MLS 516 ASSIGNMENT

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1. Acceptability of analytical run

Preliminary considerations

1. Cost per test: This is the price paid to cover the direct analytical costs of the individual tests done.
2. Make versus buy decisions: A make-or-buy decision is an act of choosing between manufacturing a product in-house or purchasing it from an external supplier. Costs are compared for both make and buy options and the one with the lower total cost is chosen. Factors like cost and capacity, people and processes, expertise and equipment are considered.
3. Safety: This is to determine if the reagent to be used is safe.
4. Required technical input: This includes highly trained personnels, Technicians, blood bank scientists, clinical chemistry scientists, cytoscientists Phlebotomists and immunology scientists.
5. Turn around time: Turn around time is defined as the usual amount of time between the time a specimen is received within the laboratory and the result is available.

 Technical considerations

1. Accuracy

A test method is said to be accurate when it measures what it is supposed to measure. This means it is able to measure the true amount or concentration of a substance in a sample. It is nearness to its true values.

1. Precision

A test method is said to be precise when repeated determinations (analyses) on the same sample give similar results. When a test method is precise, the amount of random variation is small. The test method can be trusted because results are reliably reproduced time after time. Precision is the amount of variation in the measurements. The less variation a set of measurements has, the more precise it is.

1. Diagnostic Specificity: A test method is said to be specific, when it stays true to a value. This parameter is concerned with the extent to which other substances interfere with the identification and, where appropriate, quantification, of the analyte(s) of interest. It is a measure of the ability of the method to identify/quantify the analytes in the presence of other substances, either endogenous or exogenous, in a sample matrix under the stated conditions of the method.
2. Diagnostic Sensitivity: A test method is said to be sensitive, if it is able to pick and tell how much it’s there in a sample.
3. Recovery: The recovery of an analyte in an assay is the detector response obtained from an amount of the analyte added to and extracted from the matrix, compared to the detector response for the true concentration of the pure authentic standard materials. Recovery of the analyte need not to be 100%, but the extent of recovery (of the analyte and the internal standard) should be consistent (for all concentrations tested), precise and reproducible (better than 20%). If a test has a higher recovery, the test can be used.
4. Steps in determining if an analytical run has been properly performed or not:
5. Control of pre-analytical variables: Pre-analytical variables occur prior to specimen testing and may include variables involving the process of obtaining a specimen. This involves patient identification, physical sample collection, sample transportation to the testing site and sample preparation. Pre-analytical errors include

Specimen collection: Incorrect tube or container, incorrect patient identification, inadequate volume, invalid specimen (e.g., hemolysed or too dilute), collected at wrong time, improper transport conditions.

Analytical measurement: Instrument not calibrated correctly, specimen mix up, incorrect volume of specimen, interfering substances present, and instrument precision problem. e.t.c.

1. Control of analytical variables: Analytical variables occur during actual testing of the specimen. Performance of tests in the laboratory is rigorously controlled, with quality control procedures in place that markedly reduce errors in the analytic phase of testing. All instruments needed for analysis will be controlled E.g Pipetting errors, calibration error, timing errors and equipment failure e.t.c.
2. The use of control and control materials for an analytical run: Control samples are any type of well-known samples used to ensure analyses are properly performed so that results are reliable. Running controls helps monitor and control analytic error when performing a testing procedure. These errors maybe due to test system failure, adverse environmental conditions or operator performance. The amount of the analyte present in the controls should be close to the medical decision points of the test, this means that controls should check both low values and high values. This gives the confidence that test results are accurate and reliable before patient results are reported. The overall responsibility of managing the quality control program is usually assigned to the quality manager, who monitors and reviews all quality control data on a regular basis. The quality control program monitors the accuracy and precision of laboratory assays.
3. Matching the results to provisional diagnosis: The Provisional diagnosis is what the clinician considers as the most likely among the differential diagnosis. It is a process of identifying all of the possible diagnoses that could be connected to the signs, symptoms, and laboratory findings, and then ruling out diagnoses until a final determination can be made. In many cases, diagnostic testing by the laboratory scientist can identify a condition from the test result before it is clinically apparent.
4. Matching the result of analytical run with related analytes: The laboratory scientist can match results of analtyes if random errors or systematic error are discovered. Random errors lead to fluctuations around the true value as a result of difficulty taking measurements, whereas systematic errors lead to predictable and consistent departures from the true value due to problems with the calibration of an equipment.
5. Proficiency testing: Proficiency testing is also called interlaboratory comparison it determines the performance of individual laboratories for specific tests or measurements and it is used to monitor laboratories' continuing performance. Proficiency testing samples are sent to participating labs for specified testing and results are reported to the administration centre for analysis. The administration centre then collates the results and ranks participants according to their performance. All participant labs are anonymous. This anonymity allows participating labs to see trends in their own testing performance and to compare with other labs.
6. The Corona virus is a single-stranded RNA beta-coronavirus whose genome encodes are structural proteins, non-structural proteins and accessory proteins.

The coronavirus belongs to a family of viruses that may cause various symptoms such as pneumonia, fever, difficulty in breathing, and lung infection. The disease is transmitted by inhalation or contact with infected droplets and the incubation period ranges from 2 to 14 days. These viruses are common in animals worldwide, but very few cases have been known to affect humans.

The symptoms are usually fever, cough, sore throat, breathlessness, fatigue, malaise among others.

Personal Protective Equipment (PPE) is an equipment used in protecting the user from hazard and other health risks. Example of PPE include- clothing, goggles, foot wears, etc. Example of respiratory protective equipment include the N-95 respirators which protect against fumes, dust, toxic gases, etc.

INVESTIGATIONS INCLUDE-

1. Kidney function test

The corona virus infection can circulate in the blood to reach kidney and cause damage to renal resident cells which are manifested by proteinuria, hematuria, and elevated levels of blood urea nitrogen, serum creatinine.

Investigations include

Urine tests

This includes microscopic examination of a urine sample as well as a dipstick test. The dipstick is a chemically treated strip, which is dipped into a urine sample. The strip changes color in the presence of abnormalities such as excess amounts of protein, blood, nitrogen and glucose. A urinalysis can help to detect a variety of kidney and urinary tract disorders, including chronic kidney disease, diabetes, bladder infections and kidney stones. A 24-hour urine test shows how much urine the kidneys produces, and can give a more accurate measurement of how well the kidneys are working and how much protein leaks from the kidney into the urine in one day.

Electrolytes test

An electrolyte test can help determine whether there's an electrolyte imbalance in the body. Electrolytes are salts and minerals, such as sodium, potassium, chloride and bicarbonate, which are found in the blood. They can conduct electrical impulses in the body.

Creatinine:

The serum Creatinine is present after the chemical Creatine is broken down by the body in order to make energy for the muscles. The kidneys are normally able to filter out large amounts of creatinine on a daily basis. However, when kidney problems are present, the creatinine levels will increase, reflecting less creatinine being filtered out through the kidneys.

Blood Urea Nitrogen (BUN)

The BUN reflects the amount of nitrogen that is present in the body in the form of a waste product called urea. BUN is used to determine if there is extra nitrogenous waste in the blood stream, which should have been filtered out of the kidneys. One of the symptoms of kidney problems is the failure to filter as much urea as is necessary. An excess of nitrogen compounds in the blood may lead to uremia.

Estimated GFR

This test estimates how well your kidneys are filtering waste. The test determines the rate by looking at factors, such as test results, specifically creatinine levels, age, gender, race, height, weight.

1. Liver function test

Older people and individuals with serious chronic medical conditions, including liver disease patients, are at a higher risk of becoming severely ill from the corona virus. Alcohol, drugs, some herbal supplements, and toxins can also pose a threat to the Liver. Liver function tests helps to determine the health of the liver by measuring the levels of proteins, liver enzymes, and bilirubin in the blood.

 Investigations

Alanine transaminase (ALT) test

Alanine transaminase (ALT) is used by the body to metabolize protein. If the liver is damaged or not functioning properly, ALT can be released into the blood. This causes ALT levels to increase. A higher than normal result on this test can be a sign of liver damage.

Aspartate aminotransferase (AST) test

Aspartate aminotransferase (AST) is an enzyme found in several parts of the body, including the heart, liver, and muscles. Since AST levels aren’t as specific for liver damage as ALT, it’s usually measured together with ALT to check for liver problems. When the liver is damaged, AST can be released into the bloodstream. A high result on an AST test might indicate a problem with the liver or muscles.

Alkaline phosphatase (ALP) test

Alkaline phosphatase (ALP) is an enzyme found in the bones, bile ducts, and liver. An ALP test is typically ordered in combination with several other tests. High levels of ALP may indicate liver inflammation, blockage of the bile ducts, or a bone disease.

Albumin test

Albumin is the main protein made by the liver. It performs many important bodily functions. An albumin test measures how well the liver is making this particular protein. A low result on this test can indicate that the liver isn’t functioning properly.

Bilirubin test

Bilirubin is a waste product from the breakdown of red blood cells. It’s ordinarily processed by the liver. It passes through the liver before being excreted through the stool. A damaged liver can’t properly process bilirubin. This leads to an abnormally high level of bilirubin in the blood. A high result on the bilirubin test may indicate that the liver isn’t functioning properly.

Gamma-glutamyltransferase (GGT). GGT is an enzyme in the blood. Higher-than-normal levels may indicate liver or bile duct damage.

L-lactate dehydrogenase (LD). LD is an enzyme found in the liver. Elevated levels may indicate liver damage but can be elevated in many other disorders.

Prothrombin time (PT). PT is the time it takes for blood to clot. Increased PT may indicate liver damage but can also be elevated if one takes certain blood-thinning drugs, such as warfarin.

1. Cardiac function test

Individuals with preexisting heart disease are at a greater risk for severe cardiovascular and respiratory complications from COVID-19.

Investigations

Lactate Dehydrogenase (LDH) Test

This test measures the level of lactate dehydrogenase (LDH), also known as lactic acid dehydrogenase, in the blood or sometimes in other body fluids. LDH is a type of protein, known as an enzyme. LDH plays an important role in making the body's energy. It is found in almost all the body's tissues, including those in the blood, heart, kidneys, brain, and lungs. When these tissues are damaged, they release LDH into the bloodstream or other body fluids. If LDH blood or fluid levels are high, it may mean certain tissues in the body have been damaged by disease or injury.

Creatine kinase-MB (CK-MB): This is a form of an enzyme found primarily in heart muscle cells. This test measures CK-MB in the blood. CK-MB is one of three forms (isoenzymes) of the enzyme creatine kinase (CK).

These isoenzymes include:

CK-MM (found in skeletal muscles and the heart)

CK-MB (found mostly in the heart, but small amounts found in skeletal muscles)

CK-BB (found mostly in the brain and smooth muscle, such as the intestine).

A creatine kinase-MB (CK-MB) test may be used as a follow-up test to an elevated creatine kinase (CK) in order to determine whether the increase is due to heart damage or skeletal muscle damage.

Troponins:

Troponins are a group of proteins found in skeletal and heart (cardiac) muscle fibers that regulate muscular contraction. Troponin tests measure the level of cardiac-specific troponin in the blood to help detect heart injury.

There are three types of troponin proteins: troponin C, troponin T, and troponin I. Troponin C initiates contraction by binding calcium and moves troponin I so that the two proteins that pull the muscle fiber shorter can interact. Troponin T anchors the troponin complex to the muscle fiber structure. There is little or no difference in troponin C between skeletal and cardiac muscle, but the forms of troponin I and troponin T are different. Measuring the amount of cardiac-specific troponin T or troponin I in the blood can help identify individuals who have experienced damage to their heart. Troponin is present in very small to undetectable quantities in the blood. When there is damage to heart muscle cells, troponin is released into the blood. The more damage there is, the greater the concentration in the blood. Primarily, troponin tests are used to help determine if an individual has suffered a heart attack. They may also be helpful in evaluating someone for other forms of heart injury.