



Laboratory Test Validation in Causation Analysis

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One of the many considerations in the evaluation of causation in medical-legal cases is the determination of the validity of test results. Medical-legal cases are increasingly adjudicated based upon results of scientific measurements and laboratory test results, the validity of which is generally not questioned. In most cases, laboratory test findings are ancillary data that support a clinical diagnosis. In other instances, for example, blood or breath alcohol testing results are considered to be the most crucial evidence in a case. The fact that all test results have an inherent degree of error must be taken into consideration by individuals who interpret those tests and rely on those test results, especially when they are presented as evidence in legal proceedings. The degree of error becomes an important consideration in the ultimate establishment of the reference range for the test.

Test validity is always of concern to the treating physician or laboratorian. However, in the clinical setting, the clinician has the advantage of observing the patient whose clinical presentation may be more telling than the results of an isolated test. In the forensic setting, however, test results must be looked at more critically as the ultimate outcome of the case may hinge upon results of a single test. It is for this reason that in some areas of legal practice concern over the validity of test results are more commonly observed. One example is the DUI case in which the outcome depends on the results of a single blood or breath alcohol test finding.

When laboratory tests are performed for their forensic value, their sole purpose may be the legal investigation of an accident or a crime. As in the case of the blood alcohol test, the purpose of the test may be to identify the presence of a toxic substance or poison that may have influenced the event under legal scrutiny. Such testing must be distinguished from the clinical laboratory test in which the mandator is the treating physician who orders a laboratory test for his patient. In the forensic laboratory setting, the mandators are individuals involved in the preservation of law and order. In such cases, typically a higher level of scrutiny is observed by the courts. Nevertheless, in all legal cases, whether civil or criminal, in which laboratory test results are pivotal to the case, the validity of the test result must always be questioned.

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Individuals knowledgeable in laboratory test validation are generally Ph.D.'s, scientists, and clinical pathologists who are physicians specifically trained in laboratory medicine. The process of laboratory test validation intends to assure the quality of a specific test procedure and the accuracy of test results. Determining the validity of a test result begins with a review of the handling of the test specimen and knowledge of the instrumentation utilized in the performance of the laboratory test. It takes into consideration the identification and quality of the specimen submitted for analysis including container labeling and sample delivery. The validation of a test continues with a review of all documents that relate to the validation procedure from the time the test was initially developed. It involves a review of the standard operating procedure for the test and all documentation that deal with the establishment of the test method. This includes the study of linearity, sensitivity, specificity, accuracy, precision, and carryover. It requires a review of all control test results performed during testing. In the validation procedure, all calibration data, including the calibration of pipettes and other instruments utilized in the test procedure are reviewed. The validation procedure requires that all proficiency tests during a specified time period be produced for review and that any communications from certifying agencies regarding any deficiencies relating to the specific test procedure be produced.

The records and test results that deal with the specific test run and the specific sample itself are then reviewed. Copies of all quality control findings over a specified time are requested and if available chain of custody documentation is also reviewed. Without the abovementioned information, it is not possible to certify that, in fact, the test results or scientific measurements are accurate. Once the above mentioned quality assurance evaluations are performed, the validity of the specific test can be relied upon.

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