LumiQuick Diagnostics, Inc.
2946 Scott Blvd., Santa Clara, CA 95054, USA

Tel: 408-855-0061
Fax: 408-855-0063
E-mail: info@LumiQuick.com
Web: www.lumiquick.com

Declaration of Conformity

PRODUCT IDENTIFICATION	
Product name	**Model/number**
Drugs of Abuse Test Devices See attachment for complete list of items in this family	

MANUFACTURER		
Name of company	**Address**	**Representative**
LumiQuick Diagnostics, Inc.	2946 Scott Blvd. Santa Clara, CA 95054 USA	Jeff Wang

AUTHORIZED REPRESENTATIVE		
Name of company	**Address**	**Telephone/email**
Emergo Europe	Prinsessegracht 20 2514 AP The Hague, Netherlands	+31.70.345.8570 - phone +31.70.346.7299 - fax service@emergogroup.com

CONFORMITY ASSESSMENT		
Device classification	**Route to compliance**	**Standards applied**
Class: Self-Certify	Annex III of IVDD 98/97/EC Council Directive	ISO 13485:2003

LumiQuick Diagnostics, Inc. declares that the above mentioned products meet the provision of the Council Directive 98/79/EC for In Vitro Diagnostic Medical Devices and Directive 98/79/EC as transposed in the national laws of the Member States.

COMPANY REPRESENTATIVE: Jeff Wang

TITLE: Quality Systems Manager **SIGNATURE:**

DATE: 24/09/2017

Digitally signed by Monastîrschii Viorica
Date: 2022.04.05 10:41:50 EEST
Reason: MoldSign Signature
Location: Moldova

LumiQuick Diagnostics, Inc.
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ATTACHMENT

	Product name	Model/number
1	QuickProfile Saliva Alcohol Test Strip	74001
2	QuickProfile Tramadol Test Card	74002
3	QuickProfile Tramadol Test Strip	74003
4	QuickProfile DOA-2 Panel Test	74004
5	QuickProfile DOA Panel 2 Test (MET / THC)	74004-01
6	QuickProfile DOA Panel 2 Test (OPI / THC)	74004-02
7	QuickProfile DOA-2 Panel Test Card	74004-TC
8	QuickProfile DOA-3 Panel Test	74005
9	QuickProfile DOA Panel 3 Test (AMP / COC / THC)	74005-01
10	QuickProfile DOA-3 Panel Test Card	74005-TC
11	QuickProfile DOA-4 Panel Test	74006
12	QuickProfile DOA-4 Panel Test Card	74006-TC
13	QuickProfile DOA-5 Panel Test	74007
14	QuickProfile DOA Panel 5 Test (AMP / BZO / COC / OPI / THC)	74007-01
15	QuickProfile DOA Panel 5 Test (MET / BZO / COC / OPI / THC)	74007-02
16	QuickProfile DOA-5 Panel Test-24M	74007-24M
17	QuickProfile DOA-5 Panel Test Card	74007-TC
18	QuickProfile DOA-6 Panel Test	74008
19	QuickProfile DOA Panel 6 Test (AMP / BAR / BZO / COC /OPI / THC)	74008-01
20	QuickProfile DOA Panel 6 Test (AMP / BZO / COC / MET /OPI / THC)	74008-02
21	QuickProfile DOA Panel 6 Test (AMP / COC / MET /OPI / PCP / THC)	74008-03
22	QuickProfile DOA-6 Panel Test-24M	74008-24M
23	QuickProfile DOA-6 Panel Test Card	74008-TC
24	QuickProfile DOA-7 Panel Test	74009
25	QuickProfile DOA-7 Panel Test Card	74009-TC
26	QuickProfile DOA-8 Panel Test	74010
27	QuickProfile DOA-8 Panel Test Card	74010-TC
28	QuickProfile DOA-9 Panel Test	74011
29	QuickProfile DOA Panel 9 Test (AMP / BAR / BZD / COC / MET / MTD / OPI / PCP / THC)	74011-01
30	QuickProfile DOA-9 Panel Test Card	74011-TC
31	QuickProfile DOA-10 Panel Test	74012
32	QuickProfile DOA-10 Panel Test Card	74012-TC
33	QuickProfile Amphetamine Test Strip	74013
34	QuickProfile Amphetamine Test Card	74014
35	QuickProfile Barbiturate Test Strip	74015
36	QuickProfile Barbiturate Test Card	74016
37	QuickProfile Benzodiazepine Test Strip	74017
38	QuickProfile Benzodiazepine Test Card	74018
39	QuickProfile Cocaine Test Strip	74019
40	QuickProfile Cocaine Test Card	74020
41	QuickProfile EDDP Test Strip	74021
42	QuickProfile EDDP Test Card	74022
43	QuickProfile MDMA/Ecstasy Test Strip	74023
44	QuickProfile MDMA/Ecstasy Test Card	74024
45	QuickProfile Methadone Test Strip	74025
46	QuickProfile Methadone Test Card	74026
47	QuickProfile Methamphetamine Test Strip	74027
48	QuickProfile Methamphetamine Test Card	74028
49	QuickProfile Methamphetamine Test Card-24M	74028-24M
50	QuickProfile Morphine Test Strip	74029
51	QuickProfile Morphine Test Card	74030
52	QuickProfile Morphine Test Strip-(2000)	74031
53	QuickProfile Morphine Test Card-(2000)	74032
54	QuickProfile PCP Test Strip	74033
55	QuickProfile PCP Test Card	74034
56	QuickProfile THC Test Strip	74035
57	QuickProfile THC Test Card	74036
58	QuickProfile TCA Test Strip	74037
59	QuickProfile TCA Test Card	74038
60	QuickProfile Ketamine Test Strip	74039

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61	QuickProfile Ketamine Test Card	74040
62	QuickProfile Buprenorphine Test Strip	74041
63	QuickProfile Buprenorphine Test Card	74042
64	QuickProfile Oxycodone Test Strip	74043
65	QuickProfile Oxycodone Test Card	74044
66	QuickProfile Drug of Abuse Test Cup	74046
67	QuickProfile DOA Test Cup - CYND	74046-II
68	QuickProfile Urine Alcohol Test Strip	74049
69	QuickProfile Urine Alcohol Test Card	74050
70	QuickProfile Propoxyphene Test Strip	74051
71	QuickProfile Propoxyphene Test Card	74052
72	QuickProfile DOA-11 Panel Test	74053
73	QuickProfile DOA-11 Panel Test Card	74053-TC
74	QuickProfile DOA-12 Panel Test	74054
75	QuickProfile DOA-12 Panel Test Card	74054-TC
76	QuickProfile Methylphenidate (MPD) Test Strip	74055
77	QuickProfile Methylphenidate (MPD) Test Card	74056
78	QuickProfile Fentanyl Test Strip	74057
79	QuickProfile Fentanyl Test Card	74058
80	QuickProfile Clonazepam (7-ACL) Test Strip	74059
81	QuickProfile Clonazepam (7-ACL) Test Card	74060
82	QuickProfile Cotinine Test Strip	74061
83	QuickProfile Cotinine Test Card	74062
84	QuickProfile K2 Test Strip	74065
85	QuickProfile K2 Test Card	74066
86	QuickProfile Ethyl Glucuronide (EtG) Test Strip	74075
87	QuickProfile Ethyl Glucuronide (EtG) Test card	74076

INITIAL: Jiwgo

24/09/2017

EMERGO EUROPE

24 March 2009

Mr. Jeff Wang
LumiQuick Diagnostics, Inc.
2946 Scott Blvd.
Santa Clara, CA 95054

Dear Mr.Jeff Wang:

I am writing to inform you that today, we have notified by registered mail the Competent Authority in the following countries:

Austria	Bulgaria	Cyprus	Czech Republic	Denmark	Estonia
Finland	France	Germany	Greece	Hungary	Iceland
Ireland	Italy	Latvia	Liechtenstein	Lithuania	Luxembourg
Malta	The Netherlands		Norway	Poland	Portugal
Romania	Slovakia	Slovenia	Spain	Sweden	Switzerland
United Kingdom					

With this notification, LumiQuick Diagnostics, Inc. has met the requirements of the In-vitro Diagnostics Directive, 98/79/EC for the following devices:

- Adeno/Rota Virus
- Cardiac Marker
- Dengue IgG/IgM Combo (registered only in Italy and The Netherlands)
- Drugs of Abuse
- Fecal Occult Blood (registered only in Italy and The Netherlands)
- H. Pylori Ab/Ag
- HCG
- Legionella (registered only in Italy and The Netherlands)
- LH (registered only in Italy and The Netherlands)
- Strep A (registered only in Italy and The Netherlands)

As of today and without any further notice from the respective Competent Authorities, LumiQuick Diagnostics, Inc. can consider the respective devices and Authorized Representative as officially registered.

If you have any questions, please do not hesitate to contact me.

Yours sincerely,

Rene van de Zande
President & CEO
Emergo Europe

CIBG
Ministerie van Volksgezondheid, Welzijn en Sport

> Retouradres Postbus 16114 2500 BC Den Haag

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T.a.v. mevrouw D. Tummers
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medische_hulpmiddelen@minvws.nl

Ons kenmerk:
CIBG/Informatie/ 20132435

Bijlagen
-

Uw aanvraag
15 november 2013

Het CIBG is een uitvoeringsorganisatie van het Ministerie van Volksgezondheid, Welzijn en Sport

Correspondentie uitsluitend richten aan het retouradres met vermelding van de datum en het kenmerk van deze brief.

Datum: 5 december 2013
Betreft: aanmelding In-vitro diagnostica

Geachte mevrouw Tummers,

Op 15 november 2013 ontving ik uw notificatie krachtens artikel 4, eerste lid van het Nederlandse Besluit in-vitro diagnostica (BIVD) om onder de bedrijfsnaam LumiQuick Diagnostics Inc. met Europees gemachtigde Emergo Europe B.V. onderstaande producten als in-vitro diagnostica op de Europese markt te brengen.

De producten staan geregistreerd als in-vitro diagnostica onder nummer:

QuickProfile Tramadol Test Card, QuickProfile Tramadol Test Strip, QuickProfile Amphetamine Test Strip, QuickProfile Amphetamine Test Card, QuickProfile Barbiturate Test Strip, QuickProfile Barbiturate Test Card
(NL-CA002-2013-30041)

QuickProfile Benzodiazepine Test Strip, QuickProfile Benzodiazepine Test Card, QuickProfile Cocaine Test Strip, QuickProfile Cocaine Test Card, QuickProfile EDDP Test Strip, QuickProfile EDDP Test Card
(NL-CA002-2013-30042)

QuickProfile MDMA/Ecstasy Test Strip, QuickProfile MDMA/Ecstasy Test Card, QuickProfile Methadone Test Strip, QuickProfile Methadone Test Card, QuickProfile Methamphetamine Test Strip, QuickProfile Methamphetamine Test Card
(NL-CA002-2013-30043)

QuickProfile Morphine Test Strip, QuickProfile Morphine Test Card, QuickProfile Morphine Test Strip –(2000), QuickProfile Morphine Test Card – (2000), QuickProfile PCP Test Strip, QuickProfile PCP Test Card
(NL-CA002-2013-30044)

QuickProfile THC Test Strip, QuickProfile THC Test Card, QuickProfile TCA Strip QuickProfile TCA Test Card, QuickProfile Ketamine Test Strip, QuickProfile Ketamine Test Card
(NL-CA002-2013-30045)

QuickProfile Buprenorphine Test Strip, QuickProfile Buprenorphine Test Card, QuickProfile Oxycodone Test Strip, QuickProfile Oxycodone Test Card, QuickProfile Propoxyphene Test Strip, QuickProfile Propoxyphene Test Card
(NL-CA002-2013-30046)

QuickProfile Saliva Alcohol Test Strip
(NL-CA002-2013-30047)

Hiermee heeft u voldaan aan uw verplichting op grond van artikel 4, BIVD.

In alle verdere correspondentie betreffende bovenvermelde producten verzoek ik u deze nummers te vermelden. Aan deze nummers kunnen geen verdere rechten ontleend worden, ze dienen alleen om de notificatie administratief te vergemakkelijken.

De registratie van in-vitro diagnostica als medisch hulpmiddel op grond van de Classificatiecriteria (Bijlage II) bij Richtlijn 98/79/EG betreffende medische hulpmiddelen voor in-vitro diagnostiek is onderhevig aan mogelijke revisies van Europese regelgeving inzake de classificatie van medische hulpmiddelen en aan voortschrijdend wetenschappelijk inzicht (zie artikel artikel 10, eerste lid van Richtlijn 98/79/EG).

Notificatie van in-vitro diagnostische medische hulpmiddelen impliceert dat de fabrikant, LumiQuick Diagnostics Inc. de CE-conformiteitsmarkering heeft aangebracht op de desbetreffende producten alvorens deze in een EU-lidstaat in de handel te brengen. Zodoende garandeert Emergo Europe B.V. dat de in-vitro diagnostica voldoen aan de essentiële eisen zoals opgenomen in bijlage I bij Richtlijn 98/79/EG (en in het daarmee corresponderende onderdeel 1 bij het besluit)

Volledigheidshalve wijzen wij u erop dat een in-vitro diagnosticum moet voldoen aan de eisen uit het BIVD. Het BIVD is gebaseerd op Richtlijn voor in-vitro diagnostiek, 98/79/EG. Met name wijzen wij u op de Nederlandse-taaleis zoals deze in Nederland geldt, de eisen voor het ter beschikking houden van de technische documentatie en de plicht tot het hebben van een Post Marketing Surveillance- en vigilantiesysteem.

Tot slot merk ik op dat met uw notificatie - de administratieve notificatie als fabrikant - en deze brief geen sprake is van een oordeel over de status of kwalificatie van uw product: notificering betekent niet dat daadwerkelijk sprake is van een in-vitro diagnosticum in de zin van de onderhavige wet- en regelgeving. In voorkomende gevallen kan de Inspectie voor de Gezondheidszorg, belast met het toezicht op de naleving van het bij of krachtens de wet bepaalde, een standpunt innemen over de status van een product, waarbij het volgens vaste jurisprudentie uiteindelijk aan de nationale rechter is om te bepalen of een product onder de definitie van in-vitro diagnosticum valt.

De Minister van Volksgezondheid, Welzijn en Sport,
namens dezen,
Farmatec | CIBG

Mevrouw drs. I. van den Berg
Hoofd cluster Informatie

CIBG
Ministerie van Volksgezondheid, Welzijn en Sport

> Retouradres Postbus 16114 2500 BC Den Haag

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Ons kenmerk:
CIBG/Informatie/ 20132523

Bijlagen
-

Uw aanvraag
26 november 2013

Het CIBG is een uitvoeringsorganisatie van het Ministerie van Volksgezondheid, Welzijn en Sport

Correspondentie uitsluitend richten aan het retouradres met vermelding van de datum en het kenmerk van deze brief.

Datum: 3 februari 2014
Betreft: aanmelding In-vitro diagnostica

Geachte mevrouw Tummers,

Op 26 november 2013 ontving ik uw notificatie krachtens artikel 4, eerste lid van het Nederlandse Besluit in-vitro diagnostica (BIVD) om onder de bedrijfsnaam LumiQuick Diagnostics Inc. met Europees gemachtigde Emergo Europe B.V. onderstaande producten als in-vitro diagnostica op de Europese markt te brengen.

De producten staan geregistreerd als in-vitro diagnostica onder nummer:

Drugs of Abuse Test Devices
QuickProfile Methylphenidate (MPD) Test Strip
QuickProfile Methylphenidate (MPD) Test Card
(NL-CA002-2014-30166)
QuickProfile Fentanyl Test Strip
QuickProfile Fentanyl Test Card
(NL-CA002-2014-30167)
QuickProfile Clonazepam Strip
QuickProfile Clonazepam Test Card
(NL-CA002-2014-30168)
QuickProfile Cotinine Test Strip
QuickProfile Cotinine Test Card
(NL-CA002-2014-30169)
QuickProfile K2 Test Strip
QuickProfile K2 Test Card
(NL-CA002-2014-30170)

Hiermee heeft u voldaan aan uw verplichting op grond van artikel 4, BIVD.

In alle verdere correspondentie betreffende bovenvermelde producten verzoek ik u deze nummers te vermelden. Aan deze nummers kunnen geen verdere rechten ontleend worden, ze dienen alleen om de notificatie administratief te vergemakkelijken.

De registratie van in-vitro diagnostica als medisch hulpmiddel op grond van de Classificatiecriteria (Bijlage II) bij Richtlijn 98/79/EG betreffende medische hulpmiddelen voor in-vitro diagnostiek is onderhevig aan mogelijke revisies van Europese regelgeving inzake de classificatie van medische hulpmiddelen en aan voortschrijdend wetenschappelijk inzicht (zie artikel artikel 10, eerste lid van Richtlijn 98/79/EG).

Notificatie van in-vitro diagnostische medische hulpmiddelen impliceert dat de fabrikant, LumiQuick Diagnostics Inc. de CE-conformiteitsmarkering heeft aangebracht op de desbetreffende producten alvorens deze in een EU-lidstaat in de handel te brengen. Zodoende garandeert Emergo Europe B.V. dat de in-vitro diagnostica voldoen aan de essentiële eisen zoals opgenomen in bijlage I bij Richtlijn 98/79/EG (en in het daarmee corresponderende onderdeel 1 bij het besluit)

Volledigheidshalve wijzen wij u erop dat een in-vitro diagnosticum moet voldoen aan de eisen uit het BIVD. Het BIVD is gebaseerd op Richtlijn voor in-vitro diagnostiek, 98/79/EG. Met name wijzen wij u op de Nederlandse-taaleis zoals deze in Nederland geldt, de eisen voor het ter beschikking houden van de technische documentatie en de plicht tot het hebben van een Post Marketing Surveillance- en vigilantiesysteem.

Tot slot merk ik op dat met uw notificatie - de administratieve notificatie als fabrikant - en deze brief geen sprake is van een oordeel over de status of kwalificatie van uw product: notificering betekent niet dat daadwerkelijk sprake is van een in-vitro diagnosticum in de zin van de onderhavige wet- en regelgeving. In voorkomende gevallen kan de Inspectie voor de Gezondheidszorg, belast met het toezicht op de naleving van het bij of krachtens de wet bepaalde, een standpunt innemen over de status van een product, waarbij het volgens vaste jurisprudentie uiteindelijk aan de nationale rechter is om te bepalen of een product onder de definitie van in-vitro diagnosticum valt.

De Minister van Volksgezondheid, Welzijn en Sport,
namens dezen,
Farmatec | CIBG

De heer dr. M.J. van de Velde, MBA
Clusterhoofd Farma

CIBG
Ministerie van Volksgezondheid, Welzijn en Sport

> Retouradres Postbus 16114 2500 BC Den Haag

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medische_hulpmiddelen@minvws.nl

Ons kenmerk:
CIBG/Informatie/ 20132522

Bijlagen
-

Uw aanvraag
26 november 2013

Het CIBG is een uitvoeringsorganisatie van het Ministerie van Volksgezondheid, Welzijn en Sport

Correspondentie uitsluitend richten aan het retouradres met vermelding van de datum en het kenmerk van deze brief.

Datum: 3 februari 2014
Betreft: aanmelding In-vitro diagnostica

Geachte mevrouw Tummers,

Op 26 november 2013 ontving ik uw notificatie krachtens artikel 4, eerste lid van het Nederlandse Besluit in-vitro diagnostica (BIVD) om onder de bedrijfsnaam LumiQuick Diagnostics Inc. met Europees gemachtigde Emergo Europe B.V. onderstaande producten als in-vitro diagnostica op de Europese markt te brengen.

De producten staan geregistreerd als in-vitro diagnostica onder nummer:

Drugs of Abuse Test Devices
QuickProfile DOA-2 Panel Test
QuickProfile DOA-2 Panel Test Card
QuickProfile DOA-3 Panel Test
QuickProfile DOA-3 Panel Test Card
QuickProfile DOA-4 Panel Test
QuickProfile DOA-4 Panel Test Card
(NL-CA002-2014-30160)
QuickProfile DOA-5 Panel Test
QuickProfile DOA-5 Panel Test Card
QuickProfile DOA-6 Panel Test
QuickProfile DOA-6 Panel Test Card
QuickProfile DOA-7 Panel Test
QuickProfile DOA-7 Panel Test Card
(NL-CA002-2014-30161)
QuickProfile DOA-8 Panel Test
QuickProfile DOA-8 Panel Test Card
QuickProfile DOA-9 Panel Test
QuickProfile DOA-9 Panel Test Card
QuickProfile DOA-10 Panel Test
QuickProfile DOA-10 Panel Test Card
(NL-CA002-2014-30162)
QuickProfile DOA-11 Panel Test
QuickProfile DOA-11 Panel Test Card
QuickProfile DOA-12 Panel Test
QuickProfile DOA-12 Panel Test Card
(NL-CA002-2014-30163)

Drugs of Abuse Test Devices
QuickProfile Drug of Abuse Test Cup
QuickProfile Drug of Abuse Test Cup - CYND
(NL-CA002-2014-30164)

QuickProfile Urine Alcohol Test Strip
QuickProfile Urine Alcohol Test Card
(NL-CA002-2014-30165)

Hiermee heeft u voldaan aan uw verplichting op grond van artikel 4, BIVD.

In alle verdere correspondentie betreffende bovenvermelde producten verzoek ik u deze nummers te vermelden. Aan deze nummers kunnen geen verdere rechten ontleend worden, ze dienen alleen om de notificatie administratief te vergemakkelijken.

De registratie van in-vitro diagnostica als medisch hulpmiddel op grond van de Classificatiecriteria (Bijlage II) bij Richtlijn 98/79/EG betreffende medische hulpmiddelen voor in-vitro diagnostiek is onderhevig aan mogelijke revisies van Europese regelgeving inzake de classificatie van medische hulpmiddelen en aan voortschrijdend wetenschappelijk inzicht (zie artikel artikel 10, eerste lid van Richtlijn 98/79/EG).

Notificatie van in-vitro diagnostische medische hulpmiddelen impliceert dat de fabrikant, LumiQuick Diagnostics Inc. de CE-conformiteitsmarkering heeft aangebracht op de desbetreffende producten alvorens deze in een EU-lidstaat in de handel te brengen. Zodoende garandeert Emergo Europe B.V. dat de in-vitro diagnostica voldoen aan de essentiële eisen zoals opgenomen in bijlage I bij Richtlijn 98/79/EG (en in het daarmee corresponderende onderdeel 1 bij het besluit)

Volledigheidshalve wijzen wij u erop dat een in-vitro diagnosticum moet voldoen aan de eisen uit het BIVD. Het BIVD is gebaseerd op Richtlijn voor in-vitro diagnostiek, 98/79/EG. Met name wijzen wij u op de Nederlandse-taaleis zoals deze in Nederland geldt, de eisen voor het ter beschikking houden van de technische documentatie en de plicht tot het hebben van een Post Marketing Surveillance- en vigilantiesysteem.

Tot slot merk ik op dat met uw notificatie - de administratieve notificatie als fabrikant - en deze brief geen sprake is van een oordeel over de status of kwalificatie van uw product: notificering betekent niet dat daadwerkelijk sprake is van een in-vitro diagnosticum in de zin van de onderhavige wet- en regelgeving. In voorkomende gevallen kan de Inspectie voor de Gezondheidszorg, belast met het toezicht op de naleving van het bij of krachtens de wet bepaalde, een standpunt innemen over de status van een product, waarbij het volgens vaste jurisprudentie uiteindelijk aan de nationale rechter is om te bepalen of een product onder de definitie van in-vitro diagnosticum valt.

De Minister van Volksgezondheid, Welzijn en Sport,
namens dezen,
Farmatec | CIBG

De heer dr. M.J. van de Velde, MBA
Clusterhoofd Farma

CIBG
Ministerie van Volksgezondheid, Welzijn en Sport

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medische_hulpmiddelen@
minvws.nl

Ons kenmerk:
CIBG-20172751

Bijlagen
-

Uw aanvraag
23 oktober 2017

Correspondentie uitsluitend richten aan het retouradres met vermelding van de datum en het kenmerk van deze brief.

Datum: 29 november 2017
Betreft: aanmelding In-vitro diagnostica

Geachte mevrouw Tummers,

Op 23 oktober 2017 ontving ik uw notificatie krachtens artikel 4, eerste lid van het Nederlandse Besluit in-vitro diagnostica (BIVD) om onder de bedrijfsnaam LumiQuick Diagnostics Inc. met Europees gemachtigde Emergo Europe B.V. onderstaand product als in-vitro diagnosticum op de Europese markt te brengen.

Het product staat geregistreerd als in-vitro diagnosticum onder nummer:

Drugs of Abuse Test Devices
QuickProfile Ethyl Glucuronide (EtG) Test Strip
QuickProfile Ethyl Glucuronide (EtG) Test card
(NL-CA002-2017-43151)

Hiermee heeft u voldaan aan uw verplichting op grond van artikel 4, BIVD.

In alle verdere correspondentie betreffende bovenvermeld product verzoek ik u dit nummer te vermelden. Aan dit nummer kunnen geen verdere rechten ontleend worden, het dient alleen om de notificatie administratief te vergemakkelijken.

De registratie van in-vitro diagnostica als medisch hulpmiddel op grond van de Classificatiecriteria (Bijlage II) bij Richtlijn 98/79/EG betreffende medische hulpmiddelen voor in-vitro diagnostiek is onderhevig aan mogelijke revisies van Europese regelgeving inzake de classificatie van medische hulpmiddelen en aan voortschrijdend wetenschappelijk inzicht (zie artikel artikel 10, eerste lid van Richtlijn 98/79/EG).

Notificatie van in-vitro diagnostische medische hulpmiddelen impliceert dat de fabrikant, LumiQuick Diagnostics Inc. de CE-conformiteitsmarkering heeft aangebracht op het desbetreffende product alvorens het in een EU-lidstaat in de handel te brengen. Zodoende garandeert Emergo Europe B.V. dat het in-vitro diagnosticum voldoet aan de essentiële eisen zoals opgenomen in bijlage I bij Richtlijn 98/79/EG (en in het daarmee corresponderende onderdeel 1 bij het besluit)

Volledigheidshalve wijzen wij u erop dat een in-vitro diagnosticum moet voldoen aan de eisen uit het BIVD. Het BIVD is gebaseerd op Richtlijn voor in-vitro diagnostiek, 98/79/EG. Met name wijzen wij u op de Nederlandse-taaleis zoals deze in Nederland geldt, de eisen voor het ter beschikking houden van de technische documentatie en de plicht tot het hebben van een Post Marketing Surveillance- en vigilantiesysteem.

Tot slot merk ik op dat met uw notificatie - de administratieve notificatie als fabrikant - en deze brief geen sprake is van een oordeel over de status of kwalificatie van uw product: notificering betekent niet dat daadwerkelijk sprake is van een in-vitro diagnosticum in de zin van de onderhavige wet- en regelgeving. In voorkomende gevallen kan de Inspectie voor de Gezondheidszorg, belast met het toezicht op de naleving van het bij of krachtens de wet bepaalde, een standpunt innemen over de status van een product, waarbij het volgens vaste jurisprudentie uiteindelijk aan de nationale rechter is om te bepalen of een product onder de definitie van in-vitro diagnosticum valt.

De Minister van Volksgezondheid, Welzijn en Sport,
namens deze,

Afdelingshoofd
Farmatec

Dhr. M.J. van de Velde

Dr. M.J. van de Velde

English Translation Version

On [DATE] we received your notification according to article 4 in-vitro diagnostics, under the name LumiQuick Diagnostics, with the European Representative Emergo Europe, put out into the European market the below mentioned products.

This product has been registered as an in-vitro diagnostic with the number:

[APPLICABLE PRODUCTS]

Herewith you will have fulfilled your obligations under Article 4.

For future correspondence concerning the above mentioned product we kindly request you to use this number. No rights can be derived from this number; its sole purpose is to simplify the administrative side of the notification.

The registration of the above product as a medical device APPLICABLE PRODUCTS according to the requirements with the European Directive 98/79/EC is subject to possible revisions of the European law concerning the classification of medical devices and to advanced scientific understanding (see art. 10 of the European Directive 98/79/EC).

Notification of medical devices implies that LumiQuick Diagnostics has applied the CE conformity marking on the corresponding product before bringing it out into the EU-member state market. Consequently, Emergo Europe guarantees that the medical device meets the essential requirements as stated in the Guideline and the Decision.

To complete this, we would like to point out that a medical device must comply with the demands of the Decision Medical Devices. This Decision is based upon in-vitro diagnostics 98/79/EC and the legal text requirements for The Netherlands. We especially would like to point out the language requirement as required in The Netherlands, the requirements for keeping at our disposal the technical documentation and the obligation to having a Post Marketing Surveillance and vigilance system.

Finally, I note that with your notification - the administrative notification as manufacturer - and this letter there is no judgment on an opinion on the status or classification of the in vitro diagnostic product for the purposes of this Law and regulations. Where appropriate IGZ, responsible for monitoring the compliance by or pursuant to the law, can take a position on the status of a product which, according to settled case law ultimately for the national court to determine whether a product falls within the definition of an in vitro diagnostic product.

SEPARATOR

EMERGO GROUP

26 November 2013

Jeff Wang
LumiQuick Diagnostics, Inc.
2946 Scott Blvd.
Santa Clara, CA 95054
USA

Dear Jeff:

I am writing to inform you that today, we have notified the Competent Authority in the following countries:

- **The Netherlands**

With this notification, LumiQuick Diagnostics, Inc. has met the requirements of the In-vitro Diagnostics Directive, 98/79/EC for the devices listed on the following pages.

As of today and without any further notice from the respective Competent Authorities, LumiQuick Diagnostics, Inc. can consider the respective devices and Authorized Representative as officially registered.

If you have any questions, please do not hesitate to contact me.

Yours sincerely,

Rene van de Zande
President & CEO
Emergo Europe

EMERGO GROUP

Product List

QuickProfile Rotavirus Antigen Test Card
QuickProfile Adenovirus Antigen Test Card
QuickProfile Adeno/Rota Combo Test Card
QuickProfile Adeno/Rota Combo Test Strip
QuickProfile Troponin I Serum Test Card
QuickProfile Tn I Whole Blood Test Card
QuickProfile Cardiac Panel Serum Test Card
QuickProfile Cardiac Panel Whole Blood Test Card
QuickProfile Myo Serum Test Card
QuickProfile MyO Whole Blood Test Card
QuickProfile CK-MB Serum Test Card
QuickProfile CK-MB Whole Blood Test Card
QuickProfile Troponin I Test Strip
QuickProfile CK-MB Test Strip
QuickProfile MyO Test Strip
QuickProfile Dengue IgG/IgM Test Card
QuickProfile Dengue IgG/IgM Test Strip
QuickProfile Dengue NS1 Antigen Test Card
QuickProfile Dengue NS1 Ag & IgG/IgM Ab Duo Test Card
QuickProfile Saliva Alcohol Test Strip
QuickProfile Tramadol Test Card
QuickProfile Tramadol Test Strip
QuickProfile DOA-2 Panel Test
QuickProfile DOA-2 Panel Test Card
QuickProfile DOA-3 Panel Test
QuickProfile DOA-3 Panel Test Card
QuickProfile DOA-4 Panel Test
QuickProfile DOA-4 Panel Test Card
QuickProfile DOA-5 Panel Test
QuickProfile DOA-5 Panel Test Card
QuickProfile DOA-6 Panel Test
QuickProfile DOA-6 Panel Test Card
QuickProfile DOA-7 Panel Test
QuickProfile DOA-7 Panel Test Card
QuickProfile DOA-8 Panel Test

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QuickProfile DOA-8 Panel Test Card
QuickProfile DOA-9 Panel Test
QuickProfile DOA-9 Panel Test Card
QuickProfile DOA-10 Panel Test
QuickProfile DOA-10 Panel Test Card
QuickProfile Amphetamine Test Strip
QuickProfile Amphetamine Test Card
QuickProfile Barbiturate Test Strip
QuickProfile Barbiturate Test Card
QuickProfile Benzodiazepine Test Strip
QuickProfile Benzodiazepine Test Card
QuickProfile Cocaine Test Strip
QuickProfile Cocaine Test Card
QuickProfile EDDP Test Strip
QuickProfile EDDP Test Card
QuickProfile MDMA/Ecstasy Test Strip
QuickProfile MDMA/Ecstasy Test Card
QuickProfile Methadone Test Strip
QuickProfile Methadone Test Card
QuickProfile Methamphetamine Test Strip
QuickProfile Methamphetamine Test Card
QuickProfile Morphine Test Strip
QuickProfile Morphine Test Card
QuickProfile Morphine Test Strip –(2000)
QuickProfile Morphine Test Card – (2000)
QuickProfile PCP Test Strip
QuickProfile PCP Test Card
QuickProfile THC Test Strip
QuickProfile THC Test Card
QuickProfile TCA Strip
QuickProfile TCA Test Card
QuickProfile Ketamine Test Strip
QuickProfile Ketamine Test Card
QuickProfile Buprenorphine Test Strip
QuickProfile Buprenorphine Test Card
QuickProfile Oxycodone Test Strip
QuickProfile Oxycodone Test Card

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QuickProfile Drug of Abuse Test Cup
QuickProfile Drug of Abuse Test Cup - CYND
QuickProfile Urine Alcohol Test Strip
QuickProfile Urine Alcohol Test Card
QuickProfile Propoxyphene Test Strip
QuickProfile Propoxyphene Test Card
QuickProfile DOA-11 Panel Test
QuickProfile DOA-11 Panel Test Card
QuickProfile DOA-12 Panel Test
QuickProfile DOA-12 Panel Test Card
QuickProfile Methylphenidate (MPD) Test Strip
QuickProfile Methylphenidate (MPD) Test Card
QuickProfile Fentanyl Test Strip
QuickProfile Fentanyl Test Card
QuickProfile Clonazepam Strip
QuickProfile Clonazepam Test Card
QuickProfile Cotinine Test Strip
QuickProfile Cotinine Test Card
QuickProfile K2 Test Strip
QuickProfile K2 Test Card
QuickProfile Influenza A Antigen Test
QuickProfile Influenza A+B Antigens Test
QuickProfile Fecal Occult Blood Test Card
QuickProfile Fecal Occult Blood Test Strip
QuickProfile HCG Mid-Stream Test
QuickProfile HCG Urine Test Card
QuickProfile HCG Serum/Urine Test Card
QuickProfile HCG Serum/Urine Test Strip
QuickProfile H. Pylori Antigen Test Card
QuickProfile H. Pylori Antibody Test Card – Whole Blood
QuickProfile H. Pylori Antibody Test Card - Serum
QuickProfile Legionella Test Card
QuickProfile Legionella Test Strip
QuickProfile LH Mid-Stream Test
QuickProfile LH Test Card
QuickProfile LH Test Strip
QuickProfile Malaria pf Antigen Test Card

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QuickProfile Malaria pf/pv Antigen Test Card
QuickProfile Malaria pan Antigen Test Card
QuickProfile Malaria pf/pan Antigen Test Card
QuickProfile Malaria pf Test Strip
QuickProfile Strep A Test Card
QuickProfile Strep A Test Strip
QuickProfile Syphilis Test Strip (Serum)
QuickProfile Syphilis Test Card (WB)
QuickProfile Syphilis Test Card (Serum)
QuickProfile Syphilis Test Strip (WB)
QuickProfile Salmonella typhi Antigen Test Card
QuickProfile Salmonella typhi/paratyphi Antigen Test
QuickProfile Typhi IgG/IgM Duo Test

Emergo Europe B.V.
Prinsessegracht 20
2514 AP The Hague
THE NETHERLANDS
+31 (0)70 345 8570

23 October 2017

Mr. Jeff Wang
LumiQuick Diagnostics, Inc.
2946 Scott Blvd.
Santa Clara, CA 95054
USA

Dear Jeff:

I am writing to inform you we have notified the Competent Authority in the following countries:

- **The Netherlands***

With this notification, LumiQuick Diagnostics, Inc. has met the requirements of the In-vitro Diagnostics Directive, 98/79/EC for the following devices:

- **QuickProfile Ethyl Glucuronide (EtG) Test Strip**
- **QuickProfile Ethyl Glucuronide (EtG) Test card**

As of today and without any further notice from the respective Competent Authorities, LumiQuick Diagnostics, Inc. can consider the respective devices as officially notified.

If you have any questions, please do not hesitate to contact me.

Yours sincerely,

Rene van de Zande
Director
Emergo Europe

Emergo Europe B.V.
Prinsessegracht 20
2514 AP The Hague
THE NETHERLANDS
+31 (0)70 345 8570

** Self-Certify/Other IVD notification in The Netherlands with the Dutch Healthcare Inspectorate (IGZ) grants you access to: Austria, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, The Netherlands, Norway, Poland, Portugal, Romania, Spain, Slovakia, Slovenia, Switzerland, Sweden, and the United Kingdom.*

After notification in the Netherlands, the following countries still require additional notification for Self-Certify/Other: Belgium and Croatia. Please let us know if LumiQuick Diagnostics, Inc. will require notification in any of the additional countries.

** List A, List B and Self-Test IVD notification in The Netherlands with the Dutch Healthcare Inspectorate (IGZ) grants you access to: Austria, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Liechtenstein, Lithuania, Luxembourg, Malta, The Netherlands, Norway, Poland, Slovakia, Slovenia, Sweden, Switzerland, and the United Kingdom.*

After notification in the Netherlands, the following 8 countries still require additional notification for higher IVDs: Belgium, Croatia, Italy, Latvia, Portugal, Romania, and Spain. Please let us know if LumiQuick Diagnostics, Inc. will require notification in any of the additional countries.

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

LumiQuick Diagnostics, Inc.
2946 Scott Blvd
Santa Clara
California
95054
USA

Holds Certificate No: **FM 574919**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

The design, development, manufacture and distribution of in vitro diagnostics test kits and reagents used in the diagnosis and management of disease status, including Infectious Diseases tests, Drugs of Abuse tests, Cardiac Monitor tests, Cancer Marker tests, Fertility Hormone tests, ELISA tests & Urine Chemistry tests.

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2011-10-20
Latest Revision Date: 2020-08-31

Effective Date: 2020-10-20
Expiry Date: 2023-10-19

...making excellence a habit.™

LumiQuick Diagnostics, Inc.
2946 Scott Blvd., Santa Clara, CA 95054, USA

Tel: 1-408-855-0061
Fax: 1-408-855-0063
E-mail: info@lumiquick.com
Website: www.lumiquick.com

LETTER OF AUTHORIZATION

We, LumiQuick Diagnostics, Inc., having a registered office at 2946 Scott Blvd, Santa Clara, CA 95054, USA assign SRL SANMEDICO, having a registered office at A. Corobceanu street 7A, apt. 9, Chişinău MD-2012, Moldova, as our authorized representative in correspondence with the conditions of directive 98/79/EEC.

We declare that the company mentioned above is authorized to register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova.

This letter is valid through December 31, 2023 and will automatically renewed upon the agreement of both companies. Should you have questions, please contact us.

Best regards,

Charles Yu

President

Date: January 19, 2022

LumiQuick
Diagnostics, Inc.
2946 Scott Blvd.
Santa Clara, California 95054 USA
Tel: 1-408-855-0061 info@lumiquick.com
Fax: 1-408-855-0063 www.lumiquick.com

Quick Profile™ Drugs of Abuse/Alcohol Panel Test
Plus Optional Adulterant Strip(s)

Quick Profile™ Drugs of Abuse/Alcohol Panel Test Card
Plus Optional Adulterant Strip(s)

Movies available at YouTube YouTube: www.youtube.com/lumiquick

FOR THE QUALITATIVE ASSESSMENT OF DRUGS AND/OR THEIR METABOLITES IN HUMAN URINE

and

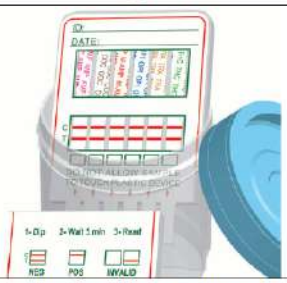
URINE ALCOHOL (Optional)
For THE SEMI-QUANTITATIVE ASSESSMENT OF ETHYL ALCOHOL IN HUMAN URINE

Plus

URINE CHECK (Optional)
For THE VALIDATION OF URINE SPECIMEN EXAMINED

For in vitro Diagnostic and Forensic Use

Drugs of Abuse/Alcohol (DOA/ALC) Panel Test Device



Quick Profile™ Drugs of Abuse/Alcohol Panel Test		Quick Profile™ Drugs of Abuse/Alcohol Panel Test Card	
Catalog Number	REF	Catalog Number	REF
74004	DOA-2 Panel Test	74004-TC	DOA-2 Test Card
74005	DOA-3 Panel Test	74005-TC	DOA-3 Test Card
74006	DOA-4 Panel Test	74006-TC	DOA-4 Test Card
74007	DOA-5 Panel Test	74007-TC	DOA-5 Test Card
74008	DOA-6 Panel Test	74008-TC	DOA-6 Test Card
74009	DOA-7 Panel Test	74009-TC	DOA-7 Test Card
74010	DOA-8 Panel Test	74010-TC	DOA-8 Test Card
74011	DOA-9 Panel Test	74011-TC	DOA-9 Test Card
74012	DOA-10 Panel Test	74012-TC	DOA-10 Test Card

Optional: Alcohol & Adulteration	
REF	Urine Alcohol Strip can be optionally integrated into DOA/Alcohol Panel Test Device. Urine check adulteration strip can also be optionally integrated into both DOA/Alcohol Panel Test Devices with custom parameters. pH and/or creatinine are the optional standard parameters whereas five other parameters are offered as options for custom made test devices. The currently available Adulteration parameters offered by LumiQuick Diagnostics, Inc. are Creatinine, pH, Specific Gravity, Nitrite, Oxidants, Glutaraldehyde, Bleach, and Pyridinium Chlorochromate.

INTENDED USE

Quick Profile™ DOA/Alcohol Panel Test and Quick Profile™ DOA/Alcohol Panel Test Card, hereinafter referred to as DOA/Alcohol Panel Test Device, is an immunochromatography based one step in vitro test. It is designed for qualitative determination of illicit drugs and their metabolites in human urine specimens. This assay may be used in the point of care setting. Below is a list of cut-off concentrations for each drug.

Amphetamine	1000 ng/ml of d-amphetamine
Barbiturate	300 ng/ml of secobarbital
Benzodiazepine	300 ng/ml of oxazepam
Buprenorphine	10 ng/ml of Buprenorphine-3-β-d-glucuronide
Cocaine	300 ng/ml of benzoylecgonine
EDDP	100 ng/ml of EDDP
Ketamine	1000 ng/ml of Ketamine
Methadone	300 ng/ml of methadone
Methamphetamine (includes Ecstasy)	1000 ng/ml of (+)methamphetamine
MDMA (Ecstasy specific)	500 ng/ml of MDMA
Opiate*	300 ng/ml of morphine
Opiate II*	2000 ng/ml of morphine
Oxycodone	100 ng/ml of oxycodone
Phencyclidine	25 ng/ml of phencyclidine
Cannabinoid (THC)	50 ng/ml of 11-nor-Δ^9-THC-9-COOH
Propoxyphene	300 ng/ml of Norpropoxyphene
Tramadol	200 ng/ml of Tramadol
Tricyclic antidepressant (TCA)	1000 ng/ml of Nortriptyline
Alcohol	40 mg/dl (0.04% BAC) of Alcohol

This assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/ mass spectrometry (GC/MS) has been established as the preferred confirmatory method by the Substance Abuse Mental Health Services Administration (SAMHSA). Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated. The optional built-in Adulteration Test is for validation of urine specimen's integrity and must not be used for In Vitro diagnostic use.

** **SAMHSA recommends a cut-off concentration of 2000 ng/ml for Opiates Test***

SUMMARY AND EXPLANATION

Drugs of Abuse

Amphetamines are a class of potent sympathominetic agents with therapeutic applications. The most common amphetamines are d-amphetamine and d, l-amphetamine. Amphetamines are central nervous stimulants that cause the neurotransmitters epinephrine, norepinephrine and dopamine to be released into the brain and body giving users feelings of euphoria, alertness, and increased energy. Chronic abuse of amphetamine leads to tolerance and drug reinforcement effect. Cardiovascular responses to amphetamine include increased blood pressure and cardiac arrhythmias. More acute responses produce anxiety, paranoia, hallucinations and psychotic behavior. Amphetamine is metabolized by a number of pathways. In general, acid urine promotes excretion whereas alkaline urine retards it. In 24 hours, approximately 79% of the amphetamine dose is excreted in acid urine and about 45% in alkaline urine. Typically, about 20% is excreted as unchanged amphetamine. Unchanged amphetamine can be detected up to 1 –2 days after use.

Barbiturates are a group of prescription drugs that are frequently abused. They can depress the central nervous system. Acute higher dose induces exhilaration, sedation and respiratory depression. More acute responses produce respiratory collapse and coma. The effects of short-acting barbiturates, such as secobarbital last 3 to 6 hours. The effects of long-acting barbiturates such as phenobarbital last 10 to 20 hours. Short-acting barbiturates normally remain detectable in urine for 4 to 6 days, while long-acting barbiturates can be detected for up to 30 days. Barbiturates are excreted in the urine in unchanged forms, hydroxylated derivatives, carboxylated derivatives and glucuronide conjugates.

Benzodiazepines are a class of widely prescribed central nervous system depressants which have anxiolytic, hypnotic, anticonvulsant and muscle relaxant effects. Chronic abuse can result in addiction and tardive dyskinnesia. Acute higher doses lead to drowsiness, dizziness, muscle relaxation, lethargy, coma and possible death. The effects of benzodiazepines use last 4 – 8 hours. Many of the benzodiazepines share a commonmetabolic route, and are excreted as oxazepam and its glucuronide in urine. Oxazepam is detectable in the urine for up to 7 days after drug use.

Buprenorphine a derivative of thebaine, is an opioid that has been marketed in the United States as the Schedule V parenteral analgesic Buprenex. In 2003, based on a reevaluation of available evidence regarding the potential for abuse, addiction, and side effect, DEA reclassified buprenorphine from a Schedule V to a Schedule III narcotic. Buprenorphine resembles morphine structurally but has a longer duration of action than morphine and can be administrated sublingually as an analgesic. In October 2002, FDA approved the use of a buprenorphine monotherapy product, Subutex, and a buprenorphine/naloxone combination product, Suboxone, for the treatment of opioid addiction. Subutex and Suboxone are the first narcotic drugs available under the US Drug Act (DATA) of 2003 for the treatment of opiate dependence that can be prescribed in the US in a physician's work place. It has also been shown that buprenorphine has abuse potential and may itself cause dependency. In addition, a number of deaths have been recorded as a result of overdose with intravenously injected buprenorphine in conjunction with other psychotropic drugs such as benzodiazepines. Buprenorphine is metabolized primarily by n-dealkylation to form glucuronide-buprenorphine and glucuronide-norbuprenorphine.

Cocaine derived from the leaves of cocoa plant, is a potent central nervous system stimulant as well as a local anesthetic. Some of the psychological effects induced by cocaine are: euphoria, confidence and a sense of increased energy, accompanied by increased heart rate, dilation of the pupils, fever, tremors and sweating. Continued ingestion of cocaine could induce tolerances and physiological dependency which leads to its abuse. Cocaine is used by smoking, intravenous, intransal or oral administration and excreted in the urine primarily as benzoylecgonine in a short period. Benzoylecgonine has a biological half-life of 5 – 8 hours, which is much longer than that of cocaine (0.5 – 1.5 hours), and can be generally detected for 12 – 72 hours after cocaine use or exposure.

EDDP 2-Ethylidine-1,5-dimethyl-3,3-diphenylpyrrolidine, is the primary metabolite of methadone. Methadone is a controlled substance and is used for detoxification and maintenance of opiate dependant patients. Patients on methadone maintenance may exhibit methadone (parent) levels that account for 5-50% of the dosage and 3-25% of EDDP in urinary excretion during the first 24 hours. The detection of EDDP is more beneficial than traditional methadone screening, because EDDP exists only in urine from individuals that ingested methadone. The tampering of specimens by spiking the urine with methadone can be prevented. Secondly, renal clearance of EDDP is not affected by urinary pH, therefore the EDDP test provides a more accurate result of methadone ingestion than the methadone parent screen.

Methadone is a synthetic opioid, clinically available. It is used clinically for the treatment of severe pain and in maintenance programs for morphine and heroine addicts. Methadone acts on the central nervous and cardiovascular systems to produce respiratory and circulatory depression. Methadone also produces miosis and increases the tone of smooth muscle in the lower gastrointestinal tract while decreasing the amplitude of contractions. Acute higher doses induce analgesia, sedation, respiratory depression and coma. After methadone administration, the major urinary excretion products are methadone and its metabolites, EDDP and EMDP. Large individual variations in the urine excretion of methadone are output of methadone from 5-22%. Typically, following a 5 mg oral dose, methadone and EDDP account for 5% of the dose in the 24-hour urine. In those individuals on maintenance therapy, methadone may account for 5 to 50% of the dose in the 24-hour urine and EDDP may account for 3 to 25% of the dose.

Methamphetamine is the most popular systhetic derivative of the amphetamines. It is a potent sympathomimetic agent with therapeutic applications. Acute large doses lead to enhanced stimulation of the central nervous system and induce euphoria, alertness, reduced appetite, and a sense of increased energy and power. More acute response produces anxiety, paranoia, psychotic behavior, and cardiac dysrhythmias. Methamphetamine is excreted in the urine as amphetamine and oxized and deaminated derivatives. However, 10-40% of methamphetamine is excreted unchanged. Methamphetamine is generally detectable in the urine for 3 to 5 days after use.

MDMA Methylenedioxymethamphetamine **(**Ecstasy) is a designer drug first synthesized in 1914 by a German drug company for the treatment of obesity. Those who take the drug frequently report adverse effects, such as increased muscle tension and sweating. MDMA is not clearly a stimulant, although it has, in common with amphetamine drugs, a capacity to increase blood pressure and heart rate. MDMA does produce some perceptual changes in the form of increased sensitivity to light, difficulty in focusing, and blurred vision in some users. Its mechanism of action is thought to be via release of the neurotransmitter serotonin. MDMA may also release dopamine, although the general opinion is that this is a secondary effect of the drug. The most pervasive effect of MDMA, occurring in almost all people who have taken a reasonable dose of the drug, is to produce a clenching of the jaws.

Ketamine is a derivative of phencyclidine. It is used medically as a veterinary and humen anaesthetic. Certain doses of ketamine can cause dream-like states and hallucinatioins. In high does, ketamine can cause delirium, amnesia, impaired motor function, high blood pressure, depression, and potentially fatal respiratory problems. Ketamine is metabolized in the liver and excreted through the kidney. The half-live of ketamine in the body is around three hours.

Opiate Opioid analgesics comprised of a large group of substances that control pain by depressing the central nervous system. Acute high dose used by abusers or addicts can cause depressed coordination, disrupted decision, decreased respiration, hypothermia and coma. Morphine is excreted unmetabolized and is the marker metabolic product of opiates. Morphine and morphine glucuronide is detectable in urine for several days after opiates dose.

Oxycodone is known as Oxycontin, Roxicodone and is an ingredient of Percodan, Percocet, Roxicet and Tylox. Oxycodone is a semi-synthetic opiates derived from opium. Like other opiates, oxycodone is characterized by its analegestic properties, and the tendency for users to form a physical dependency and develop tolerance with extended use. Oxycodone is usually administered in combination with non-opiate analegesics such as acetaminophen and salicylates for the relief of moderate to severe pain. Oxycodone is a central nervous system depressant that may cause drowsiness, dizziness, lethargy, weakness and confusion. Toxicity in an overdose of oxycodone can lead to stupor, coma, muscle flaccidity, severe respiratory depression, hypotension, and stripiac arrest. Oxycodone is metabolized by N- and O-demethylation. One of the metabolites, oxymorphone, is a potent narcotic analgesic, while the other, noroxycodone, is relatively inactive. Between 33 to 61% of a single dose of oxycodone is excreted in a 24 hour urine collection and consists of 13-19% free oxycodone, 7-29% glucuronide conjugated oxycodone, 13-14% glucuronide conjugated oxymorphone and an unknown amount of noroxycodone. The detection time window of oxycodone is 1-3 days following use.

Phencyclidine commonly known as PCP, is a hallucinogen which interacts with dopamine, cholinergic and adrenergic systems. It has dose dependent stimulant, depressant, hallucinogenic and psychological effects. PCP is mostly administered by oral or intravenously. Even moderate amount of PCP, from 5 to 100 ng/ml, can result in psychotic, violent and self-destruction. At high does, from 100 to 500 ng/ml, PCP can cause convulsions, hypertion, prolonged coma, absent peripheral sensation, and even death. PCP is metabolized via hydroxylation, oxidation, and conjugation with glucuronic acid in the liver. About 10% of the does is excreted in urine as unchanged drug. For chronic users, PCP can be detected in the urine for 7 to 8 days after drug administration.

Propoxyphene is a prescription drug for the relief of pain. Although slightly less selective than morphine, Propoxyphene binds primarily to opioid receptors and produces analgesia and other CNS effects that are similar to those seen with morphine-like opioids. It is likely that at equianalgesic doses the incidence of side effects such as nausea, anorexia, constipation, abdominal pain, and drowsiness are similar to those of codeine. After oral administration, concentrations of Propoxyphene in plasma reach their highest values at 1 to 2 hours. There is great variability between subjects in the rate of clearance and the plasma concentrations that are achieved. The percentage of excreted unchanged Propoxyphene in urine is less than 1%. In humans, the major route of metabolism is N-demethylation to yield norpropoxyphene. Norpropoxyphene has a longer half-life (30 to 36 hours) than parent Propoxyphene (6 to 12 hours), and its
accumulation with repeated doses may be responsible for some of the observed toxicity.

THC The agents of Marijuana that cause various biological effects in humans are called cannabinoid. Cannabinoid is a central nervous stimulant that alters mood and sensory perceptions, produces loss of coordination, impairs short term memory, and produces symptoms of anxiety, paranoia, depression, confusion, hallucination, and increased heart rate. Large doses of cannabinoid could cause the development of tolerances and physiological dependency and lead to abuse. A tolerance to the cardiac and psychotropic effects can occur and withdrawal syndrome produces restlessness, insomnia, anorexia and nausea. Δ^9-THC is the primary active ingredient in cannabinoids. The main metabolite excreted in the urine is 11-nor-Δ^9-THC-9-COOH, which are found within hours of exposure and remain detectable in the urine for 3-10 days after smoking.

Tramadol is a quasi-narcotic analgesic used in the treatment of moderate to severe pain. It is a synthetic analog of codeine, but has a low

binding affinity to the mu-opioid receptors. Large doses of tramadol can develop tolerance and physiological dependency and lead to its abuse. Tramadol is extensively metabolized after oral administration. Approximately 30% of the dose is excreted in the urine as unchanged drug, whereas 60% is excreted as metabolites. The major pathways appear to be N- and O- demethylation, glucoronidation or sulfation in the liver.

TCA Tricyclic antidepressants, commonly known as TCA, are a group of antidepressant drugs. TCA are mostly administered by oral or intramascularly. The progressive symptomatology of TCA includes agitation, confusion, hallucinations, hypertonicity, seizures and EKG changes. Nortriptyline, Desipramine (Pertofran) and Imipramine (Tofranil) are the most often used TCA. TCA's half life varies from a few hours to a few days. TCA are excreted with less than 1% of the unchanged drug.

Alcohol Acute alcohol intoxication can lead to loss of alertness, coma, and even death. Long term effects include internal organ damage and birth defects. The blood alcohol concentration (BAC) at which a person becomes impaired is variable. The United States Department of Transportation (DOT) has established a BAC of 0.02% (0.02g/dL) as the cut-off level at which an individual is considered positive for the presence of alcohol. Since urine alcohol concentration is normally higher than that in saliva and blood, the cutoff concentration for alcohol in urine is set at 0.04%.

UrineCheck: Adulteration Test(s)
UrineCheck adulteration tests are built-in firm plastic strips to which options of one (1) up to six (6) different reagent areas can be affixed. UrineCheck test(s) is/are read-to-use and disposable. No equipment is required for its use. Only fresh and uncentrifuged urine samples without preservatives are to be used.

UrineCheck provides tests for Creatinine, pH, Specific Gravity, Nitrite, Oxidants, Glutaraldehyde, Bleach, and Pyridinium Chlorochromate in urine. Test results may be useful for assessing the integrity of the urine sample while running Drugs-of-Abuse & Alcohol testing, for example, whether the sample is possibly diluted with water or other liquids as indicated by the Creatinine and specific gravity tests. UrineCheck detects whether the sample contains commercially available adulterants including nitrite, Glutaraldehyde, and other oxidizing agents. UrineCheck can also assess whether the sample is possibly contaminated by acidic (vinegar) or basic (ammonia solution) adulterants as indicated by the pH test.

PRINCIPLE

Drugs of Abuse
Each component strip of the DOA/Alcohol Panel Test Device is based on the principle of specific immunochemical reaction between antibodies and antigen to analyze particular compound in human urine specimen. The assay relies on the competition for binding antibody. When drug is present in the urine specimen, it competes with drug conjugate for the limited amount of antibody-dye conjugate. When the amount of drug is equal or more than the cut-off, it will prevent the binding of drug conjugate to the antibody. Therefore, a positive urine specimen will not show a colored band on the test line zone, indicating a positive result, while the presence of a colored band indicates a negative result.
A control line is present in the test window to work as procedural control. This colored band should always appear on the control line zone if the test device is stored in good condition and the test is performed appropriately.

Alcohol
Alcohol Test is based on the high specifity of alcohol oxidase (ALOx) for ethyl alcohol in the presence of peroxidase and enzyme substrate such as tetramethylbenzidine (TMB) as shown in the following:

$$EtOH + TMB \xrightarrow{ALOx/Peroxidase} CH_3CHO + Colored\ TMB$$

The distinct color on reactive pad could be observed in less than 20 seconds after the urine samples migrates over the reaction pad with the ethyl alcohol concentration greater than 0.04%. It should be pointed out that other alcohols such as methyl, propanyl and allyl alcohol would develop the similar color on the reactive pad. However, these alcohols are not normally present in urine.

UrineCheck: Adulteration Test(s)
In general, all UrineCheck Tests are based on the chemical reactions of the indicator reagents on the pads with components in the urine sample effecting color changes. Results are obtained by comparing the color on each of the test pads with the corresponding pad on the color chart provided.

Creatinine: Testing for sample dilution. In this assay, Creatinine reacts with a Creatinine indicator in an alkaline condition to form a purplish- brown color complex. The concentration of Creatinine is directly proportional to the color intensity of the test pad.

Specific Gravity: Testing for sample dilution. This test is based on the apparent pKa change of certain pretreated polylectrolytes in relation to ionic concentration. In the presence of an indicator, the colors range form dark blue or blue-green in urine of low ionic concentration to green and yellow in urine of higher ionic concentration.

pH: Testing for the presence of acidic or alkaline adulterant. This test is based on the well-known double pH indicator method that gives distinguishable colors over wide pH range. The colors range from orange (low pH) to yellow and green to blue (high pH).

Nitrite: Testing for the presence of exogenous nitrite. Nitrite. Nitrite reacts with an aromatic amine to form a diazonium compound in an acid medium. The diazonium compound in turn couples with an indicator to produce a pink-red/purple color.

Oxidants: Testing for presence of oxidizing reagents. In this reaction, a color indicator reacts with oxidants such as hydrogen peroxide, ferricyanide, persulfate, or pyridinium chlorochromate to form a blue color complex. Other colors may indicate the presence of other oxidants.

Glutaraldehyde: Testing for the presence of exogenous aldehyde. In this assay, the aldehyde group on the Glutaraldehyde reacts with an indicator to form a pink/purple color complex.

Bleach: Testing for the presence of bleach in urine. In this test, the presence of bleach forms a blue-green, brown, or orange color complex.

Pyridinium Chlorochromate: Testing for the presence of Pyridinium Chlorochromate in urine. In this test, the presence of chromate forms a blue-green color complex.

MATERIALS PROVIDED

1. ***Instructions for use***
2. ***One Drugs of* DOA/Alcohol Panel Test Device *(with optional Alcohol and /or Adulteration Test)***
   Drugs Of Abuse
   The amount of each coated antigen and/or antibody on the strip is less than 1.0 mg for antigen conjugate and is less than 1.0 mg for goat anti-rabbit IgG antibody.
   Test zone: contains drug bovine protein antigen conjugates
   Control zone: contains Goat anti-rabbit IgG antibody
   Conjugate pad: contains anti-drug antibody.

   Alcohol *(optional)*
   Each Alcohol test contains these materials:

Tetramethylbenzidine (TMB)	0.12 mg
Alcohol oxidase (EC)	0.5 IU
Peroxidase(EC)9	35 IU
Proteins	0.15mg

   Adulteration Test *(optional)*
3. ***Alcohol /Adulteration Test Color Chart*** *(When order Alcohol and/or Adulteration Tests)*

MATERIAL REQUIRED BUT NOT PROVIDED

1. ***Urine collection container.***
2. ***Timer or clock.***

STORAGE AND STABILITY

The DOA/Alcohol Panel Test Device should be stored at 4 to 30°C and will be effective until the expiration date stated on the package. The product is humidity-sensitive and should be used immediately after being open. Any improperly sealed product should be discarded.

PRECAUTIONS

1. For in vitro diagnostic and forensic use only.
2. Do not use the product beyond the expiration date.
3. Handle all specimens as potentially infectious.
4. Humidity sensitive product. Do not open foil pouch until it is ready to be tested.
5. Use a new urine specimen cup for each sample to avoid cross contamination.

SPECIMEN COLLECTION AND PREPARATION

Fresh urine does not require any special handling or pretreatment. Specimen should be collected in a clean, dry, plastic or glass container. If the assay is not performed immediately, urine specimen may be refrigerated at 2-8°C or frozen up to 7 days. Specimens should be brought to room temperature before testing. Urine specimens exhibiting a large amount of precipitate or turbidity should be centrifuged or allowed to settle before testing. Avoid contact with skin by wearing gloves and proper laboratory attire.

QUALITY CONTROL

Good Laboratory practice recommends the daily use of control materials to validate the reliability of device. Control materials should be assayed as clinical specimen and challenging to the assay cutoff concentration, e.g., 50% above and below cutoff concentration. If control

values do not fall within establish range, assay results are invalid. Control materials which are not provided with this test kit are commercially available.

Drugs of Abuse

The DOA Panel Test Device provides a built-in process control with a different antigen/antibody reaction at the control region (C). This control line should always appear regardless the presence of drug or metabolite. If the control line does not appear, the test device should be discarded and the obtained result is invalid. The presence of this control band in the control region serve as 1) verification that sufficient volume is added, 2) that proper flow is obtained.

Alcohol

Alcohol test may be qualitatively verified by using a test solution prepared by adding 0.75 ml of ethanol alcohol into 240 ml of distilled water or negative urine control. This solution should show a distinct positive result.

UrineCheck: Adulteration Test(s)

For best results, performance of UrineCheck test should be confirmed by testing known negative and positive specimens.

PROCEDURE

1

Bring all materials and specimens to room temperature.

2

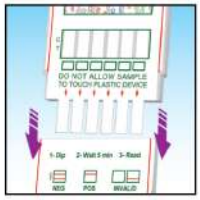
Remove the DOA/Alcohol Panel Test Device from sealed foil pouch.

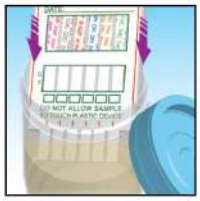
3 (For Panel Test Card Only)

Place the Panel Test Card on a flat surface and label the device with patient ID.

4

Place the sample pad end into the urine specimen. Use care to hold each pad in the urine without touching the plastic card.



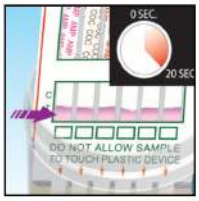


Place the transfer pipette in the specimen and depress the bulb to withdraw a sample.

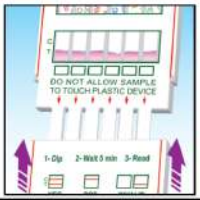
5

DOA/Alcohol Panel Test with no Alcohol nor Adulteration Tests

Hold the device in the urine until a reddish color appears at the test area (appro-ximately 20 seconds)*.

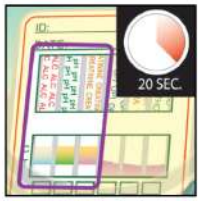


Recap the device

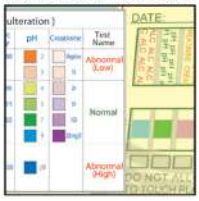


DOA/Alcohol Panel Test with Alcohol or Adulteration Tests

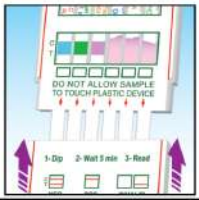
Hold the device in the urine until a reddish color appears at the test area and urine flow over Alcohol pad or Adulteration pad (approximately 20 seconds)*.



Read Reaction Alcohol Pads against Color chart provided.
Alcohol: 4-5 minutes
Adulteration: 1-2 minutes



Recap the device



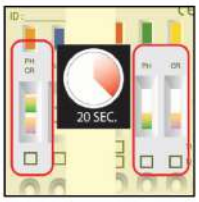
Hold the pipette in a vertical position over the sample well of the test card and deliver 2-3 drops (80-120 µl) of sample into each of the sample wells

DOA/Alcohol Panel Test with no Alcohol nor Adulteration Tests

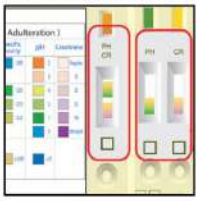
Wait 5 minutes.

DOA/Alcohol Panel Test with Alcohol or Adulteration Tests

Wait 20 seconds. Be prepared to observe Alcohol or Adulteration test windows.



Read Reaction Alcohol Pads against Color chart provided.
Alcohol: 4-5 minutes
Adulteration: 1-2 minutes

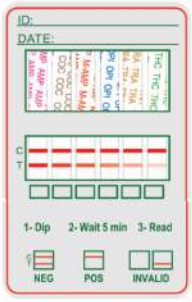
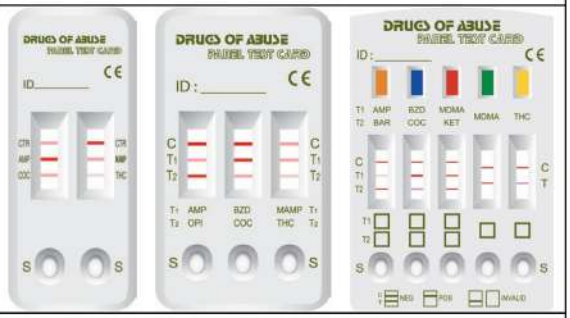
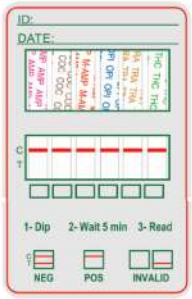
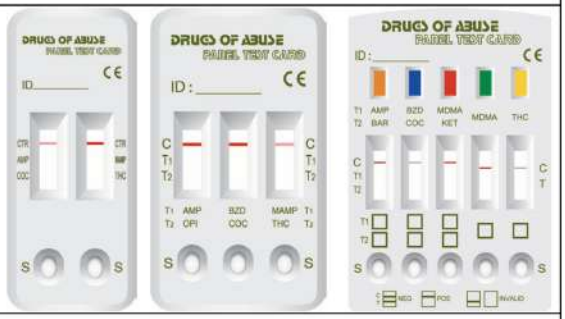
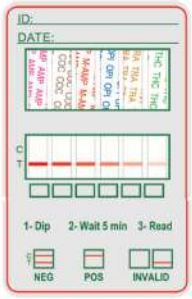
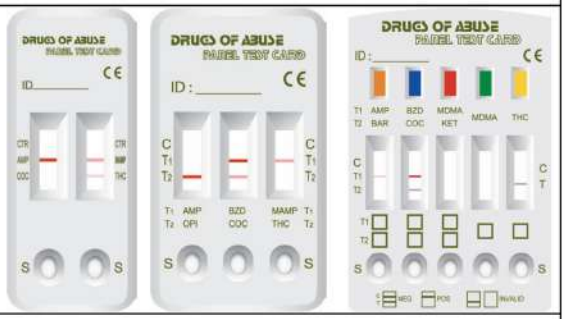
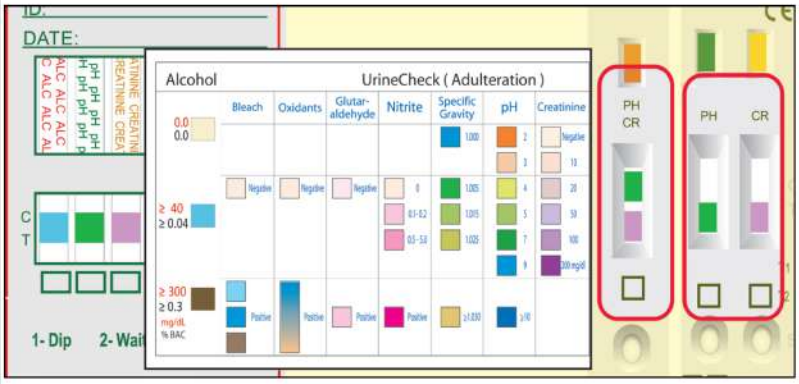


6

Read the Drugs of Abuse Test results at 5 minutes after adding the sample.

Note: If urine Alcohol strip is integrated in the DOA/Alcohol Panel Test Device, the device should be held until the whole alcohol detection pad is wet, which takes about 20 to 30 seconds.
Caution: Results of drug and alcohol after 10 minutes may not be accurate. Results of adulteration strip after 2 minutes may not be accurate.

INTERPRETATION OF RESULTS
Names of drugs on the test could be different depending on the various combination of drugs selected.

	APPEARANCE	
	Drugs of Abuse Panel Test	**Drugs of Abuse Panel Test Card**
DRUGS OF ABUSE NEGATIVE		
	Colored bands show on both test line zone (T or T1 /T 2) and control line zone (C). This is an indication of negative result for that (those) particular test(s). The negative result does not indicate the absence of drug(s) in the specimen; it only indicates the level of tested drug in the specimen is less than cut-off level.	
DRUGS OF ABUSE POSITIVE		
	One colored band form on any strip of the card. One colored band appears in control line zone. No colored band is found in test line zone (T or T1 /T 2). This is an indication the level of tested drug(s) in the specimen is above the cut-off level.	
DRUGS OF ABUSE INVALID		
	If there is no colored band in control line zone (C) of any strip, the test result is invalid. Retest the sample with a new device.	
ALCOLHOL & ADULTERATION		
	1. Read Reaction Pads against the Alcohol /Adulteration Test Color Chart provided. 2. Refer to supplied color chart for the level of each index to be tested and check if it is in the normal range.	

Note: A borderline(+/-) in test line zone should be considered negative result.

LIMITATION OF PROCEDURE

The assay is designed for use with human urine only. A positive result with any of the tests indicates only the presence of a drug/metabolite and does not indicate or measure intoxication. There is a possibility that technical or procedural error as well other substances in certain foods and medicines may interfere with the test and cause false results. Please refer "SPECIFICITY" section for lists of substances that will produce either positive results, or that do not interfere with test performance. If a drug/metabolite is found present in the urine specimen, the assay does not indicate frequency of drug use or distinguish between drug of abuse and certain foods and medicines.

EXPECTED RESULTS

The DOA/Alcohol Panel Test Device is a qualitative assay. It identifies the drug(s) in human urine at its cut-off concentration or higher. The concentration of the drug(s) can not be determined by this assay. The test is intended to distinguish negative result from presumptive positive result. All positive results must be confirmed using an alternate method, preferably GC/MS.

PERFORMANCE CHARACTERISTICS

A. Accuracy

The accuracy of the DOA/Alcohol Panel Test Device was evaluated in each component strip and in comparison to GC/MS method at the following cut-off concentration: d-amphetamine 1000ng/ml (AMP), secobarbital 300 ng/ml (BAR), oxazepam, 300 ng/ml (BZD), buprenorphine-3-β-d-glucoronide 10ng/ml (BUP), benzoylecgonine 300ng/ml (COC), EDDP 100ng/ml (EDDP), Ketamine 1000ng/ml (KET), methadone 300 ng/ml (MTD), MDMA 500ng/ml (MDMA), (+)methamphetamine 1000 ng/ml (MET), phencyclidine 25 ng/ml (PCP), morphine 300 ng/ml (OPI), morphine 2000 ng/ml (OPI II), oxycodone 100ng/ml (OXY), nor-propoxyphene 300 ng/ml (PPX), 11-nor-Δ^9-THC-9-COOH 50ng/ml (THC), Tramadol 200 ng/ml (TRA) and Nortriptyline 1000 ng/ml (TCA). The results of each component strip are listed below:

1. **Amphetamine** The accuracy of the amphetamine test was evaluated in comparison to GC/MS method and commercial kits at a cut-off of 1000 ng/ml. Three hundred and forty five (345) urine specimens which composed of one hundred thirty three (133) d-amphetamine positive samples and two hundred twelve (212) negative samples were evaluated in this study. The results are summarized and presented below:
Positive % agreement: 98.5, Negative % agreement: 100

2. **Barbiturate** The accuracy of the barbiturate test was evaluated in comparison to GC/MS method and commercial kits at a cut-off of 300 ng/ml of secobarbital. One hundred thirteen (113) urine specimens which composed of sixty four (64) barbiturate positive samples and forty nice (49) negative samples were evaluated in this study. The results are summarized as below:
Positive % agreement: 100, Negative % agreement: 100.

3. **Benzodiazepine** The accuracy of the benzodiazepine test was evaluated in comparison to GC/MS method and commercial kits at a cut-off of 300 ng/ml of oxazepam. Three hundred and forty four (344) urine specimens which composed of one hundred eleven (111) benzodiazepine positive samples and two hundred thirty three (233) negative samples were evaluated in this study. The results are summarized as below:
Positive % agreement: 98, Negative % agreement: 100

4. **Buprenorphine** The accuracy of the buprenorphine test was evaluated in comparison to GC/MS at a cut-off of 10 ng/ml of buprenorphine-3-β-d-glucoronide. One hundred and one (101) urine specimens which composed of forty nine (49) buprenorphine-3-β-d-glucoronide positive samples and fifty two (52) negative samples were evaluated in this study. The results are summarized as below:
Positive % agreement: 96, Negative % agreement: 100.

5. **Cocaine** The accuracy of the cocaine test was evaluated in comparison to GC/MS method and commercial kits at a cut-off of 300 ng/ml of benzoylecgonine. Three hundred and forty four (344) urine specimens which composed of one hundred twenty one (121) benzoylecgonine positive samples and two hundred twenty three (223) negative samples were evaluated in this study. The results are summarized as below:
Positive % agreement: 99, Negative % agreement: 99

6. **EDDP** The accuracy of the methadone metabolite (EDDP) test was evaluated in comparison to GC/MS method at a cut-off of 100 ng/mL EDDP. Ninety nine (99) specimens which composed of forty four (44) positive samples and forty five (45) negative samples were evaluated in this study. The results are summarized as below:
Positive % agreement: 98, Negative % agreement: 100

7. **Ketamine** The accuracy of the ketamine test was evaluated in comparison to GC/MS method and commercial kits at a cut-off of 1000 ng/ml of ketamine. Three hundred and forty four (344) urine specimens which composed of one hundred twenty seven (127) ketamine positive samples and two hundred seventeen (217) negative samples were evaluated in this study. The results are summarized as below:
Positive % agreement: 99, Negative % agreement: 100

8. **MDMA** The accuracy of the MDMA test was evaluated in comparison to GC/MS at a cut-off of 500 ng/ml of (+) methylenedioxymethamphetamine. Eighty (80) urine specimens with GC/MS confirmed MDMA concentration were evaluated in this study. The results are summarized and presented below:
Positive % agreement: 96, Negative % agreement: 95

9. **Methadone** The accuracy of the methadone test was evaluated in comparison to GC/MS method and commercial kits at a cut-off of 300 ng/ml of methadone. Three hundred and forty four (344) urine specimens which composed of one hundred eighty seven (187) methadone positive samples and one hundred fifty seven (157) negative samples were evaluated in this study. The results are summarized as below:
Positive % agreement: 100, Negative % agreement: 100.

10. **Methamphetamine** The accuracy of the methamphetamine test was evaluated in comparison to GC/MS method and commercial kits at a cut-off of 1000 ng/ml of (+) methamphetamine. Three hundred and forty four (344) urine specimens which composed of one hundred twenty eight (128) methamphetamine positive samples and two hundred sixteen (216) negative samples were evaluated in this study. The results are summarized as below:
Positive % agreement: 98, Negative % agreement: 100

11. **Opiate** The accuracy of the opiate test was evaluated in comparison to GC/MS method and commercial kits at a cut-off of 300 ng/ml of morphine. Three hundred and forty four (344) urine specimens which composed of one hundred fifty nine (159) opiate positive samples and one hundred eighty five (185) negative samples were evaluated in this study. The results are summarized as below:
Positive % agreement: 99, Negative % agreement: 99

12. **Opiate II** The accuracy of the opiate II test was evaluated in comparison to GC/MS method and commercial kits at a cut-off of 2000 ng/ml of morphine. One hundred and eight (108) urine specimens which composed of fifty three (53) opiate positive samples and fifty five (55) negative samples were evaluated in this study. The results are summarized as below:
Positive % agreement: 94, Negative % agreement: 100.0.

13. **Oxycodone** The accuracy of the oxycodone test was evaluated in comparison to GC/MS method and commercial kits at a cut-off of 100 ng/ml of oxycodone. One hundred and forty four (140) urine specimens which composed of fifty eight (58) opiate positive samples and eighty two (82) negative samples were evaluated in this study. The results are summarized as below:
Positive % agreement: 100, Negative % agreement: 95

14. **Phencyclidine** The accuracy of the PCP test was evaluated in comparison to GC/MS method and commercial kits at a cut-off of 25 ng/ml of phencyclidine. Eighty (80) urine specimens which composed of thirty five (35) phencycludine positive samples and forty five (45) negative samples were evaluated in this study. The results are summarized as below:
Positive % agreement: 98, Negative % agreement: 95

15. **Propoxyphene** The accuracy of the propoxyphene test was evaluated in comparison to GC/MS method at a cut-off of 300 ng/ml of nor-propoxyphene. Ninety one (91) propoxyphene positive specimens with GC/MS confirmed nor-Propoxyphene concentration and forty (40) were evaluated in this study. The results are summarized as below:
Positive % agreement: 100, Negative % agreement: 100

16. **THC** The accuracy of the THC test was evaluated in comparison to GC/MS method and commercial kits at a cut-off of 50 ng/ml of 11-nor-Δ^9-THC-9-COOH. Three hundred and forty four (344) urine specimens which composed of seventy eight (78) THC positive samples and two hundred sixty six (266) negative samples were evaluated in this study. The results are summarized as below
Positive % agreement: 100, Negative % agreement: 99

17. **Tramadol** The accuracy of the tramadol test was evaluated in comparison to GC/MS at a cut-off of 200 ng/ml of tramadol Eighty one (81) urine specimens with GC/MS confirmed tramadol concentration were evaluated in this study. The results are summarized and presented below:
Positive % agreement: 95, Negative % agreement: 98

18. **TCA** The accuracy of the TCA test was evaluated in comparison to GC/MS at a cut-off of 1000 ng/ml of Nortriptyline. One hundred (100) urine specimens with GC/MS confirmed Nortriptyline concentration were evaluated in this study. The results are summarized and presented below:
Positive % agreement: 98, Negative % agreement: 95

B. Sensitivity

The cut-off concentrations (sensitivity level) of the DOA/Alcohol Panel Test Device are determined to be: AMP 1000 ng/ml, BAR, 300 ng/ml, BZO 300 ng/ml, BUP 10 ng/ml, COC 300 ng/ml, EDDP 100 ng/ml, KET 1000 ng/ml, MTD 300 ng/ml, MET 1000 ng/ml, MDMA 500 ng/ml, OPI 300 ng/ml, OPI II 2000 ng/ml, OXY 100 ng/ml, PCP 25 ng/ml , PPX 300 ng/ml, THC 50 ng/ml, 200ng/ml of TRA and TCA 1000 ng/ml.

C. Precision

The precision of the DOA/Alcohol Panel Test Device was determined by conducting the test with spiked controls and interpreted the results by three individuals to verify the random error of visual interpretation. The results of 40 samples each of 50% above and 50% below cut-off specimens are 100% agreed by three observers. The test results were found to have no significant differences between these three observers.

D. Specificity

The specificity for the DOA/Alcohol Panel Test Device was tested by adding various drugs, drug metabolites, and other compounds that are likely to be present in urine. All compounds were prepared in drug-free normal human urine.

1. Interference testing

The performance of the DOA/Alcohol Panel Test Device at cut-off level is not affected when pH and Specific Gravity ranges of urine specimen are at 4.5 to 9.0 and 1.005 to 1.035.

The following substances were tested and confirmed did not interfere with the DOA/Alcohol Panel Test Device at the concentrations listed below.

Glucose	2000 mg/dl
Human albumin	2000 mg/dl
Human hemoglobin	10 mg/dl
Urea	4000 mg/dl
Uric acid	10 mg/dl

2. Specificity

The following table lists compounds that are detected by the DOA/Alcohol Panel Test Device which produced positive results when tested at levels equal or greater than the concentrations listed below:

Tests	Compounds	Cut-off (ng/ml)
Amphetamine	D-Amphetamine	1,000
	D/L-Amphetamine	2,000
	(±)-MDA	2,500
	L-Amphetamine	30,000
	Tyramine	50,000
Barbiturate	Alphenal	100
	Barbital	150
	Pentobarbital	150
	Phenobarbital	150
	Amobarbital	300
	Secobarbital	300
	Butalbital	5,000
Buprenorphine	Buprenorphine	200
	Buprenorphine-3-β-glucuronide	10
Benzoxiazepines	Nitrazepam	100
	Alprazolam	300
	Chloradiazepoxide	300
	Clobazam	300
	Desmethyldiazepam (nordiazepam)	300
	Estazolam	300
	Oxazepam	300
	Temazepam	300
	Lormetazepam	500
	Bromazepam	1,000
	Diazepam	1,000
	Flunitrazepam	1,000
	Lorazepam	1,000
	Triazolam	1,000
	Clonazapam	2,000
	Flurazepam	>100 ug/mL
COC	Benzoylecgonine	300
	Cocaine Hydrochloride	300
EDDP	EDDP Perchlorate	100
	EMDP	20,000
	Vanlafaxine	25,000
	(±)Methadone	50,000
	Doxylamine succinate	100,000
Ketamine	Ketamine	1,000
	Norketamine	500
	Phencyclidine (PCP)	25,000
	Methaonde	50,000
	Tetrahydrozoline	50,000
MDMA	(±)MDMA	500
	(±)MDEA	500
	(±)MDA	2,000
	(±)MBDB	5,000
Methamphetamine	(+)Methamphetamine	1,000
	(±)Methamphetamine	1,000
	(±)MDMA	1,000
	(±)MBDB	1,000
	(±)MDEA	3,000
	R(-)Methamphetamine	5,000
	Orphenadine.HCl	50,000
Methadone	(±)Methadone HCl	300
	Methadol	300
Opiate	6-Acetylmorphine	100
	Codeine	300
	Dihydrocodeine	300
	Ethylmorphine	300
	Hydromorphone	300
	Morphine	300
	Morphine-3-β-glucuronide	300
	Nalorphine	750
	Norcodeine	1,000
	Heroin	1,000
	Hydrocodone	1,000
	Normorphine	2,000
	Naloxone	25,000
	Natrexone	100,000
Opiate II	Ethylmorphine	1,000
	6-Acetylmorphine	2,000
	Codeine	2,000
	Dihydrocodeine	2,000
	Morphine	2,000
	Morphine-3-β-glucuronide	2,000
	Heroin	5,000
	Hydrocodone	7,500
	Hydromorphone	7,500
	Nalorphine	15,000

	Norcodeine	100,000
	Normorphine	100,000
OXY100	oxycodone	100
	oxymorphone	100
	Normorphine	100
	Dihydrocodeine	20,000
	Hydrocodone	50,000
	Ethylmorphine	50,000
PCP	Phencyclidine	25
	Codeine	10,000
	Nalorphine	10,000
	Natrexone	10,000
	Naloxone	10,000
	Cis-tramadol	10,000
	N-Desmethyl-cis tramadol	10,000
	O-Desmethyl-cis tramadol	10,000
	Dextramethorphan	50,000
	Oxymorphone	60,000
	Oxycodone	80,000
Propoxyphene	Propoxyphene	200
	norpropoxyphene	300
TCA	Desipramine	1,000
	Nortriptyline	1,000
	Imipramine	1,000
	Amitriotyline	2,000
	Protriptyline	2,000
	trimipramine	5,000
	Quetiapine fumarate	20,000
THC	11-nor-Δ^9-THC-9-COOH	37.5
	11-nor-Δ^9-THC-9-COOH	50
	11-hydroxy-Δ^9-THC	5,000
	Δ^8-THC	15,000
	Δ^9-THC	25,000
Tramadol	Cis-Tramadol	200
	N-Desmethyl-cis tramadol	500
	O-Desmethyl-cis tramadol	20,000
	Netrexone	10,000
	Tetrahydrozoline	10,000
	Dihydrocodeine	50,000

The following compounds show no cross-reactivity at concentration up to100 ug/mL unless specified in the table above.

Acetamidophenol	Acetaminophen	6-Acetylmorphine	Acetylsalicyclic acid
Alfentanil HCL	Alprazolam	7-Aminoclonazepam	7-Aminoflunitrazepam
7-Aminonitrazepam	Amitriptyline Hydrochloride	Amobarbital Sodium	(±)Amphetamine
Ascorbic acid	Atenolol	Atropine	Benzoylecgonine
Bromazepam	Buprenorphine	Butalbital	Caffeine
Cannabidiol	Cannabinal	Chlordiazepoxide	Chloroquine
Chlorpheniramine	Cis-Tramadol	Citalopram HBr	Clobazam
Clonazepam	Cocaine Hydrochloride	Codeine	Cortisone
Cotinine	(-)-delta8-THC	(-)-delta9-THC	Desipramine
Dextromethorphan	Diazepam	Digitoxin	Digoxin
Dihydrocodeine	Diphenhydramine	Doxepin	Doxylamine succinate
d-Pseudoephedrine	EDDP Perchlorate	EMDP	Estazolam
Ethylmorphine	(-)Ephedrine Hydrochloride	Fentanyl	Flunitrazepam
Fluoxetine	Flurazepam	Gentisic acid	Guaiacol glycer ester
Heroin	Hydrochlorothiazine	Hydrocodone	Hydromorphone
(±)-11-Hydroxy-delta9-THC	Hydroxyzine	Ibuprofen	Imipramine Hydrochloride
Isoproterenol	Ketamine	Lidocaine	Lorazepam
Lormetazepam	(±)-MBDB	(±)-MDA	(±)MDEA
(±)-MDMA	Meperidine	(±)Methadone	(±)Methamphetamine
(+)-Methamphetamine	Methaqualone	Methylphenidate	Midazolam
Morphine	Morphine-3-β-glucuronide	Nalbuphine	Nalorphine
Naloxone	Natrexone	N-Desmethyl-cis tramadol	Neomycin
Niacianamide	Nitrazepam	Norbuprenorphine	(-)-11-nor-9-Carboxy-delta 9-THC
Norcodeine	Nordiazepam	(±)-Norketamine	Normorphine
Norpropoxyphene	Norsertraline	Nortriptyline	O-Desmethyl-cis tramadol
Orphenadine	Oxazepam	Oxcarbazepine	Oxycodone
Oxymorphone	Pentobarbital	Perphenazine	Phencyclidine (PCP)
Phenobarbital	β- Phenylethylamine	Phenylpropanolamine	Prazepam
Promethazine	Propoxyphene	(±)-Propranolol	Protriptyline
Quetiapine fumarate	R(-)-Epinephrine	R(-)-Methamphetamine	Ranitidine
Ritalinic acid	S(-)-Nicotine	Salicyclic acid	Secobarbital
Sertraline	Temazepam	Tetracycline	Tetrahydrozoline
Theophyline	Thioridazine	Triazolam	Trimipramine
Tyramine	Venlafaxine	Verapamil	

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