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# Technology Review

*Eye Scan for Detection of Recent Drug Abuse*



## EYE SCAN FOR DETECTION OF RECENT DRUG ABUSE

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000/06

## **1. INTRODUCTION**

Drug abuse has been a major problem in the Malaysia, of which it is affecting the national security. Drug abuse has been identified as one of the causes of crime, moral decline and family, community and national dispute. Drug addicts are the burden of the society and the country. Since year 1988, a total of 235,495 drug addicts have been detected in Malaysia. This figure is worrying as it is about 1% of the total number of Malaysian population. In 2002 alone, 31,893 drug addicts were detected. This was an increase of about 1.07% when compared to the total of drug addicts detected in 2001 which is 31,556 (Agensi Dadah Kebangsaan)<sup>1</sup>.

Qualitative detection of drug abuse is a two-step process which involves a screening test which, if found to be positive, is followed by a confirmatory test. Screening tests tend to have relatively high sensitivity and cross-reactivity and low specificity, thus positive results must be viewed as presumptive until a confirmatory test is done. The urine, hair, sweat and saliva tests has been used as the accepted screening methods to detect drug abuse, while the gas chromatography/ mass spectrometry has been used as the standard confirmatory test for drug abuse.<sup>2</sup>

This technology review came about after the announcement made from the Ministry of Education Malaysia regarding a pilot project of detecting drug abuse among the secondary school students and teachers in Kuala Lumpur using an eye scanner. The eye scanner was reported to cost the respective ministry RM200,000<sup>3</sup>.

## **2. OBJECTIVE**

To determine the safety, effectiveness and cost-effectiveness of the eye scanning device in detection of recent drug abuse, particularly in the context of screening.

## **3. TECHNICAL FEATURES**

There are currently two types of eye scanning device or pupillometer which are currently marketed for the purpose of detecting drug abuse, which are Passpoint™ manufactured by the Street Time Technologies, and EyeCheck™ manufactured by MCJ Inc.

### **3.1 Passpoint™**

PassPoint™ measures involuntary eye-reflex reactions to light. The manufacturer claimed that it is able to measure pupil changes as small as .05 mm 60 times per second and measures eye position 500 times per second. It collects four key eye measurements and compares them to an individual's personalized baseline. These measurements were said to be able to identify the impairment related to current and recent substance use. It was also said that PassPoint™ has a 48-hour window of detection for the most commonly abused substances, including marijuana, opiates, cocaine, amphetamine, methamphetamine, depressants and inhalants.

The PassPoint™ screener is a custom designed pupillometer with an embedded computer running the Windows operating system. It is housed in ¼" steel and weighs 60 pounds so it is a very robust piece of equipment. The front of the screener has a numeric keypad and display LCD as well as an adjustable eyepiece with two buttons that initiate the test. The system comes complete with a thermal

printer, backup power supply, video monitor for pupil display, USB hub and a wheeled cart to support the equipment. Equipment installation takes about four hours, while staff orientation and training take about two days.

The screener is an ATM-like device on which the client self administers a simple 30 second eye scan. At the end of the scan, the screen beeps and immediately prints out a thermal receipt that clearly indicates to the client whether he or she needs to provide a urine sample or not.



The PassPoint™ screener

### **3.2 EyeCheck™**

The EyeCheck™ is a custom designed handheld pupillometer which looks like a binocular. It weighs 40 ounces, and comes with battery pack with charger and systems display and analysis software. The operator will have to use this device in corporation with a laptop computer.

EyeCheck™ pupillometer works similarly to the Passpoint™ concept. The manufacturer claims that it is able to detect impairment such as drugs abuse, fatigue or intoxicating compounds. An individual has to peep into the unit viewing area and a light flashes. This pupillometer tracks the pupil's reaction response to light stimuli. The data is then processed and the results are displayed on the computer screen, thus the operator will need to have a laptop computer in order for the pupillometry analysis to be done. A pass/fail screen gives the probable cause for impairment. The whole screening process is said to take only 2-3 minutes.



The EyeCheck™ operating device

#### **4. METHODOLOGY**

Retrieval of evidence-

1. Literature search was done using the MEDLINE, EBSCO, OVID and Blackwell Synergy database. The search includes studies in all languages, and no limitations were applied.

The keywords used in the search were:

- “drug abuse” AND screen\*
- “drug abuse” AND screen\* AND eye
- “drug abuse” AND screen\* AND “eye scan”
- “drug abuse” AND screen\* AND “ocular measure\*\*”
- pupillometer OR pupillometry
- (pupillometer OR pupillometry) AND (“drug abuse” OR “drug screen\*\*”)
- “pupillary measure\$” AND “drug screen\$”
- “ocular measur\$” AND “drug screen\$”
- pupillometer OR pupillometry
- (pupillometer OR pupillometry) AND drug
- (pupillometer OR pupillometry) AND (“drug screen” OR “drug abuse”)
- ocular measurement
- ocular measure
- pupillary measure
- the keywords (effectiveness OR effective OR efficacy), (cost OR cost effectiveness OR budget), (safe\* OR “adverse effects”) were not applied as the literatures retrieved from the above search gained poor results.

2. HTA databases were also searched- AHFMR, AETMIS database

3. Related links were also searched-ECRI, FDA, ICES

4. General search using Google search engine.

## **5. RESULTS & DISCUSSION**

### **5.1 SAFETY**

There were no evidences available on this matter from the selected databases.

### **5.2 EFFECTIVENESS**

There was poor quality evidence available regarding the effectiveness of the eye scanning devices for detecting recent drug abuse. However, there is a report from one pilot study done in a county probation centres in California, USA.<sup>6</sup>

In this study, 146 participants who were defendants on probation were tested using the standard urine test and the EyeCheck™ pupillometer. The author claimed that the device is effective in differentiating the drug impaired subjects from the normal person.<sup>6</sup> However, this study was lacking in reporting the sensitivity or specificity of the device (contrary to the title of the paper).

There was another observational study done by a forensic scientist at the roadside in Australia for detecting drug-impaired drivers.<sup>7</sup> In this study, the author compared roadside detection options, including: measurement of signs using DRE-type protocols; saliva testing; urine testing; observation of general signs of intoxication; and pupillometry (using the EyeCheck™). In this study it was found that EyeCheck™ has a sensitivity and specificity of 100% and 97.8% respectively with a PPV and NPV of 97.0% and 100% respectively. None of the patients stabilised on methadone returned a positive result.<sup>7</sup> However, the author did not state if any gold-standard test were used to validate the results of other tests. The author concluded that, although only pupillometry meets the criteria necessary for selection of a screening test, it will never be sufficient to be used as a confirmatory test.

In conclusion, there is poor evidence on the effectiveness of eye scanning device for detection of recent drug abuse.

### **5.3 COST IMPLICATIONS**

There were no studies done regarding the cost-effectiveness of the eye scanning devices. The only available information was the cost of the unit and anecdotal claims that the devices are cost effective.<sup>4,5</sup>

#### **5.3.1 PassPoint™**

The PassPoint™ system costs US\$53,333 (~RM200,000) per unit. The manufacturer claimed that large agencies can use PassPoint™ for as little as US 75 cents per test, while medium and smaller sized agencies can keep their cost under three dollars per test. It was said that PassPoint™ is most suitable for agencies administering at least 500 urine tests per month.<sup>6</sup>

#### **5.3.2 EyeCheck™**

This device costs about US\$10,000 (~RM38,000) per unit. However, the cost per test is zero, making this a more cost-effective option than saliva-testing after 400 tests have been done (anecdotal).<sup>7</sup>

### **5.4 LEGAL IMPLICATIONS**

There is a concern that the introduction of this device could lead to bad legal implications as there is no certainty of the false positives and false negatives rates. However, no literatures were retrieved regarding the legal aspect in use of eye scanner to detect recent drug abuse.

### **5.5 COMPETING TECHNOLOGIES**

There are five primary types of drug tests: urine, blood, hair, saliva, and sweat. The most common is the urine test which has the benefit of being inexpensive and less intrusive than the blood test.

The National Institute on Drug Abuse (NIDA) in the United States required any testing program must test for 5 specific categories of drugs (sometimes referred to as the "NIDA 5"). Because of this requirement, most drug testing companies offer a basic drug test that checks for drugs in these 5 common categories, which include:

1. Cannabinoids (marijuana, hash)
2. Cocaine (cocaine, crack, benzoylecognine)
3. Amphetamines (amphetamines, methamphetamines, speed)
4. Opiates (heroin, opium, codeine, morphine)
5. Phencyclidine (PCP)

Most drug testing companies also offer an expanded test which includes a few additional drugs in the testing process. Most do not add all of these in their expanded test, but choose a different combination of 3 or 4 to add either barbiturates (Phenobarbital, Secobarbital, Butalbital), Hydrocodone (Lortab, Vicodin), Methaqualone (Qualuudes), Benzodiazepines (Valium, Xanax, Librium, Serax, Rohypnol), Methadone, Propoxyphene (Darvon compounds), Ethanol (Alcohol), or MDMA (Ecstasy)

Laboratory-based drug testing is done in a two-tiered fashion using two different types of detection methods. The first is known as the screening test, and this is applied to all samples that go through the lab. The second, known as the confirmation test, is only applied to samples that test positive during the screening test. Screening tests are usually done by immunoassay (EMIT for urine and blood, and ELISA for hair). The screening tests are typically less sensitive and more prone to false positives and false negatives than the confirmation test. Once a suspected positive sample is detected during screening, the sample is flagged and tested using the confirmation test. Samples that are negative on the screening test are discarded and reported as negative. The confirmation test in most labs is performed using mass spectrometry, and is extremely precise but also fairly expensive to run. False positive samples from the screening test will be negative on the confirmation test. Samples testing positive during both screening and confirmation tests are reported as positive to the entity that ordered the test. Most labs save positive samples for some period of months or years in the event of a disputed result or lawsuit.

The Substance Abuse and Mental Health Services Association (SAMHSA) of the United States provides guidelines for what qualifies as a positive drug test. If a test does not give results higher than the guidelines, it does not qualify as a "positive" test. If an immunoassay test gives positive results, a second Gas Chromatography

test must also give positive results before a result of "positive" is announced. The following chart shows the guidelines by substance.

<b>SUBSTANCE</b>	<b>IMMUNOASSAY</b>	<b>GC / MS</b>
Cannabis	50 ng/ml	15 ng/ml
Cocaine	300 ng/ml	150 ng/ml
Opiates	300 ng/ml	300 ng/ml
Amphetamines	1000 ng/ml	500 ng/ml
PCP	25 ng/ml	25 ng/ml

The following chart gives approximate detection periods for each substance by test type. The ranges depend on amount and frequency of use, metabolic rate, body mass, age, overall health, and urine pH. Urine can not detect current drug use. It takes approximately 6-8 hrs. post-consumption for drug to be metabolized and excreted in urine. Similarly, hair requires two weeks, and sweat, seven days.<sup>19</sup>

<b>SUBSTANCE</b>	<b>URINE</b>	<b>HAIR</b>	<b>BLOOD</b>
Alcohol	24 hours	N/A	12 hours
Amphetamines (except meth)	2 to 3 days	up to 90 days	12 hours
Methamphetamine	2 to 5 days	up to 90 days	24 hours
Barbiturates (except phenobarbital)	2 to 3 days	up to 90 days	1 to 2 days
Phenobarbital	7 to 14 days	up to 90 days	4 to 7 days
Benzodiazepines	1 to 5 days	up to 90 days	6 to 48 hours
Cannabis (single use)	1 to 3 days	up to 90 days	24 hours
Cannabis (habitual use)	up to 84 days	up to 90 days	2 days
Cocaine	1 to 3 days	up to 90 days	24 hours
Codeine	2 to 3 days	up to 90 days	12 hours
Cotinine (a break-down product of nicotine)	2 to 4 days	up to 90 days	2 to 4 days
Morphine	2 to 3 days	up to 90 days	6 hours
Heroin	2 to 3 days	up to 90 days	6 hours
LSD	2 to 24 hours	unknown	0 to 3 hours
PCP	5 to 7 days	up to 90 days	24 hours

### 5.5.1 Urine drug/ toxicology test

This procedure requires that one provide a sample of urine. A test card is used on site for immediate results or the sample is sent to a lab to undergo gas chromatography/ mass spectrometry (GCMS), high performance liquid chromatography or immunoassay analysis. It is able to detect use primarily within the past week (longer with regular use), however the results can be affected by abstaining from use for a period of time before the test.

In a study done to assess the precision in three commercial drugs-of-abuse immunoassay systems below the SAMHSA-dictated cutoffs for amphetamines, opiates, benzoylecgonine, phencyclidine, and cannabinoids, it was found that the accuracy of urine drug-screening results between the SAMHSA-specified cutoffs and the precision-based cutoffs was less than accuracy for specimens above the SAMHSA cutoffs. However, the use of the precision-based cutoff produced a 15.6% increase in the number of screen-positive specimens and a 7.8% increase in the detection of specimens that yielded positive results on confirmatory testing.<sup>11</sup>

#### 5.5.2 Oral fluid/ saliva test

This test is considered a relatively unintrusive method of drug testing and becoming more common. It is able to detect use primarily within the past few days and was said to be able to detect more recent use than other testing methods. However, it has no accepted standards or cutoff concentrations for detection, making results greatly dependent on the specific product purchased.

In a study that reported the development and validation of a single extraction procedure for a wide range of licit and illicit drugs with subsequent analysis by both Gas chromatography–mass spectrometry (GC–MS) and liquid chromatography–mass spectrometry (LC–MS) found that a single extraction method to detect 49 licit and illicit drugs from 1 mL of oral fluid using both GC–MS and LC–MS was successfully validated. This method was found to be sensitive and selective for the analysis of drugs in oral fluid.<sup>13</sup>

In an external quality assessment (proficiency testing), the sensitivity of saliva testing for the amphetamine specific assay was 50%, methyl-amphetamines 93%, barbiturates 64%, cannabinoids 73%, cocaine and metabolites 100%, benzodiazepines 69%, methadone 95%, opiates 79% (opiates excluding oxycodone 93%), phencyclidine 93% and human gamma-globulin 97%.<sup>14</sup>

#### 5.5.3 Hair analysis

Hair analysis is considered a relatively unintrusive method of drug testing. It costs several times more expensive than urine tests (~USD\$100-\$150). In a hair analysis for drug abuse, it requires a sample of hair about the diameter of a pencil and 1.5 inches long and it cannot be done with a single hair. It is able to detect substance use over a longer period, and do not usually detect use within the past week. This test is not affected by brief periods of abstinence from drugs.



In a study done to verify the sensitivity of the immunoassay hair test in admitted cocaine users of the hair test using found that the sensitivity and specificity of the test was 97% and 100% respectively.<sup>15</sup>

#### 5.5.4 Sweat (patch) test

This test is considered a relatively intrusive method of drug testing because it requires the wearing of a patch for an extended period of time. It is still relatively uncommon and is controversial in terms of accuracy.

In two studies done at the Addiction Research Center in the US found that for the sweat patch detection of concurrent cocaine use, the sensitivity was 96.7%, specificity 60.5% and efficiency 77.7%; and for opiate use, the corresponding values were 68.6, 86.1 and 78.6%. The relatively low values for specificity and efficiency raise concern whether sweat patch testing is the appropriate methodology to be used, when false positives can lead to serious or adverse action against the test subject.<sup>17, 18</sup>

#### 5.5.5 Blood drug/ toxicology test

This test is considered the most intrusive method of testing. Although it is the most expensive method of testing, it is the most accurate method of testing. However, it is the least common method of testing (most likely due to cost). The blood sample is then sent for either immunoassay and/or mass chromatography for testing presence of drug analytes. The cut-off value for a positive test still complies with the value set by the SAMHSA.

## **6. CONCLUSION**

There is insufficient good quality evidence to support the use of the eye scanning device in detecting recent drug abuse. To date, the urine and blood test using immunoassay remain the standard methods for screening drug abuse.

## **7. APPENDIX**

### **8.1 Search strategy table**

## **8. REFERENCES**

1. Agensi Dadah Kebangsaan, Kementerian Keselamatan Dalam Negara. [www.adk.gov.my](http://www.adk.gov.my)
2. Dolan K, Rouen D & Kimber J. an overview of the use of urine, hair, sweat and saliva to detect drug use. *Drug and Alcohol Review* 2004;23: 213-217
3. Arshad Khan & Ali Mahmood. Guru Wajib Ujian Dadah-Jalani Pemeriksaan Guna Mesin Pengimbas Mata Mulai Mei. *Utusan Malaysia* 27 April 2006 .Page 1.
4. [www.passpoint.org](http://www.passpoint.org)
5. [www.mcjeyecheck.com](http://www.mcjeyecheck.com)
6. Richman J, Noriega RS. The sensitivity and specificity of infrared pupillometry measurements in identifying drug impairment in a county probation program. *Forensics Drug Study*. <http://www.mcjeyecheck.com/text/studies/forensics...>
7. Hoskins B. Roadside Detection of Drug-Impaired Driving. WPMO 2005, 7th International Conference On Clinical Forensic Medicine Of The World Police Medical Officers
8. Drug test-Wikipedia, the free encyclopedia [http://en.wikipedia.org/wiki/drug\\_test](http://en.wikipedia.org/wiki/drug_test)
9. A Huestis, ML Smith. Modern analytical technologies for the detection of drug abuse and doping. *Drug Discovery Today: Technologies*. 2006; 3(1):49-57
10. Substance Abuse and Mental Health Services Association (SAMHSA) <http://www.samhsa.gov>
11. Veronica I. Luzzi, Al N. Saunders, John W. Koenig, John Turk, Stanley F. Lo, Uttam C. Garg, and Dennis J. Dietzen. Analytic Performance of Immunoassays for Drugs of Abuse Below Established Cutoff Values. *Clinical Chemistry* 50:4:717–722 (2004)
12. Catherine A. Hammett-Stabler, Amadeo J. Pesce, Donald J. Cannon. Review: Urine drug screening in the medical setting. *Clinica Chimica Acta* 315:2002.125–135
13. F.M. Wylie, H. Torrance, R.A. Anderson, J.S. Oliver. *Forensic Science International* 150 (2005) 191–198. Drugs in oral fluid Part I. Validation of an analytical procedure for licit and illicit drugs in oral fluid.
14. J. Clarke, J.F. Wilson. Proficiency testing (external quality assessment) of drug detection in oral fluid. *Forensic Science International* 150 (2005) 161–164
15. Franca Ursitti, Julia Klein, Edward Sellers, and Gideon Koren. Use of Hair Analysis for Confirmation of Self-Reported Cocaine Use in Users with Negative Urine Tests. *Clinical Toxicology*, 39(4), 361–366 (2001)
16. KL Preston, MA Huestis, CJ Wong, A Umbricht, BA Goldberger, EJ Cone. Monitoring cocaine use in substance abuse treatment patients by sweat and urine testing. *J Anal Toxicol* 1999; 23 : 313-321
17. MA Huestis, EJ Cone, CJ Wong, A Umbricht, KL Preston. Monitoring opiate use in substance abuse treatment patients by sweat and urine testing. *J Anal Toxicol* 2000; 24: 509-521
18. [http://en.wikipedia.org/wiki/Drug\\_test](http://en.wikipedia.org/wiki/Drug_test)

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Appendix 8.1

**SEARCH STRATEGY**

Date	Database	Keywords	Year Publications	Other limit	No of search	No of relevant title	No of relevant abstract	No of full article used	Notes
31/5/06	PUBMED	-“drug abuse” AND screen*	No limits	No limits	611				
		-“drug abuse” AND screen* AND eye			4	1			
		-“drug abuse” AND screen* AND “eye scan”			0				
		-“drug abuse” AND screen* AND “ocular measure*”			0				
31/5/06	EBSCO	-“drug abuse” AND screening	No limits	No limits	177	24			
1/6/06	PUBMED	- pupillometer OR pupillometry			358				
		-(pupillometer OR pupillometry) AND (“drug abuse” OR “drug screen*”)			2				
8/6/06	OVID	- pupillometer OR pupillometry			0				
		-“pupillary measure\$”			35				

		-“drug screen\$”			2832				
		-“pupillary measure\$” AND “drug screen\$”			1	0			
		-“ocular measur\$”			50				
		-“ocular measur\$” AND “drug screen\$”			0				
9/6/06	EBSCO	-pupillometer OR pupillometry			47				
		-(pupillometer OR pupillometry) AND drug			5	0			
		-(pupillometer OR pupillometry) AND (“drug screen” OR “drug abuse”)			0				
		-ocular measurement			1	0			
		-ocular measure			0				
		-pupillary measure			4	0			
12/6/06	AETMIS	-pupillometry			0				
		-pupillometer			0				
	AHFMR	-pupillometer			0				
		-pupillometry			0				
		-“drug screen”			0				
		-“drug screening”			0				
	ICES	-pupillometer			0				
		-pupillometry			0				
		-“drug screen”			0				
		-“drug screening”			0				
		-“drug abuse”			0				
	FDA	-pupillometer			68				

		search within result for: -drug			30				
		-drug screening			6 hits	25 types of pupillometer			
		search within listing for: -passpoint -eyecheck					0 1	0	
	ECRI	-pupillometer			6	0			
		-passpoint			0				
		-eyecheck			0				
	Blackwell Synergy	-pupillometer OR pupillometry			22				
		search within result: -drug screening			2	0			