

Guayaquil, 20 de mayo de 2020

REACTIVOS PCR

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.	MICROBIOMED 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	RealTime 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	PHONTECALLING S.A. PHONTECALLING	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., LDT.	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.	PRIMERDESIGN 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 Multiplex RT-PCR Kit (Detection for 3 genes)	REPRESENTACIONES INDUSTRIALES REINDUSTRIAL CIA. LTDA.	SHANGHAI ZI BIO-TECH CO LTD.,	CHINA	RealTime PCR	TGA - Australia
16	8493-DME-0420	AccuPower COVID-19 Real-Time RT-PCR Kit/AccuPower SARS-COV-2 Real-Time RT-PCR Kit	RECOR DENTAL Y QUIMEDIC S.A.	BIONEER CORPORATION	COREA, REPUBLICA DE	RealTime 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	TIEMPO REAL PCR	FDA - EEUU
18	8528-DME-0420	LightMix Modular Sarbecovirus E-gene, C	ROCHE ECUADOR S.A.	TIB MOLBIOL SYNTHSELABOR 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	CHINA
24	8635-DME-0420	MagCore Triaxact 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 LABORATORIOS 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 DIAGNOSTICS 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	CHINA
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	NO APLICA