

LABORATORIO CENTRAL DE REFERENCIA EN SALUD PÚBLICA  
DEPARTAMENTO DE EVALUACIÓN DE INSUMOS Y REACTIVOS DE LABORATORIO

REGISTROS SANITARIOS DE REACTIVOS PARA LA DETECCIÓN DE SARS-CoV-2

N° DE REGISTRO SANITARIO	NOMBRE DEL PRODUCTO	CATÁLOGO	METODOLOGIA	DISTRIBUIDOR	PAÍS DE ORIGEN	MARCA	FABRICANTE	FECHA DE EXPEDICIÓN	FECHA DE EXPIRACIÓN
15288	GENEFINDER COVID-19 PLUS REAL AMP KIT	IFMR-45	PCR	LABORATORY TECHNOLOGIES INC. LABTECH	COREA	GENEFINDER	OSANG HEALTHCARE CO. LTD	25/3/2020	25/9/2020
15318	COBAS <sup>®</sup> SARS-CoV-2	091754311900917544019007002238190	PCR	PRODUCTOS ROCHE (PANAMA), S.A.	ESTADOS UNIDOS	COBAS	ROCHE MOLECULAR SYSTEMS, INC	23/4/2020	23/10/2020
15319	VIASURE SARS-CoV-2	VS-NCO206LVS-NCO206H VS-NCO2212LVS-NCO2121HVS-NCO213LVS-NCO236VS-NCO272	PCR	LABORATORY TECHNOLOGIES INC. LABTECH	ESPAÑA	CERTEST BIOTEC, S.L.	CERTEST BIOTEC, S.L.	22/4/2020	22/10/2020
15320	Xpert Xpress SARS-CoV-2	XPRESARS-CoV2-10	PCR	PROMED, S.A.	ESTADOS UNIDOS	CEPHEID	CEPHEID	22/4/2020	22/10/2020
15321	BIOSYNEX COVID-19 BSS	SW40005	INMUNOCROMATOGRAFIA	PRIME MEDICAL	FRANCIA/SUIZA	BIOSYNEX	BIOSYNEX, S.A./BIOSYNEX SWISS, S.A.	23/4/2020	23/10/2020
15322	CarbGene N-CoV RT-PCR kit	MNC-N10082	PCR	LAB REAGENT, INC.	COREA DEL SUR	WELLS BIO, INC.	WELLS BIO, INC.	27/4/2020	27/10/2020
15327	ELISA Anti-SARS-CoV-2 (IgG)	EI 2606-9601 G	ELISA	PACIFIC CARE CORP	ALEMANIA	EUROIMMUN	EUROIMMUN Medizinische Labordiagnostika AG	04/05/2020	04/11/2020
15328	EURONeatTime SARS-CoV-2	MP 2606-0425MP 2606-0100	PCR	PACIFIC CARE CORP	ALEMANIA	EUROIMMUN	EUROIMMUN Medizinische Labordiagnostika AG	04/05/2020	04/11/2020
15329	GENE PRO COVID-19 DETECTION TEST	CV001	PCR	MEDIQUIPUS, S.A.	COREA	GENCURIX	GENCURIX INC.	05/05/2020	05/11/2020
15330	QIASTAD -dX-RESPIRATORY SARS-CoV-2 PANEL	691214	PCR	BIO-LAB INTERNACIONAL, S.A.	ALEMANIA	QIAGEN	QIAGEN GBMH	05/05/2020	06/11/2020
15332	COVID-19 RAPID SCREENING DEVICE MODEL TEST DEVICE	COVID19C	INMUNOCROMATOGRAFIA	ALCALA PHARMA, S.A.	REINO UNIDO	SureScreen Diagnostics	SureScreen Diagnostics LTD.	08/05/2020	08/11/2020
15333	GENESIG <sup>®</sup> REAL-TIME PCR CORONAVIRUS (COVID-19) Ce-IVD KIT	Z-PATH COVID-19 CE	PCR	C.G. DE HASETH & CIA, S.A.	REINO UNIDO	GENESIG <sup>®</sup>	PRIMER DESIGN LTD.	11/05/2020	11/11/2020
15334	REACTIVO: ONE STEP RT-qPCR MASTER MIX	Z-Qsig-onestep-150	PCR	C.G. DE HASETH & CIA, S.A.	REINO UNIDO	GENESIG <sup>®</sup>	PRIMER DESIGN LTD.	11/05/2020	11/11/2020
15335	COVID-19 VIRCLIA <sup>®</sup> IgG MONOTEST	VCMM097	CLIA	PROMED, S.A.	ESPAÑA	VIRCELL, S.L	VIRCELL, S.L	11/05/2020	11/11/2020
15336	COVID-19 VIRCLIA <sup>®</sup> IgM+IgA MONOTEST	VCMM098	CLIA	PROMED, S.A.	ESPAÑA	VIRCELL, S.L	VIRCELL, S.L	11/05/2020	11/11/2020
15337	LOGIX SMART COVID-19 KIT	COVID-K-001	PCR	HEALTH TECH INNOVATION SYSTEMS, INC.	ESTADOS UNIDOS	CO-DIAGNOSTICS	CO-DIAGNOSTICS, INC.	15/5/2020	15/11/2020
15351	COVID-19 ELISA IgG	G1332	ELISA	PROMED, S.A.	ESPAÑA	VIRCELL, S.L	VIRCELL, S.L	20/5/2020	20/11/2020
15352	SARS-CoV-2 R-GENE	423720	PCR	INVERSIONES SAGRAN, S.A.	FRANCIA	ARGENE	BIOMERIEUX, S.A.	21/5/2020	21/11/2020
15360	ELECSYS ANTI SARS-CoV-2	09203095190/ 09203079190	ELIA	PRODUCTOS ROCHE (PANAMA), S.A.	ALEMANIA	COBAS	ROCHE DIAGNOSTICS GMBH	29/05/2020	29/11/2020
15364	CORONAVIRUS DISEASE 2019 ANTIBODY (IgM/IgG) COMBINED TEST KIT	CG2301Y	INMUNOCROMATOGRAFIA	CENTRAL AMERICA HEALTH, INC (CLINLAB PANAMA)	CHINA	MEDICAL SYSTEM	MEDICAL SYSTEM BIOTECHNOLOGY CO. LTD	01/06/2020	12/01/2020
15396	STANDARD Q COVID-19 Ag TEST	Q-NCOV-01G	INMUNOCROMATOGRAFIA	MIRERO CORP.	COREA	SD BIOSENSOR	SD BIOSENSOR, INC.	05/06/2020	05/12/2020
15397	STANDARD M nCoV Real-Time Detection Kit	M-NCOV-01/ 11NCO10	PCR	MIRERO CORP.	COREA	SD BIOSENSOR	SD BIOSENSOR, INC.	05/06/2020	05/12/2020
15398	PreciControl Anti-SARS-CoV-2	09216928190	CONTROL	PRODUCTOS ROCHE (PANAMA), S.A.	ALEMANIA	COBAS	ROCHE DIAGNOSTIC GMBH	09/06/2020	09/12/2020
15401	ELISA Anti-SARS-CoV-2 (IgA)	EI 2606-9601 A	ELISA	PACIFIC CARE CORP	ALEMANIA	EUROIMMUN	EUROIMMUN Medizinische Labordiagnostika AG	09/06/2020	09/12/2020
15405	SARS-CoV-2 (COVID-19) IgG	COVG0940	ELISA	BIO-LAB INTERNACIONAL, S.A.	ALEMANIA	NOVATEC	INMUNDIAGNOSTICA GmbH	15/06/2020	15/12/2020
15321	BIOSYNEX COVID-19 BSS	SW40005	INMUNOCROMATOGRAFIA	PANAMED, S.A.	FRANCIA/SUIZA	BIOSYNEX	BIOSYNEX, S.A./BIOSYNEX SWISS, S.A.	15/06/2020	15/12/2020
15288	GENEFINDER COVID-19 PLUS REAL AMP KIT	IFMR-45	PCR	DARE, S.A.	COREA	GENEFINDER	OSANG HEALTHCARE CO. LTD	18/06/2020	18/12/2020
15425	ANTI SARS-CoV-2 Total Reagent Pack	6199922	QUIMIOLUMINISCENCIA	ORTHO CLINICAL DIAGNOSTICS PANAMA	ESTADOS UNIDOS / REINO UNIDO	VITROS	Ortho Clinical Diagnostics, Inc. / Ortho Clinical Diagnostics	18/06/2020	18/12/2020
15426	ANTI SARS-CoV-2 Total Calibrators	6199923	QUIMIOLUMINISCENCIA	ORTHO CLINICAL DIAGNOSTICS PANAMA	ESTADOS UNIDOS / REINO UNIDO	VITROS	Ortho Clinical Diagnostics, Inc. / Ortho Clinical Diagnostics	18/06/2020	18/12/2020
15427	ANTI SARS-CoV-2 Total Controls	6199924	QUIMIOLUMINISCENCIA	ORTHO CLINICAL DIAGNOSTICS PANAMA	ESTADOS UNIDOS / REINO UNIDO	VITROS	Ortho Clinical Diagnostics, Inc. / Ortho Clinical Diagnostics	18/06/2020	18/12/2020
15428	LYRA DIRECT SARS-CoV-2 ASSAY	M124	PCR	JERS MEDICAL PANAMA INC.	ESTADOS UNIDOS	QUIDEL	QUIDEL CORPORATION	19/06/2020	19/06/2020
15429	CELLEX qSARS-CoV-2 IgG/ IgM Cassette Rapid Test	5513C	INMUNOCROMATOGRAFIA	PTY MEDICAL GROUP	CHINA/ USA	CELLEX	Cellex Biotech (Suzhou) Co. Ltd para Cellex Inc.	24/06/2020	24/12/2020
15429	CELLEX qSARS-CoV-2 IgG/ IgM Cassette Rapid Test	5513C	INMUNOCROMATOGRAFIA	GLOBAL MEDICAL LOGISTICS	CHINA/ USA	CELLEX	Cellex Biotech (Suzhou) Co. Ltd para Cellex Inc.	24/06/2020	24/12/2020
15349	STANDARD Q COVID-19 IgM/ IgG COMBO	Q-NCOV-01C/ 09COV50G	INMUNOCROMATOGRAFIA	MIRERO CORP.	COREA	SD BIOSENSOR	SD BIOSENSOR, INC.	24/06/2020	24/12/2020
15382	SARS-CoV-2 IgG	6R86-22, 6R86-32 (RGT), 6R86-02 (CAL), 6R86-12 (CTRLS)	ELIA	BIO-LAB INTERNACIONAL, S.A.	IRLANDA	ABBOTT	ABBOTT IRELAND	03/06/2020	03/12/2020
15448	ACCUPOWER <sup>®</sup> COVID-19 REAL-TIME RT-PCR KIT	NCV-1111	PCR	MIRERO CORP.	COREA	BIONEER	BIONEER CORPORATION	24/06/2020	24/12/2020
15454	ANTI SARS-CoV-2 IgG REAGENT PACK	6199919	QUIMIOLUMINISCENCIA	ORTHO CLINICAL DIAGNOSTICS PANAMA	ESTADOS UNIDOS / REINO UNIDO	VITROS	Ortho Clinical Diagnostics, Inc. / Ortho Clinical Diagnostics	26/06/2020	26/12/2020
15455	ANTI SARS-CoV-2 IgG CONTROLS	6199921	QUIMIOLUMINISCENCIA	ORTHO CLINICAL DIAGNOSTICS PANAMA	ESTADOS UNIDOS / REINO UNIDO	VITROS	Ortho Clinical Diagnostics, Inc. / Ortho Clinical Diagnostics	26/06/2020	26/12/2020
15456	ANTI SARS-CoV-2 IgG CALIBRATOR	6199920	QUIMIOLUMINISCENCIA	ORTHO CLINICAL DIAGNOSTICS PANAMA	ESTADOS UNIDOS / REINO UNIDO	VITROS	Ortho Clinical Diagnostics, Inc. / Ortho Clinical Diagnostics	26/06/2020	26/12/2020
15457	MIRXES FORTITUDE KIT 2.0 E COVID-19 RT-PCR TEST	4480001	PCR	LABORATORIO VDTEC, S.A.	SINGAPUR	MIRXES	MIRXES Pte Ltd	30/06/2020	30/12/2020
15458	SARS-CoV-2 (COVID-19) IgA	COVA0940	ELISA	BIO-LAB INTERNACIONAL, S.A.	ALEMANIA	NOVALISA	NOVATEC INMUNDIAGNOSTICA GmbH	30/06/2020	30/12/2020
15461	BD SARS-CoV-2 REAGENTS FOR BD MAX <sup>™</sup> SYSTEM	445003-01/ 445003, 442827	PCR	SERVI-LAB, S.A.	CANADA/ ESTADOS UNIDOS	BD MAX <sup>™</sup>	GeneOhm Sciences Canada Inc. para Becton Dickinson and Company	06/07/2020	06/01/2021
15461	BD SARS-CoV-2 REAGENTS FOR BD MAX <sup>™</sup> SYSTEM	445003-01/ 445003, 442827	PCR	PROMED, S.A.	CANADA/ ESTADOS UNIDOS	BD MAX <sup>™</sup>	GeneOhm Sciences Canada Inc. para Becton Dickinson and Company	06/07/2020	06/01/2021
15499	ABBOTT REALTIME SARS-CoV-2	09N77-090, 09N77-080	PCR	BIO-LAB INTERNACIONAL, S.A.	ESTADOS UNIDOS	ABBOTT	ABBOTT MOLECULAR INC.	15/07/2020	15/01/2021
15528	POCKIT SARS-CoV-2 (orf lab) REAGENT SET	apls-123	PCR	SEA TECHNOLOGY, INC.	TAIWAN	POCKIT <sup>™</sup>	GeneReach Biotechnology, Corp	17/07/2020	17/01/2021
15531	COVID-19 IgG/ IgM DETECTION KIT (COLLOIDAL GOLD)	SK60145954	INMUNOCROMATOGRAFIA	SERVI-LAB, S.A.	CHINA	SINGUWAY	SINGUWAY BIOTECH INC.	27/07/2020	27/01/2021
15532	2019-nCoV IgG/ IgM	RACOV1	INMUNOCROMATOGRAFIA	U.S. PHARMACY SYSTEMS INC.	REINO UNIDO	AMS	AMS UK LIMITED	27/07/2020	27/01/2021
15556	TaePath <sup>™</sup> COVID-19 CE-IVD RT-PCR KIT	A48067	PCR	PROMED, S.A.	ESTADOS UNIDOS	APPLIED BIOSYSTEMS	Life Technologies Corporation	24/07/2020	24/01/2021
15557	SARS-CoV-2 RT-qPCR Reagent kit	3501-0010	PCR	LABORATORY TECHNOLOGIES INC. LABTECH	FINLANDIA	PERKIN ELMER	WALLAC OY	27/07/2020	27/01/2021
15558	Aridia COVID-19 Real-Time PCR	P0180	PCR	DISTRIBUIDORA LAF, S.A.	ESTADOS UNIDOS	CTK BIOTECH	CTK BIOTECH, INC.	27/07/2020	27/01/2021
15586	SOPIA SARS ANTIGEN FIA	20374	FIA	JERS MEDICAL PANAMA INC.	ESTADOS UNIDOS	QUIDEL	QUIDEL CORPORATION	04/08/2020	04/08/2025
15591	COVID-19 IgG/IgM RAPID TEST CASSETTE (Whole Blood/ Serum/ Plasma)	102221	INMUNOCROMATOGRAFIA	DIPROVEA, S.A.	FINLANDIA	SIENNA	SALOFIA OY	07/08/2020	02/08/2021

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