

Guayaquil, 30 de noviembre de 2020

LISTADO DE PRUEBAS PCR
(Aprobados durante emergencia sanitaria)

ITEM	NÚMERO DE AUTORIZACIÓN	PRODUCTO	TITULAR DE LA AUTORIZACIÓN	FABRICANTE	PAÍS DE FABRICACIÓN	TÉCNICA DE DETECCIÓN	AUTORIDADES REGULADORAS DONDE ESTÁ APROBADO
1	8253-DME-0320	cobas SARS-CoV2	ROCHE ECUADOR S.A.	ROCHE MOLECULAR SYSTEMS INC	ESTADOS UNIDOS	ensayo de RT-PCR en tiempo real	FDA - EEUU
2	8263-DME-0320	VERI Q PREP M16 VRDNA SWAB / STOOL; SERUM / PLASMA, GDNA STUTUM, GDNA BLOOD//VERI Q PCR 316 SYSTEM	MASVIRTUAL S.A.	MICROBIOME D CO. LTD.	COREA, REPUBLICA DE	PCR	OTROS
3	8340-DME-0420	Xpert® Xpress SARS-CoV-2	SISTEMAS DE SALUD ROCARSYSTEM S.A.	CEPHEID	ESTADOS UNIDOS	TIEMPO REAL PCR	FDA - EEUU
4	8373-DME-0420	VIASURE SARS-CoV-2 Real Time PCR Detection kit	VIBAG C.A.	CERTEST BIOTEC, S.L.	ESPAÑA	RealTime PCR	TGA - Australia
5	8375-DME-0420	Isopollo® COVID-19 detection kit (real-time)	SALUMED S.A.	MMONITOR INC	COREA, REPUBLICA DE	RealTime PCR	OTROS
6	8384-DME-0420	GENEFINDER COVID-19 PLUS REALAMP KIT	CEDIMED CIA. LTDA.	OSANG HEALTHCARE CO. LTD.	COREA, REPUBLICA DE	PCR	FDA - EEUU

7	744-RBE-0116	FilmArray Respiratory Panel 2 (RP2)/FilmArray Respiratory Panel 2 plus (RP2plus)	SIMED S. A.	BIOFIRE DIAGNOSTICS, LLC	ESTADOS UNIDOS	PCR	FDA - EEUU
8	8381-DME-0420	Respiratory Flow Chip Kit (Auto)	VIBAG C.A.	VITRO S.A.	ESPAÑA	real-time RT-PCR	OTROS
9	8390-DME-0420	SARS-COV-2 REALTIME PCR KIT	LAB QUALITY S.C.C.	VIRCELL, SL	ESPAÑA	RealTime PCR	OTROS
10	8402-DME-0420	Coronavirus Disease 2019 (COVID-19) RT-PCR	PHONTECALLI NG S.A. PHONTECALLI NG	CO-DIAGNOSTICS, INC.	ESTADOS UNIDOS	RealTime PCR	FDA - EEUU
11	8418-DME-0420	COVID-19 (SARS-CoV-2) Nucleic Acid Test Kit//	COTEMAC S.A.	WUHAN EASYDIAGNOSIS BIOMEDICINE CO., LTD.	CHINA	tecnología de sonda de fluorescencia de PCR múltiple combinada con la tecnología de RT-PCR	NMPA - CHINA
12	AD16092013	Allplex™ 2019-nCoV Assay	SIMED S. A.	SEEGENE INC.	KOREA, REPUBLIC OF	TIEMPO REAL PCR	MFDS - COREA DEL SUR
13	8432-DME-0420	Corona Virus (Covid-19) CE-IVD genesig® Real-Time PCR	SUMINISTROS MEDICOS MANOSALVAS VILLAGOMEZ MV ASOCIADOS CIA. LTDA.	PRIMERDES IGN LTD	REINO UNIDO DE GRAN BRETAÑA	RealTime PCR	FDA - EEUU
14	8445-DME-0420	careGENE N-COV RT PCR kit	ECZANE PHARMA LABORATORIOS ECZANEPHARMA SA	WELLS BIO INC	COREA, REPUBLICA DE	RealTime PCR	MFDS - Korea
15	8494-DME-0420	Novel Coronavirus (2019-nCoV) Real Time	REPRESENTACIONES INDUSTRIALES	SHANGHAI ZJ BIO-TECH CO LTD.,	CHINA	RealTime PCR	TGA - Australia

		Multiplex RT-PCR Kit (Detection for 3 genes)	REINDUSTRIAL CIA. LTDA.				
16	8493-DME-0420	AccuPower COVID-19 Real-Time RT-PCR Kit/AccuPower SARS-CoV-2 Real-Time RT-PCR Kit	RECORDENTAL Y QUIMEDIC S.A.	BIONEER CORPORATION	COREA, REPUBLICA DE	PCR	OTROS
17	8527-DME-0420	Genesig® Real-Time PCR Coronavirus COVID-19 (CE IVD) Kit	SONIA MARIA LEON PONTON	PRIMERDESIGN LTD	REINO UNIDO DE GRAN BRETAÑA	PCR	FDA - EEUU
18	8528-DME-0420	LightMix Modular Sarbecovirus E-gene, C	ROCHE ECUADOR S.A.	TIB MOLBIOL SYNTHESELABOR GMBH	ALEMANIA	PCR	OTROS
19	8539-DME-0420	Detection Kit for 2019 Novel Coronavirus(2019-nCoV) RNA (PCR-Fluorescence Probing)	FRISONEX FRISON IMPORTADORA EXPORTADORA CIA. LTDA.	DAAN GENE CO., LTD OF SUN YAT-SEN UNIVERSITY	CHINA	PCR	NMPA - CHINA
20	8552-DME-0420	Real-time fluorescent RT-PCR kit for detecting 2019-nCoV	SIMED S. A.	BGI BIOTECHNOLOGY (WUHAN) CO., LTD.	CHINA	PCR	OTROS
21	8563-DME-0420	BioFire COVID-19 Test	SIMED S. A.	BIOFIRE DIAGNOSTICS, LLC	ESTADOS UNIDOS	PCR	FDA - EEUU
22	8566-DME-0420	Novel Coronavirus(2019-nCoV) Nucleic Acid Diagnostic Kit (PCR-Fluorescence Probing)(PCR-Fluorescence Probing)	LABOMERSA S.A.	SANSURE BIOTECH INC.	CHINA	PCR	CHINA
23	8582-DME-0420	SARS-CoV-2 NUCLEIC ACID TEST KIT	CORPOMEDICA CIA. LTDA.	WUHAN EASY DIAGNOSIS BIOMEDICINE CO., LTD	CHINA	PCR	NMPA

24	8635-DME-0420	MagCore Trixact RNA Kit (400 µl)/MagCore Total RNA Culture Cells Kits/MagCore Total RNA FFPE One-Step Kit (400 µl)/Magcore Total RNA Whole Blood Kit/MagCore Viral Nucleic Acid Large Volume Extraction Kit (2400 y 1200 µl)	VIBAG C.A.	RBC BIOSCIENCE CORP.	TAIWAN	PCR	OTROS
25	8636-DME-0420	MagCore Genomic DNA Bacterial Kit (Gram +/-)/	VIBAG C.A.	RBC BIOSCIENCE CORP.	TAIWAN	PCR	OTROS
26	8637-DME-0420	Magcore Viral Nucleic Acid Extraction Kit High Sensivity (200/400 µl)	VIBAG C.A.	RBC BIOSCIENCE CORP.	TAIWAN	PCR	OTROS
27	8643-DME-0420	Novel Coronavirus (2019-nCoV) Nucleic Acid Diagnostic Kit (PCR-Fluorescence Probing)	MORILLO ECHANIQUE PABLO DAVID	Sansure Biotech Inc.	CHINA	PCR	OTROS
28	8688-DME-0520	Abbott RealTime SARS-CoV-2 Application CD-ROM 09N77-001/Abbott RealTime SARS-CoV-2 Control Kit 09N77-080	ABBOTT LABORATORIO S DEL ECUADOR CIA LTDA	ABBOTT MOLECULAR INC.	UNITED STATES	PCR	FDA
29	8693-DME-0520	LiliFTM COVID-19 Real-time RT-PCR Kit	GREENPORTWORLD S.A.	INTRON BIOTECHNOLOGY INC.	REPÚBLICA DE KOREA	PCR	OTROS

30	8705-DME-0520	SARS-CoV-2 Nucleic Acid Detection Kit (PCR-Fluorescent Probe Method)	SALUMED S.A.	ZYBIO INC.	CHINA	PCR	OTROS
31	8789-DME-0520	Chip-based Real Time PCR Test for Beta Coronavirus (Truenat Beta CoV)	REACTLAB IMPORT CIA. LTDA	MOLBIO DIAGNOSTIC S PVT LTD.	India	PCR	INDIA
32	8802-DME-0520	COVID-19(SARS-CoV-2) IgM/IgG Antibody Test Kit/COVID-19 (SARS-CoV-2) Nucleic Acid Test Kit/Nucleic Acid Extraction Reagent	NUTRAMEDIX LABORATORIOS DEL ECUADOR S.A.	WUHAN EASYDIAGNOSIS BIOMEDICINE CO., LTD	China	PCR	NMPA
33	8854-DME-0520	TaqPath COVID-19 CE-IVD RT-PCR Kit	SIGMA HEALTH DEL ECUADOR SIGMAHEALTH CIA. LTDA.	LIFE TECHNOLOGIES CORPORATION	ESTADOS UNIDOS	PCR	OTROS
34	8896-DME-0520	COVID-19 RT-qPCR	CORPOSTETICA CIA. LTDA.	JN MEDSYS PTE LTD	SINGAPUR	PCR	OTROS
35	8921-DME-0520	SMARTCHEK Novel Coronavirus (SARS-CoV-2) Detection Kit	HYUNDAIMEDICAL ECUADOR S.A.	GENESYSTEM CO.,LTD.	KOREA	PCR	OTROS
36	8907-DME-0520	COBAS BKV/COBAS EBV/COBAS EBV/BKV Control Kit	ROCHE ECUADOR S.A.	ROCHE MOLECULAR SYSTEMS, INC	ESTADOS UNIDOS	PCR	OTROS
37	8915-DME-0520	Kaira 2019-nCoV PCR Detection Kit	VALDEZ CEDEÑO JOSE ARTURO	OPTOLANE TECHNOLOGIES INC.	REPÚBLICA DE KOREA	PCR	REPÚBLICA DE KOREA
38	8966-DME-0520	iAMP® COVID-19 Detection Kit	SIMED S. A.	ATILA BIOSYSTEMS, INC	Estados Unidos	PCR	FDA - EEUU

39	8976-DME-0520	STANDARD M nCoVReal Time Detectionkit (M-NCOV-01)	SIMED S. A.	SD BIOSENSOR, INC.	REPUBLI CA DE COREA	PCR	FDA - USA
40	9038-DME-0520	GENECHECKE R Real-Time PCR System UF-300	HYUNDAIMEDI CAL ECUADOR S.A.	GENESYS TE M CO.,LTD.	REPÚBLI CA DE KOREA	PCR	OTROS
41	9078-DME-0620	Novel Coronavirus (2019-nCoV) Nucleic Acid Diagnostic Kit (PCR- Fluorescence Probing)	CHINA SINOPHARM INTERNATION AL CORPORATION	SANSURE BIOTECH INC	CHINA	PCR	OTROS
42	9228-DME-0620	RADI COVID- 19 DETECTION KIT	AH STETICSUPPLI ES S.A.	KH MEDICAL CO., LTD.	KOREA	PCR	OTROS
43	9267-DME-0620	REAL-Q 2019-N COV DETECTION KIT	GLAMFABRIK CIA.LTDA.	BIOSEWOO M, INC.	REPÚBLI CA DE KOREA	PCR	OTROS
44	9306-DME-0620	PowerChekT M 2019-nCoV Real-time PCR Kit	SALUMED S.A.	KOGENEBIO TECH CO., LTD	Korea	PCR	OTROS
45	9653-DME-0820	SMARTCHEK Novel Coronavirus (SARS-CoV-2) Detection Kit	MEDILABOR S.A.	GENESYS TE M CO., LTD.	Korea	PCR	OTROS
46	9647-DME-0820	Platelia SARS- CoV-2 Total Ab	BENALCAZAR CARRANZA CARLOS FERNANDO	BIO-RAD	Francia	PCR	FDA - USA
47	9688-DME-0820	Novel Coronavirus (2019-nCoV) Nucleic Acid Diagnostic Kit (PCR- Fluorescence Probing)	BIOPROEC S.A.	SANSURE BIOTECH INC.	China	PCR- Fluoresce nce Probing	FDA - USA
48	9733-DME-0820	EURORealTim e SARS-CoV-2	LAB QUALITY S.C.C.	EUROIMMU N MEDIZINISC HE LABORDIAG NOSTIKA AG	ALEMAN IA	PCR	OTROS

49	9836-DME-0820	GENOME Cov19 DETECTION KIT	MERA RUIZ PATRICIA ALISON	APPLIED BIOLOGICAL MATERIALS INC	CANADA	PCR	OTROS
50	9865-DME-0920	SARS-CoV-2 RT -qPCR Reagent kit	MEDIMP S.A.	WALLAC OY	FINLANDIA	PCR	OTROS
51	9912-DME-0920	TaqPath™ COVID-19 CE- IVD RT PCR Kit	LEDA LABORATORIO S FARMACEUTIC OS CIA.LTDA.	LIFE TECHNOLOG IES CORPORATI ON	ESTADOS UNIDOS	real-time RT-PCR	OTROS
52	9900-DME-0920	WizDx COVID-19 CrystalMix PCR Kit	WAFIQ CIA. LTDA.	WIZBIOSOL UTIONS INC	REPÚBLICA DE KOREA	PCR	OTROS
53	9944-DME-0920	Novel Coronavirus (SARS-CoV-2) Multiplex Real-Time PCR Kit (detection for three genes)	IMPORPING S.A.	NANJING LIMING BIO- PRODUCTS CO., LTD.	CHINA	real-time RT-PCR	OTROS
54	9993-DME-0920	UltraGene Combo2Scree n SARS-CoV-2 Assay	FERREMUNDO S.A.	MYPOLS BIOTECH GMBH	ALEMANIA	real-time RT-PCR	OTROS
55	10296-DME-1020	VIASURE SARS-CoV-2 S GENE REAL TIME PCR DETECTION KIT, 24 REACTION TUBES, 24 TESTS (VS- NCO124)	BBR REPRESENTAC IONES CIA. LTDA.	CERTEST BIOTEC S.L	ESPAÑA	RealTime PCR	TGA - Australia
56	10314-DME-1020	Reagent Kit for the SARS- Cov-2 RNA Nucleic Acids Extraction from Biological Material in Different Versions according to TU 21.10.60- 002-	IGESTDOCTOR ECUADOR CONSULTORES STARTUP C.L.	EVOTECH- MIRAI GENOMICS LIMITED LIABILITY COMPANY	RUSIA	PCR	RUSIA

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57	10265-DME-1020	FTD-SARS-CoV-2	SIMED S. A.	FAST TRACK DIAGNOSTICS LUXEMBOURG S.A.R.L.	LUXEMBURGO	PCR	FDA
58	10362-DME-1020	SARS-CoV-2 ELITe MGB Kit /SARS-CoV-2 ELITe Positive Control	MEDILABOR S.A.	ELITECHGROUP S.P.A.	ITALIA	PCR	ITALIA
59	10371-DME-1020	Access SARS-CoV-2-IgG	SISTEMAS DE SALUD ROCARSYSTEM S.A.	BECKMAN COULTER IRELAND INC	SUIZA	PCR	FDA
60	10266-DME-1020	QIAstat-Dx Respiratory Panel	SIMED S. A.	QIAGEN GMBH	ALEMANIA	PCR	OTROS
61	10369-DME-1020	Lyra ® Directv SARS-CoV-2 Assay	VIBAG C.A.	QUIDEL CORPORATION	ESTADOS UNIDOS	PCR	FDA
62	10264-DME-1020	EDI™ Novel Coronavirus COVID-19 IgG ELISA Kit	REACTLAB IMPORT CIA. LTDA	EPITOPE DIAGNOSTICS, INC.	ESTADOS UNIDOS	PCR	OTROS
63	10389-DME-1020	SARS-CoV-2 Fluorescent PCR	COLONNAG S.A.	MACCURA BIOTECHNOLOGY CO., LTD.	CHINA	PCR	OTROS
64	10426-DME-1020	ViroQ SARS-CoV-2	SIMED S. A.	BAG DIAGNOSTICS GMBH	ALEMANIA	PCR	ANMAT, Argentina
65	10438-DME-1020	careGENE N-CoV RT-PCR kit	CLOSTERPHARMA S.A.	WELLS BIO, INC	COREA	PCR	MFDS, COREA
66	595-DMN-1020	ECUGEN SARS-CoV-2 RT-qPCR kit	STARNEWCORP S.A.	STARNEWCORP S.A.	ECUADOR	RT-PCR	ECUADOR
67	10517-DME-1020	TCM-Q Corona III kit	LATINA EXPORT CIA. LTDA	TCM BIOSCIENCES INC	COREA	RT-PCR	MFDS, COREA
68	10765-DME-1120	BD SARS-CoV-2 Reagents for BD MAX System	BBR REPRESENTACIONES CIA. LTDA.	GENEOHM SCIENCES CANADA INC.	CANADA	RT-PCR	CANADA

69	10724-DME-1120	Vitassay qPCR SARS-CoV-2	BENALCAZAR CARRANZA CARLOS FERNANDO	VITASSAY HEALTHCAR E, S.L.U.	ESPAÑA	RT-PCR	OTROS
70	10681-DME-1120	KIT COBAS 6800/8800 SARS-COV- 2/FLU	ROCHE ECUADOR S.A.	ROCHE MOLECULAR SYSTEMS	ESTADOS UNIDOS	PCR	FDA
71	10699-DME-1120	cobas SARS- CoV2 & Influenza A/B	ROCHE ECUADOR S.A.	ROCHE MOLECULAR SYSTEMS, INC.	ESTADOS UNIDOS	PCR	FDA

