

Examination Content

National Registry of Certified Microbiologists
RM: Pharmaceutical and Medical Device

The National Registry of Certified Microbiologists
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A list of the tasks tested on the exam is provided below. Questions are classified first by domain and then by task. The examination will have at least one question from each task. The number of questions from each domain is listed below the domain name in the task list.

**LABORATORY INSTRUMENTS AND EQUIPMENT
(24 questions)**

1. Validate, use, and monitor a steam autoclave.
2. Use various types of microscopes (e.g., light-field, dark-field, phase-contrast, fluorescence).
3. Use filtration equipment for sterilization of solutions.
4. Use and calibrate analytical equipment (pH meters, pH indicators, pH titration, spectrophotometers, balance, etc.).
5. Use laminar flow hood and biosafety cabinets
6. Use incubation equipment and appropriate controls.

**LABORATORY PREPARATIONS
(13 questions)**

7. Use general stains (e.g., Gram, nigrosin, spore, Ziehl-Neelsen, Kinyoun, fluorescent).
8. Prepare and perform appropriate quality control checks on media from commercial dehydrated materials and supplements.
9. Use general, selective, or differential media for bacteria.
10. Use general, selective, or differential media for fungi.
11. Prepare solutions of known molarity.

LABORATORY PROCEDURES (58 questions)

12. Isolate and identify yeasts and mold of importance in industry.
13. Isolate and identify gram-positive, aerobic bacilli.
14. Isolate and identify *Enterobacteriaceae* and other gram-negative bacilli.
15. Isolate and identify gram-positive cocci.
16. Perform broth or agar susceptibility tests of antimicrobials.
17. Detect and measure the growth of microorganisms (e.g., by substrate utilization, turbidity, impedance, rapid methodologies).
18. Determine inactivation rates of microorganisms by chemical and physical means (e.g., *D* value, cold sterilants, disinfectants).
19. Use viable plate count procedures.
20. Use "most probable" number technique.

21. Perform tests for water suitability in production systems.
22. Apply appropriate statistical and analytical techniques to test results.
23. Perform organism identification of bacteria and yeasts (e.g., biochemical, fatty acids, electrophoresis, DNA probes, ELISA, commercial kits).
24. Understand the advantages and limitations of various sterilization procedures.
25. Perform and validate tests for sterility.
26. Perform tests for particulate matter.
27. Perform and validate bacterial endotoxin tests.
28. Perform and validate bioburden tests.
29. Perform tests for the effectiveness of preservatives.
30. Perform process, equipment, and/or product validation studies.
31. Perform precipitation, agglutination, immunoassay, immunofluorescent tests.
32. Use and maintain eukaryotic cell cultures.

**LABORATORY OPERATIONS
(27 questions)**

33. Use appropriate safety techniques for the isolation and transfer of biological materials (e.g., loops, pipets, dilutor tips).
34. Handle, store, transport, and dispose of etiologic agents, hazardous chemicals, radiologic agents, or biologics in compliance with laboratory and government regulations (e.g., OSHA, DOT, International Air Transport Association).
35. Document and maintain laboratory records and procedures.
36. Monitor the environment during process operations (e.g., surface viables, airborne viables, and airborne non-viables).
37. Maintain stock cultures.
38. Perform studies to determine sources of contamination.
39. Operate within environmentally controlled rooms including clean-rooms.
40. Evaluate clean-in-place and sterilize-in-place systems (e.g., validation procedures, monitoring procedures, cleaning validation, troubleshooting).

SAMPLE COLLECTION AND HANDLING
(9 questions)

41. Prepare samples for microbiological analysis (e.g., sample size, blending, dilutions, incubation conditions).
42. Collect and evaluate industrial samples for quality assurance/quality control testing.
43. Select appropriate methods for transport, handling, and storage of samples.

STERILIZATION AND DEPYROGENATION VALIDATION
(19 questions)

44. Ethylene oxide sterilization.
45. Radiation sterilization.
46. Chemical sterilization.
47. Sterilization by filtration.
48. Depyrogenation.
49. Steam sterilization.