Standardization and implementation of lab policies ensure hemostasis sample quality

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How many of us remember the tilt-tube method for basic hemostasis testing? Fortunately, today's instruments have automated most of these manual steps. However, until recently, assuring sample quality in the pre-analytical phase of testing had remained a manual process and had been difficult to implement and standardize.

Several questions must be considered when evaluating the integrity of a hemostasis sample: Is the sample tube underfilled? Is the sample hemolyzed, icteric, or lipemic? If so, do the levels of the interferent impact the testing results? Is there a clot in the sample?

All labs have policies on sample acceptance and rejection. Inappropriate rejection of acceptable samples—requiring redraw—directly impacts patient care, patient satisfaction, and cost. Failing to reject inappropriate samples can lead to the reporting of erroneous results, impacting the quality of patient care and associated cost. Let's take a look at the most common pre-analytical quality issue culprits.

Under-filled samples

Under-filled tubes is the most common pre-analytic sample issue in the Hemostasis lab. The Clinical and Laboratory Standards Institute (CSLI) recommends that samples filled < 90 percent of recommended capacity are unacceptable and should be rejected and redrawn. These under-filled tubes may prolong clotting times.[1]

Assessing sample tubes for fill volume is a time-consuming, visual, and subjective process that is difficult to standardize and implement. However, new hemostasis analyzers now feature automation of under-filled sample tube detection. On these systems, the tube used by a facility is calibrated, establishing the desired fill-volume threshold. Test results of any samples with fill volume less than the established threshold are flagged as "Sample Tube Under-Filled." This automated tube-fill height detection allows labs to effectively standardize and implement sample acceptance and rejection.

Hemolysis, icterus, and lipemia (HIL)

Interfering substances in the patient plasma add another layer of complexity to Hemostasis testing. The most common interferents are hemolysis (hemoglobin), icterus (bilirubin), and lipemia. For samples containing HIL, some testing systems are unable to provide results, or worse, they report erroneous results. Additionally, some systems may have the ability to report accurate results for certain assays on HIL samples, but sample conditions may not be suitable for others. For example, hemolysis can activate coagulation, which can falsely decrease prothrombin time (PT) and fibrinogen results, and falsely increase D-dimer results.[2] One study found that hemolyzed samples yielded falsely normal activation partial thromboplastin times (APTTs).[3]

Historically, labs have visually inspected tubes for presence of HIL. And if detected, levels must be quantitated by the lab. This is typically performed by a visual comparison of the sample to a chart. Once the quantity of interfering substance is known, the lab refers to the respective reagent insert sheet to determine if the amount of HIL exceeds the minimum threshold identified for each interferent. This is required for each assay ordered on a sample.

Is this practical? It depends upon the number of samples received and the testing system used. The insert sheet for one testing system cites that false negative D-dimer results may be obtained with lipemic samples. If a lipemic sample is received, the lab must dilute the plasma 1:6 and verify that the absorbance value at 540 nm is < 0.35. Today, many labs do not have the appropriate staff to perform such complex manual activities.

Newer and more advanced Hemostasis testing systems feature the ability to detect levels of HIL in samples and then compare these levels to the established HIL thresholds for each assay. For example, the hemoglobin threshold for an APTT assay is 500 mg/dL, and 200 mg/dL for a dRVVT screen/confirm assay. If the hemoglobin level is 300 mg/dL, dRVVT results will be flagged with a "Hemoglobin High," while the APTT result, not impacted by hemoglobin, is not flagged. Systems with HIL detection, coupled with assay-specific threshold references, allow for easy implementation and standardization of lab policy for acceptance and rejection of samples with HIL.

Clotted samples

Hemostasis testing relies on unclotted samples. Samples with clots should be rejected.[2] Many labs employ an algorithm that prompts manual visual clot checking if abnormal results are obtained. This is accomplished by "rimming" the tube with a wooden applicator stick. Unfortunately, the sample aspiration process can pull out clots in the plasma and discard them during the probe washing process. In these cases, the lab would not be able to verify the presence of a clot.

New technology utilizes a pressure sensor for sample aspiration. If a sample-aspiration profile deviates from a normal profile, the sample result is flagged for "Fluidic Obstruction," prompting the lab to inspect the sample for the presence of clots, and eventually reject it.

Automated processes

Today, Hemostasis labs support hospital goals of improving patient care and improving patient experience, while controlling lab costs. These goals depend upon quality Hemostasis testing, and the quality of sample tested. Until now, evaluation of the quality of the sample has been manual and subjective. Automated processes that detect pre-analytical sample issues allow labs to standardize and implement their policies for rejection/acceptance of under-filled sample tubes and samples with HIL interferents, ensuring quality Hemostasis test results.

REFERENCES

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