

Deutsche Akkreditierungsstelle

Annex to the Accreditation Certificate D-ML-21258-01-00 according to DIN EN ISO 15189:2014

Valid from: 24.05.2024

Date of issue: 24.05.2024

Holder of accreditation certificate:

**Labor Deutscher Platz Leipzig MVZ GmbH
Deutscher Platz 5 D, 04103 Leipzig**

with the location

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The medical laboratory meets the requirements of DIN EN ISO 15189:2014 to carry out the conformity assessment activities listed in this annex. The medical laboratory meets additional legal and normative requirements, if applicable, including those in relevant sectoral schemes, provided that these are explicitly confirmed below.

The management system requirements of DIN EN ISO 15189 are written in the language relevant to the operations of medical laboratories and confirm generally with the principles of DIN EN ISO 9001.

This certificate annex is only valid together with the written accreditation certificate and reflects the status as indicated by the date of issue. The current status of any given scope of accreditation can be found in the directory of accredited bodies maintained by Deutsche Akkreditierungsstelle GmbH at <http://www.dakks.de>.

This document is a translation. The definitive version is the original German annex to the accreditation certificate.

Annex to the accreditation certificate D-ML-21258-01-00

Examinations in the field:

Medical Laboratory Diagnostics

Medical laboratory fields:

Clinical chemistry

Immunology

Microbiology

Virology

Transfusion medicine

Within the examination areas marked with *, the medical laboratory is permitted to freely select standardized or equivalent examination procedures without the need for prior information and consent from the Deutsche Akkreditierungsstelle GmbH. The examination procedures listed are examples. The medical laboratory has a current list of all examination procedures in the flexible accreditation area.

Test area: Clinical chemistry

Test type:

Flow cytometry (with determination of particle characteristics)*

Analyte (measured value)	Material for testing (matrix)	Test method
Basophil granulocytes	EDTA- blood, capillary blood	Fluorescence flow cytometry
Eosinophil granulocytes	EDTA- blood, capillary blood	Fluorescence flow cytometry
Erythrocytes (RBC)	EDTA- blood, capillary blood	Resistance measurement principle with hydrodynamic focusing
Hematocrit	EDTA- blood, capillary blood	Resistance measurement principle with hydrodynamic focusing
Hemoglobin	EDTA- blood, capillary blood	Sodium lauryl sulfate (SLS)-hemoglobin (HGB) method
Nuclear erythrocyte precursors (NRBC)	EDTA- blood, capillary blood	Fluorescence flow cytometry
Leukocytes	EDTA- blood, capillary blood	Fluorescence flow cytometry
Lymphocytes	EDTA- blood, capillary blood	Fluorescence flow cytometry
MCH (mean corpuscular hemoglobin)	EDTA- blood, capillary blood	Calculation
MCHC (mean corpuscular hemoglobin concentration)	EDTA- blood, capillary blood	Calculation
MCV (mean corpuscular volume)	EDTA- blood, capillary blood	Calculation
Monocytes	EDTA- blood, capillary blood	Fluorescence flow cytometry
Neutrophil granulocytes	EDTA- blood, capillary blood	Fluorescence flow cytometry
RDW-CV (erythrocyte distribution width)	EDTA- blood, capillary blood	Calculation
Reticulocytes	EDTA- blood, capillary blood	Fluorescence flow cytometry
Reticulocyte hemoglobin	EDTA- blood, capillary blood	Fluorescence flow cytometry
Platelets	EDTA- blood, capillary blood	Resistance measurement principle with hydrodynamic focusing
Immature granulocytes	EDTA- blood, capillary blood	Fluorescence flow cytometry

Test type:

Electrochemical tests*

Analyte (measured value)	Material for testing (matrix)	Test method
Chloride	Serum	ISE (ion selective electrode) indirect measurement
Potassium	Serum, urine	ISE (ion selective electrode) indirect measurement
Sodium	Serum, urine	ISE (ion selective electrode) indirect measurement

Test type:

Electrophoresis*

Analyte (measured value)	Material for testing (matrix)	Test method
Albumin	Serum	Capillary electrophoresis
Alpha-1-globulins	Serum	Capillary electrophoresis
Alpha-2-globulins	Serum	Capillary electrophoresis
β1-globulins	Serum	Capillary electrophoresis
β2-globulins	Serum	Capillary electrophoresis
Gamma-globulins	Serum	Capillary electrophoresis

Test type:

Coagulometry*

Analyte (measured value)	Material for testing (matrix)	Test method
Partial thromboplastin time	Citrated plasma	Coagulometry, optical detection
Thromboplastin time (INR, Quick)	Citrated plasma	Coagulometry, optical detection

Test type:

Ligand assays*

Analyte (measured value)	Material for testing (matrix)	Test method
Alpha-1 fetoprotein	Serum	Electrochemiluminescence immunoassay
Androstenedione	Serum	Competitive chemiluminescence immunoassay
CA 125	Serum	Electrochemiluminescence immunoassay
CA 15- 3	Serum	Electrochemiluminescence immunoassay
CA 19- 9	Serum	Electrochemiluminescence immunoassay
CEA (carcinoembryonic antigen)	Serum	Electrochemiluminescence immunoassay
17-OH Progesterone	Serum	Competitive enzyme immunoassay
Anti CCP	Serum	Electrochemiluminescence immunoassay
Anti-Müller-Hormon (AMH)	Serum	Electrochemiluminescence immunoassay
Cortisol	Serum	Electrochemiluminescence immunoassay
Dehydroepiandrosterone sulfate (DHEAS)	Serum	Electrochemiluminescence immunoassay
Digitoxin	Serum	Electrochemiluminescence immunoassay
Estradiol	Serum	Electrochemiluminescence immunoassay

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Analyte (measured value)	Material for testing (matrix)	Test method
Ferritin	Serum	Electrochemiluminescence immunoassay
Follicle stimulating hormone (FSH)	Serum	Electrochemiluminescence immunoassay
Folic acid	Serum	Electrochemiluminescence immunoassay
free tetraiodothyronine (fT4)	Serum	Electrochemiluminescence immunoassay
free triiodothyronine (fT3)	Serum	Electrochemiluminescence immunoassay
Holotranscobalamin	Serum	Electrochemiluminescence immunoassay
Human chorionic gonadotropin (hCG)	Serum	Electrochemiluminescence immunoassay
Immunglobulin E (IgE)	Serum	Electrochemiluminescence immunoassay
Luteinizing hormone (LH)	Serum	Electrochemiluminescence immunoassay
Myoglobin	Serum	Electrochemiluminescence immunoassay
NT pro BNP	Serum	Electrochemiluminescence immunoassay
Parathyroid hormone (PTH)	Serum	Electrochemiluminescence immunoassay
Progesterone	Serum	Electrochemiluminescence immunoassay
Prolactin	Serum	Electrochemiluminescence immunoassay
PSA	Serum	Electrochemiluminescence immunoassay
PSA, free	Serum	Electrochemiluminescence immunoassay
Sex hormone binding globulin (SHBG)	Serum	Electrochemiluminescence immunoassay
Testosterone	Serum	Electrochemiluminescence immunoassay
Troponin T hs	Serum	Electrochemiluminescence immunoassay
Vitamin B12	Serum	Electrochemiluminescence immunoassay
Vitamin D (25-OH)	Serum	Competitive chemiluminescence immunoassay

Test type:

Microscopy*

Analyte (measured value)	Material for testing (matrix)	Test method
Microscopic differential blood count	EDTA blood	Morphological microscopic assessment after Pappenheim staining
Urinary sediment	Urine	Morphological differentiation in the unstained specimen, bright-field microscopy

Test type:

Spectrometry (UV/VIS photometry)*

Analyte (measured value)	Material for testing (matrix)	Test method
Alanine aminotransferase (ALAT, ALT, GPT)	Serum	IFCC [International Federation of Clinical Chemistry and Laboratory Medicine] with photometric measurement
Albumin	Serum	BCG dye binding with photometric measurement
Alkaline phosphatase (AP)	Serum	IFCC with photometric measurement, color test
Alpha-HBDH (hydroxybutyrate dehydrogenase)	Serum	UV test according to a standardized method (DGKC)
Amylase	Serum	IFCC with photometric measurement, color test
Antistreptolysin O	Serum	Endpoint method with sample blank, photometry
Aspartate aminotransferase (ASAT, AST, GOT)	Serum	IFCC with photometric measurement, color test
Bilirubin, direct	Serum	Diazo method, colorimetric
Bilirubin, total	Serum	Diazo method, colorimetric
Bilirubin, indirect	Serum	Calculation
Calcium	Serum, urine	Photometry
Cholesterol	Serum	Enzymatic color test
Creatinine	Serum, urine	Jaffé with photometric measurement
Creatinine	Serum	Enzymatic color test
Creatine kinase	Serum	UV test (IFCC, NAC, optimized)
Creatine kinase (muscle, brain)	Serum	Immunologic UV test
Iron	Serum	Photometric, color test
Gamma-glutamyl transferase (GGT)	Serum	Enzymatic color test, IFCC
Glucose	Serum, urine	UV test using enzymatic method with hexokinase

Analyte (measured value)	Material for testing (matrix)	Test method
Glutamatdehydrogenase (GLDH)	Serum	UV test according to a standardized method Deutsche Gesellschaft für Klinische Chemie (DGKC) [German Association for Clinical Chemistry]
Haptoglobin	Serum	Immunological turbidity test
Uric acid	Serum, urine	Enzymatic color test, photometric, uricase
Urea nitrogen	serum, urine	Kinetic test with urease and GLDH
HDL	Serum	Enzymatic color test
Lactate dehydrogenase (LDH)	Serum	UV test, lactate to pyruvate, IFCC
LDL	Serum	Enzymatic color test
Lipase	Serum	Enzymatic color test, photometry
Lipoprotein (a)	Serum	Particle-enhanced immunological turbidity test
Magnesium	Serum	Color test with end point method, photometry
Phosphate (inorganic)	Serum, urine	End point method with sample blank, photometry
Total protein	Serum	Biuret with photometric Measurement
Transferrin	Serum	Immunological turbidity test
Triglycerides	Serum	Enzymatic color test

Test type:

Spectrometry (immunoturbidimetry/turbidimetry)*

Analyte (measured value)	Material for testing (matrix)	Test method
C-reactive protein	Serum	Particle-enhanced immunological turbidity test
CRP high sensitivity	Serum	Particle-enhanced immunological turbidity test
Cystatin C	Serum	Particle-enhanced immunological turbidity test
D-Dimer	Citrated plasma	Particle-enhanced immunological turbidity test
HbA1c	Venous whole blood, hemolysate	Turbidimetric immunological inhibition assay (TINIA)
Hemoglobin	Stool	Latex agglutination turbidimetry
soluble transferrin receptor	Serum	Particle-enhanced immunological turbidity test
Proteins	Urine	Turbidimetric method

Test type:

Spectrometry (reflectometry/carrier-based test procedures)*

Analyte (measured value)	Material for testing (matrix)	Test method
Leukocytes	Urine	Reflectrometry/carrier-based examination methods
Nitrite	Urine	Reflectrometry/carrier-based examination methods
Urobilinogen	Urine	Reflectrometry/carrier-based examination methods
Specific gravity	Urine	Reflectrometry/carrier-based examination methods
Erythrocytes (RBC)	Urine	Reflectrometry/carrier-based examination methods
pH value	Urine	Reflectrometry/carrier-based examination methods
Bilirubin	Urine	Reflectrometry/carrier-based examination methods
Protein	Urine	Reflectrometry/carrier-based examination methods
Glucose	Urine	Reflectrometry/carrier-based examination methods
Ketones	urine	Reflectrometry/carrier-based

Testing area: Immunology

Test type:

Electrophoresis*

Analyte (measured value)	Material for testing (matrix)	Test method
Kappa light chains	Serum	Capillary electrophoresis
Lambda light chains	Serum	Capillary electrophoresis
Immunofixation (IgA, IgG, IgM)	Serum	Capillary electrophoresis

Test type:

Ligand assays*

Analyte (measured value)	Material for testing (matrix)	Test method
Thyroid stimulating hormone (TSH)	Serum	Electrochemiluminescence immunoassay
Thyroid peroxidase autoantibodies (ATPO/MAK)	Serum	Electrochemiluminescence immunoassay
TSH receptor antibodies (TRAK)	Serum	Electrochemiluminescence immunoassay
Thyroglobulin (hTG) [high-sensitivity human thyroglobulin]	Serum	Sandwich chemiluminescence immunoassay

Test type:

Microscopy*

Analyte (measured value)	Material for testing (matrix)	Test method
Autoantibodies against cell nuclei (ANA)	Serum	Indirect immunofluorescence

Test type:

Spektrometrie Spectrometry (immunoturbidimetry)*

Analyte (measured value)	Material for testing (matrix)	Test method
IgA	Serum	Particle-enhanced immunological turbidity test
IgG	Serum	Particle-enhanced immunological turbidity test
IgM	Serum	Particle-enhanced immunological turbidity test

Test type:

Spectrometry (UV/VIS photometry)*

Analyte (measured value)	Material for testing (matrix)	Test method
Rheumatoid factor	Serum	Immunological turbidity test

Testing area: Microbiology

Test type:

Agglutination tests*

Analyte (measured value)	Material for testing (matrix)	Test method
Staphylococcus spp., MRSA, Streptococcus spp. (β -hemolytic)	Culture material	Latex agglutination tests

Test type:

Sensitivity testing of bacteria and fungi*

Analyte (measured value)	Material for testing (matrix)	Test method
Enterobacterial ESBL test	Culture material	Diagnostic agar diffusion test, - ESBL test
Microaerophilic bacteria: Haemophilus spp., Neisseria spp., Moraxella spp., Pneumococcus, Streptococcus spp., Staphylococcus spp., Enterobacterales, Pseudomonas spp., Nonfermenter	Culture material	Agar diffusion test according to EUCAST and NAK

Analyte (measured value)	Material for testing (matrix)	Test method
Streptococcus spp., Staphylococcus spp., Enterobacterales, Aeromonas spp., Pseudomonas spp., nonfermenter spp., yeasts	Culture material	Microdilution method as minimum inhibitor concentration (MIC) / breakpoint Vitek 2

Test type:

Microbial differentiation / identification / detection*

Analyte (measured value)	Material for testing (matrix)	Test method
Aerobic bacteria: Streptococcus spp., Staphylococcus spp., Micrococcus spp., Enterobacterales, Vibrio spp., Aeromonas spp., Pseudomonas spp., Nonfermenter, Coryneform rods, Listeria spp., Moraxella spp., Aerobic actinomycetes, Bacillus spp.	Culture material	Exploratory methods (oxidase, catalase, pneumococcal optochin testing, staphylococcal novobiocin testing)
Staphylococcus spp., MRSA, Streptococcus spp. (β -hemolytic)	Culture material	Latex agglutination tests
Aerobic bacteria: Streptococcus spp., Staphylococcus spp., Mikroococcus spp., Enterobacteriaceae, Vibrio spp., Aeromonas spp., Pseudomonas spp., Nonfermenters, Coryneform rods, Listeria spp., Moraxella spp., Aerobic actinomycetes	Cultural material	Biochemical identification Vitek
Anaerobic bacteria: Gram-positive anaerobic cocci (Anaerococcus spp., Peptostreptococcus spp.), Gram-positive anaerobic rods (Clostridium spp., Propionibacterium spp.), Gram-negative anaerobic cocci (Veionella spp.), Gram-negative anaerobic rods (Bacterioides spp., Prevotella spp., Fusobacterium spp.)	Culture material	Biochemical identification Vitek
Microaerophilic bacteria: Haemophilus spp., Neisseria spp., Pasteurelia spp., Actinobacillus, Capnocytophaga, Eikenella, Kingella	Culture material	Orienting methods (oxidase, catalase)

Analyte (measured value)	Material for testing (matrix)	Test method
Microaerophilic bacteria: Haemophilus spp., Neisseria spp., Pasteurelia spp., Actinobacillus, Capnocytophaga, Eikenella, Kingella	Culture material	Biochemical identification Vitek, Api NH
Mycoplasmas and ureaplasmas	Culture material	Plate microscopy, unstained
Yeasts	Culture material	Microscopy, unstained biochemical identification Vitek

Test type:

Culture-based tests*

Analyte (measured value)	Material for testing (matrix)	Test method
Gram-positive aerobic and facultative anaerobic rods (Streptococcus spp., Staphylococcus spp., Micrococcus spp.)	Swabs: urogenital tract, intrauterine pessary material, skin swabs and soft tissue swabs, ulcer swabs and wound swabs, conjunctival swabs, ear swabs, mouth swabs, nasal swabs, other swabs of affected areas, respiratory material (sputum, bronchial lavage, tracheal secretions, bronchial secretions), abscess material, pus, exudates, aspirated materials, wound secretions, Urine	Culture-based pathogen detection by culturing in aerobic and microaerobic atmospheres, enrichment processes, cultural growth behavior, culture on selective culture media
Gram-negative aerobic and facultative anaerobic rods, Enterobacteriaceae, Pasteurella spp. Haemophilus spp. Nonfermenters: Pseudomonas spp. and related species, Acinetobacter spp.	Swabs: urogenital tract, intrauterine pessary material, skin swabs, soft tissue swabs, ulcer swabs, wound swabs, conjunctival swabs, ENT swabs, rectal swabs, anal swabs, other swabs from affected areas, ejaculate, respiratory material (sputum, bronchial lavage, tracheal secretion, bronchial secretion), abscess material, pus, exudates, aspirated materials, wound secretions, urine	Culture-based pathogen detection by culturing in aerobic and microaerobic atmospheres, enrichment processes, culture growth behavior

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Analyte (measured value)	Material for testing (matrix)	Test method
Gram-negative aerobic and facultative anaerobic cocci (Moraxella spp., Neisseria spp.)	Ear swabs, throat swabs, nasal swabs, eye swabs, urogenital swabs, Sputum, bronchial secretions, tracheal secretions, Bronchoalveolar lavage {BAL}, punctures, other primarily sterile materials	Culture-based pathogen detection by culturing in aerobic and microaerobic atmospheres and possibly anaerobic atmospheres, cultural growth behavior
Gram-negative anaerobic cocci (Veionella spp.), Gram-negative anaerobic rods (Bacterioides spp., Prevotella spp., Fusobacterium spp., Gardnerella vaginalis)	Urine, swabs of the urogenital tract, intrauterine material, ejaculate, skin swabs, soft tissue swabs, ulcer swabs, wound swabs, conjunctival swabs, ear swabs, rectal swabs, anal swabs, oral swabs, nasal swabs, throat swabs, other swabs from affected areas, respiratory material (sputum, BAL, tracheal secretion), abscess material, pus, exudates, aspirated materials, wound secretions (primarily sterile materials)	Culture-based pathogen detection by culturing non-specific and specific anaerobic atmospheres, enrichment method, culture-based growth behavior
Gram-positive anaerobic cocci (e.g., Anaerococcus spp., Peptostreptococcus spp.), Gram-positive anaerobic rods (e.g., Clostridium spp., Propionibacterium spp.)	Urine, urogenital tract swabs, intrauterine pessary material, ejaculate, skin swabs, soft tissue swabs, ulcer swabs, wound swabs, conjunctival swabs, ear swabs, rectal swabs, anal swabs, oral swabs, nasal swabs, throat swabs, other swabs from affected areas, respiratory material (sputum, BAL, tracheal secretion), abscess material, pus, exudates, aspirated materials, wound secretions (primarily sterile materials)	Culture-based pathogen detection by culture in an anaerobic atmosphere, enrichment process, culture growth behavior

Analyte (measured value)	Material for testing (matrix)	Test method
Gram-positive aerobe and facultativ anaerobe rod (Coryneforme rod, Listeria spp., Aktinomyces spp.)	Urine, skin swabs, soft tissue swabs, ulcer swabs, wound swabs, conjunctival swabs, ear swabs, oral swabs, nasal swabs, throat swabs, other swabs from affected areas, respiratory material (sputum, BAL, tracheal secretion, broncheal secretion), abscess material, pus, exudates, aspirated materials, wound secretions (primarily sterile materials)	Culture-based pathogen detection by culture in aerobic and microaerobic atmospheres, enrichment processes, culture, cold enrichment, growth behavior, culture on selective culture media
Bacteria	Urine	Inhibitor test
Bacteria	Urine	Culture, quantitative, Colony counting
Mycoplasma and ureaplasma	Genitourinary swabs, semen, prostate secretion, urine	Culture-based detection by culture specifically in an anaerobic atmosphere
Yeasts	Swabs: Urogenital tract, intrauterine material, skin swabs, soft tissue swabs, ulcer swabs, wound swabs, conjunctival swabs, ENT swabs, rectal swabs, anal swabs, other swabs of affected areas, ejaculate, abscess material, pus, exudates, aspirated materials, wound secretions, urine	Culture-based pathogen detection by culture in a nonspecific and specific manner in an aerobic atmosphere, Culture-based growth behavior

Test type:

Ligand assays*

Analyte (measured value)	Material for testing (matrix)	Test method
Borrelia burgdorferi sensu lato IgM antibodies	Serum	Sandwich chemiluminescence immunoassay
Borrelia burgdorferi IgG, IgM antibodies	Serum	LineBlot
Borrelia burgdorferi sensu lato IgG antibodies	Serum	Sandwich chemiluminescence immunoassay
Chlamydia trachomatis IgG	Serum	Enzyme-linked immunosorbent assay
Chlamydia trachomatis IgM	Serum	Enzyme-linked immunosorbent assay
Toxoplasma gondii IgG avidity	Serum	LineBlot

Analyte (measured value)	Material for testing (matrix)	Test method
Toxoplasmen IgG	Serum	Electrochemiluminescence immunoassay
Toxoplasmen IgM	Serum	Electrochemiluminescence immunoassay
Treponema pallidum antibodies	Serum	Electrochemiluminescence immunoassay

Type of examination:

Microscopy*

Analyte (measured value)	Material for testing (matrix)	Test method
Bacteria (gram-positive and gram-negative cocci, gram-positive and gram-negative rods), actinomycetes, Lactobacillus spp., Gardnerella, Listeria spp.	Native, cultured and direct preparations	Microscopy, after specific staining, bright field microscopy
Mycoplasmas and ureaplasmas	Culture plates	Plate microscopy, unstained
Yeasts	Culture plates	Microscopy, unstained

Test type:

Molecular biological studies (amplification process)*

Analyte (measured value)	Material for testing (matrix)	Test method
Neisseria gonorrhoeae	Endocervical swabs, male urethral swabs, urine, ejaculate	Polymerase chain reaction (PCR)
Chlamydia trachomatis	Endocervical swabs, male urethral swabs, urine, ejaculate	Polymerase chain reaction (PCR)

Testing area: Virology

Test type:

Ligand assays*

Analyte (measured value)	Material for testing (matrix)	Test method
Anti HCV IgG	Serum	Electrochemiluminescence immunoassay
Anti HAV (IgG/ IgM)	Serum	Electrochemiluminescence immunoassay
Anti HAV IgM	Serum	Electrochemiluminescence immunoassay
Anti HBc (IgG)	Serum	Electrochemiluminescence immunoassay
Anti HBs	Serum	Electrochemiluminescence immunoassay

Analyte (measured value)	Material for testing (matrix)	Test method
Anti HIV 1/2, p24- Antigen	Serum	Electrochemiluminescence immunoassay
CMV IgG	Serum	Electrochemiluminescence immunoassay
CMV IgG avidity	Serum	LineBlot
CMV IgM	Serum	Electrochemiluminescence immunoassay
HBs- Antigen	Serum	Electrochemiluminescence immunoassay
Parvovirus B19 IgG	Serum	Sandwich chemiluminescence immunoassay
Parvovirus B19 IgM	Serum	Sandwich chemiluminescence immunoassay
Röteln IgG	Serum	Electrochemiluminescence immunoassay
Röteln IgM	Serum	Enzyme-linked immunosorbent assay
SARS-CoV-2 TrimericS IgG	Serum	Enzyme-linked immunosorbent assay
VZV IgG	Serum	Indirect chemiluminescence immunoassay
VZV IgM	Serum	Indirect chemiluminescence immunoassay

Test type:

Molecular biology tests (amplification process)

Analyte (measured value)	Material for testing (matrix)	Test method
SARS CoV-2-RNA	Nasal swab, throat swab, nasal wash samples, BAL, saliva	PCR
Influenza A and B Virus-RNA	Nasal swab, throat swab, nasal wash samples, BAL, saliva	PCR

Area of investigation: transfusion medicine

Test type:

Agglutinationsteste*

Analyte (measured value)	Material for testing (matrix)	Test method
ABO characteristics	EDTA whole blood	Column agglutination technique
Antibody screening test	Serum, plasma	Column agglutination technique
Kell Antigen Determination	EDTA whole blood	Column agglutination technique
Rh Determination	EDTA whole blood	Column agglutination technique