

Nomor : FR.03.01/E.V/0772/2025
Lampiran : 1 (Satu) berkas
Hal : *Update* Daftar Hasil Uji Validitas Reagen HIV

23 Mei 2025

Yth. Direktur Penyakit Menular

Sehubungan dengan surat kami sebelumnya dengan nomor FR.03.01/E.V/0524/2025 tanggal 10 April 2025 hal Permohonan Daftar Hasil Uji Validitas Reagen HIV, nomor FR.03.01/E.V/0580/2025 tanggal 23 April 2025 hal *Update* Daftar Hasil Uji Validitas Reagen HIV, dan nomor FR.03.01/E.V/0626/2025 tanggal 2 Mei 2025 hal *Update* Daftar Hasil Uji Validitas Reagen HIV, bersama ini kami sampaikan perubahan informasi terkait hasil uji alat kesehatan dalam negeri sebagai berikut:

1. Terkait hasil uji validitas yang kami sampaikan pada surat sebelumnya, terdapat *update* data, yaitu:

No	Nomor Izin Edar	Tgl Exp	Nama Produk	Pendaftar	Produsen	Nilai Validitas	Laboratorium Uji
1	AKD 30305120300	14-09-2026	INDEC® HIV 1/2 & Syphilis Combo	PT INDEC DIAGNOSTICS	PT INDEC DIAGNOSTICS	Sensitivitas: 100% Spesifisitas: 100%	RS Persahabatan
2	AKD 30305810065	1/12/2027	VIROCHECK® HIV 1/2	PT INDEC DIAGNOSTICS	PT INDEC DIAGNOSTICS	Sensitivitas: 100% Spesifisitas: 100%	RSCM
3	AKD 30305520093	8/8/2029	ONCOPROBE HIV Antibody Rapid Test	PT ONCOPROBE UTAMA	PT GENBODY INDONESIA SEHAT	Sensitivitas: 100% Spesifisitas: 100%	RSUP Dr Hasan Sadikin Bandung

2. *Update* data tersebut sebagai perbaikan dari kesalahan penulisan pada surat sebelumnya.

3. Surat ini merupakan *update* data yang ke – 2 (dua).

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

Lampiran 1

Nomor : FR.03.01/E.V/0772/2025

Tanggal : 23 Mei 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	INDEC® HIV 1/2 & Syphilis Combo	PT INDEC DIAGNOSTICS	PT INDEC DIAGNOSTICS	Sensitivitas: 100% Spesifisitas: 100%	RS Persahabatan
2	AKD 30305810065	1/12/2027	VIROCHECK® HIV 1/2	PT INDEC DIAGNOSTICS	PT INDEC DIAGNOSTICS	Sensitivitas: 100% Spesifisitas: 100%	RSCM
3	AKD 30305321167	28-10-2029	BPRO HIV/Syphilis Combo	PT PRODIA DIAGNOSTIC LINE	PT PRODIA DIAGNOSTIC LINE	Sensitivitas: 100% Spesifisitas: 99,68%	RSCM
4	AKD 30305710380	29-06-2027	UJI HIV	PT PAKAR BIOMEDIKA INDONESIA	PT PAKAR BIOMEDIKA INDONESIA	Sensitivitas: 99,33% Spesifisitas: 98,86%	RSCM
5	AKD 30305320844	30-04-2029	UJI HIV-Sifilis Duo	PT PAKAR BIOMEDIKA INDONESIA	PT PAKAR BIOMEDIKA INDONESIA	Sensitivitas: 99,24% Spesifisitas: 98,72%	RSCM
6	AKD 30305520134	26-02-2029	QUALITY ACCESSÂ® HIV Test Cassette (Whole Blood /Serum/Plasma)	PT BUANA MITRA SUKSES	PT PAKAR BIOMEDIKA INDONESIA	Sensitivitas: 99,33% Spesifisitas: 98,86%	RSCM
7	AKD 30305321026	22-08-2028	BIOQUICK HIV/Syphilis Duo	PT ONE-JECT INDONESIA	PT ONE-JECT INDONESIA	Sensitivitas: 96% Spesifisitas: 100%	BBLK Jakarta
8	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

No	Nomor Izin Edar	Tgl Exp	Nama Produk	Pendaftar	Produsen	Nilai Validitas	Laboratorium Uji
9	AKD 30305420152	5/10/2027	JB MED HIV Antibody	PT ONCOPROBE UTAMA	PT PAKAR BIOMEDIKA INDONESIA	Sensitivitas: 99,33% Spesifisitas: 98,86%	RSCM
10	AKD 30305520093	8/8/2029	ONCOPROBE HIV Antibody Rapid Test	PT ONCOPROBE UTAMA	PT GENBODY INDONESIA SEHAT	Sensitivitas: 100% Spesifisitas: 100%	RSUP Dr Hasan Sadikin Bandung
11	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)
12	AKD 30305510106	4/12/2029	ENTEBE Anti-HIV Strip	PT HEPATIKA MATARAM	PT HEPATIKA MATARAM	Sensitivitas: 98,03% Spesifisitas: 98,30%	RSCM
13	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
14	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
15	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
16	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
17	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
18	AKD 30305321020	5/8/2029	IMOQ Rapid Test Combo HIV/Sifilis	PT INSIGHT MEDICA FAME	PT INSIGHT MEDICA FAME	Sensitivitas: 100% Spesifisitas: 100%	RSCM
19	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
20	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
21	AKD	22-04-2027	EVERLIFE HIV	PT SANSICO	PT MERAH PUTIH	Sensitivitas:	RSCM

Dokumen ini telah ditandatangani secara elektronik menggunakan sertifikat elektronik yang diterbitkan oleh Balai Besar Sertifikasi Elektronik (BSrE), Badan Siber dan Sandi Negara

No	Nomor Izin Edar	Tgl Exp	Nama Produk	Pendaftar	Produsen	Nilai Validitas	Laboratorium Uji
	30305420023		1/2 Antibody Rapid Test (3 Lines)	NATURA RESOURCES	MANUFAKTURA	100% Spesifisitas: 100%	
22	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
23	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
24	AKD 30305321039	27-08-2028	MKCELLS HIV -1/2 Antibody Rapid Test	INTERSKALA MEDIKA INDONESIA	PT INTERSKALA MEDIKA INDONESIA	Sensitivitas: 100% Spesifisitas: 100%	RSCM
25	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
26	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
27	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
28	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
29	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
30	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
31	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
32	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
33	AKD 30305420143	31-03-2029	MEDICHECK HIV Ab 3-Line Rapid Test	INTERSKALA MEDIKA INDONESIA	PT INTERSKALA MEDIKA INDONESIA	Sensitivitas: 99,24% Spesifisitas:	RSCM

No	Nomor Izin Edar	Tgl Exp	Nama Produk	Pendaftar	Produsen	Nilai Validitas	Laboratorium Uji
						100%	
34	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
35	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
36	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
37	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
38	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
39	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
40	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
41	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
42	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
43	AKD 30305129279	14-09-2027	FASTCLEAR Q HIV 1/2 Ab 3-Line	PT STANDARD BIOSENSOR HEALTHCARE	PT STANDARD BIOSENSOR HEALTHCARE	Sensitivitas: 99,24% Spesifisitas: 99,34%	RSCM
44	AKD 30305220481	18-10-2027	FASTCLEAR Q HIV/Syphilis Combo	PT STANDARD BIOSENSOR HEALTHCARE	PT STANDARD BIOSENSOR HEALTHCARE	Sensitivitas: 100% Spesifisitas: 99,68%	RSCM
45	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
46	AKD	15-05-2027	TAMATECH HIV	PT MULTI NIAGA	PT INTERSKALA	Sensitivitas:	RSCM

No	Nomor Izin Edar	Tgl Exp	Nama Produk	Pendaftar	Produsen	Nilai Validitas	Laboratorium Uji
	30305520117		1/2 Combo (HIV + Syphilis) Rapid Test	MITRATAMA	MEDIKA INDONESIA	100% Spesifisitas: 100%	
47	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
48	AKD 30305321187	29-09-2029	EMTECH HIV 1/2 / Syphilis Combo	PT ELVINCO MED TECH	PT ELVINCO MED TECH	Sensitivitas: 100% Spesifisitas: 100%	RSCM
49	AKD 30305321215	7/10/2029	EMTECH HIV 1/2 Ab	PT ELVINCO MED TECH	PT ELVINCO MED TECH	Sensitivitas: 100% Spesifisitas: 100%	RSCM
50	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
51	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
52	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
53	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
54	AKD 30305520236	20-12-2027	INDOCHECK HIV Duo (HIV + Syphilis) Rapid Test	PT ARKAN JAYA NUSANTARA	PT INTERSKALA MEDIKA INDONESIA	Sensitivitas: 100% Spesifisitas: 100%	RSCM
55	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
56	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
57	AKD 30305321184	11/11/2027	GENOMIC HIV -1/2 Antibody Rapid Test	PT SETIA ANDALAN SUKSES	PT INTERSKALA MEDIKA INDONESIA	Sensitivitas: 100% Spesifisitas:	RSCM

No	Nomor Izin Edar	Tgl Exp	Nama Produk	Pendaftar	Produsen	Nilai Validitas	Laboratorium Uji
						100%	
58	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
59	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
60	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
61	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
3	AKL 30305320812	15/01/2029	Determine [trademark] HIV 1/2	PT. ALERE HEALTH	ABBOTT DIAGNOSTICS MEDICAL CO., LTD	*Sensitifitas: 100% Spesifisitas: 100%	RSCM
4	AKL 30305320775	04/06/2027	DETERMINE [trademark] 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

No	Nomor Izin Edar	Tgl Exp	Nama produk	Pendaftar	Produsen	Nilai Validitas	Laboratorium Uji
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 Quantitative RT - PCR Kit	PT. BIONEER INDIKA DIAGNOSTIK	BIONEER CORPORATION	*Sensitifitas: 99.15% Spesifisitas: 96.25%	RSK Dharmais
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%	-

No	Nomor Izin Edar	Tgl Exp	Nama produk	Pendaftar	Produsen	Nilai Validitas	Laboratorium Uji
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%	-
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	PT. ROCHE INDONESIA	ROCHE DIAGNOSTICS	*Sensitifitas: 98.46% Spesifisitas:	RSCM

No	Nomor Izin Edar	Tgl Exp	Nama produk	Pendaftar	Produsen	Nilai Validitas	Laboratorium Uji
			analyzers		GMBH	97.12%	
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 cobas 6800/8800 Systems	PT. ROCHE INDONESIA	ROCHE MOLECULAR SYSTEM, INC.	**Sensitivitas: 100 % Spesifitas: 100 %	-
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 %	-

No	Nomor Izin Edar	Tgl Exp	Nama produk	Pendaftar	Produsen	Nilai Validitas	Laboratorium Uji
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	-
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	-

No	Nomor Izin Edar	Tgl Exp	Nama produk	Pendaftar	Produsen	Nilai Validitas	Laboratorium Uji
						% (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% Spesifitas: 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% Spesifitas: 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) Spesifitas: 100%	-
44	AKL 30305917113	22/05/2029	STANDARD [trademark] Q HIV 1/2 Ab 3-Line	PT. STANDARD BIOSENSOR INDONESIA	SD BIOSENSOR INC.	*Sensitifitas: 100% Spesifitas: 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[trademark] 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% Spesifitas: 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,	*Sensitifitas: 100%	RSCM

Dokumen ini telah ditandatangani secara elektronik menggunakan sertifikat elektronik yang diterbitkan oleh Balai Besar Sertifikasi Elektronik (BSrE), Badan Siber dan Sandi Negara

No	Nomor Izin Edar	Tgl Exp	Nama produk	Pendaftar	Produsen	Nilai Validitas	Laboratorium Uji
					LTD	Spesifisitas: 100%	
2	AKL 30305715499	04/06/2027	ABON[trademark] 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[trademark] 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 BIOTECH CO., LTD	*Sensitifitas : 92.31% Spesifisitas: 100%	RSCM
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	PT. EXXEL	GUANGZHOU WONDFO	*Sensitivitas: 99.32 %	RSCM

No	Nomor Izin Edar	Tgl Exp	Nama produk	Pendaftar	Produsen	Nilai Validitas	Laboratorium Uji
			Blood/Serum/Plasma Test Cassette (2 lines)	UTAMA	BIOTECH CO., LTD.	Spesifitas: 100 %	
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 30305220501	09/08/2025	ACON HIV 1/2/O Rapid Test Cassette (Serum/Plasma/Whole Blood)	PT. MITRA BAHAGIA CITRA MEDIKA	ACON BIOTECH (HANGZHOU) CO., LTD.	*Sensitivitas: 98.46 % Spesifisitas: 99.68 %	RSCM
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%	RSCM

No	Nomor Izin Edar	Tgl Exp	Nama produk	Pendaftar	Produsen	Nilai Validitas	Laboratorium Uji
						Spesifisitas: 99.68%	
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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