Commonwealth of Virginia

Department of General Services
Division of Consolidated Laboratory Services

Laboratory Inspection Checklist - VELAP Chapter 45

Laboratory Name: _____ DCLS ID: _____

Assessor Name: _____ Inspection Date: _____

MICROBIOLOGY TESTING

	Y	N	N/A		
SOP					
1116	☐	☐	☐	796 B	Detailed testing criteria information shall be defined in either the laboratory's test methods, SOPs, quality manual, or similar documentation.
FACILITIES					
1132	☐	☐	☐	798 A	Laboratory facilities: Floors and work surfaces shall be non-absorbent and easy to clean and disinfect.
1133	☐	☐	☐	798 A	Laboratory facilities: Work surfaces shall be adequately sealed.
1134	☐	☐	☐	798 A	Laboratory facilities: Laboratories shall provide sufficient storage space.
1135	☐	☐	☐	798 A	Laboratory facilities: The laboratories shall be clean and free from dust accumulation.
1136	☐	☐	☐	798 A	Laboratory facilities: Plants, food, and drink shall be prohibited from the laboratory work area.
DEMONSTRATION OF CAPABILITY					
1109	☐	☐	☐	793 A	Method evaluation. Laboratories are required to demonstrate proficiency with the test method prior to first use. This shall be achieved by comparison to a method already approved for use in the laboratory, or by analyzing a minimum of 10 spiked samples whose quality system matrix is representative of those normally submitted to the laboratory, or by analyzing and passing one proficiency test series provided by an approved proficiency sample provider.
1110	☐	☐	☐	793 A	Method evaluation. The laboratory shall maintain the proficiency analysis documentation as long as the method is in use and for at least five years past the date of last use.
BLANK					
1100	☐	☐	☐	791 A 4	Microbiological sterility checks and blanks. Sterility checks on sample containers shall be performed on at least one container for each lot of purchased, pre-sterilized containers with nonselective growth media.
1103	☐	☐	☐	791 A 6	Microbiological sterility checks and blanks. At least one filter from each new lot of membrane filters shall be checked for sterility with nonselective growth media.
1105	☐	☐	☐	791 C 2	Negative controls. Each pre-prepared, ready-to-use lot of selective medium (including chromofluorogenic reagent) and each batch of selective medium prepared in the laboratory shall be analyzed with one or more known negative culture controls (i.e., nontarget organisms), as appropriate to the method. This shall be done prior to first use of the medium. NOTE: The provisions of this subsection shall not apply to wastewater treatment plants. However, if method requirements are more stringent, the method requirements apply per 1VAC30-45-760 A 1.
QC					
1093	☐	☐	☐	791 A	Microbiological sterility checks and blanks. The laboratory shall demonstrate that the filtration equipment and filters, sample containers, media and reagents have not been contaminated through improper handling or preparation, inadequate sterilization, or environmental exposure.
1104	☐	☐	☐	791 B 2	Positive controls. Each preprepared, ready-to-use lot of medium (including chromofluorogenic reagent) and each batch of medium prepared in the laboratory shall be tested and demonstrate a known positive response. This shall be done prior to first use of the medium.
1106	☐	☐	☐	792	Test variability and reproducibility. For test methods that specify colony counts such as membrane filter or plated media, duplicate counts shall be performed monthly on one positive sample, for each month that the test is performed.

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QC					
1107	☐	☐	☐	792	Test variability and reproducibility. If the lab has two or more analysts, each analyst shall count typical colonies on the same plate on one positive sample, for each month that the test is performed.
1108	☐	☐	☐	792	Test variability and reproducibility. For monthly variability studies, counts shall be within 10% difference to be acceptable. In a laboratory with only one microbiology analyst, the analyst shall count the same plate twice, with no more than 5.0% difference between the counts.
1111	☐	☐	☐	794 A	Test performance. All growth and recovery media shall be checked to assure that the target organism(s) respond in an acceptable and predictable manner (see 1VAC30-45-791 B).
1112	☐	☐	☐	794 B	Test performance. To ensure that analysis results are accurate, target organism identity shall be verified as specified in the method, e.g. by use of the completed test, or by use of secondary verification tests such as a catalase test.
1114	☐	☐	☐	796 A	The laboratory shall ensure that the quality of the reagents and media used is appropriate for the test concerned.
SUPPORT EQUIPMENT					
1101	☐	☐	☐	791 A 4	Microbiological sterility checks and blanks. For containers prepared and sterilized in the laboratory, a sterility check shall be performed on one container per sterilized batch with nonselective growth media.
1137	☐	☐	☐	798 B 1	Laboratory equipment (Temperature measuring devices): Temperature measuring devices such as liquid-in-glass thermometers, thermocouples, and platinum resistance thermometers used in incubators, autoclaves, and other equipment shall be the appropriate quality to meet specifications in the test method.
1138	☐	☐	☐	798 B 1	Laboratory equipment (Temperature measuring devices): The graduation of the temperature measuring devices shall be appropriate for the required accuracy of measurement.
1139	☐	☐	☐	798 B 1	Laboratory equipment (Temperature measuring devices): Temperature measuring devices shall be calibrated to national or international standards for temperature (see 1VAC30-45-740 C) at least annually.
1140	☐	☐	☐	798 B 2 A	Autoclaves: The performance of each autoclave shall be initially evaluated by establishing its functional properties and performance, for example, heat distribution characteristics with respect to typical uses.
1141	☐	☐	☐	798 B 2 A	Autoclaves: Autoclaves shall meet specified temperature tolerances.
1142	☐	☐	☐	798 B 2 A	Autoclaves: Pressure cookers shall not be used for sterilization of growth media.
1143	☐	☐	☐	798 B 2 B	Autoclaves: Demonstration of sterilization temperature shall be provided by use of continuous temperature recording device or by use of a maximum registering thermometer with every cycle.
1144	☐	☐	☐	798 B 2 B	Autoclaves: Appropriate biological indicators shall be used at least once each month to determine effective sterilization.
1145	☐	☐	☐	798 B 2 B	Autoclaves: Temperature sensitive tape shall be used with the contents of each autoclave run to indicate that the autoclave contents have been processed.
1147	☐	☐	☐	798 B 2 C	Autoclaves: Records of autoclave operations shall be maintained for every cycle. Records shall include: ___ Date ___ Contents ___ Maximum temperature reached ___ Time in sterilization mode ___ Total run time (may be recorded as time in and time out) ___ Analyst's initials
1148	☐	☐	☐	798 B 2 D	Autoclaves: Autoclave maintenance shall be performed annually, either internally or by service contract, and shall include a pressure check and calibration of temperature device. If the laboratory demonstrates regular monitoring of pressure (e.g., for each autoclaved batch) and annual calibration of the maximum registering thermometer, the annual autoclave pressure and temperature device checks shall not be required.
1149	☐	☐	☐	798 B 2 D	Autoclaves: Records of the maintenance shall be maintained in equipment logs.
1150	☐	☐	☐	798 B 2 E	Autoclaves: The autoclave mechanical timing device shall be checked quarterly against a stopwatch and the actual time elapsed documented.

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SUPPORT EQUIPMENT					
1151	☐	☐	☐	798 B 3 A-C	Volumetric equipment: Volumetric equipment shall be calibrated as follows: ___ Equipment with movable parts such as automatic dispensers, dispensers/diluters, and mechanical hand pipettes shall be verified for accuracy quarterly. ___ Equipment such as filter funnels, bottles, non-class A glassware, and other marked containers shall be calibrated once per lot prior to first use. ___ The volume of the disposable volumetric equipment such as sample bottles and disposable pipettes shall be checked once per lot.
1152	☐	☐	☐	798 B 4	UV instruments: UV instruments used for sanitization shall be tested quarterly for effectiveness with an appropriate UV light meter or by plate count agar spread plates. Replace bulbs if output is less than 70% of original for light tests or if count reduction is less than 99% for a plate containing 200 to 300 organisms.
1153	☐	☐	☐	798 B 5	Conductivity meters, oxygen meters, pH meters, hygrometers, and other similar measurement instruments shall be calibrated according to the method specified requirements (see 1VAC30-45-740 D 1 d).
1154	☐	☐	☐	798 B 6 A	Incubators and water baths: The uniformity of temperature distribution in incubators and water baths shall be established.
1155	☐	☐	☐	798 B 6 A	Incubators and water baths: Temperature of incubators and water baths shall be documented twice daily, at least four hours apart, on each day of use.
1156	☐	☐	☐	798 B 6 B	Ovens: Ovens used for sterilization shall be checked for sterilization effectiveness monthly with appropriate biological indicators. Records shall be maintained for each cycle that include date, cycle time, temperature, contents and analyst's initials.
GLASSWARE					
1157	☐	☐	☐	798 B 7 A	Labware (glassware and plasticware): The laboratory shall have a documented procedure for washing labware, if applicable. Detergents designed for laboratory use shall be used.
1158	☐	☐	☐	798 B 7 B	Labware (glassware and plasticware): Glassware shall be made of borosilicate or other non-corrosive material, free of chips and cracks, and shall have readable measurement marks.
1159	☐	☐	☐	798 B 7 C	Labware (glassware and plasticware): Labware that is washed and reused shall be tested for possible presence of residues that may inhibit or promote growth of microorganisms by performing the Inhibitory Residue Test annually, and each time the lab changes the lot of detergent or washing procedures.
1160	☐	☐	☐	798 B 7 D	Labware (glassware and plasticware): Washed labware shall be tested at least once daily, each day of washing, for possible acid or alkaline residue by testing at least one piece of labware with a suitable pH indicator such as bromothymol blue. Records of tests shall be maintained.
REAGENTS & MEDIA					
1094	☐	☐	☐	791 A 1	Microbiological sterility checks and blanks. A sterility blank shall be analyzed for each lot of pre-prepared, ready-to-use medium (including chromofluorogenic reagent) and for each batch of medium prepared in the laboratory. This shall be done prior to first use of the medium.
1099	☐	☐	☐	791 A 3	Microbiological sterility checks and blanks. For pour plate technique, sterility blanks of the medium shall be made by pouring, at a minimum, one uninoculated plate for each lot of pre-prepared, ready-to-use media and for each batch of medium prepared in the laboratory.
1102	☐	☐	☐	791 A 5	Microbiological sterility checks and blanks. A sterility blank shall be performed on each batch of dilution water prepared in the laboratory and on each batch of pre-prepared, ready-to-use dilution water with nonselective growth media.
1115	☐	☐	☐	796 B	Media prepared by the laboratory from basic ingredients shall be tested for performance (e.g. for selectivity, sensitivity, sterility, growth promotion, growth inhibition) prior to first use.
1117	☐	☐	☐	796 C	Reagents, commercial dehydrated powders and media shall be used within the shelf-life of the product and shall be documented according to 1VAC30-45-730 J.
1118	☐	☐	☐	796 D	Distilled water, deionized water or reverse osmosis produced water free from bactericidal and inhibitory substances shall be used in the preparation of media, solutions and buffers.

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REAGENTS & MEDIA					
1119	☐	☐	☐	796 D	The quality of the water used in the preparation of media, solutions, and buffers shall be monitored for chlorine residual, specific conductance, and heterotrophic bacteria plate count monthly (when in use), when maintenance is performed on the water treatment system, or at startup after a period of disuse longer than one month.
1120	☐	☐	☐	796 E	Analysis for metals and the Bacteriological Water Quality Test (to determine presence of toxic agents or growth promoting substances) shall be performed annually.
1121	☐	☐	☐	796 E	Results for the analyses of metals and the Bacteriological Water Quality Test shall meet the specifications of the required method and records of analyses shall be maintained for three years. An exception to performing the Bacteriological Water Quality Test shall be given to laboratories that can supply documentation to show that their water source meets the criteria, as specified by the method, for Type I or Type II reagent water.
1122	☐	☐	☐	796 F	Media, solutions, and reagents shall be prepared, used and stored according to a documented procedure following the manufacturer's instructions or the test method.
1123	☐	☐	☐	796 F	Documentation for media prepared in the laboratory shall include: ___ Date of preparation ___ Preparer's initials ___ Type and amount of media prepared ___ Manufacturer and lot number ___ Final pH of the media ___ Expiration date
1124	☐	☐	☐	796 F	Documentation for media purchased pre-prepared, ready-to-use shall include: ___ Manufacturer ___ Lot number ___ Type and amount of media received ___ Date of receipt ___ Expiration date of the media ___ pH of the media
1125	☐	☐	☐	797	In order to ensure identity and traceability, reference cultures used for positive and negative controls shall be obtained from a recognized national collection, organization, or manufacturer. Microorganisms may be single use preparations or cultures maintained by documented procedures that demonstrate the continued purity and viability of the organism.
1126	☐	☐	☐	797 1	Reference cultures may be revived (if freeze-dried) or transferred from slants and sub-cultured once to provide reference stocks.
1127	☐	☐	☐	797 1	The reference stocks shall be preserved by a technique that maintains the characteristics of the strains.
1128	☐	☐	☐	797 1	Reference stocks shall be used to prepare working stocks for routine work.
1129	☐	☐	☐	797 1	If reference stocks have been thawed, they shall not be refrozen and reused.
1130	☐	☐	☐	797 2	Working stocks shall not be sequentially cultured more than five times.
1131	☐	☐	☐	797 2	Working stocks shall not be sub-cultured to replace reference stocks.
MEMBRANE FILTER TECHNIQUE					
1095	☐	☐	☐	791 A 2	Microbiological sterility checks and blanks. For filtration technique, the laboratory shall conduct one beginning and one ending sterility check for each filtration series.
1096	☐	☐	☐	791 A 2	Microbiological sterility checks and blanks. For presterilized single use funnels a sterility check shall be performed on one funnel per lot. The filtration series is considered ended when more than 30 minutes elapses between successive filtrations.
1097	☐	☐	☐	791 A 2	Microbiological sterility checks and blanks. During a filtration series, filter funnels shall be rinsed with three 20-30 ml portions of sterile rinse water after each sample filtration.
1098	☐	☐	☐	791 A 2	Microbiological sterility checks and blanks. Laboratories shall insert a sterility blank after every 10 samples or sanitize filtration units by UV light after each sample filtration.
DATA ANALYSIS					

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Y N N/A

DATA ANALYSIS

1113 ☐☐☐ 795 The calculations, data reduction, and statistical interpretations specified by each test method shall be followed.