

**PRODUCTS WITH MARKETING AUTHORIZATION**

**MEDICAL DEVICES/IN VITO DIAGNOSTICS**

<b>NO.</b>	<b>NAME OF PRODUCTS</b>	<b>ACTIVE INGRIDIENT/STRENGTH</b>	<b>MANUFACTURER</b>	<b>MARKETING AUTHORIZATION NUMBER</b>	<b>DATE REGISTERED</b>
001.	Bioline Onchocerciasis IgG4	N/A	Abbott Diagnostics Korea Inc. 65 Borahagal-ro Giheung-gu, Yongin- si Gyeonggi-do 17099, Republic of Korea	PBSL-03- 22/MD/0003/ABB	15 <sup>th</sup> March, 2022
002	DETERMINE TB LAM Ag	N/A	Abbott Diagnostics Korea Inc. 65 Borahagal-ro Giheung-gu, Yongin- si Gyeonggi-do 17099, Republic of Korea	PBSL-06- 22/MD/0008/ABB	9 <sup>th</sup> June, 2022
003	DETERMINE HIV ½ SET	N/A	Abbott Diagnostics Korea Inc. 65 Borahagal-ro Giheung-gu, Yongin- si Gyeonggi-do 17099, Republic of Korea	PBSL-12- 21/MD/0008/ABB	21 <sup>st</sup> December, 2021

004	Bioline HIV/Syphilis Duo	SD (IgG, IgM, IgA) HIV - ½ Antibodies/ Treponema Pallidum (TP)	Abbott Diagnostics Korea Inc. 65 Borahagal-ro Giheung-gu, Yongin-si Gyeonggi-do 17099, Republic of Korea	PBSL-03-22/MD/0006/ABB	15 <sup>th</sup> March, 2022
005	Bioline Malaria Ag Pf/Pan	N/A	Abbott Diagnostics Korea Inc. 65 Borahagal-ro Giheung-gu, Yongin-si Gyeonggi-do 17099, Republic of Korea	PBSL-06-22/MD/0007/ABB	9 <sup>th</sup> June, 2022
006	Bioline Malaria Ag. P.f	Histidine –rich Protein II (HRP-II)	Abbott Diagnostics Korea Inc. 65 Borahagal-ro Giheung-gu, Yongin-si Gyeonggi-do 17099, Republic of Korea	PBSL-03-22/MD/0005/ABB	15 <sup>th</sup> March, 2022
007	Bioline HCV	HCV Antibodies	Abbott Diagnostics Korea Inc. 65 Borahagal-ro Giheung-gu, Yongin-si Gyeonggi-do 17099, Republic of Korea	PBSL-03-22/MD/0002/ABB	15 <sup>th</sup> March, 2022
008	Bioline HBs Ag	HBsAg	Abbott Diagnostics Korea Inc. 65 Borahagal-ro	PBSL-03-22/MD/0004/ABB	15 <sup>th</sup> March, 2022

			Giheung-gu, Yongin-si Gyeonggi-do 17099, Republic of Korea		
009	Bioline HIV ½ - 3.0	HIV 2/2 (IgG, IgM, IgA) Antibodies	Abbott Diagnostics Korea Inc. 65 Borahagal-ro Giheung-gu, Yongin-si Gyeonggi-do 17099, Republic of Korea	PBSL-03-22/MD/0009/ABB	15 <sup>th</sup> March, 2022
010	NxTek Eliminate Malaria Pf	N/A	Abbott Diagnostics Korea Inc, 65 Borahagalro Giheung-gu, Yongin-si Gyeonggi-do 17099, Republic of Korea	-	19 <sup>th</sup> November, 2021
011	Bioline Malaria Ag Pf/Pan	N/A	Abbott Diagnostics Medical Co., Ltd., 357 Matsuhidai, Matsudo-Shi, Chiba, 270-2214, Japan	-	22 <sup>nd</sup> July, 2021
012	M-PIMA HIV - ½ Detect	N/A	Abbott Diagnostics Medical Co., Ltd., 357 Matsuhidai, Matsudo-Shi, Chiba, 270-2214, Japan	-	22 <sup>nd</sup> July, 2021
013	Determine Syphilis TP	N/A	Abbott Diagnostics Medical Co., Ltd., 357 Matsuhidai, Matsudo-Shi, Chiba, 270-2214,	-	22 <sup>nd</sup> July, 2021

			Japan		
014	Determine HBsAg2	N/A	Abbott Diagnostics Medical Co., Ltd., 357 Matsuhidai, Matsudo-Shi, Chiba, 270-2214, Japan	-	22 <sup>nd</sup> July, 2021
015	Determine HIV Early Detect	N/A	Abbott Diagnostics Medical Co., Ltd., 357 Matsuhidai, Matsudo-Shi, Chiba, 270-2214, Japan	-	
016	M-PIMA HIV - ½ VL	N/A	Abbott Diagnostics Medical Co., Ltd., 357 Matsuhidai, Matsudo-Shi, Chiba, 270-2214, Japan	-	22 <sup>nd</sup> July, 2021
017	Panbio Covid-19 Ag Rapid Test (Nasal)	N/A	Abbott Diagnostics Medical Co., Ltd., 357 Matsuhidai, Matsudo-Shi, Chiba, 270-2214, Japan	-	22 <sup>nd</sup> July, 2021
018	Determine HIV Early Detect	N/A	Abbott Diagnostics Medical Co., Ltd., 357 Matsuhidai, Matsudo-Shi, Chiba, 270-2214, Japan	-	22 <sup>nd</sup> July, 2021
019	Bioline Malaria Ag Pf/Pan	N/A	Abbott Diagnostics Korea Inc, 65 Borahagalro Giheung-gu, Yongin-si Gyeonggi-do 17099,	-	22 <sup>nd</sup> July, 2021

			Republic of Korea		
020	M-PIMA HIV - ½ Detect	N/A	Abbott Rapid Diagnostics Jena GmbH, Orlaweg 1, 07743 Jena, Germany	-	22 <sup>nd</sup> July, 2021
021	M-PIMA HIV - ½ VL	N/A	Abbott Rapid Diagnostics Jena GmbH, Orlaweg 1, 07743 Jena, Germany	-	22 <sup>nd</sup> July, 2021
022	Panbio Covid- 19 Ag Rapid Test (Nasal)	N/A	Abbott Rapid Diagnostics Jena GmbH, Orlaweg 1, 07743 Jena, Germany	-	22 <sup>nd</sup> July, 2021
023	DuraNet	Alphacypermethrin - 261mg/m <sup>2</sup> ± 25%	Shobikaa Impex Private Limited, No 34 Sannathi Street Vennamalai (PO) Karur 639 006 Tamil Nadu, India	-	22 <sup>nd</sup> December, 2021