WAC 16-309-180 Microbiological testing. (1) Microbiological testing is intended to accurately measure qualitative, semi-quantitative, or quantitate results, and report microorganisms incurred through the production and processing of cannabis and cannabis products.

(2) The laboratory must have a microbiological testing SOP that contains a detailed description of the preparation of any material that does not come as a working stock (i.e., culture media, master mix, spiked controls).

(3) The laboratory may use either culture-based testing methods, immunoassay methods, molecular assay methods, or a combination of culture-based, immunoassay, and molecular assay methods for microbiological testing.

(4) Quality control must be performed on each new media lot, PCR reagent lot, or kit lot used. For molecular assays, DNA controls must be included with each analytical run and internal amplification controls (IACs) must be included with each individual reaction.

(a) Acceptability criteria for all calibration and QC materials such as controls, spikes, and blanks, must be defined, as well as the action to be taken when results are outside control limits. The laboratory must set controls at relevant limits around the decision points for the microbial assay(s) as defined above.

(b) Positive and negative controls must be included in all microbial assay tests. Quality controls must be analyzed in the same manner as samples.

(i) The laboratory must use control organisms that represent the target organism. Controls for the confirmation of a target, such as salmonella or Shiga toxin-producing *E. coli* (STEC), must be as similar as possible to the presumptive organism.

(ii) The laboratory must maintain documentation of quality control organisms and ensure purity of the control organism is maintained by limiting the number of cell divisions from the original culture.

(5) The laboratory must have a record of all microbial quality control and sample results. If the laboratory does not use equipment capable of recording and printing results (i.e., a PCR instrument or plate reader), then the laboratory must photograph all microbial quality control and sample results for recordkeeping.

(6) The laboratory must have a procedure in place which must specify any safety requirements or precautions unique to the microbial assay(s) used, including:

(a) Biohazard labels on equipment used to store biohazardous materials and waste such as restricted areas, refrigerators, and waste receptacles;

(b) Performing microbial assay(s) in either a Class II biosafety cabinet (BSC) or a designated clean room;

(c) Sterilization of biohazardous waste, including any materials that have come into contact with control organisms, either by autoclave or by chemical disinfectants;

(d) For safety reasons, biosafety level (BSL) 1 organisms for salmonella and STEC may be used as control organisms.

(e) Lab-prepared media must be sterilized by autoclave and undergo a quality control check for sterility before use.

Sterilization by autoclave must be documented using materials such as autoclave tape, and autoclave functionality must be tested using materials such as spore bioindicators.

(7) The laboratory must have a procedure and training for shipping and receiving bacterial enrichments, organisms, or presumptive

positive samples. Biohazardous shipping and receiving training must be documented.

(8) The laboratory must perform microbial analysis in a unidirectional (i.e., one way) manner to reduce possible contamination of microbial test materials.

(a) For molecular microbial assays, the laboratory must use materials to reduce contamination such as reaction tubes that are RNAase-free and DNAase-free and use aerosol barrier pipette tips.

(b) For culture-based testing methods, all samples and controls must initiate incubation within 10 minutes of inoculation.

(9) For qualitative methods, all results must be reported as qualitative designations such as "detected," "not detected," "positive," or "negative." For quantitative methods, the laboratory may only report results that are above the limit of quantification and below the upper limit of linearity.

(10) The laboratory may not report colony-forming units (CFU) counts with greater than two significant figures.

[Statutory Authority: RCW 15.150.030 and 2022 c 135. WSR 24-09-079, § 16-309-180, filed 4/17/24, effective 5/18/24.]