

Summary of Safety and Performance

This Summary of Safety and Performance (SSP) is intended to provide public access to an updated summary of the main aspects of the safety and performance of the device.

The SSP is not intended to replace the Instructions for Use as the main document to ensure the safe use of the device, nor is it intended to provide diagnostic or therapeutic suggestions.

Document Revision: A3

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The information presented below is intended for patients or lay persons.

The SSP is not intended to give general advice on the diagnosis and/or treatment of a medical condition. Please contact your healthcare professional in case you have questions about your medical condition or about the use of the device in your situation.

Manufacturer's reference number for the SSP: BTK-CE17-0606

1. Device identification and general information

1.1. Device trade name

Multiple Respiratory Multipathogen Antigen Test Kit (Immunochromatographic Assay)

1.2. Manufacturer; name and address

Manufacturer Name: BioTeke Corporation (Wuxi) Co., Ltd

Address: No. 90, Huiming Road, Huishan, Wuxi City, Jiangsu, 214000, China

1.3. Manufacturer's single registration number (SRN)

CN-MF-000007517

1.4. Basic UDI-DI

697454156017LA

1.5. European Medical Device Nomenclature (EMDN) description /

text

W0105099099

1.6. Risk class of device

Class C, rule 4a

1.7. Year when the device was first CE-marked under Regulation (EU)

2017/746 covering the device

The year when the device was first CE-marked under Regulation (EU) 2017/746 covering the device is 2025.

1.8. Authorised representative if applicable; name and the SRN

Name: MedUnion S.L.

Address: Carrer de Tapioles, 33, 2-1, 08004, Barcelona, Spain

SRN: ES-AR-000019366

Tax Number: B67973032

Contact Person: Jason Wu

Tel: +34-644173535

E-mail: rep@themedunion.com

1.9. NB's name (the NB that will validate the SSP) and the NB's single identification number

Name: Sertio Oy

Address: Biokatu 10, 33520, Tampere Finland

Single identification number: 3018

2. Intended purpose and other indications

2.1. Intended purpose (including intended patient groups)

This kit is only used for the in vitro qualitative detection of respiratory multipathogen antigen (SARS-CoV-2/Influenza A virus/Influenza B virus/Respiratory syncytial virus/Adenovirus) from human anterior nasal swab specimens. Multiple Respiratory Multipathogen Antigen Test Kit is an immunochromatographic double-antibody sandwich assay intended for the qualitative detection and differentiation of SARS-CoV-2/Influenza A virus/Influenza B virus/Respiratory syncytial virus/Adenovirus from individuals who are suspected of respiratory tract disease infection.

This kit is suitable for the auxiliary diagnosis of respiratory diseases. Results may serve as clinical reference only and cannot be used alone as the sole basis for diagnosing or excluding respiratory infections. The clinical diagnosis and treatment of patients should be considered in combination with their symptoms/signs, their medical history, other laboratory tests and treatment responses. Positive test result may need to be further confirmed, and negative result do not safely rule out viral respiratory infections.

Children under 18 years should be supported by an adult.

2.2. Indications

Indication: Individuals who are suspected of respiratory tract disease infection.

Target population: Untrained lay users

2.3. Contra-indications and/or limitations

(1) The test results of this kit can only serves reference for clinicians and should not be used as the sole basis for a clinical diagnosis and treatment. Clinical management of patients should be included the context of their signs and symptoms, their medical history other laboratory tests, and response to treatment.

(2) The quality of the sampling technique and the specimen processing have a greater impact on the detection of pathogens included in this test kit. Thus, a negative test result

does not exclude the possibility of a viral infection.

(3) Due to methodological limitations of antigen-based test, the analytical sensitivity of immunochromatographic tests is generally lower than that of nucleic acid-based test.

Therefore, any test interpretation should pay high attention to negative results and make a comprehensive judgment based on other test results. If clinically necessary, negative results in should be checked by nucleic acid test or virus culture identification.

(4) When the test result is positive, it is recommended to apply other methods such as PCR or viral culture for further confirmation if clinically relevant. if necessary or mandated by authorities, please also consult with your local public health office appropriate action.

(5) Secifically, false-negative results may occur, if:

(i) Improper sample collection, transport and processing, or low viral titers in the sample.

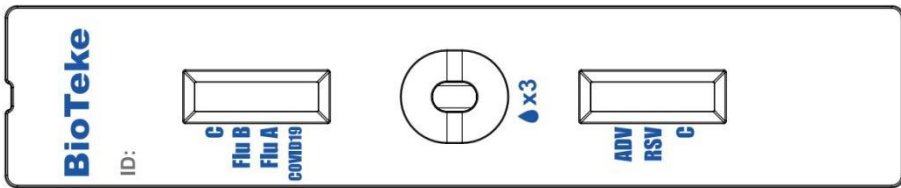
(ii) Samples were taken too early or too late after infection, so that peak viral titers were missed. Multiple samplings at multiple sites in the same patient may help avoid false negative results. Therefore, multiple sampling at multiple sites in the same patient may avoid false negatives.

3. Device description

3.1. General device description (including reference to previous generation(s) or variant(s) if such exist, and a description of the differences)

This kit is only used for the in vitro qualitative detection of respiratory multi pathogen antigen (SARS-CoV-2/Influenza A virus/Influenza B virus/Respiratory syncytial virus/Adenovirus) from human anterior nasal swab specimens. The product is for self-testing and the intended users of this product are untrained lay users. There is a previous generation exist. It is a similar device intended for professional use on the market. The intended population of the device CE marked for professional use is different.

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)

Components	Structure drawing
Tube Cap	
Anterior nasal swab	
Sample extraction tube	
Waste bag	
Test card	

The component of anterior nasal swab manufactured by BioTeke Corporation (Wuxi) Co., Ltd has been CE-marketed under Regulation (EU) 2017/745, the basic UDI-DI of swab is 697454156001KT.

3.3. Description of how the device is achieving its intended purpose

Ensure fulfilment of the intended use of the product through quality management system and performance studies. According to the intended purpose, the product are classified as class C.

**3.4. Description of accessories and/or other devices/equipment
needed to be used in combination with the device in question, if
any**

No other products or accessories are needed.

**4. Reference to any harmonised standards and common specification
applied**

4.1 Harmonised standards

No.	Document Number	Document Title
1	EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)
2	EN ISO 15223-1:2021	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements (ISO 15223-1:2021)
3	EN ISO18113-1:2011	In vitro diagnostic medical devices – Information supplied by the manufacturer (labelling) – Part 1: Terms, definitions and general requirements
4	EN ISO 14971:2019	Medical devices - Application of risk management to medical devices (ISO 14971:2019)
5	EN 13612:2002	Performance evaluation of in vitro diagnostic medical devices
6	EN ISO18113-4: 2011	In vitro diagnostic medical devices – Information supplied by the manufacturer (labelling) – Part 4: In vitro diagnostic reagents for self-testing
7	EN ISO 23640:2015	In vitro diagnostic medical devices – Evaluation of stability of in vitro diagnostic reagents
8	EN ISO 11607-1:2020	Packaging for terminally sterilized medical devices —Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2019)
9	EN ISO 11607-2:2020	Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes (ISO 11607-2:2019)

No.	Document Number	Document Title
108	EN ISO 11737-1:2018	Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products (ISO 11737-1:2018)
11	EN ISO 11737-2:2020	Sterilization of health care products - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process (ISO 11737-2:2019)
12	EN ISO 11137-1:2015	Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices (ISO 11137-1:2006, including Amd 1:2013)
13	EN ISO 11137-2:2015	Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose (ISO 11137-2:2013)
14	EN 13641:2002	Elimination or reduction of risk of infection related to in vitro diagnostic reagents

4.2 Common specification

REGULATION (EU) 2022/1107 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, 4 July 2022 (Note: only applicable for one analyte, SARS-CoV-2 (Annex XIII, Table 4 and Table 6), not for the whole kit)

5. Risks and warnings

Contact your healthcare professional if you are concerned about the use of the device or about the results. This document is not intended to replace a consultation with your healthcare professional, if needed.

5.1. How potential risks have been controlled or managed

The potential risks have been controlled through risk management. The documents formed by risk management include risk management plan and risk management report, which are all comply with regulatory requirements and are stored in Bioteke.

5.2. Remaining risks and undesirable effects

The Multiple Respiratory Multipathogen Antigen Test Kit (immunochromatographic assay) is intended use for the in vitro qualitative detection of respiratory multipathogen antigen SARS-CoV-2/Influenza Avirus/Influenza Bvirus/Respiratory syncytialvirus/Adenovirus) from human anterior nasal swab specimens in a home environment by layperson. So, the clinical benefit of the product is that it can help laypersons quickly and conveniently to detect the infection status of various respiratory viruses at home, thereby guiding layperson to take timely intervention measures, preventing layperson's condition from progressing or deteriorating.

During the outbreak of COVID-19, WHO recommends that RADTs that meet the minimum performance requirements of $\geq 80\%$ sensitivity and $\geq 97\%$ specificity can be used to diagnose SARS-CoV-2 infections in a range of settings where NAAT is unavailable or where an excessive turnaround time would preclude clinical and public health utility of results. ECDC recommends the use of rapid antigen tests is appropriate in high prevalence settings when a positive result is likely to indicate true infection, as well as in low prevalence settings to rapidly identify highly infectious cases and rapid antigen tests can help reduce further transmission through early detection of highly infectious cases, enabling a rapid start of contact tracing. This shows that the use of RADTs to detect respiratory infectious diseases similar to COVID-19 is recognized, and it is also proved to be feasible by practice.

Through risk management, the risks have been analyzed, evaluated and controlled, there are no unacceptable risks or risks that are required to be reduced as far as possible to the risk reduction end point.

To sum up, the benefit of the Multiple Respiratory Multipathogen Antigen Test Kit (immunochromatographic assay) is overweight the risk. The overall residual risk of the Multiple Respiratory Multipathogen Antigen Test Kit (immunochromatographic assay) is acceptable.

Though the overall residual risk of the product is acceptable, there are some significant residual risks should be disclosed in IFU as following:

- 1) Children under 18 years should be supported by an adult;
- 2) The test results of this kit can only serves reference for clinicians and should not be used as the sole basis for a clinical diagnosis and treatment. Clinical management of patients should be included the context of their signs and symptoms, their medical history other laboratory tests, and response to treatment.
- 3) The quality of the sampling technique and the specimen processing have a greater

impact on the detection of pathogens included in this test kit. Thus, a negative test result does not exclude the possibility of a viral infection.

4) Due to methodological limitations of antigen-based test, the analytical sensitivity of immunochromatographic tests is generally lower than that of nucleic acid-based test.

5.3. Warnings and precautions

(1) This is a single-use in vitro diagnostic reagent, do not reuse, and do not use expired products.

(2) All test specimens must be considered potentially infectious, and during collection, processing, storage, mixing of specimens appropriate protective measures should be applied. For example, gloves and masks should be used as appropriate and waste (like used swabs, test cards, extraction tubes) should be handled as potentially biohazardous items.

(3) Use the swab and sample diluent provided with this reagent for sampling, and do not use different batches of test cards and sample extraction tubes.

(4) Use fresh specimens for testing, do not use repeated freeze-thaw samples.

(5) Operate at room temperature. Test cards kept at low temperature should be brought to room temperature before opening to avoid moisture absorption.

(6) Do not use reagent kits with obvious damage or after their expiration date.

(7) The aluminum foil pouch contains desiccant and must not be ingested.

(8) Improper sample collection or processing may result in false-negative results.

(9) Ensure proper sample loading volume, results may not be valid if too much or too little sample loading volume was applied to the test card.

(10) In case of a positive result, please adhere to local rules, regulations and practices for reporting to your local public health agency.

(11) For any test result, a final diagnosis should only be made by a physician by combining individual information from the medical history, physical examination, signs and symptoms with other test results, as appropriate.

(12) If you have any questions or suggestions on the use of this kit, please contact the manufacturer.

(13) For unknown reasons, long-term use of some drugs may lead to false positive results of the test, which are not covered by the interfering substances.

(14) If the test result is negative but the patient is still symptomatic or suspected of having an infection, serial testing is recommended over the next few days.

(15) Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user

is established.

5.4. Summary of any field safety corrective actions including field safety notices, if applicable

There are no incidents data at present stage for this product because the product has not yet been launched in the market, so there are no any field safety corrective actions taken at present stage.

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

6.1. Summary of scientific validity of the device

Through reported literature and clinical studies, we can find that detecting Influenza A/Influenza B /SARS-CoV-2/Respiratory syncytial virus/ Adenovirus antigen in nasal swab could be scientific and effective to aiding in diagnosis in Influenza A virus/Influenza B virus /SARS-CoV-2/Respiratory syncytial virus/ Adenovirus infection. The effectiveness in the field of self-testing will be further demonstrated through layperson studies of this product. If the results of the layperson study meet the clinical evaluation criteria, then it can be proved that Multiple Respiratory Multipathogen Antigen Test Kit (immunochromatographic assay) is scientific and validity.

6.2. Summary of performance data from studies of the device prior to CE- marking, and if applicable from equivalent device and other sources

6.2.1 Summary of analytical performance

Analytical performance means that the ability of a device to correctly detect or measure a particular analyte. The kit is immunochromatographic and uses double-antibody sandwich method to detect Influenza A virus/Influenza B virus /SARS-CoV-2/Respiratory syncytial virus antigen. The analytical performance characteristics are as follows.

1) Limit of Detection (LOD)

The Limit of Detection (LoD) of the Multiple Respiratory Multipathogen Antigen Test Kit is 2.0×10^2 TCID₅₀/mL for SARS-CoV-2, 1.0×10^2 TCID₅₀/mL for Influenza A,

2.0×10^2 TCID₅₀/mL for Influenza B, 2.0×10^2 TCID₅₀/mL for RSV and 2.0×10^2 TCID₅₀/mL for ADV.

The Limit of Detection (LoD) of the Multiple Respiratory Multipathogen Antigen Test Kit is 40 IU/mL for 1st WHO International Standard for SARS-CoV-2 Antigen (NIBSC code: 21/368).

2) Cross-reactivity

There is no cross-reactivity with the following pathogens:

No.	Virus/ Bacteria name	Strain	Concentration/ CT value
1	Coronavirus HKU1	GZ/1804-138	CT: 23
2	Coronavirus OC43	VR-1558, OC43	4.2×10^5 TCID ₅₀ /mL
3	Coronavirus NL63	NL63	1.6×10^3 TCID ₅₀ /mL
4	Coronavirus 229E	229E/GZ/1801-3	5.6×10^4 TCID ₅₀ /mL
5	Rhinovirus (group A)	A30/GZ/1710-89	4.2×10^6 TCID ₅₀ /mL
6	Rhinovirus (group B)	70/FO2-2547	1.0×10^6 TCID ₅₀ /mL
7	Enterovirus (CA16)	CA16/Guangzhou/0302/2 011	1.8×10^7 TCID ₅₀ /mL
8	Enterovirus (Echo)	ATCC VR-39, HILL	1.0×10^6 TCID ₅₀ /mL
9	Enterovirus (EV71)	EV71/Guangzhou/0402/2 012	5.6×10^6 TCID ₅₀ /mL
10	Epstein-barr virus capsid antigen	B95-8	CT: 17
11	Measles virus	Edmonston	1.0×10^7 TCID ₅₀ /mL
12	Human cytomegalovirus	RC256	3.2×10^3 TCID ₅₀ /mL
13	Rotavirus	VR-2018	CT: 20
14	Norovirus	ATCC VR-3234SD	3.6×10^5 copies/ μ

No.	Virus/ Bacteria name	Strain	Concentration/ CT value
			L
15	Mumps virus	Jones	1.0×10^7 TCID ₅₀ /mL
16	Varicella zoster virus	VR-1367	CT: 13
17	Human Parainfluenza virus 1	PIV1/Guangzhou/0701/20 11	1.3×10^7 TCID ₅₀ /mL
18	Human Parainfluenza virus 2	PIV2/GZ/Hecin1711- 34/2017	5.6×10^7 TCID ₅₀ /mL
19	Human Parainfluenza virus 3	PIV3/Guangzhou/0903/20 12	3.2×10^5 TCID ₅₀ /mL
20	Human Parainfluenza virus 4a	ATCC VR-1378, M-25	4.5×10^5 TCID ₅₀ /mL
21	Human Parainfluenza virus 4b	ATCC VR-1377, CH19503	1.3×10^7 TCID ₅₀ /mL
22	MERS-coronavirus	EMC/2012	1.6×10^5 TCID ₅₀ /mL
23	Human metapneumovirus (hMPV)	GZ/1803-107	1.0×10^5 TCID ₅₀ /mL
24	Mycoplasma pneumoniae	ATCC 15531.	1.0×10^9 copies/mL
25	Chlamydia pneumoniae	ATCC VRJ-2282, TW- 183	4.2×10^2 TCID ₅₀ /mL
26	Haemophilus influenzae	GIM 1.961.	4.8×10^7 CFU/mL
27	Streptococcus pneumoniae	(Klein) Chester	1.0×10^6 CFU/mL
28	Streptococcus pyogenes	ATCC 19615	1.6×10^8 CFU/mL
29	Pooled human nasal washes	N/A	100%
30	Bordetella pertussis	GDM 1.952	2.6×10^9 CFU/mL
31	Legionella pneumophila	Philadelphial, Brenner et al.	1.9×10^6 CFU/mL
32	Staphylococcus aureus	CMCC(B) 26003	2.1×10^9

No.	Virus/ Bacteria name	Strain	Concentration/ CT value
			CFU/mL
33	Staphylococcus epidermidis	1191 (Winslow and Winslow) Evans	7.7×10^5 CFU/mL
34	Candida albicans	CMCC(F) 129002	1.3×10^8 CFU/mL

Bioteke test detects all the pathogens listed below: SARS-COV-2, Influenza A/B, RSV, ADV.

No.	Virus/ Bacteria name	Strain	Concentration/ CT value
1	Influenza A virus 2009H1N1	L19-A1/Si chuan/SWL1/2009	4.2×10^6 TCID ₅₀ /mL
2	Influenza A virus seasonal H1N1	L6-A1/ Liaoning huanggu /1183/2007	5.6×10^5 TCID ₅₀ /mL
3	Influenza A virus H3N2	L8-A3/ Brisbane /10/2007	1.0×10^6 TCID ₅₀ /mL
4	Influenza A virus H5N1	A/Chicken/Liaoning/SD0 07/2017(H5N1)	CT: 20
5	Influenza A virus H7N9	A/Guangd/17SF003/2016(H7N9)	CT: 20
6	Influenza B virus Yamagata	GZ/174/201803	5.6×10^6 TCID ₅₀ /mL
7	Influenza B virus Victoria	GZ/133/201712	1.0×10^6 TCID ₅₀ /mL
8	Respiratory syncytial virus A	RSVA/GZ/Hecin1705-74	1.3×10^5 TCID ₅₀ /mL
9	Respiratory adenovirus type 1	ADV1/GZ/Hecin1608-21	2.4×10^8 TCID ₅₀ /mL
10	Respiratory adenovirus type 2	GZ/1705-34/2017	5.6×10^6 TCID ₅₀ /mL
11	Respiratory adenovirus type 3	ADV3/GZ/0101/2011	1.0×10^6 TCID ₅₀ /mL
12	Respiratory adenovirus type	ADV4/GZ/Hecin1611-	5.6×10^5

No.	Virus/ Bacteria name	Strain	Concentration/ CT value
	4	72/2016	TCID ₅₀ /mL
13	Respiratory adenovirus type 5	ADV/GZ/1801-54	1.0 ×10 ⁷ TCID ₅₀ /mL
14	Respiratory adenovirus type 7	ADV7/GZ/1706-198	3.2 ×10 ⁷ TCID ₅₀ /mL
15	Respiratory adenovirus type 55	ADV55/GZ/1612-129	3.2 ×10 ⁸ TCID ₅₀ /mL
16	SARS-CoV-2	Wuhan-Hu-1	2.8 ×10 ⁶ TCID ₅₀ /mL

3) Interfering substance

The following interfering substances will also not interfere with the results of the kit.

No.	Potential Interfering Substances	Active Ingredient	Test concentration	No.	Potential Interfering Substances	Active Ingredient	Test concentration		
1	Antiviral drug	α-interferon	0.71mg/mL	23	Nasal crticosteroids	Triamcinolone acetonide	0.22mg/mL		
2		Zanamivir	10mg/mL						
3		Ribavirin	6.42mg/L	24		Budesonide	0.128mg/mL		
4		Oseltamivir	2.14mg/L	25		Mometasone	0.2mg/mL		
5		Peramivir	4.29mg/L	26		Fluticasone	0.2mg/mL		
6		Lopinavir	0.57mg/mL	27	Allergic symptom relief drug	Histamine Hydrochloride	0.18mg/L		
7		Ritonavir	0.57mg/mL						
8		Arbidol	0.43mg/mL						
9	Antibiotic	Levofloxacin	0.54mg/mL	28	Throat tablets, oral anesthetics and analgesics	Menthol	1.7mg/mL		
10		Azithromycin	0.36mg/mL						
11		Ceftriaxone	750mg/L	29		Ethyl 4-aminobenzoate	1.5mg/mL		
12		Meropenem	1.07mg/mL						
13	Systemic antibacterial drugs	Tobramycin	4.38mg/L	30	Zicam Cold Remedy Nasal Gel	Sulphur	15%		
14	Mucin	Mucin protein, Type I-S	1%						
15	Human blood		5%	31	Antibiotics,nasal	Mupirocin	10mg/mL		
16		Epinephrine	0.4mg/mL						

		(phenylephrine)			ointment		
17		Oxymetazoline	0.3mg/mL				
18	Nasal spray	Sodium chloride (with preservatives)	36mg/mL	32	Naso Gel(NeiMed)	Saline	5.0% V/V
19		Cromolyn sodium	15.0% V/V				
20	Nasal	Beclomethasone	0.2mg/mL	33	Alkalol	Galphimia glauca, Luffa operculata, Sabadilla	1:10 dilution
21	corticosteroids	Dexamethasone	0.2mg/mL				
22		Flunisolide	0.1mg/mL	34	Sore Throat Phenol Spray	Phenol	15.0% V/V

4) Hook effect

The test kit does not have high dose hook effect at the concentration of up to 1.75×10^6 TCID₅₀/mL.

5) Precision

Repeated testing was conducted for national or enterprise repeatable reference products for 10 times. The test results show that the negative detection rate is 100% for negative samples, positive detection rate is 100% for both weak positive samples and moderate positive samples. It shows that the repeatability of this kit is good.

6) Flex and Robustness Study

The result of flex and robustness study of the test kit is summarized in the following table:

Item	Study result	Operating condition claimed by BioTeke
Sample volume	Acceptable range of sample volume is 60-100 ul; Acceptable range of sample drop is 3 ~ 4 drops.	Sample volume is recommended as 3 drops.
Sample diluent volume	Acceptable range of sample diluent volume is 0.3 ~ 0.9 mL	Sample diluent volume is recommended as 0.5 mL.
Reaction time	Acceptable range of reaction time is 10 – 25 minutes	Reaction time is recommended as 15 – 20 minutes.
Environmental	Acceptable range of	Environmental temperature is

Item	Study result	Operating condition claimed by BioTeke
temperature	environmental temperature is 10 ~ 30 °C.	recommended as 10 ~ 30 °C.
Environmental humidity	Acceptable range of environmental humidity is 30% ~ 75%.	Environmental humidity is recommended as 30% ~ 75%.

7) Specimen Type

The specimen type of the test kit is anterior nasal swabs.

6.2.2 Summary of clinical performance

The manufacturer determines whether the product needs to be validated for safety and efficacy through clinical trials based on the product's risk level. For the product Multiple Respiratory Multipathogen Antigen Test Kit, clinical trials and layperson study are required to demonstrate product performance.

● Clinical Performance Study

The clinical performance study had been planned to verify the applicable clinical performance characteristics, the summary of clinical performance study is as follows.

1) COVID-19:

COVID-19		RT-PCR		Total
		Positive	Negative	
Multiple Respiratory Multipathogen Antigen Test Kit (immunochromatographic assay)	Positive	125	0	125
	Negative	12	566	578
	Total	137	566	703

Statistic	Value	95% CI
Diagnostic sensitivity	91.24%	85.20% to 95.39%
Diagnostic specificity	100.00%	99.35% to 100.00%
Accuracy	98.29%	97.04% to 99.11%

2) Influenza A:

Influenza A		RT-PCR		Total
		Positive	Negative	
Multiple Respiratory Multipathogen Antigen Test Kit (immunochromatographic assay)	Positive	25	1	26
	Negative	6	671	677
	Total	31	672	703

Statistic	Value	95% CI
Diagnostic sensitivity	80.65%	62.53% to 92.55%
Diagnostic specificity	99.85%	99.17% to 100.00%
Accuracy	99.00%	97.96% to 99.60%

3) Influenza B:

Influenza B		RT-PCR		Total
		Positive	Negative	
Multiple Respiratory Multipathogen Antigen Test Kit (immunochromatographic assay)	Positive	33	0	33
	Negative	6	664	670
	Total	39	664	703

Statistic	Value	95% CI
Diagnostic sensitivity	84.62%	69.47% to 94.14%
Diagnostic specificity	100.00%	99.45% to 100.00%
Accuracy	99.15%	98.15% to 99.69%

4) RSV:

RSV	RT-PCR	Total
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		Positive	Negative	
Multiple Respiratory Multipathogen Antigen Test Kit (immunochromatographic assay)	Positive	25	3	28
	Negative	5	670	675
	Total	30	673	703

Statistic	Value	95% CI
Diagnostic sensitivity	83.33%	65.28% to 94.36%
Diagnostic specificity	99.55%	98.70% to 99.91%
Accuracy	98.86%	97.77% to 99.51%

5) ADV:

ADV		RT-PCR		Total
		Positive	Negative	
Multiple Respiratory Multipathogen Antigen Test Kit (immunochromatographic assay)	Positive	33	0	33
	Negative	6	664	670
	Total	39	664	703

Statistic	Value	95% CI
Diagnostic sensitivity	84.62%	69.47% to 94.14%
Diagnostic specificity	100.00%	99.45% to 100.00%
Accuracy	99.15%	98.15% to 99.69%

● Layperson Study

The layperson study had been planned to verify that Multiple Respiratory Multipathogen Antigen Test Kit (Immunochromatographic Assay) is suitable for use by lay user.

The result of layperson study was summarized as following:

1) Result Interpretation

A total of 100 participants was enrolled in the result Interpretation study. The overall percentage of correctly interpretation was 98.9%.

2) Diagnostic sensitivity and specificity

A total of 210 participants was enrolled in the study, including 60 participants that were unknown their status, 30 participants that were known SARS-CoV-2 positive status, 30 participants that were known Flu A positive status, 30 participants that were known Flu B positive status, 30 participants that were known RSV positive status and 30 participants that were known ADV positive status.

The diagnostic sensitivity and specificity of Multiple Respiratory Multipathogen Antigen Test Kit (Immunochromatographic Assay) operated by the lay users compared with the PCR reagent results are summarized as following:

➤ SARS-CoV-2

For SARS-CoV-2 result		PCR		Total
		Positive	Negative	
Multiple Respiratory Multipathogen Antigen Test Kit (Immunochromatographic Assay)	Positive	30	0	30
	Negative	0	180	180
Total		30	180	210

Statistic	Value	95% CI
Sensitivity	100.00%	88.43% to 100.00%
Specificity	100.00%	97.97% to 100.00%
Total accuracy	100.00%	98.26% to 100.00%

➤ Flu A

For Flu A result		PCR		Total
		Positive	Negative	
Multiple Respiratory	Positive	29	0	29

Multipathogen Antigen Test Kit (Immunochromatographic Assay)	Negative	1	180	181
Total		30	180	210

Statistic	Value	95% CI
Sensitivity	96.67%	82.78% to 99.92%
Specificity	100.00%	97.97% to 100.00%
Total accuracy	99.52%	97.38% to 99.99%

➤ Flu B

For Flu B result		PCR		Total
		Positive	Negative	
Multiple Respiratory Multipathogen Antigen Test Kit (Immunochromatographic Assay)	Positive	29	0	29
	Negative	1	180	181
Total		30	180	210

Statistic	Value	95% CI
Sensitivity	96.67%	82.78% to 99.92%
Specificity	100.00%	97.97% to 100.00%
Total accuracy	99.52%	97.38% to 99.99%

➤ RSV

For RSV result		PCR		Total
		Positive	Negative	
Multiple Respiratory Multipathogen Antigen Test Kit (Immunochromatographic Assay)	Positive	29	0	29
	Negative	1	180	181

Total	30	180	210
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Statistic	Value	95% CI
Sensitivity	96.67%	82.78% to 99.92%
Specificity	100.00%	97.97% to 100.00%
Total accuracy	99.52%	97.38% to 99.99%

➤ ADV

For ADV result		PCR		Total
		Positive	Negative	
Multiple Respiratory Multipathogen Antigen Test Kit (Immunochromatographic Assay)	Positive	29	0	29
	Negative	1	180	181
Total		30	180	210

Statistic	Value	95% CI
Sensitivity	96.67%	82.78% to 99.92%
Specificity	100.00%	97.97% to 100.00%
Total accuracy	99.52%	97.38% to 99.99%

In summary, the Multiple Respiratory Multipathogen Antigen Test Kit (immunochromatographic assay) has shown satisfying diagnostic sensitivity, diagnostic specificity, and total agreement rate in the present evaluation. It can be used as a rapid tool to assist the early diagnosis of COVID-19, Flu A, Flu B, RSV or ADV cases for self-testing.

6.3. An overall summary of the performance and safety

- It can be concluded from above narration that the product is confirmed safe, little risk and in accordance with annex I of the REGULATION (EU) 2017/746.
- The clinical benefit of the product is that it can help laypersons quickly and

conveniently to detect the infection status of various respiratory viruses at home, thereby guiding layperson to take timely intervention measures, preventing layperson's condition from progressing or deteriorating. The benefit/risk profile according to current knowledge/the state of the art in the medical fields concerned and according to available medical alternatives, is acceptable.

- The device for the intended users and usability aspects and discrepancies is suitable.
- Between these documents and the current knowledge/ the state of the art is consistent.
- Residual risks and uncertainties or unanswered questions will be traced by PMS.

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

After the device is launched in the market, the PMPF come into play gathering relevant data regarding the safety and performance of the device. Bioteke has draw up the PMPF plan to track post-market performance, it mainly includes the related activities as below:

- 1) Serious incidents collection and analysis;
- 2) Planned real-world evidence analysis;
- 3) Surveys planned to collect information.

The activities undertaken related to PMPF plan will be documented in the PMPF report in Bioteke after the device launched. Through the collection and analysis the data generated by the above activities, the continuing safety for the performance of the device will be demonstrated, and the new residual risks will be followed if they are generated.

7. Metrological traceability of assigned values

7.1. Explanation of the unit of measurement, if applicable

N/A

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 device is a qualitative IVD reagent which including the internal control and corporate reference materials.

The internal control is part of the test strip, derived from the reagents, using the

sandwich-type immunoassay method, and plays a role in quality control.

The corporate reference materials used were prepared from purchased microorganism samples, and the corporate reference materials were prepared using a negative matrix to make the target concentrations. The metrological traceability of the corporate reference materials can be identified through microorganism category, strain, batch no. and concentration of strain original solution for the corresponding virus listed in table below, these are the link to the CoA provided by supplier.

No.	Microorganism category	Strain	Target Concentration	Concentration of strain original solution (from CoA)	Batch No. of strain original solution (from CoA)	Supplier
P1	SARS-CoV-2	Wuhan-Hu-1	4.0×10^3 TCID ₅₀ /mL	2.8×10^6 TCID ₅₀ /mL	370095-202001	Guangzhou Standa Biotechnology Co., Ltd. Address: B307-B312, 3rd Floor, Building 2, No. 1 Ruifa Road, Huangpu District, Guangzhou City
P2	SARS-CoV-2	N protein	200 pg / ml	1.0 mg/ml	20011801	HeavyBio, Inc Address: B307-B312, 3rd Floor, Building 2, No. 1 Ruifa Road, Huangpu District, Guangzhou City 304 building 30, baotian industrial zone, chentian community, xixiang street, baoan district, Shenzhen
P3	Influenza A virus 2009H1N1	L19-A1/Si chuan/SWL1/2009	1.05×10^4 TCID ₅₀ /mL	4.2×10^6 TCID ₅₀ /mL	20200706	Guangzhou Standa Biotechnology Co., Ltd. Address: B307-B312, 3rd Floor, Building 2, No. 1 Ruifa Road, Huangpu District, Guangzhou City
P4	Influenza A virus seasonal H1N1	L6-A1/Liaoning huanggu/1183/2007	1.4×10^4 TCID ₅₀ /mL	5.6×10^5 TCID ₅₀ /mL	20200106	

P5	Influenza A virus H3N2	L8- A3/Brisbane/10/ 2007	1.0×10^4 TCID ₅₀ /mL	1.0×10^6 TCID ₅₀ /mL	20200706	
P6	Influenza A virus H5N1	A/Chicken/Liao ning/SD007/201 7(H5N1)	9.2×10^3 TCID ₅₀ /mL	3.68×10^7 TCID ₅₀ /mL	20200102	
P7	Influenza A virus H7N9	A/Guangd/17SF 003/2016(H7N9)	8.4×10^3 TCID ₅₀ /mL	3.36×10^7 TCID ₅₀ /mL	20200102	
P8	Influenza B virus Victoria	GZ/133/201712	1.0×10^5 TCID ₅₀ /mL	1.0×10^6 TCID ₅₀ /mL	20200603	
P9	Influenza B virus Yamagata	GZ/174/201803	2.8×10^5 TCID ₅₀ /mL	5.6×10^6 TCID ₅₀ /mL	20200603	
P10	Respiratory syncytial virus A	RSVA/GZ/Heci n1705-74	2.6×10^4 TCID ₅₀ /mL	1.3×10^6 TCID ₅₀ /mL	20200603	

P11	Respiratory syncytial virus B	RSV-B/GZ/1704-8	2.4×10^4 TCID ₅₀ /mL	4.8×10^5 TCID ₅₀ /mL	20200103	
P12	Respiratory adenovirus type 3	ADV3/GZ/0101/2011	2.0×10^4 TCID ₅₀ /mL	1.0×10^6 TCID ₅₀ /mL	20200704	
P13	Respiratory adenovirus type 7	ADV7/GZ/1706-198	1.6×10^4 TCID ₅₀ /mL	3.2×10^7 TCID ₅₀ /mL	20200104	
N1	Staphylococcus aureus	CMCC(B) 26003	1.0×10^5 CFU/mL	2.1×10^9 CFU/mL	20200704	
N2	Streptococcus pneumoniae	(Klein) Chester	1.0×10^5 CFU/mL	1.0×10^6 CFU ₅₀ /mL	20200103	
N3	Measles virus	Edmonston	1.0×10^5 TCID ₅₀ /mL	1.0×10^7 TCID ₅₀ /mL	20200603	

N4	Mumps virus	Jones	1.0×10^5 TCID ₅₀ /mL	1.0×10^7 TCID ₅₀ /mL	20200706	
N5	Human metapneumovirus (hMPV)	GZ/1803-107	1.0×10^5 TCID ₅₀ /mL	1.0×10^5 TCID ₅₀ /mL	20200103	
N6	Mycoplasma pneumoniae	ATCC 15531	1.0×10^5 Copies/mL	1.0×10^9 Copies/mL	20200603	
N7	Human Parainfluenza virus 2	PIV2/GZ/Hecin 171134/2017	1.0×10^5 TCID ₅₀ /mL	5.6×10^7 TCID ₅₀ /mL	20200706	
N8	Candida albicans	CMCC(F)12900 2	1.0×10^5 CFU/mL	1.3×10^8 CFU/mL	20200103	
N9	Coronavirus OC43	VR-1558, OC43	1.0×10^5 TCID ₅₀ /mL	4.2×10^5 TCID ₅₀ /mL	20200601	
N10	Coronavirus 229E	229E/GZ/1801-3	1.0×10^4 TCID ₅₀ /mL	5.6×10^4 TCID ₅₀ /mL	20200601	

N11		Bordetella pertussis	GDM 1.952	1.0*10 ⁵ CFU/mL	2.6*10 ⁹ CFU/mL	20200104	Guangzhou Standa Biotechnology Co., Ltd. Address: B307-B312, 3rd Floor, Building 2, No. 1 Ruifa Road, Huangpu District, Guangzhou City
N12		Epstein-barr virus	B95-8	CT: 17 1:1000	CT:17	20200103	
N13		Enterovirus (CA16)	CAI 6/Guangzhou/03 02/2011	1.0*10 ⁵ TCID ₅₀ /mL	1.8*10 ⁷ TCID ₅₀ /mL	20200103	
N14		Rhinovirus (group A)	A30/GZ/1710-89	1.0*10 ⁵ TCID ₅₀ /mL	4.2*10 ⁶ TCID ₅₀ /mL	20200102	
N15		Rhinovirus (group B)	70/FO2-2547	1.0*10 ⁵ TCID ₅₀ /mL	1.0*10 ⁶ TCID ₅₀ /mL	20200702	
N16		Enterovirus(EV71)	EV71/Guangzho u/0402/2012	1.0*10 ⁵ CFU/mLL	5.6*10 ⁶ TCID ₅₀ /mL	20200603	
R 1	R1-1	SARS-CoV-2	N protein	20pg /mL	1.0 mg/ml	20011801	HeavyBio, Inc Address: B307-B312, 3rd Floor, Building 2, No. 1 Ruifa Road, Huangpu District, Guangzhou

	R1-2			100 pg/mL			City304 building 30, baotian industrial zone, chentian community, xixiang street, baoan district, Shenzhen
R 2	R2-1	Influenza A virus H3N2	L8-A3/ Brisbane/10/200 7	1.0*10 ³ TCID ₅₀ /mL	1.0*10 ⁶ TCID ₅₀ /mL	20200706	Guangzhou Standa Biotechnology Co., Ltd. Address: B307-B312, 3rd Floor, Building 2, No. 1 Ruifa Road, Huangpu District, Guangzhou City
	R2-2			5.0*10 ³ TCID ₅₀ /mL			
R 3	R3-1	Influenza B virus Victoria	GZ/133/201712	1.0*10 ⁴ TCID ₅₀ /mL	1.0*10 ⁶ TCID ₅₀ /mL	20200603	
	R3-2			5.0*10 ⁴ TCID ₅₀ /mL			
R 4	R4-1	Respiratory syncytial virus B	RSVB-01	2.4*10 ³ TCID ₅₀ /mL	4.8*10 ⁵ TCID ₅₀ /mL	20200103	

	R4-2			1.2*10 ⁴ TCID ₅₀ /mL			
R5	R5-1	Respiratory adenovirus type 3	ADV3/GZ/0101/2011	2.0*10 ³ TCID ₅₀ /mL	1.0*10 ⁶ TCID ₅₀ /mL	20200704	
	R5-2			1.0*10 ⁴ TCID ₅₀ /mL			
S1	S1-1	SARS-CoV-2	N protein	20pg /mL	1.0 mg/ml	20011801	HeavyBio, Inc Address: B307-B312, 3rd Floor, Building 2, No. 1 Ruifa Road, Huangpu District, Guangzhou City304 building 30, baotian industrial zone, chentian community, xixiang street, baoan district, Shenzhen
	S1-2			10 pg / ml			
	S1-3			5 pg / ml			
S2	S2-1	Influenza A virus 2009H1N1	L19-A1/Si chuan/SWL1/2009	1.05*10 ³ TCID ₅₀ /mL	4.2*10 ⁶ TCID ₅₀ /mL	20200706	Guangzhou Standa Biotechnology Co., Ltd. Address: B307-B312, 3rd Floor, Building 2, No. 1 Ruifa Road, Huangpu District, Guangzhou City
	S2-2			5.25*10 ² TCID ₅₀ /mL			

	S2-3			2.625*10 ² TCID ₅₀ /mL			
S3	S3-1	Influenza A virus seasonal H1N1	L6-A1/ Liaoning huanggu /1183/2007	1.4*10 ³ TCID ₅₀ /mL	5.6*10 ⁵ TCID ₅₀ /mL	20200106	
	S3-2			7.0*10 ² TCID ₅₀ /mL			
	S3-3			3.5*10 ² TCID ₅₀ /mL			
S4	S4-1	Influenza A virus H3N2	L8-A3/ Brisbane/10/200 7	1.0*10 ³ TCID ₅₀ /mL	1.0*10 ⁶ TCID ₅₀ /mL	20200706	
	S4-2			5.0*10 ² TCID ₅₀ /mL			
	S4-3			2.5*10 ² TCID ₅₀ /mL			
S5	S5-1	Influenza B virus Victoria	GZ/133/201712	1.0*10 ⁴ TCID ₅₀ /mL	1.0*10 ⁶ TCID ₅₀ /mL	20200603	
	S5-2			5.0*10 ³ TCID ₅₀ /mL			
	S5-3			2.5*10 ³ TCID ₅₀ /mL			
S6	S6-1	Influenza B virus Yamagata	GZ/174/201803	2.8*10 ⁴ TCID ₅₀ /mL	5.6*10 ⁶ TCID ₅₀ /mL	20200603	
	S6-2			1.4*10 ⁴ TCID ₅₀ /mL			

	S6-3			7.0*10 ³ TCID ₅₀ /mL			
S7	S7-1	Respiratory syncytial virus B	RSVB-01	2.4*10 ³ TCID ₅₀ /mL	4.8*10 ⁵ TCID ₅₀ /mL	20200103	
	S7-2			1.2*10 ³ TCID ₅₀ /mL			
	S7-3			6.0*10 ² TCID ₅₀ /mL			
S8	S8-1	Respiratory adenovirus type 3	ADV3/GZ/0101/2011	2.0*10 ³ TCID ₅₀ /mL	1.0*10 ⁶ TCID ₅₀ /mL	20200704	
	S8-2			1.0*10 ³ TCID ₅₀ /mL			
	S8-3			5.0*10 ² TCID ₅₀ /mL			

8. Suggested profile and training for users, if applicable

N/A

9. Revision history

SSP revision number	Date issued	Change description	Revision validated by the Notified Body
A0	05/10/2024	Initial release	☐ Yes Validation language: English ☐ No
A1	10/10/2024	Delete the references to technical documentation and add the more detailed content in section 4, 6 and 7.	☐ Yes Validation language: English ☐ No
A2	05/06/2025	Add LoD for WHO IS and detail result of flex and robustness study in section 6.2.1; add detail result of layperson study in Section 6.2.2.	☐ Yes Validation language: English ☐ No
A3	05/28/2025	1. Correct the year when the device was first CE-marked under Regulation (EU) 2017/746 covering the device in section 1.7; 2. Remove “the intended purpose should be validated by NB’s conformity assessment further” from section 3.3; 3. Delete the standards that are not harmonized in section 4.1; 4. Revise the description to previous generation in section 3.1; 5. Revise the description for reference to section 6.2 of RMR in section 5.2; 6. Add specimen type information in section 6.2; 7. Remove sentences such as “The information materials supplied by the CE technical documents is adequate.” and “Above all, this device is acceptable for CE marking.” from section 6.3.	☒ Yes Validation language: English ☐ No

		8. Delete the “Regarding the corporate reference materials, the standard EN ISO 17511:2021 (ISO 17511:2020) is applicable to our device.” in section 7.2.	
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