



**KEMENTERIAN KESEHATAN REPUBLIK INDONESIA  
DIREKTORAT JENDERAL KEFARMASIAN DAN ALAT KESEHATAN**

Jalan H.R. Rasuna Said Blok X-5 Kavling 4-9 Jakarta 12950  
Telepon : (021) 5201590 Pesawat 2029, 8011  
Faksimile : (021) 5296-4838 Kotak Pos : 203



Nomor : FR.03.01/E.V/2084/2023

24 Oktober 2023

Lampiran : 1 (satu) berkas

Perihal : Permohonan Data Distributor 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/10053/2023 tanggal 18 Oktober 2023 perihal Permohonan data, bersama ini kami informasikan sebagai berikut:

1. Berdasarkan Undang-Undang Republik Indonesia Nomor 11 Tahun 2020 Tentang Cipta Kerja, Pasal 60 Beberapa ketentuan dalam Undang-Undang Nomor 36 Tahun 2009 tentang Kesehatan (Lembaran Negara Republik Indonesia Tahun 2009 Nomor 144, Tambahan Lembaran Negara Republik Indonesia Nomor 5063) diubah sebagai berikut: Ketentuan Pasal 106 diubah sehingga berbunyi sebagai berikut:
  - a. Setiap orang yang memproduksi dan atau mengedarkan sediaan farmasi dan alat kesehatan harus memenuhi Perizinan Berusaha dari Pemerintah Pusat atau Pemerintah Daerah sesuai dengan kewenangannya berdasarkan norma, standar, prosedur, dan kriteria yang ditetapkan oleh Pemerintah Pusat.
  - b. Sediaan farmasi dan alat kesehatan hanya dapat diedarkan setelah memenuhi Perizinan Berusaha dari Pemerintah Pusat atau Pemerintah Daerah sesuai dengan kewenangannya berdasarkan norma, standar, prosedur, dan kriteria yang ditetapkan oleh Pemerintah Pusat.
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 mengenai distributor alat kesehatan Distributor Reagen HIV dan nilai 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.

Plt. Direktur Produksi dan Distribusi Alat  
Kesehatan



**Ir. Sodikin Sadek, M.Kes**  
NIP 196212031986031004

## Lampiran 1

Nomor : FR.03.01/E.V/2084/2023

Tanggal : 24 Oktober 2023

## DAFTAR PRODUK REAGEN UNTUK PENENTUAN HIV

## REAGEN HIV

No	Nama Perusahaan	Nomor Izin Edar	Tanggal Expired	Nama Produk	Pabrik	Nilai Validitas
1	PT. ROCHE INDONESIA	AKL 30305701380	2024-04-26	COBAS[register] AmpliPrep/COBAS[register] TaqMan HIV-1 Test, V2.0	ROCHE MOLECULAR SYSTEMS INC.	Sensitivity: 100.0% Specificity: 99.3%
2	PT. EMERALINDO ASIA PASIFIK	AKL 30305220622	2024-06-21	VITROS Immunodiagnosti c Products HIV Combo Reagent Pack	ORTHO- CLINICAL DIAGNOSTICS	Sensitivity: 99.23% Specificity: 100.0%
3	PT. GRACIA VISI PRATAMA	AKL 30305320686	2024-09-30	Autobio HIV Ab/Ag Combo CLIA Microparticles	AUTOBIO DIAGNOSTIC CO.,LTD	Sensitivity: 99.20% Specificity: 99.04%
4	PT. ABBOTT PRODUCTS INDONESIA	AKL 30305813873	2024-11-05	ALINITY i HIV Ag/Ab Combo Reagent Kit	ABBOTT GMBH & CO. KG	Sensitivity: 100.0% Specificity: 100.0%
5	PT. ABBOTT PRODUCTS INDONESIA	AKL 30305214126	2024-11-05	ARCHITECT HIV Ag/Ab Combo Reagent Kit	ABBOTT GMBH & CO., KG.	Sensitivity: 100.0% Specificity: 94.32%
6	PT. ENSEVAL MEDIKA PRIMA	AKL 30305600643	2024-12-31	VIDAS[register] HIV DUO Ultra (HIV5)	BIOMERIEUX SA.	Sensitivity: 99.33% Specificity: 97.71%
7	PT. ENSEVAL MEDIKA PRIMA	AKL 30305804208	2024-12-31	VIKIA[register] HIV 1/2	BIOMERIEUX SA.	Sensitivity: 99.79% Specificity: 100%
8	PT. MEDQUEST JAYA GLOBAL	AKL 30305321006	2024-12-31	Xpert HIV-1 Qual XC	CEPHEID AB	Specificity :100.0%
9	PT. DIASTIKA BIOTEKINDO	AKL 30305113470	2025-01-01	MP Diagnostics HIV BLOT 2.2 Western Blot Assay	MP BIOMEDICALS ASIA PACIFIC PTE., LTD.	-
10	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.	sensitivity :100% specificity : 99.8%.
11	PT. MITRASAMAYA SEJATI	AKL 30305111259	2025-02-11	ADVANCED QUALITY HIV 1&2 ELISA Test Kit (3rd Generation)	INTEC PRODUCTS INC., (XIAMEN).	Specificity : 99.9%

12	PT.	AKL	2025-02-11	ADVANCED	INTEC	specificity : 100%
	MITRASAMAYA SEJATI	30305111261		QUALITY One Step Anti-HIV (1&2) Tri-Line Test Card	PRODUCTS INC.	Sensitivity : 100%
13	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.	Sensitivity : 95 % Specificity : 100%
14	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)	sensitivity : 100.0% Specificity : 99.74%
15	PT. MINDRAY MEDICAL INDONESIA	AKL 30305712719	2025-06-29	MINDRAY HIV Antigen and Antibodies to Human Immunodeficiency Virus (CLIA)	SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD.	Sensitivity : 100 % specificity : 99.8 %.
16	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.	Sensitivity : 100% Specificity : 99.75%
17	PT. ROCHE INDONESIA	AKL 30305220224	2025-07-06	Elecsys HIV Duo cobas e analyzers	ROCHE DIAGNOSTICS GMBH	Sensitivity : 100% Specificity : 100%
18	PT. ROCHE INDONESIA	AKL 30305220590	2025-07-06	COBAS Elecsys HIV Combi PT Elecsys and Cobas e Analyzers	ROCHE DIAGNOSTICS GMBH	specificity : 99.92 % sensitivity : 100%
19	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 %
20	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 Specifitas: 98.29%

21	PT. SETIA ANUGRAH MEDIKA	AKL 30305220292	2026-02-04	YHLO iFlash HIV Combo	SHENZHEN YHLO BIOTECH CO.,LTD	Sensitivitas: 99.23% Spesifitas: Negatif Speciment: 82.05%
22	PT. ROCHE INDONESIA	AKL 30305710379	2026-02-09	COBAS[register] Ampliprep/COBAS[register] TaqMan[register] HIV-1 Qualitative Test, v2.0 (HI2QCAP)	ROCHE MOLECULAR SYSTEM INC.	Sensitifitas : 100% Spesifitas : 99.8%
23	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%
24	PT. HARSAN LABORATORIES	AKL 30305321049	2026-05-17	MACCURA HIV Ag/Ab (CLIA)	MACCURA BIOTECHNOLOGY CO., LTD.	Sensitivitas: 99.22% Spesifitas: Negatif Speciment: 98.72%
25	PT. BIOMEDIKAL SCIENTIFIC INDONESIA	AKL 30305220452	2026-05-19	LIAISON[register] XL Murex HIV Ab/Ag HT	DIASORIN S.P.A	Sensitivitas: 97.69% Spesifitas: Negatif Speciment: 95.19%
26	PT. BIOMEDIKAL SCIENTIFIC INDONESIA	AKL 30305220599	2026-05-19	LIAISON[register] XL Murex HIV Ab/Ag	DIASORIN S.P.A	Sensitivitas: 99.23% Spesifitas: Negatif Speciment: 90.06%
27	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: Negatif Speciment: 94.89%
28	PT. ROCHE INDONESIA	AKL 30305220111	2026-12-15	Cobas HIV-1/HIV- 2 Qualitative	ROCHE MOLECULAR SYSTEMS, INC.	Sensitifitas : 100% Spesifitas : 100%
29	PT. ROCHE INDONESIA	AKL 30305220168	2026-12-15	COBAS[register] HIV-1 Quantitative nucleic acid test	ROCHE MOLECULAR SYSTEMS, INC.	Sensitifitas : 100% Spesifitas : 100%
30	PT. SINERGI UTAMA SEJAHTERA	AKL 30305710396	2026-12-31	ABBOTT RealTime HIV-1 Amplification Reagent Kit	ABBOTT MOLECULAR INC.	Sensitifitas : 100% Spesifitas : 99.3%
31	PT. SINERGI UTAMA SEJAHTERA	AKL 30305910109	2026-12-31	ABBOTT RealTime HIV-1 Amplification Reagent Kit	ABBOTT MOLECULAR INC.	Sensitifity : 95% Specificity : 99,5%
32	PT. SINERGI UTAMA SEJAHTERA	AKL 30305320942	2026-12-31	ABBOTT RealTime HIV-1 Qualitative Amplification Reagent Kit	ABBOTT MOLECULAR INC.,	Sensitifity : 95% Specificity : 100%
33	PT. ABBOTT PRODUCTS INDONESIA	AKL 30305220541	2027-01-21	Abbott Alinity m HIV-1 AMP Kit	ABBOTT MOLECULAR, INC.	Sensitifity : 95% Specificity : 100%

34	PT. ROCHE INDONESIA	AKL 30305220507	2027-04-28	COBAS MPX - 480	ROCHE MOLECULAR SYSTEMS, INC.	Sensitifity : 100% Specificity : 100%
35	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.	Sensitifity : 100% Specificity : 100%
36	PT. ANDAMAN MEDICAL INDONESIA	AKL 30305320722	2027-07-19	INNO-LIA HIV I/II Score	FUJIREBIO EUROPE N.V.	Sensitifity : 95% Specificity: 99,55%
37	PT. MEDQUEST JAYA GLOBAL	AKL 30305814261	2027-09-06	PROCLEIX Ultrio Elite Assay Discriminatory Probe Reagents	GRIFOLS DIAGNOSTIC SOLUTIONS INC.	Sensitifity : 100% Specificity : 100%
38	PT. MEDQUEST JAYA GLOBAL	AKL 30305813603	2027-09-19	PROCLEIX Ultrio Elite Assay Kit	GRIFOLS DIAGNOSTIC SOLUTIONS INC.	Sensitifity : 95% Specificity : 99,9%
39	PT. BIOMEDIKAL SCIENTIFIC INDONESIA	AKL 30305220419	2027-09-27	MUREX HIV Ag/Ab Combination	DIASORIN ITALIA S.P.A UK BRANCH	Sensitifity : 99,23% Specificity : 90,06%
40	PT. SYSMEX INDONESIA	AKL 30305516634	2028-01-16	SYSMEX HISCL HIV Ag+Ab Assay Kit	SYSMEX CORPORATIO N, SEISHIN FACTORY.	Sensitifity : 98,67% Specificity : 98,86%
41	PT. ROCHE INDONESIA	AKL 30305917680	2028-02-21	ELECSYS HIV Duo cobas e analyzers	ROCHE DIAGNOSTICS GMBH.	Sensitifity : 98,14% Specificity : 99,78%

#### RAPID HIV DALAM NEGERI

No	Nama Perusahaan	Nomor Izin Edar	Tanggal Expired	Nama Produk	Pabrik	Nilai Validitas
1	PT. PAKAR BIOMEDIKA INDONESIA	AKD 30305320844	2024-05-11	UJI HIV-Sifilis Duo	PT. PAKAR BIOMEDIKA INDONESIA	Sensitivitas: 99,24% Spesifitas: 98,72%
2	PT. ARKANINDOPLAST UTAMA	AKD 30305321038	2024-08-27	ARKAN MEDICAL ONE STEP Anti-HIV (1/2) & Syphilis Test Combo (Colloidal Gold)	PT. ARKANINDOPLAST UTAMA	Sensitivitas: 100% Spesifitas: 100%
3	PT. INDEC DIAGNOSTICS	AKD 30305120300	2026-09-14	INDEC® HIV 1/2 & Syphilis Combo	PT. INDEC DIAGNOSTICS	Sensitivitas: 97,99% Spesifitas: 98,86%
4	PT. PAKAR BIOMEDIKA INDONESIA	AKD 30305710380	2027-06-29	UJI HIV	PT. PAKAR BIOMEDIKA INDONESIA.	Sensitivitas: 99,33% Spesifitas: 98,86%
5	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%

6	PT. STANDARD BIOSENSOR HEALTHCARE	AKD 30305220481	2027-10-18	FASTCLEAR Q HIV/Syphilis Combo	PT. STANDARD BIOSENSOR HEALTHCARE	Sensitivitas: 98,45% Spesifitas: 100%
7	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%
8	PT. INDEC DIAGNOSTICS	AKD 30305810065	2027-12-01	ViroCheck® HIV 1/2	PT. INDEC DIAGNOSTICS	Sensitivitas: 100% Spesifitas: 100%
9	PT. PAKAR BIOMEDIKA INDONESIA	AKD 30305320844	2024-05-11	UJI HIV-Sifilis Duo	PT. PAKAR BIOMEDIKA INDONESIA	Sensitivitas: 99,24% Spesifitas: 98,72%

#### RAPID HIV LUAR NEGERI

No	Nama Perusahaan	Nomor Izin Edar	Tanggal Expired	Nama Produk	Pabrik	Nilai Validitas
1	PT. SARANA KARYA MEDIKA	AKL 30305021428	2026-02-01	STANDAREAGEN Diagnostic Kit for Antibody to Human Immunodeficiency Virus HIV 1 + 2	NANTONG EGENS BIOTECHNOLOGY CO., LTD.	Sensitivity: 100 % Specificity: 100 %
2	PT. SARANA KARYA MEDIKA	AKL 30305023057	2028-06-01	EGENS One Step Test Device HIV (1+2) Serum/Plasma Test Cassette	NANTONG EGENS BIOTECHNOLOGY CO., LTD.	Sensitivity: 100 % Specificity: 100 %
3	PT. MITRASAMA YA SEJATI	AKL 30305111261	2025-02-11	ADVANCED QUALITY One Step Anti-HIV (1&2) Tri-Line Test Card	INTEC PRODUCTS INC.	Sensitivity: 100 % Specificity: 99.43 %
4	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	Sensitivity: 100 % Specificity: 99.43 %
5	PT. BIOCARE SEJAHTERA	AKL 30305124662	2025-09-18	BIOCARE[register] Combo 4 (HBsAg, HCV, HIV, Syphilis) Rapid Test Device	ASSURE TECH (HANGZHOU) CO., LTD.	Sensitivity: 99.33 % Specificity: 98.86 %
6	PT. AKURAT INTAN MADYA	AKL 30305220211	2025-01-08	AIM HIV 1 / 2 Tripleline Rapid Test	XIAMEN BOSON BIOTECH CO, LTD	Sensitivity: 98 % Specificity: 99.43 %
7	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.	Sensitivity: 98.46 % Specificity: 99.68 %

8	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.	Sensitivity: 96.15 Specificity: 100 %
9	PT. BIOCARE SEJAHTERA	AKL 30305220649	2025-09-14	BIOCARE HIV 1+O/2 Antibody Rapid Test Device	ASSURE TECH (HANGZHOU) CO., LTD.	Sensitivity: 95.38 % Specificity: 99.68 %
10	PT. ALERE HEALTH	AKL 30305320708	2027-06-04	BIOLINE HIV 1/2 3.0	ABBOTT DIAGNOSTICS KOREA INC	Sensitivity: 100 % Specificity: 100 %
11	PT. ALERE HEALTH	AKL 30305320775	2027-06-04	Determine [tradermark] HIV Early Detect	ABBOTT DIAGNOSTICS MEDICAL CO., LTD	Sensitivity: 98.47 % Specificity: 99.68 %
12	PT. LANIROS DIAN PHARMA	AKL 30305320801	2027-10-11	JUSCHECK[register] HIV 1.2 Rapid Test Cassette	ACRO BIOTECH INC.	Sensitivity: 100 % Specificity: 100 %
13	PT. ALERE HEALTH	AKL 30305320812	2025-06-01	Determine [tradermark] HIV 1/2	ABBOTT DIAGNOSTICS MEDICAL CO., LTD	Sensitivity: 100 % Specificity: 100 %
14	PT. RAJAERBA INDOCHEM	AKL 30305320851	2026-08-25	OnSite HIV 1/2 Ab Plus Combo Rapid Test	CTK BIOTECH, INC.	Sensitivity: 100 % Specificity: 99.68 %
15	PT. ALERE HEALTH	AKL 30305320915	2027-06-04	BIOLINE HIV/Syphilis Duo	ABBOTT DIAGNOSTICS KOREA, INC	Sensitivity: 99.24 % Specificity: 100 %
16	PT. ALERE HEALTH	AKL 30305411636	2023-12-13	SD BIOLINE HIV 1/2 3.0	STANDARD DIAGNOSTICS INC.	Sensitivity: 100 % Specificity: 98.86 %
17	PT. MACROCITRA ARDANASEJA TI	AKL 30305513360	2027-10-23	RIGHTSIGN [register] HIV 1.2.O Rapid Test Cassette (Whole Blood/Serum/Plasma)	HANGZHOU BIOTEST BIOTECH CO., LTD.	Sensitivity: 100 % Specificity: 99.43 %
18	PT. ALERE HEALTH	AKL 30305515934	2027-06-04	SD BIOLINE HIV/Syphilis Duo	STANDARD DIAGNOSTICS, INC.	Sensitivity: 95.38 % Specificity: 99.68 %
19	PT. ALERE HEALTH	AKL 30305610110	2027-06-04	ALERE[tradermark] HIV Combo	ALERE MEDICAL CO., LTD.	Sensitivity: 96.15 % Specificity: 100 %



20	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.	Sensitivity: 99.33 % Specificity: 100%
21	PT. ALERE HEALTH	AKL 30305715499	2027-06-04	ABON[tradermark] HIV 1/2/O Tri-Line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma)	ABON BIOPHARM (HANGZHOU) CO., LTD.	Sensitivity: 100 % Specificity: 98.68 %
22	PT. ALERE HEALTH	AKL 30305717662	2027-06-04	ALERE Determine HIV-1/2	ALERE MEDICAL CO., LTD.	Sensitivity: 98.66 % Specificity: 100 %
23	PT. BINABAKTI NIAGAPERKA SA	AKL 30305718712	2025-08-27	DS HIV 1/2 One Step Rapid Test	ZHEJIANG ORIENT GENE BIOTECH CO., LTD	Sensitivity: 92.31 % Specificity: 100 %
24	PT. ADIWARA WORLDWIDE	AKL 30305718717	2023-12-31	RETROCHECK[register] HIV	QUALPRO DIAGNOSTICS.	Sensitivity: 96 % Specificity: 99.43 %
25	PT. MITRASAMA YA SEJATI	AKL 30305801809	2025-02-10	ADVANCED QUALITY Rapid HIV Test Card (Serum/Plasma/Whole Blood)	INTEC PRODUCTS INC.	Sensitivity: 98.68 % Specificity: 98.68 %
26	PT. ENSEVAL MEDIKA PRIMA	AKL 30305804208	2024-12-31	VIKIA[register] HIV 1/2	BIOMERIEUX SA.	Sensitivity: 100 % Specificity: 100 %
27	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.	Sensitivity: 100 % Specificity: 100 %
28	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.	Sensitivity: 100 % Specificity: 99.85 %
29	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.	Sensitivity: 100 % Specificity: 100 %
30	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.	Sensitivity: 99.32 % Specificity: 100 %
31	PT. ONCOPROBE UTAMA	AKL 30305817111	2024-09-15	ONCOPROBE HIV 1&2 Antibody Rapid Test	FORMOSA BIOMEDICAL TECHNOLOGY CORP.	Sensitivity: 100 % Specificity: 98.86 %

32	PT. GAPURA PIRANTI PRIMA	AKL 30305913620	2023-11-10	Cell ID Smart HIV 1/2 RDT	CELL ID PTE., LTD.	Sensitivity: 97.96 % Specificity: 98.86 %
33	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	Sensitivity: 99.32 % Specificity: 100 %
34	PT. STANDARD BIOSENSOR INDONESIA	AKL 30305917113	2024-09-30	STANDARD [tradermark] Q HIV 1/2 Ab 3-Line	SD BIOSENSOR INC.	Sensitivity: 100 % Specificity: 100 %
35	PT. BINTANG MONO INDONESIA	AKL 30305917661	2024-05-02	ORIENT GENE HIV 1/2 One Step Rapid Test Cassette	ZHEJIANG ORIENT GENE BIOTECH CO., LTD.	Sensitivity: 100 % Specificity: 100 %
36	PT. BINTANG MONO INDONESIA	AKL 30305917662	2024-07-09	HEALGEN HIV 1/2 Human Immunodefficiency Virus Rapid Test	ZHEJIANG ORIENT GENE BIOTECH CO., LTD.	Sensitivity: 98.64 % Specificity: 99.43 %
37	PT. MEDQUEST JAYA GLOBAL	AKL 30305918579	2024-08-06	OraQuick Rapid HIV- 1/2 Antibody Test	PACIFIC BIOTECH CO., LTD	Sensitivity: 94.52 % Specificity: 99.43 %

Plt. Direktur Produksi dan Distribusi Alat  
Kesehatan,



**Ir. Sodikin Sadek, M.Kes**  
NIP 196212031986031004