



## INSURING TESTING LABS: TOP 4 POLICY CONSIDERATIONS

### CONTACT

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*Courtesy of AmWINS Group, Inc.*

While you may hear testing labs and first think of clinical research, businesses of all types rely on the laboratory testing services industry to perform tests on items ranging from consumer goods and food products to construction materials and industrial components. Labs perform various testing services, including electrical, environmental, agricultural, mechanical, biological, medical and more.

Although the industry suffered a revenue decline in 2020 due to COVID-19 shutdowns and slowdowns, the testing business is expected to rebound strongly, particularly with additional requirements anticipated in the wake of the pandemic. Additionally, we saw several new states legalize cannabis during the 2020 elections, which means there will be new state-specific regulations and business for testing labs verifying compliance.

With more than 10,000 testing labs across the country, this \$18 billion revenue market<sup>1</sup> presents a strong opportunity for retail agents to grow their professional liability business. However, with opportunity comes the need for expertise. Since testing labs span numerous industries, each with their own regulation standards and risk factors, the following areas should be thoroughly considered when developing a coverage plan.

### 1. FEDERAL, STATE AND LOCAL REGULATORY ENTITIES

Testing labs face scrutiny from numerous regulators at the federal level, including the FDA, EPA, and USDA, as well as at the state level. Labs also adhere to ISO standards within their own operations around quality control, quality assurance and management.

As you would expect, when a product injures consumers, the plaintiffs will not only look at the manufacturer but also the testing labs that verified the safety and regulatory compliance. Testing labs may get second guessed about missing flaws in the product or materials, not following regulated guidelines while testing the product or materials, or other wrongful acts, errors or omissions.

### 2. POTENTIAL LIABILITY AND LOSSES

When determining the appropriate limits in a policy, it's important to understand the testing lab's unique exposure and how much and to whom they will be liable for in the event of regulatory action.

- **Regulatory entities.** Regulatory action has consequences ranging from fines for noncompliance to shutdowns of individual testing operations or entire labs. Testing labs deemed in violation need to come back into compliance and potentially re-test products that were incorrectly handled.

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- **Current Customers.** Because any action that disrupts a testing process has the potential to delay customers' operations or product rollouts, labs face the risk of third-party liability claims. Also, if the lab misses a flaw during testing that causes their customer to do a product recall, that customer may sue or subrogate against the lab for their recall and re-manufacturing expenses.
- **Future Business.** Testing labs face reputational risk from violations with potentially long-term business impact. The availability of insurance funds to help resolve a conflict may reduce the reputational damage caused by a protracted fight with customers or regulators.

### 3. CLASS-SPECIFIC EXPOSURES

Exposures and risk factors can vary widely. The greater the complexity of testing or the hazard of the items being tested, the more agency oversight and risk involved. Municipal water supply testing, infant formula, hazardous chemicals and underground storage tanks are examples that fall into this category. The following are classes with unique exposures.

#### Cannabis

Cannabis products face increased scrutiny not only from state regulations for medicinal and recreational use, but also health-conscious consumers. Testing parameters vary by state. California, for example, requires at least 14 testing criteria – the majority of which are not cannabinoid-specific – including moisture content, pesticides, heavy metals, residual solvents and various microbial impurities. In addition to regulatory requirements, retailers and dispensaries rely heavily on testing labs for accurate results so they may transparently display strain, cannabinoid profile and, in some states, the name of the independent testing lab on product labels.

For example, a testing lab is hired by a dispensary to analyze the THC potency of medicinal gummies. Utilizing high pressure liquid chromatography, the sample gummy bear is not adequately dissolved and the equipment over-reports THC content. As a result of customer complaints, the dispensary engages a second testing lab to analyze the gummies – this time using the more accurate cryo-milling method – and discovers the gummies contained less than 50% of the originally reported THC content. Due to the original testing error and mislabeling, the dispensary refunds their clients, pulls the product from their shelves, and sues the testing lab for financial loss.

#### Product Manufacturers

Labs testing products and components face exposures beyond negligence and omissions, including:

- Inaccurate premise – A “range” of “value” that yields a result is established when testing. If this is inaccurate, the lab's results could be as well.
- Faulty testing – The premise may be accurate, but the testing could yield an incorrect result due to not having proper testing methods, sequencing, technique, etc.
- Delay – The premise and testing methods may be sound, but testing may be delayed due to another factor, such as not enough testing material, supply shortage, staffing, etc.

For example, a lab is hired to test support strength of wood materials used in a new construction high-rise building and advise acceptable load factors. Due to faulty testing, they advise support strength that is overreported. During production and inspection, it is determined the support strength is NOT adequate and the construction project cannot proceed. The project owner and other stakeholders incur significant consequential financial loss and in-turn sue to the testing lab to recover their loss.

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### Environmental

Labs in the environmental sector typically conduct testing for water, geotechnical engineering, research and development, asbestos, products and other environmental-related impacts.

Environmental exposures faced by labs include:

- **Pollution-related:** Improper storage of hazardous samples, discharge of lab waste into soil/groundwater or municipal wastewater treatment plants, acidic lab wastes corroding sewer pipes, building contamination attributable to facility HVAC system, and unknown pollution conditions caused by prior site operations.
- **Professional-related:** Failure to detect contaminants due to inaccurate data interpretation, improper storage or preparation of samples, incorrect tests or analytical methods, and lack of adherence to QA/QC procedures leading to contaminated samples.

For example, a lab discharged its liquid waste down a drain. The toxic liquids contaminated a publicly owned treatment works (POTW), forcing its temporary closure. The lab was charged with \$650,000 environmental cleanup and contingent business loss that resulted from the contamination of the POTW.

### COVID-19 and Other Life Sciences

Labs testing for COVID-19 face many regulatory exposures. In today's environment, knowledge of the applicability of the PREP Act is critical. Having an attorney who is well versed in this space will save the lab countless hours and major dollars due to the immunity available to them under the [PREP Act](#), if they qualify. Important questions to ask when a lab is engaged in COVID-19 testing include:

- Is the test approved by the FDA? Does the testing qualify for Emergency Use Authorization? If not, is their test 510K approved? Who is ordering the test and doing the read? Does the lab have direct patient contact? Typical professional liability policies exclude direct patient care.

Outside of COVID-19, testing labs in the life sciences sector have varying exposures and regulatory approvals depending on the type of client they are working with. It's important for the lab's attorneys to stay up to date on the latest developments in their space.

For example, labs involved in clinical trials that will determine if or how a product gets made will need robust errors and omissions coverage for the financial damage exposure.

## 4. PUTTING THE RIGHT COVERAGE IN PLACE TO PROTECT TESTING LABS

As noted above, each testing lab has unique exposure based on the nature of what is being tested. However, there are key coverages that should be considered for each testing lab.

Professional liability insurance is needed to cover losses related to any wrongful or negligent acts performed by the testing lab. E&O coverage applies to third-party financial loss arising from the services provided by the lab.

In addition, the best policies provide coverage tailored to the specific needs of testing lab, including:

- **Defense of licensing.** Depending on the agency involved and the nature of violations, testing labs are entitled to defend against fines and loss of licensure.

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- **Pollution liability.** If a laboratory certifies a product that is later found to cause environmental damage, defense, cleanup and other related costs would be covered.
- **Contingent bodily injury.** Particularly important to agricultural and food testing labs, this coverage applies if a laboratory's testing inaccuracy or error leads to consumers' injury or illness.
- **Contingent property damage.** Similar to contingent bodily injury, this coverage applies to property damage attributed to inaccurate or erroneous testing. .

## SUMMARY

In this highly specialized market, buyers need a specialized policy. It is insufficient to write testing labs on a miscellaneous professional liability form and attempt to fill gaps with manuscript endorsements. Labs need a policy that is designed to specifically address their unique areas of risk.

AmWINS has specialist brokers who are well-versed in the current issues of testing labs space. This expertise allows us to guide our retail clients through the placement process and help them understand all lines of coverage needed to build a comprehensive risk management and insurance program for their insureds.

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## SOURCES

<sup>1</sup> IBISWorld Analysis.

