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HELLENIC ACCREDITATION SYSTEM

# Annex to the G1/14 Certificate No. **907**-5

# SCOPE of ACCREDITATION

of the

Diagnostic Laboratory

of

# LABOGEN Immunology Private Diagnostic Laboratory Medical S.A. (LABOGEN S.A.)

| **Materials / Products tested** | **Types of test / Properties measured** | **Applied methods / Techniques used** |
|---|---|---|
| **Biochemical Testing** | | |
| Blood serum | **Determination of 25 parameters** | **Automated immunochemical analyzer ABBOTT Architect ci 16200, ci8200* Quality Manual Annex 1 version 8/30.12.2024** |
| | 1. Alanine aminotransferase (ALT/GPT) | NADH (without P-5'-P) |
| | 2. Albumin | Colorimetric assay with Bromocresol Purple |
| | 3. Amylase | Enzymatic kinetic with CNPG3 Substrate |
| | 4. Calcium (Ca) | Colorimetric assay with Arsenazo III |
| | 5. Aspartateaminotransferase (AST/GOT) | NADH (without P-5'-P) |
| | 6. Gamma-glutamyl trasferase (γ-GT) | Enzymatic reaction with L-gamma-glutamyl-3-carboxy-4-nitroanilide Substrate |
| | 7. Lactate dehydrogenase (LDH) | IFCC, lactate to pyruvate |
| | 8. Glucose | Colorimetric assay with Hexokinase /G-6-PDH |
| | 9. Potassium (K) | Ion-selective electrode potentiometry |
| | 10. Creatine kinase (CPK) | Colorimetric assay with *N*-acetyl-*L*-cysteine (NAC) |
| | 11. Creatinine | JAFFE Method Kinetic Alkaline Picrate |
| | 12. Magnesium (Mg) | Enzymatic (isocitrate deydrogenase) |
| | 13. Sodium (Na) | Ion-selective electrode potentiometry |

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| Materials / Products tested | Types of test / Properties measured | Applied methods / Techniques used |
|---|---|---|
| | 14. Urea | Urease Method |
| | 15. Total Protein (TP) | Biuret Method |
| | 16. Uric Acid | Hexokinase Method |
| | 17. Iron (Fe) | Colorimetric assay with Ferene |
| | 18. Triglycerides | Enzymatic reaction with Glycerol Phosphate Oxidase |
| | 19. Alkaline Phosphatase(ALP) | Colorimetric assay with Para-nitrophenyl Phosphate |
| | 20. Phosphorus (P) | Photometric with Phosphomolybdenic Acid |
| | 22. Cloride (Cl) | Ion-selective electrode potentiometry |
| | 22. Direct Bilirubin (DBIL) | Diazo reaction |
| | 23. Total Bilirubin (TBIL) | Diazonium salt |
| | 24. Cholesterol (total) | Enzymatic reaction |
| | 25. Cholesterol (HDL) | Enzymatic reaction with Accelerator Selective Detergent |
| Blood serum | **Determination of 8 parameters** | **Automated immunochemical analyzer ABBOTT Architect ci16200* Quality Manual Annex 1 version 8/30.12.2024** |
| | 1. Immunoglobulin A (IgG) | Immunoturbidimetric |
| | 2. Immunoglobulin G (IgA) | |
| | 3. Immunoglobulin M (IgM) | |
| | 4. Complement C3 | |
| | 5. Complement C4 | |
| | 6. C reactive protein CRP | Immunoturbidimetric with latex microparticles |
| | 7. Antistreptolycin-O (ASO) | |
| | 8. Rheumatoid Factor RF | |
| **Immunological Tests** | | |
| Blood serum | **Determination of 3 parameter** | **Automated immunochemical analyzer ABBOTT Architect ci 16200, ci8200 * Quality Manual Annex 1 version 8/30.12.2024** |
| | 1. Vitamin B-12 | Chemiluminescent Microparticle Immunoassay CMIA |

| Materials / | Types of test / | Applied methods / |
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| Products tested | Properties measured | Techniques used |
|---|---|---|
| Blood serum<br><br>(cont.) | 2. Ferritin (Ferr) | |
| | 3. Folate acid | |
| Blood serum | **Determination of 1 parameter** | **Automated immunochemical analyzer ABBOTT Architect ci8200*<br>Quality Manual<br>Annex 1 version 8/30.12.2024** |
| | Insulin | Chemiluminescent Microparticle Immunoassay CMIA |
| Blood serum | **Determination of 1 parameter** | **Automated immunochemical analyzer ABBOTT Architect ci16200*<br>Quality Manual<br>Annex 1 version 8/30.12.2024** |
| | Valproic Acid | Chemiluminescent Microparticle Immunoassay CMIA |
| Blood serum | **Determination of 3 parameters** | **Automated immunochemical analyzer ABBOTT Architect i2000*<br>Quality Manual<br>Annex 1 version 8/30.12.2024** |
| | 1. 25 (OH) Vitamin D | Chemiluminescent Microparticle Immunoassay CMIA |
| | 2. Thyroid - stimulating hormone (TSH) | |
| | 3. Parathormone (PTH) | |
| Blood serum | **Determination of 12 parameters** | **Automated immunochemical analyzer SIEMENS ADVIA CENTAUR XP*<br>Quality Manual<br>Annex 1 version 8/30.12.2024** |
| | 1. Triidothyronine total (T3) | Chemiluminescent CLIA |
| | 2. Free Triidothyronine (FT3) | |
| | 3. Thyroxin total (T4) | |
| | 4. Free Thyroxin (FT4) | |
| | 5. Thyroid - stimulating hormone (TSH) | |
| | 6. Alpha-fetoprotein (AFP) | |
| | 7. Carcinoembryonic antigen (CEA) | |
| | 8. Prostate-specific antigen (PSA) | |
| | 9. Cancer marker CA 15. 3 | |
| | 10. Cancer marker CA 125 | |
| | 11. Cancer marker CA 19. 9 | |

| Materials / Products tested | Types of test / Properties measured | Applied methods / Techniques used |
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| | 12. Immunoglobulin E (IgE) | |
| Blood serum | **Determination of 16 parameters** | **Automated immunochemical analyzer ROCHE COBAS e601*** **Quality Manual** **Annex 1 version 8/30.12.2024** |
| | 1. B-Human chorionic gonadotropin (β-HCG) | Electrochemiluminescence Immunoassay ECLIA |
| | 2. Luteinizing Hormone (LH) | |
| | 3. Prolactin (PRL) | |
| | 4. Estradiol (E2) | |
| | 5. Progesterone (PRG) | |
| | 6. Follicle stimulating hormone (FSH) | |
| | 7. Total Testosterone (TESTO-T) | |
| | 8. Dehydroepiandrosterone-sulfate (DHEA-S) | |
| | 9. Sex hormone-binding globulin (SHBG) | |
| | 10. Cortisol (CORT) | |
| | 11. Thyroglobubin (Tg) | |
| | 12. Hepatitis B surface antigen (HBsAg) | |
| | 13. Hepatitis B surface antibody (HBsAb | |
| | 14. Hepatitis C antibodies (anti HCV) | |
| | 15. HIV1/2 antibodies & HIV1 p24 antigen (Anti-HIV) | |
| | 16. Hepatitis A total antibodies (anti HAV) | |
| Blood serum | **Determination of 1 parameter** | **Automated immunochemical analyzer SNIBE Maglumi X3** **Quality Manual** **Annex 1 version 8/30.12.2024** |
| | 17(OH) Progesterone | Chemiluminescent CLIA |
| Blood serum | **Determination of 8 parameters** | **Automated immunochemical analyzer ABBOTT Alinity i*** **Quality Manual** **Annex 1 version 8/30.12.2024** |
| | 1. EBV IgG-Epstein Barr Virus Antibody IgG | Chemiluminescent Microparticle Immunoassay CMIA |
| | 2. EBV IgM- Epstein Barr Virus Antibody IgM | |

| **Materials / Products tested** | **Types of test / Properties measured** | **Applied methods / Techniques used** |
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|---|---|---|
| Blood serum<br><br>(cont.) | 3. Rubella virus IgG antibodies | |
| | 4. Rubella virus IgM antibodies | |
| | 5. Cytomegalovirus IgG antibodies (CMV IgG) | |
| | 6. Cytomegalovirus IgM antibodies (CMV IgM) | |
| | 7. Toxoplasma IgG antibodies | |
| | 8. Toxoplasma IgM antibidies | |
| **Immunochemical Tests** | | |
| Blood serum | **Determination of 1 parameter** | **Automated immunochemical analyzer SIEMENS Immulite 2000 XPi* Quality Manual Annex 1 version 8/30.12.2024** |
| | Androstendione | Chemiluminescent CLIA |
| Blood serum | **Determination of 219 allergens (Specific immunoglobulin IgE - RAST)** | **Automated immunochemical analyzer SIEMENS Immulite 2000 XPi* Quality Manual Annex 1 version 8/30.12.2024** |
| | 1. c1 Penicilloyl G | Chemiluminescent CLIA |
| | 2. c2 Penicilloyl V | |
| | 3. c203 Ampicillin | |
| | 4. c204 Amoxicillin | |
| | 5. d1 Dermatophagoides pteronyssinus | |
| | 6. d2 Dermatophagoides farinae | |
| | 7. d3 Dermatophagoides microceras | |
| | 8. d70 Acarus siro | |
| | 9. d71 Lepidoglyphus destructor | |
| | 10. d72 Tyrophagus putrescentiae | |
| | 11. d73 Glycyphagus domesticus | |
| | 12. e1 Cat Dander-Epithelium | |
| | 13. e2 Dog epithelium | |
| | 14. e3 Horse dander | |

| **Materials / Products tested** | **Types of test / Properties measured** | **Applied methods / Techniques used** |
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|---|---|---|
| Blood serum (cont.) | 15. e4 Cow dander | |
| | 16. e5 Dog dander | |
| | 17. e70 Goose feathers | |
| | 18. e71 Mouse epithelium | |
| | 19. e80 Goat epithelium | |
| | 20. e81 Sheep epithelium | |
| | 21. e82 Rabbit epithelium | |
| | 22. e85 Chicken feathers | |
| | 23. e86 Duck feathers | |
| | 24. e215 Pigeon feathers | |
| | 25. f1 Egg white | |
| | 26. f2 Milk | |
| | 27. f3 Codfish | |
| | 28. f4 Wheat | |
| | 29. f5 Rye | |
| | 30. f6 Barley | |
| | 31. f7 Oat | |
| | 32. f8 Corn | |
| | 33. f9 Rice | |
| | 34. f10 Sesame seed | |
| | 35. f11 Buckwheat | |
| | 36. f12 Green pea | |
| | 37. f13 Peanut | |
| | 38. f14 Soybean | |
| | 39. f15 White bean | |
| | 40. f17 Hazelnut | |

| **Materials / Products tested** | **Types of test / Properties measured** | **Applied methods / Techniques used** |
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|---|---|---|
| Blood serum (cont.) | 41. f18 Brazil nut | |
| | 42. f20 Almond | |
| | 43. f23 Crab | |
| | 44. f24 Shrimp | |
| | 45. f25 Tomato | |
| | 46. f26 Pork | |
| | 47. f27 Beef | |
| | 48. f31 Carrot | |
| | 49. f33 Orange | |
| | 50. f35 Potato | |
| | 51. f36 Coconut | |
| | 52. f37 Blue Mussel | |
| | 53. f40 Tuna | |
| | 54. f41 Salmon | |
| | 55. f44 Strawberry | |
| | 56. f45 Baker's yeast | |
| | 57. f47 Garlic | |
| | 58. f48 Onion | |
| | 59. f49 Apple | |
| | 60. f59 Octopus | |
| | 61. f61 Sardine | |
| | 62. f75 Egg yolk | |
| | 63. f76 Alpha Lactalbumin | |
| | 64. f77 Beta Lactoglobulin | |
| | 65. f78 Casein | |
| | 66. f79 Gluten | |

| **Materials / Products tested** | **Types of test / Properties measured** | **Applied methods / Techniques used** |
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|---|---|---|
| Blood serum (cont.) | 67. f80 Lobster | |
| | 68. f81 Cheese,Cheddar | |
| | 69. f82 Cheese,Mold-type | |
| | 70. f83 Chicken meat | |
| | 71. f84 Kiwi Fruit | |
| | 72. f85 Celery | |
| | 73. f86 Parsley | |
| | 74. f87 Melon | |
| | 75. f88 Lamb | |
| | 76. f89 Mustard | |
| | 77. f90 Malt | |
| | 78. f92 Banana | |
| | 79. f93 Cacao | |
| | 80. f94 Pear | |
| | 81. f95 Peach | |
| | 82. f96 Avocado | |
| | 83. f105 Σοκολάτα | |
| | 84. f170 Swiss cheese | |
| | 85. f202 Cashew | |
| | 86. f203 Pistachio | |
| | 87. f204 Trout | |
| | 88. f208 Lemon | |
| | 89. f210 Pineapple | |
| | 90. f212 Mushroom | |
| | 91. f213 Rabbit | |
| | 92. f214 Spinach | |

| **Materials / Products tested** | **Types of test / Properties measured** | **Applied methods / Techniques used** |
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|---|---|---|
| Blood serum (cont.) | 93. f215 Lettuce | |
| | 94. f216 White cabbage | |
| | 95. f221 Coffee | |
| | 96. f222 Tea | |
| | 97. f231 Boiled milk | |
| | 98. f232 Ovalbumin | |
| | 99. f233 Ovomucoid | |
| | 100. f235 Lentil | |
| | 101. f237 Apricot | |
| | 102. f242 Cherry | |
| | 103. f245 Egg | |
| | 104. f247 Honey | |
| | 105. f255 Plum | |
| | 106. f256 Walnut | |
| | 107. f258 Squid | |
| | 108. f259 Grape | |
| | 109. f260 Broccoli | |
| | 110. f262 Eggplant | |
| | 111. f280 Black Pepper | |
| | 112. f284 Turkey Meat | |
| | 113. f291 Cauliflower | |
| | 114. f299 Chestnut | |
| | 115. f302 Mandarin | |
| | 116. f309 Chick pea | |
| | 117. f402 Fig | |
| | 118. f409 Goat's Milk | |

| **Materials / Products tested** | **Types of test / Properties measured** | **Applied methods / Techniques used** |
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|---|---|---|
| Blood serum (cont.) | 119. g1 Sweet Vernal Grass | |
| | 120. g2 Bermuda grass | |
| | 121. g3 Orchard grass | |
| | 122. g4 Meadow Fescue | |
| | 123. g5 Perennial Rye grass | |
| | 124. g6 Timothy grass | |
| | 125. g7 Common Reed Grass | |
| | 126. g8 June Grass | |
| | 127. g9 Red Top | |
| | 128. g10 Johnson Grass | |
| | 129. g11 Brome Grass | |
| | 130. g12 Cultivated Rye Grass | |
| | 131. g13 Velvet grass | |
| | 132. g14 Cultivated Oat Grass | |
| | 133. g15 Cultivated Wheat Grass | |
| | 134. g16 Meadow Foxtail Grass | |
| | 135. g17 Bahia grass | |
| | 136. g70 Wild Rye Grass | |
| | 137. g71 Canary Grass | |
| | 138. g202 Cultivated Corn | |
| | 139. h1 House dust -Greer | |
| | 140. i1 Honey Bee venom | |
| | 141. i2 White-faced Hornet | |
| | 142. i3 Yellow Jacket Venom | |
| | 143. i4 Paper wasp Venom | |
| | 144. i5 Yellow hornet | |

| **Materials / Products tested** | **Types of test / Properties measured** | **Applied methods / Techniques used** |
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| Blood serum (cont.) | 145. i6 Cockroach | |
| | 146. i70 Imported Fire Ant | |
| | 147. i71 Mosquito | |
| | 148. i75 European Hornet | |
| | 149. k20 Wool | |
| | 150. k74 Silk | |
| | 151. k82 Latex | |
| | 152. m1 Penicillium notatum | |
| | 153. m2 Cladosporium herbarum | |
| | 154. m3 Aspergilus fumigatus | |
| | 155. m4 Mucor racemosus | |
| | 156. m5 Candida albicans | |
| | 157. m6 Alternaria tenuis | |
| | 158. m7 Botrytis cinerea | |
| | 159. m8 Helminthosporium halodes | |
| | 160. m9 Fusarium moniliforme | |
| | 161. m207 Aspergillus niger | |
| | 162. p1 Ascaris | |
| | 163. p4 Anisakis | |
| | 164. t1 Maple | |
| | 165. t2 Alder | |
| | 166. t3 Birch | |
| | 167. t4 Hazelnut | |
| | 168. t5 Beech | |
| | 169. t6 Mountain Cedar | |
| | 170. t7 Oak | |

| **Materials / Products tested** | **Types of test / Properties measured** | **Applied methods / Techniques used** |
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| Blood serum (cont.) | 171. t8 Elm | |
| | 172. t9 Olive | |
| | 173. t10 Walnut | |
| | 174. t11 Sycamore | |
| | 175. t12 Willow | |
| | 176. t14 Cottonwood | |
| | 177. t15 White Ash | |
| | 178. t16 White Pine | |
| | 179. t18 Eucalyptus | |
| | 180. t19 Acacia | |
| | 181. t23 Italian Cypress | |
| | 182. t70 White Mulberry | |
| | 183. t201 Spruce | |
| | 184. t210 Privet | |
| | 185. w1 Common Ragweed | |
| | 186. w2 Western Ragweed | |
| | 187. w3 Giant Ragweed | |
| | 188. w4 False Ragweed | |
| | 189. w5 Wormwood | |
| | 190. w6 Mugwort | |
| | 191. w7 Ox-Eye Daisy | |
| | 192. w8 Dandelion | |
| | 193. w9 English Plantain | |
| | 194. w10 Lamp's Quarters | |
| | 195. w11 Russian Thistle | |
| | 196. w12 Goldenrod | |

| **Materials / Products tested** | **Types of test / Properties measured** | **Applied methods / Techniques used** |
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|---|---|---|
| Blood serum (cont.) | 197. w13 Cocklebur | |
| | 198. w14 Rough Pigweed | |
| | 199. w16 Rough Marsh Elder | |
| | 200. w18 Sheep Sorrel | |
| | 201. w19 Parietaria officinalis | |
| | 202. w20 Nettle | |
| | 203. w21 Parietaria Judaica | |
| | 204. EP1 Epidermals mix (E1, E3, E4, E5) | |
| | 205. EP71 Farm fowl mix (E70, E85, E86, E89) | |
| | 206. FP1 Nut mix (f13, 17, 18, 20, 36) | |
| | 207. FP2 Fish/Shell mix (f3, 24, 37, 40, 41) | |
| | 208. FP3 Cereal mix (f4, 7, 8, 10, 11) | |
| | 209. FP73 Meat mix (f26, 27, 83, 88) | |
| | 210. FP13 Vegetable mix (f12, 15, 31, 35) | |
| | 211. FP15 Fruit mix 1 (f33, 49, 92, 95) | |
| | 212. GP1 Grass mix, Early blooming (g3, 4, 5, 6, 8) | |
| | 213. GP4 Grass mix, Late blooming (g1, 5, 7, 12, 13) | |
| | 214. HP1 House mix 1 (d1, d2, h1, i6) | |
| | 215. MP1 Mold mix (m1, 2, 3, 5, 6) | |
| | 216. TP5 Tree mix, Early blooming (t2, 4, 8, 12, 14) | |
| | 217. TP6 Tree mix, Late blooming (t1, 3, 5, 7, 10) | |
| | 218. WP1 Weed mix (w1, 6, 9, 10, 11) | |
| | 219. WP5 Weed mix 2 (w1, 6, 7, 8, 12) | |

| **Materials /** | **Types of test /** | **Applied methods /** |
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| Products tested | Properties measured | Techniques used |
|---|---|---|
| **Hematological Tests** | | |
| Whole blood (EDTA) | **Determination of 1 parameter** | **Automated Chromatographic analyzer** |
| | | **BIO-RAD VARIANT II TURBO*** |
| | | **Quality Manual** |
| | | **Annex 1 version 8/30.12.2024** |
| | Determination of glycated hemoglobin (HbA1C) | HPLC (ion exchange High-performance chromatography) |
| **Complete Blood Count** | | |
| Whole blood (EDTA) | **Determination of 10 parameter** | **Automated hematology analyzer SYSMEX XN-550* Quality Manual Annex 1 version 8/30.12.2024** |
| | Hematocrit (HCT) | Count of DC pulse hight via RBC measurement |
| | Hemoglobin (Hb) | Photometric (SLS) |
| | Mean cell hemoglobin (MCH) | Calculated |
| | Mean cell hemoglobin concentration (MCHC) | Calculated |
| | Mean cell volume (MCV) | Calculated |
| | Mean Platelet Volume (MPV) | Calculated (impedance) |
| | Platelets (PLT) | Hydrodymamic focusing & DC pulse count |
| | Red distribution width (RDW) | Calculated |
| | Red blood cell (RBC) | Hydrodymamic focusing & DC pulse count |
| | White blood cell (WBC) | Flow cytomery with laser beam fluorescence/Scattering |
| **Hemostasis tests** | | |
| Plasma (Citrate) | **Determination of 5 parameter** | **Automated hematology analyzer SIEMENS BCS XP*** |
| | | **Quality Manual** |
| | | **Annex 1 version 8/30.12.2024** |
| | Partial thromboplastin time (aPTT) | Clotting det. |
| | Prothrombin Time (PT) | |
| | Prothrombin time international normalized ratio (PT INR) | |

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| | Antithrombin (ATIII) | Chromatometric, via factor Xa excess. |
| | Fibrinogen (FIBR) | Clotting det. under thrombin excess, based on Clauss method |

** Reference to the commercial name of a specific analyzer refers to a specific analytical method and protocol*

Site of assessment: **Permanent premises, 37-39 Antheon str., Athens, Greece.**
Approved signatories: **F. Vlasopoulou, P. Makridou**.

This scope of Accreditation replaces the previous one dated 27.07.2026.
The Accreditation Certificate No. **907**-5, to ELOT EN ISO 15189:2022, is valid until 13.02.2031.

Athens, 16th of September 2026

Konstantinou Evangelos Apostolos
*CEO of ESYD*