



Summary of NMPA approved novel coronavirus 2019-nCoV test kits

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Since January 2020, following the principle of "unified command, early involvement, prompt review and approval based on science", the Center for Medical Device Evaluation has fulfilled its duty to review medical products that meet the requirements of "safety, effectiveness and quality control". By April 2, 25 2019-nCoV test kit registrations have been reviewed and fast issued by National Medical Product Administration (NMPA), through the emergency review and approval procedures. The intended use and basic information of these products are available :

1. Nucleic acid test kits for 2019-nCoV

1.1 Test kits detecting of 2019-nCoV

Specific genes

Intended use:

In vitro qualitative detection of target genes of 2019-nCoV from specimen of pneumonia patients suspected of 2019-nCoV infection, patients suspected of clustered cases, and other individuals requiring test for diagnosis or differential diagnosis with 2019-nCoV infections.

Product list:

Product Name: Nucleic Acid reagent test kit for novel coronavirus 2019-nCoV (fluorometric PCR)

Manufacturer Name: Shanghai ZJ Bio-Tech Co., Ltd.

Manufacturing Site: Building #26, 588 Xinjunhuan Road, Minhang District, 201114 Shanghai, China

Applicable Specimen: Oropharyngeal swabs, Sputum, Bronchoalveolar Lavage Fluid (BALF)

Target Gene: ORF1ab gene, N gene and E gene

Product Name: Nucleic Acid reagent test kit for novel coronavirus 2019-nCoV (fluorometric PCR)

Manufacturer Name: Shanghai GeneoDx Biotechnology Co., Ltd.

Manufacturing Site: 1st Floor, Building 3, Juke Bio-Park, 466 Yindu Road, Room 201, 203, 2nd Floor, Building 1, Juke Bio-Park, 466 Yindu Road, Room 104, 106, 108, Building 1, 2715 Longwu Road, Xuhui District, 200237 Shanghai, China

Applicable Specimen: Nasopharyngeal swabs, Sputum

Target Gene: ORF1ab gene and N gene

Product Name: Nucleic Acid reagent test kit for novel coronavirus 2019-nCoV (fluorometric PCR)

Manufacturer Name: BGI Biotechnology (Wuhan) Co., Ltd.

Manufacturing Site: 5th floor Building B2, 1st floor Building B1, Zone B/C/D, Wuhan National Bioindustry Base, NO.666 Gaoxin Avenue, East Lake High-tech Development Zone, Wuhan, Hubei, China

Applicable Specimen: Oropharyngeal swabs, Bronchoalveolar Lavage Fluid (BALF)

Target Gene: ORF1ab gene

Product Name: Nucleic Acid reagent test kit for novel coronavirus 2019-nCoV (fluorometric PCR)

Manufacturer Name: Da An Gene Co., Ltd. of Sun Yat-sen University

Manufacturing Site: No.19, Xiangshan Road, Science Park, High&New Technology Development District, Guangzhou; No.6, Lizhishan Road, Science Park, High&New Technology Development District, Guangzhou, China

Applicable Specimen: Oropharyngeal swabs, Sputum

Target Gene: ORF1ab gene and N gene

Product Name: Nucleic Acid reagent test kit for novel coronavirus 2019-nCoV (fluorometric PCR)

Manufacturer Name: Sansure Biotech Inc.

Manufacturing Site: No. 680, Lusong Road, 410205 Changsha, Hunan, China

Applicable Specimen: Oropharyngeal swabs, Bronchoalveolar Lavage Fluid (BALF)

Target Gene: ORF1ab gene and N gene

Product Name: Nucleic Acid reagent test kit for novel coronavirus 2019-nCoV (fluorometric PCR)

Manufacturer Name: Shanghai BioGerm Medical Biotechnology Co., Ltd.

Manufacturing Site: Room 1302, 1303, 1304, 1305, 1306, 1307, 1309, Building 3, No. 1588 Huhang Highway, Fengxian District, Shanghai, China

Applicable Specimen: Oropharyngeal swabs, Nasopharyngeal swabs, Sputum

Target Gene: ORF1ab gene and N gene

Product Name: Nucleic Acid reagent test kit for novel coronavirus 2019-nCoV (fluorometric PCR)

Manufacturer Name: Beijing Applied Biological Technologies Co., Ltd.

Manufacturing Site: Room A204, 3rd floor B304, 2nd floor D203, D203-1, No.29 Shengmingyuan Road, Science Park, Changping District, 102206 Beijing, China

Applicable Specimen: Oropharyngeal swabs, Sputum

Target Gene: ORF1ab gene, N gene and E gene

Product Name: Nucleic Acid reagent test kit for novel coronavirus 2019-nCoV (fluorometric PCR)

Manufacturer Name: Maccura Biotechnology Co., Ltd.

Manufacturing Site: 16#, Baichuan Road, Hi-tech Zone, 611731 Chengdu, Sichuan China

Applicable Specimen: Oropharyngeal swabs, Sputum

Target Gene: ORF1ab gene, N gene and E gene

Product Name: Nucleic Acid reagent test kit for novel coronavirus 2019-nCoV (fluorometric PCR)

Manufacturer Name: Wuhan Easy Diagnosis Biomedicine Co., Ltd.

Manufacturing Site: No. A8 2-2 Building, Optics Valley Biomedical Industry Park Phase II, No.858 Gaoxin Road, East Lake High-tech Development Zone, 430074 Wuhan, Hubei, China

Applicable Specimen: Oropharyngeal swabs, Nasopharyngeal swabs, Sputum

Target Gene: ORF1ab gene and N gene

Product Name: Nucleic Acid reagent test kit for novel coronavirus 2019-nCoV (Isothermal amplification-real time fluorometric PCR)

Manufacturer Name: Ustar Biotechnologies (Hangzhou) Ltd.

Manufacturing Site: Bldg C, Fl 1-2 and Bldg A, Fl 5, 399 Qiuyi Rd, Changhe Street, Binjiang Dist, 310052, Hangzhou, Zhejiang, China

Applicable Specimen: Oropharyngeal swabs, Sputum

Target Gene: ORF1ab gene and N gene

Product Name: Nucleic Acid reagent test kit for novel coronavirus 2019-nCoV

(hybridization capture immunofluorescence)

Manufacturer Name: Anbio (Xiamen) Biotechnology Co., Ltd.

Manufacturing Site: No.2016, Wengjiao West Road, Xinyang Street, Haicang District, 361026, Xiamen, Fujian, China

Applicable Specimen: Oropharyngeal swabs, Sputum

Target Gene: ORF1ab gene, N gene and E gene

Product Name: Nucleic Acid reagent test kit for novel coronavirus 2019-nCoV (fluorometric PCR)

Manufacturer Name: Shanghai Fosun Long March Medical Science Co., Ltd.

Manufacturing Site: No.830 Cheng Yin Road, Baoshan District, 200444 Shanghai, China

Applicable Specimen: Oropharyngeal swabs, Sputum

Target Gene: ORF1ab gene, N gene and E gene

Product Name: Nucleic Acid reagent test kit for novel coronavirus 2019-nCoV (RNA capture probe method)

Manufacturer Name: Shanghai Rendu Biotechnology Co., Ltd.

Manufacturing Site: 3rd Floor, Building 10-B, 528 Ruiqing Rd., Zhangjiang Hi-Tech Park (East), Pudong, 201201, Shanghai, China; 528 Ruiqing Rd., Building 8-A, 6th Floor, Zhangjiang Hi-Tech Park (East), Pudong, 201201 Shanghai, China; 590 Ruiqing Rd., Building 7, Suite 301, Zhangjiang Hi-Tech Park (East), Pudong, 201201 Shanghai, China

Applicable Specimen: Oropharyngeal swabs, Sputum

Target Gene: ORF1ab gene

Product Name: Nucleic Acid reagent test kit for novel coronavirus 2019-nCoV (Dual amplification)

Manufacturer Name: Wuhan Zhongzhi Biotechnologies INC.

Manufacturing Site: Building A6-2, No. 858, Gaoxin Avenue, East Lake Hi-Tech Development Zone, 430075, Wuhan, Hubei, China

Applicable Specimen: Oropharyngeal swabs, Sputum

Target Gene: ORF1ab gene and E gene

Product Name: Nucleic Acid reagent test kit for novel coronavirus 2019-nCoV (RNA isothermal amplification lateral flow assay)

Manufacturer Name: Wuhan Zhongzhi Biotechnologies INC.

Manufacturing Site: Building A6-2, No. 858, Gaoxin Avenue, East Lake Hi-Tech Development Zone, 430075, Wuhan, Hubei, China

Applicable Specimen: Oropharyngeal swabs, Sputum

Target Gene: ORF1ab gene and E gene

1.2 Test kits detecting of 2019-nCoV nucleic

Acid through next generation sequencing

Intended use:

In vitro qualitative detection of nucleic acid of 2019-nCoV through next generation sequencing from specimens of pneumonia patients suspected of 2019-nCoV infection, patients suspected of clustered cases, and other individuals requiring test for diagnosis or differential diagnosis with 2019-nCoV infections. The kit is exclusively used in combination with the approved sequencing system and analysis software.

Product list:

Product Name: Nucleic Acid reagent test kit for novel coronavirus 2019-nCoV (combinatorial probe-anchor synthesis sequencing)

Manufacturer Name: BGI Biotechnology(Wuhan) Co., Ltd.

Manufacturing Site: 5th floor Building B2, 1st floor Building B1, Zone B/C/D, Wuhan National Bioindustry Base, NO.666 Gaoxin Avenue, East Lake High-tech Development Zone, Hubei, China

Applicable Specimen: Oropharyngeal swabs, Bronchoalveolar Lavage Fluid (BALF)

Target: Whole genome

1.3 Test kits detecting of 2019-nCoV and

Other virus

Intended use:

In vitro qualitative detections of S and N target genes of 2019-nCoV, as well as nucleic acid from Influenza A Virus, New Influenza A H1N1 Virus (2009), Influenza A H3N2 Virus, Influenza B Virus, Respiratory Syncytial Virus, from specimen of pneumonia patients suspected of 2019-nCoV infection, patients suspected of clustered cases, and other individuals requiring test for diagnosis or differential diagnosis with 2019-nCoV infections.

Product list:

Product Name: Nucleic Acid reagent test kit for six respiratory viruses (constant temperature amplification chip)

Manufacturer Name: Chengdu CapitalBio Biotechnology Co., Ltd.

Manufacturing Site: Building 3-2 3rd floor, building 3-3, building 3-4(1st floor E-109, 2nd floor, top floor 3-3 to 3-5), building 4(101, 103), building 5, No.88, North Bayi Road, Yongning Town, Wenjiang District, Chengdu, Sichuan, China

Applicable Specimen: Oropharyngeal swabs

Target Gene: S gene and N gene from 2019-nCoV, and specific genes from the other five respiratory viruses

2.Anti-2019-nCoV antibody test kits

Intended use:

In vitro qualitative detection of Anti-2019-nCoV antibody from specimen. It is only intended for the supplementary indicator for suspected cases of negative 2019-nCoV nucleic acid detection, or combination with nucleic acid detection in the diagnosis of

suspected cases. Results from antibody testing should not be used as the sole basis to diagnose or exclude 2019-nCoV infection. It is not intended for screening in general population. Positive test results need further confirmation. Negative results do not exclude 2019-nCoV infection. These kits are for medical use only.

Product list:

Product Name: Antibody test kit for novel coronavirus 2019-nCoV (colloidal gold method)

Manufacturer Name: Guangzhou Wondfo Biotech Co., Ltd.

Manufacturing Site: No.8 Lizhishan Road, Science City, Luogang District, 510663, Guangzhou, China

Applicable Specimen: Serum, Plasma, Venous whole blood

Target: Anti-2019-nCoV IgM/IgG antibody (no distinguishing between IgM and IgG antibody)

Product Name: Antibody test kit for novel coronavirus 2019-nCoV (colloidal gold method)

Manufacturer Name: INNOVITA(Tangshan) Biological Technology Co., Ltd.

Manufacturing Site: No. 699 Juxin street, High-tech Industrial Development Zone, Qian'an 064400, Tangshan, Hebei, China

Applicable Specimen: Serum, Plasma

Target: Anti-2019-nCoV IgM and IgG antibody

Product Name: IgM Antibody test kit for novel coronavirus 2019-nCoV (magnetic particle-based chemiluminescence immunoassay)

Manufacturer Name: Bioscience (Chongqing) Diagnostic Technology Co., Ltd.

Manufacturing Site: No.2, no.3, no.4, building 2, no.5, gangcheng donghuan road, jiangbei district, Chongqing, China

Applicable Specimen: Serum

Target: Anti-2019-nCoV IgM antibody

Product Name: IgG Antibody test kit for novel coronavirus 2019-nCoV (magnetic particle-based chemiluminescence immunoassay)

Manufacturer Name: Bioscience (Chongqing) Diagnostic Technology Co., Ltd.

Manufacturing Site: No.2, no.3, no.4, building 2, no.5, gangcheng donghuan road, jiangbei district, Chongqing, China

Applicable Specimen: Serum

Target: Anti-2019-nCoV IgG antibody

Product Name: Antibody test kit for novel coronavirus 2019-nCoV (chemiluminescence microparticle immunoassay)

Manufacturer Name: Xiamen Innodx Biotech Co., Ltd.

Manufacturing Site: Southern Area, A area and B area, Building 4, No. 130; Building 5, No. 130; 2/F, No. 124, Xinyuan Road, Xinyang Street, Haicang District, Xiamen, Fujian, China

Applicable Specimen: Serum, Plasma

Target: Anti-2019-nCoV total antibody

Product Name: IgM antibody test kit for novel coronavirus 2019-nCoV (colloidal gold method)

Manufacturer Name: Hecin Scientific, Inc.

Manufacturing Site: 4F, Building 2, #1 Ruifa Rd, Luogang District, Guangzhou, China

Applicable Specimen: Serum, Plasma

Target: Anti-2019-nCoV IgM antibody

Product Name: IgM/IgG antibody test kit for novel coronavirus 2019-nCoV (colloidal gold method)

Manufacturer Name: Nanjing Vazyme Medical Technology Co., Ltd.

Manufacturing Site: Floor 1-3, Building C2, Red Maple Park of Technological Industry, Kechuang Road, Economy & Technology Development Zone, Nanjing, Jiangsu, China

Applicable Specimen: Serum, Plasma

Target: Anti-2019-nCoV IgM and IgG antibody

Product Name: IgM/IgG antibody test kit for novel coronavirus 2019-nCoV (colloidal gold method)

Manufacturer Name: Zhuhai Livzon Diagnostics Inc.

Manufacturing Site: No. 266 Tongchang Road, Xiangzhou District, 519060 Zhuhai, Guangdong, China

Applicable Specimen: Serum, Plasma, Venous whole blood

Target: Anti-2019-nCoV IgM and IgG antibody

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