

1 **Rule 64-4.0XX Standards for Marijuana Testing Laboratories.**

2 (1) For the purposes of the department's marijuana testing standards rules, the following words and phrases
3 shall have the meanings indicated.

4 (a) Agricultural agents – any pesticide, herbicide, fungicide, fertilizer, or root stimulant applied to the plant or
5 substrate, at any stage of cultivation or processing, for the purposes of increased growth, vigor, and pest resistance.

6 (b) Analytical batch – A group of testing samples, which behave similarly with respect to the sampling or the
7 testing procedures being employed, that are processed as a unit. For mycotoxin, residual solvent, agricultural agents,
8 and heavy metals analysis, if the number of testing samples in a group is greater than 20, then each group of 20
9 samples or less is a separate laboratory batch.

10 (c) Calibration – Set of analyses that establish, under conditions specified in the analysis standard operating
11 procedure, the relationship between values of quantities indicated by measuring instrument or measuring system, or
12 values represented by a material measure of a reference material, and the corresponding values realized by
13 standards.

14 (d) Calibration Curve – The graphical relationship between the known values, such as the concentrations, of a
15 series of calibration standards and their instrument response. Calibration standards are prepared by successively
16 diluting a standard solution to produce working standards, which cover the working range of the instrument.

17 (e) Calibration Standard – A substance or reference material used to calibrate an instrument.

18 (f) Cannabinoid Profile – The amount of each individual cannabinoid tested for in section (13) relative to the
19 total amount of all cannabinoids tested, given in percent.

20 (g) Certified Reference material – Reference material characterized by a metrologically valid procedure for one
21 or more specified properties, accompanied by a certificate that provides the value of the specified property, its
22 associated uncertainty, and a statement of metrological traceability. All reference material must be purchased from
23 a vendor accredited to ISO/IEC 17043:2010 standards.

24 (h) Contaminants unsafe for human consumption – Any microbe, mycotoxin, fungus, yeast, mildew,
25 agricultural agent, residual solvent, or metal found in an amount that exceeds any of the department's accepted
26 limitations.

27 (i) Continuing calibration verification – A standard solution from a source that is certified and traceable. These
28 standards are used to check the accuracy of a calibration curve on daily basis (before the run and every 12hours
29 thereafter.

30 (j) Data packages – Analytical testing data that is prepared by a marijuana testing laboratory and which contains
31 information about the testing performed, quality assurance and quality control data, and the results of any tests
32 performed.

33 (k) Environmental testing – Physical and biological laboratory analyses, to include chemistry and biochemistry
34 in compliance with sections 64E-1.005 F.S.

35 (l) Filth and foreign materials – Hair, insects, feces, packaging contaminants, manufacturing waste, and other
36 similar marijuana cultivation and processing by-products.

37 (m) Final Product – Any packaged and sealed product intended for use by a qualified patient.

38 (n) Increment – A subsample taken from an edible product for the purposes of homogeneity testing.

39 (o) Initial calibration verification – A standard solution from a source, other than normal calibration standards,
40 that is certified and traceable. These standards are used to check the accuracy of a calibration curve.

41 (p) Initial display of competency – An examination, provided by a marijuana testing laboratory, undertaken by
42 an analyst to determine whether he or she can correctly, accurately, and repeatedly perform a specific analysis or
43 analyze a specific measurement.

44 (q) Internal Standard – A pure analyte of known amounts added to the final extract prior to analysis used to
45 measure the relative response of other analytes and surrogates to correct for variations. The internal standard must
46 be a compound that is not expected to be found in the sample.

47 (r) Laboratory batch – A set that includes the analytical batch as well as all applicable quality control samples,
48 to include one method blank, duplicate laboratory fortified blanks, and duplicate matrix spikes for mycotoxin,
49 residual solvents, agricultural agents, and heavy metals. For microbial analysis by qPCR, the well plate shall
50 include the following: at a minimum one positive control, one negative control, and replicate sample per analytical
51 batch.

52 (s) Laboratory fortified blank – A quality control sample, created using a matrix similar to the sample matrix,
53 and initially without analytes of interest prepared along with testing samples that have been fortified with a known
54 concentration of a target analyte or analytes for competency assessment purposes.

55 (t) Life science testing – Microbial laboratory analysis, to include microbiology and mycology, including yeast
56 and mildew.

57 (u) Limit of detection (LOD) – The lowest quantity of a substance or analyte that can be distinguished from the
58 absence of that substance within a stated confidence limit. This limit must be no less than 1/10th of the action limit
59 for the analyte tested. LOD applicable for metals, residual solvents, agricultural agents, mycotoxins, and potency.

60 (v) Limit of quantitation – The minimum concentration of an analyte in a specific matrix that can be reliably
61 quantified while also meeting predefined goals for bias and imprecision. LOQ applicable for metals, residual
62 solvents, agricultural agents, mycotoxins, and potency.

63 (w) Matrix – The component or substrate containing an analyte of interest. The three matrix types contemplated
64 are: dried marijuana (plant material), derivative product(concentrates), and edibles.

65 (x) Matrix spike sample – A aliquot from a testing sample, which has been fortified with a known concentration
66 of an analyte or analytes of interest to test for potential matrix interference.

67 (y) Method blank – An analyte free matrix, (reagent water, or appropriate solvent), which is carried through the
68 complete preparation and analytical procedure, used to evaluate contamination resulting from the complete
69 analytical procedure. For a method blank to be acceptable for use with the accompanying samples, the
70 concentration in the blank of any analyte of concern shall not be higher than the limit of detection.

71 (z) Potency testing – The amount, in milligrams, of total active THC and total active CBD in the final derivative
72 product.

73 (aa) Processed batch – A homogenous portion of usable whole flower marijuana, derivative product, or edible,
74 not to exceed 25 kilograms dry weight, 75 liters volume diluted, or 2 liters volume concentrate. Processed batches
75 exceeding these sizes must be split into even portions below the maximum size with unique identifiers.

76 (ab) Reagent – A compound or mixture added to a system to cause a chemical reaction or test if a reaction
77 occurs. A reagent may be used to tell whether a specific chemical substance is present by causing a reaction to occur
78 with the chemical substance. (ac) Residual Percent Deviation (RPD) – A calculation of the precision of the
79 measured recovered concentration of duplicate lab fortified blanks, matrix spikes, or duplicate samples, calculated as
80 follows: $RPD = |A-B|/(A+B) \times 200$. The RPD should be equal to or less than 20% to constitute a pass.

81 (ac) Retail Batch – The portion of one processed batch used to create a final product that consists of one product
82 type, at one concentration, at one weight or volume.

83 (ad) Spike Solution – A solution of method analytes of known concentrations that is used to fortify an aliquot of
84 laboratory reagent water or sample matrix.

85 (ae) Standard Operating Procedure (SOP) – A written document which details the method of an operation,
86 analysis or action whose techniques and procedures are thoroughly described and which is appropriate as a method
87 of performing certain routine or repetitive tasks.

88 (af) Surrogate – A pure analyte that is added to all testing and QC samples before extraction to measure method
89 accuracy. Surrogates should be similar in behavior to method analytes, but not expected to appear in the sample.

90 (ag) Usable Whole Flower Marijuana – The dried flowers of the female marijuana plant, including low-THC
91 cannabis, that is suitable to be dispensed from a medical marijuana treatment center for medical use by a qualified
92 patient. Usable whole flower marijuana does not include seeds, resin extracted from any part of the plant, or any
93 compound, manufacture, salt, derivative, mixture, or preparation of the plant or its seeds or resin.

94 (2) Marijuana testing laboratories shall develop, maintain, and implement test methods and corresponding
95 written quality documentation in conformity with this rule, any required accreditation pursuant to Rule 64-4.XXX,
96 and Florida law. Standard operating procedures shall be created for the analytes and materials within subsections
97 (12), (13), (14), and (15) as well as the following testing functions and responsibilities:

98 (a) identification, calibration, and maintenance of equipment and instruments;

99 (b) chain of custody protocols;

100 (c) data review and internal review processes;

101 (d) analytical methods;

102 (e) cleaning procedures for equipment, workspaces, and secure storage;

103 (f) contingency plans for data that is not within control limits, or is otherwise unacceptable for analysis;

104 (g) employee training;

105 (h) premises and sample security;

106 (i) proficiency testing instructions provided with proficiency testing samples;

107 (j) quality assurance and quality control procedures;

108 (k) recordkeeping and record retention;

109 (l) sample preparation;

110 (m) sample identification;

111 (n) sample rejection;

112 (o) sample destruction;

113 (p) sample disposal;
114 (q) disposal of non-marijuana laboratory waste;
115 (r) sample storage;
116 (s) schedule and process for internal audits and corrective actions; and
117 (t) disposal of marijuana and laboratory waste.
118 (3) Marijuana testing laboratory standard operating procedures for analytical methods shall conform to the
119 following:

120 (a). Standard operating procedures shall include the following information:

- 121 1. The name of the testing method;
- 122 2. A list of all analytes tested for using said method;
- 123 3. The applicable matrix or matrices;
- 124 4. Method sensitivity;
- 125 5. Common potential interferences;
- 126 6. The analytical instrument used;
- 127 7. Consumable supplies, reagents, and standards;
- 128 8. Sample preservation and hold time;
- 129 9. Type, frequency, and acceptable criteria for quality control samples;
- 130 10. Type, frequency, and acceptable criteria for calibration standards;
- 131 11. Procedures for analyzing batch samples;
- 132 12. Data quality assessment and acceptance criteria;
- 133 13. Calibration of results; and
- 134 14. Reagent solution and reference material preparation.

135 (b) Laboratory directors shall review, approve, sign, and date each standard operating procedure and each
136 revision to a standard operating procedure. All standard operating procedures shall include the dates of issue and
137 dates of revision.

138 (c) The latest revised standard operating procedures must be kept on testing facility premises and be accessible
139 to all employees during all hours of operation.

140 (4) Marijuana testing laboratory testing methods shall conform, to the extent practicable, to the following
141 methods:

142 (a) United States Food and Drug Administration, Bacterial Analytical Manual:

- 143 1. Chapter 4: Enumeration of Escherichia coli and the Coliform Bacteria (July 2017), incorporated by reference
144 herein and available at <https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX>;
- 145 2. Chapter 4A: Diarrheagenic Escherichia coli (October 2017), incorporated by reference herein and available
146 at <https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX>;
- 147 3. Chapter 5: Salmonella (March 2018), incorporated by reference herein and available at
148 <https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX>; and
- 149 4. Chapter 18: Yeasts, Molds and Mycotoxins (April 2001), incorporated by reference herein and available at
150 <https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX>.

151 (b) Chapter 4.7 of the U.S. Food and Drug Administration, Elemental Analysis Manual for Food and Related
152 Products, Version 1.1 (March 2015), incorporated by reference herein and available at
153 <https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX>.

154 (c) The U.S. Food and Drug Administration, Water Activity (Aw) in Foods (April 1984), incorporated by
155 reference herein and available at <https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX>.

156 (d) AOAC International, Official Methods of Analysis for Contaminant Testing of AOAC International (20th
157 edition, 2016), incorporated by reference herein and available at
158 <https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX>. The department has determined that posting the
159 incorporated material on the internet would constitute a violation of the federal copyright law. The incorporated
160 material will be available for public inspection and examination at the Florida Department of Health, 4052 Bald
161 Cyprus Way, Tallahassee, Florida 32399.

162 (e) Methods of analysis for contamination testing within United States Pharmacopeia and the National
163 Formulary (USP-NF) (2018), incorporated by reference herein and available at
164 <https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX>. The department has determined that posting the
165 incorporated material on the internet would constitute a violation of the federal copyright law. The incorporated
166 material will be available for public inspection and examination at the Florida Department of Health, 4052 Bald
167 Cyprus Way, Tallahassee, Florida 32399.

168 (f) The U.S. Environmental Protection Agency Testing Methods for Evaluating Solid Waste: Physical/Chemical
169 Methods Compendium (SW-846), incorporated by reference herein and available at
170 <http://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX>.

171 (g) A marijuana testing laboratory may provide an alternative, scientifically valid testing methodology, subject
172 to the following requirements:

173 1. Any alternative, scientifically valid testing methodologies must be validated in accordance with either:

174 a. the U.S. Food and Drug Administration, Guidelines for the Validation of Methods for the Detection of
175 Microbial Pathogens in Foods and Feeds (2nd edition, 2015), incorporated by reference herein and available at
176 <https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX>; or

177 b. the U.S. Food and Drug Administration, Guidelines for the Validation of Chemical Methods for FDA FVM
178 Program (2nd edition, 2015), incorporated by reference herein and available at
179 <https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX>.

180 2. The marijuana testing laboratory must submit alternative, scientifically valid testing methodologies to an
181 independent third party that is qualified in the qualitative validation of testing methodologies. Such validation shall
182 include proficiency testing in which the marijuana testing laboratory must successfully achieve two consecutive
183 passes.

184 3. A marijuana testing laboratory may only utilize an alternative, scientifically valid testing methodology upon
185 the successful completion of subparagraphs (g)1. and 2., and the submission to the department of documentary
186 evidence that the requirements of this paragraph have been met. Proof and supporting documentation shall be
187 transmitted to the Office of Medical Marijuana Use at OMMULicenseOperation@flhealth.gov.

188 (5) An analyst must demonstrate an initial display of competency (IDOC) prior to analyzing any sample. An
189 IDOC is comprised of one blank and four lab-fortified blanks spiked with the analyte or analytes for a specific test
190 to a known concentration, and prepared and analyzed according to the same SOPs as testing samples. To pass, the
191 calculated RPD must be less than 20%, the recovery of each analyte in each lab fortified blank must be between
192 80% and 120% of the spiked concentration, and the blank must not have any analytes test above the LOD for that
193 analysis. If an analyst has not run a specific analysis within one calendar year, he or she must successfully complete
194 an IDOC for this analysis prior to analyzing any testing samples.

195 (6) Marijuana testing laboratories shall use testing equipment that satisfies the requirements of any required
196 accreditation pursuant to Rule 64-4.XXX. If any piece of equipment is not suitable for a specific method, it shall not
197 be engaged for that purpose. Testing equipment shall be used and maintained according to the manufacturer's
198 instructions and shall be calibrated pursuant to the requirements of any accreditation under which it is operated.
199 Marijuana testing laboratories shall retain records of all equipment repairs, maintenance, and calibrations.

200 (a) Marijuana testing laboratories shall authorize any contracted ISO/IEC 17043 accredited proficiency test
201 provider to submit all proficiency testing results to the department and marijuana testing laboratory concurrently.
202 After the closing date, no modification to any aspect of the reported results, method/technology, measurement units,
203 or the associated report information shall be made unless it is necessary due to a documented error made by the
204 accredited proficiency testing provider.

205 (b) Marijuana testing laboratories must manage, analyze, and report all proficiency testing samples in the same
206 manner as customer samples, including adherence to the same sample tracking, sample preparation, analysis
207 methods, standard operating procedures, calibrations, quality control, and acceptance criteria used in testing
208 customer samples.

209 (c) The sample matrix of the proficiency testing sample must match, as closely as possible, the matrix type
210 designated in the SOPs being used to prepare and analyze the proficiency testing sample.

211 (7) A medical marijuana treatment center must submit to the marijuana testing laboratory it contracts with,
212 finished products in their final, sealed retail packaging. For sampling purposes, 2 individual final retail products, or
213 a of number of individual final retail products that sum to two 5g or two 2ml increments from each retail batch, shall
214 be used for marijuana testing.

215 (a) Samples for testing must be from a retail batch that is intended for use by qualified patients, and must be
216 chosen at random, with the entirety of the retail batch available.

217 (b) Samples for testing shall be transported from the marijuana treatment center facility to the marijuana testing
218 laboratory as quickly as possible. Transport of samples from a marijuana treatment center to a marijuana testing
219 laboratory, or from one marijuana testing laboratory to another, must follow 381.986 (8)(g)1.-6., F.S.

220 (c) A marijuana testing laboratory may also test usable whole flower, derivative product, or edibles from any
221 point in cultivation or processing. The satisfactory analysis of these samples that meet the enumerated acceptable
222 limits in this rule shall not constitute a pass of any future retail batch created.

223 (8) Marijuana testing laboratories shall reject marijuana for testing in accordance with this subsection.

224 (a) A marijuana testing laboratory may reject, retain, and not analyze any sample which does not conform with
225 the requirements of any agreement between it and the providing medical marijuana treatment center, any standard
226 operating procedure or analytical method, or this rule.

227 (b) A marijuana testing laboratory must reject and not analyze any sample that:

228 1. upon inspection, has any outer packaging that the laboratory deems to have been tampered with,
229 contaminated, damaged, or otherwise unfit for its intended use;

230 2. upon inspection, the laboratory deems to have been tampered with, or otherwise in a condition unsuitable for
231 testing, or to be or have been at an improper temperature, or to have improper moisture content;

232 3. is not accompanied by a sample field log, chain of custody documentation, or a travel manifest;

233 4. the laboratory deems to have a forged or altered sample field log, chain of custody documentation, or travel
234 manifest; or

235 5. was not initially collected or acquired from a medical marijuana treatment center by a sampler.

236 (c) Marijuana testing laboratories shall not remediate any rejected sample.

237 (d) Samples rejected pursuant to this subsection are not considered to have failed any accepted limitation, and
238 the originating medical marijuana treatment center may have the retail batch resampled and analyzed.

239 (e) Rejected samples must be destroyed by the marijuana testing laboratory. Samples must be removed from
240 packaging. Usable whole flower marijuana, solid edibles, and other solid marijuana products rejected for
241 testing must be ground and mixed with general waste to a 50:50 ratio. Liquid marijuana products rejected for
242 testing may be mixed with methylene chloride to a 50:50 ratio and disposed of as hazardous waste.

243 (9) A marijuana testing laboratory may transfer testing samples to another certified marijuana testing laboratory
244 for testing purposes if the originating marijuana testing laboratory cannot meet the obligations of all tests requested
245 by the contracted medical marijuana treatment center, pursuant to this subsection.

246 (a) When transferring testing samples, a marijuana testing laboratory shall conform with the requirements of
247 sections 381.986(8)(g)1.-6. F.S.

248 (b) Prior to any analysis of any transferred testing sample, the receiving marijuana testing laboratory shall
249 determine whether to accept or reject any transferred testing sample in conformity with subsection (8) and any
250 standard operation procedure related to transfer testing sample acceptance or rejection.

251 (c) Rejected testing samples shall be not be analyzed and must be destroyed in accordance with subsection (8)

252 (e). The receiving marijuana testing laboratory shall provide notice to the transferring marijuana testing laboratory,
253 the originating medical marijuana treatment center, and the department, at OMMULicenseOperation@flhealth.gov,
254 within 24 hours of the rejection of any transferred testing sample.

255 (d) Samples rejected pursuant to this subsection are not considered to have failed any accepted limitation, and
256 the originating medical marijuana treatment center may have the retail batch resampled.

257 (e) A sample rejected pursuant to this subsection shall not be returned to the medical marijuana treatment center
258 from which it was collected. Rejected samples must be maintained for at least three (3) months before being
259 destroyed pursuant to subsection (8)e. Marijuana testing laboratories shall log all instances of sample rejection and
260 destruction along with the specific reason for the rejection.

261 (f) Samples generated from a processed batch rejected pursuant to this subsection are not considered to have
262 failed any accepted limitation, and the originating medical marijuana treatment center may have the processed batch
263 resampled and analyzed.

264 (10) All usable whole flower marijuana, derivative product, and edibles must be tested within the state of
265 Florida.

266 (11) Preparation of samples for analysis must begin within seven days from the sample departure date on the
267 marijuana transportation manifest.

268 (12) Marijuana testing laboratories must test for the following: tetrahydrocannabinol potency, concentration of
269 cannabidiol, and contaminants unsafe for human consumption. Contaminants unsafe for human consumption
270 include, but are not limited to, microbiology, mycotoxins, residual solvents, heavy metals, agricultural agents,
271 moisture, water activity, and filth and foreign material. Notwithstanding the accepted limitations associated with
272 subparagraphs (a)1.-3., results shall be reported accurately to three (3) significant figures as the concentration in
273 milligrams per gram dry-weight for any test reported in parts per million (ppm) and to three (3) significant figures as
274 the concentration in micrograms per gram dry-weight for any test reported in parts per billion (ppb). Any determined
275 test result that exceeds an enumerated acceptable limitation in this rule or Florida law, whichever is more restrictive,
276 shall constitute a failure. No processed batch which has been awarded a failure of any accepted limitation shall be
277 dispensed. Any determined test result that meets the requirements of an enumerated accepted limitation in this rule
278 or Florida law, whichever is more restrictive, shall constitute a pass. Accepted limitation failures and passes must be
279 reported to both the medical marijuana treatment center which provided the sample and to the Office of Medical

280 Marijuana, at OMMULicenseOperation@flhealth.gov, within 24 hours of the finding. For the purposes of this rule,
281 a test result is considered verified when the laboratory director, or other authorized employee, signs or authenticates
282 the report containing those results.

283 (a) Microbiology (bacteria, fungus,) accepted limitations, minimum of 1.0g testing sample size:

284 1. Shiga toxin producing *Escherichia coli*, no detection within 1 gram.

285 2. Any *Salmonella* species, no detection within 1 gram.

286 3. *Aspergillus niger*, *Aspergillus fumigatus*, *Aspergillus flavus*, *Aspergillus terreus*, and *Clostridium botulinum*,
287 no detection within 1 gram.

288 (b) The aggregate of aflatoxins, as enumerated in this subparagraph, 20 parts per billion or less, minimum of
289 0.5g testing sample size.

290 1. B1 (CAS No. 1162-65-8);

291 2. B2 (CAS No. 7220-81-7);

292 3. G1 (CAS No. 1165-39-5);

293 4. G2 (CAS No. 7241-98-7); and

294 5. Ochratoxin A (CAS No. 303-47-9), 20 parts per billion or less, minimum of 0.5g testing sample size.

295 (b) Residual solvents, accepted limitations for all derivative product, minimum of 0.25g testing sample size:

296 1. Acetone (CAS No. 67-64-1), 750 parts per million or less.

297 2. Any butane (CAS No. 106-97-8), 2,000 parts per million or less.

298 3. Ethanol (CAS No. 64-17-5), 5,000 parts per million or less.

299 4. Ethyl acetate (CAS No. 141-78-6), 400 parts per million or less.

300 5. Ethyl ether (CAS No. 60-29-7), 500 parts per million or less.

301 6. Heptane (CAS No. 142-82-5), 500 parts per million or less.

302 5. Isopropyl alcohol (CAS No. 67-63-0), 500 parts per million or less.

303 6. Methanol (CAS No. 67-56-1), 250 parts per million or less.

304 7. Pentane (CAS No. 109-66-0), 750 parts per million or less.

305 8. Propane (CAS No. 74-98-6), 2,100 parts per million or less.

306 9. Any other solvent not allowed pursuant to department rule, none detected.

307 (c) Residual solvents not approved for use, but potentially present in testing due to the possible presence in
308 department approved solvents, accepted limitations for all derivative product, minimum of 0.25g testing sample size:

309 1. Acetonitrile (CAS No. 75-05-8), 60 parts per million or less.

310 2. Benzene (CAS No. 71-43-3), one (1) part per million or less.

311 3. Chloroform (CAS No. 67-66-3), two (2) parts per million or less.

312 4. 1, 2- dichloroethane (CAS No. 107-06-2), two (2) parts per million or less;

313 5. 1, 1- dichloroethene (CAS No. 75-35-4), eight (8) parts per million or less;

314 6. Ethylene oxide (CAS No. 75-21-8), five (5) parts per million or less;

315 7. Hexane (CAS No. 110-54-3), 60 parts per million or less.

316 8. Methylene chloride (CAS No. 75-09-2), 125 parts per million or less.

317 9. Naphtha (CAS No. 8030-30-6), 400 parts per million or less.

318 10. Petroleum ether (CAS No. 8032-32-4), 400 parts per million or less.

319 11. Trichloroethylene (CAS No. 79-01-6), 25 parts per million or less.

320 12. Toluene (CAS No. 108-88-3), 150 parts per million or less.

321 13. Total xylenes (m, p, o-xylenes) (CAS No. 1330-20-7), 150 parts per million or less.

322 (d) Heavy metals, accepted limitations for usable whole flower marijuana, or derivative product meant for
323 inhalation, minimum of 0.5g testing sample size:

324 1. Lead (CAS No. 7439-92-1), less than 500 parts per billion.

325 2. Arsenic (CAS No. 7440-38-2), less than 200 parts per billion.

326 3. Cadmium (CAS No. 7440-43-9), less than 200 parts per billion.

327 4. Mercury (CAS No. 7439-97-6), less than 100 parts per billion.

328 (e) Heavy metals, accepted limitations for usable whole flower marijuana, or derivative product not meant for
329 inhalation, minimum of 0.5g testing sample size:

330 1. Lead (CAS No. 7439-92-1), less than 500 parts per billion.

331 2. Arsenic (CAS No. 7440-38-2), less than 1500 parts per billion.

332 3. Cadmium (CAS No. 7440-43-9), less than 500 parts per billion.

333 4. Mercury (CAS No. 7439-97-6), less than 3000 parts per billion.

334 (f) Agricultural agents, accepted limitations for usable whole flower marijuana, or derivative product meant for
335 inhalation, minimum of 0.5g testing sample size:

- 336 1. Abamectin (CAS No.71751-41-2), 100 parts per billion or less.
337 2. Acephate (CAS No.30560-19-1), 100 parts per billion or less.
338 3. Acequinocyl (CAS No.57960-19-7), 100 parts per billion or less.
339 4. Acetamiprid (CAS No.135410-20-7), 50 parts per billion or less.
340 5. Aldicarb (CAS No.116-06-3), 50 parts per billion or less.
341 6. Azoxystrobin (CAS No.131860-33-8), 50 parts per billion or less.
342 7. Bifenazate (CAS No.149877-41-8), 100 parts per billion or less.
343 8. Bifenthrin (CAS No. 82657-04-3), 100 parts per billion or less.
344 9. Chlorfenapyr (CAS No.122453-73-0), 50 parts per billion or less.
345 10. Chlorpyrifos (CAS No.2921-88-2), 100 parts per billion or less.
346 11. Clofentezine (CAS No.74115-24-5), 200 parts per billion or less.
347 12. Coumaphos (CAS No.56-72-4), 50 parts per billion or less.
348 13. Cyfluthrin (CAS No.68359-37-5), 100 parts per billion or less.
349 14. Cypermethrin (CAS No.52315-07-8), 500 parts per billion or less.
350 15. Daminozide (CAS No.1596-84-5), 500 parts per billion or less.
351 16. DDVP (Dichlorvos) (CAS No.62-73-7), 100 parts per billion or less.
352 17. Diazinon (CAS No.333-41-5), 50 parts per billion or less.
353 18. Dimethoate (CAS No.60-51-5), 50 parts per billion or less.
354 19. Dimethomorph (CAS No.110488-70-5), 50 parts per billion or less.
355 20. Ethoprop(hos) (CAS No.13194-48-4), 50 parts per billion or less.
356 21. Etofenprox (CAS No.80844-07-1), 50 parts per billion or less.
357 22. Etoxazole (CAS No.153233-91-1), 50 parts per billion or less.
358 23. Fenhexamid (CAS No.126833-17-8), 100 parts per billion or less.
359 24. Fenoxycarb (CAS No.72440-01-8), 50 parts per billion or less.
360 25. Fenpyroximate (CAS No.134098-61-6), 500 parts per billion or less.
361 26. Fipronil (CAS No.120068-37-3), 50 parts per billion or less.
362 27. Flonicamid (CAS No.158062-67-0), 400 parts per billion or less.
363 28. Fludioxonil (CAS No.131341-86-1), 100 parts per billion or less.
364 29. Hexythiazox (CAS No.78587-05-0), 250 parts per billion or less.
365 30. Imazalil (CAS No.35554-44-0), 50 parts per billion or less.
366 31. Imidacloprid (CAS No.138261-41-3), 100 parts per billion or less.
367 32. Kresoxim-methyl (CAS No.143390-89-0), 100 parts per billion or less.
368 33. Malathion (CAS No.121-75-5), 50 parts per billion or less.
369 34. Metalaxyl (CAS No.57837-19-1), 50 parts per billion or less.
370 35. Methiocarb (CAS No.2032-65-7), 50 parts per billion or less.
371 36. Methomyl (CAS No.16752-77-5), 100 parts per billion or less.
372 37. Methyl parathion (CAS No.289-00-0), 100 parts per billion or less.
373 38. Mevinphos (CAS No.7786-34-7), 50 parts per billion or less.
374 39. Myclobutanil (CAS No.88671-89-0), 100 parts per billion or less.
375 40. Naled (CAS No.300-76-5), 250 parts per billion or less.
376 41. Oxamyl (CAS No.23135-22-0), 250 parts per billion or less.
377 42. Paclobutrazol (CAS No.76738-62-0), 50 parts per billion or less.
378 43. Pentachloronitrobenzene (CAS No.82-68-8), 150 parts per billion or less.
379 44. Permethrin (CAS No.52645-53-1), 100 parts per billion or less.
380 45. Phosmet (CAS No.732-11-6), 100 parts per billion or less.
381 46. Piperonyl butoxide (CAS No.51-03-6), 3000 parts per billion or less.
382 47. Prallethrin (CAS No.23031-36-9), 100 parts per billion or less.
383 48. Propiconazole (CAS No.60207-90-1), 100 parts per billion or less.
384 49. Propoxur (CAS No.144-26-1), 100 parts per billion or less.
385 50. Pyrethrins (CAS No.8003-34-7), 500 parts per billion or less.
386 51. Pyridaben (CAS No.96489-71-3), 200 parts per billion or less.
387 52. Spinetoram (CAS No.187166-15-0), 200 parts per billion or less.
388 53. Spinosad A (CAS No.168316-95-8), 100 parts per billion or less.
389 54. Spinosad D (CAS No.131929-60-7), 100 parts per billion or less.
390 55. Spiromesifen (CAS No.283594-90-1), 100 parts per billion or less.
391 56. Spirotetramat (CAS No.203313-25-1), 100 parts per billion or less.

- 392 57. Spiroxamine (CAS No.118134-30-8), 50 parts per billion or less.
393 58. Tebuconazole (CAS No.107534-96-3), 50 parts per billion or less.
394 59. Thiachloprid (CAS No.111988-49-9), 50 parts per billion or less.
395 60. Thiamethoxam (CAS No.153719-23-4), 50 parts per billion or less.
396 61. Trifloxystrobin (CAS No.141517-21-7), 100 parts per billion or less.
397 (g) Agricultural agents, accepted limitations for usable whole flower marijuana, or derivative product not meant
398 for inhalation, minimum of 0.5g testing sample size:
399 1. Abamectin (CAS No.71751-41-2), 300 parts per billion or less.
400 2. Acephate (CAS No.30560-19-1), 5000 parts per billion or less.
401 3. Acequinocyl (CAS No.57960-19-7), 4000 parts per billion or less.
402 4. Acetamiprid (CAS No.135410-20-7), 5000 parts per billion or less.
403 5. Aldicarb (CAS No.116-06-3), 500 parts per billion or less.
404 6. Azoxystrobin (CAS No.131860-33-8), 40000 parts per billion or less.
405 7. Bifenazate (CAS No.149877-41-8), 5000 parts per billion or less.
406 8. Bifenthrin (CAS No. 82657-04-3), 500 parts per billion or less.
407 9. Chlorfenapyr (CAS No.122453-73-0), 1500 parts per billion or less.
408 10. Chlorpyrifos (CAS No.2921-88-2), 500 parts per billion or less.
409 11. Clofentazine (CAS No.74115-24-5), 500 parts per billion or less.
410 12. Coumaphos (CAS No.56-72-4), 200 parts per billion or less.
411 13. Cyfluthrin (CAS No.68359-37-5), 1000 parts per billion or less.
412 14. Cypermethrin (CAS No.52315-07-8), 1000 parts per billion or less.
413 15. Daminozide (CAS No.1596-84-5), 500 parts per billion or less.
414 16. DDVP (Dichlorvos) (CAS No.62-73-7), 100 parts per billion or less.
415 17. Diazinon (CAS No.333-41-5), 200 parts per billion or less.
416 18. Dimethoate (CAS No.60-51-5), 200 parts per billion or less.
417 19. Dimethomorph (CAS No.110488-70-5), 20000 parts per billion or less.
418 20. Ethoprop(hos) (CAS No.13194-48-4), 200 parts per billion or less.
419 21. Etofenprox (CAS No.80844-07-1), 400 parts per billion or less.
420 22. Etoxazole (CAS No.153233-91-1), 1500 parts per billion or less.
421 23. Fenhexamid (CAS No.126833-17-8), 10000 parts per billion or less.
422 24. Fenoxycarb (CAS No.72440-01-8), 200 parts per billion or less.
423 25. Fenpyroximate (CAS No.134098-61-6), 500 parts per billion or less.
424 26. Fipronil (CAS No.120068-37-3), 400 parts per billion or less.
425 27. Flonicamid (CAS No.158062-67-0), 2000 parts per billion or less.
426 28. Fludioxonil (CAS No.131341-86-1), 30000 parts per billion or less.
427 29. Hexythiazox (CAS No.78587-05-0), 2000 parts per billion or less.
428 30. Imazalil (CAS No.35554-44-0), 200 parts per billion or less.
429 31. Imidacloprid (CAS No.138261-41-3), 3000 parts per billion or less.
430 32. Kresoxim-methyl (CAS No.143390-89-0), 1000 parts per billion or less.
431 33. Malathion (CAS No.121-75-5), 5000 parts per billion or less.
432 34. Metalaxyl (CAS No.57837-19-1), 15000 parts per billion or less.
433 35. Methiocarb (CAS No.2032-65-7), 200 parts per billion or less.
434 36. Methomyl (CAS No.16752-77-5), 100 parts per billion or less.
435 37. Methyl parathion (CAS No.289-00-0), 200 parts per billion or less.
436 38. Mevinphos (CAS No.7786-34-7), 50 parts per billion or less.
437 39. Myclobutanil (CAS No.88671-89-0), 9000 parts per billion or less.
438 40. Naled (CAS No.300-76-5), 500 parts per billion or less.
439 41. Oxamyl (CAS No.23135-22-0), 1500 parts per billion or less.
440 42. Paclbutrazol (CAS No.76738-62-0), 400 parts per billion or less.
441 43. Pentachloronitrobenzene (CAS No.82-68-8), 200 parts per billion or less.
442 44. Permethrin (CAS No.52645-53-1), 20000 parts per billion or less.
443 45. Phosmet (CAS No.732-11-6), 200 parts per billion or less.
444 46. Piperonyl butoxide (CAS No.51-03-6), 8000 parts per billion or less.
445 47. Prallethrin (CAS No.23031-36-9), 400 parts per billion or less.
446 48. Propiconazole (CAS No.60207-90-1), 20000 parts per billion or less.
447 49. Propoxur (CAS No.144-26-1), 200 parts per billion or less.

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- 50. Pyrethrins (CAS No.8003-34-7), 1000 parts per billion or less.
- 51. Pyridaben (CAS No.96489-71-3), 3000 parts per billion or less.
- 52. Spinetoram (CAS No.187166-15-0), 3000 parts per billion or less.
- 53. Spinosad A (CAS No.168316-95-8), 3000 parts per billion or less.
- 54. Spinosad D (CAS No.131929-60-7), 3000 parts per billion or less.
- 55. Spiromesifen (CAS No.283594-90-1), 12000 parts per billion or less.
- 56. Spirotetramat (CAS No.203313-25-1), 13000 parts per billion or less.
- 57. Spiroxamine (CAS No.118134-30-8), 400 parts per billion or less.
- 58. Tebuconazole (CAS No.107534-96-3), 2000 parts per billion or less.
- 59. Thiaplopid (CAS No.111988-49-9), 200 parts per billion or less.
- 60. Thiamethoxam (CAS No.153719-23-4), 4500 parts per billion or less.
- 61. Trifloxystrobin (CAS No.141517-21-7), 30000 parts per billion or less.

(h) A testing sample that contains levels of any microbiology, residual solvent, metal, agricultural agent, not otherwise enumerated in this rule or by Florida law, that could be toxic if consumed or applied, fails acceptable limitation testing.

(i) Marijuana testing laboratories shall analyze a minimum of 0.5g of usable whole flower marijuana for water-activity levels according to the limitations listed below. Any usable whole flower marijuana, derivative product, or edible which meets its respective criteria shall pass water-activity testing. Results shall be reported accurately to two

(2) significant figures.

1. Usable whole flower marijuana, water activity 0.65 Aw or less.

2. Solid and semi-solid derivative product or edible, water activity of 0.85 Aw or less, with the exception of water-based products which shall be not be held to water activity standards.

(j) Marijuana testing laboratories shall analyze a minimum of 0.5g of usable whole flower marijuana for moisture content analysis. Usable whole flower marijuana which has a moisture content below 13.0% shall pass moisture-content testing. Results shall be reported to the nearest tenth of a percent.

(k) Filth and foreign materials, accepted limitations for usable whole flower marijuana, derivative product, or edibles:

1. Foreign material (to include mold, mildew, fungus, hair, insects, packaging contaminants, manufacturing waste, and other similar marijuana cultivation and processing by-products), not otherwise contemplated by this subsection, not more than an average of 5% by weight, or cover more than ¼ of the total sample area.

2. Any feces, not more than 0.5 mg per kilogram.

(13) Potency testing for usable whole flower marijuana, derivative product, and edibles must include the amount, in milligrams, of total active THC and total active CBD in the final retail product. The total amount of active THC and active CBD in in oral products and edibles shall be reported in milligrams, accurately to three (3) significant figures, as the concentration of cannabinoid in milligrams per gram x the total weight of the product. For inhalation products, total active THC in milligrams shall be calculated as the concentration of THC + (concentration of THCA x 0.877) in milligrams per gram x the total weight of the product. For inhalation products, total active CBD in milligrams shall be calculated as the concentration of CBD + (concentration of CBDA x 0.877) in milligrams per gram x the total weight of the product. Findings must be reported to both the medical marijuana treatment center which provided the sample and to the Office of Medical Marijuana Use, at OMMULicenseOperation@flhealth.gov, within 24 hours of the finding.

(14) The cannabinoid profile results shall be reported in percentage, accurate to 3 significant figures, as the concentration in milligrams per gram of each individual cannabinoid / the total concentration of all cannabinoids in milligrams per gram x 100. The following cannabinoids must be tested for:

(a) d9-Tetrahydrocannabinoid (d9-THC), CAS No. 1972-08-3.

(b) d8-Tetrahydrocannabinoid (d8-THC), CAS No. 5957-75-5.

(c) d9-Tetrahydrocannabinolic acid (THCA), CAS No. 23978-85-0.

(d) Tetrahydrocannabivarin (THCV), CAS No. 31262-37-0.

(e) Cannabidiol (CBD), CAS No. 13956-29-1.

(f) Cannabidiolic acid (CBDA), CAS No. 1244-58-2.

(g) Cannabidivarin (CBDV), CAS No. 24274-48-4.

(h) Cannabigerol (CBG), CAS No. 25654-31-3.

(i) Cannabigerolic acid (CBGA), CAS No. 25555-57-1.

(j) Cannabinol (CBN), CAS No. 521-35-7.

(k) Cannabichromene (CBC), CAS No. 20675-51-8.

503 (15) When testing edibles, marijuana testing laboratories shall perform a homogeneity analysis for the
504 cannabinoids enumerated in subsection (14). Homogeneity tests require at least 10 increments from one final
505 product per retail batch. The relative standard deviation of the cannabinoid content between the 10 or more
506 increments must be less than or equal to 15% to constitute a pass. The relative standard deviation is the standard
507 deviation expressed as a percentage of the mean recovery. It is the coefficient of variation multiplied by 100,
508 calculated as (the standard deviation ÷ mean recovery) × 100. If any results are less than the limit of quantitation, the
509 value of the limit of quantitation shall be used to calculate the relative standard deviation. A processed batch is
510 homogenous if the relative standard deviation, with no outliers per Grubb's outlier test with a significance level of
511 0.05, is less than or equal to 15%, and the potency variance is no greater than 15 %. Edibles that do not meet these
512 criteria fail homogeneity testing.

513 (16) Marijuana testing laboratories must report any testing sample that is found to contain a level of any
514 contaminant not listed in this rule that could be injurious to human health if consumed or otherwise introduced to the
515 human body. The marijuana testing laboratory shall report such findings to the originating medical marijuana
516 treatment center and the department at OMMULicenseOperation@flhealth.gov within 24 hours of the finding.

517 (17) Marijuana testing laboratories must maintain at least one untested portions of each testing sample, whether
518 having passed or failed any accepted limitation analysis These testing samples must be securely stored for a
519 minimum of 90 days before being destroyed. Every testing sample that is destroyed must be logged by the marijuana
520 testing laboratory.

521 (18) Marijuana testing laboratories shall use quality control samples for each assay for chemical and
522 microbiological analysis. Quality control samples shall be analyzed in the same manner as test samples for
523 validation purposes.

524 (a) Marijuana testing laboratories shall prepare at least one method blank sample per laboratory batch. All
525 method blank samples shall be prepared and analyzed in the same manner as testing samples. Method blanks that
526 contain analytes of interest above the limit of detection must be reanalyzed. If upon reanalysis the method blank is
527 again above the limit of detection the marijuana testing laboratory shall determine and correct the source of the
528 contamination, repeat the preparation of the laboratory batch, and reanalyze the testing samples. If method blank
529 results continue to read above the limit of detection, the marijuana testing laboratory shall discontinue conducting
530 the analysis until such time it is able to test at or below the limit of detection.

531 (b) Marijuana testing laboratories shall prepare and analyze laboratory fortified blanks for each laboratory
532 batch. The percent of recovery for any analyte within each fortified blank, calculated as the quantitative sample
533 result ÷ expected result × 100, shall be recorded. The acceptable range of recovery fortified blank is as follows:

- 534 1. Microbial: 90%-110%;
- 535 2. Mycotoxins: 80%-120%;
- 536 3. Residual solvents: 80%-120%;
- 537 4. Heavy Metals: 80%-120%;
- 538 5. agricultural agent: 80%-120%; and
- 539 6. Cannabinoids: 90%-110%.

540 (c) Marijuana testing laboratories shall prepare and analyze matrix spike samples for each laboratory batch. The
541 percent of recovery for any analyte within each matrix spike, calculated as the quantitative sample result ÷ expected
542 result × 100, shall be recorded. The acceptable range of recovery for any matrix spike sample is the following;
543 unless the testing sample from which the matrix spike sample was derived is positive for any analyte within the
544 matrix spike sample;

- 545 1. Microbial: 80%-120%;
- 546 2. Mycotoxins: 70%-130%;
- 547 3. Residual solvents: 70%-130%;
- 548 4. Heavy metals: 70%-130%;
- 549 5. agricultural agent: 70%-130%; and
- 550 6. Cannabinoids: 80%-120%.

551 (d) Marijuana testing laboratories shall run duplicate laboratory fortified blanks and matrix spikes and shall
552 calculate their relative percent differences pursuant to this subsection. Relative percent difference is calculated as
553 (quantitative sample result A – quantitative sample result B) ÷ ((quantitative sample result A + quantitative sample
554 result B) ÷ 2) × 100. The relative percent difference between duplicates must be as follows;

- 555 1. Microbial: 10% or less;
- 556 2. Mycotoxins: 20% or less;
- 557 3. Residual solvents: 20% or less;
- 558 4. Heavy metals: 15% or less;

559 5. agricultural agents: 20% or less; and

560 6. Cannabinoids: 10% or less.

561 (e) Marijuana testing laboratories shall generate quality control sample reports that contain the date of the
562 analysis, the parameters of the analysis, the matrix or matrixes used, the analytes or materials tested for, the
563 instrument of analysis, and measurements.

564 (19) Marijuana testing laboratories shall prepare calibration standards pursuant to this subsection. Calibration
565 standards shall be prepared by diluting a standard solution to produce working standards to be used in the calibration
566 of instruments, the quantitation of analysis samples, and for use in fortified blanks and matrix spikes. Standard
567 solutions shall either be:

568 (a) obtained from an independent body accredited as ISO/IEC 17034:2017 compliant, or has a current, valid
569 ISO/IEC 17034:2005 by an accreditation body that is a signatory for reference material producer (RMP) to mutual
570 recognition arrangement (MRA) recognized through ILAC; or

571 (b) created by the marijuana testing laboratory and found to be ISO/IEC 17034:2017 compliant by an
572 independent accreditation body that is a signatory for RMP to MRA recognized through ILAC.

573 (20) The limit of detection shall be calculated, where applicable, in one of the following ways:

574 (a) the signal-to-noise ratio, as calculated by comparing the measured signals of known analyte concentrations
575 with those within the method blanks to establish the minimum concentration an analyte can be consistently detected.
576 Acceptable ratios shall be within the range of 3:1 to 2:1;

577 (b) based on the standard deviation of the instrument's response and the slope of the calibration curve,
578 calculated as $3.3 \times$ the standard deviation of the response \div the slope of the calibration curve. The standard deviation
579 of the response shall be determined by comparing seven blank samples. The limit of detection for chemical methods
580 must be less than 1/10 of the action level for each analyte; or

581 (c) any other method published by the U.S. Food and Drug Administration or the U.S. Environmental Protection
582 Agency. A marijuana testing laboratory utilizing a method pursuant to this paragraph shall provide the method to the
583 Office of Medical Marijuana Use at OMMULicenseOperation@flhealth.gov.

584 (21) The limit of quantification shall be calculated, where applicable, in one of the following ways:

585 (a) the signal-to-noise ratio, as calculated by comparing the measured signals of know analyte concentrations
586 with those of method blanks to establish the minimum concentration an analyte can be consistently detected. The
587 minimum acceptable ratio is 10:1;

588 (b) based on the standard deviation of the instrument's response and the slope of the calibration curve,
589 calculated as $10 \times$ the standard deviation of the response \div the slope of the calibration curve. Standard deviation of
590 the response is determined by comparing seven blank samples; or

591 (c) any other method published by the U.S. Food and Drug Administration or the U.S. Environmental Protection
592 Agency. A marijuana testing laboratory utilizing a method pursuant to this paragraph shall provide the method to the
593 Office of Medical Marijuana Use at OMMULicenseOperation@flhealth.gov.

594 (22) Marijuana testing laboratories shall create and maintain data packages for every analyzed laboratory batch.
595 Data packages shall contain:

596 (a) the name and address of the laboratory that performed the testing;

597 (b) the names, titles, and signatures of the employees that performed any sample preparation, the sample
598 analysis, and reviewed and approved the collected data;

599 (c) sample and batch quality control results;

600 (d) raw data for each sample;

601 (e) instrument raw data, if any;

602 (f) instrument test method with parameters;

603 (g) instrument tune reports, where applicable;

604 (h) all instrument calibration and/or tune data;

605 (i) internal standard report;

606 (j) initial calibration verification report;

607 (k) continuing calibration verification report;

608 (l) sample preparation worksheets;

609 (m) laboratory workbook sheets relevant to the analysis run;

610 (n) analytical batch sample sequence;

611 (o) chain of custody documentation; and

612 (p) a copy of any report required by subsection (23).

613 (23) Upon the completion of any analysis, a marijuana testing laboratory must generate a report for their client
614 containing all the information required in paragraph (a) below, and all the information required in paragraphs (b)

615 and/or (c) below depending on the nature of the analysis. Additional information, analysis, or graphics not expressly
616 required by paragraphs (a) through (c) may be included on any report contemplated by this subsection.

617 (a) Marijuana testing laboratory reports for environmental, life sciences, and potency testing must contain:

618 1. the name of the medical marijuana treatment center that provided the sample;

619 2. the cultivation facility where the marijuana was cultivated;

620 3. the processing facility where the marijuana was processed;

621 4. the strain or strains making up the sample;

622 5. the batch number and date and time the retail batch was created;

623 6. the batch number and date and time any laboratory batch was created;

624 7. the copy of any travel manifest or chain of custody documentation accompanying the laboratory batch;

625 8. the date and time sample preparation occurred;

626 9. the total weight or volume of the total retail product received for testing;

627 10. the name of any person who performed the sample preparation;

628 11. the date and time of the samples preparation;

629 12. the title of the standard operation procedure used to prepare the sample;

630 13. the date and time sample analysis occurred; and

631 14. the name of any person who performed the sample analysis.

632 (b) Marijuana testing laboratory reports for environmental and potency testing must contain:

633 1. the title of the standard operation procedure used in the sample analysis;

634 2. the type of instrument used to analyze the sample;

635 3. the final volume of the sample used in the analysis;

636 4. the sample matrix;

637 5. the analytes measured in the test;

638 6. the numerical concentration for each analyte and its limit of detection;

639 7. the dilution factor of each analyte;

640 8. the percentage of each cannabinoid enumerated in subsection (13), and the total percentage of these

641 cannabinoids within the sample; and

642 9. whether the sample has passed or failed in relation to accepted limits set by department rule for individual
643 analytes.

644 (c) Marijuana testing laboratory results for life science testing must contain:

645 1. presence or absence of microbes in 1 gram;

646 2. concentration of aflatoxins;

647 3. concentration of ochratoxin;

648 4. the sample matrix;

649 5. the analytes measured in the test;

650 6. the limit for the analysis conducted; and

651 7. whether the sample passed or failed in relation to the accepted limitations for bacteria, fungus, and yeast.

652 (d) Reports generated by the marijuana testing laboratory must be delivered electronically within 30 days of the
653 sample departure date noted on the marijuana transportation manifest.

654 (24) Prior to the dissemination of any documentation contemplated by sections (21) and (22) to the department
655 or a medical marijuana treatment center, the marijuana testing laboratory's laboratory director, or other authorized
656 employee, shall:

657 (a) review the quantitative analytical results for technical correctness and completeness;

658 (b) verify that the results of each analysis are accurately reported, and that the results can be traced back to the
659 specific laboratory batch; and

660 (c) verify approval of the results by signing and dating the data package.

661 (24) Marijuana testing laboratories must maintain data packages for seven (7) years from the date created.

662 Travel manifests, initial display of competency documentation, medical marijuana treatment center audit reports,

663 and medical marijuana treatment center onsite inspection reports shall be retained for a minimum of three (3) years

664 from the date created. Quality control and proficiency testing reports shall be retained for a minimum of two (2)

665 years from the date of receipt by the marijuana testing laboratory. Video surveillance recordings must be maintained

666 for a minimum of 45 days or longer upon the request of a law enforcement agency or as ordered by any court of

667 competent jurisdiction.

668 (25) Upon request by the department, a marijuana testing laboratory shall provide the department copies of the
669 following within three business days of the department's request:

670 (a) proof of accreditation pursuant to Rule 64-4.XXX, Marijuana Testing Laboratory Certification and Renewal;

671 (b) standard operation procedures;
672 (c) analytical methods;
673 (d) equipment logs;
674 (e) raw analytical data;
675 (f) initial display of competency documentation;
676 (g) medical marijuana treatment center travel manifests;
677 (h) marijuana testing laboratory travel manifests;
678 (i) chain of custody documentation;
679 (j) sample rejection logs;
680 (k) quality assurance reports;
681 (l) proficiency testing reports;
682 (m) quality assurance manual;
683 (n) personnel qualification, training, and competency documentation;
684 (o) purchasing and supply records;
685 (p) method verification and validation records;
686 (q) quality assurance and quality control records;
687 (r) customer service records;
688 (s) nonconforming work and corrective action records;
689 (t) internal and external audit records;
690 (u) testing facility and secure storage area security records;
691 (v) data packages;
692 (w) data backup records;
693 (x) laboratory data reports, data review, and data approval records;
694 (y) any report created for a medical marijuana treatment center;
695 (z) raw data;
696 (aa) traceability records;
697 (ab) standards records;
698 (ac) calibration records;
699 (ad) extraction logs, reference materials records;
700 (ae) analyst laboratory notebooks and logbooks;
701 (af) sample analysis reports;
702 (ag) laboratory contamination records;
703 (ah) laboratory cleaning records;
704 (ai) safety and chemical-hygiene records;
705 (aj) any other generated report related to the testing of marijuana; and
706 (ak) any other generated report related to the audit or onsite inspection of medical marijuana treatment centers,
707 to include any materials used in the creation of such report.

708 (26) The department may initiate an administrative action for violations of section 381.986, F.S., section
709 381.988, F.S., or this rule chapter.

710 (a) The following shall result in revocation of the marijuana testing laboratory's certification:

- 711 1. Knowingly falsifying results, to include peak shaving.
- 712 2. Knowingly testing marijuana that did not originate from a medical marijuana treatment center.
- 713 3. Knowingly testing samples that were rejected pursuant to this rule.
- 714 4. Dispensing any marijuana.
- 715 5. Performing any analysis on marijuana while certification is suspended.
- 716 6. Falsifying any required accreditation pursuant to Rule 64-4.XXX.

717 (b) The first instance of the following shall result in a 180-day suspension of certification. The marijuana testing
718 laboratory's certification shall be revoked upon the second instance of a violation within one calendar year of the
719 initial occurrence of the first instance.

- 720 1. Allowing an analyst without a current, valid, initial display of competency to perform any analysis.
- 721 2. Allowing a non-analyst to perform any analysis.
- 722 3. Using expired standards, surrogates, internal standards, or spikes.
- 723 5. Failure to follow and maintain proper security measures.
- 724 6. Using preparation or analytical methods that have not been approved pursuant to this rule.
- 725 7. Failure to transport marijuana in accordance section 381.986(8)(g)1.-6., F.S., and this rule.
- 726 8. Falsifying travel manifests, field reports, instrument maintenance logs, or chain of custody reports.

727 (c) The certification of a marijuana testing laboratory that provides to the department documentary evidence
728 that the laboratory has taken remedial action to correct the first instance of a violation listed in paragraph (b), shall
729 be suspended for not less than 60 days from the date the department receives evidence of the violation. The
730 certification shall be revoked upon the second instance of a violation within one calendar year of the initial
731 occurrence of the first instance.

732 (d) The first instance of the following shall result in a 60-day suspension of certification. The marijuana testing
733 laboratory's certification shall be suspended for 180 days upon the second instance of a violation within two
734 calendar years of the initial occurrence of the first instance. The marijuana testing laboratory's certification shall be
735 revoked upon the third instance of a violation within two calendar years of the initial occurrence of the first instance.

736 1. Following any outdated standard operating procedure, or manual.

737 2. Knowingly hiring any employee who does not meet this rule's criteria of employment.

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739 *Rulemaking Authority Section 381.986(8)(K), 381.988(2), (3), (9) FS. Law Implemented Section*

740 *381.986(8)(e)10.d., 381.988 FS. History–New*.

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