Collection Kit (Cat. #43903)

Application Case

Using 2019-nCoV Pseudotyped Virus (10¹⁰ copies/mL) (Zeesan Biotech, Cat. ZS-JL-NP-001), BeaverBeads™ Viral DNA/RNA Kit (Cat. #70406), and PrimeDirect™ Probe RT-qPCR Mix (Takara, #RR650A), 2019-nCoV N Gene Primer and Probe (GENEWIZ) and ABI-7500Fast (Applied Biosystems)

Table 1: Data of different viral samples placed for 5 days using storage tubes from different brands

Sample/Conc./ Ct	10 ⁸	10 ⁶	10 ⁴	10 ²
BEAVER (-20°C)	35.54	32.08	28.9	25.38
BEAVER (RT)	35.15	32.53	28.99	25.63
Competitor (-20°C)	35.22	32.57	28.35	25.96
Competitor (RT)	36.06	32.86	28.82	25.22

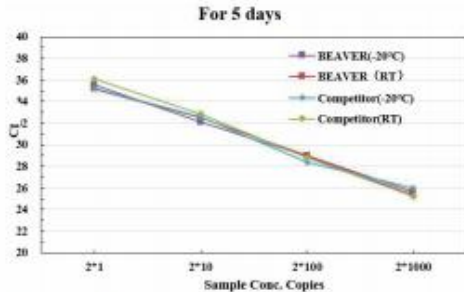


Figure 1: Data of different viral samples placed for 5 days using storage tubes from different brands

Viral RNA samples stored in the preservative did not degrade much at RT for 5 days compared with stored at -20C. Compared with competitors, BEAVER virus storage tubes show better results, especially in low copies samples (10²-10³ copies/mL) storage. Ct values by RT-qPCR increase by 0.3.

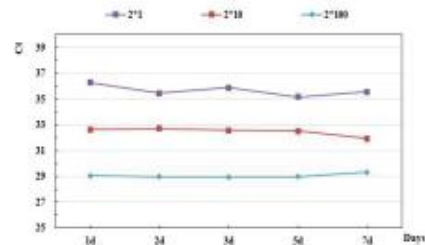


Figure 2: Change of Ct value of low copies (10²-10⁴ copies/mL) virus in storage tubes

After 7 days of storage, data of viral nucleic acid detected by RT-qPCR remain stable. The concentrations of viral samples did not change much.



Figure 3: Curves of qPCR Test for 5 days at RT and -20C

Viral RNA samples stored in the preservative remained highly stable at RT for 5 days compared with stored at -20C. For the sensitivity analysis, viral sample concentration as low as 100 copies/mL and corresponding 2 copies tested using RT-qPCR can be detected.



BEAVER NEVER STOP

Product List

 <p>Sample Collection Kit I: Sterile preservative with surfactant II: Sterile preservative with guanidine salt Cat. No. # 43903</p>	 <p>Sample Collection Kit (VTM) VTM preservative Cat. No. # 43904</p>	 <p>Cell Free DNA Tube With preservative for cell free DNA Cat. No. # 43803</p>
 <p>Saliva Collector # 43805: One-piece # 43806: Separate version Cat. No. # 43805</p>	 <p>Swab Collection Kit (A): Single / Double Dry Swab (B): Nasopharyngeal swab / oropharyngeal swab Cat. No. # 44001</p>	

Sample Processing

BeaverBeads™ Viral DNA / RNA Kit

This product (#70406) is composed of superparamagnetic magnetic beads as microcarriers for nucleic acid separation and extraction when used with high-efficiency biological reagent. It is suitable for the extraction of viral DNA and RNA from fresh or frozen samples of plasma, serum, urine, secretion, virus concentrate, virus preservation fluid, cell culture supernatant, or acellular body fluids. The purified samples can be directly used for PCR detection, digestion and other nucleic acid detection tests. This product can be adapted to various models of nucleic acid extraction instruments and automatic extraction workstation. One single batch is able to complete the extraction process in 9 minutes. This product has been qualified as Class One of Medical instrument and has *European Union CE certificate*.

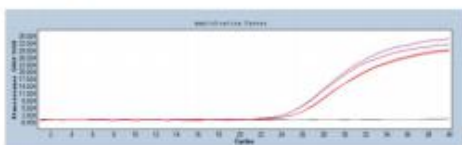


High Yield
Automatable
High Purity
Rapid Extraction within 9 min

Application Case

1. Viral DNA Extraction Performance

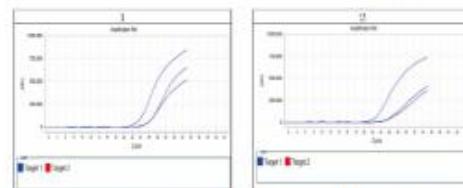
Sample	BEAVER	Competitor
HBV Serum	24.55	25.21



Test data show BeaverBeads™ Viral DNA/RNA Kit extracts DNA more efficiently than competitor's on HBV sample extraction since Ct value (obtained by RT-qPCR) of the sample extracted by BEAVER product is 0.6 less than that by competitor's.

2. Viral RNA Performance

HCV Serum Sample Viral Concentration	BEAVER (Ct)	Competitor (Ct)
300	24.08	24.08
1000	24.21	24.38
10000	21.52	21.00



Test data show BeaverBeads™ Viral DNA/RNA Kit extracts DNA as efficient as competitor on HBV sample extraction with close Ct value.



BEAVER NEVER STOP

9min Rapid Viral Nucleic Acid Extraction

Leading level in the industry
Extraction in 4 holes can be completed within 9 min
Breakthrough in time and efficiency

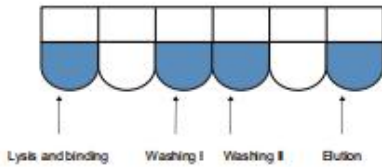
BeaverDevice™ Rosetta 32 automated extraction instrument with
BeaverBeads™ Viral DNARNA Kit (prefilling) can extract samples
within 9 min automatically



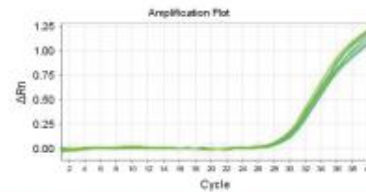
BeaverBeads™ Viral DNARNA Kit (prefilling)



BeaverDevice™ Rosetta 32



32-person Kit, Hole Placement Illustration



Sample / Ct	Automatic Operation (9min)	Manual Operation (About 40min)
1	30.08	29.86
2	30.19	30.25
3	30.68	30.59
4	30.33	30.67

Specification

Cat. NO.	Product Name	Specification
70406-32FV	BeaverBeads™ Viral DNARNA Kit	32runs, Deep Well Plates, V bottom
70406-32FU		32runs, Deep Well Plates, U bottom
70406-48FV		48runs, Deep Well Plates, V bottom
70406-48FU		48runs, Deep Well Plates, U bottom
70406-96FV		96runs, Deep Well Plates, V bottom
70406-100		Bottled

BEAVER Biomedical Engineering Co., Ltd.

Address: 1 Huayun Rd., Bldg. B4, Suzhou Industrial Park, China

TEL: +86 - 512 - 85187639

FAX: +86 - 512 - 85187635

E-mail: sales@beaverbio.com

Web: www.beaverbio.com



Official Website

Disclaimer: This document is for informational purposes only. It is not intended to be used as a substitute for professional advice. The user of this product is responsible for ensuring that the product is used in accordance with the instructions provided. The user of this product is responsible for ensuring that the product is used in accordance with the instructions provided. The user of this product is responsible for ensuring that the product is used in accordance with the instructions provided.

Copyright © 2013 BEAVER Biomedical Engineering Co., Ltd. All rights reserved. Any of the contents of this User's Guide may be used in whole or in part without the prior written consent of BEAVER Biomedical Engineering Co., Ltd. The Company reserves the right to change the contents of this User's Guide without notice. For more information, please contact sales@beaverbio.com.

6. Test Data

1. Materials and Apparatus

The preservative, the same reagent from Sample Collection kit (BEAVER, Cat. #43903);

Pseudotyped Virus sample: 2019-nCoV Pseudotyped Virus (1010cope/mL) (Zeesan Biotech, Cat. ZS-JL-NP-001);

Extraction Kit: BeaverBeads™ Viral DNA/RNA Kit (Cat. #70406);

qPCR Kit: PrimeDirect™ Probe RT-qPCR Mix (Takara, #RR650A);

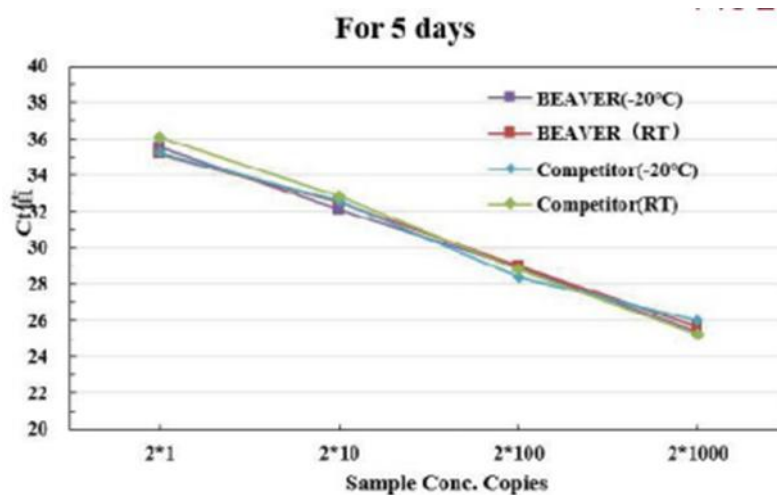
Primer and Probe: 2019-nCoV N Gene Primer and Probe (GENEWIZ)

Instrument: ABI-7500Fast (Applied Biosystems);

2. Results

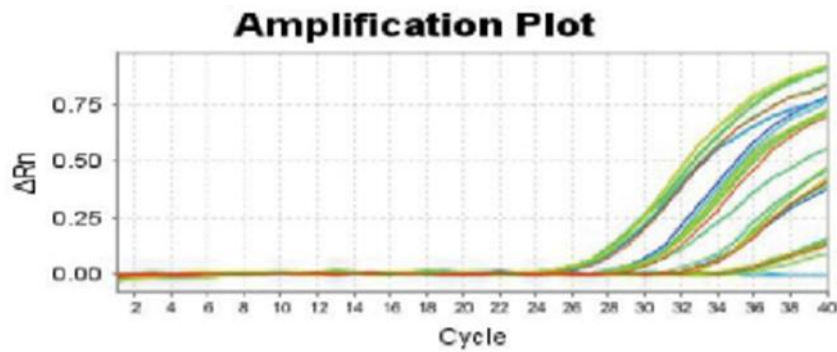
2.1 RT-PCR Test Data

Sample Conc./ Ct	10 ²	10 ³	10 ⁴	10 ⁵
BEAVER (-20°C)	35.54	32.08	28.9	25.38
BEAVER (RT)	35.15	32.53	28.99	25.63
Competitor (-20°C)	35.22	32.57	28.35	25.96
Competitor (RT)	36.06	32.86	28.82	25.22



Conclusion: Viral RNA samples stored in the preservative were highly stable at RT for at least 5 days compared with stored at -20°C.


2.2 RT-PCR Test Spectrum



Conclusion: For the sensitivity analysis, viral sample concentration at 10^2 copies/mL and corresponding 2 copies tested using RT-PCR can be detected.

7. Certificates

U.S. Department of Health & Human Services
a A


U.S. FOOD & DRUG ADMINISTRATION

[Follow FDA](#) | [En Español](#)

[Home](#) | [Food](#) | [Drugs](#) | [Medical Devices](#) | [Radiation-Emitting Products](#) | [Vaccines, Blood & Biologics](#) | [Animal & Veterinary](#) | [Cosmetics](#) | [Tobacco Products](#)

Establishment Registration & Device Listing

[FDA Home](#) | [Medical Devices](#) | [Databases](#)

[New Search](#)
[Back To Search Results](#)

Proprietary Name:	Disposable Sampling Tube; Sample Collection Kit; Sample Collector; Sample Storage Tube; Swab Transport Medium
Classification Name:	CONTAINER, SPECIMEN MAILER AND STORAGE, STERILE
Product Code:	KDT
Device Class:	1
Regulation Number:	864.3250
Medical Specialty:	Pathology
Registered Establishment Name:	BEAVER BIOMEDICAL ENGINEERING CO., LTD
Registered Establishment Number:	3016647440
Owner/Operator:	BEAVER Biomedical Engineering Co., Ltd
Owner/Operator Number:	10066795
Establishment Operations:	Manufacturer

Page Last Updated: 08/30/2021
 Note: If you need help accessing information in different file formats, see [Instructions for Downloading Viewers and Players](#).
 Language Assistance Available: [Español](#) | [繁體中文](#) | [Tiếng Việt](#) | [한국어](#) | [Tagalog](#) | [Русский](#) | [العربية](#) | [Kreyòl Ayisyen](#) | [Français](#) | [Polski](#) | [Português](#) | [Italiano](#) | [Deutsch](#) | [日本語](#) | [فارسی](#) | [English](#)



EU Declaration of Conformity



BEAVER

Declaration of Conformity

Manufacturer: BEAVER Biomedical Engineering Co., Ltd
 1 Huayun Rd., Bldg. B4, Suzhou Industrial Park, China
 Tel: 86-512-85187639
 whose single Authorized EU-Representative: Luxus Lebenswelt GmbH
 Kochstr.1, 47877, Willich, Germany
 DIMID: DE/0000047791
 Lin Sun
 Tel: 0049- 1715605732
 E-mail: info.m@luxuslw.de

Product Name: Sample Collection Kit
 GIVD code: 51.09.10.01
 Classification: CLASS A
 Conformity Assessment Route: Annex VIII,Rule 5

We here with declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

General applicable directives:
 REGULATION (EU) 2017/746
 Harmonized standards:
 EN ISO 13485:2016 EN ISO 15223-1:2016 EN ISO 14971:2012
 EN ISO 18113:2011 EN 1041:2008+A1:2003

Signature: 
 Name: Hui Ren
 Title: E
 Position: Suzhou, Jiangsu
 Date: 2020.05.20





Certificate of Registration



This is to certify that the Quality Management System of

BEAVER Biomedical Engineering Co., Ltd.

Unified Social Credit Code : 913205945837761683

Operation Address : 1 Huayun Rd., Bldg. B4, Suzhou Industrial Park, Suzhou City, Jiangsu Province, China

Registered Address : 1 Huayun Rd., Bldg. B4, Suzhou Industrial Park, Suzhou City, Jiangsu Province, China

applicable to

Development, production and sales of biological magnetic beads and magnetic bead kits; sales of conventional cell culture consumables and disposable laboratory plastic containers

has been assessed and registered by NQA against the provisions of

ISO 9001:2015

This registration is subject to the company maintaining a quality management system, to the above standard, which will be monitored by NQA.

Certified Clients shall accept regular surveillance assessments, the validity of certificates shall be maintained for the positive result of audit.

The information of this certificate can be checked on CNCA's website (www.cnca.gov.cn)

SNQA's website : www.snqa.com.cn

Managing Director



Certificate Number **47719**

Date: 08 June 2020

Valid Until: 08 June 2023

EAC Code: 14/13/29





Certificate of Registration



This is to certify that the Quality Management System of

BEAVER Biomedical Engineering Co., Ltd.

Unified Social Credit Code : 913205945837761683

Operation Address : 1 Huayun Rd., Bldg. B4, Suzhou Industrial Park, Suzhou City, Jiangsu Province, China

Registered Address : 1 Huayun Rd., Bldg. B4, Suzhou Industrial Park, Suzhou City, Jiangsu Province, China

applicable to

R&D, production and sales of in vitro diagnostic reagents, sampling equipment and instruments(see list for attachment)(within the scope of license qualification)

has been assessed and registered by NQA against the provisions of

ISO 13485: 2016

This registration is subject to the company maintaining a quality management system, to the above standard, which will be monitored by NQA.

Certified Clients shall accept regular surveillance assessments, the validity of certificates shall be maintained for the positive result of audit.

The information of this certificate can be checked on CNCA's website (www.cnca.gov.cn)

SNQA's website : www.snqa.com.cn

Managing Director

Certificate Number

47902

Date:

16 July 2020

Valid Until:

16 July 2023

EAC Code:

13/19



第一类医疗器械备案信息表

备案号：苏苏械备 20201165 号

备案人名称	苏州海狸生物医学工程有限公司
备案人统一社会信用代码	913205945837761683
备案人注册地址	苏州工业园区华云路1号东坊产业园B区4号楼
生产地址	苏州工业园区华云路1号东坊产业园B区4号楼
产品名称	一次性使用病毒采样管
型号/规格	型号：VTM 规格：1个/包
产品描述	由拭子和/或含保存液的样本采样管等组成。非无菌提供。
预期用途	用于样本的收集、运输和储存等。
备注	/
备案单位和日期	苏州市市场监督管理局 二〇二〇年十二月九日
变更情况	/

第一类医疗器械备案凭证

苏州海狸生物医学工程有限公司：

根据相关法规要求，对你单位第一类医疗器械：一次性使用病毒采样管 予以备案，备案号：苏苏械备 20201165 号。

苏州市市场监督管理局
二〇二〇年十二月九日



第一类医疗器械备案信息表

备案号：苏苏械备 20210888 号

备案人名称	苏州海狸生物医学工程有限公司
备案人统一社会信用代码	913205945837761683
备案人注册地址	苏州工业园区华云路1号东坊产业园B区4号楼
生产地址	苏州工业园区华云路1号东坊产业园B区4号楼
产品名称	一次性使用病毒采样管
型号/规格	II
产品描述	由含保存液的样本采样管组成。非无菌提供。保存液主要由水、异硫氰酸胍、三(羟甲基)氨基甲烷组成。
预期用途	用于样本的收集、运输和储存等。
备注	/
备案单位和日期	苏州市市场监督管理局 苏州市医疗器械监督管理局 医疗器械备案专用章
变更情况	/

第一类医疗器械备案凭证

苏州海狸生物医学工程有限公司：

根据相关法规要求，对你单位第一类医疗器械：一次性使用病毒采样管 予以备案，备案号：苏苏械备 20210888 号。





中华人民共和国
PEOPLE'S REPUBLIC OF CHINA
医疗器械产品出口销售证明
CERTIFICATE FOR EXPORTATION OF MEDICAL
PRODUCTS

证书编号： 苏苏药监械出 20210252 号

Certificate NO.: SSYJXC20210252

产品名称： 见附件；

Product(s): See Attachment

规格型号： 见附件；

Model: See Attachment;

产品注册或备案凭证号： 见附件；

Registration certificate(s): See Attachment;

生产企业： 苏州海狸生物医学工程有限公司

Manufacturer: BEAVER Biomedical Engineering Co., Ltd

生产企业住所： 苏州工业园区华云路 1 号东坊产业园 B 区 4 号楼

Address of manufacturer: 1 Huayun Rd., Bldg. B4, Suzhou Industrial Park, China

生产许可或备案凭证号： 苏苏食药监械生产备 20161010 号

Manufacturing License(s): NO.SSSYJXSCB20161010

兹证明上述产品已准许在中国生产和销售。

This is to certify that the above products have been registered to be manufactured and sold in China.

证明有效日期至： 2023 年 01 月 29 日

This certification valid until: 2023-01-29

备注： /

Remark: /





附件:

证书编号: 苏苏药监械出 20210252 号

Certificate NO.: SSYJXC20210252

序号 NO	产品名称 (中文) Product(s) (chinese)	产品名称 (英文) Product(s)	规格型号 (中文) Specification/model (c hinese)	规格型号 (英文) Specification/mode	产品注册证 或备案凭证 号(中文) Registration certificate(s)	产品注册证 或备案凭证 号(英文) Registration certificate(s)
1	核酸提取试剂 盒	BeaverBeads Viral DNA/RNA Kit	20 人份/盒、100 人份/ 盒	20 rxns、100 rxns	苏苏械备 20150135 号	NO.SSXB201 50135
2	唾液基因组 DNA 提取试剂 盒	BeaverBeads Saliva DNA Kit	20 人份/盒、100 人份/ 盒	20 rxns、100 rxns	苏苏械备 20190085 号	NO.SSXB201 90085
3	唾液采集器	Saliva Collector	1 个/盒	1Preps	苏苏械备 20190113 号	NO.SSXB201 90113
4	一次性使用病 毒采样管	Sample Collection Kit	VTM, 1 个/包	VTM, 1Preps/Pk	苏苏械备 20201165 号	NO.SSXB202 01165
5	核酸提取试剂 盒	BeaverBeads Viral DNA/RNA Kit	10 人份/盒、100 人份/ 盒	20 rxns、100 rxns	苏苏械备 20150136 号	NO.SSXB201 50136
6	样本保存液	Sample Storage Tube	2mL/支	2mL	苏苏械备 20170447 号	NO.SSXB201 70447
7	一次性使用病 毒采样管	Sample Collection Kit	型号: I 型, II 型; 规格: 1 套/包, 500 套/箱; 50 套/盒, 500 套/箱	Model: I, II; Spec: 1 Preps/Pk, 500 Preps/Case; 50 Preps/Pk, 500 Preps/Case	苏苏械备 20200086 号	NO.SSXB202 00086
8	一次性使用采 样器	Sample Collector	1 个/袋 (鼻拭子)、1 个/ 袋 (咽拭子)	1/Preps(Nasal), 1/Preps(T hroat)	苏苏械备 20200367 号	NO.SSXB202 00367
9	血液基因组 DNA 提取试剂 盒	BeaverBeads Blood DNA Kit	10 人份/盒、100 人份/ 盒	10 rxns、100 rxns	苏苏械备 20190084 号	NO.SSXB201 90084
10	病毒 DNA/RNA 提 取试剂盒	BeaverBeads Viral DNA/RNA Kit	20 人份/盒、32 人份/盒、 96 人份/盒、100 人份/ 盒	20 rxns、32 rxns、96rxns、100 rxns	苏苏械备 20200087 号	NO.SSXB202 00087
11	粪便核酸提取 试剂盒	BeaverBeads Stool DNA Kit	20 人份/盒、100 人份/ 盒	20 rxns、100 rxns	苏苏械备 20200865 号	NO.SSXB202 00865
12	核酸提取试剂 盒	BeaverBeads Viral DNA/RNA Kit	20 人份/盒、100 人份/ 盒	20 rxns、100 rxns	苏苏械备 20160053 号	NO.SSXB201 60053



13	样本保存液	Sample Storage Tube	DNA型, RNA型, 48人份/盒	DNA, RNA, 48Preps/Pk	苏苏械备 20201051号	NO.SSXB20201051
14	游离 DNA 提取试剂盒	BeaverBeads Circulating DNA Kit	20 人份/盒、100 人份/盒	20 rxns、100 rxns	苏苏械备 20190083号	NO.SSXB20190083

中国认可
检验
INSPECTION
CNAS 83271

NO.2021370275

货物运输条件鉴定书

Certification for Safe Transport of Chemical Goods

非限制性货物

样品名称： 一次性使用病毒采样管

Sample Name: Sample Collection Kit

委托单位： 苏州海狸生物医学工程有限公司

生产单位： 苏州海狸生物医学工程有限公司



SICIT 上海化工院检测有限公司
Shanghai Institute of Chemical Industry Testing Co., Ltd



货物运输条件鉴定书

Certification for Safe Transport of Chemical Goods

NO. 2021370275

Page 1 / 2

样品名称 Sample Name	中文 Chinese	一次性使用病毒采样管
	英文 English	Sample Collection Kit
委托单位 Consignor	苏州海狸生物医学工程有限公司	
生产单位 Manufacturer	苏州海狸生物医学工程有限公司	
检验方法、程序 Inspection Methods and Procedures	国际海事组织《国际海运危险货物规则》(2018版) IMO International Maritime Dangerous Goods Code (2018 Edition)	
样品外观与气味 Appearance & Odor	无色透明和红色塑料外壳(内含无色透明液体), 稍有气味 Colorless transparent and red Plastic shell(containing colorless transparent liquid), Weak odor	
鉴定结论 IDENTIFICATION CONCLUSION	1. 危险性识别(Hazards identification)	
	无。 None. 2. 海运按照IMO IMDG Code办理的类项(Suggestion according to IMO IMDG Code) 可按非限制性货物条件办理。 The substance is not subject to IMO IMDG Code.	
备注 Comment	3. 包装要求(Packaging requirements)	
	无。 None. 检验日期: 2020-12-13 签发日期: 2020-12-14 生效日期: 2021-01-01 Inspection Date: Issue Date: Effective Date:	

 批准
Approver: 

 审核
Checker: 

 主检
Appraiser: 


货物运输条件鉴定书

Certification for Safe Transport of Chemical Goods

NO. 2021370275

Page 2 / 2

鉴定项目 Identification Items	鉴定结果 Identification Results
爆炸危险性鉴定 Identification of Explosive Hazards	该货物不属于爆炸品。 The product is not classified in Explosives.
易燃危险性鉴定 Identification of Flammable Hazards	经闭杯闪点测试，在70度下没有发生闪燃，表明该货物不属于第3类易燃液体。 In the closed-cup flash point test, no flash was detected below 70°C, so the product is not classified in Class 3 (Flammable Liquids).
氧化危险性鉴定 Identification of Oxidative Hazards	该货物不属于氧化剂和有机过氧化物。 The product is not classified in oxidizing substances and organic peroxides.
毒害及传染危险性鉴定 Identification of Toxic & Infectious Hazards	该货物不属于有毒和感染性物质。 The product is not classified in toxic and infectious substances.
放射危险性鉴定 Identification of Radioactive Hazard	该货物无放射危险性。 The product is not classified in radioactive material.
腐蚀危险性鉴定 Identification of Corrosive Hazard	该货物不属于腐蚀品。 The product is not classified in corrosives.
其他危险性鉴定 Identification of other Hazards	该货物无其它危险性。 The product presents no other dangerous properties.

-验证码:995030-

报告结束



货物运输条件鉴定书

Certification for Safe Transport of Chemical Goods

NO. 2021494255

Page 1 / 2

样品名称 Sample Name	中文 Chinese	一次性使用病毒采样管
	英文 English	Sample Collection Kit
委托单位 Consignor	苏州海狸生物医学工程有限公司	
生产单位 Manufacturer	苏州海狸生物医学工程有限公司	
检验方法、程序 Inspection Methods and Procedures	国际航空运输协会《危险品规则》62版 IATA Dangerous Goods Regulations (DGR) 62nd Edition	
样品外观与气味 Appearance & Odor	无色透明和红色塑料管 (内含紫红色液体), 稍有气味 Colorless transparent and red Plastic tube (containing purple red liquid), Weak odor	
鉴定结论 IDENTIFICATION CONCLUSION	1. 危险性识别 (Hazards identification)	
	无。 None.	
	2. 空运按照IATA DGR办理的类型 (Suggestion according to IATA DGR)	
可按非限制性货物条件办理。 The substance is not subject to IATA DGR.		
3. 包装要求 (Packaging requirements)		
无。 None.		
检验日期: 2020-12-20 签发日期: 2020-12-21 生效日期: 2021-01-01 Inspection Date: Issue Date: Effective Date:		
备注 Comment	无。 None.	



批准 Approver: 张永明

审核 Checker: 董学胜

主检 Appraiser: 周敏





货物运输条件鉴定书

Certification for Safe Transport of Chemical Goods

NO. 2021494255

Page 2 / 2

鉴定项目 Identification Items	鉴定结果 Identification Results
爆炸危险性鉴定 Identification of Explosive Hazards	该货物不属于爆炸品。 The product is not classified in Explosives.
易燃危险性鉴定 Identification of Flammable Hazards	该货物不属于易燃危险品。 The product is not classified in flammable substance.
氧化危险性鉴定 Identification of Oxidative Hazards	该货物不属于氧化剂和有机过氧化物。 The product is not classified in oxidizing substances and organic peroxides.
毒害及传染危险性鉴定 Identification of Toxic & Infectious Hazards	该货物不属于有毒和感染性物质。 The product is not classified in toxic and infectious substances.
放射危险性鉴定 Identification of Radioactive Hazard	该货物无放射危险性。 The product is not classified in radioactive material.
腐蚀危险性鉴定 Identification of Corrosive Hazard	该货物不属于腐蚀品。 The product is not classified in corrosives.
其他危险性鉴定 Identification of other Hazards	该货物无其它危险性。 The product presents no other dangerous properties.

-验证码:675687-

报告结束





✈️ 空运
By Air



NO.2021370273



中国认可
检测
INSPECTION
CNAS 60071

货物运输条件鉴定书 Certification for Safe Transport of Chemical Goods

非限制性货物

样品名称： 一次性使用病毒采样管

Sample Name: Sample Collection Kit

委托单位： 苏州海狸生物医学工程有限公司

生产单位： 苏州海狸生物医学工程有限公司



Without Border Life
SICIT 上海化工院检测有限公司
Shanghai Institute of Chemical Industry Testing Co., Ltd

✈️ 空运
By Air

✈️ 空运
By Air



货物运输条件鉴定书

Certification for Safe Transport of Chemical Goods

NO. 2021370273

Page 1 / 2

样品名称 Sample Name	中文 Chinese	一次性使用病毒采样管
	英文 English	Sample Collection Kit
委托单位 Consignor	苏州海狸生物医学工程有限公司	
生产单位 Manufacturer	苏州海狸生物医学工程有限公司	
检验方法、程序 Inspection Methods and Procedures	国际航空运输协会《危险品规则》62版 IATA Dangerous Goods Regulations (DGR) 62nd Edition	
样品外观与气味 Appearance & Odor	无色透明和红色塑料外壳（内含无色透明液体），稍有气味 Colorless transparent and red Plastic shell (containing colorless transparent liquid), Weak odor	
I D E N T I F I C A T I O N 鉴 定 结 论 C O N C L U S I O N	1. 危险性识别 (Hazards identification) 无。 None.	
	2. 空运按照IATA DGR办理的类项 (Suggestion according to IATA DGR) 可按非限制性货物条件办理。 The substance is not subject to IATA DGR.	
	3. 包装要求 (Packaging requirements) 无。 None.	
	检验日期: Inspection Date: 2020-12-13	签发日期: Issue Date: 2020-12-14
	生效日期: Effective Date: 2021-01-01	
备注 Comment	无。 None.	



批准 Approver: 审核 Checker: 主检 Appraiser:



货物运输条件鉴定书

Certification for Safe Transport of Chemical Goods

NO. 2021370273

Page 2 / 2

鉴定项目 Identification Items	鉴定结果 Identification Results
爆炸危险性鉴定 Identification of Explosive Hazards	该货物不属于爆炸品。 The product is not classified in Explosives.
易燃危险性鉴定 Identification of Flammable Hazards	经闭杯闪点测试，在70度下没有发生闪燃，表明该货物不属于第3类易燃液体。 In the closed-cup flash point test, no flash was detected below 70°C, so the product is not classified in Class 3 (Flammable Liquids).
氧化危险性鉴定 Identification of Oxidative Hazards	该货物不属于氧化剂和有机过氧化物。 The product is not classified in oxidizing substances and organic peroxides.
毒害及传染危险性鉴定 Identification of Toxic & Infectious Hazards	该货物不属于有毒和感染性物质。 The product is not classified in toxic and infectious substances.
放射危险性鉴定 Identification of Radioactive Hazard	该货物无放射危险性。 The product is not classified in radioactive material.
腐蚀危险性鉴定 Identification of Corrosive Hazard	该货物不属于腐蚀品。 The product is not classified in corrosives.
其他危险性鉴定 Identification of other Hazards	该货物无其它危险性。 The product presents no other dangerous properties.

-验证码:561851-

报告结束