Is it acceptable to release results from an analyzer with flags or alarms if a pathologist sends an email instructing to do so, even if the manufacturer's instructions state that results with flags or alarms should be verified by another method before reporting?

Q. Is it acceptable to release results from an analyzer with flags or alarms if a pathologist sends an email instructing to do so, even if the manufacturer's instructions state that results with flags or alarms should be verified by another method before reporting? I am referring to hematology analyzer auto-differential results with asterisk flags. The emailed instructions from the pathologist are applied to all samples but are not incorporated into our standard operating procedure.

We report auto-differential results that have asterisk flags and then perform a manual differential. The report, therefore, contains two differential results that, when compared, are almost always different clinically and statistically.

A. It generally is not acceptable to release results from a hematology analyzer with flags or alarms if doing so contradicts the manufacturer's instructions. Instrument flags are in place to prevent inaccurate results from being reported and allow laboratorians to detect cell types (such as blasts) that are not part of the standard automated differential. If a numeric flagged result is released before being confirmed by another method (usually a manual differential), it could lead to conflicting results in the medical record.

Going against a manufacturer's instructions necessitates that the FDA-approved test be reclassified as a laboratory-developed test. LDTs require extensive additional validation before being used for patient testing.[1] Because a purpose of instrument flags is to prevent errors, such validation is not advisable and may not be possible.

If turnaround time is a concern, the pathologist should consider reporting only the valid parts of the automated test as a preliminary result and following up with a manual differential.

1. Graden KC, Bennett SA, Delaney SR, Gill HE, Willrich MAV. A high-level overview of the regulations surrounding a clinical laboratory and upcoming regulatory challenges for laboratory developed tests. *Lab Med*. 2021;52(4):315–328.

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