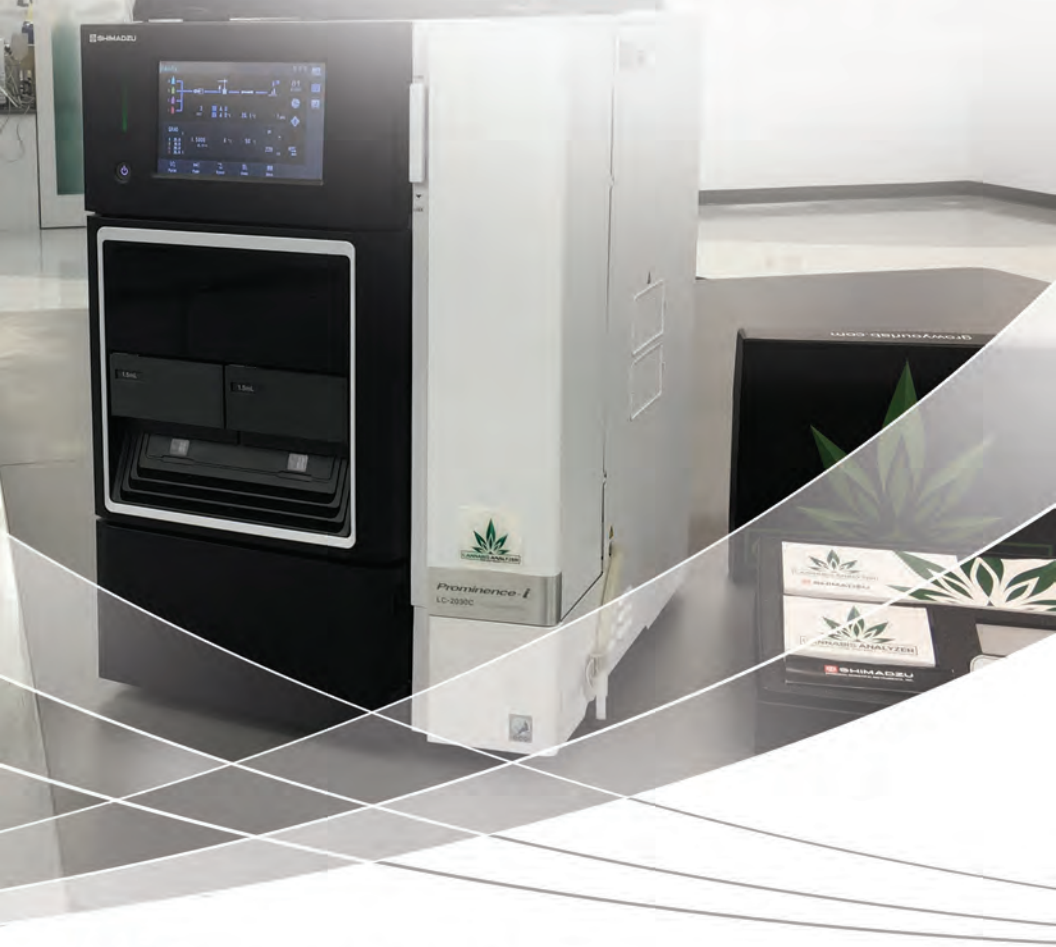
CANNABIS LAB START-UP GUIDE

Everything You Need to Grow Your New Testing Lab



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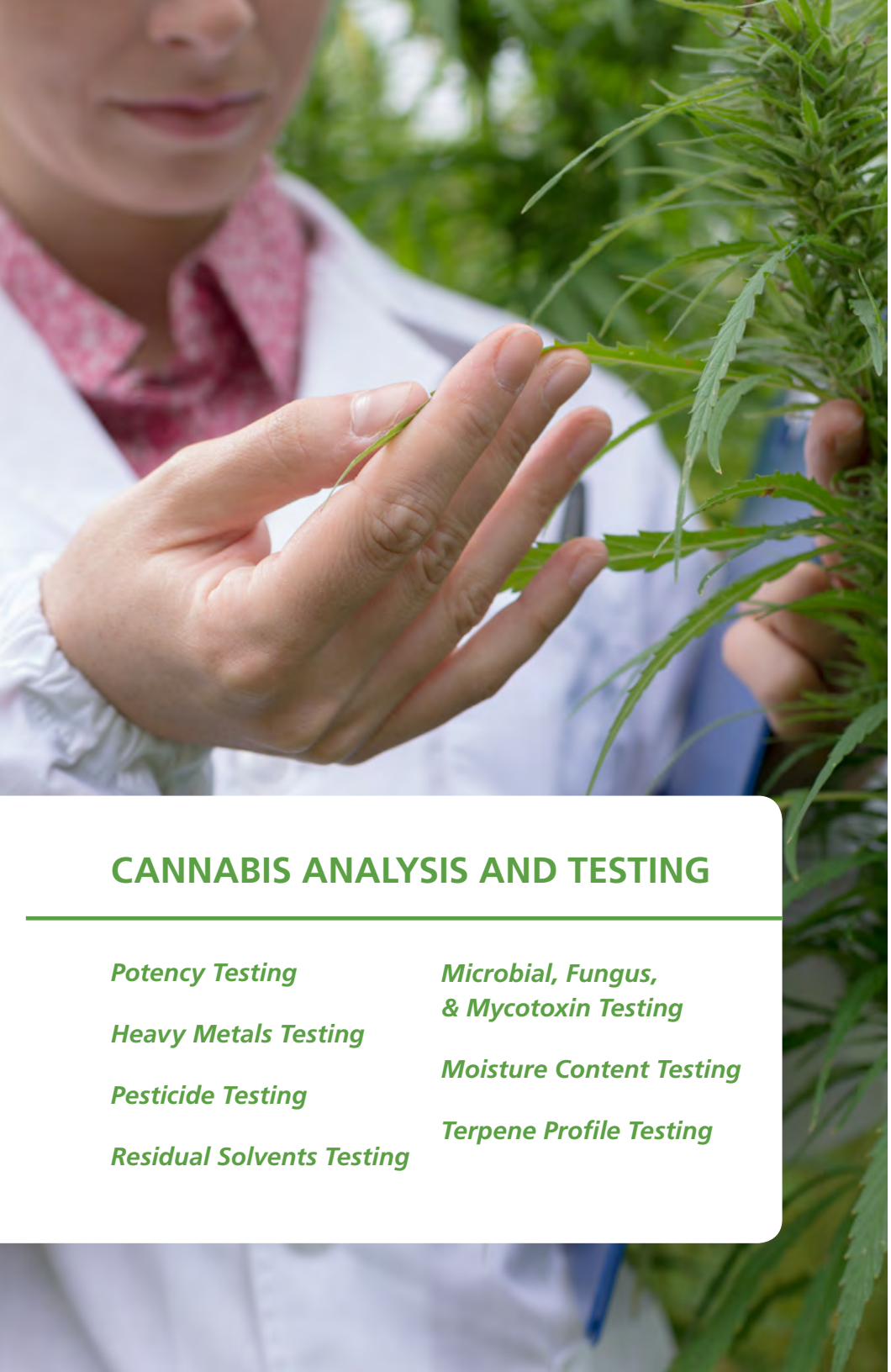


CANNABIS ANALYSIS AND TESTING

Potency Testing

Heavy Metals Testing

Pesticide Testing

Residual Solvents Testing

Microbial, Fungus, & Mycotoxin Testing

Moisture Content Testing

Terpene Profile Testing

The cannabis industry is growing exponentially and the use of marijuana for medical purposes is being adopted across the nation. With this boom in cannabis consumers, there has been an increasing need for knowledge about the product.

The role of testing labs has become crucial to the process, which makes owning and operating a lab more and more lucrative. Scientists testing for potency, heavy metals, pesticides, etc. are able to make meaningful contributions to the medical industry by making sure products are safe, while simultaneously generating large profits and a significant return on investment.

This start-up guide is designed to inform and guide decisions regarding how to best furnish a laboratory with the sole purpose of testing any medical cannabis product or marijuana-infused product. Tests include – potency, heavy metals, pesticides, bacterial, fungi, mycotoxins, residual solvents, and moisture content – with recommended equipment, preparation, estimated cost, revenue and ROI. Note the instrument prices are shown as list price, not selling price. The ROI calculations are intended for general reference only; Shimadzu does not guarantee testing volumes nor prices. The ROI calculation doesn't include the salary of the worker. Also, before each ROI calculation, the more expensive consumables are described but are not included in the ROI calculation. This is not a comprehensive list of consumables, but a high level look at weekly consumed items. There are considerable lab start-up costs outside of instrumentation, around $25,000 to $35,000. If there is interest in start-up costs, request Shimadzu's "Start-Up Supplies.xls" document.

This guide will take into account most state regulations. Cannabis analytical testing requirements may vary by state, so be sure to check out your state regulations here.

POTENCY TESTING

The most important component of cannabis testing is the analysis of cannabinoid profiles, also known as potency.

Cannabis plants naturally produce cannabinoids that determine the overall effect and strength of the strain. There are many different cannabinoids that all have distinct medicinal effects. However, most states only require testing and reporting for the dry weight percentages of tetrahydrocannabinol (THC) and cannabidiol (CBD).

EQUIPMENT

For potency testing, traditional high performance liquid chromatography (HPLC) is recommended and has become the gold standard for analyzing cannabinoid profiles.

RECOMMENDED INSTRUMENT

For this testing, Shimadzu offers the Cannabis Analyzer for Potency. This is the only instrument in the market designed specifically for cannabis potency profiling. This turnkey HPLC analyzer delivers a comprehensive package that integrates instrument hardware, software, consumables, and proven HPLC methods to meet your analytical needs.

Most states only require testing and reporting for THC and CBD.

SAMPLE PREPARATION

Weigh 200 mg of flowers or cuttings into a 50 mL centrifuge tube. Add two 9.5 mm steel balls into the tube. Shake at 1000 rpm for 1 minute with the SPEX 2010 Geno/Grinder®. Add 20 mL of methanol to the tube. Shake at 1000 rpm for 1 minute.

Wait for 15 minutes. Mix using a vortex mixer for 1 minute. Transfer 1 mL of the mixture into a 1.5 mL micro-tube and centrifuge at 3000 rpm for 5 minutes.

Transfer 100 µL of supernatant to a new 1.5 mL micro-tube. Add 900 µL of methanol. Filter the mixture through a 0.45 µm syringe filter and transfer to a 1.5 mL sample vial.

COST, REVENUE AND ROI BREAKDOWN

Cannabis Analyzer for Potency:

Instrument Cost: $55,000 List Price

Estimated Weekly Operating Cost (1 Week):

- Flow rate: 1.5 mL/min
- Solvent A*: 0.1% Formic Acid in Water
- Solvent B*: 0.1% Formic Acid in Acetonitrile
- Water, HPLC Grade, JT Baker, six 1L bottles: $36.80
- Acetonitrile, JT Baker, six 1L bottles: $136.52

**It is highly recommended to use only HPLC or UHPLC grade solvents.*

All calculations are assuming operation of 8 hours a day and 5 days a week. These calculations also assume there are enough samples to keep the analyzer constantly running. If you run at 1.5 mL/min of water and acetonitrile 50:50 mix, operating for one week, you will go through 45 mL/hour of water and 45 mL/hour of acetonitrile. This yields 1800 mL/week of both acetonitrile and water. You will expect to go through two 1L bottles of each. At the case price, this means you will spend $12.27/week on water and $45.51/week on acetonitrile for a total operation cost/week of $57.78.

Calibration standards are run periodically, but every organization has different Standard Operation Procedures (SOPs) of how frequently they are rerun and thus a total cost can't be listed. However, to provide a concept of costs, the 10 mix cannabinoid standard (P/N 220-91239-20) sells for $750, while the 11 mix cannabinoid standard (P/N 220-91239-21) costs $850.

Below are the costs of two methods developed by Shimadzu with the High Throughput Method for analysis of 10 cannabinoids and the High Sensitivity Method for analysis of 11 cannabinoids. Also, periodic replacement of the Consumable Guard Column (3/pk @ $750) and Analytical Column ($750) are required.

Return on Investment (ROI) Calculation for Potency

8 Hour Day/5 Days a Week	High Throughput	High Sensitivity
# Cannabinoids Measured	10	11
Cannabinoids	THC, d8-THC, THCA, CBD, CBDA, CBDV, CBN, CBG, CBGA, CBC	THCV, THC, d8-THC, THCA, CBD, CBDA, CBDV, CBN, CBG, CBGA, CBC
Expected Revenue/Sample	$50	$50
Total Run Time (minutes)	8	10
Samples/Day	60	48
Samples/Week	300	240
Expected Revenue/Week	$15,000	$12,000
Instrument Cost	$55,000	$55,000
Break Even (weeks)	3.7	4.6

HEAVY METALS TESTING

Different types of metals can be found in soils and fertilizers and as cannabis plants grow, they tend to draw in these metals from the soil.

Heavy metals are a group of metals considered to be toxic, and the most common include lead, cadmium, arsenic and mercury. Most labs are required to test and confirm that samples are under the allowable toxic concentration limits for these four hazardous metals.

EQUIPMENT

Heavy metal testing is performed by inductively coupled plasma mass spectrometry, or ICP-MS. ICP-MS uses the different masses of each element to determine which elements are present within a sample and at what concentrations.

RECOMMENDED INSTRUMENT

For this testing, Shimadzu recommends the ICPMS-2030. Included in the ICPMS-2030 software are two assistant functions that simplify analysis. The Development Assistant simplifies the process of developing analytical methods, whereas the Diagnosis Assistant automatically diagnoses spectral interference. Together, they provide analytical results with exceptionally high reliability and unparalleled ease of operation. In addition to the user-friendly software, a unique hardware system developed by Shimadzu, including the proprietary mini-torch, results in a reduction of the consumption of argon gas and electricity. Furthermore, the plasma ignition sequence is optimized for lower-purity Argon gas (i.e., 99.9% Argon as opposed to more expensive 99.9999% used by other manufacturers). Combined, this results in the industry's lowest running costs among ICP-MS instruments.

SAMPLE PREPARATION

Similar to HPLC prep, you will need a liquid sample to introduce to the ICP-MS. This is commonly accomplished by using a microwave digestion process. The samples are first weighed and then placed in a vessel that contains a small amount of acid (usually HNO_3 or nitric acid, though hydrochloric acid is also acceptable). This dissolution process on its own could take hours, so the incorporation of the microwave digester speeds up the process dramatically.

Once digestion is complete, the sample is rinsed out of the digestion container and placed in a sample vial. It is then inserted into the autosampler of the ICP-MS and the analysis begins.

COST, REVENUE AND ROI BREAKDOWN

ICP-MS:

Instrument Cost: $125,000 List Price

Estimated Weekly Operating Cost (1 Week):

- 1 Dewar of Argon Gas (Pure): $1,250
  You will typically run about 10 Liters/min of argon through the system when it is in use. A 230 liter of liquid argon Dewar yields 180,492 liters of gaseous argon. Thus, the Dewar will run an ICP-MS for 18,049 minutes or about 300 hours or 7.5 weeks.
- Price of gas per week: $167.50
  Also ask about Shimadzu's "ICPMS-2030 Cost of Ownership" document where cost per sample over a one year period is approximately $1/sample.

All calculations are assuming operation of 8 hours a day and 5 days a week. These calculations also assume there are enough samples to keep the analyzer constantly running.

Return on Investment (ROI) Calculation for Heavy Metals by ICP-MS

8 Hour Day/5 Days a Week	ROI
Expected Revenue/Sample	$50
Total Run Time (minutes)	5
Samples/Day	96
Samples/Week	480
Expected Revenue/Week	$24,000
Instrument Cost	$125,000
Break Even (weeks)	5.2

PESTICIDE TESTING

The detection of pesticides in cannabis has been a challenge.

There are many pesticides that are used in commercial cannabis grow operations to kill the pests that thrive on the plants and in greenhouses. These chemicals are toxic to humans, so confirming their absence from cannabis products is crucial. A majority of states require labs to test for an average of 18 different pesticides.

EQUIPMENT

Testing for pesticides is one of the more problematic analyses, resulting in the need for two different instruments. For a majority of pesticides, liquid chromatography mass spectrometry (LCMS) is acceptable and operates much like HPLC, but utilizes a different detector and sample preparation.

Pesticides that do not ionize well in an LCMS source require the use of a gas chromatography mass spectrometry (GCMS) instrument. The principles of HPLC still apply – you inject a sample, separate it on a column, and detect with some detector. However, in this case, a gas (typically helium) is used to carry the sample.

RECOMMENDED INSTRUMENTS

Shimadzu recommends the LCMS-8050 which is a LC-MS/MS system or HPLC system with a triple quadrupole mass spectrometer. The ultra-low detection limits, high sensitivity and excellent throughput provided by the Shimadzu LCMS make this technique ideal for analysis of a majority of pesticides used in the cannabis industry. The Shimadzu LCMS-8050 can analyze 211 pesticides in 12 minutes.

LCMS-8050

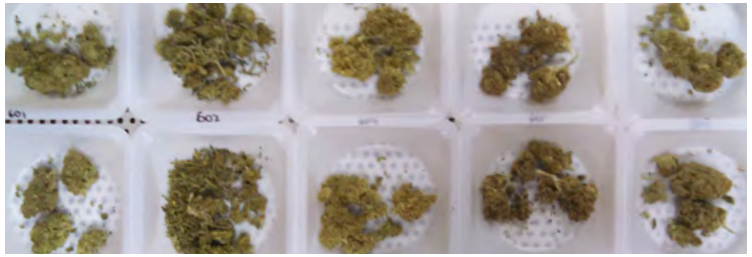
GCMS-TQ8050

For GCMS analysis, Shimadzu recommends the GCMS-TQ8050 with HS-20 Headspace Autosampler. This instrument is designed with enhanced instrument functionality, analysis software, databases, and a sample introduction system. It utilizes a triple quadrupole mass spectrometer to help maximize the capabilities of your laboratory. The HS-20 Headspace Autosampler will also be used for residual solvent testing (see next section).

SAMPLE PREPARATION

A homogenized dried cannabis flower (1 g) was extracted with 10 mL acetonitrile with vortexing and sonication. After centrifugation to remove solid material, the supernatant was treated with either the 'universal' dSPE or the 'verde' dSPE as described below.

For LCMS analysis, a 'universal' dSPE (50-50-7.5 mixture of PSA-C18-GCB, Restek) was used to treat a 6 mL sample aliquot. For GCMS, a 3 mL aliquot was treated with Supel™ QuE Verde dSPE (Supelco). A separate dSPE treatment was used as neither type of cleanup was suitable for use with both analysis techniques.



Typical dried flower samples

COST, REVENUE AND ROI BREAKDOWN

LCMS-8050:

Instrument Cost: ~$350,000 List Price

Estimated Weekly Operating Cost (1 Week):

- Chemical:
  - – Extraction (Restek no. 26237): $177.94/50 pack x 4 per week = $711.75
  - – Cleanup dSPE (Restek no. 26243): $154.37/100 pack x 2 per week = $308.74

  Restek products can be purchased through Shimadzu.

- Gas:
  - – Dewar of Liquid Nitrogen (160 L): $92.50 x 2 per week = $185.00
    (Purchasing a nitrogen generator would bring down cost)

- Flow rate: 0.5 mL/min
- Solvent A*: 5 mM NH4OAC & 0.1% Formic Acid in Water
- Solvent B*: Methanol
- Water, LCMS Grade, Honeywell B+J, four 4L bottles: $300
- Methanol, LCMS Grade, Honeywell B+J, four 4L bottles: $400

**It is highly recommended to use only UHPLC or LCMS grade solvents.*

Also, a periodic replacement of the Consumable Guard Column (3/pk @ $750) and Analytical Column ($750) are required.

All calculations are assuming operation of 8 hours a day and 5 days a week. These calculations also assume there are enough samples to keep the analyzer constantly running. If you run at 0.5 mL/min of water and methanol 50:50 mix, operating for one week, you will go through 15 mL/hour of water and 15 mL/hour of methanol. This yields 600 mL/week of both methanol and water. You will expect to go through less than 1L bottle of each. At the case price, this means you will spend $75/week on water and $67/week on acetonitrile. Your total operating cost/week for solvents will be $142, and your total operating cost/week for pesticide analysis will be $1,348.

Return on Investment (ROI) Calculation for Pesticides by LCMS

8 Hour Day/5 Days a Week	ROI
Expected Revenue/Sample	$50
Total Run Time (minutes)	12
Samples/Day	40
Samples/Week	200
Expected Revenue/Week	$10,000
Instrument Cost	$350,000
Break Even (weeks)	35.0

NOTE: This same LCMS can be used for the mycotoxins/aflatoxin analysis discussed later.

COST, REVENUE AND ROI BREAKDOWN (CONT.)

GCMS-TQ8050 with HS-20 Headspace Autosampler:

Instrument Cost: $159,000 List Price

Estimated Weekly Operating Cost (1 Week):

- One Helium Research Grade Gas Cylinder, 6.0, SIZE 300: $522.40
  Flow rate 30 mL/min of Helium with 300 L cylinder would last 10,000 minutes or 4 weeks.

- Price of gas per week: $130.60

Return on Investment (ROI) Calculation for Pesticides by GCMS

8 Hour Day/5 Days a Week	ROI
Expected Revenue/Sample	$50
Total Run Time (minutes)	20
Samples/Day	24
Samples/Week	120
Expected Revenue/Week	$6,000
Instrument Cost	$159,000
Break Even (weeks)	26.5

NOTE: This same GCMS with headspace sampler can be used for the residual solvents and terpenes analysis discussed later.

RESIDUAL SOLVENTS TESTING

Residual solvents are chemicals left over from the process of extracting cannabinoids from the cannabis plant. Common solvents for such extractions include ethanol, butane, propane and hexane.

These solvents are evaporated to prepare high concentration oils and waxes. However, it is sometimes necessary to use large quantities of solvent in order to increase extraction efficiency and to achieve higher levels of purity. Since these solvents are not safe for human consumption, most states require labs to verify that all traces of the substances have been removed.

EQUIPMENT

Testing for residual solvents requires gas chromatography (GC). For this process, a small amount of extract is put into a vial and heated to mimic the natural evaporation process. The amount of solvent that is evaporated from the sample and into the air is referred to as the "headspace." You then extract the headspace with a syringe and place the gas in the injection port of the GC. This technique is called full-evaporated technique, or FET, and utilizes the headspace autosampler for the GC.

RECOMMENDED INSTRUMENT

Shimadzu recommends a GCMS-TQ8050 with an HS-20 Headspace Autosampler.

NOTE: This same GCMS with headspace sampler can be used for pesticides and terpenes analysis.

SAMPLE PREPARATION

This is the easiest preparation in this guide. Simply take an aliquot of oil/resin and put it in a headspace vial. Take the sample, heat it up and inject it into the headspace autosampler.

COST, REVENUE AND ROI BREAKDOWN

See Pesticide Cost, Revenue and ROI Breakdown for GCMS-TQ8050 with Headspace Autosampler (page 16).

MICROBIAL, FUNGUS, & MYCOTOXIN TESTING

Most states mandate that cannabis testing labs analyze samples for any fungal or microbial growth...

resulting from production or handling, as well as mycotoxins, which is a class of toxins produced by fungi. With the potential to become lethal, continuous exposure to mycotoxins can lead to a buildup of progressively worse allergic reactions.

EQUIPMENT

LCMS should be used to qualify and identify strains of mycotoxins. However, determining the amount of microorganisms present is another challenge. For that, Quantitative Polyerase Chain Reaction, or qPCR, should be used. This is a technique that is strongly recommended for labs to research and get to know.

RECOMMENDED INSTRUMENT

For mycotoxins analysis, Shimadzu recommends LCMS-8050. The equipment's high sensitivity makes it the ideal instrument for screening for mycotoxins. In addition to standard LC, using an MS selective detector enables labs to obtain limits of detection up to 1000 times greater than conventional LC-UV instruments.

For microbial and fungus testing, Shimadzu recommends the PathogenDx Multiplexed Microarray technology, which analyzes all of the pathogens in the same reaction.

SAMPLE PREPARATION

The process is simple and easy, with no enrichment needed. Samples are prepped, into a two-step centrifugation process where a pellet containing the microbes is then lysed, taking it straight into DNA amplification and labeled with a fluorophore. The sample is hybridized on the microarray and finally imaged. Reports are delivered in less than 6 hours from sample to result. PathogenDx technology is the leading solution in DNA microbial testing, with a better, faster and more cost-effective solution for the Cannabis and Hemp sector.

LC-MS/MS sample prep of mycotoxins is usually done in 3 steps with an affinity column. First, a solution of the sample mixture is poured into the affinity column. The unwanted material drains through the column to waste. The mycotoxins and aflatoxins are retained on the column. Second, to ensure the unwanted material is removed from the sample, a wash stage with a solvent removes more of the unwanted material while retaining the mycotoxins/aflatoxins. Third, a different solvent is used to wash off the mycotoxins/aflatoxins, and the solution is collected for LC-MS/MS analysis.

COST, REVENUE AND ROI BREAKDOWN

See Pesticide Cost, Revenue and ROI Breakdown for LCMS-8050 (pages 15-16). The affinity column costs approximately $5 per sample.

MOISTURE CONTENT TESTING

Moisture content is not a required test by most states. However, moisture can be extremely detrimental to the quality of stored cannabis products.

Dried cannabis typically has a moisture content of 10-12%. A moisture content above 12% in dried cannabis is prone to fungal growth (mold). As medical users may be immune deficient and are highly vulnerable to the effects of mold, constant monitoring of moisture is needed.

EQUIPMENT:

The best way to analyze the moisture content of any product is the thermo-gravimetric method. This process involves placing the sample of cannabis into the sample chamber and taking an initial reading. Then, the moisture balance will heat up until all the moisture has been evaporated out of the sample. A final reading is then taken to determine the percent weight of moisture that was contained in the original sample.

RECOMMENDED INSTRUMENT

For moisture content analysis, Shimadzu recommends the MOC63u balance.

The MOC63u is applicable to a variety of cannabis products and its long-life and high-power halogen heater provides quick and accurate measurement.

SAMPLE PREPARATION

There is no prep; simply place the sample in the balance.

COST, REVENUE AND ROI BREAKDOWN

MOC63u Moisture Balance:
Instrument Cost: $2,100 List Price

Estimated Weekly Operating Cost (1 Week): None

Return on Investment (ROI) Calculation for Moisture Balance

8 Hour Day/5 Days a Week	ROI
Expected Revenue/Sample	$5
Total Run Time (minutes)	10
Samples/Day	48
Samples/Week	240
Expected Revenue/Week	$1,200
Instrument Cost	$2,100
Break Even (weeks)	1.8

TERPENE PROFILE TESTING

Terpenes are produced in the trichomes of the cannabis leaves, where THC is created, and are common constituents of the plant's distinctive flavor and aroma.

Terpenes also act as essential, medicinal hydrocarbon building blocks, influencing the overall homeopathic and therapeutic effect of the product. The characterization of terpenes and their synergistic effect with cannabinoids are key for identifying the correct cannabis treatment plan for patients with pain, anxiety, epilepsy, depression, cancer and other illnesses. This test is not required by most states, but it is recommended.

EQUIPMENT

The instrumentation that is used for analyzing terpene profiles is a GCMS with headspace autosampler with appropriate spectral library – which has already been discussed for residual solvents testing. Since residual solvents testing is a required analysis by most states, all of the instrumentation required for terpene profiling will already be in your lab.

RECOMMENDED INSTRUMENT

Shimadzu recommends the GCMS-TQ8050 with headspace sampler. Refer to the section on Residual Solvents Testing (pages 18-19) for preparation and pesticides for ROI (page 16).

Shimadzu does not support or promote the use of its products or services in connection with illegal use, cultivation or trade of cannabis products. Shimadzu products are intended to be used for research purposes only or state-approved medical research. Shimadzu Scientific Instruments is not condoning the use of recreational nor medical marijuana. We are merely providing a market summary of the cannabis testing industry.

Shimadzu cannot guarantee cannabis testing volumes, and our Return on Investment (ROI) calculation tables are intended as estimates only. Testing regulations and requirements vary by state, so please check with your state for current cannabis testing regulations and requirements.

To learn more about QC testing
for cannabis labs, visit
www.GrowYourLab.com

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