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Performance assessment: Medetomidine test strips

The purpose of this resource is to share results from a performance assessment conducted by **Ontario's Drug Checking Community** of medetomidine test strips available for sale and marketed for harm reduction in Canada by **BTNX**.

This performance assessment used samples of drugs collected from the unregulated (or "street") drug supply and followed practices used by community agencies to check drugs using test strips.

Summary of our findings

- BTNX medetomidine test strips **reported the correct result 96% of the time**
- BTNX medetomidine test strips **successfully detected medetomidine in the lowest amount we quantified** in the samples included in this performance assessment: as low as 0.05% of a sample
- **When instructions to use are closely followed, BTNX medetomidine test strips are an effective tool for detecting medetomidine in the trace amounts that are circulating in Ontario's unregulated drug supply**

Our motivation

In Canada, when test strips are used to check drugs, they are considered **consumer products**, meaning they are not assessed by Health Canada to determine their safety, effectiveness, or quality prior to being authorized for sale. This is in contrast to test strips used to check urine, which are considered **medical devices**, and are assessed by Health Canada. In the absence of any regulation of tools and technologies used for community-based drug checking, our public health and safety program assesses and publicly shares information on their performance as part of our commitment to:

- Ensuring service user safety
- Supporting community agencies to deliver the best possible drug checking service
- Accurate monitoring of the unregulated drug supply and education on drug market trends
- Addressing inequities experienced by people who use drugs in our health and social systems

At this time, there is no perfect drug checking tool or technology:

- All have limitations, particularly when it comes to checking drugs most likely to contribute to overdose and related harms (i.e., those bought or got as unregulated opioids)
- All have trade-offs in terms of ease of use, quality of results, turnaround times for results, and cost

What is most important is that service providers understand that all drug checking tools and technologies have limitations, understand what the limitations of the tools and technologies they use are, and can clearly communicate those limitations to service users.

Our process

This performance assessment included:

- 100 **BTNX medetomidine test strips** (product code MED-18S2)
- 100 samples of unregulated (or "street") drugs that had already been checked as part of our provincial public health and safety program using mass spectrometry technologies

The BTNX test strips had a cut-off concentration of 1,000 ng of medetomidine/1 mL of water, which implies they should be able to detect medetomidine in incredibly trace amounts.

The 100 samples of unregulated drugs were collected from people who use drugs (i.e., service users) in Toronto, Kingston, or Peterborough between February and August 2025 by **our collection site members**. Collected samples were analyzed by our analysis site members (the clinical laboratory at the **Centre for Addiction and Mental Health** or **St. Michael's Hospital**) using **gold standard technologies that are validated for overdose prevention drug checking**, including gas chromatography- or high-resolution liquid chromatography-mass spectrometry.

Mass spectrometry results are considered the "reference result," which test strip results were compared to. Of the 100 samples selected by our team for inclusion in this performance assessment, 75 contained medetomidine and 25 did not (as per the reference result).

Samples had been turned into solutions with a concentration of 10 mg of drug/1 mL of methanol for mass spectrometry analysis. As a first step in preparing samples for this performance assessment, we evaporated the methanol, returning each sample to a powder. Following the instructions provided by BTNX, we again turned each sample into a solution with a concentration of approximately 1 mg of drug/1 mL of water (equivalent to approximately 5 mg of drug/5 mL of water).

A test strip was dipped into each solution, allowing about 15 seconds for the solution to be absorbed by the strip. The strip was then removed from the solution and set aside on a flat clean surface to await results.

Results for medetomidine were positive or negative. None of the test strips used reported an invalid result. Results were recorded and compared to the reference result.

Our findings

	BTNX medetomidine test strips
Lowest amount of medetomidine detected that we quantified[1]	0.05% of a sample
Sensitivity[2] How often the strips correctly reported a positive result (i.e., a true positive)	95%
Specificity How often the strips correctly reported a negative result (i.e., a true negative)	100%
False negative rate[3] How often the strips incorrectly reported a positive result as a negative result	5%
False positive rate How often the strips incorrectly reported a negative result as a positive result	0%
Accuracy (or Correctness) How often the test strip result matched the reference (i.e., mass spectrometry) result	96%

[1] Using high-resolution liquid chromatography-mass spectrometry, we often report the precise amount (or concentration) of medetomidine in the samples we check. The lowest amount of medetomidine quantified in the samples included in this performance assessment was 0.05% of a sample (0.05% of 10 mg/mL is equal to 0.005 mg/mL or 5,000 ng/mL). Based on their advertised cut-off concentration of 1,000 ng/mL, the BTNX medetomidine test strips should be able to detect medetomidine in much more trace amounts than we quantified and are currently finding in Ontario's unregulated fentanyl supply.

[2] The sensitivity of the BTNX medetomidine test strips was impacted by false negatives for (i.e., missing) medetomidine in four samples included in this performance assessment. See note 3 to learn more.

[3] The BTNX medetomidine test strips missed that medetomidine was present (i.e., reported a false negative) in four samples included in this performance assessment. We investigated those false negatives but were unable to determine what caused them. We confirmed the amount of medetomidine found in those samples was not below the strip's cut-off concentration (i.e., limit of detection). We confirmed there were no other

obvious trends in the composition of those samples (e.g., high amounts of other drugs or unique combinations of drugs). Understanding why the BTNX medetomidine test strips missed medetomidine in those four samples requires further research.

Learn more

Education is crucial for understanding when to use test strips, how to use test strips, and what test strip results mean. You may also be interested in other **resources on drug checking tools and technologies** developed by our program.

We are committed to ensuring our public health and safety program adds value to the communities it serves. If you have any questions, comments, or feedback about this resource or our program, please contact hello@drugchecking.community.

This performance assessment was undertaken by Meera Bissram, Dr. Sarah Delaney, Karen McDonald, Dr. Cristiana Stefan, and Hayley Thompson. This resource was reviewed by Jason Sereda and our colleagues at the Ontario Harm Reduction Distribution Program.

About Ontario's Drug Checking Community: Ontario's Drug Checking Community is a national leader in drug checking service delivery and community-led unregulated drug market monitoring and education. This public health and safety program offers the most precise, timely, and accessible information on the unregulated drug supply to reduce harm and inform evidence-based responses to the worsening toxic opioid supply crisis.

Our program is comprised of a group of members, including collection sites, analysis sites, and a small central team that operates from within St. Michael's Hospital in Toronto.

Our work would not be possible if people who use drugs did not donate their drugs to our program in an effort to reduce the harms associated with using unregulated substances and facilitate community-led drug market monitoring and education.

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