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PATHOLOGY
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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 substance (amphetamine & methylamphetamine) 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 be negative response to all drugs listed below.

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

Device: Surestep E-Z Split key Cup II
Lot no: DOA5090213
Expiry Date: 08/2017

Testing Date: 25/05/2016

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

Testing was performed as per manufacturers guidelines stated in the package insert and carried out by Alere representatives under the supervision of Douglass Hanly Moir staff.

This report applies to the Surestep E-Z Split key Cup II device and is no longer valid if the manufacturer modifies the device. [See Appendix A 3.2(b) in AS/NZS 4308:2008]

The device Surestep E-Z Split Cup II meets the acceptable level of performance as set out in Appendix B of AS/NZS 4308:2008, and is therefore fit for purpose.

Date Reported: S Hawkins
Report issued by: 14/06/2016

Toxicology Department
Douglass Hanly Moir Pathology
NATA accreditation No: 2178
AS/NZS 4308:2008
ISO 15189
ISO 17025