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**ANSWERS**

**QUESTION NUMBER ONE**

The processes involved in ascertaining the suitability of the new method of glucose estimation promoted by Yeenx Inc. can be referred to as **Validation of Assay.** Laboratory medicine is amongst the fastest growing fields in medicine, crucial in diagnosis, support of prevention and in the monitoring of disease for individual patients and for the evaluation of treatment for populations of patients. Therefore, high quality and safety in laboratory testing has a prominent role in high-quality healthcare. Applied knowledge and competencies of professionals in laboratory medicine increases the clinical value of laboratory results by decreasing laboratory errors, increasing appropriate utilization of tests, and increasing cost effectiveness.

Validation of a laboratory assay or method is defined as confirmation through the provision of objective evidence that the requirements for a specific intended use or application have been fulfilled. In-vitro diagnostics (IVD) manufacturers would be expected to provide such evidence as part of their design input. Adequate method validation studies are needed before laboratory methods are considered for clinical use.

Prior to method validation/verification, performance specifications for each measurement should be established.

**Performance specifications:** All test results are fraught with uncertainty despite every laboratories’ ambition to its minimization. The knowledge of this uncertainty, observed during an extended period, is needed for the proper clinical use of the results. In order to compare uncertainty among different measurement systems and methods, and to define performance specifications, we need tools to express the uncertainty and specify the performance numerically. Such data might also be used, e.g. to decide if it is possible to share common reference intervals and decision limits, or to decide if results from two assays are compatible

The following steps are crucial in determining the suitability of the new glucose testing method

**Biological variation:** One of the ways to derive performance specifications rely on biological variability of the measurand. One of the most useful tools in recent years has been the development of the “Ricos’ database”, including specifications for desirable allowable total error, imprecision and bias, based on an ever-evolving literature review of biological variation of analytes

**Measurement of uncertainty:** The goal of standardization of measurements in laboratory medicine is to achieve compatible results in human samples, independent of the laboratory and/or the method used. This can be achieved by the adoption of the “reference system” approach, based on the concept of metrological traceability and a hierarchy of measurement procedures. The reference system requires reference procedures, reference materials and reference laboratories, which are able to produce results within defined limits of uncertainty

**Verification of imprecision and bias:** A majority of the measurement methods used in laboratory medicine are produced by diagnostic companies, which have already validated them and established that they are fit for the intended purpose. The end-user laboratory, however, is requested to independently verify that the essential performance characteristics, including imprecision and bias of the measurement method and/ or measurement system found during manufacturer’s validation, can be reproduced locally. Verification is also required when substantial changes occur over time, e.g. change of a measurement system, relocation or when results of IQC or EQA schemes indicate that the performance of the method has worsened with time

The following is a brief summary of the most widely employed approaches:

– Bias studies: Clinical laboratories commonly measure in the order of 20–200 human samples having as wide a concentration range as possible, using both the comparison (“reference”) method and the evaluated method. At least 20 repeated measurements of at least two pooled patient samples may also be used. This latter approach may actually be an advantage when the medical decision limit is close to the detection limit of the measurement method or system.

– Imprecision studies: For estimating imprecision, suitable stable control materials for IQC at two concentration levels are measured in at least two replicates for at least 5 consecutive days each week for 2 weeks.

– Data presentation and analysis: Linear regression, preferably orthogonal linear regression, bias plots and analysis of variance techniques are used to quantify bias and within- and between series imprecision, respectively.

**Limit of blank, limit of detection, limit of quantification and limit of decision:** Limit of blank (LoB), limit of detection (LOD), limit of quantitation (LOQ) and limit of decision are concepts and terms used to describe the lowest concentration of a measurand that can be reliably measured by a measurement procedure. The LoB is the highest apparent concentration of a measurand expected when replicates of a blank sample containing no measurand are measured. The LoB refers to test results or signals and not to actual concentrations. The limit of decision (CCα) is the concentration of the measurand that is significantly different from zero. The concept is, e.g. used when determining whether a material is contaminated or not. LOD is the lowest concentration of the measurand detectable at a specified level of confidence. The LOD of the measurement system/instrument and of the method should be kept apart. The LOD of the measurement system is determined by presenting the system directly with the reagent blank or with other types of samples. When the LOD of the measurement method is determined, the sample is processed through all the steps of the measurement procedure. LOQ is the lowest concentration at which the performance of a method or measurement system is acceptable for a specified use.

**Statistical approaches:** to compare methods and analytical systems when a new analytical system or method is replacing the existing one, laboratory professionals have to investigate if there are differences between obtained results that could have an impact on clinical decision-making.

**Verification of reference intervals:**

Accreditation programs play a pivotal role in clinical laboratories for the management of the patient safety. In clinical practice, a widespread and practiced way for interpreting laboratory results rely on a two-sided comparison based on reference interval The clinical laboratory staff has to define and consistently verify the accuracy of pre-analytical conditions, the analytical method and its performance and the characteristics of the population to be analyzed

**QUESTION NUMBER TWO**

An analytical run is an analysis/ a test that is run at once.

The major steps i will employ in determining if an analytical run has been properly performed or not includes:

a. Use of controls: A control can be defined as a standard of comparison for checking or verifying the results of an experiment (A standard can on the other hand be defined as a substance of known concentration). Precision is monitored in laboratory by using control material. When controls are being used, the result of the test is examined if correct via the control. The value of control gotten should be ±2 (0.3) of the normal value.

b. Matching the results gotten with provisional diagnosis: The result gotten from analytical run can be matched with an associated provisional diagnosis. A provisional diagnosis is a diagnosis that is given by a clinician that thinks a particular disorder is present but realizes more information is required to be confident of a specific diagnosis. For instance, if it is to test for glucose, a provisional diagnosis may indicate diabetes mellitus, with this diagnosis the test is expected to indicate hyperglycemia so should have a result indicative of D.M but if the result gotten after repetitions is indicative of normal or hypoglycemic state then the analytical run may be ruled out as it is not accurate. Also if one is diagnosed with acidosis the bicarbonate cannot be high as it is alkali in nature.

c. Matching the results gotten with other related analytes: This entails passing a result of the run with other parameters. Urea, creatinine and uric acid are all markers of renal/glomerular functions. Potassium and Bicarbonate can be matched. If potassium is high then bicarbonate should be low.

**QUESTION NUMBER THREE**

Coronavirus disease 2019 (COVID-19) is an infectious disease caused by Severe Acute Respiratory Syndrome Corona Virus 2 (SARS-CoV-2) .The **Signs and Symptoms:** Those infected with the virus may be [asymptomatic](https://en.wikipedia.org/wiki/Asymptomatic_carrier) or develop [flu-like symptoms,](https://en.wikipedia.org/wiki/Influenza-like_illness) including fever, cough, fatigue, and shortness of breath Emergency symptoms include difficulty breathing, persistent chest pain or pressure, confusion, difficulty waking and bluish face or lips; immediate medical attention is advised if these symptoms are present. Less commonly, [upper respiratory](https://en.wikipedia.org/wiki/Upper_respiratory) symptoms, such as [sneezing](https://en.wikipedia.org/wiki/Sneeze), [runny nose](https://en.wikipedia.org/wiki/Rhinorrhoea) or [sore throat](https://en.wikipedia.org/wiki/Sore_throat) may be seen. Symptoms such as [nausea](https://en.wikipedia.org/wiki/Nausea), [vomiting](https://en.wikipedia.org/wiki/Vomiting) and [diarrhoea](https://en.wikipedia.org/wiki/Diarrhoea) have been observed in varying percentages. Also in addition to these symptoms, recent findings have shown that people infected with covid 19 present with disseminated intravascular haemolysis i.e formation of blood clot. This blood clot blocks major and minor blood vessel resulting in multiple organ failure. Organs such as lungs, kidneys, heart, brain, liver among others are affected. The following are tests that can be taken to assess imminent multiple organ/ system failure sequel to COVID 19 infection.

1. Liver: The liver is an essential organ that has many functions in the body, including making proteins, blood clotting factors, manufacturing triglycerides and cholesterol, glycogen synthesis and bile production. Liver function tests/ Hepatic panel are a group of blood tests that provide information about the state of a patient’s liver. These tests include: Albumin, bilirubin. The liver transaminases, aspartate and alanine transaminase are useful biomarkers of liver injury while gamma glutamyl transferase and alkaline phosphatase are linked to the biliary tract. Other tests include; 5’Nucleotidase, Ceruloplasmin, Alpha-Fetoprotein, Coagulation tests, serum glucose, Lactate dehydrogenase.
2. Lungs: General lung tests may include: Blood test/ cultures, Oximetry, Arterial blood gases, Bronchoscopy, lung biopsy, Thoracentesis, Transtracheal mucus cultures and computed tomography
3. Kidneys: Kidney function tests are tests that provide information about the state of a patient’s liver. These tests include; Urinalysis, serum creatinine test, Blood urea nitrogen, Estimated GFR etc.
4. Brain: brain tests include Urinalysis to screen for infection, which if present a urine culture test is done., Pulse oximetry for blood oxygen, Lumbar puncture to diagnose subarachnoid hemorrhage and other radiologic tests like CT scans, MRI scans

The following Personal protective equipment should be strictly followed during the course of assessment:

Patients with confirmed or possible COVID-19 infection should wear a facemask when being evaluated medically

Healthcare personnel should adhere to standard and transmission based precautions when caring for patients with COVID 19 infection.

* A PPE isolation gown should be worn
* Hand hygiene should be performed using alcohol based hand sanitizer
* Filtering face mask respirator should be put on
* Face shield or goggles should be put on
* Hand hygiene should be performed before putting on gloves