



**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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**RAPID TEST SEROLOGI COVID-19 YANG SUDAH TERDAFTAR DI FDA
NEGARA**

(NATIONAL REGULATORY AUTHORITIES IN IMDRF)

(SUMBER: WHO 08 APRIL 2020)

PDS PatKLIn, UPDATE TGL 20 APRIL 2020 JAM 14.00

A. FDA AMERIKA SERIKAT

1. Cellex Inc. USA; qSARS-CoV-2 IgG/IgM Rapid Test (1 April 2020)
2. DPP® COVID-19 IgM/IgG System; CHEMBIO DIAGNOSTICS BRAZIL LTDA. (14 April 2020)
3. COVID-19 ELISA IgG Antibody Test; Mount Sinai Laboratory Center for Clinical Laboratories. (15 April 2020)

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

1. Wantai SARS-CoV-2 Ab Rapid Test kit; Beijing Wantai Biologicalpharmacy Enterprise Co Ltd (China) (01-Jan-20)
2. OnSite COVID-19 IgG/IgM Rapid Test; CTK Biotech Inc (USA) (19-Mar-20)
3. VivaDiag™ COVID-19 IgM/IgG Rapid Test; VivaCheck Biotech (Hangzhou) Co Ltd (China) (20-Mar-20)
4. 2019-n-CoV IgG/IgM Rapid Test Cassette; Hangzhou Alltest Biotech Co Ltd (China) (23-Mar-20)
5. SARS-CoV-2 Antibody Test (Lateral Flow Method); Guangzhou Wondfo Biotech Co Ltd (China) (25-Mar-20)
6. COVID-19 IgG/IgM Rapid Test Cassette; Hangzhou Clongene Biotech Co Ltd (China) (26-Mar-20)
7. VivaDiag™ COVID-19 IgM/IgG Rapid Test; VivaChek Biotech (Hangzhou) Co Ltd (China) (26-Mar-20)
8. Cellex qSARS-CoV-2 IgG/IgM Cassette Rapid Test kit; Cellex Inc (United States Of America) (31-Mar-20)
9. SARS-CoV-2 IgM/IgG Antibody Rapid Test; Qingdao Hightop Biotech Co Ltd (China) (31-Mar-20)
10. COVID-19 IgG/IgM Rapid Test Cassette; Zhejiang Orient Gene Biotech Co Ltd (China) (01-Apr-20)



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11. 2019-nCoV Ab Test (Colloidal Gold); Innovita (Tangshan) Biological Technology Co Ltd (China) (04-Apr-20)
12. COVID-19 IgG/IgM Rapid Test Cassette; Hangzhou Clongene Biotech Co Ltd (China) (04-Apr-20)
13. COVID-19 IgG/IgM Rapid Test Cassette; Hangzhou Biotest Biotech Co Ltd (China) (04-Apr-20)
14. COVID-19 IgG/IgM Rapid Test Cassette; Hangzhou Clongene Biotech Co Ltd (China) (06-Apr-20)
15. Novel Coronavirus (2019-nCoV) IgM/IgG Antibody Combo Test Kit (Colloidal Gold); Hangzhou Laihe Biotech Co Ltd (China) (06-Apr-20)
16. VivaDiag™ COVID-19 IgM/IgG Rapid Test; VivaChek Biotech (Hangzhou) Co Ltd (China) (06-Apr-20)
17. SARS-CoV-2 IgM/IgG Antibody Rapid Test; Qingdao Hightop Biotech Co Ltd (China) (07-Apr-20)
18. 2019-nCoV Ab Test (Colloidal Gold); Innovita (Tangshan) Biological Technology Co Ltd (China) (08-Apr-20)
19. SARS-CoV-2 Antibody Test (Lateral Flow Method); Guangzhou Wondfo Biotech Co Ltd (China) (09-Apr-20)
20. 2019-nCoV Ab Test (Colloidal Gold); Innovita (Tangshan) Biological Technology Co Ltd (China) (11-Apr-20)
21. COVID-19 IgG/IgM Rapid Test Cassette; Zhejiang Orient Gene Biotech Co Ltd (China) (14-Apr-20)
22. 2019-nCov Ab Test (Colloidal Gold); Innovita (Tangshan) Biological Technology Co Ltd (China) (16-Apr-20)
23. 2019-nCOV/COVID-19 IgG/IgM Rapid Test Device; Hangzhou Realy Tech Co Ltd (China) (16-Apr-20)
24. SARS-CoV-2 Antibody Test (Lateral Flow Method); Guangzhou Wondfo Biotech Co Ltd (China) (17-Apr-20)

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

1. VivaCheck Biotech Co., Ltd., China; VivaDiag COVID-19 IgM/IgG Rapid Test (20 Maret 2020)
2. Nanjing Vazyme Medical Technology Co., Ltd., China; 2019-NCOV IgG/IgM Diagnostic Kit (20 Maret 2020)
3. Guangzhou Wondfo Biotech Co., Ltd., China; Wondfo SARS-CoV-2 Antibody Test (9 April 2020)



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4. Camtech Diagnostics Pte., Ltd., Singapore; Camtech COVID-19 IgM/IgG (9 April 2020)

D. CHINA (NMPA APPROVED, 2 April 2020)

1. Guangzhou Wondfo Biotech Co., Ltd., China; Wondfo SARS-CoV-2 Antibody Test
2. Innovita Biological Technology, China; 2019-NCOV AB Test
3. Bioscience (Chongqing) Diagnostic Technology Co., Ltd.; IgM Antibody test kit for novel coronavirus 2019-nCoV (magnetic particle-based chemiluminescence immunoassay)
4. Bioscience (Chongqing) Diagnostic Technology Co., Ltd.; IgG Antibody test kit for novel coronavirus 2019-nCoV (magnetic particle-based chemiluminescence immunoassay)
5. Xiamen Innodx Biotech Co., Ltd.; Antibody test kit for novel coronavirus 2019-nCoV (chemiluminescence microparticle immunoassay)
6. Guangdong Hecin Biotech Co., Ltd., China; Novel Coronavirus (2019-nCoV-2) IgM Antibody Test
7. Nanjing Vazyme Medical Technology Co., Ltd., China; 2019-NCOV IgG/IgM Diagnostic Kit
8. Zhuhai Livzon Diagnostic, Inc., China; Diagnostic Kit for IgM/IgG Antibody to Coronavirus (SARS-CoV-2)

E. BRASIL

1. AFIAS COVID-19 Ab; BODITECH MED INC (16/04/20)
2. COVID-19 IgG/IgM LF; ADVAGEN BIOTECH LTDA (03/04/20)
3. BasePoint COVID-19 IgG/IgM; GUANGZHOU WONDFO BIOTECH CO., LTD (16/04/20)
4. Teste Rápido OnSite™ COVID-19 IgG/IgM Rapid Test; BEIJING GENESEE BIOTECH, INC (03/04/20)
5. Celer One Step COVID-2019 Test; Guangzhou Wondfo Biotech Co., Ltd. (24/03/20)
6. COVID-19 IgG/IgM; QINGDAO HIGHTOP BIOTECH CO., LTD. (03/04/20)
7. DPP® COVID-19 IgM/IgG System; CHEMBIO DIAGNOSTICS BRAZIL LTDA. (25/03/20)
8. COVID-19 igG/IgM test; HUMASIS CO LTD (09/04/20)



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9. CORONAVÍRUS RAPID TEST; GUANGZHOU WONDFO BIOTECH CO., LTD (24/03/20)
10. CORONAVÍRUS IgG/IgM (COVID-19); EBRAM PRODUTOS LABORATORIAIS LTDA (20/03/20)
11. ECO F COVID-19 Ag; Eco Diagnostica Ltda (24/03/20)
12. COVID-19 IgG/IgM ECO Teste; Eco Diagnostica Ltda (24/03/2020)
13. COVID-19 Ag ECO Teste Eco Diagnostica Ltda (24/03/2020)
14. TR DPP® COVID-19 IGM/IGG; Bio-Manguinhos (16/04/20)
15. Anti COVID-19 IgG/IgM Rapid Test; LABTEST DIAGNOSTICA S/A (24/03/20)
16. LUMIRATEK COVID-19 (IgG/IgM); HANGZHOU BIOTEST BIOTECH CO., LTD. (25/03/20)
17. BIOSYNEX COVID-19 BSS; BIOSYNEX SA (16/04/20)
18. MedTeste Coronavírus (COVID-19) IgG/IgM (TESTE RAPIDO); HANGZHOU BIOTEST BIOTECH CO., LTD. (24/03/2020)
19. Teste Rápido Covid-19 15 minutos Nutriex; HANGZHOU SINGCLEAN MEDICAL PRODUCTS CO., LTD (16/04/20)
20. Família Teste Rápido em Cassete 2019-nCoV IgG/IgM (sangue total/soro/plasma); ACRO BIOTECH INC. (24/03/20)
21. Família AllTest COVID-19 IgG/IgM Teste Rápido (Sangue total/Soro/Plasma); HANGZHOU ALLTEST BIOTECH CO., LTD. (03/04/20)
22. COVID-19 IgG/IgM BIO; QUIBASA QUÍMICA BÁSICA LTDA (09/04/20)
23. QuickProfile COVID-19 IgG/IgM Combo Test Card; LUMIQUICK DIAGNOSTICS, INC. (16/04/20)
24. Smart Test Covid-19 Vyttra; VYTTRA DIAGNOSTICOS IMPORTACAO E EXPORTACAO S.A. (31/03/20)

F. FDA PHILIPPINES (16 April 2020, 4:00PM)

1. NANJING VAZYME 2019-nCoV IgG/IgM DETECTION KIT; Biolidics Limited.
2. NOVEL CORONAVIRUS (2019- NCOV) IgM/IgG ANTIBODY DETECTION KIT (COLLOIDAL GOLD METHOD); Nanjing Vazyme Medical Technology Co., Ltd
3. DIAGNOSTIC KIT FOR IgM/IgG ANTIBODY TO CORONAVIRUS (SARS-CoV-2) (COLLOIDAL GOLD); Zhuhai Livzon Diagnostic Inc.
4. 2019-nCoV ANTIBODY TEST (COLLOIDAL GOLD); Innovita (Tangshan) Biological Technology Co., Ltd.



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5. SARS-CoV-2 ANTIBODY TEST (LATERAL FLOW METHOD); Guangzhou Wondfo Biotech Co., Ltd.
6. WANTAI SARS- CoV Ab RAPID TEST KIT; Beijing Wantai Biological Pharmacy Enterprise Co., Ltd.
7. 2019 n-CoV IgG/IgM RAPID TEST CASSETTE; Hangzhou Alltest Biotech Co., Ltd.
8. OnSite COVID-19 IgG/IgM Rapid Test; CTK Biotech, Inc.
9. HIGHTOP SARS-CoV-2 IgM/IgG ANTIBODY RAPID TEST; Qingdao Hightop Biotech Co., Ltd.
10. Cellex qSARS-CoV-2 IgG/IgM Cassette Rapid Test; Cellex, Inc.,
11. COVID-19 IgG/IgM RAPID TEST KIT; Hangzhou Biotest Biotech Co., Ltd.
12. DIAGNOSTIC KIT FOR NOVEL CORONAVIRUS (2019-nCoV) IgM ANTIBODY (MAGNETIC PARTICLE CLIA); Bioscience (Chongqing) Diagnostic Technology Co., Ltd
13. DIAGNOSTIC KIT FOR NOVEL CORONAVIRUS (2019-nCoV) IgG ANTIBODY (MAGNETIC PARTICLE CLIA); Bioscience (Chongqing) Diagnostic Technology Co., Ltd
14. COVID-19 IgG/IgM Rapid Test Cassette; Healgen Scientific Limited
15. COVID-19 IgG/IgM RAPID TEST CASSETTE; Zhejiang Orient Gene Biotech Co., Ltd
16. BIOLIDICS 2019-nCoV IgG/IgM DETECTION KIT; Biolidics Limited.

G. KOREA (IVD CERTIFIED)

1. STANDARD™ Q COVID-19 IgM/IgG Duo Test; SD Biosensor
2. STANDARD™ Q COVID-19 Ag Test; SD Biosensor
3. STANDARD™ F COVID-19 Ag FIA; SD Biosensor
4. SGTi-flex COVID-19 IgM/IgG; Sugentech
5. SGTi-flex COVID-19 IgM; Sugentech
6. SGTi-flex COVID-19 IgG; Sugentech
7. GenBody COVID-19 IgM/IgG; GenBody
8. Humasis COVID-19 IgG/IgM Test; Humasis

Jakarta, 22 April 2020 jam 14.30

Ketua Umum

Sekjen



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

Dr. Marina Ludong, Sp.PK