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Report of Verification of Performance of Onsite Devices

The following product(s) were evaluated to the requirements of Appendix B in AS/NZS 4308:2008. The performance of the device(s) was assessed by blind-testing a minimum of 40 different urine specimens containing the substance used by the manufacturer to calibrate the device. The control material consisted of a minimum of 10 urine specimens spiked at a concentration of –30% of the cut-off value and a minimum of 10 urine specimens spiked at a concentration of +25% of the cut-off value. For each device tested, not more than a total of 10% shall return an incorrect result for each drug class. To negate the effect of cross reactivity between the amphetamine type substances (amphetamine & methyla amphetamine) the total number of control materials was increased to 40.

Control materials were prepared using class A volumetric glassware, calibrated Evol syringes, certified primary standards (Cerillient, Lipomed) and certified drug free urine.

Drug free urine tested and found to be negative to all compounds listed below using both GC/MS and LC/MS/MS.

The target test cups were also tested against the certified blank urine (x5) and were found to have a negative response to all drugs listed below.

This verification was performed on behalf of Alere. The results were as follows:

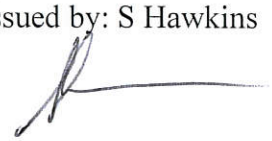
Device: Medix Pro-split Intergrated Cup
Lot no: DOA 5090209
Expiry Date: 08/2017

Target Drug	Level Tested	Cut-off level	Result	Pass/ Fail
d-Amphetamine	210	300	9/10	PASS
d-Amphetamine	375	300	10/10	
Oxazepam	140	200	10/10	PASS
Oxazepam	250	200	9/10	
Benzoylecgonine	210	300	9/10	PASS
Benzoylecgonine	375	300	10/10	
(-)THC-COOH	35	50	10/10	PASS
(-)THC-COOH	62.5	50	9/10	
d-Methylamphetamine	210	300	9/10	PASS
d-Methylamphetamine	375	300	9/10	
Morphine	210	300	9/10	PASS
Morphine	375	300	10/10	

Testing was performed as per manufacturers guidelines stated in the package insert and carried out by Alere representatives.

This report applies to any devices that use these Intergrated E-Z Split Key Cup II and is no longer valid if the product is modified in any way. [See Appendix A 3.2(b) in AS/NZS 4308:2008]

Date Reported: 30/09/2015
Report issued by: S Hawkins



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