Appendix B3 – Onsite Creatinine Testing Devices.
Report on the Evaluation of Medix Pro-Split Integrated Onsite Urine Drug Device

Introduction

Appendix B3 of AS/NZS 4308:2023 requires on-site devices to be verified as fit for purpose for the analysis of onsite creatinine. As per the standard, no more than a total of 10% shall return an incorrect "false low" or "false acceptable".

In this randomised, blind study, twenty (20) 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 the creatinine level of true patient urine samples.

Protocol

Over the course of two weeks, samples flagged under the creatinine cut-off on the immunoassay machines were recorded and collected.

Ten (10) of these samples were determined to have a creatinine concentration of between 0.88-1.76mmol/L, and these samples were deemed 'abnormal' for this study.

A further ten (10) of the collected samples were determined to have a creatinine concentration of between 1.76-2.64mmol/L, and these samples were deemed 'normal' for this study.

10x 'abnormal' and 10x 'normal' creatinine 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 creatinine levels were combined and tabulated in Table 1.

Table 1: Combined results of creatinine cup readings.

	MEDIX PRO-SPLIT INTEGRATED DRUG SCREENING CUP	
	NORMAL	**ABNORMAL**
Creatinine correctly detected	10/10	9/10
PASS OR FAIL	PASS	PASS

Table 2 shows the comparison between the immunoassay creatinine result and the iCUP creatinine results.

The criterion for abnormal results is between 0.88-1.76mmol/L, which is at no more than 100mg/L (0.88mmol/L) below the cut-off of 1.76mmol/L. Alternatively, the criterion for normal results is between 1.76-2.64mmol/L, which is at no more than 100mg/L (0.88mmol/L) above the cut-off of 1.76mmol/L.

Table 2: Creatinine immunoassay and instant cup values.

Sample	Immunoassay result (mmol/L)	Creatinine cup detection results
1	0.93	Abnormal
2	1.17	Abnormal
3	1.26	Abnormal
4	1.38	Abnormal
5	1.42	Abnormal
6	1.49	Abnormal
7	1.54	**Normal ****
8	1.6	Abnormal
9	1.66	Abnormal
10	1.7	Abnormal
11	1.8	Normal
12	1.93	Normal
13	2	Normal
14	2.04	Normal
15	2.12	Normal
16	2.24	Normal
17	2.34	Normal
18	2.4	Normal
19	2.57	Normal
20	2.59	Normal

***Incorrectly recorded creatinine result.*

Conclusion

Based on this study, Medix Pro-Split Ingrated Drug Screening cup satisfy the criteria laid out in Appendix B3 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.

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