

Appendix B4 – Onsite Drug Screening Devices. Report on the Evaluation of Medix Pro-Split Integrated Onsite Urine Drug Device

Introduction

Appendix B4 of AS/NZS 4308:2023 requires on-site devices to be verified against the screening cut-offs indicated in the standard prior to use. This is achieved by testing a minimum of ten kits with urine samples spiked at -30% off the screening cut-offs, and ten kits with urine samples spiked at +25% of the screening cut-offs.

As per the standard, no more than a total of 10% shall return an incorrect result for each drug class.

In this randomised, blind study, thirty (30) of the following instant urine drug screen cups were tested:

- MEDIX PRO-SPLIT INTEGRATED DRUG SCREENING CUP
 - Lot number: 0000906474
 - Expiration date: 11/08/2026

The cups were tested to determine their ability to correctly detect the presence of drugs in urine samples.

Protocol

Certified negative urine samples were prepared for this study and spiked with an in-house spike made to achieve the concentrations below.

The concentrations of the spiked urine were then confirmed via liquid-chromatography mass-spectrometry (LCMS) to ensure the following concentrations were achieved:

Drug Class	Low (-30%) µg/L	Cut-off µg/L	High (+25%) µg/L
d-Amphetamine	210	300	375
d-Methamphetamine	210	300	375
Morphine	210	300	375
Benzoyllecgonine	105	150	187.5
Oxazepam	140	200	250
11-nor-9-carboxy-Δ9-tetrahydrocannabinol	35	50	62.5

After the spike concentrations were confirmed, 10x 'positive' urine, 10x 'negative' urine, and 10x true-negative certified blank urine samples were poured into allocated, unlabelled cups. The cups were then evaluated as blind, randomised samples by a Western Diagnostic Pathology collector and 2 toxicology scientists. These results were read as per the manufacturer's instructions. The results were tabulated by the recorders and then compared to the true results.

Results

The results from the recorded readings of the instant cup drug levels were combined and recorded in Table 1.

Table 1: Combined recorded results of drug cup readings.

Drug Class	MEDIX PRO-SPLIT INTEGRATED DRUG SCREENING CUP		
	True-Negative	Negative	Positive
d-Amphetamine	10/10	10/10	10/10
d-Methamphetamine	10/10	10/10	10/10
Morphine	10/10	10/10	9/10
Benzoyllecgonine	10/10	10/10	10/10

Oxazepam	10/10	10/10	10/10
THCCOOH	10/10	10/10	10/10
PASS OR FAIL	PASS	PASS	PASS

Table 1: Combined recorded results of drug cup readings.

Conclusion

Based on this study, the Medix Pro-Split Integrated drug screening cup satisfy the criteria laid out in Appendix B4 of the AS/NZS 4308:2023 standard.

Conflict of Interest Statement

This study was conducted by Western Diagnostic Pathology (WDP) part of the Healius Pathology Pty Ltd network. WDP has a commercial supplier agreement with Abbott Diagnostics, as the laboratory does with many other suppliers. Abbott Diagnostics assisted by providing collection and transportation devices for the study and by reimbursing the laboratory for cost of consumables and labour required to perform the verification study. This has no influence on the performance of the investigation, or the conclusions reached.

A handwritten signature in black ink, appearing to be 'Emma Brooks'.

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