Automated testing in hematology: the role of rules in setting a standard

By Jyh-Ching Yaur

Rules—they are the backbone of the successful operation of any system. They bring order out of (potential) chaos, and give the people who follow and depend on them the ability to predict behavior and outcomes.

Laboratories certainly require rules; lab leaders call them "review criteria" or "clinical testing guidelines." They are the predetermined guidelines that dictate a follow-up action based on a specific test result. There are four layers of "rules" in the lab: (1) reference ranges; (2) quality control (QC); (3) delta checks; and (4) flags. An abnormal result in any of these categories can trigger a specific and predefined response. If a patient sample completes testing without violating any of the predefined rules, the test results are cleared for release to the physicians.

Rules can be enforced either manually, with lab personnel responsible for initiating the follow-up action, or through automation, by leveraging modern data management systems. Known as autoverification, this process not only improves quality but offers potential reduction in both time to results and cost. The time that was originally spent manually reviewing and validating normal results is now dedicated only to results that require attention. Because each laboratory is different, rules can be modified to meet the specific needs of the lab and the expectations of the clinicians they support. For many laboratories, data automation has become a first, important step toward gains in efficiency.

Automation can help laboratories to achieve their core goals. From pre- to post-analytics, automation can help labs increase their testing capacity, improve turnaround time, and minimize human error. They also can realize significant cost savings while keeping specialized staff focused on the most essential tasks: those that put critical information in the hands of care-givers and treatment decision-makers.

With reduced staffing becoming the norm in today's clinical labs, the value of automation is becoming even more apparent—and that brings us more specifically to the hematology lab. Hematology benefits significantly from advances in automation, with automated labs attaining 30-minute STAT times, even with 60 percent increases in per-hour sample volume. As automation touches more and more aspects of testing in the hematology lab, however, additional checks and balances are required to ensure that results are reported with the same level of quality that clinicians have come to expect. To obtain this level of confidence, hematology labs need to look beyond their automation track, test tubes, and analyzers, and focus on their data management system and, more importantly, the rules that define them.

Rule criteria

While automated rules can be developed to meet each lab's individual standards, they generally fall into one of four categories:

1. **Reference ranges** refer to rules that compare results against an assay's pre-established normal range being used at the time.
2. Automated review of **QC** can detect when an analyzer deviates from predefined control levels for a specific assay; the data management system can hold all future results from that analyzer for the particular assay for further review. The results will then remain on hold until an operator takes the proper actions to address the deviation.
3. **Delta checking** offers laboratories an additional layer of security, comparing a patient's current result to a previous result to establish if the result is truly abnormal, or, in fact, trending.
4. **Instrument flags**. Many laboratory information systems (LIS) ignore flags. While an operator may see an asterisk next to a result, the severity of that flag may not be distinguished and may contribute to an abnormality being overlooked. Newer data management systems allow for flag rules to be applied not only to patient results, but also to system-generated flags, giving labs a higher level of validation confidence.

Rule development and customization

Modern data management systems are designed with the notion that laboratories are not one-size-fits-all. Testing discipline, patient population, analysis technology, and the demands of pathologists and clinicians the lab supports, all contribute to the creation of rules. Still, every lab, including every hematology lab, needs a starting point for its individual rule development, and advanced data management systems can help facilitate that. For example, new systems allow for integration with the International Society for Laboratory Hematology (ISLH) consensus guidelines. This option makes it easy to implement a baseline set of rules that can improve quality from day one, and can later be customized to suit the specific needs of the lab.

When labs are ready to take the next step in their rule development journey, the testing capabilities of their analyzers should factor in heavily. The technology being used in a hematology laboratory will influence how its rules are defined. Whether performing quantitative RBC morphology or accurately distinguishing a platelet from a small interfering substance (e.g., microcytic RBC or red cell fragment), the capabilities of the analyzers being used must be considered to create the most appropriate rules that will shorten time to results, reduce errors, and create confidence in the accuracy of the data.

Creating confidence

Automation is an indispensable resource for today's hematology laboratory, creating efficiency that improves laboratory operations and delivers faster results, thus allowing caregivers to make more timely and effective treatment decisions. But as the number and types of analyzers being added to automation tracks grows, there is a real need for labs to take a proactive role in ensuring that the quality of their results remains consistent and in accordance with the standards of each stakeholder. To do this, labs need to take a hard look at their data management systems and the rules that they employ.

Recent advances in data management software have helped streamline rule development so that quality can be attained with ease. But the journey should not stop there. The rules that a hematology lab chooses to implement need to be the product of a thorough evaluation of its testing capabilities and should account for the needs of the clinicians that it supports.

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