

Listado de Pruebas PCR aprobadas por la Agencia Nacional de Regulación, Control y Vigilancia Sanitaria - Arcsa

| Razón Social de Solicitante | Registro Sanitario | Nombre del Producto | TIPO DE PRUEBA | País de Fabricante |
|---|--------------------|--|----------------|--------------------|
| AH STETICSUPPLIES S.A. | 9228-DME-0620 | RADI COVID-19 DETECTION KIT | PCR | COREA |
| BBR REPRESENTACIONES CIA. LTDA. | 12001-DME-0721 | BD SARS-CoV-2/Flu for BD MAX™ System | PCR | ESTADOS UNIDOS |
| BBR REPRESENTACIONES CIA. LTDA. | 10296-DME-1020 | VIASURE SARS-CoV-2 S GENE REAL TIME PCR DETECTION KIT, 24 REACTION TUBES, 24 TESTS (VS-NCO124) | PCR | ESPAÑA |
| BBR REPRESENTACIONES CIA. LTDA. | 11895-DME-0621 | VIASURE SARS-CoV-2 (N1+N2) REAL TIME PCR DETECTION KIT FOR BD MAX™ SYSTEM | PCR | ESPAÑA |
| BENALCAZAR CARRANZA CARLOS FERNANDO | 10724-DME-1120 | Vitassay qPCR SARS-CoV-2 | PCR | ESPAÑA |
| BIOPROEC S.A. | 9688-DME-0820 | Novel Coronavirus (2019-nCoV) Nucleic Acid Diagnostic Kit (PCR-Fluorescence Probing) | PCR | CHINA |
| CALDERON MORA SILVIA SARA | 11216-DME-0221 | Novel Coronavirus (2019-nCoV) Nucleic Acid Diagnostic Kit (PCR-Fluorescence Probing) | PCR | CHINA |
| CEDIMED CIA. LTDA. | 8384-DME-0420 | GENEFINDER COVID-19 PLUS REALAMP KIT | PCR | COREA |
| CHINA SINOPHARM INTERNATIONAL CORPORATION | 9078-DME-0620 | Novel Coronavirus (2019-nCoV) Nucleic Acid Diagnostic Kit (PCR-Fluorescence Probing) | PCR | CHINA |
| CHOEZ CHIQUITO MARIBEL ANTONIA | 11727-DME-0521 | COVID-19 RT-PCR Real TM Fast | PCR | URUGUAY |
| CLOSTERPHARMA S.A. | 10438-DME-1020 | careGENE N-CoV RT-PCR kit | PCR | COREA |
| COLONNAG S.A. | 10389-DME-1020 | SARS-CoV-2 Fluorescent PCR | PCR | CHINA |
| CORPOSTETICA CIA. LTDA. | 8896-DME-0520 | COVID-19 RT-qPCR | PCR | SINGAPUR |
| COTEMAC S.A. | 8418-DME-0420 | COVID-19 (SARS-CoV-2) Nucleic Acid Test Kit | PCR | CHINA |

| | | | | |
|---|----------------|--|-----|----------------|
| ECZANE PHARMA LABORATORIOS ECZANEPHARMA SA | 8445-DME-0420 | careGENE N-COV RT PCR kit | PCR | COREA |
| FERREMUNDO S.A. | 9993-DME-0920 | UltraGene Combo2Screen SARS-CoV-2 Assay | PCR | ALEMANIA |
| FRISONEX FRISON IMPORTADORA EXPORTADORA CIA. LTDA. | 8539-DME-0420 | Detection Kit for 2019-nCoV (PCR-Fluorescence) | PCR | CHINA |
| FRISONEX FRISON IMPORTADORA EXPORTADORA CIA. LTDA. | 11436-DME-0321 | FTD FLU/HRSV | PCR | LUXEMBURGO |
| GENLIFE CIA LTDA | 8527-DME-0420 | Genesig® Real-Time PCR Coronavirus COVID-19 (CE IVD) Kit | PCR | REINO UNIDO |
| GLAMFABRIK CIA.LTDA. | 9267-DME-0620 | REAL-Q 2019-N COV DETECTION KIT | PCR | COREA |
| GREENPORTWORLD S.A. | 8693-DME-0520 | LiliFTM COVID-19 Real-time RT-PCR Kit | PCR | COREA |
| HYUNDAIMEDICAL ECUADOR S.A. | 8921-DME-0520 | SMARTCHEK Novel Coronavirus (SARS-CoV-2) Detection Kit | PCR | COREA |
| IGESTDOCTOR ECUADOR CONSULTORES STARTUP C.L. | 10314-DME-1020 | Kit for the SARS-Cov-2 RNA Presence in Biological Material Using Real-Time Isothermal Amplification Method in Different Versions according to TU 21-10.60-004-06931260-2020. | PCR | RUSIA |
| IMPORPING S.A. | 9944-DME-0920 | Novel Coronavirus (SARS-CoV-2) Multiplex Real-Time PCR Kit (detection for three genes) | PCR | CHINA |
| IMPORTADORA DISTRIBUIDORA MAKOLECUADOR CIA. LTDA. | 10741-DME-1120 | System For Rapid Detection of SARSCoV-2 | PCR | ESTADOS UNIDOS |
| IVDTRADING S.A. | 11382-DME-0321 | Real Time PCR Kit for Novel Coronavirus 2019-nCoV | PCR | CHINA |
| LABOMERSA S.A. | 11156-DME-0121 | 3DMed 2019-nCoV RT-qPCR Detection Kit | PCR | CHINA |
| LABOMERSA S.A. | 11710-DME-0521 | ANDiS FAST SARS-CoV-2 RT-qPCR | PCR | CHINA |
| LABOMERSA S.A. | 11111-DME-0121 | COVID-19 Coronavirus Real Time PCR Kit | PCR | CHINA |
| LABOMERSA S.A. | 12167-DME-0921 | COVID-19 Coronavirus (ORF1ab/N/E) Real Time PCR Kit | PCR | CHINA |
| LABOMERSA S.A. | 8566-DME-0420 | Novel Coronavirus(2019-nCoV) Nucleic Acid Diagnostic Kit (PCR-Fluorescence Probing)(PCR-Fluorescence Probing) | PCR | CHINA |
| LAB QUALITY S.C.C. | 10861-DME-1220 | Convergys® POC RT-PCR COVID-19 Detection Kit | PCR | ALEMANIA |

| | | | | |
|---|----------------|--|-----|----------------|
| LAB QUALITY S.C.C. | 12698-DME-0122 | SARS-CoV-2 ELITe MGB® Kit | PCR | ITALIA |
| LAB QUALITY S.C.C. | 9733-DME-0820 | EURORealTime SARS-CoV-2 | PCR | ALEMANIA |
| LAB QUALITY S.C.C. | 12726-DME-0122 | GB SARS-CoV-2 Real-Time RT-PCR | PCR | TAIWAN |
| LAB QUALITY S.C.C. | 11364-DME-0221 | Vita PCR™ SARS-CoV-2 Gen 2 Assay | PCR | TAIWAN |
| LAB QUALITY S.C.C. | 8390-DME-0420 | SARS-COV-2 REALTIME PCR KIT | PCR | ESPAÑA |
| LATINA EXPORT CIA. LTDA | 10517-DME-1020 | TCM-Q Corona III kit | PCR | COREA |
| LEDA LABORATORIOS FARMACEUTICOS CIA.LTDA. | 9912-DME-0920 | Taqpath 1-Step Multiplex Master Mix (No ROX) (A480999) | PCR | ESTADOS UNIDOS |
| MASKAF S.A.S. | 11609-DME-0421 | El Logix Smart ABC Influenza A/B, SARS-CoV-2 | PCR | ESTADOS UNIDOS |
| MASKAF S.A.S. | 11845-DME-0621 | the Logix Smart SARS-CoV-2 (genes RdRp/E) | PCR | ESTADOS UNIDOS |
| MEDILABOR S.A. | 10362-DME-1020 | SARS-CoV-2 ELITe MGB Kit | PCR | ITALIA |
| MEDILABOR S.A. | 9653-DME-0820 | SMARTCHEK Novel Coronavirus (SARS-CoV-2) Detection Kit | PCR | COREA |
| MEDILABOR S.A. | 12539-DME-1221 | 2019-Novel Coronavirus (2019-nCoV) Triplex RT-qPCR Detection Kit | PCR | CHINA |
| MEDIMP S.A. | 9865-DME-0920 | SARS-CoV-2 RT -qPCR Reagent kit | PCR | FINLANDIA |
| MERA RUIZ PATRICIA ALISON | 9836-DME-0820 | GENOME Cov19 DETECTION KIT | PCR | CANADA |
| MORILLO ECHANIQUE PABLO DAVID | 8643-DME-0420 | Novel Coronavirus (2019-nCoV) Nucleic Acid Diagnostic Kit (PCR-Fluorescence Probing) | PCR | CHINA |
| PHONTECALLING S.A. PHONTECALLING | 8402-DME-0420 | Coronavirus Disease 2019 (COVID-19) RT-PCR | PCR | ESTADOS UNIDOS |
| REACTLAB IMPORT CIA. LTDA | 8789-DME-0520 | Chip-based Real Time Duplex PCR Test for COVID-19 (Truenat COVID-19) | PCR | INDIA |
| RECOR DENTAL Y QUIMEDIC CIA. LTDA | 8493-DME-0420 | AccuPower COVID-19 Real-Time RT-PCR Kit | PCR | COREA |
| REPRESENTACIONES INDUSTRIALES REINDUSTRIAL CIA. LTDA. | 8494-DME-0420 | Novel Coronavirus (2019-nCoV) Real Time Multiplex RT-PCR Kit (Detection for 3 genes) | PCR | CHINA |
| SALUMED S.A. | 9306-DME-0620 | PowerChek™ 2019-nCoV Real-time PCR Kit | PCR | COREA |
| SALUMED S.A. | 8375-DME-0420 | Isopollo® COVID-19 detection kit (real-time) | PCR | COREA |
| SALUMED S.A. | 8705-DME-0520 | SARS-CoV-2 Nucleic Acid Detection Kit (PCR-Fluorescent Probe Method) | PCR | CHINA |

| | | | | |
|--|----------------|---|-----|----------------|
| SIGMA HEALTH DEL ECUADOR SIGMAHEALTH CIA. LTDA. | 8854-DME-0520 | TaqPath COVID-19 CE-IVD RT-PCR Kit | PCR | ESTADOS UNIDOS |
| SIMED S. A. | 8966-DME-0520 | iAMP® COVID-19 Detection Kit | PCR | ESTADOS UNIDOS |
| SIMED S. A. | 10426-DME-1020 | ViroQ SARS-CoV-2 | PCR | ALEMANIA |
| SIMED S. A. | 8563-DME-0420 | BioFire COVID-19 Test | PCR | ESTADOS UNIDOS |
| SIMED S. A. | 11598-DME-0421 | HG COVID 19 Assay | PCR | IRLANDA |
| SIMED S. A. | 8976-DME-0520 | STANDARD M nCoVReal Time Detectionkit (M-NCOV-01) | PCR | COREA |
| SIMED S. A. | 10265-DME-1020 | FTD-SARS-CoV-2 | PCR | LUXEMBURGO |
| STARNEWCORP S.A. | 595-DMN-1020 | ECUGEN SARS-CoV-2 RT-qPCR kit | PCR | ECUADOR |
| SUMEDICBIOGEN S.A. | 11084-DME-0121 | PCL COVID19 Speedy RT-PCR | PCR | COREA |
| SUMINISTROS MEDICOS MANOSALVAS VILLAGOMEZ MV ASOCIADOS CIA. LTDA. | 8432-DME-0420 | Corona Virus (Covid-19) CE-IVD genesig® Real-Time PCR | PCR | REINO UNIDO |
| VALDEZ CEDEÑO JOSE ARTURO | 8915-DME-0520 | Kaira 2019-nCoV PCR Detection Kit | PCR | COREA |
| WAFIQ CIA. LTDA. | 9900-DME-0920 | WizDx COVID-19 CrystalMix PCR Kit | PCR | COREA |
| | | | | |