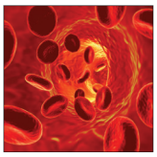


COVER STORY

By Su-Chieh Pamela Sun, MPA, MT(ASCP); Juan David Garcia, MBA, BS(MT); and Joshua Hayden, PhD, DABCC, FACB

Proper QC of Hematology Critical Values

The reporting of critical values—laboratory results that indicate a possible life-threatening situation for a patient—requires rapid clinical intervention in order to avert significant patient morbidity and mortality. Given the imperative of clear, accurate, and expeditious communication of critical value results from the laboratory to clinicians, one method of ensuring prompt handling is to create a protocol that optimizes workflow by eliminating waste and placing checks and balances throughout the process.

As with most vital aspects of laboratory work, managing hematology critical values depends largely on the acumen and aptitude of staff. Thus, an instituted protocol will only be successful if staff technologists are properly trained, gain sufficient knowledge of all involved systems and automation, and are equipped with tools to recognize the effectiveness of checks and balances.

In a hematology laboratory, the most commonly defined critical value parameters for automated complete blood counts (CBCs) are white blood cell (WBC), platelet, hemoglobin, and hematocrit. Assuming fundamental quality control measures (ie, QCs, calibration, and maintenance) have been implemented, performed, and verified on the analytical systems in use, lab management must consider what more (or less) it should do to add value to the results.

Considerations for Reporting Hematology Critical Values

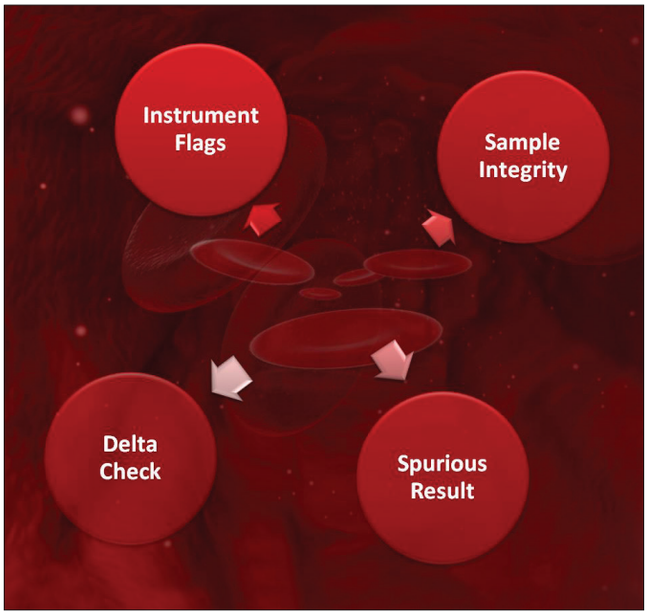


Image courtesy of the author.

Verify Specimen Integrity

Pre-analytic errors account for the highest number of errors in the total testing process. The number of errors in this phase is estimated to be 46% to 68% based on different studies.[1] In addition, the most common pre-analytical error that causes sample rejection in the clinical laboratory is a clotted specimen.[2] While checking a CBC specimen for clots before reporting results seems elementary, the practice is essential in order to ensure quality critical results due to the prevalence of pre-analytical errors, as well as to satisfy requirements of accrediting agencies, such as the College of American Pathologists (CAP). More specific, the current CAP Hematology and Coagulation Checklist includes the following: *HEM.22150: Specimen Quality Assessment - CBC specimens are checked for clots (visual, applicator sticks, or automated analyzer histogram inspection/flags) before reporting results. [NOTE: This may be done visually or with applicator sticks before testing. Additionally, microclots will often present themselves histographically on automated and semi-automated particle counters or by flagging, and the testing personnel must become familiar with such patterns. Finally, platelet clumps or fibrin may be microscopically detected if a blood film is prepared on the same sample.]*

The most common methods by which to detect clots in specimens are:

- Visual inspection using applicator sticks
- Atypical histograms or flags generated by analyzers
- Microscopic identification of fibrin strands on slides

Although visual inspection is the most sensitive and reliable way to detect a clot in a specimen, it is not practical for a high volume laboratory to visually inspect every single tube before analysis or reporting. For high testing volumes, personnel should become familiar with, and rely on, recognition of histographical patterns or analyzer flagging associated with clot detection, and selectively verify any flagged specimens by physically checking for clots. Keep in mind, with a critically low WBC, hemoglobin, and platelet result, specimen integrity must be confirmed prior to result reporting, regardless of flagging or histograms, due to the inherent existence of false negative instrument flag rates in all hematology platforms.

Use of Delta Check

The practice of delta checking is a long-standing quality control measure used by clinical laboratories to identify pre-analytic and analytic errors. While the traditional perception of its utility has been the detection of mislabeled specimens, a recent CAP Q-Probes study found that the delta check is not as effective in picking up misidentified samples as previously thought.[3] Although different studies in the literature indicate variability in the usefulness of delta checks, the combination of a patient's new critical result with a delta check failure can compel the operator to investigate further and rule out all pre-analytical errors before reporting the result. In other words, the delta check can serve as a second flagging layer, in addition to an electronic critical value alert. However, each laboratory must establish appropriate delta check triggering points based on the patient population served, and find a balance between sensitivity and effectiveness. Excessive delta checking is disruptive to testing workflow and desensitizes the technologists to this important safeguard.

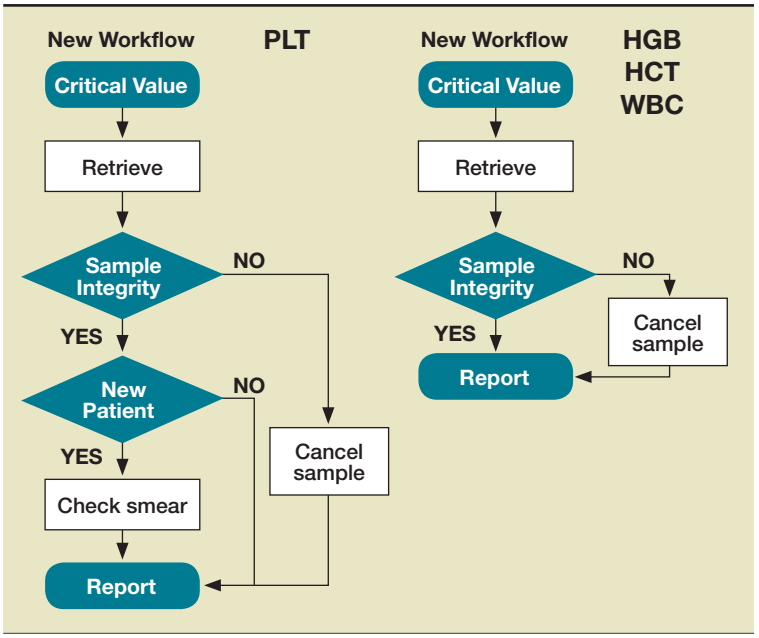
When to Perform Manual Intervention

As with other specialized divisions in the clinical lab, even with the incorporation of different technological advancements and automation, there remains a manual component necessary to the practice of hematology. For example, when performing a critical platelet count on a new patient with no clinical history or previous lab results, a manual smear review should be performed prior to reporting in order to rule out pseudothrombocytopenia (eg, platelet clumps or platelet satellitosis). In other instances, such as a finding of a falsely low hematocrit level (that could be in the critical value range) in cold agglutination, it takes a well-trained and experienced technologist to recognize the spurious results and the atypical presentation of indices to incubate the specimen, and repeat the analysis. Obviously, further manual intervention is warranted if instrument flags indicate so.

FIGURE 1

Hematology Critical Value Workflow

Repeat analysis has been removed from the critical value workflow based on our study. Once the specimen integrity is verified, critical HGB, HCT, and WBC can be released. For critical platelet count, a smear review must be done prior to reporting for a new patient.



To Repeat or Not to Repeat

As one of many process improvement initiatives, the New York Presbyterian-Weill Cornell Central Laboratory performed a prospective study to evaluate the necessity of repeating critical values and determine the financial and clinical impact associated with the repeat testing. Over 950 consecutive hematology and coagulation critical values were recorded with the results

FIGURE 2

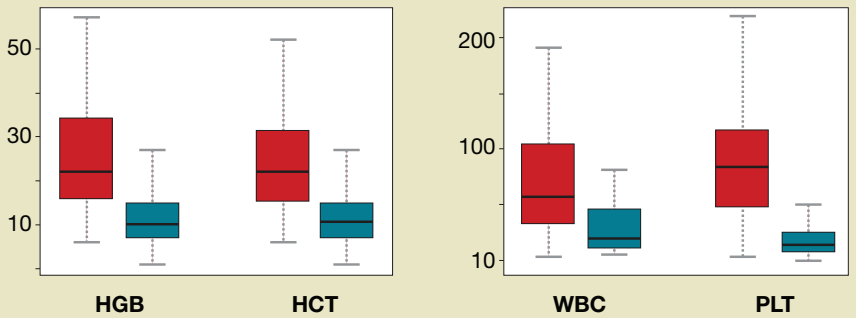
Repeating Hematology Critical Values Delays TAT

Delayed TAT in reporting critical hematology results was evident. After repeat analysis was removed from the protocol, there was an overall reduction in 50% median TAT (time measured in minutes) for all hematology critical results.

Using box-and-whisker diagrams, we are able to analyze the TAT data both with and without repeating critical values. It is immediately evident that we experienced a significant decrease in TAT without repeating critical values.

Key

■ With Repeats ■ Without Repeats



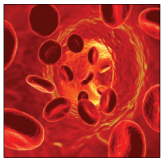


TABLE
Costs for Repeating Critical Values

	Critical Values per Month	Hours Spent per Month	Total Cost per Year	FTE
Low Month	368	172.96	$72,643.20	1.14
Peak Month	784	368.48	$154,761.60	2.43
Average	576	270.72	$113,702.40	1.78

Total cost (reagent + labor) and FTE calculated based on average median delay of 28 minutes (0.47 hours) due to repeat analysis.

from the initial and repeated runs, as well as the times of the analyses and of the final reporting. We found that a majority of the hematology critical values (97%-100%) remained as critical after the repeat. Of the small percent that changed to non-critical values, only one specimen exceeded the laboratory's established precision limit, but was deemed clinically insignificant. Using a monthly average of 580 critical values combined with a cost-per-reportable (CPRR) of 47 cents ($0.47), and taking into account the time associated with repeat testing, we projected the annual costs of labor and reagent for repeating critical values to be more than $100,000, while also requiring approximately 1.8 full time equivalents (see **TABLE**).

Since repeat analysis as a confirmation step provides no additional value, it was removed from the critical value handling policy (see **FIGURE 1**). Another set of more than 600 critical values were then collected after implementing the revised protocol and compared to the initial data set. More than a 50% reduction in median turnaround time (TAT) from initial analysis to reporting critical results was noted for all the hematology analytes (see **FIGURE 2**). Subsequently, a chart review of 15 randomly selected critical hemoglobins with repeats, and 15 without repeats, looked at time of the initial analysis, time of reporting, and the time of the RBC order from blood bank—the total time from initial analysis to RBC order decreased by 13 minutes. It was evident that repeat testing in this case delays clinical action.

The study was simple and fruitful. However, keep in mind that since analytical system performance and stability varies, each institution should conduct its own study using a site-specific platform before making any change to critical value policy. Furthermore, the financial impact may vary based on test volume.

Conclusion

When managing hematology critical values, specimen integrity must be verified prior to reporting, in addition to all the steps necessary to ensure proper performance of the analytical system. In the absence of instrument flags, technologists should consider performing delta checks, weighing the possibility of spurious results, and executing manual interventions, such as microscopic review of a smear.

The entire health care industry is under constant pressure to optimize performance and mitigate costs, and the laboratory needs to examine its various customary processes and review and rethink traditional practices. As it turns out, repeating critical values may not be necessary. Performing medically unnecessary testing wastes valuable lab resources, delays reporting TAT, and negatively impacts clinical action. In this case, doing less is better for the patient and the lab. ■

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