Q&A column

Editor: Frederick L. Kiechle, MD, PhD

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.

Q. When using a sodium citrate blue-top tube due to platelet clumping, should the sample be kept warm, and does it have to be run within a certain time frame?

A.December 2023—Pseudothrombocytopenia resulting from platelet clumping is a common problem in the hematology laboratory and is most often caused by a reaction to EDTA anticoagulant. Using sodium citrate in lieu of EDTA as an anticoagulant may resolve pseudothrombocytopenia. However, this does not always make a difference, particularly if the platelet clumping is due to factors other than EDTA, such as cold agglutinins. Warming the EDTA sample to 37°C or using heparin as an alternative anticoagulant may also help resolve pseudothrombocytopenia.

Citrate samples do not need to be kept warm before testing, but specimen stability is an issue. Citrate platelet counts decline steadily over time, so testing should be performed as soon as possible, ideally within one to three hours. Furthermore, because sodium citrate is a liquid anticoagulant, the platelet count must be corrected by a factor of 10 percent or more to account for the dilution. A specific correction factor would need to be validated for each laboratory and take into account the type of tube used and the typical delays between collection and testing.

A broader issue is that anticoagulants other than EDTA cannot be used to run a platelet count on an automated analyzer that is FDA cleared only for EDTA-anticoagulated samples without taking prescribed steps. Before using citrate to run the platelet count, it must be validated as a laboratory-developed test by evaluating its accuracy, precision, limit of detection, reportable range, and reference range and determining the correction factor via validation studies. Once validation is complete and has been approved by the medical director, citrate samples can be used for patient testing at ambient temperature.

Dumont P, Goussot V, David A, Lizard S, Riedinger JM. Identification and validation of a factor of commutability between platelet counts performed on EDTA and citrate. *Ann Biol Clin (Paris)*. 2017;75(1):61–66.

Standard: Establishment and verification of performance specifications. 42 CFR §493.1253 (2022). www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-493/subpart-K/subject-group-ECFRc96daead380f6ed/section-493.1253

Weber D, Nakashima MO. Platelet count in sodium citrate-anticoagulated whole blood: comparison to EDTA-anticoagulated results and stability over time. *Int J Lab Hematol*. 2021;43(1):e35–e37.

Zhang L, Xu J, Gao L, Pan S. Spurious thrombocytopenia in automated platelet count. *Lab Med*. 2018;49(2):130–133.

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Q. Does the CAP require instrument-to-instrument comparability studies at least twice a year for waived point-of-care testing instruments, such as glucose meters, or nonwaived instruments, such as critical care analyzers? Are we required to perform a linearity study twice a year on all waived and nonwaived POC testing instruments?

A.Per CAP checklist requirement COM.04250 Comparability of Instruments and Methods—Nonwaived Testing, all nonwaived methods and instruments, including nonwaived POC testing instruments, need to be checked against each other at least twice a year for comparability of results. The laboratory may use a control product or patient sample for the studies. If the main laboratory and POC testing areas are under the same CAP number, at least one of the nonwaived POC testing instruments must be compared with the main laboratory instruments that report the same analyte. The remaining nonwaived POC instruments can then be compared to the POC instrument that was compared to the main laboratory instruments.

The CAP does not require instrument-to-instrument comparisons for waived testing as long as the laboratory follows all of the manufacturer's instructions as defined for the test system and has not modified the test.

The CAP does not mandate that laboratories perform linearity studies on nonwaived POC testing instruments. However, they must verify the analytical measurement range for such instruments at least every six months following defined criteria. While linearity materials can be used for such purposes, the POC testing checklist requirement POC.08500 AMR Verification Materials describes other suitable materials as well. Furthermore, POC.08600 AMR Verification contains information on an alternative process in which the analytical measurement range can be verified on a sampling of devices when a large number of single-use devices are in use.

For waived testing, laboratories are required to follow the manufacturer's instructions for calibration, calibration verification, and related processes. Manufacturer instructions that require performing linearity studies at a defined frequency must also be followed.

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