I enjoyed Roy Midyett’s article, “HeMYTHology,” in the November 2003 issue of MLO on page 24. The presence of increased band forms is of great importance. This is one great myth that is worth keeping.

When a patient is symptomatic and the CBC/Diff results are normal, band forms are indicators of infection and inflammation. This is especially true in the elderly population where fever may be absent. This group often has obscure, nonspecific symptoms, such as dizziness and weakness. Physicians should not rule out infection simply because the absolute neutrophil count and automated differential are within normal limits.

The pediatric population presents similar challenges. We had a case of meningococcemia in a 10-year-old. Initially, the physician was sure it was just a viral infection. The automated differential was within normal limits; the white cell count on the lower end of normal. There were no suspect flags.

It took two visits to the physician and two more to the ER to make the diagnosis. If it had not been for the quick-thinking veteran tech who noted the child’s symptoms, the child would have died or suffered serious sequelae.

The smear showed 56% band forms, complete with dohle bodies, vacuoles, and toxic granulation. And, by the way, complete with dohle bodies, vacuoles, and increased band forms, toxic granulation, and dohle bodies. Physicians should not rule out infection simply because the absolute neutrophil count and automated differential are within normal limits.

A comprehensive slide review is now the better option. A manual diff count may not capture a few blast cells lurking on the edge of a smear, for example. A review is a quick and easy process and “better hematology” practice overall. Abnormal cells, band forms, and reactive lymphocytes are easily detected and numbers estimated when the slide is scanned by an expert.

While band counts may not always be accurate, their presence should not be dismissed so easily. Manufacturers sponsor studies to dismiss the “accuracy” of band counts. This lulls the lab community into thinking bands are no longer significant.

It is not so important whether one tech counts 20 and another 30; the increased presence of these cells is important, especially when automated numbers are within normal limits. The same concern is attached to low white cell counts where sepsis is the biggest fear.

Laboratorians must warn physicians not to depend on automated numbers in all cases. In small community hospitals, the laboratory may take the initiative in reviewing slides from ER patients presenting with significant symptoms. Most large hospitals cannot use this guideline for inpatients and outreach populations for sheer numbers alone. They must rely on the skill and knowledge of caregivers to order the right procedure.

Introduction of VCS (volume, conductivity, scatter) technology has improved the accuracy of automated differentials, but a healthy dose of caution is still in order. Many manufacturers have disclaimers attached to the autodiff. We have one that reads: “Automated differentials may not always detect band forms, reactive lymphocytes, or abnormal cells. Interpret normal results with caution in symptomatic patients. Order slide review or manual differential when clinically indicated.”

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Calibration verification and CAP

The requirement for calibration verification (see “Tips from the clinical experts,” December 2003, page 30) has been a confusing concept since the publication of the final rules for CLIA ’67 in 1990 by the Centers for Medicare and Medicaid Services, (then HCFA). The requirement was updated in the final rules for CLIA ’88 in 1992, and it is a component of the quality systems requirements of CLIA ’88 (Sec. 493.1255). This section lists specific situations when calibration verification must be done, but there are differences of opinion regarding which tests require calibration verification, and how it should be performed. CAP, through its resource committees and its CLA, has developed a reasonable approach to this requirement, based on review of the regulations and interaction with relevant governmental agencies. We feel that the current checklist questions on calibration verification are consistent with the regulations and with good laboratory practice.

CLIA ’88 exempted waived tests from this requirement (though accrediting agencies may choose to do so). However, when the final rules for CLIA ’88 were first published (57FR7165), there was disagreement over whether the rules exempted moderately complex tests, as well. CLA took the stance that the requirement for calibration verification applied to both moderately and highly complex quantitative tests. CLA’s interpretation was confirmed by the most recent revision of Subpart K of CLIA ’88, published Jan. 24, 2003, (68FR3619-3714). This subpart, now entitled “Quality Systems.

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for Nonwaived Testing,” states that “[e]ach laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in Sec. 493.1251 through 493.1283.” These system requirements include calibration verification. [Authors’ italics]

CLIA ‘88 states that “[c]alibration and calibration verification procedures are required to substantiate the continued accuracy of the test system throughout the laboratory’s reportable range of test results for the test system” (Sec. 493.1255). It should be emphasized that the term calibration verification, as used in CLIA ‘88, actually includes two distinct concepts: verification of previously established calibration status (i.e., set point), and verification of the analytic measurement range (i.e., the slope of the response curve of the instrument; in other words, the range of analyte over which calibration is valid without any pre-treatment of the specimen, such as dilution or concentration). In the CAP Laboratory Accreditation Program, the term “calibration verification” is used to refer only to the former concept.

Both CAP and CLIA ’88 require that calibration or calibration verification be performed at least every six months, and after reagent lot changes, unacceptable quality control, major service to the instrument, and when recommended by the manufacturer (Sec. 493.1255 (b)). The CLIA regulations require that the reportable range be verified by the evaluation of appropriate material at a minimum of three levels: “[A] minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range” (Sec. 493.1255(b)(2)(ii)). As noted in the above paragraph, CAP considers this to be validation of the AMR, while calibration verification, as used in the CAP checklists, verifies only the set-point of the test system. Thus, to satisfy the CLIA ’88 requirement in Sec. 493.1255(b), CAP requires both calibration verification (as defined by CAP) and validation of the AMR. The requirements of AMR validation are satisfied if the laboratory performs either calibration or calibration verification with material at three or more concentrations, including levels near the upper and lower limits of the AMR and if the laboratory performs this procedure whenever required by Sec. 493.1255(b).

Manufacturers may state that calibration verification is not required by the FDA for a specific method, either with an explicit statement or implicitly by not requiring this validation. However, CAP has not seen any situation where CMS has allowed a more-stringent requirement in CLIA ’88 to be superceded by a less-stringent exemption from another regulatory agency. In a contest between the FDA-approved manufacturer’s claim and a CMS inspector’s citation of non-compliance with CLIA standards, the inspector will win.

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Inter-regional Commissioner,
CAP Laboratory Accreditation Program;
Chair, CAP Standards and Instrumentation Resource Committee
—Stephen J. Sarewitz, MD
Checklist Commissioner,
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