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. California Senate Bill 864 requires that fentanyl screening be included in every drug screen performed in a general acute-care hospital laboratory. The problem is there are no FDA-approved platforms for rapid screening of fentanyl. I found several for forensic use only. The only reagents I found are third-party products to run on open channels on large chemistry analyzers. This is a huge amount of work and expense for a small laboratory. Is sensitivity the stumbling block for rapid testing? How useful is a urine screen if an overdose is an immediate effect and it takes hours for fentanyl to show up in urine and then another hour to run it on a chemistry analyzer?

A.June 2023—Fentanyl is a challenge for immunoassay drug screens. Due to its high potency, much lower concentrations are found in biological fluids compared to other opioids. These lower concentrations are much easier to detect using mass spectrometry-based methods than using immunoassays. That said, there are some immunoassays on the market that, in general, use third-party reagents and that can be run on clinical chemistry analyzers. Examples include fentanyl assays from ARK Diagnostics, Immunalysis Corp., and Thermo Fisher Scientific. Depending on the level of support from the instrument vendor and reagent manufacturer, these assays can be challenging to set up on some platforms, which can be a major hurdle for smaller clinical laboratories. Specificity issues have also been seen with some fentanyl immunoassays. At least one point-of-care platform for fentanyl screening (Ryan, Bioeasy USA) is available, although clinical experience with this novel platform is limited.

Patients often require immediate treatment for an overdose, well before any drug screen results would be available. Illicit sources of fentanyl may contain co-drugs, like xylazine, for which there are very limited options for rapid screening. Lastly, there are medicolegal implications for testing, as fentanyl represents a major cause of drug fatalities and injuries, including increasingly in children.

Delaney SR, Tacker DH, Snozek CLH. The North American opioid epidemic: opportunities and challenges for clinical laboratories. *Crit Rev Clin Lab Sci*. 2022;59(5):309–331.

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Q. How should a laboratory calculate analyzer throughput? Has a formula been published?

A.The throughput rate of an analyzer is defined as the number of test results that can be obtained in one hour (tests/time). Alternative units of time for measuring throughput include per week or per month, depending on the desired data resolution. This generic formula can be tailored to a specific laboratory environment or workflow.

Certain variables should be considered when calculating throughput, such as the method of testing, type of test, and when testing is performed. Tests conducted on multi-module testing systems in which some modules run subtests or use multiple measurement methods will have varying run times and affect throughput values. An instrument that runs multiple complicated tests or tests of longer duration may have a lower throughput than one that runs a single assay. For example, potentiometric tests have a much faster throughput than colorimetric or

antibody tests. Furthermore, average throughput time will be based on the volume of each test type performed during weekdays versus weekends and may also depend on the work shift. All of these factors must be considered when interpreting throughput values and deciding whether or not the throughput rates are realistic and equate to what is occurring within the laboratory.

Whether to consider other factors depends on the depth of detail sought by the laboratorian. For example, factoring analyzer downtime into the tests/time equation effectively reduces throughput because it takes into account when specimens cannot be run. If downtime is not factored into the equation, then throughput is effectively increased. By factoring in these types of workflow variables, a laboratorian may more effectively quantify realistic throughput expectations.

An example of how to calculate productivity parameters for immunoassay analyzers was published by Hendriks, et al. The parameters can be used to improve throughput and workflow. Furthermore, most instrument vendors advertise throughput values for their analyzers. These values can be used to compare potential throughput to actual throughput and may pinpoint inefficiency in an operating system.

Hendriks HA, Kortlandt W, Verweij WM. Standardized comparison of processing capacity and efficiency of five new-generation immunoassay analyzers. *Clin Chem*. 2000;46(1):105–111.

McPherson RA, Pincus MR. Optimizing laboratory workflow and performance. In: McPherson RA, Pincus MR. *Henry's Clinical Diagnosis and Management by Laboratory Methods.* Elsevier; 2022:13–21.

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