

Nomor : FR.03.01/E.V/0580/2025
Lampiran : 1 (Satu) berkas
Hal : *Update* Daftar Hasil Uji Validitas
Reagen HIV

23 April 2025

Yth. Direktur Penyakit Menular

Sehubungan dengan surat kami sebelumnya dengan nomor FR.03.01/E.V/0524/2025 tanggal 10 April 2025 perihal Permohonan Daftar Hasil Uji Validitas Reagen HIV, bersama ini kami sampaikan ***update* daftar izin edar Alat Kesehatan Diagnostik In Vitro Dalam Negeri dan Impor untuk pemeriksaan HIV yang masih berlaku berikut hasil uji validitasnya.**

Demikian keterangan ini kami sampaikan, atas perhatian dan kerjasamanya kami ucapkan terima kasih.

Direktur Produksi dan Distribusi Alat
Kesehatan,



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

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

Lampiran 1

Nomor : FR.03.01/E.V/0580/2025

Tanggal : 23 April 2025

1. Reagen CLIA Dalam Negeri untuk Deteksi HIV

No	Nomor Izin Edar	Tgl Exp	Nama Produk	Pendaftar	Produsen	Nilai Validitas	Laboratorium Uji
1	AKD 30305420306	2/7/2029	VIRTUEDX CS HIV Ag/Ab Combo Reagent Kit	PT VIRTUE DIAGNOSTICS INDONESIA	PT VIRTUE DIAGNOSTICS INDONESIA	Sensitivitas: 100% Spesifisitas: 100%	RSUD dr. Chasbullah Abdulmadjid Kota Bekasi

2. Rapid Test Dalam Negeri untuk Deteksi HIV

No	Nomor Izin Edar	Tgl Exp	Nama Produk	Pendaftar	Produsen	Nilai Validitas	Laboratorium Uji
1	AKD 30305120300	14-09-2026	INDECA® HIV 1/2 & Syphilis Combo	PT INDEC DIAGNOSTICS	PT INDEC DIAGNOSTICS	Sensitivitas: 97,99% Spesifisitas: 98,86%	RSCM
2	AKD 30305120300	14-09-2026	INDECA® HIV 1/2 & Syphilis Combo	PT INDEC DIAGNOSTICS	PT INDEC DIAGNOSTICS	Sensitivitas: 97,99% Spesifisitas: 98,86%	RSCM
3	AKD 30305810065	1/12/2027	VIROCHECK® HIV 1/2	PT INDEC DIAGNOSTICS	PT INDEC DIAGNOSTICS	Sensitivitas: 97,99% Spesifisitas: 98,86%	RSCM
4	AKD 30305321167	28-10-2029	BPRO HIV/Syphilis Combo	PT PRODIA DIAGNOSTIC LINE	PT PRODIA DIAGNOSTIC LINE	Sensitivitas: 100% Spesifisitas: 99,68%	RSCM
5	AKD 30305710380	29-06-2027	UJI HIV	PT PAKAR BIOMEDIKA INDONESIA	PT PAKAR BIOMEDIKA INDONESIA	Sensitivitas: 99,33% Spesifisitas: 98,86%	RSCM
6	AKD 30305320844	30-04-2029	UJI HIV-Sifilis Duo	PT PAKAR BIOMEDIKA INDONESIA	PT PAKAR BIOMEDIKA INDONESIA	Sensitivitas: 99,24% Spesifisitas: 98,72%	RSCM
7	AKD 30305520134	26-02-2029	QUALITY ACCESS® HIV Test Cassette (Whole Blood /Serum/Plasma)	PT BUANA MITRA SUKSES	PT PAKAR BIOMEDIKA INDONESIA	Sensitivitas: 99,33% Spesifisitas: 98,86%	RSCM
8	AKD 30305321026	22-08-2028	BIOQUICK HIV/Syphilis Duo	PT ONE-JECT INDONESIA	PT ONE-JECT INDONESIA	Sensitivitas: 96%	BBLK Jakarta

No	Nomor Izin Edar	Tgl Exp	Nama Produk	Pendaftar	Produsen	Nilai Validitas	Laboratorium Uji
						Spesifisitas: 100%	
9	AKD 30305321016	16-08-2028	BIOQUICK Â® HIV 1/2 3.0	PT ONE-JECT INDONESIA	PT ONE-JECT INDONESIA	Sensitivitas: 100% Spesifisitas: 100%	BBLK Jakarta
10	AKD 30305420152	5/10/2027	JB MED HIV Antibody	PT ONCOPROBE UTAMA	PT PAKAR BIOMEDIKA INDONESIA	Sensitivitas: 99,33% Spesifisitas: 98,86%	RSCM
11	AKD 30305520093	8/8/2029	ONCOPROBE HIV Antibody Rapid Test	PT ONCOPROBE UTAMA	PT GENBODY INDONESIA SEHAT	Sensitivitas: 100% Spesifisitas: 100%	RSCM
12	AKD 30305121015	20-05-2026	ENTEBE Anti HIV Cassette	PT HEPATIKA MATARAM	PT HEPATIKA MATARAM	Sensitivitas: 98,68% Spesifisitas: 98,86%	Dinas Kesehatan Balai Laboratorium Kesehatan Pengujian dan Kalibrasi (NTB)
13	AKD 30305510106	4/12/2029	ENTEBE Anti-HIV Strip	PT HEPATIKA MATARAM	PT HEPATIKA MATARAM	Sensitivitas: 98,03% Spesifisitas: 98,30%	RSCM
14	AKD 30305420250	1/8/2027	BIOCARE HIV 1+2 Antibody Rapid Test Device	PT BIOCARE SEJAHTERA	PT PROVITAL PERDANA	Sensitivitas: 100% Spesifisitas: 99,36%.	RSCM
15	AKD 30305520159	1/8/2027	BIOCARE Combo 3 (HIV, SYP, HBsAg) Rapid Test Device	PT BIOCARE SEJAHTERA	PT PROVITAL PERDANA	Sensitivitas: 100% Spesifisitas: 99,36%.	RSCM
16	AKD 30305320988	24-05-2028	MEDLAB Rapid Test Anti Body HIV 1/2 Triline	PT GRAHA MEGATAMA INDONESIA	PT INSIGHT MEDICA FAME	Sensitivitas: 100% Spesifisitas: 100%	RSCM
17	AKD 30305420089	6/3/2029	GB Rapid HIV 1/2	PT GENBODY INDONESIA SEHAT	PT GENBODY INDONESIA SEHAT	Sensitivitas: 100% Spesifisitas: 100%	RSUP Dr Hasan Sadikin Bandung
18	AKD 30305420219	15-05-2029	GB Rapid HIV/Syphilis Combo	GENBODY INDONESIA SEHAT	PT GENBODY INDONESIA SEHAT	Sensitivitas: 100% Spesifisitas: 100%	RSUP Dr Hasan Sadikin Bandung
19	AKD 30305321020	5/8/2029	IMOQ Rapid Test Combo HIV/Sifilis	PT INSIGHT MEDICA FAME	PT INSIGHT MEDICA FAME	Sensitivitas: 100% Spesifisitas: 100%	RSCM

No	Nomor Izin Edar	Tgl Exp	Nama Produk	Pendaftar	Produsen	Nilai Validitas	Laboratorium Uji
20	AKD 30305321034	5/8/2029	IMOQ Rapid Test Ab HIV 1/2 Triline	PT INSIGHT MEDICA FAME	PT INSIGHT MEDICA FAME	Sensitivitas: 100% Spesifisitas: 100%	RSCM
21	AKD 30305321132	31-07-2029	EVERLIFE HIV & Syphilis Combo Antibody Rapid Test	PT SANSICO NATURA RESOURCES	PT MERAH PUTIH MANUFAKTURA	Sensitivitas: 100% Spesifisitas: 100%	RSCM
22	AKD 30305420023	22-04-2027	EVERLIFE HIV 1/2 Antibody Rapid Test (3 Lines)	PT SANSICO NATURA RESOURCES	PT MERAH PUTIH MANUFAKTURA	Sensitivitas: 100% Spesifisitas: 100%	RSCM
23	AKD 30305320786	20-04-2027	D3TEKS1 HIV & Syphilis Combo Antibody Rapid Test	PT SANSICO NATURA RESOURCES	PT MERAH PUTIH MANUFAKTURA	Sensitivitas: 100% Spesifisitas: 100%	RSCM
24	AKD 30305420405	6/8/2027	D3TEKS1 [®] HIV 1/2 Antibody Rapid Test (3 Lines)	PT SANSICO NATURA RESOURCES	PT MERAH PUTIH MANUFAKTURA	Sensitivitas: 100% Spesifisitas: 100%	RSCM
25	AKD 30305321039	27-08-2028	MKCELLS HIV -1/2 Antibody Rapid Test	INTERSKALA MEDIKA INDONESIA	PT INTERSKALA MEDIKA INDONESIA	Sensitivitas: 100% Spesifisitas: 100%	RSCM
26	AKD 30305321079	14-09-2028	G-SCIENTIFIC HIV -1/2 Antibody Rapid Test	PT INTERSKALA MEDIKA INDONESIA	PT INTERSKALA MEDIKA INDONESIA	Sensitivitas: 100% Spesifisitas: 100%	RSCM
27	AKD 30305321164	16-10-2028	IS HIV Duo (HIV + Syphilis) Rapid Test	PT INTERSKALA MEDIKA INDONESIA	PT INTERSKALA MEDIKA INDONESIA	Sensitivitas: 100% Spesifisitas: 100%	RSCM
28	AKD 30305321186	24-10-2028	IS HIV Ab 3-Line Rapid Test	PT INTERSKALA MEDIKA INDONESIA	PT INTERSKALA MEDIKA INDONESIA	Sensitivitas: 99,24% Spesifisitas: 100%	RSCM
29	AKD 30305321272	7/12/2028	IS HIV 1/2 Combo (HIV + Syphilis) Rapid Test	PT INTERSKALA MEDIKA INDONESIA	PT INTERSKALA MEDIKA INDONESIA	Sensitivitas: 100% Spesifisitas: 100%	RSCM
30	AKD 30305420094	8/3/2029	G-SCIENTIFIC HIV Duo (HIV + Syphilis) Rapid Test	PT INTERSKALA MEDIKA INDONESIA	PT INTERSKALA MEDIKA INDONESIA	Sensitivitas: 100% Spesifisitas: 100%	RSCM
31	AKD 30305420090	6/3/2029	G-SCIENTIFIC HIV Ab 3-Line Rapid Test	PT INTERSKALA MEDIKA INDONESIA	PT INTERSKALA MEDIKA INDONESIA	Sensitivitas: 99,24% Spesifisitas: 100%	RSCM

No	Nomor Izin Edar	Tgl Exp	Nama Produk	Pendaftar	Produsen	Nilai Validitas	Laboratorium Uji
32	AKD 30305420142	31-03-2029	MEDICHECK HIV Duo (HIV + Syphilis) Rapid Test	PT INTERSKALA MEDIKA INDONESIA	PT INTERSKALA MEDIKA INDONESIA	Sensitivitas: 100% Spesifisitas: 100%	RSCM
33	AKD 30305420151	1/4/2029	MEDICHECK HIV 1/2 Combo (HIV + Syphilis) Rapid Test	PT INTERSKALA MEDIKA INDONESIA	PT INTERSKALA MEDIKA INDONESIA	Sensitivitas: 100% Spesifisitas: 100%	RSCM
34	AKD 30305420143	31-03-2029	MEDICHECK HIV Ab 3-Line Rapid Test	INTERSKALA MEDIKA INDONESIA	PT INTERSKALA MEDIKA INDONESIA	Sensitivitas: 99,24% Spesifisitas: 100%	RSCM
35	AKD 30305320802	26-03-2029	IS HIV-1/2 Antibody Rapid Test	PT INTERSKALA MEDIKA INDONESIA	PT INTERSKALA MEDIKA INDONESIA	Sensitivitas: 100% Spesifisitas: 100%	RSCM
36	AKD 30305320885	6/6/2029	DIAGNOSE HIV -1/2 Antibody Rapid Test	PT INTERSKALA MEDIKA INDONESIA	PT INTERSKALA MEDIKA INDONESIA	Sensitivitas: 100% Spesifisitas: 100%	RSCM
37	AKD 30305320893	6/6/2029	MEDICHECK HIV -1/2 Antibody Rapid Test	PT INTERSKALA MEDIKA INDONESIA	PT INTERSKALA MEDIKA INDONESIA	Sensitivitas: 100% Spesifisitas: 100%	RSCM
38	AKD 30305420403	5/9/2029	DIAGNOSE HIV Duo (HIV + Syphilis) Rapid Test	PT INTERSKALA MEDIKA INDONESIA	PT INTERSKALA MEDIKA INDONESIA	Sensitivitas: 100% Spesifisitas: 100%	RSCM
39	AKD 30305420404	5/9/2029	DIAGNOSE HIV Ab 3-Line Rapid Test	PT INTERSKALA MEDIKA INDONESIA	PT INTERSKALA MEDIKA INDONESIA	Sensitivitas: 99,24% Spesifisitas: 100%	RSCM
40	AKD 30305420395	1/9/2029	MKCELLS HIV Duo (HIV + Syphilis) Rapid Test	PT INTERSKALA MEDIKA INDONESIA	PT INTERSKALA MEDIKA INDONESIA	Sensitivitas: 100% Spesifisitas: 100%	RSCM
41	AKD 30305420408	8/9/2029	MKCELLS HIV Ab 3-Line Rapid Test	PT INTERSKALA MEDIKA INDONESIA	PT INTERSKALA MEDIKA INDONESIA	Sensitivitas: 99,24% Spesifisitas: 100%	RSCM
42	AKD 30305520221	23-03-2030	DIAGNOSE HIV 1/2 Combo (HIV + Syphilis) Rapid Test	PT INTERSKALA MEDIKA INDONESIA	PT INTERSKALA MEDIKA INDONESIA	Sensitivitas: 100% Spesifisitas: 100%	RSCM
43	AKD 30305320777	19-03-2028	I-Test HIV 1.2 & Syphilis Combo Rapid Test	PT TAISHAN ALKES INDONESIA	PT TAISHAN ALKES INDONESIA	Sensitivitas: 100% Spesifisitas: 100%	RSCM

No	Nomor Izin Edar	Tgl Exp	Nama Produk	Pendaftar	Produsen	Nilai Validitas	Laboratorium Uji
44	AKD 30305129279	14-09-2027	FASTCLEAR Q HIV 1/2 Ab 3-Line	PT STANDARD BIOSENSOR HEALTHCARE	PT STANDARD BIOSENSOR HEALTHCARE	Sensitivitas: 95,38% Spesifisitas: 99,68%	RSCM
45	AKD 30305220481	18-10-2027	FASTCLEAR Q HIV/Syphilis Combo	PT STANDARD BIOSENSOR HEALTHCARE	PT STANDARD BIOSENSOR HEALTHCARE	Sensitivitas: 98,45% Spesifisitas: 100%	RSCM
46	AKD 30305420489	15-05-2027	TAMATECH HIV-1/2 Antibody Rapid Test	PT MULTI NIAGA MITRATAMA	PT INTERSKALA MEDIKA INDONESIA	Sensitivitas: 100% Spesifisitas: 100%	RSCM
47	AKD 30305520117	15-05-2027	TAMATECH HIV 1/2 Combo (HIV + Syphilis) Rapid Test	PT MULTI NIAGA MITRATAMA	PT INTERSKALA MEDIKA INDONESIA	Sensitivitas: 100% Spesifisitas: 100%	RSCM
48	AKD 30305321280	10/8/2025	VITROGEN HIV -1/2 Antibody Rapid Test	PT MITRA MEDIKA FARMA	PT INTERSKALA MEDIKA INDONESIA	Sensitivitas: 100% Spesifisitas: 100%	RSCM
49	AKD 30305321187	29-09-2029	EMTECH HIV 1/2 / Syphilis Combo	PT ELVINCO MED TECH	PT ELVINCO MED TECH	Sensitivitas: 100% Spesifisitas: 100%	RSCM
50	AKD 30305321215	7/10/2029	EMTECH HIV 1/2 Ab	PT ELVINCO MED TECH	PT ELVINCO MED TECH	Sensitivitas: 100% Spesifisitas: 100%	RSCM
51	AKD 30305420468	3/10/2029	ONE DIAGNOSTIC HIV 1/2 Ab Rapid Test	PT RAPID INTI INDONESIA	PT RAPID INTI INDONESIA	Sensitivitas: 100% Spesifisitas: 100%	RSCM
52	AKD 30305520200	19-03-2030	RAPINDO HIV Screen Rapid Test Device	PT TULIP DIAGNOSTICS INDONESIA	PT TULIP DIAGNOSTICS INDONESIA	Sensitivitas: 100% Spesifisitas: 100%	BBLK Jakarta
53	AKD 30305520086	9/2/2030	GENOTEST Rapid Test HIV 1.2/Syphilis Combo	PT MUGI BERKAH BIOTEKNOLOGI	PT MUGI BERKAH BIOTEKNOLOGI	Sensitivitas: 100% Spesifisitas: 100%	Pusat Riset Bioteknologi Molekuler dan Bioinformatika, Universitas Padjadjaran
54	AKD 30305520198	20-12-2027	INDOCHECK HIV 1/2 Combo (HIV + Syphilis) Rapid Test	PT ARKAN JAYA NUSANTARA	PT INTERSKALA MEDIKA INDONESIA	Sensitivitas: 100% Spesifisitas: 100%	RSCM
55	AKD	20-12-2027	INDOCHECK HIV	PT ARKAN JAYA	PT INTERSKALA	Sensitivitas:	RSCM

No	Nomor Izin Edar	Tgl Exp	Nama Produk	Pendaftar	Produsen	Nilai Validitas	Laboratorium Uji
	30305520236		Duo (HIV + Syphilis) Rapid Test	NUSANTARA	MEDIKA INDONESIA	100% Spesifisitas: 100%	
56	AKD 30305520237	20-12-2027	INDOCHECK HIV Ab 3-Line Rapid Test	PT ARKAN JAYA NUSANTARA	PT INTERSKALA MEDIKA INDONESIA	Sensitivitas: 99,24% Spesifisitas: 100%	RSCM
57	AKD 30305520199	18-11-2029	CHRONACARE Rapid Test Anti Body HIV 1/2	PT BUANA INTIPRIMA USAHA	PT INSIGHT MEDICA FAME	Sensitivitas: 100% Spesifisitas: 100%	RSCM
58	AKD 30305321184	11/11/2027	GENOMIC HIV -1/2 Antibody Rapid Test	PT SETIA ANDALAN SUKSES	PT INTERSKALA MEDIKA INDONESIA	Sensitivitas: 100% Spesifisitas: 100%	RSCM
59	AKD 30305420018	11/11/2027	GENOMIC HIV Ab 3-Line Rapid Test	PT SETIA ANDALAN SUKSES	PT INTERSKALA MEDIKA INDONESIA	Sensitivitas: 99,24% Spesifisitas: 100%	RSCM
60	AKD 30305220499	25-10-2027	KIFATEST HIV 1/2 3.0 MD/25T	KIMIA FARMA Tbk	PT KIMIA FARMA TBK	Sensitivitas: 90,77% Spesifisitas: 99,36%	RSCM
61	AKD 30305420466	1/10/2029	ARKAN MEDICAL ONE STEP Anti-HIV (1/2) Rapid Test (Colloidal Gold)	PT ARKANINDOPLAST UTAMA	PT ARKANINDOPLAST UTAMA	Sensitivitas: 100% Spesifisitas: 100%	RSCM
62	AKD 30305520087	9/2/2030	ARKAN MEDICAL ONE STEP Anti-HIV (1/2) & Syphilis Test Combo (Colloidal Gold)	PT ARKANINDOPLAST UTAMA	PT ARKANINDOPLAST UTAMA	Sensitivitas: 100% Spesifisitas: 100%	RSCM

3. Reagen Luar Negeri untuk Deteksi HIV

No	Nomor Izin Edar	Tgl Exp	Nama produk	Pendaftar	Produsen	Nilai Validitas	Laboratorium Uji
1	AKL 30305813873	10/01/2029	ALINITY i HIV Ag/Ab Combo Reagent	PT. ABBOTT PRODUCTS INDONESIA	ABBOTT GMBH	*Sensitivitas: 99.24% Spesifisitas: 96.13%	RSCM
2	AKL 30305214126	09/01/2029	ARCHITECT HIV Ag/Ab Combo Reagent Kit	PT. ABBOTT PRODUCTS INDONESIA	ABBOTT GmbH	*Sensitivitas: 99.24% Spesifisitas: 96.13%	RSCM

No	Nomor Izin Edar	Tgl Exp	Nama produk	Pendaftar	Produsen	Nilai Validitas	Laboratorium Uji
3	AKL 30305320812	15/01/2029	Determine [tradermark] HIV 1/2	PT. ALERE HEALTH	ABBOTT DIAGNOSTICS MEDICAL CO., LTD	*Sensitifitas: 100% Spesifisitas: 100%	RSCM
4	AKL 30305320775	04/06/2027	DETERMINE [tradermark] HIV Early Detect	PT. ALERE HEALTH	ABBOTT DIAGNOSTICS MEDICAL CO., LTD	*Sensitifitas: 98.47% Spesifisitas: 99.68%	RSCM
5	AKL 30305320708	04/06/2027	BIOLINE HIV 1/2 3.0	PT. ALERE HEALTH	ABBOTT DIAGNOSTICS KOREA INC	**Sensitifitas: 100% Spesifisitas: 99.8%	-
6	AKL 30305717662	04/06/2027	ALERE Determine HIV-1/2	PT. ALERE HEALTH	ALERE MEDICAL CO., LTD.	*Sensitifitas : 98.66% Spesifisitas: 100%	RSCM
7	AKL 30305420608	13/08/2029	BIO-RAD Genscreen ULTRA HIV Ag- Ab	PT. ANDAMAN MEDICAL INDONESIA	BIO-RAD (STEENVOORDE)	*Sensitifitas: 100% Spesifisitas: 97,44%	RSCM
8	AKL 30305420575	13/08/2029	Geenius HIV 1/2 Confirmatory Assay	PT. ANDAMAN MEDICAL INDONESIA	BIO-RAD	*Sensitifitas: - Spesifisitas: 99,68%	RSCM
9	AKL 30305320722	19/07/2027	INNO-LIA HIV I/II Score	PT. ANDAMAN MEDICAL INDONESIA	FUJIREBIO EUROPE N.V.	*Sensitivitas: - Spesifisitas: 100%	RSCM
10	AKL 30305420658	23/10/2028	RealBest HBV/HCV/HIV PCR	PT. BIOCARE SEJAHTERA	AO VECTOR-BEST	*Sensitifitas: 100% Spesifisitas: 100%	RSCM
11	AKL 30305520057	30/09/2025	Aptima® HIV-1 Quant Dx Assay	PT. BIOMEDIKAL SCIENTIFIC INDONESIA	HOLOGIC, INC	*Sensitifitas: 100% Spesifisitas: 100%	UNPAD
12	AKL 30305420626	27/09/2027	LIAISON® XL Murex HIV Ab/Ag HT	PT. BIOMEDIKAL SCIENTIFIC INDONESIA	DIASORIN ITALIA S.P.A	*Sensitifitas: 100% Spesifisitas: 94,25%	RSCM
13	AKL 30305220599	19/05/2026	LIAISON[register] XL Murex HIV Ab/Ag	PT. BIOMEDIKAL SCIENTIFIC INDONESIA	DIASORIN ITALIA S.P.A.	*Sensitifitas: 97.69% Spesifisitas: 95.19%	RSCM
14	AKL 30305220419	27/09/2027	MUREX HIV Ag/Ab Combination	PT. BIOMEDIKAL SCIENTIFIC INDONESIA	DIASORIN ITALIA S.P.A UK BRANCH	*Sensitifitas: 99.23% Spesifisitas: 90.06%	RSCM
15	AKL 30305420434	08/05/2027	AccuPower® HIV-1	PT. BIONEER INDIKA	BIONEER CORPORATION	*Sensitifitas: 99.15%	RSK Dharmais

No	Nomor Izin Edar	Tgl Exp	Nama produk	Pendaftar	Produsen	Nilai Validitas	Laboratorium Uji
			Quantitative RT - PCR Kit	DIAGNOSTIK		Spesifisitas: 96.25%	
16	AKL 30305321205	10/02/2026	Access HIV combo V2	PT. DHH TRADING INDONESIA	BIO-RAD	*Sensitifitas : 99.24% Spesifisitas : 97.12%	RSCM
17	AKL 30305113470	31/12/2026	MP Diagnostics HIV BLOT 2.2 Western Blot Assay	PT. DIASTIKA BIOTEKINDO	MP BIOMEDICALS ASIA PACIFIC PTE., LTD.	**Sensitivitas HIV 1 Blot 2.2 : GAG, POL and ENV 97.5%; p24, p31, gp41 and/or gp120/gp160 94.9%; ENV and GAG or POL 100.0%	-
18	AKL 30305520089	17/11/2028	DIRUI HIV Ag + Ab (CLIA)	PT. DIRUI MEDICAL INDONESIA	DIRUI INDUSTRIAL CO., LTD.	*Sensitifitas: 99.24% Spesifisitas: 98.08%	RSCM
19	AKL 30305220622	24/02/2028	VITROS Immunodiagnostic Products HIV Combo Reagent Pack	PT. EMERALINDO ASIA PASIFIK	ORTHO-CLINICAL DIAGNOSTICS	*Sensitivitas: 99.23% Spesifisitas: 100%	RSCM
20	AKL 30305600643	31/12/2028	VIDAS[register] HIV DUO Ultra (HIV5)	PT. ENSEVAL MEDIKA PRIMA	BIOMERIEUX SA.	*Sensitifitas: 100% Spesifisitas: 99.04%	RSCM
21	AKL 30305320686	01/10/2027	Autobio HIV Ab/Ag Combo CLIA Microparticles	PT. GRACIA VISI PRATAMA	AUTOBIO DIAGNOSTIC CO.,LTD	*Sensitifitas: 99.20% Spesifisitas: 99.04%	RSCM
22	AKL 30305321219	23/11/2027	VIRIDICT 4 DEVICE	PT. GRAVIA CITRA LESTARI	QUALPRO DIAGNOSTICS A DIVISION OF TULIP DIAGNOSTICS	*Sensitivitas: 99.24% Spesifisitas: 100%	RSCM
23	AKL 30305321049	17/05/2026	MACCURA HIV Ag/Ab (CLIA)	PT. HARSEN LABORATORIES	MACCURA BIOTECHNOLOGY CO., LTD.	*Sensitifitas : 99.22% Spesifisitas : 98.72%	RSCM
24	AKL 30305321006	31/12/2025	Xpert HIV-1 Qual XC	PT. MEDQUEST JAYA GLOBAL	CEPHEID AB	**Sensitifitas: 95-100% Spesifisitas: 100%	-

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25	AKL 30305813603	19/09/2027	PROCLEIX Ultrio Elite Assay Kit	PT. MEDQUEST JAYA GLOBAL	GRIFOLS DIAGNOSTIC SOLUTIONS INC.	**Sensitifitas: 100% Spesifisitas : 100%	-
26	AKL 30305420275	18/10/2025	PROCLEIX UltrioPlex E Assay	PT. MEDQUEST JAYA GLOBAL	GRIFOLS DIAGNOSTIC SOLUTIONS INC	**Sensitifitas: 100% Spesifisitas : 100%	-
27	AKL 30305712719	29/06/2025	MINDRAY HIV Antigen and Antibodies to Human Immunodeficiency Virus (CLIA)	PT. MINDRAY MEDICAL INDONESIA	SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD.	*Sensitivitas: 99.24 % Spesifitas: 100 %	RSCM
28	AKL 30305715936	31/12/2025	MAGLUMI HIV Ab/Ag Combi (CLIA)	PT. MULTIMEDILAB KARYAMANDIRI	SHENZHEN NEW INDUSTRIES BIOMEDICAL ENGINEERING CO., LTD.	*Sensitivitas: 99.22 % Spesifisitas: 98.08 %	RSCM
29	AKL 30305220224	05/11/2029	Elecsys HIV Duo cobas e analyzers	PT. ROCHE INDONESIA	ROCHE DIAGNOSTICS GMBH	*Sensitifitas: 98.46% Spesifisitas: 97.12%	RSCM
30	AKL 30305220590	23/10/2029	COBAS Elecsys HIV Combi PT Elecsys and Cobas e Analyzers	PT. ROCHE INDONESIA	ROCHE DIAGNOSTICS GMBH	*Sensitifitas: 99.23% Spesifisitas: 99.04%	RSCM
31	AKL 30305917680	21/02/2028	ELECSYS HIV Duo cobas e analyzers	PT. ROCHE INDONESIA	ROCHE DIAGNOSTICS GMBH.	*Sensitifitas: 99,24% Spesifisitas: 98,40%	RSCM
32	AKL 30305420536	01/04/2029	COBAS[register] MPX	PT. ROCHE INDONESIA	ROCHE MOLECULAR SYSTEMS, INC.	**Sensitifitas: 100% Spesifisitas: 100%	-
33	AKL 30305220507	28/04/2027	COBAS MPX - 480	PT. ROCHE INDONESIA	ROCHE MOLECULAR SYSTEMS, INC.	**Sensitivitas: 99.9% Spesifisitas: 99.95%	-
34	AKL 30305220111	15/12/2026	Cobas HIV-1/HIV-2 Qualitative	PT. ROCHE INDONESIA	ROCHE MOLECULAR SYSTEMS, INC.	**Sensitifitas: 100% Spesifisitas: 100%	-
35	AKL 30305811059	17/05/2027	COBAS MPX Multiplex HIV, HCV & HBV nucleic acid test for use on the	PT. ROCHE INDONESIA	ROCHE MOLECULAR SYSTEM, INC.	**Sensitivitas: 100 % Spesifitas: 100 %	-

No	Nomor Izin Edar	Tgl Exp	Nama produk	Pendaftar	Produsen	Nilai Validitas	Laboratorium Uji
			cobas 6800/8800 Systems				
36	AKL 30305220168	15/12/2026	COBAS[register] HIV-1 Quantitative nucleic acid test	PT. ROCHE INDONESIA	ROCHE MOLECULAR SYSTEMS, INC.	**Sensitivitas: - Spesifitas: 100 %	-
37	AKL 30305713142	15/04/2026	COBAS [register] HIV-1 Quantitative Nucleic Acid Test for Use on The cobas 4800 System (c4800 HIV-1 AMP/ DET)	PT. ROCHE INDONESIA	ROCHE MOLECULAR SYSTEMS.,INC	**Sensitivitas: - Spesifitas: 100 %	-
38	AKL 30305710379	09/02/2026	COBAS[register] Ampliprep/ COBAS[register] TaqMan[register] HIV-1 Qualitative Tes, v2.0 (HI2QCAP)	PT. ROCHE INDONESIA	ROCHE MOLECULAR SYSTEM INC.	**Sensitifitas EDTA plasma 100% (one sided lower 95% confidence limit: > 98.2%) adult DBS (one sided lower 95% confidence limit: > 98.3%) Spesitifitas 99.8% (one- sided lower 95% confidence limit: > 99.5%) in EDTA plasma 99.9% (one-sided lower 95% confidence limit: > 99.5%) in DBS specimens	-

No	Nomor Izin Edar	Tgl Exp	Nama produk	Pendaftar	Produsen	Nilai Validitas	Laboratorium Uji
39	AKL 30305214232	12/11/2025	COBAS HIV Combi PT Elecsys and Cobas e Analyzer	PT. ROCHE INDONESIA	ROCHE DIAGNOSTICS GMBH.	**Sensitifitas 100 %. The 95 % lower confidence limit was 99.76 % Spesitifitas Clinical specificity (95 % lower confidence limit) - Blood donors 99.88 % (99.77 %) - Unselected samples from daily routine 99.74 % (99.47 %) - Dialysis patients 99.60 % (97.80 %) - Pregnant women 100 % (99.67 %)	-
40	AKL 30305211864	08/11/2027	HUMAN Hexagon HIV	PT. SALI POLAPA BERSAMA	HUMAN Gesellschaft für Biochemica und Diagnostica mbH	*Sensitifitas: 100% Spesifisitas: 100%	RSCM
41	AKL 30305021428	01/02/2026	STANDAREAGE N Diagnostic Kit for Antibody to Human Immunodeficiency Virus HIV 1 + 2	PT. SARANA KARYA MEDIKA	NANTONG EGENS BIOTECHNOLOGY CO., LTD.	*Sensitifitas : 100% Spesifisitas: 100%	RSCM
42	AKL 30305220292	04/02/2026	YHLO iFlash HIV Combo	PT. SETIA ANUGRAH MEDIKA	SHENZHEN YHLO BIOTECH CO.,LTD	*Sensitivitas : 99.23% Spesifitas: 82.05%	RSCM
43	AKL 30305320942	31/12/2026	ABBOTT RealTime HIV-1 Qualitative Amplification Reagent Kit	PT. SINERGI UTAMA SEJAHTERA	ABBOTT MOLECULAR INC.,	**Sensitifitas: 95.5% (DBS); 97.8% (plasma) Spesifisitas: 100%	-

No	Nomor Izin Edar	Tgl Exp	Nama produk	Pendaftar	Produsen	Nilai Validitas	Laboratorium Uji
44	AKL 30305917113	22/05/2029	STANDARD [tradermark] Q HIV 1/2 Ab 3- Line	PT. STANDARD BIOSENSOR INDONESIA	SD BIOSENSOR INC.	*Sensitifitas: 100% Spesifisitas: 100%	RSCM
45	AKL 30305504659	28/06/2026	WANTAI Anti- HIV (1+2) ELISA Kit	PT. SUMIFIN CITRA ABADI	BEIJING WANTAI BIOLOGICAL PHARMACY ENTERPRISE CO., LTD.	*Sensitivitas: 100 % Spesifitas: 94.89 %	RSCM
46	AKL 30305911338	01/07/2025	AiD[tradermark] HIV 1+2 Ag/Ab ELISA Plus	PT. SUMIFIN CITRA ABADI	BEIJING WANTAI BIOLOGICAL PHARMACY ENTERPRISE CO., LTD.	*Sensitivitas: 100 % Spesifitas: 95.98 %	RSCM
47	AKL 30305516634	16/01/2028	SYSMEX HISCL HIV Ag+Ab Assay Kit	PT. SYSMEX INDONESIA	SYSMEX CORPORATION, SEISHIN FACTORY.	*Sensitifitas: 99.22% Spesifisitas: 100%	RSCM

4. Rapid Test Luar Negeri untuk Deteksi HIV

No	Nomor Izin Edar	Tgl Exp	Nama produk	Pendaftar	Produsen	Nilai Validitas	Laboratorium Uji
1	AKL 30305220211	18/01/2028	AIM HIV 1/2 Tripleline Rapid Test	PT. AKURAT INTAN MADYA	XIAMEN BOSON BIOTECH CO, LTD	*Sensitifitas: 100% Spesifisitas: 100%	RSCM
2	AKL 30305715499	04/06/2027	ABON[tradermark] HIV 1/2/O Tri-Line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma)	PT. ALERE HEALTH	ABON BIOPHARM (HANGZHOU) CO., LTD.	*Sensitifitas : 100% Spesifisitas : 98.86%	RSCM
3	AKL 30305320915	04/06/2027	BIOLINE HIV/Syphilis Duo	PT. ALERE HEALTH	ABBOTT DIAGNOSTICS KOREA, INC	*Sensitifitas: 99.24% Spesifisitas: 100%	RSCM
4	AKL 30305515934	04/06/2027	SD BIOLINE HIV/Syphilis Duo	PT. ALERE HEALTH	STANDARD DIAGNOSTICS, INC.	*Sensitifitas : 95.38% Spesifisitas: 99.68%	RSCM
5	AKL 30305610110	04/06/2027	ALERE[tradermark] HIV Combo	PT. ALERE HEALTH	ALERE MEDICAL CO., LTD.	*Sensitifitas : 96.15% Spesifisitas: 100%	RSCM
6	AKL 30305718712	27/08/2025	DS HIV 1/2 One Step Rapid Test	PT. BINABAKTI NIAGAPERKASA	ZHEJIANG ORIENT GENE	*Sensitifitas : 92.31%	RSCM

No	Nomor Izin Edar	Tgl Exp	Nama produk	Pendaftar	Produsen	Nilai Validitas	Laboratorium Uji
					BIOTECH CO., LTD	Spesifisitas: 100%	
7	AKL 30305917662	31/01/2029	HEALGEN HIV 1/2 Human Immunodeficiency Virus Rapid Test	PT. BINTANG MONO INDONESIA	ZHEJIANG ORIENT GENE BIOTECH CO., LTD.	*Sensitifitas: 98.64% Spesifisitas: 99.43%	RSCM
8	AKL 30305917661	23/11/2027	ORIENT GENE HIV 1/2 One Step Rapid Test Cassette	PT. BINTANG MONO INDONESIA	ZHEJIANG ORIENT GENE BIOTECH CO., LTD.	*Sensitifitas: 100% Spesifisitas: 100%	RSCM
9	AKL 30305124662	18/09/2025	BIOCARE[register] Combo 4 (HBsAg, HCV, HIV, Syphilis) Rapid Test Device	PT. BIOCARE SEJAHTERA	ASSURE TECH (HANGZHOU) CO., LTD.	*Sensitivitas: 99.33% Spesifisitas: 98.86%	RSCM
10	AKL 30305815196	27/08/2026	RAPIDAN TESTER Anti-HIV 1/2 Test (WB/S/P)	PT. CAKRA MEDIKA UTAMA	TURKLAB TIBBI MALZEMELER SAN, TIC. A.S.	*Sensitivitas: 100 % Spesifisitas: 100 %	RSCM
11	AKL 30305220581	30/11/2027	ONE STEP Cassette Style Anti HIV 1+2 Rapid Screen Test (Whole Blood)	PT. DANPAC PHARMA	NANTONG EGENS BIOTECHNOLOGY CO., LTD.	*Sensitifitas : 96.15% Spesifisitas: 100%	RSCM
12	AKL 30305321228	25/01/2026	ANSWER HIV 1/2/O Tri line Rapid Test Cassette (Serum/Plasma /Whole Blood)	PT. EXXEL UTAMA	ACON BIOTECH (HANGZHOU) CO., LTD.	*Sensitifitas : 100% Spesifisitas : 99.68%	RSCM
13	AKL 30305815341	08/09/2026	WONDFO One Step HIV 1/2 Whole Blood/Serum/Plasma Test Cassette (2 lines)	PT. EXXEL UTAMA	GUANGZHOU WONDFO BIOTECH CO., LTD.	*Sensitivitas: 99.32 % Spesifitas: 100 %	RSCM
14	AKL 30305815193	08/09/2026	WONDFO One Step HIV 1/2 Whole Blood/Serum/Plasma Test Strip (2 lines)	PT. EXXEL UTAMA	GUANGZHOU WONDFO BIOTECH CO., LTD.	*Sensitivitas: 100 % Spesifitas: 98.85 %	RSCM
15	AKL 30305320801	11/10/2027	JUSCHECK[register] HIV 1.2 Rapid Test Cassette	PT. LANIROS DIAN PHARMA	ACRO BIOTECH INC.	*Sensitifitas: 100% Spesifisitas: 100%	RSCM
16	AKL 30305513360	23/10/2027	RIGHTSIGN [register] HIV 1.2.O Rapid Test Cassette (Whole Blood/Serum/Plasma)	PT. MACROCITRA ARDANASEJATI	HANGZHOU BIOTEST BIOTECH CO., LTD.	*Sensitifitas : 100% Spesifisitas: 99.43%	RSCM
17	AKL 30305918579	16/04/2026	OraQuick Rapid HIV-1/2 Antibody Test	PT. MEDQUEST JAYA GLOBAL	PACIFIC BIOTECH CO., LTD	**Sensitifitas: 100% Spesifisitas : 100%	-
18	AKL	09/08/2025	ACON HIV 1/2/O Rapid	PT. MITRA	ACON BIOTECH	*Sensitivitas:	RSCM

No	Nomor Izin Edar	Tgl Exp	Nama produk	Pendaftar	Produsen	Nilai Validitas	Laboratorium Uji
	30305220501		Test Cassette (Serum/Plasma/Whole Blood)	BAHAGIA CITRA MEDIKA	(HANGZHOU) CO., LTD.	98.46 % Spesifisitas: 99.68 %	
19	AKL 30305520101	17/04/2029	ADVANCED QUALITY One Step Anti- HIV (1&2) Test Card (WholeBlood/ Serum/Plasma)	PT. MITRASAMAYA SEJATI	INTEC PRODUCTS., INC CHINA	*Sensitifitas: 100% Spesifisitas: 99.04%	RSCM
20	AKL 30305520082	17/04/2029	ADVANCED QUALITY One Step Anti-HIV (1&2) Test Strip (WholeBlood/Serum /Plasma)	PT. MITRASAMAYA SEJATI	INTEC PRODUCT., INC	*Sensitifitas: 100% Spesifisitas: 99.04%	RSCM
21	AKL 30305111261	17/04/2029	ADVANCED QUALITY One Step Anti-HIV (1&2) Tri-Line Test Card	PT. MITRASAMAYA SEJATI	INTEC PRODUCTS INC.	*Sensitifitas: 100% Spesifisitas: 99,43%	RSCM
22	AKL 30305801809	17/04/2029	ADVANCED QUALITY Rapid HIV Test Card (Serum/Plasma/Whole Blood)	PT. MITRASAMAYA SEJATI	INTEC PRODUCTS INC.	*Sensitifitas: 98.47% Spesifisitas: 99.36%	RSCM
23	AKL 30305805361	17/04/2029	ADVANCED QUALITY[register] Rapid Anti-HIV (1 & 2) Test Strip (Whole Blood/Serum/Plasma)	PT. MITRASAMAYA SEJATI	INTEC PRODUCTS INC.,P.R.	*Sensitifitas: 98.47% Spesifisitas: 99.36%	RSCM
24	AKL 30305420247	24/01/2029	EZiTELL HIV 1. 2 Rapid Test Cassette	PT. ONCOPROBE UTAMA	HANGZHOU ALL TEST BIOTECH CO., LTD	*Sensitivitas: 100% Spesifisitas: 100%	RSCM
25	AKL 30305320851	25/08/2026	OnSite HIV 1/2 Ab Plus Combo Rapid Test	PT. RAJAERBA INDOCHEM	CTK BIOTECH, INC.	*Sensitifitas: 100% Spesifisitas: 99.68%	RSCM
26	AKL 30305023057	01/06/2028	EGENS One Step Test Device HIV (1+2) Serum/Plasma Test Cassette	PT. SARANA KARYA MEDIKA	NANTONG EGENS BIOTECHNOLOGY CO., LTD.	*Sensitifitas: 100% Spesifisitas: 100%	RSCM
27	AKL 30305914705	12/04/2025	WEMED Rapid Test For Antibody to Human Immunodeficiency Virus (Colloidal Gold Device) Cassette	PT. WEGO MEDIKA INDONESIA	BEIJING WANTAI BIOLOGICAL PHARMACY ENTERPRISE CO.,LTD	*Sensitivitas: 99.32 % Spesifitas: 100 %	RSCM

Note:

* Nilai sensitivitas dan spesifisitas diperoleh dari hasil uji validasi yang dilakukan oleh Laboratorium Nasional

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