

Nomor : FR.03.01/E.V/1116/2024

3 Mei 2024

Lampiran : 1 (satu) berkas

Perihal : Permohonan Daftar Hasil Uji Validitas Reagen HIV

Yth. **Direktur Pencegahan dan Pengendalian Penyakit Menular**

Jl. HR. Rasuna Said Blok X-5 Kav. 4-9

Jakarta 12950

Sehubungan dengan surat dari Direktur Pencegahan dan Pengendalian Penyakit Menular Nomor PM.02.02/C.III/3935/2024 tanggal 24 April 2024 perihal Permohonan data, bersama ini kami informasikan sebagai berikut:

1. Berdasarkan Undang-Undang Republik Indonesia Nomor 17 Tahun 2023 Tentang Kesehatan, Pasal 143: bahwa:
  - a. Setiap Orang yang memproduksi dan/ atau mengedarkan Sediaan Farmasi, Alat Kesehatan, dan PKRT harus memenuhi perizinan berusaha dari Pemerintah Pusat atau Pemerintah Daerah sesuai dengan kewenangannya berdasarkan norma, standar, prosedur, dan kriteria sesuai dengan ketentuan peraturan perundang-undangan.
  - b. Setiap Orang yang memproduksi dan/ atau mengedarkan Sediaan Farmasi, Alat Kesehatan, dan PKRT yang telah memperoleh perizinan berusaha, yang terbukti tidak memenuhi persyaratan keamanan, khasiat/kemanfaatan, dan mutu dikenai sanksi administratif sesuai dengan ketentuan peraturan perundang-undangan di bidang perizinan berusaha.
2. Sesuai dengan Permenkes 62 Tahun 2017 tentang Izin Edar Alat Kesehatan, Alat Kesehatan Diagnostik In Vitro dan Perbekalan Kesehatan Rumah Tangga, Pasal 4 ayat 1 bahwa Alat Kesehatan, Alat Kesehatan Diagnostik In Vitro dan PKRT yang diproduksi, diimpor, dirakit dan/atau dikemas ulang, yang akan diedarkan di wilayah Negara Republik Indonesia harus memiliki Izin Edar.
3. Direktorat Produksi dan Distribusi Alat Kesehatan Ditjen Kefarmasian dan Alat Kesehatan, telah memiliki sistem informasi berbasis web yang menyediakan informasi alat kesehatan dan PKRT yang memiliki izin edar. Sistem informasi tersebut dapat diakses melalui website <http://infoalkes.kemkes.go.id>
4. Terlampir data distributor alat kesehatan tes HIV per tanggal 2 Mei 2024 dengan Nomor ijin edar produk yang masih berlaku berikut hasil uji validitasnya.

5. Sehubungan dengan standar yang berkaitan dengan alat kesehatan lebih lanjut dapat menghubungi kelompok tim kerja pembakuan dan pengujian Direktorat Pengawasan Alat Kesehatan.

Demikian disampaikan, atas kerjasamanya diucapkan terima kasih

Direktur Produksi dan Distribusi Alat  
Kesehatan,

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**Dede Mulyadi, SKM., M.Kes., CRMP**

Kementerian Kesehatan tidak menerima suap dan/atau gratifikasi dalam bentuk apapun. Jika terdapat potensi suap atau gratifikasi silahkan laporkan melalui HALO KEMENKES 1500567 dan <https://wbs.kemkes.go.id>. Untuk verifikasi keaslian tanda tangan elektronik, silahkan unggah dokumen pada laman <https://tte.kominfo.go.id/verifyPDF>.

Lampiran  
 Nomor : FR.03.01/E.V/1116/2024  
 Tanggal : 3 Mei 2024

**DATA DISTRIBUTOR ALAT KESEHATAN TES HIV  
 PER TANGGAL 2 MEI 2024**

**REAGEN HIV IMPOR**

No	Nama Perusahaan	Nomor Izin Edar	Tanggal Expired	Nama Produk	Pabrik	Nilai Validitas
1	PT. ANDAMAN MEDICAL INDONESIA	AKL 30305320722	19/07/2027	INNO-LIA HIV I/II Score	FUJIREBIO EUROPE N.V.	Sensitivitas: 100 % Spesifitas: 100 %
2	PT. ROCHE INDONESIA	AKL 30305220507	28/04/2027	COBAS MPX – 480	ROCHE MOLECULAR SYSTEMS, INC.	Sensitivitas: 100 % Spesifitas: 100 %
3	PT. ABBOTT PRODUCTS INDONESIA	AKL 30305214126	09/01/2029	ARCHITECT HIV Ag/Ab Combo Reagent Kit	ABBOTT GmbH	Sensitivitas: 99.24 % Spesifitas: 96.13 %
4	PT. BIOMEDIKAL SCIENTIFIC INDONESIA	AKL 30305220599	19/05/2026	LIAISON[register] XL Murex HIV Ab/Ag	DIASORIN ITALIA S.P.A.	Sensitivitas: 99.23 % Spesifitas: 90.06 %
5	PT. BIOMEDIKAL SCIENTIFIC INDONESIA	AKL 30305220452	19/05/2026	LIAISON[register] XL Murex HIV Ab/Ag HT	DIASORIN ITALIA S.P.A	Sensitivitas: 97.69 % Spesifitas: 95.19 %
6	PT. GRAVIA CITRA LESTARI	AKL 30305321219	23/11/2027	VIRDICT 4 DEVICE	QUALPRO DIAGNOSTICS A DIVISION OF TULIP DIAGNOSTICS	Sensitivitas: 99.24 % Spesifitas: 100 %
7	PT. DHH TRADING INDONESIA	AKL 30305321205	10/02/2026	Access HIV combo V2	BIO-RAD	Sensitivitas: 99.24 % Spesifitas: 97.12 %
8	PT. EMERALINDO ASIA PASIFIK	AKL 30305220622	2024-06-21	VITROS Immunodiagnostic Products HIV Combo Reagent Pack	ORTHO-CLINICAL DIAGNOSTICS	Sensitivitas: 99.23% Spesifitas: 100.0%
9	PT. GRACIA VISI PRATAMA	AKL 30305320686	2024-09-30	Autobio HIV Ab/Ag Combo CLIA Microparticles	AUTOBIO DIAGNOSTIC CO.,LTD	Sensitivitas: 99.20% Spesifitas: 99.04%
10	PT. ABBOTT PRODUCTS INDONESIA	AKL 30305813873	2024-11-05	ALINITY i HIV Ag/Ab Combo Reagent Kit	ABBOTT GMBH & CO. KG	Sensitivitas: 100.0% Spesifitas: 100.0%
11	PT. ENSEVAL MEDIKA PRIMA	AKL 30305600643	2024-12-31	VIDAS[register] HIV DUO Ultra (HIV5)	BIOMERIEUX SA.	Sensitivitas: 99.33% Spesifitas: 97.71%
12	PT. ENSEVAL MEDIKA PRIMA	AKL 30305804208	2024-12-31	VIKIA[register] HIV 1/2	BIOMERIEUX SA.	Sensitivitas: 99.79% Spesifitas: 100%
13	PT. MEDQUEST JAYA GLOBAL	AKL 30305321006	2024-12-31	Xpert HIV-1 Qual XC	CEPHEID AB	Spesifitas : 100.0%
14	PT. DIASTIKA BIOTEKINDO	AKL 30305113470	2025-01-01	MP Diagnostics HIV BLOT 2.2	MP BIOMEDICALS ASIA PACIFIC	-

				Western Blot Assay	PTE., LTD.	
15	PT. JAFAREL MEDIATICS	AKL 30305714527	2025-02-05	DALF[register] IQ HIV 1/2 DROP TEST	QUALPRO DIAGNOSTICS - A DIVISION OF TULIP DIAGNOSTICS ( P ) LTD.	Sensitivitas : 100% Spesifitas : 99.8%.
16	PT. MITRASAMAYA SEJATI	AKL 30305111259	2025-02-11	ADVANCED QUALITY HIV 1&2 ELISA Test Kit (3rd Generation)	INTEC PRODUCTS INC., (XIAMEN).	Spesifitas : 99.9%
17	PT.MITRASAMAYA SEJATI	AKL 30305111261	2025-02-11	ADVANCED QUALITY One Step Anti-HIV (1&2) Tri-Line Test Card	INTEC PRODUCTS INC.	Sensitivitas : 100% Spesifitas : 100%
18	PT. ROCHE INDONESIA	AKL 30305614173	2025-02-27	COBAS [register] HIV-1 Quantitative nucleic acid test for use on the COBAS [register] 6800/8800 Systems	ROCHE MOLECULAR SYSTEMS INC.	Sensitivitas : 95 % Spesifitas : 100%
19	PT. SIEMENS HEALTHINEERS INDONESIA	AKL 30305220310	2025-03-04	ADVIA Centaur HIV Ag/Ab Combo (CHIV)	SIEMENS HEALTHCARE DIAGNOSTICS INC. (EAST WALPOLE) UNTUK SIEMENS HEALTHCARE DIAGNOSTICS INC. (TARRYTOWN)	Sensitivitas : 100.0% Spesifitas : 99.74%
20	PT. MINDRAY MEDICAL INDONESIA	AKL 30305712719	2025-06-29	MINDRAY HIV Antigen and Antibodies to Human Immunodeficient Virus (CLIA)	SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD.	Sensitivitas : 100 % Spesifitas : 99.8 %.
21	PT. SUMIFIN CITRA ABADI	AKL 30305911338	2025-07-01	AiD[trademark] HIV 1+2 Ag/Ab ELISA Plus	BEIJING WANTAI BIOLOGICAL PHARMACY ENTERPRISE CO., LTD.	Sensitivitas : 100% Spesifitas : 99.75%
22	PT. ROCHE INDONESIA	AKL 30305220224	2025-07-06	Elecsys HIV Duo cobas e analyzers	ROCHE DIAGNOSTICS GMBH	Sensitivitas : 100% Spesifitas : 100%
23	PT. ROCHE INDONESIA	AKL 30305220590	2025-07-06	COBAS Elecsys HIV Combi PT Elecsys and Cobas e Analyzers	ROCHE DIAGNOSTICS GMBH	Spesifitas : 99.92 % Sensitivitas : 100%
24	PT. ROCHE INDONESIA	AKL 30305214232	2025-11-12	COBAS HIV Combi PT. Elecsys and Cobas e Analyzer	ROCHE DIAGNOSTICS GMBH.	Sensitivitas: 100% Spesifitas: 99.88 %
25	PT. MULTIMEDILAB KARYAMANDIRI	AKL 30305715936	2025-12-31	MAGLUMI HIV Ab/Ag Combi (CLIA)	SHENZHEN NEW INDUSTRIES BIOMEDICAL ENGINEERING CO., LTD.	Sensitivitas : 100% Spesifitas: Negatif Speciment: 98.29%
26	PT. SETIA	AKL	2026-02-04	YHLO iFlash	SHENZHEN YHLO	Sensitivitas

	ANUGRAH MEDIKA	30305220292		HIV Combo	BIOTECH CO.,LTD	: 99.23% Spesifitas: Negatif Speciment: 82.05%
27	PT. ROCHE INDONESIA	AKL 30305710379	2026-02-09	COBAS[register] Ampliprep/C OBAS[register] TaqMan[register] HIV-1 Qualitative Tes, v2.0 (HI2QCAP)	ROCHE MOLECULAR SYSTEM INC.	Sensitifitas : 100% Spesifitas : 99.8%
28	PT. ROCHE INDONESIA	AKL 30305713142	2026-04-15	COBAS [register] HIV- 1 Quantitative Nucleic Acid Test for Use on The cobas 4800 System &#40;c4800 HIV- 1 AMP/ DET&#41;	ROCHE MOLECULAR SYSTEMS.,INC	Sensitifitas : 99.58% Spesifitas : 100%
29	PT. HARSEN LABORATORIES	AKL 30305321049	2026-05-17	MACCURA HIV Ag/Ab (CLIA)	MACCURA BIOTECHNOL OGY CO., LTD.	Sensitivitas : 99.22% Spesifitas: 98.72%
30	PT. SUMIFIN CITRA ABADI	AKL 30305504659	2026-06-28	WANTAI Anti- HIV (1+2) ELISA Kit	BEIJING WANTAI BIOLOGICAL PHARMACY ENTERPRISE CO., LTD.	Sensitivitas : 100% Spesifitas: 94.89%
31	PT. ROCHE INDONESIA	AKL 30305220111	2026-12-15	Cobas HIV-1/HIV- 2 Qualitative	ROCHE MOLECULAR SYSTEMS, INC.	Sensitifitas : 100% Spesifitas : 100%
32	PT. ROCHE INDONESIA	AKL 30305220168	2026-12-15	COBAS[register] HIV-1 Quantitative nucleic acid test	ROCHE MOLECULAR SYSTEMS, INC.	Sensitifitas : 100% Spesifitas : 100%
33	PT. SINERGI UTAMA SEJAHTERA	AKL 30305710396	2026-12-31	ABBOTT RealTime HIV- 1 Amplification Reagent Kit	ABBOTT MOLECULAR INC.	Sensitifitas : 100% Spesifitas : 99.3%
34	PT. SINERGI UTAMA SEJAHTERA	AKL 30305910109	2026-12-31	ABBOTT RealTime HIV- 1 Amplification Reagent Kit	ABBOTT MOLECULAR INC.	Sensitivitas : 95% Spesifitas : 99,5%
35	PT. SINERGI UTAMA SEJAHTERA	AKL 30305320942	2026-12-31	ABBOTT RealTime HIV- 1 Qualitative Amplification Reagent Kit	ABBOTT MOLECULAR INC.,	Sensitivitas : 95% Spesifitas : 100%
36	PT. ABBOTT PRODUCTS INDONESIA	AKL 30305220541	2027-01-21	Abbott Alinity m HIV- 1 AMP Kit	ABBOTT MOLECULAR, INC.	Sensitivitas : 95% Spesifitas : 100%
37	PT. ROCHE INDONESIA	AKL 30305811059	2027-05-17	COBAS MPX Multiplex HIV, HCV & HBV nucleic acid test for use on the cobas 6800/8800 Systems	ROCHE MOLECULAR SYSTEM, INC.	Sensitivitas : 100% Spesifitas : 100%

38	PT. MEDQUEST JAYA GLOBAL	AKL 30305814261	2027-09-06	PROCLEIX Ultrio Elite Assay Discriminatory Probe Reagents	GRIFOLS DIAGNOSTIC SOLUTIONS INC.	Sensitivitas : 100% Spesifitas : 100%
39	PT. MEDQUEST JAYA GLOBAL	AKL 30305813603	2027-09-19	PROCLEIX Ultrio Elite Assay Kit	GRIFOLS DIAGNOSTIC SOLUTIONS INC.	Sensitivitas : 95% Spesifitas : 99,9%
40	PT. BIOMEDIKA L SCIENTIFIC INDONESIA	AKL 30305220419	2027-09-27	MUREX HIV Ag/Ab Combination	DIASORIN ITALIA S.P.A UK BRANCH	Sensitivitas : 99,23% Spesifitas : 90,06%
41	PT. SYSMEX INDONESIA	AKL 30305516634	2028-01-16	SYSMEX HISCL HIV Ag+Ab Assay Kit	SYSMEX CORPORATION, SEISHIN FACTORY.	Sensitivitas : 98,67% Spesifitas : 98,86%
42	PT. ROCHE INDONESIA	AKL 30305917680	2028-02-21	ELECSYS HIV Duo cobas e analyzers	ROCHE DIAGNOSTICS GMBH.	Sensitivitas : 98,14% Spesifitas : 99,78%
43	PT. MEDQUEST JAYA GLOBAL	AKL 20305420039	28/02/2024	XPERT HIV-1 Viral Load XC	CEPHEID AB	Sensitivitas: 100 % Spesifitas: 100 %
44	PT. ALERE HEALTH	AKL 20305120011	6/7/2025	m-PIMA[trademark] HIV-1/2 VL	ABBOTT RAPID DIAGNOSTICS JENA GMBH	Sensitivitas: 95.45 % Specificity: 95.96 %

## RAPID HIV IMPOR

No	Nama Perusahaan	Nomor Izin Edar	Tanggal Expired	Nama Produk	Pabrik	Nilai Validitas
1	PT. SALI POLAPA BERSAMA	AKL 30305211864	8/11/2027	HUMAN Hexagon HIV	HUMAN Gesellschaft für Biochemica und Diagnostica mbH	Sensitivitas: 98.66 % Spesifitas: 98.30 %
2	PT. BINTANG MONO INDONESIA	AKL 30305917661	19/12/2023	ORIENT GENE HIV 1/2 One Step Rapid Test Cassette	ZHEJIANG ORIENT GENE BIOTECH CO., LTD.	Sensitivitas: 100 % Spesifitas: 100 %
3	PT. EXXEL UTAMA	AKL 30305321228	18/11/2023	ANSWER HIV 1/2/O Tri line Rapid Test Cassette (Serum/Plasma / Whole Blood)	ACON BIOTECH (HANGZHOU) CO., LTD.	Sensitivitas: 100 % Spesifitas: 99.68 %
4	PT. ALERE HEALTH	AKL 30305715499	14/11/2023	ABON[trademark] HIV 1/2/O Tri-Line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma)	ABON BIOPHARM (HANGZHOU) CO., LTD.	Sensitivitas: 100 % Spesifitas: 98.86 %
5	PT. SARANA KARYA MEDIKA	AKL 30305021428	2026-02-01	STANDAREAG EN Diagnostic Kit for Antibody to Human Immunodeficiency Virus HIV 1 + 2	NANTONG EGENS BIOTECHNOLOGY CO., LTD.	Sensitivitas: 100 % Spesifitas: 100 %
6	PT. SARANA KARYA MEDIKA	AKL 30305023057	2028-06-01	EGENS One Step Test Device HIV (1+2)	NANTONG EGENS BIOTECHNOLOGY	Sensitivitas: 100 % Spesifitas: 100 %

				Serum/Plasma Test Cassette	Y CO., LTD.	
7	PT. MITRASAMA YA SEJATI	AKL 30305111261	2025-02-11	ADVANCED QUALITY One Step Anti-HIV (1&2) Tri-Line Test Card	INTEC PRODUCTS INC.	Sensitivitas: 100 % Spesifitas: 99.43 %
8	PT. BIOCARE SEJAHTERA	AKL 30305120047	2024-06-10	KHB Diagnostic Kit for HIV (1+2) Antibody (Colloidal Gold) V2	SHANGHAI KEHUA BIO-ENGINEERING CO., LTD	Sensitivitas: 100 % Spesifitas: 99.43 %
9	PT. BIOCARE SEJAHTERA	AKL 30305124662	2025-09-18	BIOCARE[register] Combo 4 (HBsAg, HCV, HIV, Syphilis) Rapid Test Device	ASSURE TECH (HANGZHOU) CO., LTD.	Sensitivitas: 99.33 % Spesifitas: 98.86 %
10	PT. AKURAT INTAN MADYA	AKL 30305220211	2025-01-08	AIM HIV 1 / 2 Tripleline Rapid Test	XIAMEN BOSON BIOTECH CO, LTD	Sensitivitas : 98 % Spesifitas: 99.43 %
11	PT. MITRA BAHAGIA CITRA MEDIKA	AKL 30305220501	2025-08-09	ACON HIV 1/2/O Rapid Test Cassette (Serum/Plasma/ Whole Blood)	ACON BIOTECH (HANGZHOU) CO., LTD.	Sensitivitas: 98.46 % Spesifitas: 99.68 %
12	PT. DANPAC PHARMA	AKL 30305220581	2027-11-30	ONE STEP Cassette Style Anti HIV 1+2 Rapid Screen Test (Whole Blood)	NANTONG EGENS BIOTECHNOLOGY CO., LTD.	Sensitivitas: 96.15 Spesifitas: 100 %
13	PT. BIOCARE SEJAHTERA	AKL 30305220649	2025-09-14	BIOCARE HIV 1+O/2 Antibody Rapid Test Device	ASSURE TECH (HANGZHOU) CO., LTD.	Sensitivitas: 95.38 % Spesifitas: 99.68 %
14	PT. ALERE HEALTH	AKL 30305320708	2027-06-04	BIOLINE HIV 1/2 3.0	ABBOTT DIAGNOSTICS KOREA INC	Sensitivitas: 100 % Spesifitas: 100 %
15	PT. ALERE HEALTH	AKL 30305320775	2027-06-04	Determine [trademark] HIV Early Detect	ABBOTT DIAGNOSTICS MEDICAL CO., LTD	Sensitivitas: 98.47 % Spesifitas: 99.68 %
16	PT. LANIROS DIAN PHARMA	AKL 30305320801	2027-10-11	JUSCHECK[register] HIV 1.2 Rapid Test Cassette	ACRO BIOTECH INC.	Sensitivitas: 100 % Spesifitas: 100 %
17	PT. ALERE HEALTH	AKL 30305320812	2025-06-01	Determine [trademark] HIV 1/2	ABBOTT DIAGNOSTICS MEDICAL CO., LTD	Sensitivitas: 100 % Spesifitas: 100 %
18	PT. RAJAERBA INDOCHEM	AKL 30305320851	2026-08-25	OnSite HIV 1/2 Ab Plus Combo Rapid Test	CTK BIOTECH, INC.	Sensitivitas: 100 % Spesifitas: 99.68 %
19	PT. ALERE HEALTH	AKL 30305320915	2027-06-04	BIOLINE HIV/Syphilis Duo	ABBOTT DIAGNOSTICS KOREA, INC	Sensitivitas: 99.24 % Spesifitas: 100 %
20	PT. MACROCITRA ARDANASEJATI	AKL 30305513360	2027-10-23	RIGHTSIGN [register] HIV 1.2.O Rapid Test Cassette (Whole Blood/Serum/Plasma)	HANGZHOU BIOTEST BIOTECH CO., LTD.	Sensitivitas: 100 % Spesifitas: 99.43 %
21	PT. ALERE	AKL	2027-06-04	SD BIOLINE	STANDARD	Sensitivitas:

	HEALTH	30305515934		HIV/Syphilis Duo	DIAGNOSTICS, INC.	95.38 % Spesifitas: 99.68 %
22	PT. ALERE HEALTH	AKL 30305610110	2027-06-04	ALERE[trademark] HIV Combo	ALERE MEDICAL CO., LTD.	Sensitivitas: 96.15 % Spesifitas: 100 %
23	PT. JAFAREL MEDIATICS	AKL 30305714527	2025-02-05	DALF[register] IQ HIV 1/2 DROP TEST	QUALPRO DIAGNOSTICS - A DIVISION OF TULIP DIAGNOSTICS ( P ) LTD.	Sensitivitas: 99.33 % Spesifitas: 100%
24	PT. ALERE HEALTH	AKL 30305715499	2027-06-04	ABON[trademark] HIV 1/2/O Tri-Line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma)	ABON BIOPHARM (HANGZHOU) CO., LTD.	Sensitivitas: 100 % Spesifitas: 98.68 %
25	PT. ALERE HEALTH	AKL 30305717662	2027-06-04	ALERE Determine HIV-1/2	ALERE MEDICAL CO., LTD.	Sensitivitas: 98.66 % Spesifitas: 100 %
26	PT. BINABAKTI NIAGAPERKASA	AKL 30305718712	2025-08-27	DS HIV 1/2 One Step Rapid Test	ZHEJIANG ORIENT GENE BIOTECH CO., LTD	Sensitivitas: 92.31 % Spesifitas: 100 %
27	PT. MITRASAMA YA SEJATI	AKL 30305801809	2025-02-10	ADVANCED QUALITY Rapid HIV Test Card (Serum/Plasma/Whole Blood)	INTEC PRODUCTS INC.	Sensitivitas: 98.68 % Spesifitas: 98.68 %
28	PT. ENSEVAL MEDIKA PRIMA	AKL 30305804208	2024-12-31	VIKIA[register] HIV 1/2	BIOMERIEUX SA.	Sensitivitas: 100 % Spesifitas: 100 %
29	PT. MITRASAMA YA SEJATI	AKL 30305805361	2025-02-11	ADVANCED QUALITY[register] Rapid Anti-HIV (1 & 2) Test Strip (Whole Blood/Serum/Plasma)	INTEC PRODUCTS INC.,P.R.	Sensitivitas: 100 % Spesifitas: 100 %
30	PT. EXXEL UTAMA	AKL 30305815193	2026-09-08	WONDFO One Step HIV 1/2 Whole Blood/Serum/Plasma Test Strip (2 lines)	GUANGZHOU WONDFO BIOTECH CO., LTD.	Sensitivitas: 100 % Spesifitas: 99.85 %
31	PT. CAKRA MEDIKA UTAMA	AKL 30305815196	2026-08-27	RAPIDAN TESTER Anti-HIV 1/2 Test ( WB/S/P)	TURKLAB TIBBI MALZEMELER SAN, TIC. A.S.	Sensitivitas: 100 % Spesifitas: 100 %
32	PT. EXXEL UTAMA	AKL 30305815341	2026-09-08	WONDFO One Step HIV 1/2 Whole Blood/Serum/Plasma Test Cassette (2 lines)	GUANGZHOU WONDFO BIOTECH CO., LTD.	Sensitivitas: 99.32 % Spesifitas: 100 %
33	PT. ONCOPROBE UTAMA	AKL 30305817111	2024-09-15	ONCOPROBE HIV 1&2 Antibody Rapid Test	FORMOSA BIOMEDICAL TECHNOLOGY	Sensitivitas: 100 % Spesifitas:



					CORP.	98.86 %
34	PT. WEGO MEDIKA INDONESIA	AKL 30305914705	2025-04-12	WEMED Rapid Test For Antibody to Human Immunodeficiency Virus (Colloidal Gold Device) Cassette	BEIJING WANTAI BIOLOGICAL PHARMACY ENTERPRISE CO.,LTD	Sensitivitas: 99.32 % Spesifitas: 100 %
35	PT. STANDARD BIOSENSOR INDONESIA	AKL 30305917113	2024-09-30	STANDARD [trademark] Q HIV 1/2 Ab 3- Line	SD BIOSENSOR INC.	Sensitivitas: 100 % Spesifitas: 100 %
36	PT. BINTANG MONO INDONESIA	AKL 30305917661	2024-05-02	ORIENT GENE HIV ½ One Step Rapid Test Cassette	ZHEJIANG ORIENT GENE BIOTECH CO., LTD.	Sensitivitas: 100 % Spesifitas: 100 %
37	PT. BINTANG MONO INDONESIA	AKL 30305917662	2024-07-09	HEALGEN HIV ½ Human Immunodeficiency Virus Rapid Test	ZHEJIANG ORIENT GENE BIOTECH CO., LTD.	Sensitivitas: 98.64 % Spesifitas: 99.43 %
38	PT. MEDQUEST JAYA GLOBAL	AKL 30305918579	2024-08-06	OraQuick Rapid HIV- 1/2 Antibody Test	PACIFIC BIOTECH CO., LTD	Sensitivitas: 94.52 % Spesifitas: 99.43 %

### RAPID HIV DALAM NEGERI

No	Nama Perusahaan	Nomor Izin Edar	Tanggal Expired	Nama Produk	Pabrik	Nilai Validitas
1	PT. ANUGRAH BESAR BERSAMA	AKD 30305320845	5/11/2024	WEGEN HIV 1/2 & Syphilis Combo Rapid Test	PT AGARINDO BIOLOGICAL COMPANY	Sensitivitas: 100% Spesifitas: 100%
2	PT. ARKANINDOPL AST UTAMA	AKD 30305321038	2024-08-27	ARKAN MEDICAL ONE STEP Anti-HIV (1/2) & Syphilis Test Combo (Colloidal Gold)	PT ARKANINDOPLAS T UTAMA	Sensitivitas: 100% Spesifitas: 95,83%
3	PT. ARKANINDOPL AST UTAMA	AKD 30305320926	6/21/2024	ARKAN MEDICAL ONE STEP Anti-HIV (1/2) Rapid Test (Colloidal Gold)	PT ARKANINDOPLAS T UTAMA	Sensitivitas: 100% Spesifitas: 95,83%
4	PT. ELVINCO MED TECH	AKD 30305321187	10/25/2024	EMTECH HIV 1/2 / Syphilis Combo	PT ELVINCO MED TECH	Sensitivitas: 100% Spesifitas: 100%
5	PT. ELVINCO MED TECH	AKD 30305321215	11/7/2024	EMTECH HIV 1/2 Ab	PT ELVINCO MED TECH	Sensitivitas: 99,24% Spesifitas: 100%
6	PT. ELVINCO MED TECH	AKD 30305321239	11/19/2024	EMTECH HCV Ab	PT ELVINCO MED TECH	Sensitivitas: 100% Spesifitas: 100%
7	PT. FOKUS DIAGNOSTIC INDONESIA	AKD 30305320838	5/8/2024	FOKUS HIV 1/2 3 Cassette	PT FOKUS DIAGNOSTIC INDONESIA	Sensitivitas: 100% Spesifitas: 100%
8	PT. GENBODY INDONESIA SEHAT	AKD 30305420089	3/6/2029	GB Rapid HIV 1/2	PT GENBODY INDONESIA SEHAT	Sensitivitas: 100% Spesifitas: 100%
9		AKD 30305910926	10/28/2024	GB Rapid HIV 1/2	PT GENBODY INDONESIA SEHAT	Sensitivitas: 99,32% Spesifitas:

	PT. GENBODY INDONESIA SEHAT					98,28%
10	PT. HEPATIKA MATARAM	AKD 30305510106	12/6/2024	ENTEBE ANTI HIV STRIP	PT HEPATIKA MATARAM	Sensitivitas: 98,03% Spesifitas: 98,3%
11	PT. HEPATIKA MATARAM	AKD 30305121015	5/20/2026	ENTEBE Anti HIV Cassette	PT HEPATIKA MATARAM	Sensitivitas: 98,68% Spesifitas: 98,86%
12	PT. INDEC DIAGNOSTICS	AKD 30305120300	2026-09-14	INDEC® HIV 1/2 & Syphilis Combo	PT INDEC DIAGNOSTICS	Sensitivitas: 977,99% Spesifitas: 98,86%
13	PT. INDEC DIAGNOSTICS	AKD 30305810065	2027-12-01	ViroCheck® HIV 1/2	PT INDEC DIAGNOSTICS	Sensitivitas: 100% Spesifitas: 100%
14	PT. GRAHA MEGATAMA INDONESIA	AKD 30305320988	7/28/2024	MEDLAB Rapid Test Anti Body HIV 1/2 Triline	PT INSIGHT MEDICA FAME	Sensitivitas: 100% Spesifitas: 100%
15	PT. INSIGHT MEDICA FAME	AKD 30305321020	8/20/2024	IMOQ Rapid Test Combo HIV/Sifilis	PT INSIGHT MEDICA FAME	Sensitivitas: 100% Spesifitas: 100%
16	PT. INSIGHT MEDICA FAME	AKD 30305321034	8/23/2024	IMOQ Rapid Test Ab HIV 1/2 Triline	PT INSIGHT MEDICA FAME	Sensitivitas: 100% Spesifitas: 100%
17	PT. INTERSKALA MEDIKA INDONESIA	AKD 30305320802	3/26/2029	IS HIV-1/2 Antibody Rapid Test	PT INTERSKALA MEDIKA INDONESIA	Sensitivitas: 100% Spesifitas: 100%
18	PT. INTERSKALA MEDIKA INDONESIA	AKD 30305321164	10/16/2028	IS HIV Duo (HIV + Syphilis) Rapid Test	PT INTERSKALA MEDIKA INDONESIA	Sensitivitas: 100% Spesifitas: 100%
19	PT. INTERSKALA MEDIKA INDONESIA	AKD 30305321186	10/24/2028	IS HIV Ab 3-Line Rapid Test	PT INTERSKALA MEDIKA INDONESIA	Sensitivitas: 99,24% Spesifitas: 100%
20	PT. INTERSKALA MEDIKA INDONESIA	AKD 30305420094	3/8/2029	G-SCIENTIFIC HIV Duo (HIV + Syphilis) Rapid Test	PT INTERSKALA MEDIKA INDONESIA	Sensitivitas: 100% Spesifitas: 100%
21	PT. INTERSKALA MEDIKA INDONESIA	AKD 30305420142	3/31/2029	MEDICHECK HIV Duo (HIV + Syphilis) Rapid Test	PT INTERSKALA MEDIKA INDONESIA	Sensitivitas: 100% Spesifitas: 100%
22	PT. INTERSKALA MEDIKA INDONESIA	AKD 30305420143	3/31/2029	MEDICHECK HIV Ab 3-Line Rapid Test	PT INTERSKALA MEDIKA INDONESIA	Sensitivitas: 99,24% Spesifitas: 100%
23	PT. INTERSKALA MEDIKA INDONESIA	AKD 30305320885	6/5/2024	DIAGNOSE HIV -1/2 Antibody Rapid Test	PT INTERSKALA MEDIKA INDONESIA	Sensitivitas: 100% Spesifitas: 100%
24	PT. INTERSKALA MEDIKA INDONESIA	AKD 30305320893	6/7/2024	MEDICHECK HIV -1/2 Antibody Rapid Test	PT INTERSKALA MEDIKA INDONESIA	Sensitivitas: 100% Spesifitas: 100%
25	PT. INTERSKALA MEDIKA INDONESIA	AKD 30305321039	8/27/2028	MKCELLS HIV -1/2 Antibody Rapid Test	PT INTERSKALA MEDIKA INDONESIA	Sensitivitas: 100% Spesifitas: Negatif

						Speciment: 100% Difficult Speciment: 91,67%
26	PT. INTERSKALA MEDIKA INDONESIA	AKD 30305321079	9/14/2028	G-SCIENTIFIC HIV -1/2 Antibody Rapid Test	PT INTERSKALA MEDIKA INDONESIA	Sensitivitas: 100% Spesifitas: 100%
27	PT. SETIA ANDALAN SUKSES	AKD 30305321184	11/11/2024	GENOMIC HIV -1/2 Antibody Rapid Test	PT INTERSKALA MEDIKA INDONESIA	Sensitivitas: 100% Spesifitas: 100%
28	PT. INTERSKALA MEDIKA INDONESIA	AKD 30305321272	12/7/2028	IS HIV 1/2 Combo (HIV + Syphilis) Rapid Test	PT INTERSKALA MEDIKA INDONESIA	Sensitivitas: 100% Spesifitas: 100%
29	PT. MITRA MEDIKA FARMA	AKD 30305321280	8/10/2025	VITROGEN HIV -1/2 Antibody Rapid Test	PT INTERSKALA MEDIKA INDONESIA	Sensitivitas: 100% Spesifitas: 100%
30	PT. SETIA ANDALAN SUKSES	AKD 30305420018	11/11/2024	GENOMIC HIV Ab 3-Line Rapid Test	PT INTERSKALA MEDIKA INDONESIA	Sensitivitas: 99,24% Spesifitas: 100%
31	PT. SETIA ANDALAN SUKSES	AKD 30305420021	1/17/2025	GENOMIC HIV Duo (HIV + Syphilis) Rapid Test	PT INTERSKALA MEDIKA INDONESIA	Sensitivitas: 100% Spesifitas: 100%
32	PT. INTERSKALA MEDIKA INDONESIA	AKD 30305420090	3/6/2029	G-SCIENTIFIC HIV Ab 3-Line Rapid Test	PT INTERSKALA MEDIKA INDONESIA	Sensitivitas: 99,24% Spesifitas: 100%
33	PT. INTERSKALA MEDIKA INDONESIA	AKD 30305420151	4/1/2029	MEDICHECK HIV 1/2 Combo (HIV + Syphilis) Rapid Test	PT INTERSKALA MEDIKA INDONESIA	Sensitivitas: 100% Spesifitas: 100%
34	PT. KIMIA FARMA TBK.	AKD 30305220499	2027-10-25	KIFATEST HIV 1/2 3.0 MD/25T	PT KIMIA FARMA TBK	Sensitivitas: 90,77% Spesifitas: 99,36%
35	PT. KIMIA FARMA	AKD 30305420052	1/31/2025	KIFATEST HIV 1/2 3.0	PT KIMIA FARMA TBK	Sensitivitas: 100% Spesifitas: 100%
36	PT. SANSICO NATURA RESOURCES	AKD 30305320786	3/24/2025	D3TEKS1 HIV & Syphilis Combo Antibody Rapid Test	PT MERAH PUTIH MANUFAKTURA	Sensitivitas: 100% Spesifitas: 100%
37	PT. SANSICO NATURA RESOURCES	AKD 30305320861	5/20/2024	d3TEKS1 HIV 1/2 Antibody Rapid Test (3 Lines)	PT MERAH PUTIH MANUFAKTURA	Sensitivitas: 100% Spesifitas: 100%
38	PT. SANSICO NATURA RESOURCES	AKD 30305321132	10/4/2024	EVERLIFE HIV & Syphilis Combo Antibody Rapid Test	PT MERAH PUTIH MANUFAKTURA	Sensitivitas: 100% Spesifitas: 100%
39	PT. SANSICO NATURA RESOURCES	AKD 30305420023	1/17/2025	EVERLIFE HIV 1/2 Antibody Rapid Test (3 Lines)	PT MERAH PUTIH MANUFAKTURA	Sensitivitas: 100% Spesifitas: 100%
40	PT. ONE-JECT INDONESIA	AKD 30305321016	8/16/2028	BIOQUICK HIV 1/2 3.0	PT ONE-JECT INDONESIA	Sensitivitas: 100% Spesifitas: 100%
41	PT. ONE-JECT INDONESIA	AKD 30305321026	8/22/2028	BIOQUICK HIV/Syphilis	PT ONE-JECT INDONESIA	Sensitivitas: 100%

				Duo		Spesifitas: 100%
42	PT. ONCOPROBE UTAMA	AKD 30305420152	10/5/2027	JB MED HIV Antibody	PT PAKAR BIOMEDIKA INDONESIA	Sensitivitas: 99,24% Spesifitas: 98,72%
43	PT. PAKAR BIOMEDIKA INDONESIA	AKD 30305320844	2024-05-11	UJI HIV-Sifilis Duo	PT PAKAR BIOMEDIKA INDONESIA	Sensitivitas: 99,33% Spesifitas: 98,86%
44	PT. PAKAR BIOMEDIKA INDONESIA	AKD 30305710380	2027-06-29	UJI HIV	PT PAKAR BIOMEDIKA INDONESIA	Sensitivitas: 99,33% Spesifitas: 98,86%
45	PT. PRODIA DIAGNOSTIC LINE	AKD 30305321167	10/17/2024	BPRO HIV/Syphilis Combo	PT PRODIA DIAGNOSTIC LINE	Sensitivitas: 100% Spesifitas: 99,68%
46	PT. STANDARD BIOSENSOR HEALTHCARE	AKD 30305129279	2027-09-14	FastClear Q HIV 1/2 Ab 3-Line	PT STANDARD BIOSENSOR HEALTHCARE	Sensitivitas: 95,38% Spesifitas: 99,68%
47	PT. STANDARD BIOSENSOR HEALTHCARE	AKD 30305220481	2027-10-18	FASTCLEAR Q HIV/Syphilis Combo	PT STANDARD BIOSENSOR HEALTHCARE	Sensitivitas: 98,45% Spesifitas: 100%
48	PT. TAISHAN ALKES INDONESIA	AKD 30305320777	3/19/2028	I-Test HIV 1.2 & Syphilis Combo Rapid Test	PT TAISHAN ALKES INDONESIA	Sensitivitas: 100% Spesifitas: 100%