

VALIDATION:	Evaluation of DOA Quick Cup On-Site Testing Device
DEPARTMENT:	
APPROVED BY:	National Chief Scientist

INTRODUCTION

In order for an on-site device to be used there is an evaluation to be completed to ensure the trueness of results, with respect to the cut-offs as specified in AS/NZS 4308:2008 Table 1. (*see Table 1*). This is achieved by adopting an acceptable level of performance for reading +25% and -30% of the screening cut-offs.

**TABLE 1
IMMUNOASSAY SCREENING TEST CUT-OFF LEVELS**

Class Of Drug	Cut-off level, µg/L
Amphetamine type substances	300
Benzodiazepines	200
Cannabis metabolites	50
Cocaine metabolites	300
Opiates	300

This document covers the evaluation and verification of an on-site device DOA Quick cup. This achieved by testing a minimum of ten kits with negative urine samples spiked at -30% of the screening cut-offs, and ten kits with negative urine samples spiked at +25% of the screening cut-offs.

The standard states that if a total of twenty kits are tested, there shall be no more than two failures in total, whether that be false positive in the case of the -30% spiked urine samples, or false negatives with respect to the +25% spiked urine samples.

In this study the DOA Quick Cup was evaluated, test device uses the same analytes as their calibrators.

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The following materials were used to spike the urine samples. (*see Table 2*).

TABLE 2

Calibrator	-30% (µg/L)	+25% (µg/L)
S(+)-Amphetamine	210	375
S(+)-Methylamphetamine	210	375
Oxazepam	140	250
Benzoyllecgonine	210	375
Morphine	210	375
(-)-11-Nor- Δ^9 -THC-9-COOH	35	62.5

PROCEDURE

Two groups of 10 blank urine specimens were spiked with a mixture of all relevant analytes, one group at +25% of the screening cut-off concentrations and the other at -30% of the screening cut-off concentration. The LCMS methods used were the current NATA approved methods for SafeWork Laboratories for the five drug groups. All assays included four calibrators, two $\pm 25\%$ commercial controls, one blank and two groups of ten prepared urine spikes at +25% and -30% of the cut-offs. The devices were evaluated as blind samples by two staff members according to the manufacturer's directions. Results were agreed upon both accredited collectors and staff members and recorded accordingly.

All concentrations of spiked samples were confirmed by using mass spectroscopy and raw data were attached.

At the completion of the study, the identity of the samples were revealed and the table of results were generated. (*see Table 3*).

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RESULTS

The results for the evaluation of the DOA Quick Cup and the LCMS analysis of the prepared urine specimens are shown in Table 3.

The LCMS results for all drug groups were within accepted tolerances. Nine out of ten samples for all drug groups in the +25% samples were within range, and ten out of ten samples in the -30% group were in range. This passes the verification criteria required for AS/NZS 4308:2008.

The results for both the -30% and +25% urine spiked across all drug groups for the DOA Quick Cup were good with 2 failures in the benzoylecgonine +25% group and 1 failure each in the THC and morphine +25% groups. On the basis, the DOA Quick Cup would pass the AS/NZS 4308:2008 verification criteria. (*see Table 4*).

CONCLUSION

In conclusion of this study, the results for the DOA Quick Cup satisfies the criteria stated by AS/NZS 4308:2008

**TABLE 3 –
LCMS Results (+25%)**

Drug Type	Cutoff (µg/L)	Target Value (µg/L)	Acceptable Range (µg/L)	Number of samples within range
THC	50	62.5	50 – 75	9/10
Benzoylecgonine	300	375	300 – 450	9/10
Oxazepam	200	250	200 – 300	9/10
Morphine	300	375	300 – 450	9/10
Amphetamine	300	375	300 – 450	9/10
Methylamphetamine	300	375	300 – 450	9/10

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**TABLE 3 -
LCMS Results (-30%)**

Drug Type	Cutoff (µg/L)	Target Value (µg/L)	Acceptable Range (µg/L)	Number of samples within range
THC	50	35	28 - 42	10/10
Benzoylcegonine	300	210	168 - 252	10/10
Oxazepam	200	140	112 - 168	10/10
Morphine	300	210	168 - 252	10/10
Amphetamine	300	210	168 - 252	10/10
Methylamphetamine	300	210	168 - 252	10/10

**TABLE 4 -
DOA Quick Cup™ LOT: 201505001 Expiry Date: 2017 - 05**

	Amphetamine	Methylamphetamine	Benzodiazepine	Cocaine	Morphine	THC
+ 25 %	10/10	10/10	10/10	8/10	9/10	9/10
- 30 %	10/10	10/10	10/10	10/10	10/10	10/10

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REFERENCES

1. Australian/New Zealand Standard, Procedures for specimen collection and the detection and quantitation of drugs of abuse in urine. AS/NZS 4308:2008 Appendix B.
2. Agilent Library Database
www.agilent.com.au

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