Reference Methods for the Testing of Retail and Medical Marijuana

Introduction

Cannabis is a novel industry and, currently, no recognized standard methods exist for the testing of cannabis or cannabis products. The purpose of this document is to provide guidance to testing facilities on the selection of applicable methodology pertaining to the testing of retail and medical marijuana/marijuana products. The methods outlined in this library are applicable by comparative use in areas similar to the testing of cannabis product; it should not, however, be construed that these methods are necessarily fit-for-purpose in all aspects of cannabis testing. The outlined applicable method references lack complete validation or matrix extension verification specific to all cannabis products and thus, may not be fully applicable for use in the testing of cannabis matrices. Any selected methods must be shown as fit-for-purpose through in-house validation. The potency methods referenced for the analysis of marijuana/marijuana products are not derived from applicable standard methods as no proper standard method is available. Any method employed that was not derived from a standard method must be rigorously tested and validated prior to analysis of cannabis and cannabis product.

Note: The sources listed in this document are not exhaustive; other methodologies may be appropriate for use. Due to the constant evolution of scientific analytical methods, this reference library represents a living document that will be updated as needed. Marijuana testing facilities are encouraged to consult with the CDPHE certification program during selection and implementation of testing methodologies.

Microbial Pathogens and Total Yeast and Mold

Concerning the testing of cannabis product for microbiological contaminants, there is a large pool of standard methods on which to draw. All microbiological methods employed must include applicable controls. Qualitative pathogen methods must confirm presumptive results as either positive or negative by the inclusion of a confirmation step. Confirmation of pathogens should not be addressed by simply re-running positive sample enrichments or retesting remaining sample.

Methods applicable to *Salmonella* spp. and Shiga toxin-producing *Escherichia coli* testing:

- Salfinger, Yvonne and Tortorello, Mary Lou, 2015. *Compendium of Methods for the Microbiological Examination of Foods, 5th Edition*. American Public Health Association.
- Food and Drug Administration (FDA), 2016. Bacteriological Analytical Manual (BAM). http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm2006949.htm
- United States Department of Agriculture: Food Safety and Inspection Service (USDA FSIS), 2016. Microbiology Laboratory Guidebook. http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm2006949.htm
- International Standards Organization (ISO), 2012. "ISO/TS 13136:2012." http://www.iso.org/iso/catalogue_detail.htm?csnumber=53328
- International Standards Organization (ISO), 2002. "ISO/TS 6579:2002."
- Association of Analytical Communities (AOAC) 2016. "Salmonella in Foods, 967.25" http://www.eoma.aoac.org/methods/info.asp?ID=47595

Methods applicable to total yeast and mold testing:

- Salfinger, Yvonne and Tortorello, Mary Lou, 2015. *Compendium of Methods for the Microbiological Examination of Foods, 5th Edition*. American Public Health Association.
- Food and Drug Administration (FDA), 2016. Bacteriological Analytical Manual (BAM). http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm2006949.htm
- Association of Analytical Communities (AOAC) 2016. "Yeast and Mold Counts in Foods, 997.02." http://www.eoma.aoac.org/methods/info.asp?ID=46847

Residual Solvent Testing

Concerning residual solvent testing, there is a large pool of standard methods from which to draw. All methods employed must include applicable controls.

Methods applicable to residual solvent testing:

- Environmental Protection Agency (EPA), 2016. "310B-Residual Solvents." http://www3.epa.gov/ttn/emc/methods/method310b.html
- American Society for Testing Materials (ASTM), 2016. https://global.ihs.com/standards.cfm?publisher=ASTM&RID=Z56&MID=ASTM&gclid=CJTImMLNosoCFQIHaQodhgoHkQ
- United States Pharmacopeia (USP), 2008. "<467> Residual Solvents." http://www.usp.org/usp-nf/official-text/accelerated-revision-process/accelerated-revision-history/general-chapter-organic-volatile

- Lake, Rick., 2016. "RESTEK Revised USP 467 Residual Solvent Method." RESTEK: http://www.restek.com/Technical-Resources/Technical-Library/Pharmaceutical/pharm_A017

Pesticide Residue Testing

Concerning pesticide testing, there is a large pool of standard methods from which to draw. All methods employed must include applicable controls.

Methods applicable to pesticide residue testing:

- Food and Drug Administration (FDA), 2016: Pesticide Analytical Manual (PAM). http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm2006955.htm
- United States Department of Agriculture: Food Safety and Inspection Service (USDA FSIS), 2016. Chemistry Laboratory Guidebook. http://www.fsis.usda.gov/wps/portal/fsis/topics/science/laboratories-and-procedures/guidebooks-and-methods/chemistry-laboratory-guidebook
- International Standards Organization (ISO), 2016. http://www.iso.org/iso/home.html
- Association of Analytical Communities. AOAC 2016. http://www.eoma.aoac.org/notices.asp

Potency Determination

Concerning potency analysis, only a small number of methods are available but none have been validated to the level of a standard method. The following is a list of appropriate reference methods. Potency methods must be validated extensively to ensure they meet the requirements of testing.

Methods applicable to potency determination:

- Bovens, Michael., et al., 2009. Recommended method for the identification and analysis of cannabis and cannabis products: manual for use by National drug analysis laboratories. United Nations. https://www.unodc.org/documents/scientific/ST-NAR-40-Ebook.pdf
- L. Ambach, F. Penitschka, A. Broillet, S. König, W. Weinmann., 2014. Simultaneous quantification of delta-9-THC, THC-acid A, CBN and CBD in seized drugs using HPLC-DAD. *Forensic Science International* 243, 107-111.
- Swift, Wendy., et al., 2013. Analysis of Cannabis Seizures in NSW, Australia: Cannabis Potency and Cannabinoid Profile, *PLOS One* v.8 i.7 e70052.
- Backer, Benjamin De., et al., 2009. Innovative development and validation of an HPLC/DAD method for the qualitative and quantitative determination of major cannabinoids in cannabis plant material. *Journal of Chromatography B*, 887 4115-4124.
- Gambaro, Veniero., et al., 2002. Determination of primary active constituents in Cannabis preparations by high-resolution gas chromatography/flame ionoization detection and high-performance liquid chromatography/UV detection. *Analytica Chimica Acta* 468, 245-254.

- Stolker, A.A.M., et al., 2004. Determination of cannabinoids in cannabis products using liquid chromatography –ion trap mass spectrometry. *Journal of Chromatography A*, 1058, 143-151.
- Upton, Roy., et al., 2014. Cannabis Inflorescence Cannabis Spp.: Standards of Identity, Analysis, And Quality Control. American Herbal Pharmacopoeia.