Q & A, 5/13

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Submit your pathology-related question for reply by appropriate medical consultants. CAP TODAY will make every effort to answer all relevant questions. However, those questions that are not of general interest may not receive a reply. For your question to be considered, you must include your name and address; this information will be omitted if your question is published in CAP TODAY.

Submit a Question

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[pulledquote]Q. We are relocating to a new laboratory on a different floor in our hospital. There is little guidance from regulatory agencies on revalidating analyzers after the move. Decisions are left to the discretion of our pathologist. What kind of precision/accuracy/ normal range/patient sample/control testing do you recommend?[/pulledquote]

A. The equipment manufacturer should be consulted for specific guidance on correct procedures for instrument relocation. The manufacturer may have field service personnel who can perform the relocation and the necessary checks to ensure that the instrument is performing to specification after the move.

The correct equipment shutdown protocol should be followed. Depending on the equipment, a shutdown may secure moving parts, such as fluid-handling elements, and optics, so they are less likely to be disturbed during instrument relocation.

After relocation, the manufacturer's and laboratory's protocols for checking instrument function after a major service should be followed. For all assays, the analytical measurement range should be revalidated after a major instrument service. Calibration verification or recalibration should be performed. Quality control materials and a number of patient samples should be retested, and the acceptability of the results should be confirmed. Precision studies are recommended, especially around medical decision limits. We suggest retesting at least 20 patient specimens on several assays; however, the laboratory director is responsible for determining the number and types of analyses to validate the operation of the instrument after relocation. Finally, interfaces to the laboratory information system should be tested at the new location.

References

1. College of American Pathologists Commission on Laboratory Accreditation. Chemistry and Toxicology Checklist. Sept. 25, 2012 edition. Northfield, Ill.: College of American Pathologists.

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[pulledquote]Q. How should smudge cells present on peripheral smear review be handled in reporting results? Should albumin preparation be performed each time the smudge cells are present in an individual patient with known smudge cell results? Should the smudge cells be counted as lymphocytes in a peripheral smear manual differential, or should smudge cells be reported as a gradient 1+, 2+, and so on, or just as present? What is the general practice carried out in most laboratories? [/pulledquote]

A. Smudge, or basket, cells are the remnant of a fragile cell that has been damaged in the process of making a blood smear. Most commonly these cells are lymphoid in nature. Precise lineage assignment cannot be done, as the cell is not intact. The "smudge" is condensed nuclear material without identifiable cytoplasm. This artifact can be avoided by adding a drop of serum albumin to four to five drops of blood before making the blood smear. Smudge cells are most commonly seen in disorders characterized by lymphocyte fragility, such as chronic lymphocytic leukemia (CLL) and infectious mononucleosis.

Most laboratories do not report smudge cells in the white blood cell differential, but do note the presence of smudge cells. Ideally, albumin is added to the blood and the white blood cell differential is performed using the albumin smear. Smudge cells should not be assumed to be lymphocytes, and thus a manual differential should be performed only on intact leukocytes. Red blood cell morphology, however, should be reported using the smear prepared without albumin, because albumin will alter the erythrocyte morphology.

In some laboratories, grading of smudge cells is performed in patients with known CLL. In an informal survey of CAP Hematology/Clinical Microscopy Resource Committee members, all laboratory directors recommended that the presence of smudge cells be noted, but none of the members graded smudge cells. However, a literature search reveals that in some laboratories the percentage of smudge cells may be a prognostic factor in CLL. Your laboratory's policy on smudge cells will also depend on whether your hematologist/oncologists find this information useful in the setting of chronic lymphocytic leukemia; discussions with your institution's hematologist/oncologists will clarify this point.

References

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2. Nowakowski GS, Hoyer JD, Shanafelt TD, et al. Percentage of smudge cells on routine blood smear predicts survival in chronic lymphocytic leukemia. *J Clin Oncol*. 2009;27(11):1844–1849.
3. Paydas S. Smudge cells: very old history and new conclusions. *Leuk Res*. 2010; 34(12):1680.

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