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. What can laboratories expect to see after a medication such as Narcan is given for an opioid overdose?

A. November 2020—Narcan is a trade name for naloxone, a reversing agent for opioids that acts on the mu opioid receptor. Most hospital laboratories would not detect naloxone unless they were running sensitive LC-TOF-MS–based or LC-MS/MS–based screening methods that include it in their target compound database. GC-MS–based drug screening methods may not detect naloxone unless it is part of a targeted opiate assay.

If a sufficient amount of naloxone is present, it sometimes can produce a positive result in opioid immunoassay screening methods for such opiates as codeine and morphine or such opioids as oxycodone, oxymorphone, hydrocodone, and hydromorphone. Naloxone has very low cross-reactivity in opioid immunoassay screening methods—usually less than one percent—and will not typically give a positive response. Cross-reactivity in the fentanyl immunoassay kits is even lower or absent.

Even with low cross-reactivity, whether naloxone elicits a positive immunoassay response depends on the amount administered, route of administration, and timing of the dose relative to urine collection. If the dose is high or repeated, a positive immunoassay response due to naloxone is more likely. If urine is collected too soon after naloxone administration, insufficient drug will reach the urine to cause a positive mass spectrometry or immunoassay response. But too long a time between naloxone administration and urine collection will also lessen the chances of detection due to metabolism and clearance from the body. For example, detection of naloxone after a single intramuscular dose is far less likely than if naloxone is administered intravenously in repeated doses to counter a serious opioid overdose.

Jenkins AJ, Poirier JG III, Juhascik MP. Cross-reactivity of naloxone with oxycodone immunoassays: implications for individuals taking Suboxone. *Clin Chem.* 2009;55(7):1434–1436.

Straseski JA, Stolbach A, Clarke W. Opiate-positive immunoassay screen in a pediatric patient. *Clin Chem.* 2010;56(8):1220–1223.

Graham R. Jones, PhD
Member, CAP Toxicology Committee

Michael A. Graham, MD
Vice Chair, CAP Toxicology Committee

Q. There are conflicting views among my colleagues regarding the meaning of initial competency assessment. Some think that using a training checklist for new staff counts as the initial competency assessment because we are signing off that the staff are competent to perform patient testing and report results. Others believe an initial competency assessment is done shortly after training is completed, followed by the mid-cycle/six-month competency assessment and annual competency assessment. Please clarify.

A. Your inquiry regarding training and competency is addressed in two checklist requirements: GEN.55450

“Personnel Training” and GEN.55500 “Competency Assessment–Nonwaived Testing.”

A common misconception among laboratories is that training and competency are the same process. Training is required for all new employees and when new methods, tests, or instruments are implemented. Training is the development of skills, knowledge, and experience for a particular test, method, or instrument *prior* to reporting patient test results. Training must be documented. The laboratory may develop a training checklist that lists the essential steps for performing a test or use a manufacturer’s checklist when training an employee on an instrument, or both. There are no educational requirements for the person performing training. However, the trainer must be aware of all steps in patient testing—from sample preparation to test reporting and troubleshooting. Staff may be trained by a technical specialist from an instrument manufacturer and obtain a checklist and certificate of completion. Both the trainer and the employee should sign and date the training document. If an employee develops performance problems related to testing at any time, retraining must be conducted and documented.

Once an employee has successfully completed training and is allowed to report patient test results, the clock starts for performing competency assessment.

Competency is the application of the skills, knowledge, and experience *after* initial training to assess if personnel are performing testing correctly. In contrast to training, there are strict requirements regarding the frequency of competency assessment and who can perform the assessment. During the first year of an employee’s duties, competency must be assessed at least semiannually. If a person has completed training in one discipline but still has several areas in which to train, the clock will start for the semiannual competency assessment once the employee starts reporting patient test results. The laboratory should not wait until all training is completed.

Standard: Personnel Assessment. 42 CFR §493.1713 (1992).
Standard: Technical Consultant Responsibilities. 42 CFR §493.1413. https://j.mp/345dR11
Standard: Technical Supervisor Responsibilities. 42 CFR §493.1451(b). https://j.mp/2SXvEQK

Joan K. Kosiek, MS, MT(ASCP)SH, MB
Technical Analyst, CAP Accreditation Programs
College of American Pathologists
Northfield, Ill.

Q. How do you calculate RDW-SD and RDW-CV values in dimorphic anemia cases on the Sysmex XN-3000? Most of the dimorphic anemia cases report a masked parameter.

A. The XN-Series analyzers use algorithms for the red blood cell curve to determine normal (Gaussian) distribution of RBCs analyzed in the impedance aperture. When there is evidence of multiple populations, the red cell distribution width–coefficient of variation (RDW-CV) and red cell distribution width–standard deviation (RDW-SD) are masked (indicated by four dashes) and a “dimorphic population” flag is generated. This alerts the instrument operator to possible interference in the RBC count and related indices. Instances in which this may occur include fragmented RBCs, poikilocytosis, rouleaux, RBC agglutination, interference from small round lymphocytes, and multiple RBC populations. When this flag is generated, Sysmex recommends that the operator review the smear for the presence of the aforementioned features and report any abnormal morphologies.

There is no service or research data available to the operator that can be used to manually calculate the RDW results. The “RBC abnormal distribution” interpretive message that sometimes accompanies a curve with multiple peaks should be handled in the same manner as the “dimorphic population” flag.

XN-Series flagging interpretation guide. Rev. 5. Sysmex America; 2019.

Kimberley Kabb, MT(ASCP)SH[CM]
Manager, Scientific Communication and Education
Sysmex America

Lincolnshire, Ill.