



Alere™ DDS®2 – A novel approach to drugs of abuse screening

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May 27, 2015



Overview

- Introduction
- Test system
- Test panels and cut-offs
- Quality Control
- Testing process
- Performance evaluation
- Performance in the field
- Conclusion



The Alere™ DDS®2 Mobile Test System

- Rapid screening of drugs of abuse in oral fluid
- Digital imaging device
- Hand held, truly portable unit
- Test cartridge is a lateral flow immunoassay
- Test cartridge is single use, disposable and contains dried reagents and liquid buffer
- LCD colour screen
- On-screen prompts
- Storage of 10,000 tests
- Print capability
- Data management suite





Contents of Test Kit





Cut offs

- DDS2-403 – 6 Panel: **OPI/COC/AMP/MAMP/THC/BZO**
- DDS2-404 – 5 Panel: **OPI/COC/AMP/MAMP/THC**
- DDS2-407 – 6 Panel: **OPI/COC/AMP/MAMP/MTD/BZO**

Drug Group	Target Compound	Cut-off (ng/mL)
Amphetamine	D-amphetamine	50
Benzodiazepines	Temazepam	20
Cannabis	Delta-9-THC	25
Cocaine	Benzoyllecgonine	30
Methadone	Methadone	15
Methamphetamine	Methamphetamine	50
Opiates	Morphine	40



Quality Control (QC) Testing

- Advise to do QC testing prior to each testing session
- Ensure that test cartridges are clean and undamaged
- Simply insert PQC and NQC at the beginning of each session and follow the screen prompts





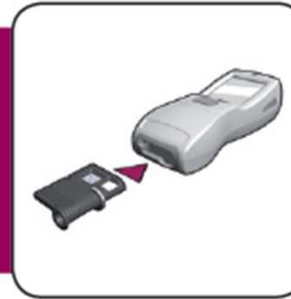
Contents of Alere™ DDS®2 Mobile Test System



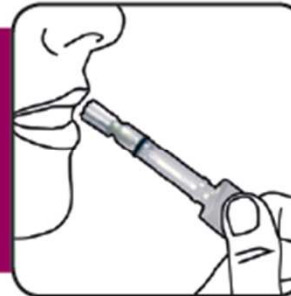


Testing as easy as A, B, C

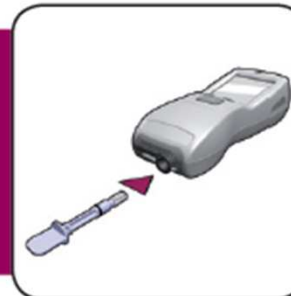
A Insert test cartridge into analyser.



B Collect oral fluid sample.



C Insert collection device into test cartridge.





Performance Evaluation

- Assess performance of test kit prior to release
- Test a proportion of each batch of cartridges
- Laboratory based performance test
- Challenge the device **close to cut-off**
 - Test solutions 50% below and 100% above cut-off
- Use matrix which gives same performance as real saliva
 - Real saliva is ideal
 - Buffer solution not acceptable
 - De-proteinised real saliva not suitable
- Laboratory based evaluation should mimic 'real world'



Evaluation Results

	COC	OPI	MAMP	THC	BZO	AMP	MTD
Number of tests	3000	3000	3100	3100	2600	3000	400
Sensitivity	97.9%	99.9%	98.3%	95.9%	96.2%	99.8%	98.0%
Specificity	99.7%	99.8%	98.7%	99.5%	99.4%	99.7%	99.0%
Accuracy	98.8%	99.8%	98.5%	97.7%	97.8%	99.7%	98.5%



Performance in the field

- Device used to test drug using population
 - Positivity rates in excess of 40%
- Testing for cocaine and opiates only
- Over 160,000 tests conducted annually
- Disputed tests sent back to laboratory for LC-MS-MS analysis
- Less than 4% of tests are disputed



Performance in the field - Results

2014	% samples sent to lab overturned	% of samples tested overturned (approx.)
January	1.2%	<0.1%
February	1.3%	<0.1%
March	1.6%	<0.1%
April	1.5%	<0.1%
May	1.8%	<0.1%
June	1.7%	<0.1%
July	2.5%	<0.1%
August	1.1%	<0.1%
September	1.2%	<0.1%
October	1.9%	<0.1%
November	1.8%	<0.1%
December	2.4%	<0.1%
2014	1.7%	<0.1%



Conclusion

- Truly handheld device
- Simple to use
- Innovative features driven by user experience
- Rigorous pre-sale evaluation programme
- Evaluation mimics 'real life'
- Performance data meets specifications
- Use in the field replicates evaluation performance



Any Questions

