Q&A column

Dr. Kiechle is consultant, clinical pathology, Cooper City, Fla. Submit your inquiries to Sherrie Rice, srice@cap.org. Questions that are of general interest will be answered.

Q. My laboratory is struggling with the revised CAP checklist requirement COM.40850 "LDT and Class I ASR Reporting," which says we need to describe the method and performance characteristics in our reports unless the information is available to the clinician in an equivalent format. Can you explain further?

A. The CAP has received several comments with concerns about the recent revision to the CAP's all common checklist requirement COM.40850 on laboratory-developed tests and class I analyte-specific reagent reporting, including some comments on the American Association for Clinical Chemistry's Artery discussion forum. The portion of the requirement under discussion is the statement that test reports include "a brief description of the method and performance characteristics needed for clinical use, unless the information is readily available to the clinician in an equivalent format (eg, test catalog)." The comments posted have included concerns that this information may clutter the patient report or not be of value to the clinician, and that there may be insufficient space in the test catalog to include this information.

The CAP Checklists Committee members would like to share insight on how to interpret this requirement. The information provided on the method and performance characteristics should be a brief summary. It is not intended to include detailed information as may be described in the laboratory's procedures. The test catalog is listed as one example of an alternative location; however, laboratories may identify other formats for providing this information on demand as appropriate to their setting. It does not need to be provided routinely for each test every time it is reported.

This topic is also addressed in another checklist requirement, COM.40700 "Method Performance Specifications Availability." There are also separate requirements in some of the checklists that already require a summary of the method to be included in the patient report, such as in the molecular pathology (MOL.49570) and histocompatibility (HSC.21275) checklists, where this information is essential to understanding the level of testing performed.

The Checklists Committee will review this topic again for the 2019 checklist edition to further clarify the intent of this requirement.

1. Clinical and Laboratory Standards Institute. MM19-A: Establishing Molecular Testing in Clinical Laboratory Environments; Approved Guideline, 1st ed.; 2011.
2. Medical devices; classification/reclassification; restricted devices; analyte specific reagents. *Fed Regist.* 1997;62(225):62243. To be codified at 7 CFR §809 and §864.
3. Caldwell CW. Analyte-specific reagents in the flow cytometry laboratory. *Arch Pathol Lab Med.* 1998;122:861–864.
4. American College of Medical Genetics and Genomics. Standards and guidelines for clinical genetics laboratories, 2018. Rev. January 2018.

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Chair, CAP Checklists Committee

Q. Can we see reactive lymphocytes in the pediatric population (under age two), and can we report them? Our laboratory policy does not support reporting reactive lymphocytes, although we frequently see them in various viral infections.

A. Pediatric CBC parameters in the neonatal (<28 days of age), infant (28 days to one year), and toddler (one to two years) populations vary. Lymphocytes, in particular, vary in normal range from a low of 30 percent (of total WBC) in the immediate neonatal period to near 70 percent in the infant period, and dropping off in the toddler period and beyond.[1] Outside of the context of infection, moreover, neonatal lymphocyte morphology can be strikingly atypical, with lymphocytes in the term neonate allowably large, with ample cytoplasm, occasionally resembling blasts.[2] Indeed, from anecdotal experience, reactive lymphocytes can be observed across these age ranges, albeit with increasing frequency in older children.

In addition to the challenges that age ranges may play in laboratory hematology, it should also be noted that the identification/classification of reactive lymphocytes is subject to significant interobserver variation.[3] As a point of practicality, therefore, centers are encouraged to take advantage of opportunities for secondary review, follow-up, or use of ancillary techniques in worrisome cases. Indeed, while the risk that a perceived reactive or atypical lymphocyte is malignant is usually vanishingly low in patients under two years, malignant lymphoproliferative disorders do indeed occur in infancy, and malignant lymphocytoses presenting without convincing peripheral smear evidence of malignity have been described (see, for example, Tao, et al.[4]). Readers are encouraged, when faced with persistent atypical circulating lymphocytes, especially in the context of evolving cytopenias, significant biochemical derangements, or worrisome clinical features, to be cautious and consider ancillary studies such as flow cytometry or molecular assessment.

1. Palis J, Segel GB. Hematology of the fetus and newborn. In: Kaushansky K, Lichtman MA, Prchal JT, et al., eds. *Williams Hematology.* 9th ed. New York, NY: McGraw-Hill Education; 2015.
2. Proytcheva MA. Issues in neonatal cellular analysis. *Am J Clin Pathol.* 2009;131(4):560–573.
3. van der Meer W, van Gelder W, de Keijzer R, Willems H. The divergent morphological classification of variant lymphocytes in blood smears. *J Clin Pathol.* 2007;60(7):838–839.
4. Tao J, Valderrama E, Kahn L. Congenital acute T lymphoblastic leukaemia: report of a case with immunohistochemical and molecular characterisation. *J Clin Pathol.* 2000;53(2):150–152.

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