

## Accreditation scope

Name of the accredited subject: **Medirex, a.s.**

Holubyho 35, 902 01 Pezinok

**Western Slovakia, Central Laboratory Bratislava**

Galvaniho 17/C, 821 04 Bratislava

**Western Slovakia, Central Laboratory Nitra**

Novozámocká 67, 949 05 Nitra

**Eastern Slovakia, Central Laboratory Košice**

Magnezitárska 2/C, 040 13 Košice

Laboratory with a fixed accreditation scope.

| Item | Object of examination  |  | Established method |                                    | Other specification<br>(range, uncertainty, purpose,<br>equipment, etc.)   |
|------|------------------------|--|--------------------|------------------------------------|--|
|      | Biological<br>material | Analyte /<br>Parameter                 | Principle          | Identification of a<br>method      |  |
| 1.1  | serum                  | Alanine<br>Aminotransferase<br>(ALT)   | photometry         | ALT, Lachema<br>(SOP-M 1.1)        | IFCC method with pyridoxal-5-<br>phosphate<br><i>BA/KE</i>                 |
| 1.2  |                        | Albumin (ALB)                          |                    | Albumin, Siemens<br>(SOP-M 1.2)    | bromocresol green<br><i>BA/KE</i>  |
| 1.3  |                        | Alkaline<br>Phosphatase (ALP)          |                    | ALP, Lachema<br>(SOP-M 1.3)        | IFCC method with AMP<br><i>BA/KE</i>                                       |
| 1.4  |                        | α-Amylase (AMS)                        |                    | AMS, Lachema<br>(SOP-M 1.4)        | 4,6 -ethyliden-4-nitrophenyl-α-D-<br>maltoheptaoside, IFCC<br><i>BA/KE</i> |
| 1.5  |                        | Aspartate<br>Aminotransferase<br>(AST) |                    | AST, Lachema<br>(SOP-M 1.5)        | IFCC method with pyridoxal-5-<br>phosphate<br><i>BA/KE</i>                 |
| 1.6  |                        | Bilirubin Total<br>(BILT)              |                    | BILT, Lachema<br>(SOP-M 1.6)       | method with 2,4-dichloroaniline<br><i>BA/KE</i>                            |
| 1.7  |                        | Total Protein (TP)                     |                    | TP, Siemens<br>(SOP-M 1.7)         | Biuret<br><i>BA/KE</i>   |
| 1.8  |                        | γ-Glutamyl-<br>transferase (GGT)       |                    | GMT, Lachema<br>(SOP-M 1.8)        | IFCC method<br><i>BA/KE</i>  |
| 1.9  |                        | Cholesterol Total<br>(CHOL)            |                    | CHOL, Lachema<br>(SOP-M 1.9)       | enzymatic CHOD-PAP method<br><i>BA/KE</i>                                  |
| 1.10 |                        | Creatine Kinase<br>(CK)                |                    | CK, Lachema<br>(SOP-M 1.10)        | IFCC method<br><i>BA/KE</i>  |
| 1.11 |                        | Lactate<br>Dehydrogenase<br>(LDH)      |                    | LDH, Lachema<br>(SOP-M 1.11)       | IFCC method<br><i>BA/KE</i>  |
| 1.12 |                        | Triacylglycerols<br>(TAG)              |                    | TG, Lachema<br>(SOP-M 1.12)        | enzymatic GPO-PAP method<br><i>BA/KE</i>                                   |
| 1.13 |                        | Iron (Fe)                              |                    | IRON_2, Siemens<br>(SOP-M 1.13)    | colorimetric method with ferrozine<br><i>BA/KE</i>                         |
| 1.14 | serum, urine           | Phosphorus (P)                         | photometry         | IP, Siemens<br>(SOP-M 1.14)        | UV method, phosphomolybdate<br><i>BA/KE</i>                                |
| 1.15 |                        | Glucose (GLU)                          |                    | GLU, Lachema<br>(SOP-M 1.15)       | enzymatic GOD-PAP method<br><i>BA/KE</i>                                   |
| 1.16 |                        | Magnesium (Mg)                         |                    | MG, Siemens<br>(SOP-M 1.16)        | colorimetric method with xylylid<br>blue<br><i>BA/KE</i>                   |
| 1.17 |                        | Creatinine (CREA)                      |                    | Creatinine, Dialab<br>(SOP-M 1.17) | modified Jaffe method<br>with compensation<br><i>BA/KE</i>                 |



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|------|------------------------|--|---|--|--|
|      | Biological<br>material | Analyte /<br>Parameter   | Principle                                     | Identification of a<br>method                                |  |
| 1.18 | serum, urine           | Uric Acid (UA)   | photometry                                    | UA, Lachema<br>(SOP-M 1.18)                                  | enzymatic method uricase-PAP<br>BA/KE                                    |
| 1.19 |                        | Urea (UREA)  |   | UREA, Lachema<br>(SOP-M 1.19)                                | enzymatic UV method<br>urease-GLDH<br>BA/KE                              |
| 1.20 |                        | Calcium (Ca)   |   | CA, Siemens<br>(SOP-M 1.20)                                  | colorimetric method with<br>o-cresolphthalein complexone<br>BA/KE        |
| 1.21 |                        | Chloride (Cl)  | potentiometry                                 | Chloride, Siemens<br>(SOP-M 1.21)                            | ISE with dilution<br>BA/KE   |
| 1.22 |                        | Potassium (K)  |   | Potassium,<br>Siemens<br>(SOP-M 1.22)                        | ISE with dilution<br>BA/KE   |
| 1.23 |                        | Sodium (Na)  |   | Sodium, Siemens<br>(SOP-M 1.23)                              | ISE with dilution<br>BA/KE   |
| 1.24 | serum                  | C-Reactive Protein<br>(CRP)  | immunoturbidimetry                            | CRP, DiaSys<br>(SOP-M 1.24)                                  | BA/KE  |
| 1.25 |                        | Immunoglobulin A<br>(IgA)  |   | IgA, DiaSys<br>(SOP-M 1.25)                                  | BA/KE  |
| 1.26 |                        | Immunoglobulin G<br>(IgG)  |   | IgG, DiaSys<br>(SOP-M 1.26)                                  | BA/KE  |
| 1.27 |                        | Immunoglobulin M<br>(IgM)  |   | IgM, DiaSys<br>(SOP-M 1.27)                                  | BA/KE  |
| 1.28 |                        | Transferrin (Trf)  |   | TRF, Siemens<br>(SOP-M 1.28)                                 | BA/KE/NR   |
| 2.1  |                        | $\alpha$ -Fetoprotein<br>(AFP)   | electrochemi –<br>luminiscence<br>immunoassay | AFP cobas, Roche<br>(SOP-M 2.1)                              | BA/KE  |
| 2.2  |                        | Procollagen-type 1<br>N-terminal<br>propeptide (P1NP)                            |   | total P1NP cobas,<br>Roche<br>(SOP-M 2.2)                    | BA/KE  |
| 2.3  |                        | $\beta$ – Isomerized C –<br>terminal<br>telopeptides of type<br>I collagen (CTx) |   | $\beta$ - CrossLaps/<br>serum cobas,<br>Roche<br>(SOP-M 2.3) | BA/KE  |
| 2.4  | unoccupied             |  |   |  |  |
| 2.5  | serum                  | 17 $\beta$ -Estradiol (E2)   | electrochemi –<br>luminiscence<br>immunoassay | Estradiol III cobas,<br>Roche<br>(SOP-M 2.5)                 | BA/KE  |
| 2.6  |                        | Follicle stimulating<br>hormone (FSH)  |   | FSH cobas,<br>Roche<br>(SOP-M 2.6)                           | BA/KE  |
| 2.7  |                        | Choriogonado-<br>tropin (hCG)  |   | HCG+ $\beta$ cobas,<br>Roche<br>(SOP-M 2.7)                  | BA/KE  |
| 2.8  |                        | Immunoglobulin E<br>(IgE)  | chemiluminiscence<br>immunoassay              | IgE Advia Centaur,<br>Siemens<br>(SOP-M 2.8)                 | BA/KE  |
| 2.9  | unoccupied             |  |   |  |  |
| 2.10 | serum                  | Luteinizing<br>hormone (LH)  | electrochemi –<br>luminiscence<br>immunoassay | LH cobas, Roche<br>(SOP-M 2.10)                              | BA/KE  |
| 2.11 | unoccupied             |  |   |  |  |



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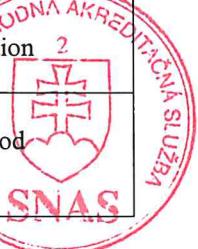
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|------|------------------------|--|--|--|--|
|      | Biological<br>material | Analyte /<br>Parameter                                   | Principle  | Identification of a<br>method                                      |  |
| 2.12 | serum                  | Pregnancy-<br>associated plasma<br>protein A<br>(PAPP-A) | electrochemi –<br>luminiscence<br>immunoassay        | PAPP-A cobas,<br>Roche<br>(SOP-M 2.12)                             | BA/KE  |
| 2.13 |                        | Parathyroid<br>hormone intact<br>(PTH)                   |  | PTH cobas,<br>Roche<br>(SOP-M 2.13)                                | BA/KE  |
| 2.14 |                        | Progesterone<br>(PROG)                                   |  | Progesterone III<br>cobas, Roche<br>(SOP-M 2.14)                   | BA/KE  |
| 2.15 |                        | Testosterone (TST)                                       |  | Testosterone II<br>cobas, Roche<br>(SOP-M 2.15)                    | BA/KE  |
| 2.16 |                        | Troponin T cardiac<br>– high sensitive<br>(hs cTnT)      |  | Troponin T hs,<br>STAT cobas,<br>Roche<br>(SOP-M 2.16)             | BA/KE  |
| 2.17 | serum                  | Ferritin (FER)   | chemiluminiscence<br>immunoassay                     | FER Advia<br>Centaur, Siemens<br>(SOP-M 2.17)                      | BA/KE  |
| 2.18 |                        | Prostate-specific<br>antigen (tPSA)                      |  | tPSA Advia<br>Centaur, Siemens<br>(SOP-M 2.18)                     | BA/KE  |
| 2.19 |                        | Prostate-specific<br>antigen free (fPSA)                 |  | fPSA Advia<br>Centaur, Siemens<br>(SOP-M 2.19)                     | BA/KE  |
| 2.20 | serum                  | Thyrotropin (TSH)  | electrochemi –<br>luminiscence<br>immunoassay        | TSH cobas, Roche<br>(SOP-M 2.20)                                   | BA/KE  |
| 2.21 |                        | Triiodothyronine<br>free (fT3)                           |  | FT3 III cobas,<br>Roche<br>(SOP-M 2.21)                            | BA/KE  |
| 2.22 |                        | Thyroxine free<br>(fT4)                                  |  | FT4 III cobas,<br>Roche<br>(SOP-M 2.22)                            | BA/KE  |
| 3.1  | serum, urine           | Protein<br>electrophoresis<br>(ELFO)                     | agarose gel<br>electrophoresis                       | Hydragel 54 β1-<br>β2, Sebia<br>(SOP-M 3.1)                        | BA/KE  |
| 3.2  |                        | Monoclonal<br>proteins (IF)                              | agarose gel<br>electrophoresis<br>and immunofixation | Hydragel 4 IF,<br>Hydragel 4 Urine<br>Profil, Sebia<br>(SOP-M 3.2) | qualitative method<br>BA/KE  |
| 3.3  | unoccupied             |  |  |  |  |
| 3.4  | peripheral<br>blood    | Glycated<br>haemoglobin A1c<br>(HbA1c)                   | HPLC   | Variant II Turbo,<br>D-100, BioRad<br>(SOP-M 3.4)                  | ionex HPLC method<br>BA/KE/NR  |



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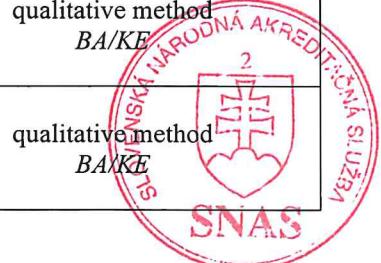
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|------|---|-------------------------------------|--|---|--|
|      | Biological<br>material                        | Analyte /<br>Parameter              | Principle                              | Identification of a<br>method   |  |
| 4.1  | peripheral blood                              | Blood cell count with differential: |  |   |  |
|      |   | Hemoglobin (HGB)                    | photometry                             |   |  |
|      |   | Erythrocytes (RBC)                  | electrical impedance                   |   |  |
|      |   | Platelets (PLT)                     |  |   |  |
|      |   | Leukocytes (WBC)                    | flow cytometry                         | BC-6800,<br>BC-6200,<br>BC-6000<br>Auto Hematology Analyzer,<br>Mindray (SOP-M 4.1) |  |
|      |   | Neutrophils granulocytes (NEU)      |  |   | BA/KE/NR   |
|      |   | Lymphocytes (LYM)                   |  |   |  |
|      |   | Monocytes (MONO)                    |  |   |  |
|      |   | Eosinophils granulocytes (EOS)      |  |   |  |
|      |   | Basophils granulocytes (BASO)       |  |   |  |
| 4.2  | plasma  | Prothrombin time (PT)               | coagulation assay                      | Thromborel S, Siemens (SOP-M 4.2)   | BA/KE/NR   |
| 4.3  | unoccupied                                    |                                     |  |   |  |
| 4.4  | plasma  | Fibrinogen (FBG)                    | coagulation assay                      | Dade Thrombin Reagent, Siemens (SOP-M 4.4)  | BA/KE/NR   |
| 4.5  |   | Antithrombin III (AT III)           | chromogenic assay                      | Berichrom Antithrombin III, Siemens (SOP-M 4.5)                                     | BA/KE  |
| 4.6  |   | D-dimer                             | immuno-turbidimetric assay             | INNOVANCE D-Dimer, Siemens (SOP-M 4.6)  | BA/KE/NR   |
| 5.1  | peripheral blood                              | CD3+                                | flow cytometry                         | Navios Flow Cytometer, Monoclonal Antibodies, Beckman Coulter (SOP-M 5.1)           |  |
|      |   | CD3+CD4+                            |  |   |  |
|      |   | CD3+CD8+                            |  |   |  |
|      |   | NK cells                            |  |   | BA/KE/NR   |
|      |   | B lymphocytes                       |  |   |  |
| 5.2  | serum   | Specific IgE                        | fluorescence immunoassay               | ImmunoCAP 250, ImmunoCAP 1000, Phadia, Specific IgE (SOP-M 5.2)                     | investigated allergens according to the manufacturer's offer of the mentioned measuring systems<br>BA/KE |
| 6.1  | peripheral blood, bone marrow                 | Fusion genes (BCR-ABL)              | Real Time PCR                          | Reference 6.1 (SOP-M 6.1)   | RTQ-PCR<br>reverse quantitative method<br>BA   |
| 6.2  | peripheral blood, bone marrow                 | V617F mutation of JAK2 gene         | Real Time PCR                          | Reference 6.2 (SOP-M 6.2)   | qualitative method<br>RQ PCR<br>alelic discrimination 2<br>BA  |
| 6.3  | peripheral blood, bone marrow, amniotic fluid | Molecular - cytogenetic analysis    | FISH fluorescent in situ hybridization | Reference 6.3 (SOP-M 6.3)   | qualitative method<br>BA   |



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|------|--|---|---|--|--|
|      | Biological<br>material   | Analyte /<br>Parameter  | Principle   | Identification of a<br>method                  |  |
| 6.4  | peripheral blood   | Karyotyping of chromosomes                                      | Cytogenetic analysis of chromosomes after 72 hours peripheral blood cultivation | Reference 6.4 (SOP-M 6.4)                      | qualitative method BA  |
| 6.5  | amniotic fluid   | Chromosome aneuploidy 13,18,21,X and Y                          | PCR/fluorescent PCR   | Reference 6.5 (SOP-M 6.5)                      | qualitative method QF PCR BA   |
| 7.1  | serum, plasma  | Hepatitis B virus surface antigen (HBsAg)                       | electrochemi – luminiscence immunoassay   | HBsAg II cobas, Roche (SOP-M 7.1)              | qualitative method BA/KE   |
| 7.2  |  | (anti-HBs)  |   | Anti-HBs II cobas, Roche (SOP-M 7.2)           | BA   |
| 7.3  |  | (anti-HBc IgM)  |   | Anti-HBc IgM cobas, Roche (SOP-M 7.3)          | qualitative method BA  |
| 7.4  |  | (anti-HBc total)  |   | Anti-HBc total cobas, Roche (SOP-M 7.4)        | qualitative method BA  |
| 7.5  |  | Hepatitis B virus e antigen (HBeAg)                             |   | HBeAg cobas, Roche (SOP-M 7.5)                 | qualitative method BA  |
| 7.6  |  | Hepatitis B virus e antibodies (anti-HBe)                       |   | Anti-HBe cobas, Roche (SOP-M 7.6)              | qualitative method BA  |
| 7.7  | serum, plasma  | Hepatitis C virus antibodies (anti-HCV)                         | electrochemi – luminiscence immunoassay   | Anti-HCV II cobas, Roche (SOP-M 7.7)           | qualitative method BA/KE   |
| 7.8  |  | Human immunodeficiency virus antigen and antibodies (HIV Ag/Ab) |   | HIV Combi PT, HIV duo cobas, Roche (SOP-M 7.8) | qualitative method BA/KE   |
| 7.9  |  | Hepatitis B virus DNA (HBV DNA)                                 | Real Time PCR   | HBV cobas, Roche (SOP-M 7.9)                   | BA   |
| 7.10 |  | Hepatitis C virus RNA (HCV RNA)                                 | Real Time PCR   | HCV cobas, Roche (SOP-M 7.10)                  | Real Time RT PCR BA  |
| 8.1  | blood culture  | The presence of diagnostically significant microorganisms       | cultivation   | Reference 8.1 (SOP-M 8.1)                      | qualitative method BA/KE/NR  |
| 8.2  | body fluid cultures (excluding blood, cerebrospinal fluid and urine) | The presence of diagnostically significant microorganisms       |   | Reference 8.2 (SOP-M 8.2)                      | qualitative method BA/KE/NR  |
| 8.3  | catheter tip cultures  | The presence of diagnostically significant microorganisms       |   | Reference 8.3 (SOP-M 8.3)                      | qualitative method BA/KE   |
| 8.4  | cerebrospinal fluid  | The presence of diagnostically significant microorganisms       |   | Reference 8.4 (SOP-M 8.4)                      | qualitative method BA/KE   |



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|      | Biological<br>material  | Analyte /<br>Parameter  | Principle   | Identification of a<br>method  |  |
| 8.5  | fecal and other<br>gastrointestinal specimens   | The presence of<br>diagnostically<br>significant<br>microorganisms                                      | cultivation   | Reference 8.5<br>(SOP-M 8.5)   | qualitative method<br><i>BA/KE/NR</i>                                    |
| 8.6  | specimens<br>from genital<br>tract  | The presence of<br>diagnostically<br>significant<br>microorganisms                                      |   | Reference 8.6<br>(SOP-M 8.6)   | qualitative method<br><i>BA/KE/NR</i>                                    |
| 8.7  | human<br>biological<br>material<br>(wound, ocular<br>and otitis<br>cultures)            | The presence of<br>diagnostically<br>significant<br>microorganisms                                      |   | Reference 8.7<br>(SOP-M 8.7)   | qualitative method<br><i>BA/KE/NR</i>                                    |
| 8.8  | specimens<br>from<br>respiratory<br>tract   | The presence of<br>diagnostically<br>significant<br>microorganisms                                      |   | Reference 8.8<br>(SOP-M 8.8)   | qualitative method<br><i>BA/KE/NR</i>                                    |
| 8.9  | urine   | The presence of<br>diagnostically<br>significant<br>microorganisms                                      | mass spectrometry   | Reference 8.9<br>(SOP-M 8.9)   | qualitative method<br><i>BA/KE/NR</i>                                    |
| 8.10 | culture of<br>microorga-nisms   | Identification of<br>microorganisms   |   | Reference 8.10<br>(SOP-M 8.10) | qualitative method<br><i>BA/KE</i>                                       |
| 8.11 | human<br>biological<br>material<br>and culture of<br>microorga-nisms                    | The presence of<br>microorganisms,<br>cellular elements<br>and identification<br>of microorganisms      | microscopic<br>examination/staining<br>procedures   | Reference 8.11<br>(SOP-M 8.11) | qualitative method<br><i>BA/KE/NR</i>                                    |
| 8.12 | culture of<br>microorga-nisms   | Identification of<br>aerobic, fakultative<br>anaerobic,<br>microaerophilic<br>and anaerobic<br>bacteria | conventional<br>biochemical tests,<br>growth properties and<br>antigen characteristic           | Reference 8.12<br>(SOP-M 8.12) | qualitative method<br><i>BA/KE/NR</i>                                    |
| 8.13 | culture of<br>microorga-nisms   | Growth and/or<br>inhibition growth<br>in the presence of<br>antimicrobial<br>agents                     | antimicrobial<br>susceptibility testing<br>(disc diffusion and<br>microdilution method,<br>MIC) | Reference 8.13<br>(SOP-M 8.13) | qualitative method<br><i>BA/KE/NR</i>                                    |
| 8.14 | biological<br>indicators for<br>monitoring<br>efficacy of<br>sterilization<br>processes | Grow of<br>microorganism –<br>biological indicator  | cultivation   | Reference 8.14<br>(SOP-M 8.14) | qualitative method<br><i>BA/KE/NR</i>                                    |
| 9.1  | human<br>biological<br>material   | The presence of<br>microscopic fungi  |   | Reference 9.1<br>(SOP-M 9.1)   | qualitative method<br><i>BA</i>  |
| 9.2  |   | The presence of<br>microscopic fungi<br>and cell elements   | microscopic<br>examination  | Reference 9.2<br>(SOP-M 9.2)   | qualitative method<br><i>BA</i>  |
| 9.3  | cultures of<br>microscopic<br>fungi   | Micromorphologic<br>al features of<br>microscopic fungi   |   | Reference 9.3<br>(SOP-M 9.3)   | qualitative method<br><i>BA</i>  |



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|      | Biological<br>material              | Analyte /<br>Parameter   | Principle                                     | Identification of a<br>method                               |  |
| 9.4  | cultures of<br>microscopic<br>fungi | Growth of<br>microscopic fungi<br>in presence specific<br>substance and<br>temperature | analysis of metabolic<br>and growth features  | Reference 9.4<br>(SOP-M 9.4)                                | qualitative method<br>BA   |
| 10.1 | serum, plasma                       | IgM antibodies<br>against<br><i>Toxoplasma gondii</i>                                  | electrochemi –<br>luminiscence<br>immunoassay | Elecsys Toxo IgM<br>cobas, Roche<br>(SOP-M 10.1)            | qualitative method<br>BA   |
| 10.2 |                                     | IgG antibodies<br>against<br><i>Toxoplasma gondii</i>                                  |   | Elecsys Toxo IgG<br>cobas, Roche<br>(SOP-M 10.2)            | BA   |
| 10.3 |                                     | Avidity of IgG<br>antibodies against<br><i>Toxoplasma gondii</i>                       |   | Elecsys Toxo IgG<br>Avidity cobas,<br>Roche<br>(SOP-M 10.3) | qualitative method<br>BA   |
| 10.4 | stool                               | The presence of<br>helminth eggs and<br>protozoan cysts                                | microscopy                                    | Reference 10.4<br>(SOP-M 10.4)                              | qualitative method<br>BA   |
| 10.5 | perianal tape<br>test               | The presence of<br><i>Enterobius<br/>vermicularis</i>                                  | microscopy                                    | Reference 10.5<br>(SOP-M 10.5)                              | qualitative method<br>BA   |

**NOTES:**

OP-M - Standard Operating Procedure for Method

BA - examination is done in Medirex, a.s. Western Slovakia, Central Laboratory Bratislava

KE - examination is done in Medirex, a.s. Eastern Slovakia, Central Laboratory Košice

NR - examination is done in Medirex, a.s. Western Slovakia, Central Laboratory Nitra

**References:**

6.1 FusionQuant Kits for Real-time Quantitative PCR Analysis of Fusion Gene Transcripts, Ipsogen, Cancer profiler, Instructions for use, 2009

<https://www.qiagen.com/us/shop/detection-solutions/personalized-healthcare/ipsogen-bcr-abl-1-mbcr-is-mmrr-kits/#orderinginformation>

Tempus TM Spin RNA Isolation Kit (kat. č. 4380204), (Life technologies)

[https://tools.lifetechnologies.com/content/sfs/brochures/cms\\_057271.pdf](https://tools.lifetechnologies.com/content/sfs/brochures/cms_057271.pdf)

[www.implen.co.uk/product.php5?id=100](http://www.implen.co.uk/product.php5?id=100)

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