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Validation is the process of determining the performance characteristics of a method/procedure or process. It is a prerequisite for judgement of the suitability of produced analytical data for the intended use. This implies that a method may be valid in one situation and invalid in another. Consequently, the requirements for data may, or rather must, decide which method is to be used. When this is ill-considered, the analysis can be unnecessarily accurate (and expensive), inadequate if the method is less accurate than required, or useless if the accuracy is unknown. Two main types of validation may be distinguished:

1. Validation of standard procedures. The validation of new or existing methods or procedures intended to be used in many laboratories, including procedures (to be) accepted by national or international standardization organizations.

2. Validation of own procedures. The in-house validation of methods or procedures by individual user-laboratories.

Validation Tools: The following tools can be used to demonstrate the ability to meet method specifications of performance:

 1. Blanks: Use of various types of blanks enables assessment of how much is attributable to the analyte and how much is attributable to other causes.

 2. Reference materials and certified reference materials: Use of known materials can be used to assess the accuracy of the method, as well as obtaining information on interferences.

 3. Fortified (spiked) materials and solutions: Recovery determinations can be made from fortification or spiking with a known amount of analyte.

 4. Incurred materials: These are materials in which the analyte of interest may be essentially alien, but has been introduced to the bulk at some point prior to the material being samples.

 5. Measurement standards: These are substances used for calibration or identification purposes. When placed periodically in an analytical batch, checks can be made that the response of the analytical process to the analyte is stable.

6. Replication: Replicate analysis provides a means of checking for changes in precision in an analytical process which could adversely affect the results.

 7. Statistics: Statistical techniques are employed to evaluate accuracy, precision, linear range, limits of detection and quantification, and measurement uncertainty.

8. Analyze calibration check standards/sample: Each Initial Calibration Verification (ICV) and Continuing Calibration Verification (CCV) must have a percent recovery of 90-110% unless otherwise specified, i.e. by in-house statistical analysis.

9. Analyze duplicate matrix/reagent spike or sample duplicate to assess and demonstrate precision.

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To specify the performance characteristics of a procedure, a selection of the following basic parameters is determined:

* Use of control
* Matching results gotten with provisional diagnosis
* Precision – Precision is the agreement between a set of replicate measurements without assumption of knowledge of the true value or is the amount of variation in the measurements. The less variation a set of measurements has, the more precise it is. Types of precision include; Repeatability expresses the precision under the same operating conditions over a short period of time. Intermediate precision expresses within-laboratory variations, such as different days, different analysts, and different equipment. Reproducibility expresses the precision between laboratories.
* Accuracy – Accuracy is the nearness of a result or the mean of a set of measurements to the true value.
* Range – A range is the interval between the upper and lower concentration of analyte in sample for which it has been demonstrated that the analytical procedure has an acceptable level of accuracy, precision, and linearity.
* Linearity – Linearity is the ability of the method to elicit results that are directly proportional to analyte concentration within a given range.
* Ruggedness or robustness – Ruggedness is a measure of an analytical procedure’s capacity to remain unaffected by small, but deliberate variations in method parameters and provides an indication of its reliability during normal usage.
* Limit of quantitation (LOQ) – This is the level above which quantitative results may be determined with acceptable accuracy and precision.
* Detection limit – A detection limit is the lowest amount of analyte in a sample which can be detected but not necessarily quantitated as an exact value. It is often called the limit of detection (LOD) which is the lowest concentration level that can be determined statistically different from a blank at a specified level of confidence. It is determined from the analysis of sample blanks. Method detection limit (MDL) is the minimum concentration of a substance than can be measured and reported with 99% confidence that the analyte concentration is greater than zero. It is determined from analysis of a sample in a given matrix containing the analyte.
* Specificity – Specificity is the ability to assess unequivocally the analyte in the presence of components which may be expected to be present.

3.

Coronavirus disease 2019 (COVID-19) is a respiratory illness caused by a novel coronavirus (SARS-CoV-2). COVID-19 was first described in Wuhan, China in December 2019 and is now a global pandemic. Most of those affected have milder illness (80%), 15% will be severely ill (require oxygen) and 5% will require ICU care. Of those who are critically ill, most require early intubation and mechanical ventilation. Other complications include septic shock and multi-organ failure, including acute kidney injury and cardiac injury. Older age and comorbid diseases, such as COPD, hypertension and diabetes increase risk of death. The virus is highly contagious and spread via respiratory droplets, direct contact, and if aerosolized, airborne routes. The most common symptoms include fever, fatigue, dry cough, and shortness of breath.

As a laboratory scientist, there are various test to assess multiple organ failure in a COVID 19 patient. Blood sample are been drawn from the infected patients are the following test are being analysed.

1. For the liver: the test includes aspartate amino transferase (AST), alanine amino transferase (ALT), gamma – glutamyl transferase (GGT), N-nucleotidase etc.
2. For the kidney: Electrolytes test, urea test, creatinine test
3. For the heart: high density lipid, low density lipid, cholesterol, triglycerides, Troponin, interlukin 6 etc.
4. Other includes: urinalysis ( for protein), proclacitonin,, ferritin, D-dimer etc.