CANADIAN COLLEGE OF MICROBIOLOGISTS

SYLLABUS FOR EXAMINATION PREPARATION

FOR SPECIALIST IN CLINICAL MICROBIOLOGY

1997
(updated; 2003)

SPECIALIST IN CLINICAL MICROBIOLOGY SYLLABUS OVERVIEW:

The Canadian College of Microbiologists provides the following overview of the expectations for candidates preparing for the Specialist in Clinical Microbiology examination. Following the overview are the specific Syllabus guidelines for the Phase 1 Written Exam (Section I) and the Phase 2 Oral Exam (Section II).

The Scientific and Laboratory Basis of Microbiology:

The candidates should be able to:

1. Discuss the various bacterial, viral, fungal and parasitic pathogens in terms of their physiology, genetics and molecular biology.

2. Describe the epidemiology of infections caused by these infectious agents.

3. Describe the elements of the immune system which relate to microbial defences and should know the tests required to evaluate immune function.

4. List the significant normal human indigenous microflora.

5. Describe the clinical criteria for the submission of specimens for microbiologic examination.

6. Discuss the procedures relevant to the collection, transport, storage and processing of clinical specimens.

7. Discuss the appropriate methods for the examination of microbiology specimens and for the presumptive and definitive identification of microbial pathogens.

8. Describe the nature and activity of antimicrobial agents in general use and discuss the laboratory principles for testing antimicrobial activity and the measurement of antimicrobial levels.

9. Explain quality assurance principles applicable to each division of the microbiology laboratory.

10. Interpret the results of the microbiology testing to the clinician.

11. Discuss the laboratory principles of disinfection and sterilization.

12. Discuss WHMIS, biosafety cabinets; universal precautions and chemical spill clean up and be able to discuss their role in the provision of diagnostic services within a hospital.

13. Discuss their role in the provision of diagnostic services within the hospital.

Issues Related to Infection Control:

The candidates should be able to:

1. Describe the epidemiology of hospital acquired infections and the principles involved in their prevention.

2. Discuss the structure and functions of a hospital infection control program.

3. Describe the infection control isolation procedures appropriate to specific disease entities.

4. Direct laboratory investigation of a nosocomial outbreak.

The Clinical Practice of Medical Microbiology Related to Infectious Diseases:

The candidate should be able to:

1. Describe the clinical manifestations of infectious diseases, microbiologic diagnostic methodologies available and treatment principles applicable to patients with infectious diseases.

2. Discuss the principles of passive and active immunization in the prevention of infectious diseases.

3. Discuss ethics and confidentiality as related to patients with infectious diseases.

In addition to the above specific objectives, candidates should be able to:

1. Discuss the public health applications of the information generated by the microbiology laboratory.

2. Demonstrate basic statistical skills and discuss the principles and application of these tests to laboratory practice.

3. Discuss the apparent and inapparent costs incurred by the microbiology laboratory and develop a cost conscious approach to the provision of the diagnostic services.

4. Apply the principles of historical data analysis and usage estimate and test planning.

5. Use computers for data retrieval and analysis.

SECTION I BASIC MICROBIOLOGY SYLLABUS (For Written Exam)

Study Guides:

1. Multiple choice questions (Section Ia) Written Exam:

   Examination and Board Review; Medical Microbiology and Immunology 4th Edition Levinson and Jawetz , Appleton and Lange publishers.

2. Case Stem with Multiple choice questions (Section Ib) Written Exam:

   Cases in Medical Microbiology and Infectious Diseases, Gilligan, Shapiro and Smiley, American Society for Microbiology publishers.

1. **Basic Bacteriology**

   - Structural components (cell wall, capsule, pili, flagella, cytoplasmic membrane)
   - Bacterial growth, cell division and metabolism
   - Normal Flora
   - Pathogenesis/Virulence Factors/Host Defenses
   - Sterilization and Disinfection
   - Antimicrobial Drugs: Testing, Mechanisms of Action & Resistance Mechanisms
   - Bacterial vaccines

2. **Clinical Bacteriology**

   For each group of organisms, understand and be able to discuss current knowledge regarding; disease(s) caused, pathogenesis, diagnostic approaches, antibiotic susceptibility, development of antibiotic resistance, epidemiology, public health issues and prevention measures.

   A) **Bacteria**

      The following is a representative list of bacteria with which candidates should be familiar.

      Gram-positive cocci- *Staphylococcus*, *Streptococcus, Enterococci, Peptostreptococcus*

Gram-positive rods- *Mycobacterium*, *Corynebacterium, Listeria, Nocardia, Actinomyces, Bacillus*, *Clostridium, Propionibacterium*

Enteric Gram-negative rods- *Escherichia coli*, *Salmonella, Klebsiella, Enterobacter, Proteus, Morganella, Yersinia, Shigella, Vibrio, Aeromonas*, *Campylobacter, Helicobacter*, *Fusobacterium, Bacteroides*

Other Gram-negative rods- *Haemophilus*, *Bordetella*, *Pseudomonas, Legionella*, *Pasteurella, Brucella, Francisella, Burkolderia*

Gram-negative cocci- *Neisseria, Moraxella*

Spirochaetes- *Treponema, Borrelia , Leptospira*

Wall-less bacteria- *Mycoplasma, Ureaplasma, L-forms*

Obligate intracellular bacteria- *Chlamydiae*, *Rickettsiae*

3. **Basic Virology**

- Structural components
- Viral replication
- Classification of medically important viruses
- Antiviral drugs
- Antiviral vaccines

4. **Clinical Virology**

For each group of viruses, be able to discuss current knowledge regarding; disease(s) caused, pathogenesis, diagnostic approaches, antiviral therapy, public health issues and prevention measures.

- DNA enveloped viruses (Hepadnavirus, Herpes virus, Poxvirus)
- DNA non enveloped viruses (Parvovirus, Papovavirus, Adenovirus)
- RNA enveloped viruses (Flavivirus, Togavirus, Retrovirus, Orthomyxovirus, Paramyxovirus, Rhabdovirus, Filovirus, Coronavirus, Arenavirus, Bunyavirus)
- RNA non enveloped viruses (Picornavirus, Calicivirus)

5. **Mycology**

- Structure, replication
- Medically important fungi; for each group of fungi be able to discuss current

knowledge regarding disease(s) caused, pathogenesis, diagnostic approaches, antifungal therapy, public health issues and prevention measures

- Cutaneous, Subcutaneous Mycoses
- Systemic Mycoses
- Opportunistic Mycoses

· Susceptibility Testing/Resistance

6. **Parasitology**

For each group of parasites be able to discuss current knowledge regarding disease(s) caused, pathogenesis (life cycle), diagnostic approaches, anti-parasitic therapy, public health issues and prevention measures.

· Protozoa (Entamoeba, Giardia, Cryptosporidium, Cyclospora, Trichomonas)
· Blood Protozoa (Plasmodium, Toxoplasma, Trypanosoma, Leishmania)
· Cestodes
· Tremadodes
· Nematodes

7. **Immunology**

Candidates should be familiar with laboratory techniques used for the detection and measurement of antigens and antibodies, e.g., immunoprecipitation, agglutination, complement fixation, counterimmunoelectrophoresis, ELISA, radioimmunoassay, and western blots. The list below provides a number of topics which serve as a study guide for immunology.

-Lymphoid system and antibody
-*In vitro* antibody interactions
-B-cells and monoclonal antibody
-Complement
-Phagocytic cells
-Histocompatibility complex
-Lymphocyte traffic and T-cells
-Cell-mediated immunity
-Lymphokines, interferons, interleukins, tumor necrosis factor
-Regulation of humoral immunity
-Mucosal immunity
-Mast cells
-Types of hypersensitivity
-Immunity to virus infections versus bacterial infections
-Humoral and phagocytic deficiencies
-T-cell deficiency diseases
-Secondary immune deficiency

-Anaphylaxis
-Urticaria and food allergy
-Pathologic mechanisms of autoimmunity
-Loss of tolerance
-HLA and disease
-Transplantation immunology
-Immunosuppression
-Immunization: active and passive
-Vaccines: live and dead

SECTION II DIAGNOSTIC LABORATORY SYLLABUS (For Oral Exam)

Reference Books:

1. Principles and Practice of Infectious Diseases - Mandell, Bennett, Dolin Editors, Churchill, Livingstone Publishers.

2. Clinical Microbiology Procedures Handbook - Isenberg Editor, ASM Publisher.

I. BACTERIOLOGY: SPECIFIC SYLLABUS

A) Specimen Processing:

Candidates will be expected to be able to discuss;

1. How to keep records of specimens received, materials, supplies, and reagents used in this area of the laboratory.

2. The special transport requirements for CSF, Bordetella, genital, and anaerobic specimens.

3. The processing and planting protocols appropriate for specimens submitted.

4. Biosafety concerns in this area of the laboratory.

5. How specimen receiving and processing can be optimally integrated with the function of the rest of the laboratory.

B) Blood Culture:

Candidates will be expected to be able to discuss:

1. The indications for collecting blood cultures and the variables determining isolation and contamination rates.

2. The advantages and disadvantages of the various blood culture systems available (e.g. Bactec, BacT/Alert, etc.)

3. The rationale behind the routine processing of blood culture specimens.

4. The procedures involved in the processing of blood cultures when unconventional microorganisms are suspected.
5. How to evaluate the clinical significance of blood culture isolates. May

involve reviewing the patient's chart on the hospital ward.

6. How to provide rapid, presumptive information to the clinician.

C) **Respiratory:**

Candidates will be expected to be able to discuss:

1. The indications for specimen submission to this section.

2. The appropriate collection and transport of respiratory specimens such as sputum nasopharyngeal aspirates etc.

3. The screening criteria for the evaluation of the quality of respiratory specimens.

4. The epidemiology and pathogenesis of infections in the respiratory tract due to *H. influenzae, S. pneumoniae, Moraxella catarrhalis*, *Chlamydia, Legionella, Mycobacteria* and *Enterobacteriaceae*.

5. The normal bacterial microflora of the respiratory tract.

D) **Urine Processing:**

Candidates will be expected to be able to discuss:

1. The indications for submitting urine specimens to the microbiology laboratory and the principle of significant bacteriuria ($\geq 100 \times 10^6$/L).

2. The relevance of low urine bacterial counts ($<100 \times 10^6$/L) in patients with acute symptomatic infection.

3. The optimal methods of specimen transport and processing.

4. List those bacteria that frequently cause urinary tract infections, both community and hospital acquired, and be able to discuss key tests used for identifying these organisms.

5. Antimicrobial susceptibility testing as applied to urinary isolates and the different antibiotics tested for urinary tract isolates.

6. The currently available methods for urine screening, their advantages and limitations.

E) **Anaerobic Microbiology:**

Candidates will be expected to be able to discuss:

1. The normal anaerobic bacterial flora of the gastrointestinal tract, the skin, the oropharynx and the female genitourinary tracts and the male genitourinary tract.

2. The clinical circumstances when one should suspect an anaerobic infection and the appropriate specimens which should be submitted for anaerobic culture.

3. The appropriate methods for specimen collection and transport when anaerobic bacteria are suspected.

4. The methods routinely employed to achieve anaerobiosis.

5. The extent to which anaerobic microbiology should be performed in various laboratory clinical settings.

6. The morphology of anaerobic bacteria frequently isolated in the clinical setting.

7. The methods used for the definitive and presumptive identification of clinically significant isolates.

8. The principles of anaerobic antimicrobial susceptibility testing, including the advantages and limitations of each methodology (e.g. E-test, broth dilution).

9. When antimicrobial susceptibility testing is appropriate and the extent to which susceptibility testing should be performed.

10. How to interpret the results of anaerobic cultures in the context of the patient's own endogenous microflora.

F) **Enteric Microbiology Section:**

Candidates will be expected to be able to discuss:

1. The indications for submitting specimens for bacterial culture, related to length of hospitalization as well as those settings in which unusual organisms should be requested.

2. The appropriate methods for transport of specimens to the laboratory.

3. The methods applied to processing stool specimens for the isolation of pathogens.

4. The normal aerobic gastrointestinal flora.

5. The morphologic features of pathogens frequently isolated from the gastrointestinal tract.

6. The methods employed in the definitive identification of *Salmonella* spp.*, Shigella* spp.*, Campylobacter* spp., *E. coli* 0157:H7, *Yersinia* spp., *Aeromonas hydrophila* and *Plesiomonas shigelloides.*

7. The media commonly employed in this area of the laboratory, and in particular, the biochemical principles relevant to their use.

G) **STD Section:**

Candidates will be expected to be able to discuss:

1. The indications for submitting genital specimens and specimens from other sites when sexually transmitted pathogens are suspected.

2. The methods available for the transport of genital specimens to the microbiology laboratory and/or direct bedside inoculation of specimen.

3. The normal genital microflora.

4. The morphologic characteristics of common genital pathogens.

5. The schemes for the presumptive or definitive identification of genital pathogens e.g. *Neisseria gonorrhoeae, Chlamydia trachomatis, Treponema pallidum, Haemophilus ducreyi,* and *Herpes simplex* virus.

6. The method(s) for screening Group B streptococci (*S. agalactiae*) in pregnant females.

7. Use of nucleic acid test methods for STD screening and diagnostic testing.

H) **Fluids, Tissues and Wound Swabs:**

Candidates will be expected to be able to discuss:

1. The appropriate collection and transport of specimens.

2. The value and limitations of broth enrichment.

3. The role of anaerobes in these specimens.

4. The potential role of normal flora in these types of specimens.

5. The types of microscopy stains that can help differentiate bacterial and fungal elements in these types of specimens.

6. The pathogens most commonly isolated from these types of specimens.

I) **Miscellaneous:**

Candidates will be expected to be able to discuss:

1. The methods routinely employed for the processing of body fluids from normally sterile sites.

2. The indications for environmental sampling and the methodologies to be employed in this area.

3. How to perform a cell count and differential using a hemacytometer chamber.

4. The various important bacterial antigen detection kits available.

J) **Specialized Bacteriology:**

The candidates should be able to discuss specialized reference microbiology including: typing of enteric organisms (e.g. *Salmonella* spp.), *Streptococcus* spp., *Haemophilus* spp.; specialized toxin assays such as for *C. difficile*, verotoxin producing *E. coli*; diagnostic methods for the detection of *Chlamydia trachomatis* including fluorescence, enzyme immunoassay, PCR and ligase chain reaction methods.

The candidates should be able to describe the appropriate technical methods and external reference services that provide backup facilities for bacteriology. The candidates should be familiar with both internal and external quality control programs in bacteriology.

K) **Mycobacteriology Section:**

The candidate will be expected to be able to discuss:

1. The mycobacteria encountered in the clinical laboratory and their significance as human pathogens.

2. The morphological factors, nutritional environmental requirements, and biochemical reactions of the above that allow their detection in a clinical specimen and provide and accurate identification.

3. The clinical indications for performing a mycobacterial work-up.

4. The optimal specimens required, for any given mycobacterial infection, as well as appropriate collection and transportation methods.

5. Decontamination processing of clinical specimens and be able to perform the necessary tests for detection, isolation and identification of the possible pathogen, including the principles and operation of the Bactec 460.

6. The indications for antimicrobial susceptibility testing, the agents to be tested and the methods used.

7. The principles of interpretation of laboratory results in terms of significance for, and care of, the patient.

8. The reporting format and documentation of laboratory results in the T.B. section of the laboratory.

9. How molecular methods may speed up the process of detecting and/or identifying mycobacteria.

L) **Mycology Section:**

The candidates will be expected to be able to discuss:

1. Classification of the fungi pathogenic for humans.

2. The morphological features, nutritional and environmental requirements and biochemical reactions of the above fungi which allow their detection in the clinical laboratory.
3. The clinical indications for performing a mycological work-up.

4. The clinical specimens required for any given mycoses, as well as be able to describe appropriate methods of collection and transportation of the specimens to the laboratory.

5. The indications for, and how to determine the minimal inhibitory concentrations and serum levels, of selected antifungal agents.

6. The methods, principles and limitations of the various serologic procedures available for the human mycoses.

7. The role of direct DNA probe methods for culture confirmation of systemic fungi (*Blastomyces dermatitidis, Histoplasma capsulatum, Coccidioides immitis*).

M) **Quality Control Section:**

The candidates will be expected to be able to discuss:

1. The methods and established schedules for monitoring stains, reagents and media for expected performance.

2. The schedules and methods available for monitoring equipment used in the laboratory, including maintenance schedules to ensure ongoing optimal function for the full life of the equipment.

3. The various methods available for evaluating technologist and technician performance, including internal proficiency testing methods as well as appropriate external sources of proficiency testing programs, and evaluation of final culture reports.

4. The methods for maintenance of quality control cultures.

5. The methods available for quality control of the clinical specimen, including requisition documentation, screening methods for assessing the quality of specimen, guidelines for specimen collection and accepted methods for transportation of the clinical laboratory.

6. The requirements for documentation of specimens, laboratory procedures and quality control results.

7. How to monitor susceptibility testing results and the role that NCCLS has in establishing laboratory guidelines.

8. The performance of audits of laboratory performance as it relates to the

patient's diagnosis, clinical course and/or response to therapy.

9. The federal postal requirements for shipping infected materials (Biohazardous transport regulations).

N) **Antimicrobial Susceptibility Testing:**

The candidates will be expected to be able to discuss:

1. The following susceptibility testing methods: Kirby-Bauer, Minimum Inhibitory Concentration (MIC), Minimum Bactericidal concentration (MBC), Agar dilution and E-test.

2. The NCCLS guidelines regarding break points for different groups of organisms, and which antimicrobials to report on the final report.

3. The organisms such as *H. influenzae, Enterococcus* spp*., S. aureus* and *S. pneumoniae* that have shown changes in their susceptibility profile.

4. The basis for Oxacillin disk screening for *S. pneumoniae*.

5. The interaction with Infection Control needed to curtail the spread of multi-resistant, or unusually resistant organisms in the hospital.

6. Surveillance procedures for MRSA and VRE.

7. Mechanisms of antibiotic resistance.

II MOLECULAR TECHNIQUES GENERAL SYLLABUS

The candidate should be able to discuss the molecular techniques available for diagnostic, culture confirmation and typing of clinically relevant pathogens. The candidates should be able to discuss the concepts of hybridization, amplification, sequencing, genotyping based on restriction fragment methods and protein profile analysis and how these can be applied to the practice of Clinical Microbiology in the areas of bacteriology, mycology, parasitology and virology.

MOLECULAR TECHNIQUES: SPECIFIC SYLLABUS

A) Candidates will be expected to be able to discuss:

1. Isolation and analysis techniques for DNA and RNA

   - Cell lysis for Gm (+) vs Gm (-)
   - DNA/protein determinations/quantitation
   - Agarose gel for separation of DNA and RNA fragments
   - Southern Blotting
   - DNA sequencing

2. Isolation and analysis techniques for Protein

   - Sodium dodecylsulfate - polyacrylamide gel electrophoresis (SDS - PAGE)
   - Western Blotting
   - Enzyme linked immunosorbent assay (ELISA)

3. Hybridization:

   The candidate should be able to describe and discuss:

   - How hybridization occurs
   - The use of this technique for culture confirmation for *Mycobacterium* spp.*, N. gonorrhoeae*, and systemic fungi.
   - Limitations of nucleic acid based test methods for culture confirmation as well as direct specimen testing

4. Amplification:

   The candidate should be able to describe and discuss:

   - PCR, LCR and other amplification techniques
   - Rapid PCR thermocyler methods (e.g. light cycler etc)
   - Application of these techniques to diagnostic microbiology (e.g. *Chlamydia trachomatis, Mycobacterium tuberculosis*, Herpes Simplex Virus, etc.)
   - Inhibitors in clinical material
   - Amplicon contamination control methods (uracil N-glycosylase)
   - Appropriate laboratory set up for PCR

5. Genotyping:

The candidate should be able to describe and discuss:

- PFGE (pulsed field gel electrophoresis)
- RFLP (restriction fragment length polymorphism)
- RT-PCR (reverse transcriptase - polymerase chain reaction)
- Ribotyping
- The role these techniques play in infection control
- How to interpret band patterns, and the reliability for each method listed above

6. DNA Sequencing:

- Methods such as dideoxy sequencing
- How this can be used for identification and for typing of strains for epidemiology
- Alternatives to radioactive labelling.
- DNA databases (e.g. BLAST searches)

7. Protein Analysis:

- How Western Blotting is used as a confirmatory test for HIV serology.

III VIROLOGY: GENERAL SYLLABUS

The candidates should be able to discuss viral taxonomy and the clinically relevant issues and molecular features of the major virus groups, their pathogenesis in human disease, host immune response, epidemiology, prevention and treatment, with an emphasis on the following viruses:

a) Respiratory tract viruses - respiratory syncytial virus (RSV), parainfluenza viruses, adenoviruses, and the influenza viruses, coronaviruses, rhinoviruses and SARs-associated coronavirus.

b) Sexually transmitted viruses - herpes simplex virus (HSV), cytomegalovirus (CMV), human papillomaviruses (HPV), human immunodeficiency virus (HIV) types 1 and 2, hepatitis B virus (HBV) and hepatitis C virus (HCV).

c) Viruses causing systemic disease in immunocompromised patients - herpes simplex virus, cytomegalovirus, varicella zoster virus (VZV), Epstein Barr virus (EBV), Adenovirus.

d) Enteric viruses - enteroviruses, rotaviruses, enteric adenoviruses, small round enteric viruses.

e) Vector-borne viruses - western equine encephalitis virus (WEE) (Dengue virus), West Nile Virus.

f) Viruses causing rash illness - measles, rubella, enteroviruses, human parvovirus B-19, human herpes virus 6 (HHV6) and human herpes virus 7 (HHV7).

g) Zoonotic viruses - Hantavirus, rabies.

The candidates should be able to describe the common technical methods of virus detection, including: cell culture with detection of virus cytopathic effect, ELISA, electron microscopy, PCR and nucleic acid hybridization, and immunological methods to identify viruses, including: neutralization, hemagglutination-inhibition, immunofluorescence, latex agglutination, and ELISA.

The candidates should be able to discuss optimal sampling method and transport conditions of specimens from patients with the above viral diseases.

The candidates should be familiar with the design, implementation, and review of quality control procedures for standard diagnostic viral methods described above. The candidates should be able to discuss which technical methods are used to provide more detailed reference diagnostic virology, and where the reference tests can be performed in Canada.

VIROLOGY: SPECIFIC SYLLABUS

A) Objectives for Cell Culture:

The candidates should be able to describe:

1. The normal morphology of common cell lines and their growth and maintenance requirements.

2. How to trypsinize the monolayers and how to count cells.

3. The optimal procedures for long term storage of cell lines in the frozen state.

4. How to conduct myoplasma contamination detection.

5. The general categories of cell lines and their properties, i.e. primary, continuous, etc.

6. The most appropriate cell line for each of the cultivable viruses.

B) **Objectives for Rapid Viral Diagnosis:**

The candidates should be able to discuss:

1. The principles and technical methods of direct and indirect immunofluorescence procedures, including the use of appropriate controls.

2. The principles and specific technical methods of enzyme immunoassay for antigen detection, with appropriate controls.

3. The principles and technical methods of latex agglutination tests for antigen detection, with appropriate controls.

4. The specimen preparation methods for direct EM and immune electron microscopy procedures. The resident should also be able to describe the morphology and size characteristics of the major human viral groups.

5. The principles and technical methods of PCR spot nucleic acid hybridization of Southern Blot analysis for the detection of virus genomes, and the appropriate use of controls.

C) **Objectives for the Detection of Viruses by Cytopathic Effect:**

The candidates should be able to describe:

1. The morphologic changes of the cytopathic effect of the major human virus groups.

2. The principles and technical methods used in identification of viruses by neutralization.

3. The technical methods used in virus identification by hemadsorption inhibition and hemagglutination inhibition, with appropriate use of controls.

4. How to inoculate the amniotic and allantoic cavities of embryonated eggs for myxovirus detection.

5. How to differentiate toxicity of clinical specimens from cytopathic effects of viruses.

D) **Objectives for the Virology Specimen Receiving:**

The candidates should be able to discuss:

1. The optimum specimen sampling site and method of sampling for each of the major human viruses.

2. The optimal specimen transport and storage methods for various types of clinical samples.

3. The principles of laboratory safety, especially the utilization of biohazard hoods and the processing of specimens that may contain hazardous viruses (hepatitis B virus or HIV).

4. The principles and practical methods of specimen treatment of all human specimens, including respiratory, gastrointestinal, and tissue specimens for both rapid diagnosis and cell culture methods.

IV SEROLOGY/IMMUNOLOGY SPECIFIC SYLLABUS

The candidates should be able to discuss the host immune response as it pertains to cell medicated immunity and the production of specific antibodies against a range of microbial pathogens. The understanding of the host response should apply to humans of various ages, those with natural infections, as well as those receiving vaccines, and for individuals who are immunocompromised. The candidate should be able to describe the molecular basis of antibody diversity, the hypothesized mechanisms of antigen-antibody interaction at the molecular level and factors which can interfere with antigen-antibody reactions.

The candidates should be able to discuss the standard approaches to technical methods of serological diagnosis: complement fixation, agglutination, immunofluorescence, enzyme immunoassay, radioimmunoassay and passive hemagglutination tests.

The candidates should be able to interpret and apply the appropriate serological tests for viral infections, bacterial infections (including toxin detection), unusual infections caused by *Brucella* spp., rickettsiae, legionella, fungi and parasites.

SEROLOGY

1. The candidates should be able to:

Describe the principles and applications of the following serological tests:

- ELISA - both sandwich and competitive binding
- Radioimmunoassay
- Direct/Indirect Immunofluorescence
- Complement Fixation Test (CFT)
- Anti-complementary Immunofluorescence
- Hemagglutination Inhibition

- Direct-passive Hemagglutination
- Western Blot analysis
- IFA, both quantitative and qualitative

2. Discuss the protocols and procedures for proper specimen collection, submission and requisite information requirements for serological examinations.

3. Discuss quality control requirements for, and the interpretation of results of the following tests:

   - Hepatitis A, B, C antibody testing
   - Hepatitis B markers
   - CFT for respiratory viruses
   - HIV screening and confirmatory tests
   - Syphilis screening and confirmatory tests
   - West Nile Virus
   - Immune status protocols for health care workers, organ donors and transplant recipients
   - PCR-HCV, qualitative and quantitative
   - Cryptococcal antigen determinations; detection and quantitation.
   - Bacterial antigen detection - DFA & ELISA - Chlamydia, CNS pathogens/

4. Discuss the application of methods used for:

   - Specific IgM testing, sucrose gradient and column separation techniques.
   - Removal of IgG from a serum sample using polyvalent anti-human IgG, recombinant protein G, or protein A.

5. Discuss the factors of serology related to:

   - The selection of tests based on patient history.
   - Time requirements for test completion.
   - The instrumentation required to perform serological tests.

V ENVIRONMENTAL SCIENCES:

The candidates should be able to describe the common environmental pathogens (and their toxins) found in food, drinking water, as well as recreational water. These may include the *Enterobacteriaceae*, *Staphylococcus aureus, Pseudomonas aeruginosa* and *Enterococcus* spp. The candidates should be able to discuss the role of public health and environmental programs relating to analysis and monitoring.

The candidates should be familiar with technical methods for:

a) food microbiology
b) drinking water microbiology
c) recreational water microbiology

VI PARASITOLOGY:

The candidates should be able to discuss the taxomy, life cycle, immunology, diagnosis, treatment, prevention and control of important human parasitic diseases.

The candidates should be able to discuss:

1. The principles and applications of routine methods employed in the diagnosis of parasitic diseases.

2. Specimen preparation and examinations for the identification of common and less common parasites such as:

   - *Plasmodium falciparum, P. vivax, P. ovale,* and *P. malariae*
   - *Entamoeba histolytica*
   - *Blastocystis hominus*
   - *Giardia lamblia*
   - *Enterobius vermicularis*
   - *Ascaris lumbricoides*
   - *Trichuris trichiuria*
   - *Strongyloides stercoralis*
   - *Cryptosporidium parvum*
   - *Microsporidia*
   - *Dientamoeba fragilis*
   - *Echinococcus granulosus*
   - *Schistosoma mansoni, S. hematobium*, and *S. japonicum*

3. The protocols and procedures for proper specimen collection, submission, and requisite information for parasitic examinations.

4. Test interpretation and reporting requirements.

VII SAFETY:

The candidates must be able to discuss:

1. The Workplace Safety and Health Act and its applications to the clinical laboratory.

2. The Workplace Hazardous Materials Information system (WHMIS) related to:

   - What WHMIS is, its rationale and major elements.
   - Compliance mechanisms and penalties which accompany WHMIS legislation.
   - Educational and record keeping requirements under WHMIS.
   - How to classify and label regulated hazardous products.

3. The Transport of Dangerous Goods Regulations related to:

   - The nine classes of dangerous goods under the Acts.
   - The responsibilities of the shipper, the carrier and the receiver of dangerous goods.
   - The requirements for placards, labels and shipping documents.
   - Differentiating between consumer products and regulated dangerous goods.
   - Resources that may further assist in complying with the Acts.
   - Checklists to determine whether a shipment complies with Transport of Dangerous Goods Regulations before you release it to a carrier.
   - Incidence reports when necessary.

4. The Principles and Practices of Biosafety in the Clinical Laboratory related to:

   - Recognition and categorization of biohazards.
   - Categorization of containment levels and biosafety cabinets.
   - The requirements for certification of biosafety cabinets.
   - Decontamination of wastes and regulations regarding waste disposal.

5. Laboratory Acquired Infections

   - The role of aerosols, and direct contact in risk to health care workers.
   - The classification of biosafety level of various pathogens.

A **Procedure Manual (Bench Protocol):**

The candidates should be able to:

a) Describe how to update bench protocols and discuss the various aspects that affect the decision making process (e.g. what is practical for the lab benches, vs what sounds good on paper).

b) Discuss how to get input from lab technologists in how to best update/change bench protocols and procedure manuals to make it an effect and useful document.

c) Discuss the NCCLS and ASM recommendations pertaining to how procedure manuals should be developed and how often they should be updated and how this is documented.

d) Describe the role these procedure manuals play in accreditation.

B **Collective Agreement and Organizational Structure:**

The candidates should be able to:

a) Describe the organizational structure and how the reporting lines function. Discuss how this may differ between institutions and the advantages/disadvantages of the various structures.

b) Discuss how the collective agreement may constrain management staff as it pertains to rates of pay, changes in schedule, holidays, promotion, etc.

c) Discuss the grievance process.

C **Workload Management Systems:**

The candidates should be able to discuss the Guidelines for Management Information Systems in Canadian health care facilities related to:

- Indicators for staffing, productivity workload and utilization.
- The management use of these indicators and their limitations.
- Development of a plan for equipment and staffing for a hypothetical laboratory.

D **Conflict Resolution:**

The candidates should be able to discuss:

- Guidelines for progressive discipline.
- The guidelines for the institution and the laboratory for progressive discipline.
- The function of the Human Resources Department and the Collective Agreement.
- Hypothetical situations which will require these tools.

E **Accreditation:**

The candidates should be able to discuss the general requirements under the protocols of:

- The Canadian Council on Health Services Accreditation.
- The College of American Pathologists.
- The Provincial College of Physicians and Surgeons - Accreditation and Licensing requirements.

F **Government Regulation:**

The candidates should be able to discuss:

- The Medical Act
- The Hospital Services Act or its successor
- The Public Health Act

G **Information Systems:**

The candidates should be able to discuss the principles and applications of the following:

- Laboratory Computer System:
  - What features are optimal
  - Confidentiality

- Laboratory Information Systems:
  - Patient results
  - Epidemiology

- Local area networks

- The Internet and the Bulletin Board Systems

H **Performance Appraisals:**

The candidates should be able to:

a) Determine performance standards for laboratory personnel;
b) Describe the limitations of proficiency testing;
c) Determine criteria that will link competence assurance and continuing education to performance standards;
d) Develop education action plans for deficient personnel.

I **Confidentiality Issues:**

The candidates should be able to:

a) Describe what Public Health Information Access (PHIA) is about.
b) Recognize what would be deemed conflict situations where PHIA has not been properly observed
c) Discuss what actions to take when PHIA transgressions occur.