



Saudi Laboratory Specialist Licensure Examination (SLLE)

EXAMINATION CONTENT GUIDELINE



EXAMINATION MODEL

General Rules

What are Licensure Examinations?

Licensure Examinations are assessments to ensure that the public will not be harmed by the incompetence of healthcare practitioners. It assesses the ability to apply knowledge, concepts, and principles that constitute the basis of safe and effective health care.

What is Saudi Laboratory Specialist Licensure Examination (SLLE)?

The SLLE is an exam that assesses the readiness of a Laboratory Specialist to practice and/or proceed to postgraduate training. It consists of 200 MCQs which may include up to 10 pilot questions. It is divided into two parts of 100 questions each with time allocation of 120 minutes for each part. There is a scheduled 30-minute break between the two parts. These questions have four options from which the candidate will choose one best answer.

The examination shall contain recall questions that test knowledge and questions with scenarios that test other skills (interpretation, analysis, decision making, reasoning and problem solving). Examination questions are related to the subtest areas (outlined in Appendix A), may be both theoretical and procedural. Theoretical questions measure skills necessary to apply knowledge, calculate results, and correlate patient results to disease states. Procedural questions measure skills necessary to perform laboratory techniques, evaluate laboratory data, and follow quality assurance protocol.

How is the SLLE pass score established?

The SCFHS brings together a panel of Saudi physicians to define an acceptable level of performance and establish the pass score for the SLLE through a standard setting exercise. The panel then recommends its pass score to the Central Assessment Committee (CAC) for approval.



In November 2019, the SCFHS conducted a rigorous standard setting exercise with a diverse panel of physicians. Following the standard setting exercise, the panel recommended a pass score of 554 on the reporting scale of 200-800. This pass score was reviewed and approved by the CAC.

What is a test blueprint, and what is its purpose?

A test blueprint is a document that reflects the content of your specialty licensure examination. The blueprint is the plan used for “building” the exam. The purpose of the blueprint is to ensure including questions related to what you are expected to know.

Examination Sections:

The SLLE questions encompass different sections within the area of Medical/Clinical Laboratory Science: Blood Banking, Urinalysis and Other Body Fluids, Clinical Chemistry, Hematology, Immunology, Microbiology, and Laboratory Operations. Each of these sections comprises a specific percentage of the overall 200-questions licensure examination. The SLLE sections are described in the following table:

Subjects	Description	Exam Percentages
BLOOD BANK	Blood Group Systems and HLA system, Antibody Screen & Identification, Antibody Titration, Pre-Warm Technique Crossmatch, DAT, Elution/Adsorption, Blood Donation (Whole blood and Apheresis), Blood Component, Transfusion Therapy, Autoimmune hemolytic Anemias, Transfusion Reactions, HDFN, Phenotyping/Genotyping (molecular testing)	15-20%
URINALYSIS AND OTHER BODY FLUIDS	Physical, Chemical & Microscopic Urinalysis and Body Fluid Analysis (CSF, Amniotic, Synovial, Serous, Semen & Feces)	5-10%
CLINICAL CHEMISTRY	Carbohydrates, Acid Base, Electrolytes, Proteins & Other Nitrogen-Containing Compounds, Enzymes, Heme Derivatives, Lipids & Lipoproteins, Endocrinology, Tumor Markers, TDM, Toxicology,	15-20%
HEMATOLOGY	Erythrocytes & Leukocytes, Reticulocyte Count, ESR, Sickle Cell Test, Hemoglobin Electrophoresis, RBC Enzymes, RBC/WBC Morphology & Differentials, Platelets, Hemostasis,	15-20%

IMMUNOLOGY AND SEROLOGY	Autoimmunity, Immune Responses, Physiology of the Immune system, Immunology of Viral & Mycobacteria, Parasites, Molecular Biology & Cytogenetics	5-10%
HISTO- AND CYTO TECHNIQUES	Sample types , Processing, Embedding, Cutting, stains, Frozen section, Sample storage and disposal, Molecular Pathology	5-10%
MICROBIOLOGY	General Microbiology, Bacteriology (Gram - Positive Cocci, Gram-negative Bacilli, Gram-Negative Cocci, Gram-positive Bacilli, Anaerobes, Mycobacteria, Spirochetes, Other Atypical Bacteria), Mycology, Virology, Parasitology	15-20%
LABORATORY OPERATIONS	Quality Assessment/Troubleshooting, Safety, Management, Laboratory Mathematics, Instrumentation, Molecular Techniques, Education and Communication, Laboratory Information Systems	5-10%
PATIENT SAFETY AND PROFESSIONALISM	Regulations of Saudi healthcare system, Teamwork and inter-professional collaboration, Professional attitudes and ethical behaviors of healthcare workers, Islamic, legal and ethical principles in professional practice	5-10 %



1. For a more specific overview of the areas on the SLLE, please refer to the CONTENT OUTLINE (See Appendix A & B).
2. Examination outlines adapted from:
 - SCFHS Laboratory Specialist Licensure Examination
 - ASCP Board of Certification
 - American Medical Technologist Certification

Appendix A: Saudi Laboratory Specialist Licensure Examination Content Outline

I. BLOOD BANK (15 – 20% of total exam)

1. Blood Group Systems

A. Genetics

- 1) Basic
- 2) Molecular
- 3) Inheritance of Blood Groups
- 5) Relationship Testing

B. Blood group Nomenclature and Antigens

- 1) ABO
- 2) Lewis
- 3) Rh
- 4) MNS
- 5) P, Globoside
- 6) Ii
- 7) Kell
- 8) Kidd
- 9) Duffy
- 10) Lutheran
- 11) Other Blood Group Systems
- 12) Antigens of High incidence
- 13) Antigens of Low incidence
- 14) HLA System
- 15) Platelet/ Granulocyte Specific Antigens and Antibodies

C. Role of Blood Groups in Transfusion

- 1) Immunogenicity
- 2) Antigen Frequency

2. Antibody Screen and Identification and ABO Discrepancy

- A. Antibody Screen
- B. Antibody Identification
 - 1) Alloantibodies
 - 2) Autoantibodies
- C. ABO Discrepancy

3. Crossmatch and Special Tests

- A. Crossmatch
- B. Special Tests
 - 1) Direct Antiglobulin Test (DAT)
 - 2) Phenotyping and Genotyping (Molecular Testing)
 - 3) Elution/adsorption
 - 4) Antibody Titration
 - 5) Pre-warm Technique

4. Blood Donation, Transfusion Therapy, Transfusion Reactions and Hemolytic Disease of the Fetus and Newborn (HDFN)

- A. Blood Donation and Components Preparation
 - 1) Types of Donations (Whole blood and Apheresis donation)
 - 2) Special Donor Categories (Autologous and Directed blood donation)
 - 3) Donor selection and Qualification
 - 4) Donor testing, Transfusion Transmitted diseases and Re-entry
 - 5) Components Preparation and Storage
- B. Transfusion Therapy
 - 1) RBC
 - 2) PLT
 - 3) FFP
 - 4) Cryoprecipitated AHF
 - 5) Granulocyte
- C. Autoimmune Hemolytic Anemias
- D. Blood bank role in Stem Cell and Solid Organ Transplant
- E. Transfusion Reactions
- F. Hemolytic Disease of the Fetus and the Newborn (HDFN)
 - 1) Types (ABO and Non-ABO HDFN)
 - 2) Antenatal and Postnatal Testing
 - 3) Intrauterine Transfusion (IUT)
 - 4) Neonatal Exchange Transfusion
 - 5) Cord blood Testing and Rh Immunoglobulin (RhIG) Eligibility
 - 6) Rosette and Kleihauer-Betke Test

II. URINALYSIS and OTHER BODY FLUIDS (5 – 10% of total exam)

1. Urinalysis

- A. Physical
 - 1) Color, Volume, Odor and Clarity
 - 2) Specific Gravity/Osmolality
- B. Chemical
 - 1) Reagent Strip
 - 2) Confirmatory Tests (pH, blood, leukocytes, Nitrites, protein, glucose, ketones, bilirubin, urobilinogen, electrolytes (Na, K, Cl, Ca, P, Mg) , uric acid, amino acids).

C. Microscopic

- Sample Preparation

- 1) Cells
- 2) Casts
- 3) Crystals
- 4) Contaminants
- 5) Artifacts/microorganisms

D. Urine specimen

- 1) Types
- 2) Collection techniques
- 3) Sample preservation (Storage and handling)

2. Other Body Fluids (Qualitative and Quantitative)

A. CSF (physiology and composition, physical and chemical examination, microscopic and microbiological examination).

B. Amniotic, Synovial, Serous, Semen and Feces (physiology and composition, physical and chemical examination, microscopic and microbiological examination).

III. CLINICAL CHEMISTRY (15 – 20% of total exam)

1. Carbohydrates, Acid Base and Electrolytes

A. Carbohydrates

- 1) Glucose
- 2) Glycated hemoglobin

B. Acid Base

- 1) pH, pCO₂, pO₂
- 2) Osmolality, base excess

C. Electrolytes

- 1) Sodium, potassium, chloride, bicarbonate, anion gap
- 2) Calcium, magnesium, phosphorus

2. Proteins and Other Nitrogen-Containing Compounds

A. Protein and Other Nitrogen-Containing Compounds

- 1) Total protein, albumin
- 2) Globulins (alpha 1, alpha 2, beta, gamma)
- 3) Ferritin, transferrin
- 4) Iron and TIBC
- 5) Ammonia
- 6) Creatinine, BUN
- 7) Uric acid
- 8) Troponin
- 9) Other (e.g., BNP)

B. Heme Derivatives

- 1) Bilirubin, urobilinogen

3. Enzymes, Lipids and Lipoproteins

A. Enzymes

- 1) Amylase, lipase
- 2) AST, ALT
- 3) CK, LD
- 4) ALP
- 5) GGT
- 6) Other

B. Lipids and Lipoproteins

- 1) Cholesterol (total, HDL, LDL)
- 2) Triglycerides
- 3) Phospholipids (PG)

4. Special Chemistry (Endocrinology, Tumor Markers, TDM, Toxicology)

A. Endocrinology and Tumor Markers

- 1) T₃, T₄, TBG, TSH
- 2) hCG, FSH, LH, estradiol
- 3) Other hormones (e.g. cortisol)
- 4) Tumor markers (e.g., alpha fetoprotein, CEA, hCG, PSA)

B. TDM and Toxicology

- 1) Therapeutic drug monitoring
- 2) Drugs of abuse
- 3) Other toxicology (e.g., carbon monoxide)

5. Molecular Techniques

A. Targeted Mutation Analysis (e.g. PCR)

B. Detection of Unknown Mutations (e.g. SSCP)

C. Detection of Copy Number Variations (e.g. Southern Blot)

D. Basic Molecular Biology

IV. HEMATOLOGY (15 – 20% of total exam)

1. Sampling and acceptance criteria

A. Types of tubes used

B. Adequacy (EDITA-Sodium citrate)

C. Integrity of samples (clotted-hemolytic-lipemic)

2. Erythrocytes, Leukocytes and PLT

A. Red Blood Cells and Indices

- 1) RBC count
- 2) Hemoglobin, hematocrit and indices
- 3) Histograms interpretation on instrument (Normo-Macro-Micro)

B. White Blood Cells

- 1) WBC count
- 2) Differential (Neut, Mono, Lymph, Eos & Baso)
- 3) Histograms interpretation on instrument (Lobularity Vs Mononucleated cells distributions)

C. Platelet count

- 1) PLT count
- 2) Histograms interpretation on instrument (PLT clump)

3. Other Tests

A. Reticulocyte Count

B. ESR

C. Tests for Hemoglobin Defects

- 1) Sickle cell tests
- 2) Hemoglobin electrophoresis

D. RBC enzymes (e.g. G-6PD)

4. Morphology and Differentials

A. Red Blood Cell Morphology

- 1) RBC shape, size and color (normal Vs abnormal)
- 2) RBC Inclusions
- 3) RBC parasite (Plasmodium sp. Babesia, Microfilaria and Trypanosomes)

B. White Blood Cell Morphology

- 1) WBC differential lineage (Mature Vs Immature)
- 2) WBC inclusions

C. Platelet Morphology

- 1) Manual Estimation (Adequate Vs Thrombocytopenia)
- 2) Recognize PLT Clumping (pseudothrombocytopenia)

5. Flow cytometry, Cytogenetics, and Molecular Biology

A. Flow Cytometry

- 1) Basic Knowledge of Principle
- 2) Main CD markers (Blast, Myeloid and Lymphoid)

B. Cytogenetics & Molecular Biology (JAK2 - Philadelphia chromosome – BCR-ABL)

6. Coagulation and Hemostasis

- 1) PT, INR & ISI (calculated using establish normal population with each new lot#), aPTT, TT
- 2) Fibrinogen, D-dimer (calibration with new lot#)
- 3) Factor Assays (intrinsic-extrinsic pathways)
- 4) Inhibitors Anticoagulants (lupus)
- 5) Mixing Studies
- 6) Anticoagulant Therapy Vs Prophylaxis and Their Effect on the Patient Result (warfarin & HMWH Vs aspirin, LMWH, apixaban & enoxaparin)
- 7) Hypercoagulability tests (protein C & S)
- 8) Disease Correlation (most common, DIC, Sepsis, Liver disease, Hemophilia, Christmas disease, ext)



Note: General understanding of normal reference range, critical values & correlation of patient's previous result

V. IMMUNOLOGY AND SEROLOGY (5 – 10% of total exam)

1. Immunity

A. Autoimmunity

- 1) ANA, anti-DNA
- 2) CRP/RF
- 3) Thyroid Antibodies
- 4) Special Tests

B. Immune Responses

- C. Physiology of the Immune System

2. Infectious Diseases

A. Viral

- 1) EBV/infectious mononucleosis
- 2) Hepatitis
- 3) HIV/HTLV/CMV
- 4) Rubella/measles
- 5) Special Viral Immunoassays

B. Microbial

- 1) Syphilis
- 2) Other Than Syphilis

VI. HISTO- AND CYTO- TECHNIQUES (5 – 10% of total exam)

A. Pre- Analytical:

- 1) Patient or specimen identification
- 2) Sample types and containers
- 3) Sample Preparation and Fixation
- 4) Grossing
- 5) Sample rejection

B. Analytical:

- 1) Processing
- 2) Embedding
- 3) Cutting
- 4) Staining, special stains
- 5) Immunohistochemistry
- 6) Frozen section

- 7) Molecular Pathology
 - 8) Cytological Technique (Liquid Base Cytology)
 - 9) Cytological Technique (Cell Block Processing)
 - 10) Cytological Technique (FNA Sample Processing)
- C. Post-Analytical:**
- 1) Sample retention and storage
 - 2) Sample disposal laws and regulations
 - 3) Report and Document Retention
 - 4) Quality Assurance in Histopathology and Cytology
 - 5) Safety Histopathology and Cytology

VII. MICROBIOLOGY (15 – 20% of total exam)

Includes biochemical, immunologic, serologic, and other molecular methodologies

(e.g. MALDI-TOF) required for identification and detection of microorganisms and antimicrobial susceptibility testing

1. General Principle of medical and clinical microbiology:

- A. Microbial Taxonomy, Structure, Metabolism, Genetics and host interaction
- B. Normal flora
- C. Safety, specimen management, sterilization and disinfection, and QC in microbiology
- D. Diagnostic Approaches for detection, identification and analysis of microbial pathogens (bacteria, fungi, virus and parasites)
- E. Evaluation of Antimicrobial Activity

2. Bacteriology:

- A. Gram-positive Cocci:
 - 1) Staphylococcus
 - 2) Streptococcus
 - 3) Enterococcus
 - 4) Micrococcus
- B. Gram – positive Bacilli:
 - 1) Bacillus
 - 2) Corynebacterium
 - 3) Erysipelothrix
 - 4) Gardnerella, Lactobacillus
 - 5) Listeria
 - 6) Nocardia
 - 7) Streptomyces
- C. Gram-negative Bacilli:
 - 1) Enterobacteriaceae (e.g., *Citrobacter*, *Escherichia*, *Enterobacter*, *Klebsiella*, *Morganella*, *Proteus*, *Providencia*, *Salmonella*, *Serratia*, *Shigella*, *Yersinia*)
 - 2) Other Gram-negative Bacilli (e.g., *Acinetobacter*, *Aeromonas*, *Bordetella*, *Brucella*, *Campylobacter*, *Eikenella*, *Francisella*, *Haemophilus*, *Helicobacter*, *Legionella*, *Pasteurella*, *Plesiomonas*, *Pseudomonas*, *Burkholderia*, *Stenotrophomonas*, *Chryseobacterium*, *Vibrio*, HACEK, *Bartonella*, *Capnocytophaga*)
- D. Gram-negative Cocci:
 - 1) Neisseria and Moraxella
- E. Anaerobes:
 - 1) Gram-positive (e.g., *Bifidobacterium*, *Clostridium*, *Eubacterium*, *Actinomyces*, *Peptostreptococcus*, *Propionibacterium*)
 - 2) Gram-negative (e.g., *Bacteroides*, *Fusobacterium*, *Porphyromonas*, *Prevotella*, *Veillonella*)
- F. Mycobacteria:
 - 1) Mycobacterium tuberculosis complex (e.g., *M. tuberculosis*)
 - 2) Mycobacteria Other than MTB (e.g., *M. avium-intracellulare*, *M. leprae*)
- G. Spirochetes:
 - 1) Treponema
 - 2) Borrelia
 - 3) Leptospira

H. Other Atypical bacteria:

- 1) *Chlamydiae*
- 2) *Richettsiae*
- 3) *Mycoplasma*

I. Gram-negative Coccobacilli

3. Mycology:

- A. **Yeast** (e.g., *Candida*, *Cryptococcus*, *Geotrichum*, *Malassezia*)
- B. **Dimorphic fungi** (e.g., *Blastomyces*, *Coccidioides*, *Histoplasma*, *Sporothrix*)
- C. **Dermatophytes** (e.g., *Epidermophyton*, *Microsporum*, *Trichophyton*)
- D. **Zygomycetes** (e.g., *Absidia*, *Mucor*, *Rhizopus*)
- E. **Opportunistic molds/septate hyaline molds** (e.g., *Aspergillus*, *Penicillium*)
- F. **Dematiaceous molds**
- G. ***Pneumocystis***

4. Virology:

- A. **Viruses in human disease** (e.g., B19 Virus, Papillomavirus, Adenovirus, Hepatitis A - E viruses, Herpesvirus, Poxvirus, Poliovirus, Rotavirus, Norovirus, Dengue Virus, Rubella virus, HIV, HTLV, Influenza virus, Measles virus, mumps virus, RSV, Rabies virus, Ebola virus and Coronavirus and similar related viruses)

5. Parasitology:

- A. **Blood and tissue protozoa** (e.g., *Plasmodium*, *Trypanosoma*, and similar parasites)
- B. **Intestinal and urogenital protozoa** (e.g., *Cryptosporidium*, *Entamoeba*, *Giardia*, *Trichomonas* and similar parasites)
- C. **Intestinal and tissue helminths** (e.g., *Ascaris*, *Enterobius*, hookworm, *Schistosoma*, *Strongyloides*, *Taenia*, *Trichinella*, *Trichuris*, filarial worms and similar helminths)

VIII. LABORATORY OPERATIONS (5 – 10% of total exam)

1. Quality Assessment/Troubleshooting

A. Pre-Analytical, Analytical, Post-Analytical

- 1) **Pre Analytical** (e.g. Knowledge of sampling methods and sample receipt rule,
- 2) **Analytical** (e.g. Reference values, Prevalence and Predictive value, Clinical Sensitivity and Specificity test.
- 3) **Post-Analytical**: Results Reporting, Recording, Documentation and Medical Confidentiality.

B. Quality Control

- 1) Knowledge of parameters enabling long term follow up
- 2) Controls curves
- 3) Proficiency testing
- 4) Westgard Rules

C. Compliance

- 1) Procedures
- 2) Policy and general approach in laboratory

D. Regulation

- 1) Standard Operating Procedures
- 2) Corrective actions
- 3) OSHA, CLIA, HIPAA (Lab law)

2. Safety

- A. **Safety Levels**
- B. **Biological Pathogens**
- C. **Biological Safety**
- D. **Exposure and Infection**
- E. **Ionizing and Non-ionizing radiations**
- F. **Chemical, Fire**
- G. **Electricity Risks**
- H. **Waste Handling**

3. Management

A. Purchasing

- 1) Items specifications and analyze needs

B. Inventory Control

C. Competency

- 1) Employees performance

4. Laboratory Mathematics

A. Concentrations

B. Units, Dilutions

C. Standard deviation

5. Instrumentation

A. Manual Laboratory Instrumentation

B. Calibration

C. Automated Laboratory Instruments

6. Education and Communication

A. Training programs

B. Developing technical skills

C. Problem Solving

7. Laboratory Information Systems

A. Software and Information Security

VIII. PATIENT SAFETY AND PROFESSIONALISM (5 – 10% of total exam)

1. Saudi Law for Health Practitioners

2. Patients' Rights, Safety and Privacy

END OF CONTENT GUIDELINE



See the SCFHS website for the most up-to-date information.

Appendix B: Competency Statement

For the laboratory areas of Body Fluids, Blood Bank, Clinical Chemistry, Hematology, Immunology and Microbiology, the following competencies are tested:

APPLIES KNOWLEDGE OF

- theory and principles related to:
 - anatomy (Body Fluids) – biochemistry (Chemistry and Hematology)
 - education – genetics (Blood Bank)
 - growth characteristics/diagnostic and infective forms (Microbiology)
 - immunology (Blood Bank and Immunology)
 - laboratory information systems
 - physiology (Body Fluids, Chemistry, Hematology, Immunology)
- data security/patient confidentiality
- fundamental biological characteristics related to laboratory testing
- medical terminology • principles of performing basic/special laboratory procedures
- sources of error in laboratory testing • standard operating procedures
- theory and practice related to laboratory operations (management/safety/education/R&D)

SELECTS APPROPRIATE

- controls for test performed
- course of action
- instruments for new laboratory procedures
- instruments to perform requested test
- quality control procedures
- reagents/media/blood products
- routine/special procedures to verify test results
- type of sample and method for test requested

PREPARES / PROCESSES

- controls
- equipment and instruments

CALCULATES RESULTS

ASSESSES TEST RESULTS BY CORRELATING LABORATORY DATA WITH

- clinical or other laboratory data
- physiologic processes to validate test results and procedures
- quality control data
- results obtained by alternate methodologies



EVALUATES

- appropriate actions and methods
- corrective actions • patient-related requirements
- possible sources of error or inconsistencies
- quality control procedures
- specimen-related requirements

EVALUATES LABORATORY DATA TO

- assess test for procedural validity/accuracy
- assure personnel safety
- check for procedural/technical problems
- make identifications
- recognize and report abnormal test results and/or the need for additional testing
- recognize and resolve possible inconsistent results/sources of error
- recognize related disease states
- take corrective action
- verify test results for reporting

ATTRIBUTES OF PROFESSIONALISM BY THE ABILITY TO

- Adhere to the regulations of Saudi healthcare system in the Kingdom
- Respect teamwork and inter-professional collaboration
- Demonstrate professional attitudes and ethical behaviors of healthcare worker
- Apply Islamic, legal and ethical principles in professional practice

Appendix C: References

Subjects	Reference
BLOOD BANK	<ul style="list-style-type: none"> Harmening D.M.(2012). Modern Blood Banking & Transfusion Practices.6th Ed.Philadelphia, PA: F.A.Davis Company Fung M.K., Eder A.F., Spitalnik S. L., Westhoff C. M.(2017). Technical Manual. 19th Ed. Bethesda, MD: AABB Press
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MICROBIOLOGY (MICR)	<ul style="list-style-type: none"> Tille, P. (2013). Bailey & Scott's Diagnostic Microbiology (13th ed.). Mosby. Procop, G. W., & Koneman, E. W. (2016). Koneman's Color Atlas and Textbook of Diagnostic Microbiology (7th or latest ed.). LWW.
LABORATORY OPERATIONS (LO)	<ul style="list-style-type: none"> Landsverk, M. L., & Wong, L. C. (n.d.). Clinical Molecular Diagnostic Techniques: A Brief Review. Laboratory Quality Management System Handbook WHO
PATIENT SAFETY AND PROFESSIONALISM	<ul style="list-style-type: none"> وثيقة حقوق ومسؤوليات المرضى (Link) اللائحة التنفيذية لنظام مزولة المهن الصحية (Link) المعايير الوطنية للمختبرات وبنوك الدم (Link)



Note: This list is intended for use as a study aid only. SCFHS does not intend the list to imply endorsement of these specific references, nor are the exam questions necessarily taken from these sources.



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