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Laboratory Test Report and Its Reliability – Dr. Th. Dhabali Singh MD

A laboratory test is a procedure in which a sample from a person is examined to get information about his or her health. In today's age of evidence-based medicine, nothing is more important than the quality of laboratory tests. Some laboratory tests provide precise and reliable information about specific health problems. Other tests provide more general information that helps doctors identify or rule out possible health problems. Doctors often use other types of investigation, such as imaging, in addition to laboratory tests to learn more about a person's health. Today, laboratory tests provide two-thirds to three-fourths of the information used for making medical decisions.

LABORATORY QUALITY

Laboratory quality can be defined as accuracy, reliability, and timeliness of the reported test results. The laboratory results must be as accurate as possible, all aspects of the laboratory operations must be reliable, and reporting must be timely in order to be useful in a clinical or public health setting.

RATIONALE FOR LAB TESTS

Lab tests are generally done for one or more of the following reasons:

- To find the cause of symptoms
- To confirm a diagnosis
- To screen for a disease before any symptoms occur
- To help rule out a disease or condition
- To assess the activity or severity of a disease
- To monitor the progression of a disease
- To evaluate the response to treatment

HOW ARE LAB TESTS ANALYSED?

Sample collected from a person is submitted to a laboratory for testing. Laboratories perform tests on the sample using various technologies, methodologies and sophisticated equipment. The tests are performed by trained and experienced technicians followed by reporting and validation of the results by qualified medical specialists.

WHAT DO THE RESULTS MEAN?

Lab tests show whether or not the results fall within normal ranges. Normal test values are usually given as a range, rather than as a specific number, because normal values may vary from person to person. Certain tests belonging to disciplines like cytology, histopathology, microbiology, etc. are assessed and reported by concerned specialists (pathologist, cytologist, microbiologist, etc.) to ascertain a specific pathologic condition or otherwise.

Lab test results may also be positive, negative, or inconclusive.

- A **positive** test result means the substances or condition tested for was found. In some instances, positive test results can also mean that the amount of a substance being tested for is higher or lower than normal.

- A **negative** test result means that the substance or condition tested for was not found. Negative results can also mean that the substance being tested for was present in a normal amount.
- Inconclusive test results are those that was not clearly positive or negative.

FALSE-POSITIVE AND FALSE-NEGATIVE RESULTS

- A **FALSE-POSITIVE** test result is one that suggests a disease or condition is present when it is not so. For example, a false-positive pregnancy test result would appear to detect the substance that confirms pregnancy, when in reality the woman is not pregnant.
- A **FALSE-NEGATIVE** test result is one that does not detect what is being tested for even though it is present. A false-negative pregnancy test result, for example, would be one that does not detect the substance that confirms pregnancy, when the woman is really pregnant.

INDICATORS OF TEST RELIABILITY

Four indicators are most commonly used to determine the reliability of a clinical laboratory test. Two of these, accuracy and precision, reflect how well the test method performs day to day in a laboratory. The other two, sensitivity and specificity, deal with how well the test is able to distinguish disease from absence of disease. The accuracy and precision of each test method are established and are frequently monitored by the professional laboratory personnel. Sensitivity and specificity data determined by research studies.

- **ACCURACY (or TRUENESS):** A test method is said to be accurate when the test value approaches the absolute “true” value of the substance being measured. Results from every test performed are compared to known “control substances” that have undergone multiple evaluations and compared to the “gold” standard for that assay, thus analysed to the best testing standards available.
- **PRECISION (or REPEATABILITY):** A test method is said to be precise when repeated analyses on the same sample give similar results. When a test method is precise, the extent of variation is small. The test method can be trusted because results are reliably reproduced time after time.
- **SENSITIVITY:** Sensitivity is the ability to correctly identify individuals who have a given disease or condition. For example, a certain test may have proven to be 90% sensitive. If 100 people are known to have a certain disease, the test identifies that disease will correctly do so for 90 of those 100 cases (90%). The more sensitive a test, the fewer false-negative results will be produced.
- **SPECIFICITY:** Specificity is the ability of a test to correctly exclude individuals who does not have a given disease or condition. For example, a certain test may have proven to be 90% specific. If 100 healthy individuals are tested with that method, only 90 of those 100 healthy people (90%) will be found “normal” (disease-free) by the test. The more specific a test, the fewer false-positive results.

CONCLUSION

Laboratory testing is a science professionally conducted with rigorous statistical analysis and quality controls. It is an important component in the diagnostic tool kit of a health care provider. However, the results should always be interpreted in correlation with clinical and other relevant parameters to arrive at a conclusive diagnosis and subsequent patient management.

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