



Ministerio de Salud y Desarrollo Social
Secretaría de Gobierno de Salud
A.N.M.A.T.

DECLARACIÓN DE CONFORMIDAD

En nombre y representación de la firma Tecnolab S.A., declaramos bajo juramento, en los términos previstos por la Disposición ANMAT N° 2275/06, que los Productos Médicos para Diagnóstico de Uso In-Vitro cuyos datos identificatorios y demás características se detallan a continuación, CUMPLEN los requisitos técnicos previstos en el Anexo I de la Disposición ANMAT N° 2674/99 Cumple las normas técnicas IEC 61010-1 "Requisitos de seguridad de equipos eléctricos de medida, control y uso en laboratorio. Parte 1: Requisitos generales" e IEC 61010-2-101 "Requisitos de seguridad de equipos eléctricos de medida, control y uso en laboratorio. Parte 2-101: Requisitos particulares para equipos médicos para diagnóstico in vitro (DIV) , conservándose la documentación respaldatoria a disposición de las autoridades en el domicilio de la empresa.

Número de PM:

1252-180

Nombre técnico del producto:

17-093 - Reactivos para Inmunodiagnóstico

Nombre comercial:

A. LISTADO DE ANTICUERPOS POLICLONALES PARA INMUNODIAGNÓSTICO MULTIPARAMÉTRICO.

B. SISTEMAS PARA TINCIÓN AUTOMATIZADA EN INMUNODIAGNÓSTICO (REACTIVOS AUXILIARES E INSTRUMENTOS).

Modelos:

A. LISTADO DE ANTICUERPOS POLICLONALES PARA INMUNODIAGNÓSTICO MULTIPARAMÉTRICO

1 A0001, Polyclonal Rabbit Anti-Human Albumin, 2mL

- 2 A0002, Polyclonal Rabbit Anti-Human Prealbumin, 2mL
- 3 A0008, Polyclonal Rabbit Anti-Human Alpha-1-Fetoprotein, 0.2mL
- 4 A0012, Polyclonal Rabbit Anti-Human Alpha-1-Antitrypsin, 2mL
- 5 A0021, Polyclonal Rabbit Anti-Human Gc-Globulin, 2mL
- 6 A0024, Polyclonal Rabbit Anti-Human Tau, 1mL
- 7 A0030, Polyclonal Rabbit Anti-Human Haptoglobin, 2mL
- 8 A0040, Polyclonal Rabbit Anti-Human Retinol-Binding Protein, 2mL
- 9 A0061, Polyclonal Rabbit Anti-Human Transferrin, 2mL
- 10 A0062, Polyclonal Rabbit Anti-Human C3c Complement, 2mL
- 11 A0063, Polyclonal Rabbit Anti-Human C3d Complement, 2mL
- 12 A0072, Polyclonal Rabbit Anti-Human Beta-2-Microglobulin, 2mL
- 13 A0080, Polyclonal Rabbit Anti-Human Fibrinogen, 2mL
- 14 A0082, Polyclonal Rabbit Anti-Human Von Willebrand Factor, 2mL
- 15 A0092, Polyclonal Rabbit Anti-Human IgA, 2mL
- 16 A0093, Polyclonal Rabbit Anti-Human IgD, 2mL
- 17 A0094, Polyclonal Rabbit Anti-Human IgE, 2mL
- 18 A0099, Polyclonal Rabbit Anti-Human Lysozyme EC 3.2.1.17, 2mL
- 19 A0100, Polyclonal Rabbit Anti-Human Kappa Free Light Chains, 2mL
- 20 A0101, Polyclonal Rabbit Anti-Human Lambda Free Light Chains, 2mL
- 21 A0136, Polyclonal Rabbit Anti-Human C1q Complement, 2mL
- 22 A0146, Polyclonal Rabbit Anti-Human Gelsolin, 1mL
- 23 A0190, Polyclonal Rabbit Anti-Human IgA, IgG, IgM, 2mL
- 24 A0191, Polyclonal Rabbit Anti-Human Kappa Light Chains, 2mL
- 25 A0192, Polyclonal Rabbit Anti-Human Kappa Light Chains, 2mL
- 26 A0193, Polyclonal Rabbit Anti-Human Lambda Light Chains, 2mL
- 27 A0194, Polyclonal Rabbit Anti-Human Lambda Light Chains, 2mL
- 28 A0206, Polyclonal Rabbit Anti-Human Serum, 2mL
- 29 A0231, Polyclonal Rabbit Anti-Human Chorionic Gonadotropin, 2mL
- 30 A0245, Polyclonal Rabbit Anti-Human Fibronectin, 2mL
- 31 A0251, Polyclonal Rabbit Anti-Human Thyroglobulin, 2mL
- 32 A0262, Polyclonal Rabbit Anti-Human IgA, 1mL
- 33 A0384, Polyclonal Rabbit Anti-Human Protein S, 1mL
- 34 A0398, Polyclonal Rabbit Anti-Human Myeloperoxidase, 0.2mL
- 35 A0423, Polyclonal Rabbit Anti-Human IgG, 1mL
- 36 A0424, Polyclonal Rabbit Anti-Human IgG, 2mL
- 37 A0425, Polyclonal Rabbit Anti-Human IgM, 1mL
- 38 A0426, Polyclonal Rabbit Anti-Human IgM, 2mL
- 39 A0452, Polyclonal Rabbit Anti-Human CD3, 1mL
- 40 A0485, Polyclonal Rabbit Anti-Human c-erbB-2 Oncoprotein, 1mL
- 41 A0568, Polyclonal Rabbit Anti-Human Gastrin, 1mL
- 42 A0576, Polyclonal Rabbit Anti-Human Calcitonin, 1mL
- 43 B0114, Polyclonal Rabbit Anti- Herpes Simplex Virus Type 1, 2mL
- 44 B0357, Polyclonal Rabbit Anti- Escherichia Coli, 2mL
- 45 B0471, Polyclonal Rabbit Anti- Helicobacter Pylori, 0.2mL
- 46 C0222, Polyclonal Rabbit Anti-Human Kappa Light Chains/APC Rabbit F(ab')₂, 1mL
- 47 D0306, Polyclonal Swine Anti- Rabbit Immunoglobulins/AP, 1mL
- 48 D0314, Polyclonal Rabbit Anti- Mouse Immunoglobulins/AP, 2mL
- 49 D0336, Polyclonal Rabbit Anti-Human IgG/AP, 1mL
- 50 D0486, Polyclonal Goat Anti- Mouse Immunoglobulins/AP, 2mL
- 51 D0487, Polyclonal Goat Anti- Rabbit Immunoglobulins/AP, 1mL
- 52 E0353, Polyclonal Swine Anti- Rabbit Immunoglobulins/ Biotinylated, 1mL

- 53 E0354, Polyclonal Rabbit Anti- Mouse Immunoglobulins/ Biotinylated, 1mL
- 54 E0413, Polyclonal Rabbit Anti- Mouse Immunoglobulins/ Biotinylated Rabbit F(ab')₂, 1mL
- 55 E0431, Polyclonal Swine Anti- Rabbit Immunoglobulins/ Biotinylated Swine F(ab')₂, 1mL
- 56 E0433, Polyclonal Goat Anti- Mouse Immunoglobulins/ Biotinylated, 1mL
- 57 E0466, Polyclonal Rabbit Anti- Goat Immunoglobulins/ Biotinylated, 1mL
- 58 F0054, Polyclonal Swine Anti- Rabbit Immunoglobulins/ FITC Swine F(ab')₂, 1mL
- 59 F0058, Polyclonal Rabbit Anti-Human IgM/FITC Rabbit F(ab')₂, 1mL
- 60 F0111, Polyclonal Rabbit Anti-Human Fibrinogen/FITC, 2mL
- 61 F0117, Polyclonal Rabbit Anti-Human Albumin/FITC, 2mL
- 62 F0169, Polyclonal Rabbit Anti-Human C4c Complement/FITC, 2mL
- 63 F0185, Polyclonal Rabbit Anti-Human IgG/FITC Rabbit F(ab')₂, 1mL
- 64 F0188, Polyclonal Rabbit Anti-Human IgA/FITC Rabbit F(ab')₂, 1mL
- 65 F0189, Polyclonal Rabbit Anti-Human IgD/FITC Rabbit F(ab')₂, 1mL
- 66 F0198, Polyclonal Rabbit Anti-Human Kappa Light Chains/FITC, 2mL
- 67 F0199, Polyclonal Rabbit Anti-Human Lambda Light Chains/FITC, 2mL
- 68 F0200, Polyclonal Rabbit Anti-Human IgA, IgG, IgM, Kappa, Lambda/FITC, 2mL
- 69 F0201, Polyclonal Rabbit Anti-Human C3c Complement/FITC, 2mL
- 70 F0202, Polyclonal Rabbit Anti-Human IgG/FITC, 2mL
- 71 F0203, Polyclonal Rabbit Anti-Human IgM/FITC, 2mL
- 72 F0204, Polyclonal Rabbit Anti-Human IgA/FITC, 2mL
- 73 F0205, Polyclonal Swine Anti- Rabbit Immunoglobulins/ FITC, 2mL
- 74 F0254, Polyclonal Rabbit Anti-Human C1q Complement/FITC, 2mL
- 75 F0261, Polyclonal Rabbit Anti- Mouse Immunoglobulins/ FITC, 2mL
- 76 F0313, Polyclonal Rabbit Anti- Mouse Immunoglobulins/ FITC Rabbit F(ab')₂, 2mL
- 77 F0315, Polyclonal Rabbit Anti-Human IgG/FITC Rabbit F(ab')₂, 1mL
- 78 F0316, Polyclonal Rabbit Anti-Human IgA/FITC Rabbit F(ab')₂, 1mL
- 79 F0317, Polyclonal Rabbit Anti-Human IgM/FITC Rabbit F(ab')₂, 1mL
- 80 F0372, Polyclonal Rabbit Anti-Human Lysozyme EC 3.2.1.17/FITC, 1mL
- 81 F0434, Polyclonal Rabbit Anti-Human Kappa Light Chains/FITC Rabbit F(ab')₂, 1mL
- 82 F0435, Polyclonal Rabbit Anti-Human Lambda Light Chains/FITC Rabbit F(ab')₂, 1mL
- 83 F0479, Polyclonal Goat Anti- Mouse Immunoglobulins/ FITC Goat F(ab')₂, 2mL
- 84 GA500, FLEX Polyclonal Rabbit Anti-Human Alpha-1-Fetoprotein Ready-to-Use (Dako Omnis), 12mL
- 85 GA503, FLEX Polyclonal Rabbit Anti-Human CD3 Ready-to-Use (Dako Omnis), 12mL
- 86 GA504, FLEX Polyclonal Rabbit Anti- S100 Ready-to-Use (Dako Omnis), 12mL
- 87 GA505, FLEX Polyclonal Rabbit Anti-Human Alpha-1-Antitrypsin Ready-to-Use (Dako Omnis), 12mL
- 88 GA506, FLEX Polyclonal Rabbit Anti-Human Kappa Light Chains Ready-to-Use (Dako Omnis), 12mL
- 89 GA507, FLEX Polyclonal Rabbit Anti-Human Lambda Light Chains Ready-to-Use (Dako Omnis), 12mL
- 90 GA508, FLEX Polyclonal Rabbit Anti-Human Chorionic Gonadotropin Ready-to-Use (Dako Omnis), 12mL
- 91 GA509, FLEX Polyclonal Rabbit Anti-Human Thyroglobulin Ready-to-Use (Dako Omnis), 12mL
- 92 GA510, FLEX Polyclonal Rabbit Anti-Human IgA Ready-to-Use (Dako Omnis), 12mL
- 93 GA511, FLEX Polyclonal Rabbit Anti-Human Myeloperoxidase Ready-to-Use (Dako Omnis), 12mL
- 94 GA512, FLEX Polyclonal Rabbit Anti-Human IgG, RTU (Dako Omnis), 12mL
- 95 GA513, FLEX Polyclonal Rabbit Anti-Human IgM, RTU (Dako Omnis), 12mL
- 96 GA515, FLEX Polyclonal Rabbit Anti-Human Calcitonin Ready-to-Use (Dako Omnis), 12mL
- 97 GA519, FLEX Polyclonal Rabbit Anti-Human Gastrin Ready-to-Use (Dako Omnis), 12mL

- 98 GA521, FLEX Polyclonal Rabbit Anti- Herpes Simplex Virus Type 1 Ready-to-Use (Dako Omnis), 12mL
- 99 GA523, FLEX Polyclonal Rabbit Anti- Helicobacter Pylori Ready-to-Use (Dako Omnis), 12mL
- 100 GA524, FLEX Polyclonal Rabbit Anti- Glial Fibrillary Acidic Protein Ready-to-Use (Dako Omnis), 12mL
- 101 GA527, FLEX Polyclonal Rabbit Anti-Human Von Willebrand Factor Ready-to-Use (Dako Omnis), 12mL
- 102 IR500, FLEX Polyclonal Rabbit Anti-Human Alpha-1-Fetoprotein Ready-to-Use (Link), 40-60 Tests
- 103 IR503, FLEX Polyclonal Rabbit Anti-Human CD3 Ready-to-Use (Link), 40-60 Tests
- 104 IR504, FLEX Polyclonal Rabbit Anti- S100 Ready-to-Use (Link), 40-60 Tests
- 105 IR505, FLEX Polyclonal Rabbit Anti-Human Alpha-1-Antitrypsin Ready-to-Use (Link), 40-60 Tests
- 106 IR506, FLEX Polyclonal Rabbit Anti-Human Kappa Light Chains Ready-to-Use (Link), 40-60 Tests
- 107 IR507, FLEX Polyclonal Rabbit Anti-Human Lambda Light Chains Ready-to-Use (Link), 40-60 Tests
- 108 IR508, FLEX Polyclonal Rabbit Anti-Human Chorionic Gonadotropin Ready-to-Use (Link), 40-60 Tests
- 109 IR509, FLEX Polyclonal Rabbit Anti-Human Thyroglobulin Ready-to-Use (Link), 40-60 Tests
- 110 IR510, FLEX Polyclonal Rabbit Anti-Human IgA Ready-to-Use (Link), 40-60 Tests
- 111 IR511, FLEX Polyclonal Rabbit Anti-Human Myeloperoxidase Ready-to-Use (Link), 40-60 Tests
- 112 IR512, FLEX Polyclonal Rabbit Anti-Human IgG Ready-to-Use (Link), 40-60 Tests
- 113 IR513, FLEX Polyclonal Rabbit Anti-Human IgM Ready-to-Use (Link), 40-60 Tests
- 114 IR515, FLEX Polyclonal Rabbit Anti-Human Calcitonin Ready-to-Use (Link), 40-60 Tests
- 115 IR517, FLEX Polyclonal Rabbit Anti-Human IgD Ready-to-Use (Link), 40-60 Tests
- 116 IR519, FLEX Polyclonal Rabbit Anti-Human Gastrin Ready-to-Use (Link), 40-60 Tests
- 117 IR521, FLEX Polyclonal Rabbit Anti-Herpes Simplex Virus Type 1 Ready-to-Use (Link), 40-60 Tests
- 118 IR523, FLEX Polyclonal Rabbit Anti- Helicobacter Pylori Ready-to-Use (Link), 40-60 Tests
- 119 IR524, FLEX Polyclonal Rabbit Anti- Glial Fibrillary Acidic Protein Ready-to-Use (Link), 40-60 Tests
- 120 IR527, FLEX Polyclonal Rabbit Anti-Human Von Willebrand Factor Ready-to-Use (Link), 40-60 Tests
- 121 IR002 , FLEX Polyclonal Guinea Pig Anti-Insulin, Ready-to-Use (Link), 40-60 Tests
- 122 P0141, Polyclonal Rabbit Anti- Guinea Pig Immunoglobulins/HRP, 2mL
- 123 P0160, Polyclonal Rabbit Anti- Goat Immunoglobulins/HRP, 2mL
- 124 P0161, Polyclonal Rabbit Anti- Mouse Immunoglobulins/ HRP, 2mL
- 125 P0212, Polyclonal Rabbit Anti-Human IgA, IgG, IgM, Kappa, Lambda/HRP, 2mL
- 126 P0214, Polyclonal Rabbit Anti-Human IgG/HRP, 2mL
- 127 P0215, Polyclonal Rabbit Anti-Human IgM/HRP, 2mL
- 128 P0216, Polyclonal Rabbit Anti-Human IgA/HRP, 2mL
- 129 P0217, Polyclonal Swine Anti- Rabbit Immunoglobulins/ HRP, 2mL
- 130 P0226, Polyclonal Rabbit Anti-Human Von Willebrand Factor/HRP, 2mL
- 131 P0260, Polyclonal Rabbit Anti- Mouse Immunoglobulins/ HRP, 2mL
- 132 P0399, Polyclonal Swine Anti- Rabbit Immunoglobulins/ HRP, 1mL
- 133 P0447, Polyclonal Goat Anti- Mouse Immunoglobulins/ HRP, 1mL
- 134 P0448, Polyclonal Goat Anti- Rabbit Immunoglobulins/ HRP, 1mL
- 135 P0449, Polyclonal Rabbit Anti- Goat Immunoglobulins/HRP, 1mL
- 136 Q0102, Polyclonal Rabbit Anti-Human Alpha-2-Macroglobulin, 5mL

- 137 Q0122, Polyclonal Rabbit Anti-Human Fibrinogen, 5mL
- 138 Q0149, Polyclonal Rabbit Anti-Human Fibronectin, 5mL
- 139 Q0326, Polyclonal Rabbit Anti-Human Orosomucoide (Alpha-1-Acid Glycoprotein), 5mL
- 140 Q0327, Polyclonal Rabbit Anti-Human Transferrin, 5mL
- 141 Q0328, Polyclonal Rabbit Anti-Human Albumin, 5mL
- 142 Q0329, Polyclonal Rabbit Anti-Human C-Reactive Protein, 10mL
- 143 Q0330, Polyclonal Rabbit Anti-Human Haptoglobina, 5mL
- 144 Q0331, Polyclonal Rabbit Anti-Human IgG, 5mL
- 145 Q0332, Polyclonal Rabbit Anti-Human IgA, 5mL
- 146 Q0333, Polyclonal Rabbit Anti-Human IgM, 5mL
- 147 Q0362, Polyclonal Rabbit Anti-Human Prealbumin (Transthyretin), 5mL
- 148 Q0363, Polyclonal Rabbit Anti-Human Alpha-1-Antitripsina, 5mL
- 149 Q0368, Polyclonal Rabbit Anti-Human C3c Complement, 5mL
- 150 Q0369, Polyclonal Rabbit Anti-Human C4c Complement, 5mL
- 151 Q0495, Polyclonal Rabbit Anti-Human Alpha-1-Microglobulina, 5mL
- 152 Q0496, Polyclonal Rabbit Anti-Human Apolipoproteína A-I, 5mL
- 153 Q0497, Polyclonal Rabbit Anti-Human Apolipoproteína B, 5mL
- 154 Q0498, Polyclonal Rabbit Anti-Human Kappa Light Chains, 5mL
- 155 Q0499, Polyclonal Rabbit Anti-Human Lambda Light Chains, 5mL
- 156 R0436, Polyclonal Rabbit Anti-Human Kappa Light Chains/RPE Rabbit F(ab')₂, 1mL
- 157 R0437, Polyclonal Rabbit Anti-Human Lambda Light Chains/RPE Rabbit F(ab')₂, 1mL
- 158 R0439, Polyclonal Rabbit Anti- Mouse Immunoglobulins/ RPE, Rabbit F(ab')₂, 1mL
- 159 R0480, Polyclonal Goat Anti- Mouse Immunoglobulins/ RPE, Goat F(ab')₂, 1mL
- 160 R5111, Polyclonal Rabbit Anti-Human IgM/RPE, Rabbit F(ab')₂, 1mL
- 161 R5112, Polyclonal Rabbit Anti-Human IgD/RPE, Rabbit F(ab')₂, 1mL
- 162 A0570 , Polyclonal Rabbit Anti-Human Growth Hormone, 1mL
- 163 A4502 , Polyclonal Rabbit Anti-Human CD117, c-kit, 0.2mL
- 164 Z0622 , Polyclonal Rabbit Anti-Cytokeratin, Wide Spectrum Screening, 1mL

B. SISTEMAS PARA TINCIÓN AUTOMATIZADA EN INMUNODIAGNÓSTICO (REACTIVOS AUXILIARES E INSTRUMENTOS).

- 165 AR210, Artisan Link (Instrumento para realizar de forma automatizada tinciones especiales en IHC)
- 166 AR310, Artisan Link Pro (Instrumento para realizar de forma automatizada tinciones especiales en IHC. Permite realizar múltiples protocolos de tinción al mismo tiempo)
- 167 AR102 , Artisan 50x Wash Solution, 200mL
- 168 AR158 , Artisan Iron Stain Kit, 100 Tests
- 169 AR160 , Artisan Alcian Blue pH 2.5 Stain Kit, 100 Tests
- 170 AR161 , Artisan Congo Red Stain Kit, 100 Tests
- 171 AR162 , Artisan Acid-Fast Bacteria (AFB) Stain Kit, 100 Tests
- 172 AR163 , Artisan Elastic Stain Kit, 100 Tests
- 173 AR164 , Artisan Giemsa Stain Kit, 50 Tests
- 174 AR165 , Artisan Periodic Acid Schiff Stain Kit, 100 Tests
- 175 AR166 , Artisan Gomori's Green Trichrome Stain Kit, 50 Tests
- 176 AR167 , Artisan Gomori's Trichrome Stain Kit, 50 Tests
- 177 AR168 , Artisan Mucicarmine Stain Kit, 100 Tests
- 178 AR169 , Artisan Alcian Blue/PAS Stain Kit, 100 Tests
- 179 AR171 , Artisan Alpha-Amylase, 100 Tests
- 180 AR172 , Artisan PAS-Green Stain Kit, 100 Tests
- 181 AR173 , Artisan Masson's Trichrome Stain Kit, 100 Tests
- 182 AR175 , Artisan Gram Stain Kit, 50 Tests
- 183 AR176 , Artisan Grocott's Methenamine Silver Stain Kit, 100 Tests

- 184 AR178 , Artisan Alcian Blue/PAS/Hematoxylin Stain Kit, 100 Tests
- 185 AR179 , Artisan Reticulin/Nuclear Fast Red Stain Kit, 100 Tests
- 186 AR180 , Artisan Jones' Basement Membrane Stain Kit, 100 Tests
- 187 AR181 , Artisan Warthin-Starry Stain Kit, 100 Tests
- 188 AR182 , Artisan Reticulin/No Counterstain Stain Kit, 100 Tests
- 189 AR185 , Artisan User Fillable #1, 200 Tests
- 190 AR187 , Artisan User Fillable #3, 200 tests
- 191 AR188 , Artisan User Fillable #4, 200 tests
- 192 AR189 , Artisan User Fillable #5, 200 tests
- 193 AR190 , Artisan User Fillable #6, 200 tests
- 194 AR191 , Artisan User Fillable #7, 200 tests
- 195 AR192 , Artisan User Fillable #8, 200 tests
- 196 AR193 , Artisan User Fillable #9, 200 tests
- 197 AR194 , Artisan User Fillable #10, 200 tests
- 198 AR195 , Artisan User Fillable #11, 200 tests
- 199 AR196 , Artisan User Fillable #12, 200 tests
- 200 AR198 , Artisan User Fillable #14, 200 tests
- 201 AR306 , Artisan Gram Yellow Stain Kit, 50 Tests
- 202 AR307 , Artisan Colloidal Iron Stain Kit, 50 Tests
- 203 AR309 , Artisan Clearing Solution, 100 Tests
- 204 AR313 , Artisan Orcein Stain Kit, 50 Tests
- 205 AR314 , Artisan Maintenance Kit, 100 Tests
- 206 AR362 , Artisan Acid-Fast Bacteria (AFB) Light Green Stain Kit, 50 Tests
- 207 AR376 , Artisan Grocott's Methenamine Silver Eosin Stain Kit, 50 Tests
- 208 AR380 , Artisan Jones' Basement Membrane Light Green (PAS-M) Stain Kit, 50 Tests
- 209 AR480 , Artisan Jones Basement Membrane H&E (PAS-M) Stain Kit, 100 Tests
- 210 AS480, Autostainer Link 48 (Instrumento para realizar de forma automatizada tinciones en IHC)
- 211 K8000 , EnVision FLEX, High pH, (Link), 400-600 Tests
- 212 K8002 , EnVision FLEX+, Mouse, High pH, (Link), 400-600 Tests
- 213 K8004 , EnVision FLEX Target Retrieval Solution, High pH (50x), 30mL
- 214 K8005 , EnVision FLEX Target Retrieval Solution, Low pH (50x), 30mL
- 215 K8006 , EnVision FLEX Antibody Diluent, 120mL
- 216 K8007 , EnVision FLEX Wash Buffer (20x), 1L
- 217 K8008 , EnVision FLEX Hematoxylin, (Link), 45mL
- 218 K8009, EnVision FLEX+ Rabbit (LINKER), (Link), 40mL
- 219 K8010 , EnVision FLEX, High pH, (Dako Autostainer/Autostainer Plus), 400-600 Tests
- 220 K8012 , EnVision FLEX+, Mouse, High pH, (Dako Autostainer/Autostainer Plus), 400-600 Tests
- 221 K8018 , EnVision FLEX Hematoxylin, (Dako Autostainer/Autostainer Plus), 13mL
- 222 K8019 , EnVision FLEX+ Rabbit (LINKER), (Dako Autostainer/Autostainer Plus), 13mL
- 223 K8021 , EnVision FLEX+ Mouse (LINKER), (Link), 40mL
- 224 K8022 , EnVision FLEX+ Mouse (LINKER), (Dako Autostainer/Autostainer Plus), 13mL
- 225 K8023 , EnVision FLEX Mini Kit, High pH, (Link), 125-190 Tests
- 226 K8024 , EnVision FLEX Mini Kit, High pH, (Dako Autostainer/Autostainer Plus), 125-190 Tests
- 227 K5355, EnVision G|2 System/AP Rabbit/Mouse (Permanent Red), 50 Tests
- 228 K5361, EnVision G|2 Doublestain System, Rabbit/Mouse (DAB+/Permanent Red), 150 Tests
- 229 K8000, EnVision FLEX, High pH (Link), 400-600 Tests
- 230 K8002, EnVision FLEX+, Mouse, High pH (Link), 400-600 Tests
- 231 K8004, EnVision FLEX Target Retrieval Solution High pH (50x), 30mL

- 232 K8005, EnVision FLEX Target Retrieval Solution Low pH (50x), 30mL
- 233 K8006, EnVision FLEX Antibody Diluent, 120mL
- 234 K8007, EnVision FLEX Wash Buffer (20x), 1L
- 235 K8008, EnVision FLEX Hematoxylin (Link), 45mL
- 236 K8009, EnVision FLEX+ Rabbit (LINKER) (Link), 40mL
- 237 K8010, EnVision FLEX, High pH (Dako Autostainer/Autostainer Plus), 400-600 Tests
- 238 K8012, EnVision FLEX+, Mouse, High pH (Dako Autostainer/Autostainer Plus), 400-600 Tests
- 239 K8018, EnVision FLEX Hematoxylin (Dako Autostainer/ Autostainer Plus), 13mL
- 240 K8019, EnVision FLEX+ Rabbit (LINKER) (Dako Autostainer/ Autostainer Plus), 13mL
- 241 K8020, FLEX IHC Microscope Slides, 5 x 100 slides, 25 x 75 mm
- 242 K8021, EnVision FLEX+ Mouse (LINKER) (Link), 40mL
- 243 K8022, EnVision FLEX+ Mouse (LINKER) (Dako Autostainer/ Autostainer Plus), 13mL
- 244 K8023, EnVision FLEX Mini Kit, High pH (Link), 125-190 Tests
- 245 K8024, EnVision FLEX Mini Kit, High pH (Dako Autostainer/Autostainer Plus), 125-190 Tests
- 246 SK110 , EnVision DuoFLEX Doublestain System (Link), 100-150 Tests
- 247 LX004, Cystatin C Immunoparticles (ERM-DA471/IFCC Standardized), 10mL
- 248 P0397, Streptavidin/HRP, 1mL
- 249 S2002, Dako Pen, for Immunocytochemistry
- 250 K5005, Dako REAL Detection System Alkaline Phosphatase/RED Rabbit/Mouse, 500 Tests
- 251 K5007, Dako REAL EnVision Detection System Peroxidase/DAB+, Rabbit/Mouse, 500 Tests
- 252 S2022, Dako REAL Antibody Diluent, 250mL
- 253 S2023, Dako REAL Peroxidase-Blocking Solution, 250mL
- 254 C0563 , Dako Glycergel Mounting Medium, 15mL
- 255 S2367, Dako Target Retrieval Solution, pH 9 (10x), 500mL
- 256 S2368, Dako Target Retrieval Solution, pH 9 Ready-to-Use, 500mL
- 257 S2369, DakoCytomation Target Retrieval Solution Citrate pH 6 (x 10), 500mL
- 258 S2375, Dako Target Retrieval Solution, pH 9, (10x) (3-in-1), 500mL
- 259 S2452, Hybridizer Humidity Control Strips, Strips
- 260 IR600 , FLEX Negative Control, Rabbit, Ready-to-Use (Link), 80-120 Tests
- 261 IR750 , FLEX Negative Control Mouse, Ready-to-Use (Link), 80-120 Tests
- 262 DL110 , DakoLink Cassette Printer
- 263 DL200 , DakoLink Cassettes
- 264 DL201 , DakoLink Cassettes
- 265 DL202 , DakoLink Cassettes
- 266 DL211 , True Positive ID Software
- 267 CS100, DAKO CoverStainer (instrumento para la tinción automatizada con Hematoxilina y Eosina utilizada para IHC)
- 268 CS700, Dako Hematoxylin, 1L
- 269 CS701, Dako Eosin, 1L
- 270 CS702, Dako Bluing Buffer, 1L
- 271 CS703, Dako Mounting Medium, 473mL
- 272 CS704, Dako Coverglass 24 x 50 mm, 1000 pcs, 24 x 50 mm
- 273 CS705, Dako Toluene-Free Mounting Medium, 500 mL, 500mL
- 274 CS707, Dako Differentiation Solution, 1L
- 275 CS708, Dako Gill's 3 Hematoxylin, 1L
- 276 CS709, Dako Harris Hematoxylin, 1L
- 277 CS710, Dako Eosin Y Phloxine B, 1L
- 278 CS711, Dako Modified Eosin Y, 4L
- 279 GI100, DAKO Omnis (Instrumento diseñado para realizar de manera automática tinciones para IHC, FISH y CISH)

- 280 GA600 , FLEX Universal Negative Control, Rabbit, Ready-to-Use (Dako Omnis), 24mL
- 281 GA750 , FLEX Universal Negative Control, Mouse, Ready-to-Use (Dako Omnis), 24mL
- 282 GC203 , Sulfuric Acid, 0.3 M (Dako Omnis), 10mL
- 283 GC807, Wash Buffer (20x) (Dako Omnis), 175mL
- 284 GC808, Hematoxylin (Dako Omnis), 22.5mL
- 285 GM300, ISH Ethanol Solution 96% (Dako Omnis), 14mL
- 286 GM301, ISH Pre-Treatment Solution (20x) (Dako Omnis), 175mL
- 287 GM302, ISH Pepsin (Dako Omnis), 7mL
- 288 GM303, ISH Stringent Wash Buffer (20x) (Dako Omnis), 175mL
- 289 GM304, Fluorescence Mounting Medium (Dako Omnis), 0.8mL
- 290 GV800, EnVision FLEX, High pH (Dako Omnis), 600 Tests
- 291 GV804, EnVision FLEX Target Retrieval Solution High pH (50x) (Dako Omnis), 68mL
- 292 GV805, EnVision FLEX Target Retrieval Solution Low pH (50x) (Dako Omnis), 68mL
- 293 GV809, EnVision FLEX+ Rabbit LINKER (Dako Omnis), 75 Tests
- 294 GV821, EnVision FLEX+ Mouse LINKER (Dako Omnis), 75 Tests
- 295 GV823, EnVision FLEX Mini Kit, High pH (Dako Omnis), 150 Tests
- 296 GV825, EnVision FLEX DAB+ Substrate Chromogen System (Dako Omnis), 150 Tests
- 297 GV900, EnVision FLEX HRP Magenta, High pH (Dako Omnis), 600 Tests
- 298 GV925, EnVision FLEX HRP Magenta Substrate Chromogen System (Dako Omnis), 150 Tests
- 299 PT200, DAKO PT Link (Instrumento para realizar de forma automatizada los procesos de pre-tratamiento de muestras para IHC que incluye la desparafinización, rehidratación y recuperación de epitope)
- 300 K4001 , Dako EnVision+ System-HRP Labelled Polymer Anti-mouse, 110mL
- 301 K4003 , Dako EnVision+ System-HRP Labelled Polymer Anti-Rabbit, 110mL
- 302 K4005 , Dako EnVision+ System-HRP (AEC) For Use with Mouse Primary Antibodies , 1100 Tests
- 303 K4009 , Dako EnVision+ System-HRP (AEC) For Use with Rabbit Primary Antibodies , 1100 Tests
- 304 K4061 , Dako EnVision+ Dual Link System-HRP, 11mL
- 305 K4063 , Dako EnVision+ Dual Link System-HRP, 15mL
- 306 K4065 , Dako EnVision+ Dual Link System-HRP (DAB+), 150 Tests
- 307 K0598, Dako BCIP/NBT Substrate System, 150 Tests
- 308 K0601, In Situ Hybridization Detection System For Biotinylated Probes, 50 Tests
- 309 K0620 , GenPoint Tyramide Signal Amplification System for Biotinylated Probes, 65 Tests
- 310 K0625 , Dako Fuchsin+ Substrate-Chromogen System, 150 Tests
- 311 K0626 , Chemiluminescent System for Nucleic Acid Blotting, 20 tests
- 312 K0640 , Dako Liquid Permanent Red, 300 Tests
- 313 K0675 , Dako LSAB2 System-HRP, 1100 Tests
- 314 K1497 , CSA II Biotin-Free Tyramide Signal Amplification System, 150 Tests
- 315 K1501, CSA II Rabbit Link, 15mL
- 316 K3461 , Dako AEC+ High Sensitivity Substrate Chromogen, Ready-to-Use, 15mL
- 317 K3464 , Dako AEC Substrate Chromogen, Ready-to-Use, 110mL
- 318 K3467 , Dako Liquid DAB+ Substrate Chromogen System, 50 Tests
- 319 K3468 , Dako Liquid DAB+ Substrate Chromogen System, 1100 Tests
- 320 K3469 , Dako AEC+ High Sensitivity Substrate Chromogen, Ready-to-Use, 110mL
- 321 K0110, FluoroSpheres Calibration Beads for Flow Cytometry, 40 Tests
- 322 K2311, IntraStain, 100 Tests
- 323 S2005, Dako Turbidimetry/Nephelometry Dilution Buffer 1, 1L
- 324 S2006, Dako Turbidimetry/Nephelometry Reaction Buffer 3, 1L
- 325 S2007, Dako Turbidimetry/Nephelometry Reaction Buffer 1, 1L

326 S2011, Dako Turbidimetry/Nephelometry Reaction Buffer 4, 1L
327 S2361, Dako Turbidimetry/ Nephelometry Reaction Buffer 9, 100mL
328 S2364, EasyLyse Erythrocyte-Lysing Reagent, 5mL
329 X0908, Human Serum Protein Calibrator, 1mL
330 X0923, Human Serum C-Reactive Protein Calibrator, 1mL
331 X0925, Human Serum C-Reactive Protein Low Control, 5mL
332 X0926, Human Serum C-Reactive Protein High Control, 5mL
333 X0927, Isotype Reagent Mouse IgG1/FITC, 1mL
334 X0928, Isotype Reagent Mouse IgG1/RPE, 1mL
335 X0929, Ig Reagent Rabbit F(ab')₂/FITC, 1mL
336 X0930, Ig Reagent Rabbit F(ab')₂/RPE, 1mL
337 X0931, Negative Control Mouse IgG1, 1mL
338 X0933, Isotype Reagent Mouse IgG2a/FITC, 1mL
339 X0934, Isotype Reagent Mouse IgM/FITC, 1mL
340 X0936, Negative Control Rabbit Immunoglobulin Fraction (Solid-Phase Absorbed), 2mL
341 X0939, Human Serum Protein Low Control, 1mL
342 X0940, Human Serum Protein High Control, 1mL
343 X0941, Isotype Reagent Mouse IgG2b/FITC, 1mL
344 X0942, Negative Control Mouse IgM, 1mL
345 X0943, Negative Control Mouse IgG2a, 1mL
346 X0944, Negative Control Mouse IgG2b, 1mL
347 X0950, Isotype Reagent Mouse IgG2a/RPE, 1mL
348 X0955, Isotype Reagent Mouse IgG1/RPE-Cy5, 1mL
349 X0958, Human Serum Lipoprotein Calibrator, 1mL
350 X0961, Human Serum Lipoprotein Low Control, 1mL
351 X0962, Human Serum Lipoprotein High Control, 1mL
352 X0968, Isotype Reagent Mouse IgG1/APC, 1mL
353 X0998, Ig Reagent Rabbit F(ab')₂/APC, 1mL
354 X7912, Cystatin C Calibrator (ERM-DA471/IFCC Standardized), 1mL
355 X7913, Cystatin C Control Set (ERM-DA471/IFCC Standardized), 6 x 1 mL
356 Z0259, Polyclonal Rabbit Anti- Mouse Immunoglobulins, 2mL
357 Z0334, Polyclonal Rabbit Anti- Glial Fibrillary Acidic Protein, 1mL
358 Z5116, Polyclonal Rabbit Anti- PGP 9.5, 1mL
359 S0809 , Dako Antibody Diluent, 50mL
360 S1599 , Dako TMB+, 1000mL
361 S1601 , Dako TMB Blue, 1000mL
362 S1699 , Dako Target Retrieval Solution, 10X Concentrate, 500mL
363 S1700 , Dako Target Retrieval Solution, Ready-to-Use, 500mL
364 S1801 , Hybridization Solution, Nucleic Acid Blotting, 250mL
365 S1803 , Stringent Wash (2X SSC), Nucleic Acid Blotting, 57.54g
366 S1961 , Dako DAB Enhancer, 30mL
367 S1962 , Dako Methyl Green Histological Staining Reagent, 500mL
368 S1964 , Dako Ultramount Aqueous Permanent Mounting Medium, 15mL
369 S1966 , Dako Tween 20, 100mL
370 S1967 , Dako DAB Away DAB Chromogen Removal System, 50 Tests
371 S1968 , Dako Tris-Buffered Saline (TBS), pH 7.6, 2 x 5L
372 S2003 , Dako Dual Endogenous Enzyme Block, 15mL
373 S2451 , Hybridizer, 220V (instrumento para realizar desnaturalización e hibridación automatizada en técnicas de hibridación in situ, FISH/CISH)
374 S2452 , Hybridizer Humidity Control Strips
375 S3001 , Dako TBS, 6 X 1 L

376 S3002 , Dako Pepsin, 6 X 2 g
 377 S3003 , Dako Silanized Slides, 25 x 75 mm
 378 S3004 , Dako Proteinase K, 2mL
 379 S3006 , Dako Wash Buffer 10x, 1L
 380 S3020 , Dako Proteinase K, Ready-to-Use, 110mL
 381 S3022 , Dako Antibody Diluent with Background Reducing Components, 50mL
 382 S3023 , Dako Fluorescence Mounting Medium, 15mL
 383 S3024 , Dako PBS, 11.6g
 384 S3301 , Dako Automation Hematoxylin Histological Staining Reagent, 500mL
 385 S3302 , Hematoxylin Histological Staining Reagent, 500mL
 386 S3306 , Dako TBST Tris Buffered Saline with Tween 20, 10x Concentrate, 500mL
 387 S3309 , Dako Mayer's Hematoxylin (Lillie's Modification) Histological Staining Reagent, 500mL
 388 SK200 , User-Fillable Reagent Bottle, 5 mL Capacity (Link), 5mL
 389 SK201 , User-Fillable Reagent Bottle, 12 mL Capacity (Link), 12mL
 390 SK202 , User-Fillable Reagent Bottle, 25 mL Capacity (Link), 25mL
 391 SK203 , User-Fillable Reagent Bottle, 50 mL Capacity (Link), 50mL
 392 SK301 , Instrument Cleaning Kit (Link), 17 Tests
 393 SK308 , Hematoxylin (Link), 45mL
 394 SL002 , Dako Clear-It Cleaning Solution, Ready-to-Use, 3,8 L
 395 X0590 , Dako Biotin Blocking System, 150 Tests
 396 X0909 , Protein Block Serum-Free, Ready-to-Use, 110mL
 397 X3021 , Dako Levamisol Endogenous Alkaline Phosphatase Inhibitor, 15mL
 398 K5499, Cytology FISH Accessory Kit, 20 Tests

Presentaciones:

por unidad (VER LISTADO DE PRODUCTO).

Uso previsto:

Para el análisis multiparamétrico utilizando diferentes técnicas para inmunodiagnóstico: IHC (inmunohistoquímica), ICQ (inmunocitoquímica), CF (Citometría de Flujo), IB (Inmunoblotting). IP (Inmunoprecipitación), TB (Turbidimetría), NF (Nefelometría), ELISA (Enzimainmunoensayo), IF (imunofijación), FISH (hibridización in situ fluorescente), CISH (hibridización in situ cromogénica).

Período de vida útil:

- No aplica: 165 / 166 / 210 / 262 al 266 / 267 / 279 / 299 / 373 y 374.
- Vida útil de 120 meses: 388 al 391.
- Vida útil de 72 meses: 1 al 21 / 23 al 38 / 41 al 44 / 60 al 62 / 66 al 75 / 122 al 155 / 340 / 356 al 358.
- Vida útil de 60 meses: 189 al 200 / 387.
- Vida útil de 36 meses: 22 / 39 y 40 / 45 / 58 y 59 / 76 al 83 / 334 / 335 / 337 y 338 / 343 / 345 y 346 / 349 al 351.
- Vida útil de 24 meses: 46 al 53 / 56 y 57 / 63 al 65 / 84 al 93 / 95 al 97 / 99 al 120 / 156 al 162 / 164 / 229 / 241 / 247 al 249 / 254 / 256 / 258 y 259 / 268 al 273 / 300 al 303 / 316 al 320 / 323 al 328 / 334 / 336 / 339 / 344 / 347 y 348 / 352 al 355 / 361 al 366 / 371 / 375 / 377 y 378 / 383 / 394.
- Vida útil de 18 meses: 54 y 55 / 94 / 98 / 121 / 233 / 251 y 252 / 260 / 274 al 278 / 280 / 285 al 289 / 359 y 360 / 370 / 381 / 386 / 395 al 398.
- Vida útil de 15 meses: 179 / 257 / 329 al 332 / 341 y 342 / 367.

- Vida útil de 14 meses: 171.
- Vida útil de 12 meses: 163 / 167 / 170 / 172 / 188 / 202 y 203 / 205 y 206 / 211 al 228 / 230 al 232 / 234 al 240 / 242 al 246 / 253 / 255 / 261 / 281 al 284 / 290 al 298 / 304 al 315 / 368 y 369 / 372 / 376 / 379 y 380 / 382 / 384 y 385 / 392 y 393.
- Vida útil de 10 meses: 168 y 169 / 173 al 178 / 181 al 187 / 201 / 207 y 208.
- Vida útil de 9 meses: 204.
- Vida útil de 8 meses: 209 / 250.
- Vida útil de 7 meses: 180.
- Vida útil de 6 meses: 321 y 322

- Almacenamiento a temperatura ambiente (de 15 a 30 °C): 167 al 173 / 174 - caja 1 de 2 / 175 al 176 / 177 - caja 1 de 2 / 180 - caja 2 de 2 / 181 y 182 / 183 al 186 – caja 2 de 2 / 188 – caja 2 de 2 / 189 al 200 / 201 y 202 – caja 1 de 2 / 203 al 206 / 207 al 209 – caja 2 de 2 / 217 / 221 / 235 / 239 / 241 / 249 / 259 / 268 al 278 / 282 / 284 / 322 / 365 / 367 al 371 / 374 al 377 / 383 al 385 / 387 al 394.
- Almacenamiento de 2 a 8°C: 1 al 164 / 174 – caja 2 de 2 / 177 – caja 2 de 2 / 178 y 179 / 180 – caja 1 de 2 / 183 al 186 – caja 1 de 2 / 187 / 188 – caja 1 de 2 / 201 y 202 – caja 2 de 2 / 207 al 209 – caja 1 de 2 / 211 al 216 / 218 al 220 / 222 al 234 / 236 al 238 / 240 / 242 al 248 / 250 al 258 / 260 y 261 / 280 y 281 / 283 / 2865 al 298 / 300 al 321 / 323 al 364 / 366 / 372 / 378 al 382 / 386 / 395 al 398.

Nombre y domicilio del fabricante:

Dako Denmark A/S, Produktionsvej 42, 2600 Glostrup, Dinamarca: 1 al 120 / 122 al 161 / 227 al 245 / 247 al 253 / 255 al 259 / 267 al 279 / 283 al 299 / 321 al 358 / 398.

Dako North America Inc, 6392 Via real, Carpinteria, CA USA 93013, Estados Unidos de América: 121 / 162 al 226 / 246 / 254 / 260 al 266 / 280 al 282 / 300 al 320 / 359 al 397

Categoría:

Venta exclusiva a laboratorios de análisis clínicos. USO PROFESIONAL EXCLUSIVO

LUGAR Y FECHA: Argentina, 27 junio 2019

Responsable Legal
Firma y Sello

Responsable Técnico
Firma y Sello



Ministerio de Salud
Secretaría de Regulación y Gestión Sanitaria
A.N.M.A.T.

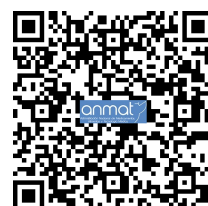
La presente DECLARACIÓN DE CONFORMIDAD ha sido emitida de acuerdo con las previsiones de la Disposición ANMAT N° 2275/06, quedando autorizada la comercialización del/los producto/s identificados en la misma.

Inscripta en el Registro Nacional de Productores y Productos de Tecnología Médica (R.P.P.T.M.) bajo el número PM **1252-180**

Ciudad de Buenos Aires a los días 27 junio 2019

Dirección de Evaluación de Registro
Firma y Sello

Dirección Nacional de Productos Médicos
Firma y Sello



Tramitada por Expediente N°: 1-0047-3110-003370-19-5