

CHOOSING THE CORRECT TEST FOR THE DESIRED RESULT

ARUP offers tests using different methodologies to most efficiently give physicians the result needed to provide patients with the best clinical care. Most often, clinical assays (tests) are designed to provide a qualitative, quantitative, or semi-quantitative result. In certain conditions, a titered result is requested.

The following definitions may be helpful in ordering testing that will provide the result most useful for the physician to treat the patient:

Qualitative Assays

Qualitative assays help to identify the presence or absence of the analyte (pathogen, toxin, antigen, antibody) being tested and are often useful as initial screening tests. Qualitative assays may also be useful in monitoring disease or treatment progress.

Qualitative results are typically reported as positive/negative, detected/not detected. In some cases, the result may be reported as equivocal, indicating a level of response that falls in a gray zone of neither positive nor negative.

Detection limits are set by the laboratory and based on the analyte tested, confidence level (controls), and kit used in order to provide the optimum combination of sensitivity and specificity. Results of similar qualitative assays performed by the same methodology in different laboratories may have slight variations in sensitivity and specificity, but these variations should not be significant.

Quantitative Assays

Quantitative assays may be used as an initial test or as a reflex test added after the analyte has been found present by a qualitative assay. Quantitative results provide information on the amount of the analyte in the sample relative to the reference materials established by the World Health Organization (WHO) or other standards. Each CLIA-certified laboratory calibrates its quantitative assays to WHO reference materials.

Quantitative results are reported numerically and are compared against an accompanying reference interval for interpretation. Numeric results of quantitative assays performed by similar methods are comparable from laboratory to laboratory.

Semi-Quantitative Assays

Semi-quantitative assays are similar to qualitative assays in detecting the presence or absence of an analyte but then go on to provide a numeric representation of the amount of the analyte in the specimen that is relative to the normal/abnormal threshold.

Semi-quantitative results are compared against an accompanying reference interval to provide a qualitative interpretation of the result. WHO reference materials generally do not exist for an analyte reported as a semi-quantitative result, and response ranges may vary significantly between laboratories. Therefore, semi-quantitative numeric results from different performing laboratories may not be comparable, though the qualitative interpretation of the results will be similar.

Titered Assays

Titers are a variation of a semi-quantitative assay and report the relative amount of an analyte within the sample. The assay requires titration of the specimen into serial dilutions to detect the point at which the analyte is no longer detected. Dilution standards are set by the performing laboratory and can vary significantly between laboratories.

Titers are usually reported as a ratio of the highest dilution that still allows detection of the analyte, for example 1:320, or as the reciprocal of the dilution, which would be 320 in this example. The method involves visual observation by a trained technologist, and therefore will be subjective with some variation from laboratory to laboratory.