



**PERHIMPUNAN DOKTER SPESIALIS
PATOLOGI KLINIK DAN KEDOKTERAN LABORATORIUM INDONESIA
(PDS PatKLIn)**

Sekretariat:

Jl. Lontar Raya No.5 RT.002/05 Menteng Atas-Sahardjo Jakarta Selatan - 12960
Telp. 021-8308195, Fax: (021) 8308295
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**PCR COVID-19 YANG TELAH DISETUJUI/APPROVED
OLEH FDA NEGARA MASING-MASING
(NATIONAL REGULATORY AUTHORITIES IN IMDRF)
(SUMBER: WHO 08 APRIL 2020 dan ECDC)**

A. FDA AMERIKA SERIKAT

• In Vitro Diagnostic Product (Date of EUA Issuance)

1. CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel (CDC) (04-Feb-20)
2. New York SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Panel (Wadsworth Center, NYSDOH) (15-Mar-20)
3. Cobas SARS-CoV-2 (Roche Molecular Systems, Inc. (RMS) (12-Mar-20)
4. TaqPath COVID-19 Combo Kit (Thermo Fisher Scientific, Inc.) (13-Mar-20)
5. Panther Fusion SARS-CoV-2 (Hologic, Inc.) (16-Mar-20)
6. COVID-19 RT-PCR Test (Laboratory Corporation of America) (16-Mar-20)
7. Lyra SARS-CoV-2 Assay (Quidel Corp.) (17-Mar-20)
8. Quest SARS-CoV-2 rRT-PCR (Quest Diagnostics Infectious Disease, Inc.) (17-Mar-20)
9. Abbott RealTime SARS-CoV-2 assay (Abbott Molecular) (18-Mar-20)
10. Simplexa COVID-19 Direct (DiaSorin Molecular LLC) (19-Mar-20)
11. ePlex SARS-CoV-2 Test (GenMark Diagnostics, Inc.) (19-Mar-20)
12. Primerdesign Ltd COVID-19 genesig Real-Time PCR assay (Primerdesign Ltd) (20-Mar-20)
13. Xpert Xpress SARS-CoV-2 test (Cepheid) (20-Mar-20)
14. BioFire COVID-19 Test (BioFire Defense, LLC) (23-Mar-20)
15. Accula SARS-Cov-2 Test (Mesa Biotech Inc.) (23-Mar-20)
16. PerkinElmer New Coronavirus Nucleic Acid Detection Kit (PerkinElmer, Inc.) (24-Mar-20)
17. AvellinoCoV2 test (Avellino Lab USA, Inc.) (25-Mar-20)
18. Real-Time Fluorescent RT-PCR Kit for Detecting SARS-2019-nCoV (BGI Genomics Co. Ltd) (26-Mar-20)
19. ID NOW COVID-19 (Abbott Diagnostics Scarborough, Inc.) (27-Mar-20)
20. NxTAG CoV Extended Panel Assay (Luminex Molecular Diagnostics, Inc.) (27-Mar-20)
21. NeuMoDx SARS-CoV-2 Assay (NeuMoDx Molecular, Inc.) (30-Mar-20)



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22. QIAstat-Dx Respiratory SARS-CoV-2 Panel (QIAGEN GmbH) (30-Mar-20)
23. Cellex Inc. qSARS-CoV-2 IgG/IgM Rapid Test (Cellex Inc.) (01-Apr-20)
24. COV-19 IDx assay (Ipsium Diagnostics, LLC) (01-Apr-20)
25. BioGX SARS-CoV-2 Reagents for BD MAX System (Becton, Dickinson & Company (BD) (02-Apr-20)
26. ARIES SARS-CoV-2 Assay (Luminex Corporation) (03-Apr-20)
27. ScienCell SARS-CoV-2 Coronavirus Real-time RT-PCR (RT-qPCR) Detection Kit (ScienCell Research Laboratories) (03-Apr-20)
28. Logix Smart Coronavirus Disease 2019 (COVID-19) Kit (Co-Diagnostics, Inc.) (03-Apr-20)
29. Gnomegen COVID-19 RT-Digital PCR Detection Kit (Gnomegen LLC) (06-Apr-20)
30. Smart Detect SARS-CoV-2 rRT-PCR Kit (InBios International, Inc.) (07-Apr-20)
31. BD SARS-CoV-2 Reagents for BD MAX System (Becton, Dickinson & Company) (08-Apr-20)
32. QuantiVirus SARS-CoV-2 Test kit (DiaCarta, Inc.) (08-Apr-20)
33. iAMP COVID-19 Detection Kit (Atila BioSystems, Inc.) (10-Apr-20)
34. VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total Reagent Pack (Ortho Clinical Diagnostics, Inc.) (14-Apr-20)
35. DPP COVID-19 IgM/IgG System (Chembio Diagnostic System, Inc.) (14-Apr-20)
36. SARS-CoV-2 Fluorescent PCR Kit (Maccura Biotechnology (USA) LLC) (15-Apr-20)
37. COVID-19 ELISA IgG Antibody Test (Mount Sinai Laboratory) (15-Apr-20)
38. GS™ COVID-19 RT-PCR KIT (GenoSensor, LLC) (16-Apr-20)
39. Curative-Korva SARS-Cov-2 Assay (KorvaLabs Inc.) (16-Apr-20)
40. Fosun COVID-19 RT-PCR Detection Kit (Fosun Pharma USA Inc.) (17-Apr-20)
41. GeneFinder COVID-19 Plus RealAmp Kit (OSANG Healthcare) (18-Apr-20)



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• **Molecular-Based Laboratory Developed Test (Date of EUA Issuance)**

1. SARS-CoV-2 PCR test (31-Mar-20)
2. SARS-CoV-2 RT-PCR test (2-Apr-20)
3. SARS-Cov-2 Assay (2-Apr-30)
4. MGH COVID-19 qPCR assay (3-Apr-20)
5. Viracor SARS-CoV-2 assay (6-Apr-20)
6. Stanford SARS-CoV-2 assay (8-Apr-20)
7. SDI SARS-CoV-2 Assay (10-Apr-20)
8. ThermoFisher - Applied Biosystems TaqPath COVID-19 Combo Kit (10-Apr-20)
9. Orig3n 2019 Novel Coronavirus (COVID-19) Test (10-Apr-20)
10. UNC Health SARS-CoV-2 real-time RT-PCR test (10-Apr-20)
11. COVID-19 RT-PCR Test (13-Apr-20)
12. SARS-CoV-2 Assay (13-Apr-20)
13. SARS-CoV-2 Test (14-Apr-20)
14. Childrens-Altona-SARS-CoV-2 Assay (14-Apr-20)
15. CirrusDx SARS-CoV-2 Assay (15-Apr-20)
16. CDI Enhanced COVID-19 Test (15-Apr-20)

• **Test Kit Manufacturers and Commercial Laboratories Table Manufacturer; Diagnostic (letter of Authorization); Date EUA Issued**

1. Wadsworth Center, New York State Department of Public Health's (CDC); New York SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Panel. (29/02/2020)
2. Thermo Fisher Scientific, Inc.; TaqPath COVID-19 Combo Kit. (13/03/2020)
3. ScienCell Research Laboratories; ScienCell SARS-CoV-2 Coronavirus Real-time RT-PCR (RT-qPCR) Detection Kit. (03/04/2020)
4. Roche Molecular Systems, Inc. (RMS); Cobas SARS-CoV-2 (12/03/2020)
5. Quidel Corporation; Lyra SARS-CoV-2 Assay. (17/03/2020)
6. Quest Diagnostics Infectious Disease, Inc.; Quest SARS-CoV-2 rRT-PCR (17/03/2020)



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7. QIAGEN GmbH; QIAstat-Dx Respiratory SARS-CoV-2 Panel. (30/03/2020)
8. Primerdesign Ltd.; Primerdesign Ltd COVID-19 genesig Real-Time PCR assay. (20/03/2020)
9. PerkinElmer, Inc.; PerkinElmer New Coronavirus Nucleic Acid Detection Kit. (24/03/2020)
10. OSANG Healthcare; GeneFinder COVID-19 Plus RealAmp Kit. (18/04/2020)
11. NeuMoDx Molecular, Inc.; NeuMoDx SARS-CoV-2 Assay. (30/03/2020)
12. Mesa Biotech Inc.; Accula SARS-Cov-2 Test. (23/03/2020)
13. Maccura Biotechnology (USA) LLC; SARS-CoV-2 Fluorescent PCR Kit. (15/04/2020)
14. Luminex Molecular Diagnostics, Inc.; NxTAG CoV Extended Panel Assay. (27/03/2020)
15. Luminex Corporation; ARIES SARS-CoV-2 Assay. (03/04/2020)
16. Laboratory Corporation of America (LabCorp); COVID-19 RT-PCR Test. (16/03/2020)
17. KorvaLabs Inc.; Curative-Korva SARS-Cov-2 Assay. (16/04/2020)
18. Ipsum Diagnostics, LLC; COV-19 IDx assay. (01/04/2020)
19. InBios International, Inc; Smart Detect SARS-CoV-2 rRT-PCR Kit. (07/04/2020)
20. Hologic, Inc.; Panther Fusion SARS-CoV-2. (16/03/2020)
21. Gnomegen LLC; Gnomegen COVID-19 RT-Digital PCR Detection Kit. (06/04/2020)
22. GenoSensor, LLC; GS™ COVID-19 RT-PCR KIT. (16/04/2020)
23. GenMark Diagnostics, Inc.; ePlex SARS-CoV-2 Test. (19/03/2020)
24. Fosun Pharma USA Inc.; Fosun COVID-19 RT-PCR Detection Kit. (17/04/2020)
25. DiaSorin Molecular LLC; Simplexa COVID-19 Direct assay. (19/03/2020)
26. DiaCarta, Inc; QuantiVirus SARS-CoV-2 Test kit. (08/04/2020)
27. Co-Diagnostics, Inc.; Logix Smart Coronavirus Disease 2019 (COVID-19) Kit. (03/04/2020)



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28. Cepheid; Xpert Xpress SARS-CoV-2 test. (20/03/2020)
29. Centers for Disease Control and Prevention's (CDC); CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel (CDC). (04/02/2020)
30. BioFire Defense, LLC; BioFire COVID-19 Test. (23/03/2020)
31. BGI Genomics Co. Ltd; Real-Time Fluorescent RT-PCR Kit for Detecting SARS-2019-nCoV. (26/03/2020)
32. Becton, Dickinson & Company (BD); BioGX SARS-CoV-2 Reagents for BD MAX System. (02/04/2020)
33. Becton, Dickinson & Company; BD SARS-CoV-2 Reagents for BD MAX System (08/04/2020)
34. Avellino Lab USA, Inc.; AvellinoCoV2 test. (25/03/2020)
35. Atila BioSystems, Inc.; iAMP COVID-19 Detection Kit. (10/04/2020)
36. Abbott Molecular; Abbott RealTime SARS-CoV-2 assay. (18/03/2020)
37. Abbott Diagnostics Scarborough, Inc.; ID NOW COVID-19. (27/03/2020)

**B. AUSTRALIA [THE AUSTRALIAN REGISTER OF THERAPEUTIC GOODS
(ARTG) 17 April 2020]**

1. Abbott RealTime SARS-CoV-2; Molecular Division Abbott Molecular Inc (United States Of America). (17-Apr-20)
2. Allplex™ 2019-nCoV Assay; Seegene Inc (Korea - Republic of). (27-Mar-20)
3. AusDiagnostics respiratory virus panel (including SARS-CoV-2) test; AusDiagnostics Pty Ltd (Australia). (19-Mar-20)
4. BD SARS-CoV-2 Reagents for BD MAX™ System; Becton Dickinson and Company (United States Of America). (17-Apr-20)
5. Cobas® SARS-CoV-2; Roche Molecular Systems Inc (USA). (20-Mar-20)
6. EasyScreen™ SARS-CoV-2 Detection Kit; Genetic Signatures Ltd (Australia). (13-Apr-20)
7. Novel Coronavirus (2019-nCoV) Real Time Multiplex RT-PCR Kit (Detection for 3 genes); Shanghai ZJ Bio-Tech Co Ltd (China). (22-Mar-20)



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8. Panther Fusion® SARS-CoV-2 Assay (Panther Fusion® System); Hologic Inc (USA). (20-Mar-20)
9. PowerChek™ 2019-nCoV Real-time PCR Kit; Kogene Biotech Co Ltd (Korea - Republic of). (16-Apr-20)
10. Real-time fluorescent RT-PCR kit for detecting SARS-CoV-2; BGI Europe A/S (Denmark). (10-Apr-20)
11. TaqPath COVID-19 Combo Kit; Life Technologies Corporation (USA). (24-Mar-20)
12. VIASURE SARS-CoV-2 Real Time PCR Detection Kit; CerTest Biotec SL (Spain). (31-Mar-20)
13. VIASURE SARS-CoV-2 S gene Real Time PCR Detection Kit; CerTest Biotec SL (Spain). (21-Mar-20)
14. Xpert® Xpress SARS-CoV-2; Cepheid (USA). (22-Mar-20)

C. SINGAPORE [THE HEALTH SCIENCES AUTHORITY (HAS) SINGAPURA]

1. Diagnostics Development Hub (DxD); FORTITUDE KIT 2.0 RT-PCR. (07-Feb-20)
2. Veredus Laboratories Pte Ltd; VereCoV™ Detection Kit Multiplex RT-PCR/microarray-based in-vitro diagnostic test. (18-Feb-20)
3. AITbiotech Pte Ltd; abTES™ COVID-19 qPCR I Kit. (05-Mar-20)
4. DSO National Laboratories; Real-Time PCR Assay for the Detection of SARS-CoV-2 Virus. (10-Mar-20)
5. Roche Diagnostics Asia Pacific Pte Ltd; Cobas® SARS-CoV-2. (19-Mar-20)
6. JN Medsys Pte Ltd; ProTect™ COVID-19 RT-qPCR Kit. (19-Mar-20)
7. Life Technologies Holdings Pte Ltd; TaqPath™ COVID-19 Combo Kit real-time RT-PCR. (20-Mar-20)
8. Biowalker Pte Ltd; Kit for Novel-Coronavirus (2019-nCoV) RNA (Isothermal Amplification-Real Time Fluorescence Assay). (24-Mar-20)
9. SPD Scientific Pte Ltd ; Cepheid® Xpert® Xpress SARS-CoV-2 real-time RT-PCR. (26-Mar-20)



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10. MiRXES Pte Ltd; MiRXES FORTITUDE KIT 2.0 RT-PCR. (30-Mar-20)
11. Acumen Research Laboratories; Acu-Corona™ 2.0 One-step RT-PCR. (31-Mar-20)
12. Credo Diagnostics Biomedical Pte Ltd; VitaPCR™ SARS-CoV-2 Assay real-time RT-PCR. (01-Apr-20)
13. Abbott Laboratories (Singapore) Pte Ltd; Abbott RealTime SARS-CoV-2 assay real-time RT-PCR. (01-Apr-20)
14. All Eight (Singapore) Pte Ltd; Seegene Allplex™ 2019-nCoV Assay real-time RT-PCR. (02-Apr-20)
15. Acumen Research Laboratories Pte Ltd; Acu-Corona 3.0 One-step RT-PCR. (13-Apr-20)

D. CHINA (NMPA APPROVED, 2 April 2020)

Nucleic acid test kits for 2019-nCoV

• Test kits detecting of 2019-nCoV specific genes

1. Nucleic Acid reagent test kit for novel coronavirus 2019-nCoV (fluorometric PCR); Shanghai ZJ Bio-Tech Co., Ltd.
2. Nucleic Acid reagent test kit for novel coronavirus 2019-nCoV (fluorometric PCR); Shanghai GeneDx Biotechnology Co., Ltd.
3. Nucleic Acid reagent test kit for novel coronavirus 2019-nCoV (fluorometric PCR); BGI Biotechnology (Wuhan) Co., Ltd.
4. Nucleic Acid reagent test kit for novel coronavirus 2019-nCoV (fluorometric PCR); Da An Gene Co., Ltd. of Sun Yat-sen University
5. Nucleic Acid reagent test kit for novel coronavirus 2019-nCoV (fluorometric PCR); Sansure Biotech Inc.
6. Nucleic Acid reagent test kit for novel coronavirus 2019-nCoV (fluorometric PCR); Shanghai BioGerm Medical Biotechnology Co., Ltd.
7. Nucleic Acid reagent test kit for novel coronavirus 2019-nCoV (fluorometric PCR); Beijing Applied Biological Technologies Co., Ltd.
8. Nucleic Acid reagent test kit for novel coronavirus 2019-nCoV (fluorometric PCR); Maccura Biotechnology Co., Ltd.



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9. Nucleic Acid reagent test kit for novel coronavirus 2019-nCoV (fluorometric PCR); Wuhan Easy Diagnosis Biomedicine Co., Ltd.
 10. Nucleic Acid reagent test kit for novel coronavirus 2019-nCoV (Isothermal amplification-real time fluorometric PCR); Ustar Biotechnologies (Hangzhou) Ltd.
 11. Nucleic Acid reagent test kit for novel coronavirus 2019-nCoV (hybridization capture immunofluorescence); Anbio (Xiamen) Biotechnology Co., Ltd.
 12. Nucleic Acid reagent test kit for novel coronavirus 2019-nCoV (fluorometric PCR); Shanghai Fosun Long March Medical Science Co., Ltd.
 13. Nucleic Acid reagent test kit for novel coronavirus 2019-nCoV (RNA capture probe method); Shanghai Rendu Biotechnology Co., Ltd.
 14. Nucleic Acid reagent test kit for novel coronavirus 2019-nCoV (Dual amplification); Wuhan Zhongzhi Biotechnologies INC.
 15. Nucleic Acid reagent test kit for novel coronavirus 2019-nCoV (RNA isothermal amplification lateral flow assay); Wuhan Zhongzhi Biotechnologies INC.
- **Test kits detecting of 2019-nCoV nucleic acid through next generation sequencing**
 1. Nucleic Acid reagent test kit for novel coronavirus 2019-nCoV (combinatorial probe-anchor synthesis sequencing); BGI Biotechnology(Wuhan) Co., Ltd.
 - **Test kits detecting of 2019-nCoV and other virus**
 1. Nucleic Acid reagent test kit for six respiratory viruses (constant temperature amplification chip); Chengdu CapitalBio Biotechnology Co., Ltd.



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E. BRASIL

1. Família Abbott RealTime SARS-CoV-2 EUA; ABBOTT MOLECULAR INC. USA (03/04/2020)
2. SARS-CoV-2 S gene for BD Max; CERTEST BIOTEC S.L. ESPANHA (03/04/2020)
3. Família Kit de Detecção por PCR em Tempo Real VIASURE SARS-CoV-2; BIOMÉDICA EQUIPAMENTOS E SUPRIMENTOS HOSPITALARES LTDA. (24/03/2020)
4. COVID-19 Real-Time PCR Kit; CHAOZHOU HYBRIBIO BIOCHEMISTRY CHINA (09/04/2020)
5. Xpert Xpress SARS-CoV-2; CEPHEID - USA (09/04/2020)
6. SARS CoV-2 ECO Detect; Eco Diagnostica Ltda BRASIL (16/04/2020)
7. Kit MOLECULAR SARS-CoV2 (E/P1); Bio-Manguinhos BRASIL (06/04/2020)
8. TaqPath™ COVID-19 CE-IVD RT PCR Kit; LIFE TECHNOLOGIES BRASIL COMERCIO E INDUSTRIA DE PRODUTOS PARA BIOTECNOLOGIA LTDA USA (09/04/2020)
9. Família cobas SARS-CoV-2; ROCHE DIAGNÓSTICA BRASIL LTDA USA (24/03/2020)
10. SARS-COV-2 RT-PCR KIT; VIRCELL MICROBIOLOGISTS – ESPANHA, VIRION DIAGNOSTICA LTDA (09/04/2020)

F. Health Canada (17 APRIL 2020)

1. 1copy COVID-19 QPCR Kit; 1DROP INC. (imported by Luminarie Canada Inc.) (South Korea). (30/03/2020)
2. Abbott Realtime SARS-COV-2; Abbott Molecular Inc. (United States). (25/03/2020)
3. Allplex 2019-NCoV Assay; Seegene Inc. (Korea). (09/04/2020)
4. DiaPlexQ Novel Coronavirus (2019-nCoV) Detection Kit; SolGent Co., Ltd (represented by JK Toxpert) (South Korea). (05/04/2020)



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5. DiaSorin Simplexa COVID-19 Direct Molecular Assay on the LIAISON MDX Instrument; DiaSorin Molecular LLC (United States). (09/04/2020)
6. LYRA SARS-COV-2 ASSAY; Diagnostic Hybrids, Inc. - Also trading as Quidel Corporation (United States). (25/03/2020)
7. NxTAG COV Extended Panel; Luminex Molecular Diagnostics, Inc. (Canada). (26/03/2020)
8. PerkinElmer New Coronavirus Nucleic Acid Detection Kit; PerkinElmer, Inc. (United States). (06/04/2020)
9. SARS-CoV-2 Assay (Panther Fusion System); Hologic (United States). (25/03/2020)
10. Spartan Cube COVID-19 System; Spartan Bioscience Inc. (Canada). (11/04/2020)
11. TaqPath™ COVID-19 Combo Kit; Thermo Fisher (United States). (18/03/2020)
12. Xpert Xpress SARS-CoV-2; Cepheid (United States) (24/03/2020)

G. EUROPE, EU/EEA, Stockholm: ECDC; Foundation for Innovative New Diagnostics (FIND) (1 April 2020)

• **Manual (open) PCR tests included in the round 1 evaluation**

1. Altona Diagnostics; RealStar® SARS-CoV-2 RT-PCR Kit 1.0 Germany (CE-IVD)
2. BGI Health (HK) Co. Ltd; Real-time fluorescent RT-PCR kit for detecting 2019-nCoV China (China EUA)
3. BIONEER Corporation; AccuPower® SARS-CoV-2 Real-Time RT-PCR Kit Rep. of Korea (CE-IVD)
4. CerTest Biotec S.L.; VIASURE SARS-CoV-2 Real Time PCR Detection Kit Spain (CE-IVD)
5. DAAN Gene Co., Ltd. of Sun Yat-sen University; Detection Kit for 2019 Novel Coronavirus (2019-nCoV) RNA (PCR-Fluorescence Probing) China (China EUA)



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6. KH Medical Co. Ltd; RADI COVID-19 Detection Kit (RV008) Rep. of Korea (CE-IVD)
 7. PerkinElmer Inc.; PerkinElmer® SARS-CoV-2 Realtime RT-PCR Assay China (CE-IVD)
 8. Primerdesign Ltd; Primerdesign Ltd COVID-19 genesig Real-Time PCR assay England (USA FDA-EUA, WHO-EUL, CE-IVD)
 9. Sansure Biotech Inc.; Novel Coronavirus (2019-nCoV) Nucleic Acid Diagnostic Kit China (CE-IVD)
 10. SD BIOSENSOR, INC.; STANDARD M nCoV Real-Time Detection kit Rep. of Korea (KOREA EUA, CE-IVD)
 11. Seegene, Inc.; Allplex 2019-nCoV assayS Rep. of Korea (KOREA EUA, CE-IVD)
 12. ThermoFisher Scientific; TaqPath COVID-19 CE-IVD RT-PCR Kit USA (CE-IVD)
- **AUTOMATED LAB-BASED, NEAR-POC NAT OR POC NAT**
1. 3D Medicines; ANDiS® SARS-CoV-2 RT-qPCR Detection Kit (US FDA-EUA - CE-IVD)
 2. Abbott Molecular Inc.; Abbott RealTime SARS-CoV-2 EUA test (US FDA-EUA - CE-IVD)
 3. AITbiotech; abTES COVID-19 qPCR I Kit (CE-IVD)
 4. Anatolia Geneworks; Bosphore Novel Coronavirus (2019-nCoV) Detection Kit (lab-based) (CE-IVD)
 5. AniCon Labor GmbH; Kylt® SARS-CoV-2 Confirmation RT-Qpcr (CE-IVD)
 6. Anlongen; nConV-19 Nucleic Acid qPCR Kit (China FDA-EUA - CE-IVD)
 7. Appolon Biotech; Detection Kit for 2019 Novel Coronavirus (2019-nCoV) RNA (PCR-Fluorescence Probing) (China FDA-EUA - CE-IVD)
 8. Bai-care (Tianjin) Biotechnology Co., Ltd; Multiplex Nucleic Acid Detection Kit for Respiratory Pathogens (CE-IVD)
 9. Beijing Applied Biological Technologies Co., Ltd; Multiple Real-Time PCR Kit for Detection of 2019-nCoV (China FDA-EUA - CE-IVD)



**PERHIMPUNAN DOKTER SPESIALIS
PATOLOGI KLINIK DAN KEDOKTERAN LABORATORIUM INDONESIA
(PDS PatKLIn)**

Sekretariat:

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**PCR COVID-19 YANG TELAH DISETUJUI/APPROVED
OLEH FDA NEGARA MASING-MASING
(NATIONAL REGULATORY AUTHORITIES IN IMDRF)
(SUMBER: WHO 08 APRIL 2020 dan ECDC)**

10. Beijing Hotgen Biotech Co., Ltd; Coronavirus disease(COVID-19) Nucleic Acid Test Kit (PCR-Fluorescent Probe Method) (China FDA-EUA - CE-IVD)
11. Beijing Microread Genetics Co.,Ltd; COVID-19 (SARS-CoV-2) Detection Kit (LAMP) - lab-based or near-POC (CE-IVD)
12. Bioeksen R&D Technologies; Bio-Speedy SARS-CoV-2 (2019-nCoV) qPCR Detection Kit (CE-IVD)
13. BIONEER Corporation; AccuPower® COVID-19 Real-Time RT-PCR kit (lab-based automated kit: NCV-1111) (CE-IVD)
14. CerTest Biotec, S.L.; VIASURE SARS-CoV-2 S gene Real Time PCR Detection Kit adapted for BD MAX™ System (CE-IVD)
15. Diagnostics for the Real World Ltd; SAMBA II COVID-19 Test (near-POC NAT) (CE-IVD)
16. DiaSorin Molecular, LLC; Simplexa™ COVID-19 Direct RT-PCR Kit (CE-IVD)
17. Eryigit Endustriyel Makina ve Tibbi Cihazlar; Senteligo Covid-19 qRT PCR Detection Kit (CE-IVD)
18. gerbion GmbH & Co., KG; virellaSARS-CoV-2 seqc real time RT-PCR Kit 2.0 (CE-IVD)
19. Medical System; Coronavirus PCR test (China FDA-EUA - CE-IVD)
20. MiCo Biomed Co. Ltd; VERI-QTM PCR 316 COVID-19 detection system (CE-IVD)
21. OsangHealthcare; GeneFinder COVID-19 Plus RealAmp Kit (CE-IVD)
22. QIAGEN GmbH; QIAstat-Dx Respiratory Panel 2019-nCoV (China FDA-EUA - CE-IVD)
23. Seegene, Inc.; Allplex 2019-nCoV assay (Korea MFDS-EUA - CE-IVD)
24. Sente Biolab; Senteligo Covid-19 qRT PCR Detection Kit (CE-IVD)
25. Solgent Co.Ltd ; DiaPlexQ™ Novel Coronavirus (2019-nCoV) Detection Kit (Korea FDA-EUA - CE-IVD)
26. Veredus Laboratories Pte Ltd; VereCoV™ Detection Kit and VerePLEX™ Biosystem (Singapore HSA - CE-IVD)
27. Xiamen Zeesan Biotech Co., Ltd.; SARS-CoV-2 Test Kit (CE-IVD)



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28. Veredus Laboratories Pte Ltd VereCoV™ Detection Kit and VerePLEX™ Biosystem (Singapore HSA - CE-IVD)

Jakarta, 22 April 2020 jam 15.00
Ketua Umum

Sekjen



Prof. DR. Dr. Aryati, MS., Sp.PK(K)

Dr. Marina Ludong., Sp.PK