

**CERTIFICADO**  
**REVISIÓN DE ANTECEDENTES QUE ACOMPAÑAN AL DISPOSITIVO MÉDICO**  
**Nº DDM / 2146 / 19**

El Departamento Dispositivos Médicos del Instituto de Salud Pública de Chile, ha recibido los antecedentes presentados por la empresa **Global Partners SpA.**, para la conformidad de los siguientes dispositivos médicos:

**Test Rápidos para la detección de drogas**  
Inmunoensayos para la detección cualitativa de drogas de abuso  
Clase B (II)

<b>Fabricante Legal</b>	Hangzhou All Test Biotech Co. Ltd.
<b>Dirección</b>	#550, Yin Hai Street Hangzhou, Zhejiang, 310018, China
<b>Planta de Fabricación</b>	Hangzhou All Test Biotech Co. Ltd.
<b>Dirección</b>	#550, Yin Hai Street Hangzhou, Zhejiang, 310018, China
<b>Distribuidor en Chile:</b>	Global Partners SpA.
<b>Dirección</b>	Lota 2257, Oficina 901, Providencia, Santiago, Chile.

**USO PREVISTO POR EL FABRICANTE:**

Indicado para la detección rápida y cualitativa de drogas de abuso y a utilizar con distintos tipos de muestras (ver Anexo).

**DESCRIPCIÓN DEL DISPOSITIVO MÉDICO:**

Familia de test rápidos de lectura visual basados en técnicas de inmunocromatografía. No requiere el uso de instrumental especial. Detecta selectivamente la presencia de drogas existentes en la muestra. Se indican los puntos de corte de cada droga, a partir de los cuales se considera un resultado positivo demostrado por la aparición de una línea coloreada en la zona de prueba del dispositivo (ver Anexo).

**CÓDIGO UMDNS:** 19-196: Reactivos/Kits para ensayos de DIV, Inmunoensayo, Rápido, Droga de hábito.

A través de este certificado se otorga conformidad a los antecedentes tenidos a la vista y se deja constancia que el producto cuenta con la siguiente certificación:

- 1. Certificado para Gobierno Extranjero**, Nº 15001-9-2017 emitido por la *Food and Drug Administration de Estados Unidos (FDA)*, certificando que los productos fabricados por Hangzhou All Test Biotech Co. Ltd. de China (ver listado en Anexo), pueden ser comercializados en Estados Unidos y legalmente exportados. La planta de fabricación de estos productos está sujeta a inspecciones periódicas. Válido hasta el 19 de septiembre de 2019.
- 2. Certificado del Sistema de Gestión de Calidad**, Nº Q5 095123 0007 Rev. 01 otorgado por *TÜV SÜD Product Service GmbH*, certificando que Hangzhou All Test Biotech Co. Ltd. de China, tiene implementado un Sistema de Gestión de Calidad que cumple con los requisitos de la Norma EN ISO 13485:2016 que aplica a las actividades de diseño y desarrollo, producción y distribución de kits para diagnóstico *in vitro* de drogas de abuso y enfermedades infecciosas entre otros. Válido hasta el 24 de septiembre de 2020.

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3. **Carta de Autorización**, emitida por el fabricante Hangzhou All Test Biotech Co. Ltd. de China; autorizando a Global Partners SpA; domiciliado en Lota Nº 2257, Oficina 901, Providencia, Santiago, Chile, como su distribuidor autorizado de la línea de productos All Test para Chile. Emitido el 14 de enero de 2019.

**Estos dispositivos médicos actualmente no se encuentran sometidos a exigencia de registro sanitario en Chile y la seguridad, calidad y efectividad de éstos, es de exclusiva responsabilidad del fabricante legal, importador y distribuidor.**

El presente documento se otorga a solicitud del interesado y está sujeto a la vigencia de los documentos que lo respaldan.





**DR. MARÍA CECILIA LÓPEZ GUTIÉRREZ**

**JEFA (S)**

**DEPARTAMENTO DISPOSITIVOS MÉDICOS**  
**INSTITUTO DE SALUD PÚBLICA DE CHILE**

**Sistema de Tecnovigilancia (Artículo 28 Reglamento D.S. 825/1998)**

El sistema de Tecnovigilancia corresponde a un conjunto de actividades encaminadas a la prevención, detección, investigación y difusión oportuna de información sobre eventos adversos con dispositivos médicos durante su uso, que puedan generar algún daño al usuario, al operador o al medio ambiente que lo rodea. Este sistema se sustenta en la notificación de eventos adversos por parte de profesionales de la salud.

**Profesionales de la Salud:** Favor notificar cualquier evento adverso asociado a los dispositivos médicos mediante el Formulario DDM/006 o el Formulario DDM/010 si se trata de un reactivo de diagnóstico *in vitro*.

**Fabricante/importador:** Favor notificar las investigaciones de eventos adversos, mediante el formulario DDM/008. Todos los formularios están disponibles en la página web <http://www.ispch.cl/Dispositivos Médicos/Tecnovigilancia>. Estos formularios se deben enviar completos con letra legible al correo [tecnovigilancia@ispch.cl](mailto:tecnovigilancia@ispch.cl)

Santiago, 12 de julio de 2019.

  
**MCL/JPF/lps**

Nº Ref.: 2968/19

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**ANEXO CERTIFICADO**  
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**Listado de Productos**

Cat. No.	Descripción del Producto	Muestra	Formato	Punto de corte
DABP-102	AB-PINACA (ABP) Rapid Test Cassette	Urine	Cassette	10 ng/mL*
DABP-114	AB-PINACA (ABP) Rapid Test Panel	Urine	Panel	
DABP-101	AB-PINACA (ABP) Rapid Test Dipstick	Urine	Dipstick	
DAC-102	Acetaminophen (ACE) Rapid Test Cassette	Urine	Cassette	5000 ng/mL*
DAC-114	Acetaminophen (ACE) Rapid Test Panel	Urine	Panel	
DAC-101	Acetaminophen (ACE) Rapid Test Dipstick	Urine	Dipstick	
DACL-102	7-Aminoclonazepam (7-ACL) Rapid Test Cassette	Urine	Cassette	300 ng/mL*
DACL-114	7-Aminoclonazepam(7-ACL)RapidTestPanel	Urine	Panel	
DACL-101	7-Aminoclonazepam (7-ACL) Rapid Test Dipstick	Urine	Dipstick	
DAL-102	Alcohol (ALC) Rapid Test Cassette	Urine	Cassette	0.02%
DAL-114	Alcohol (ALC) Rapid Test Panel	Urine	Panel	
DAL-101	Alcohol (ALC) Rapid Test Dipstick	Urine	Dipstick	
DAM-102	Amphetamine (AMP) Rapid Test Cassette	Urine	Cassette	300 ng/mL, 500 ng/mL, 1000 ng/mL*
DAM-114	Amphetamine (AMP) Rapid Test Panel	Urine	Panel	
DAM-101	Amphetamine (AMP) Rapid Test Dipstick	Urine	Dipstick	
DAP-102	$\alpha$ -Pyrrolidinovalerophenone ( $\alpha$ -PVP) Rapid Test Cassette	Urine	Cassette	1000 ng/mL*, 500ng/mL, 300ng/mL
DAP-114	$\alpha$ -Pyrrolidinovalerophenone ( $\alpha$ -PVP) Rapid Test Panel	Urine	Panel	
DAP-101	$\alpha$ -Pyrrolidinovalerophenone ( $\alpha$ -PVP) Rapid Test Dipstick	Urine	Dipstick	
DBA-102	Barbiturate (BAR) Rapid Test Cassette	Urine	Cassette	200 ng/mL, 300 ng/mL*
DBA-114	Barbiturate (BAR) Rapid Test Panel	Urine	Panel	
DBA-101	Barbiturate (BAR) Rapid Test Dipstick	Urine	Dipstick	
DBU-102	Buprenorphine (BUP) Rapid Test Cassette	Urine	Cassette	10 ng/mL*
DBU-114	Buprenorphine (BUP) Rapid Test Panel	Urine	Panel	
DBU-101	Buprenorphine (BUP) Rapid Test Dipstick	Urine	Dipstick	
DBZ-102	Benzodiazepines (BZO) Rapid Test Cassette	Urine	Cassette	100 ng/mL, 200 ng/mL, 300 ng/mL*
DBZ-114	Benzodiazepines (BZO) Rapid Test Panel	Urine	Panel	
DBZ-101	Benzodiazepines (BZO) Rapid Test Dipstick	Urine	Dipstick	
DCA-102	Cathine (CAT) Rapid Test Cassette	Urine	Cassette	150 ng/mL*
DCA-114	Cathine (CAT) Rapid Test Panel	Urine	Panel	
DCA-101	Cathine (CAT) Rapid Test Dipstick	Urine	Dipstick	
DCAF-102	Caffeine(CAF) Rapid Test Cassette	Urine	Cassette	
DCAF-114	Caffeine(CAF) Rapid Test Panel	Urine	Panel	

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DCAF-101	Caffeine(CAF) Rapid Test Dipstick	Urine	Dipstick	1000 ng/mL*
DCL-102	Clonazepam (CLO) Rapid Test Cassette	Urine	Cassette	400 ng/mL*
DCL-114	Clonazepam (CLO) Rapid Test Panel	Urine	Panel	
DCL-101	Clonazepam (CLO) Rapid Test Dipstick	Urine	Dipstick	
DCO-102	COCAINE (COC) Rapid Test Cassette	Urine	Cassette	100 ng/mL, 150 ng/mL, 300ng/mL*
DCO-114	COCAINE (COC) Rapid Test Panel	Urine	Panel	
DCO-101	COCAINE (COC) Rapid Test Dipstick	Urine	Dipstick	
DCT-102	Cotinine (COT) Rapid Test Cassette	Urine	Cassette	50 ng/mL, 100ng/mL,200 ng/mL*, 500 ng/mL
DCT-114	Cotinine (COT) Rapid Test Panel	Urine	Panel	
DCT-101	Cotinine (COT) Rapid Test Dipstick	Urine	Dipstick	
DCFY-102	Carfentanyl(CFYL) Rapid Tests Cassette	Urine	Cassette	500 ng/mL*
DCFY-114	Carfentanyl(CFYL) Rapid Tests Panel	Urine	Panel	
DCFY-101	Carfentanyl(CFYL) Rapid Tests Dipstick	Urine	Dipstick	
DDI-102	Diazepam (DIA) Rapid Test Cassette	Urine	Cassette	300 ng/mL*
DDI-114	Diazepam (DIA) Rapid Test Panel	Urine	Panel	
DDI-101	Diazepam (DIA) Rapid Test Dipstick	Urine	Dipstick	
DED-102	Ethylenediamine-dimethylphosphinic acid (EDDP) Rapid Test Cassette	Urine	Cassette	100 ng/mL*
DED-114	Ethylenediamine-dimethylphosphinic acid (EDDP) Rapid Test Panel	Urine	Panel	
DED-101	Ethylenediamine-dimethylphosphinic acid (EDDP) Rapid Test Dipstick	Urine	Dipstick	
DET-102	Ethyl Glucuronide (ETG) Rapid Test Cassette	Urine	Cassette	500ng/mL*, 1000 ng/mL
DET-114	Ethyl Glucuronide (ETG) Rapid Test Panel	Urine	Panel	
DET-101	Ethyl Glucuronide(ETG)RapidTestDipstick	Urine	Dipstick	
DFY-102	Fentanyl (FYL) Rapid Test Cassette	Urine	Cassette	10 ng/mL ,20 ng/mL*
DFY-114	Fentanyl (FYL) Rapid Test Panel	Urine	Panel	
DFY-101	Fentanyl (FYL) Rapid Test Dipstick	Urine	Dipstick	
DGHB-102	γ-Hydroxybutyric acid (GHB) Rapid Test Cassette	Urine	Cassette	10µg/mL
DKE-102	Ketamine (KET)Rapid Test Cassette	Urine	Cassette	500 ng/mL, 1000 ng/mL*
DKE-114	Ketamine (KET)Rapid Test Panel	Urine	Panel	
DKE-101	Ketamine (KET)Rapid Test Dipstick	Urine	Dipstick	
DMA-102	6-Monoacetylmorphine (6-MAM) Rapid Test Cassette	Urine	Cassette	10 ng/mL*
DMA-114	6-Monoacetylmorphine (6-MAM)Rapid Test Panel	Urine	Panel	
DMA-101	6-Monoacetylmorphine(6-MAM) Rapid Test Dipstick	Urine	Dipstick	
DMCA-102	Methcathinone(MCAT) Rapid Test Cassette	Urine	Cassette	500 ng/mL
DMCA-114	Methcathinone(MCAT) Rapid Test Panel	Urine	Panel	
DMCA-101	Methcathinone(MCAT) Rapid Test Dipstick	Urine	Dipstick	
DMD-102	Ecstasy (MDMA) Rapid Test Cassette	Urine	Cassette	

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DMD-114	Ecstasy (MDMA) Rapid Test Panel	Urine	Panel	500 ng/mL*, 1000 ng/mL
DMD-101	Ecstasy (MDMA) Rapid Test Dipstick	Urine	Dipstick	
DMDA-102	Tenamfetamine (MDA) Rapid Test Cassette	Urine	Cassette	500 ng/mL*
DMDA-114	Tenamfetamine (MDA) Rapid Test Panel	Urine	Panel	
DMDA-101	Tenamfetamine (MDA) Rapid Test Dipstick	Urine	Dipstick	
DMDP-102	Methylenedioxyprovalerone (MDPV) Rapid Test Cassette	Urine	Cassette	1000 ng/mL*, 500ng/mL, 300ng/mL
DMDP-114	Methylenedioxyprovalerone (MDPV) Rapid Test Panel	Urine	Panel	
DMDP-101	Methylenedioxyprovalerone (MDPV) Rapid Test Dipstick	Urine	Dipstick	
DMP-102	Methylphenidate(MPD) Rapid Test Cassette	Urine	Cassette	1000 ng/mL* 300 ng/mL
DMP-114	Methylphenidate(MPD) Rapid Test Panel	Urine	Panel	
DMP-101	Methylphenidate(MPD) Rapid Test Dipstick	Urine	Dipstick	
DME-102	Methamphetamine (MET) Rapid Test Cassette	Urine	Cassette	300 ng/mL, 500 ng/mL, 1000 ng/mL*
DME-114	Methamphetamine (MET) Rapid Test Panel	Urine	Panel	
DME-101	Methamphetamine (MET) Rapid Test Dipstick	Urine	Dipstick	
DMEP-102	Mephedrone HCl(MEP) Rapid Test Cassette	Urine	Cassette	100 ng/mL
DMEP-114	Mephedrone HCl(MEP) Rapid Test Panel	Urine	Panel	
DMEP-101	Mephedrone HCl(MEP) Rapid Test Dipstick	Urine	Dipstick	
DMO-102	Morphine (MOP) Rapid Test Cassette	Urine	Cassette	100 ng/mL, 300 ng/mL*
DMO-114	Morphine (MOP) Rapid Test Panel	Urine	Panel	
DMO-101	Morphine (MOP) Rapid Test Dipstick	Urine	Dipstick	
DMQ-102	Methaqualone (MQL) Rapid Test Cassette	Urine	Cassette	300 ng/mL*
DMQ-114	Methaqualone (MQL) Rapid Test Panel	Urine	Panel	
DMQ-101	Methaqualone (MQL) Rapid Test Dipstick	Urine	Dipstick	
DMT-102	Methadone (MTD) Rapid Test Cassette	Urine	Cassette	200 ng/mL, 300 ng/mL*
DMT-114	Methadone (MTD) Rapid Test Panel	Urine	Panel	
DMT-101	Methadone (MTD) Rapid Test Dipstick	Urine	Dipstick	
DOP-102	Opiates (OPI) Rapid Test Cassette	Urine	Cassette	2000 ng/mL*
DOP-114	Opiates (OPI) Rapid Test Panel	Urine	Panel	
DOP-101	Opiates (OPI) Rapid Test Dipstick	Urine	Dipstick	
DOX-102	Oxycodone (OXY) Rapid Test Cassette	Urine	Cassette	100 ng/mL*
DOX-114	Oxycodone (OXY) Rapid Test Panel	Urine	Panel	
DOX-101	Oxycodone (OXY) Rapid Test Dipstick	Urine	Dipstick	
DPC-102	Phencyclidine (PCP) Rapid Test Cassette	Urine	Cassette	25 ng/mL*
DPC-114	Phencyclidine (PCP) Rapid Test Panel	Urine	Panel	
DPC-101	Phencyclidine (PCP) Rapid Test Dipstick	Urine	Dipstick	
DPG-102	Pregabalin (PGB) Rapid Test Cassette	Urine	Cassette	

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DPG-114	Pregabalin (PGB) Rapid Test Panel	Urine	Panel	50µg/mL*
DPG-101	Pregabalin (PGB) Rapid Test Dipstick	Urine	Dipstick	
DPP-102	Propoxyphene (PPX) Rapid Test Cassette	Urine	Cassette	300 ng/mL*
DPP-114	Propoxyphene (PPX) Rapid Test Panel	Urine	Panel	
DPP-101	Propoxyphene (PPX) Rapid Test Dipstick	Urine	Dipstick	
DSM-102	Synthetic Marijuana (K2) Rapid Test Cassette	Urine	Cassette	50 ng/mL*, 30 ng/mL,
DSM-114	Synthetic Marijuana (K2) Rapid Test Panel	Urine	Panel	
DSM-101	Synthetic Marijuana (K2) Rapid Test Dipstick	Urine	Dipstick	
DTC-102	Tricyclic Antidepressants (TCA) Rapid Test Cassette	Urine	Cassette	500 ng/mL, 1000 ng/mL*
DTC-114	Tricyclic Antidepressants (TCA) Rapid Test Panel	Urine	Panel	
DTC-101	Tricyclic Antidepressants (TCA) Rapid Test Dipstick	Urine	Dipstick	
DTH-102	Marijuana (THC) Rapid Test Cassette	Urine	Cassette	25 ng/mL, 20 ng/mL, 50 ng/mL*, 150 ng/mL, 300 ng/mL
DTH-114	Marijuana (THC) Rapid Test Panel	Urine	Panel	
DTH-101	Marijuana (THC) Rapid Test Dipstick	Urine	Dipstick	
DTM-102	Tramadol (TML) Rapid Test Cassette	Urine	Cassette	100 ng/mL*, 200 ng/mL, 300 ng/mL
DTM-114	Tramadol (TML) Rapid Test Panel	Urine	Panel	
DTM-101	Tramadol (TML) Rapid Test Dipstick	Urine	Dipstick	
DTRO-102	Tropicamide (TRO) Rapid Test Cassette	Urine	Cassette	350 ng/mL*
DTRO-114	Tropicamide (TRO) Rapid Test Panel	Urine	Panel	
DTRO-101	Tropicamide (TRO) Rapid Test Dipstick	Urine	Dipstick	
DLS-102	Lysergic Acid Diethylamide (LSD) Rapid Test Cassette	Urine	Cassette	10 ng/mL, 20 ng/mL*, 50 ng/mL
DLS-114	Lysergic Acid Diethylamide (LSD) Rapid Test Panel	Urine	Panel	
DLS-101	Lysergic Acid Diethylamide (LSD) Rapid Test Dipstick	Urine	Dipstick	
DZO-102	Zolpidem (ZOL) Rapid Test Cassette	Urine	Cassette	50 ng/mL*
DZO-114	Zolpidem (ZOL) Rapid Test Panel	Urine	Panel	
DZO-101	Zolpidem (ZOL) Rapid Test Dipstick	Urine	Dipstick	
DALP-102	Alprazolam (ALP) Rapid Test Cassette	Urine	Cassette	100 ng/mL*
DALP-114	Alprazolam (ALP) Rapid Test Panel	Urine	Panel	
DALP-101	Alprazolam (ALP) Rapid Test Dipstick	Urine	Dipstick	
DZOP-102	Zopiclone (ZOP) Rapid Test Cassette	Urine	Cassette	50 ng/mL*
DZOP-114	Zopiclone (ZOP) Rapid Test Panel	Urine	Panel	
DZOP-101	Zopiclone (ZOP) Rapid Test Dipstick	Urine	Dipstick	
DAT-111	Adulteration Dipstick	Urine	Dipstick	/
DOA-125	Multi-Drug 2 Drugs Rapid Test Cassette	Urine	Cassette	
DOA-135	Multi-Drug 3 Drugs Rapid Test Cassette	Urine	Cassette	
DOA-145	Multi-Drug 4 Drugs Rapid Test Cassette	Urine	Cassette	

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DOA-155	Multi-Drug 5 Drugs Rapid Test Cassette	Urine	Cassette	
DOA-165	Multi-Drug 6 Drugs Rapid Test Cassette	Urine	Cassette	
DOA-175	Multi-Drug 7 Drugs Rapid Test Cassette	Urine	Cassette	
DOA-185	Multi-Drug 8 Drugs Rapid Test Cassette	Urine	Cassette	
DOA-195	Multi-Drug 9 Drugs Rapid Test Cassette	Urine	Cassette	
DOA-1105	Multi-Drug 10 Drugs Rapid Test Cassette	Urine	Cassette	/
DOA-1115	Multi-Drug 11 Drugs Rapid Test Cassette	Urine	Cassette	
DOA-1125	Multi-Drug 12 Drugs Rapid Test Cassette	Urine	Cassette	
DOA-124	Multi-Drug 2 Drugs Rapid Test Panel	Urine	Panel	
DOA-134	Multi-Drug 3 Drugs Rapid Test Panel	Urine	Panel	
DOA-144	Multi-Drug 4 Drugs Rapid Test Panel	Urine	Panel	
DOA-154	Multi-Drug 5 Drugs Rapid Test Panel	Urine	Panel	
DOA-164	Multi-Drug 6 Drugs Rapid Test Panel	Urine	Panel	
DOA-174	Multi-Drug 7 Drugs Rapid Test Panel	Urine	Panel	
DOA-184	Multi-Drug 8 Drugs Rapid Test Panel	Urine	Panel	
DOA-194	Multi-Drug 9 Drugs Rapid Test Panel	Urine	Panel	
DOA-1104	Multi-Drug 10 Drugs Rapid Test Panel	Urine	Panel	
DOA-1114	Multi-Drug 11 Drugs Rapid Test Panel	Urine	Panel	
DOA-1124	Multi-Drug 12 Drugs Rapid Test Panel	Urine	Panel	
DOA-1134	Multi-Drug 13 Drugs Rapid Test Panel	Urine	Panel	/
DOA-1144	Multi-Drug 14 Drugs Rapid Test Panel	Urine	Panel	
DOA-1154	Multi-Drug 15 Drugs Rapid Test Panel	Urine	Panel	
DOA-1164	Multi-Drug 16 Drugs Rapid Test Panel	Urine	Panel	
DOA-127-A1	Multi-Drug 2 Drugs Rapid Test 1-Step Cup	Urine	Cup	
DOA-137-A1	Multi-Drug 3 Drugs Rapid Test 1-Step Cup	Urine	Cup	
DOA-147-A1	Multi-Drug 4 Drugs Rapid Test 1-Step Cup	Urine	Cup	
DOA-157-A1	Multi-Drug 5 Drugs Rapid Test 1-Step Cup	Urine	Cup	
DOA-167-A1	Multi-Drug 6 Drugs Rapid Test 1-Step Cup	Urine	Cup	
DOA-177-A1	Multi-Drug 7 Drugs Rapid Test 1-Step Cup	Urine	Cup	
DOA-187-A1	Multi-Drug 8 Drugs Rapid Test 1-Step Cup	Urine	Cup	
DOA-197-A1	Multi-Drug 9 Drugs Rapid Test 1-Step Cup	Urine	Cup	
DOA-1107-A1	Multi-Drug 10 Drugs Rapid Test 1-Step Cup	Urine	Cup	
DOA-1117-A1	Multi-Drug 11 Drugs Rapid Test 1-Step Cup	Urine	Cup	
DOA-1127-A1	Multi-Drug 12 Drugs Rapid Test 1-Step Cup	Urine	Cup	/
DOA-1137-A1	Multi-Drug 13 Drugs Rapid Test 1-Step Cup	Urine	Cup	
DOA-1147-A1	Multi-Drug 14 Drugs Rapid Test 1-Step Cup	Urine	Cup	
DOA-1157-A1	Multi-Drug 15 Drugs Rapid Test 1-Step Cup	Urine	Cup	

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DOA-127-A2	Multi-Drug 2 Drugs Rapid Test 1-Step Cup	Urine	Cup	/
DOA-137-A2	Multi-Drug 3 Drugs Rapid Test 1-Step Cup	Urine	Cup	
DOA-147-A2	Multi-Drug 4 Drugs Rapid Test 1-Step Cup	Urine	Cup	
DOA-157-A2	Multi-Drug 5 Drugs Rapid Test 1-Step Cup	Urine	Cup	
DOA-167-A2	Multi-Drug 6 Drugs Rapid Test 1-Step Cup	Urine	Cup	
DOA-177-A2	Multi-Drug 7 Drugs Rapid Test 1-Step Cup	Urine	Cup	
DOA-187-A2	Multi-Drug 8 Drugs Rapid Test 1-Step Cup	Urine	Cup	
DOA-197-A2	Multi-Drug 9 Drugs Rapid Test 1-Step Cup	Urine	Cup	
DOA-1107-A2	Multi-Drug 10 Drugs Rapid Test 1-Step Cup	Urine	Cup	
DOA-1117-A2	Multi-Drug 11 Drugs Rapid Test 1-Step Cup	Urine	Cup	
DOA-1127-A2	Multi-Drug 12 Drugs Rapid Test 1-Step Cup	Urine	Cup	
DOA-127-A3	Multi-Drug 2 Drugs Rapid Test 1-Step Cup	Urine	Cup	
DOA-137-A3	Multi-Drug 3 Drugs Rapid Test 1-Step Cup	Urine	Cup	
DOA-147-A3	Multi-Drug 4 Drugs Rapid Test 1-Step Cup	Urine	Cup	
DOA-157-A3	Multi-Drug 5 Drugs Rapid Test 1-Step Cup	Urine	Cup	
DOA-167-A3	Multi-Drug 6 Drugs Rapid Test 1-Step Cup	Urine	Cup	
DOA-177-A3	Multi-Drug 7 Drugs Rapid Test 1-Step Cup	Urine	Cup	
DOA-187-A3	Multi-Drug 8 Drugs Rapid Test 1-Step Cup	Urine	Cup	
DOA-197-A3	Multi-Drug 9 Drugs Rapid Test 1-Step Cup	Urine	Cup	
DOA-1107-A3	Multi-Drug 10 Drugs Rapid Test 1-Step Cup	Urine	Cup	
DOA-1117-A3	Multi-Drug 11 Drugs Rapid Test 1-Step Cup	Urine	Cup	
DOA-1127-A3	Multi-Drug 12 Drugs Rapid Test 1-Step Cup	Urine	Cup	
DOA-1137-A3	Multi-Drug 13 Drugs Rapid Test 1-Step Cup	Urine	Cup	
DOA-1147-A3	Multi-Drug 14 Drugs Rapid Test 1-Step Cup	Urine	Cup	
DOA-1157-A3	Multi-Drug 15 Drugs Rapid Test 1-Step Cup	Urine	Cup	
DOA-127-B1	Multi-Drug 2 Drugs Rapid Test 2-Step Cup	Urine	Cup	/
DOA-137-B1	Multi-Drug 3 Drugs Rapid Test 2-Step Cup	Urine	Cup	
DOA-147-B1	Multi-Drug 4 Drugs Rapid Test 2-Step Cup	Urine	Cup	
DOA-157-B1	Multi-Drug 5 Drugs Rapid Test 2-Step Cup	Urine	Cup	
DOA-167-B1	Multi-Drug 6 Drugs Rapid Test 2-Step Cup	Urine	Cup	
DOA-177-B1	Multi-Drug 7 Drugs Rapid Test 2-Step Cup	Urine	Cup	
DOA-187-B1	Multi-Drug 8 Drugs Rapid Test 2-Step Cup	Urine	Cup	
DOA-197-B1	Multi-Drug 9 Drugs Rapid Test 2-Step Cup	Urine	Cup	
DOA-1107-B1	Multi-Drug 10 Drugs Rapid Test 2-Step Cup	Urine	Cup	
DOA-1117-B1	Multi-Drug 11 Drugs Rapid Test 2-Step Cup	Urine	Cup	
DOA-1127-B1	Multi-Drug 12 Drugs Rapid Test 2-Step Cup	Urine	Cup	
DOA-127-B2	Multi-Drug 2 Drugs Rapid Test 2-Step Cup	Urine	Cup	



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DOA-137-B2	Multi-Drug 3 Drugs Rapid Test 2-Step Cup	Urine	Cup	
DOA-147-B2	Multi-Drug 4 Drugs Rapid Test 2-Step Cup	Urine	Cup	
DOA-157-B2	Multi-Drug 5 Drugs Rapid Test 2-Step Cup	Urine	Cup	
DOA-167-B2	Multi-Drug 6 Drugs Rapid Test 2-Step Cup	Urine	Cup	
DOA-177-B2	Multi-Drug 7 Drugs Rapid Test 2-Step Cup	Urine	Cup	
DOA-187-B2	Multi-Drug 8 Drugs Rapid Test 2-Step Cup	Urine	Cup	
DOA-197-B2	Multi-Drug 9 Drugs Rapid Test 2-Step Cup	Urine	Cup	
DOA-1107-B2	Multi-Drug 10 Drugs Rapid Test 2-Step Cup	Urine	Cup	
DOA-1117-B2	Multi-Drug 11 Drugs Rapid Test 2-Step Cup	Urine	Cup	
DOA-1127-B2	Multi-Drug 12 Drugs Rapid Test 2-Step Cup	Urine	Cup	
DOA-1137-B2	Multi-Drug 13 Drugs Rapid Test 2-Step Cup	Urine	Cup	/
DOA-1147-B2	Multi-Drug 14 Drugs Rapid Test 2-Step Cup	Urine	Cup	
DOA-1157-B2	Multi-Drug 15 Drugs Rapid Test 2-Step Cup	Urine	Cup	
DOA-1167-B2	Multi-Drug 16 Drugs Rapid Test 2-Step Cup	Urine	Cup	
DAL-801	Alcohol Rapid Test Dipstick	Oral Fluid	Dipstick	0.0002
DAL-802	Alcohol Rapid Test Cassette	Oral Fluid	Cassette	0.0002
DAM-802	Amphetamine (AMP) Rapid Test Cassette	Oral Fluid	Cassette	50 ng/mL
DAM-803	Amphetamine (AMP) Rapid Test Midstream	Oral Fluid	Midstream	50 ng/mL
DAP-802	$\alpha$ -Pyrrolidinovalerophenone ( $\alpha$ -PVP) Rapid Test Cassette	Oral Fluid	Cassette	300 ng/mL
DAP-803	$\alpha$ -Pyrrolidinovalerophenone ( $\alpha$ -PVP) Rapid Test Midstream	Oral Fluid	Midstream	300 ng/mL
DBA-802	Barbiturates (BAR) Rapid Test Cassette	Oral Fluid	Cassette	50 ng/mL*
DBA-803	Barbiturates (BAR) Rapid Test Midstream	Oral Fluid	Midstream	50 ng/mL*
DBU-802	Buprenorphine (BUP) Rapid Test Cassette	Oral Fluid	Cassette	10 ng/mL*
DBU-803	Buprenorphine (BUP) Rapid Test Midstream	Oral Fluid	Midstream	10 ng/mL*
DBZ-802	Benzodiazepines (BZO) Rapid Test Cassette	Oral Fluid	Cassette	20 ng/mL, 30 ng/mL
DBZ-803	Benzodiazepines (BZO) Rapid Test Midstream	Oral Fluid	Midstream	30 ng/mL, 50 ng/mL *
DCO-802	COCAINE (COC) Rapid Test Cassette	Oral Fluid	Cassette	20 ng/mL
DCO-803	COCAINE (COC) Rapid Test Midstream	Oral Fluid	Midstream	20 ng/mL
DCFY-802	Carfentanyl (CFYL) Rapid Test Cassette	Oral Fluid	Cassette	50 ng/mL
DCFY-803	Carfentanyl (CFYL) Rapid Test Midstream	Oral Fluid	Midstream	50 ng/mL
DCT-802	Cotinine (COT) Rapid Test Cassette	Oral Fluid	Cassette	20 ng/mL
DCT-803	Cotinine (COT) Rapid Test Midstream	Oral Fluid	Midstream	20 ng/mL

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DFY-802	Fentanyl (FYL) Rapid Test Cassette	Oral Fluid	Cassette	20ng/ml
DFY-803	Fentanyl (FYL) Rapid Test Midstream	Oral Fluid	Midstream	20ng/ml
DKE-802	Ketamine(KET) Rapid Test Cassette	Oral Fluid	Cassette	50 ng/mL*
DKE-803	Ketamine(KET) Rapid Test Midstream	Oral Fluid	Midstream	50 ng/mL*
DMA-802	6-Monoacetylmorphine (6-MAM) Rapid Test Cassette	Oral Fluid	Cassette	10 ng/mL
DMA-803	6-Monoacetylmorphine (6-MAM) Rapid Test Midstream	Oral Fluid	Midstream	10 ng/mL
DMD-802	Ecstasy (MDMA) Rapid Test Cassette	Oral Fluid	Cassette	50 ng/mL
DMD-803	Ecstasy (MDMA) Rapid Test Midstream	Oral Fluid	Midstream	50 ng/mL
DMDP-802	Methylenedioxypropylvalerone (MDPV) Rapid Test Cassette	Oral Fluid	Cassette	300 ng/mL
DMDP-803	Methylenedioxypropylvalerone (MDPV) Rapid Test Midstream	Oral Fluid	Midstream	300 ng/mL
DME-802	Methamphetamine(MET) Rapid Test Cassette	Oral Fluid	Cassette	50 ng/mL
DME-803	Methamphetamine (MET) Rapid Test Midstream	Oral Fluid	Midstream	50 ng/mL
DMT-802	Methadone (MTD) Rapid Test Cassette	Oral Fluid	Cassette	30 ng/mL
DMT-803	Methadone (MTD) Rapid Test Midstream	Oral Fluid	Midstream	30 ng/mL
DOP-802	Opiates (OPI) Rapid Test Cassette	Oral Fluid	Cassette	40 ng/mL
DOP-803	Opiates (OPI) Rapid Test Midstream	Oral Fluid	Midstream	40 ng/mL
DOX-802	Oxycodone (OXY) Rapid Test Cassette	Oral Fluid	Cassette	20 ng/mL
DOX-803	Oxycodone (OXY) Rapid Test Midstream	Oral Fluid	Midstream	20 ng/mL
DPC-802	Phencyclidine (PCP) Rapid Test Cassette	Oral Fluid	Cassette	10 ng/mL
DPC-803	Phencyclidine (PCP) Rapid Test Midstream	Oral Fluid	Midstream	10 ng/mL
DSM-802	Synthetic Marijuana (K2) Rapid Test Cassette	Oral Fluid	Cassette	25 ng/mL
DSM-803	Synthetic Marijuana (K2) Rapid Test Midstream	Oral Fluid	Midstream	25 ng/mL
DTH-802	Marijuana (THC) Rapid Test Cassette	Oral Fluid	Cassette	12 ng/mL, 20 ng/mL*
DTH-803	Marijuana (THC) Rapid Test Midstream	Oral Fluid	Midstream	50 ng/mL
DTM-802	Tramadol(TML) Rapid Test Cassette	Oral Fluid	Cassette	30 ng/mL*
DTM-803	Tramadol(TML) Rapid Test Midstream	Oral Fluid	Midstream	30 ng/mL*
DSD-823-A	Multi-Drug 2 Drugs Rapid Test Midstream	Oral Fluid	Midstream	/
DSD-833-A	Multi-Drug 3 Drugs Rapid Test Midstream	Oral Fluid	Midstream	
DSD-843-A	Multi-Drug 4 Drugs Rapid Test Midstream	Oral Fluid	Midstream	
DSD-853-A	Multi-Drug 5 Drugs Rapid Test Midstream	Oral Fluid	Midstream	
DSD-863-A	Multi-Drug 6 Drugs Rapid Test Midstream	Oral Fluid	Midstream	
DSD-873-A	Multi-Drug 7 Drugs Rapid Test Midstream	Oral Fluid	Midstream	
DSD-823-B	Multi-Drug 2 Drugs Rapid Test Midstream	Oral Fluid	Midstream	/
DSD-833-B	Multi-Drug 3 Drugs Rapid Test Midstream	Oral Fluid	Midstream	
DSD-843-B	Multi-Drug 4 Drugs Rapid Test Midstream	Oral Fluid	Midstream	
DSD-853-B	Multi-Drug 5 Drugs Rapid Test Midstream	Oral Fluid	Midstream	
DSD-863-B	Multi-Drug 6 Drugs Rapid Test Midstream	Oral Fluid	Midstream	
DSD-873-B	Multi-Drug 7 Drugs Rapid Test Midstream	Oral Fluid	Midstream	

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DSD-873-B	Multi-Drug 7 Drugs Rapid Test Midstream	Oral Fluid	Midstream	/
DSD-883-B	Multi-Drug 8 Drugs Rapid Test Midstream	Oral Fluid	Midstream	
DSD-893-B	Multi-Drug 9 Drugs Rapid Test Midstream	Oral Fluid	Midstream	
DSD-825-A	Oral Fluid Multi-Drug 2 Drugs Test A Cassette	Oral Fluid	Cassette	/
DSD-835-A	Oral Fluid Multi-Drug 3 Drugs Test A Cassette	Oral Fluid	Cassette	
DSD-845-A	Oral Fluid Multi-Drug 4 Drugs Test A Cassette	Oral Fluid	Cassette	
DSD-855-A	Oral Fluid Multi-Drug 5 Drugs Test A Cassette	Oral Fluid	Cassette	
DSD-865-A	Oral Fluid Multi-Drug 6 Drugs Test A Cassette	Oral Fluid	Cassette	
DSD-875-A	Oral Fluid Multi-Drug 7 Drugs Test A Cassette	Oral Fluid	Cassette	
DSD-885-A	Oral Fluid Multi-Drug 8 Drugs Test A Cassette	Oral Fluid	Cassette	
DSD-895-A	Oral Fluid Multi-Drug 9 Drugs Test A Cassette	Oral Fluid	Cassette	
DSD-827	Multi-Drug 2 Drugs Rapid Test Cup	Oral Fluid	Cup	
DSD-837	Multi-Drug 3 Drugs Rapid Test Cup	Oral Fluid	Cup	
DSD-847	Multi-Drug 4 Drugs Rapid Test Cup	Oral Fluid	Cup	
DSD-857	Multi-Drug 5 Drugs Rapid Test Cup	Oral Fluid	Cup	
DSD-867	Multi-Drug 6 Drugs Rapid Test Cup	Oral Fluid	Cup	
DSD-877	Multi-Drug 7 Drugs Rapid Test Cup	Oral Fluid	Cup	
DSD-887	Multi-Drug 8 Drugs Rapid Test Cup	Oral Fluid	Cup	
DSD-897	Multi-Drug 9 Drugs Rapid Test Cup	Oral Fluid	Cup	
DSD-8107	Multi-Drug 10 Drugs Rapid Test Cup	Oral Fluid	Cup	
DSD-8117	Multi-Drug 11 Drugs Rapid Test Cup	Oral Fluid	Cup	
DSD-8127	Multi-Drug 12 Drugs Rapid Test Cup	Oral Fluid	Cup	
DAC-X14	Acetaminophen (ACE) Rapid Test Panel	Powder	Panel	5000 ng/mL
DAM-X14	Amphetamine (AMP) Rapid Test Panel	Powder	Panel	1000 ng/mL
DAP-X14	α-Pyrrolidinovalerophenone (α-PVP) Rapid Test Panel	Powder	Panel	1000 ng/mL
DBA-X14	Barbiturate (BAR) Rapid Test Panel	Powder	Panel	300 ng/mL
DBU-X14	Buprenorphine (BUP) Rapid Test Panel	Powder	Panel	10 ng/mL
DBZ-X14	Benzodiazepines (BZO) Rapid Test Panel	Powder	Panel	300 ng/mL
DCO-X14	COCAINE (COC) Rapid Test Panel	Powder	Panel	300 ng/mL
DCFY-X14	Carfentanyl (CFYL) Rapid Test Panel	Powder	Panel	500 ng/mL
DCT-X14	Cotinine (COT) Rapid Test Panel	Powder	Panel	200 ng/mL
DDI-X14	Diazepam (DIA) Rapid Test Panel	Powder	Panel	300 ng/mL
DFY-X14	Fentanyl (FYL) Rapid Test Panel	Powder	Panel	200 ng/mL
DKE-X14	Ketamine (KET) Rapid Test Panel	Powder	Panel	1000 ng/mL
DLS-X14	Lysergic Acid Diethylamide (LSD) Rapid Test Panel	Powder	Panel	20 ng/mL
DMA-X14	6-Monoacetylmorphine (6-MAM) Rapid Test Panel	Powder	Panel	10 ng/mL
DMD-X14	Ecstasy (MDMA) Rapid Test Panel	Powder	Panel	500 ng/mL

## ANEXO CERTIFICADO

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DMDA-X14	Tenamfetamine (MDA) Rapid Test Panel	Powder	Panel	500 ng/mL
DMDP-X14	Methylenedioxypropylvalerone (MDPV) Rapid Test Panel	Powder	Panel	1000 ng/mL
DMP-X14	Methylphenidate(MPD) Rapid Test Panel	Powder	Panel	300 ng/mL
DME-X14	Methamphetamine (MET) Rapid Test Panel	Powder	Panel	1000 ng/mL
DMO-X14	Morphine (MOP) Rapid Test Panel	Powder	Panel	300 ng/mL
DMQ-X14	Methaqualone (MQL) Rapid Test Panel	Powder	Panel	300 ng/mL
DMT-X14	Methadone (MTD) Rapid Test Panel	Powder	Panel	300 ng/mL
DOX-X14	Oxycodone (OXY) Rapid Test Panel	Powder	Panel	100 ng/mL
DPC-X14	Phencyclidine (PCP) Rapid Test Panel	Powder	Panel	25 ng/mL
DPP-X14	Propoxyphene (PPX) Rapid Test Panel	Powder	Panel	300 ng/mL
DTC-X14	Tricyclic Antidepressants (TCA) Rapid Test Panel	Powder	Panel	1000 ng/mL
DTM-X14	Tramadol (TML) Rapid Test Panel	Powder	Panel	100 ng/mL
DZO-X14	Zolpidem(ZOL) Rapid Test Panel	Powder	Panel	50 ng/mL
DOA-X24	Multi-Drug 2 Drugs Rapid Test Panel	Powder	Panel	/
DOA-X34	Multi-Drug 3 Drugs Rapid Test Panel	Powder	Panel	
DOA-X44	Multi-Drug 4 Drugs Rapid Test Panel	Powder	Panel	
DOA-X54	Multi-Drug 5 Drugs Rapid Test Panel	Powder	Panel	
DOA-X64	Multi-Drug 6 Drugs Rapid Test Panel	Powder	Panel	
DOA-X74	Multi-Drug 7 Drugs Rapid Test Panel	Powder	Panel	
DOA-X84	Multi-Drug 8 Drugs Rapid Test Panel	Powder	Panel	
DOA-X94	Multi-Drug 9 Drugs Rapid Test Panel	Powder	Panel	
DOA-X104	Multi-Drug 10 Drugs Rapid Test Panel	Powder	Panel	
DOA-X114	Multi-Drug 11 Drugs Rapid Test Panel	Powder	Panel	
DOA-X124	Multi-Drug 12 Drugs Rapid Test Panel	Powder	Panel	
DAM-402	AMP Rapid Test Cassette	WB/S/P	Cassette	
DBA-402	BAR Rapid Test Cassette	WB/S/P	Cassette	100 ng/mL
DBU-402	BUP Rapid Test Cassette	WB/S/P	Cassette	5 ng/mL
DBZ-402	BZO Rapid Test Cassette	WB/S/P	Cassette	100 ng/mL
DCO-402	COC Rapid Test Cassette	WB/S/P	Cassette	50 ng/mL
DCT-402	COT Rapid Test Cassette	WB/S/P	Cassette	10 ng/mL, 100 ng/mL*
DED-402	EDDP Rapid Test Cassette	WB/S/P	Cassette	50 ng/mL
DMD-402	MDMA Rapid Test Cassette	WB/S/P	Cassette	50 ng/mL
DME-402	MET Rapid Test Cassette	WB/S/P	Cassette	70 ng/mL
DMO-402	MOP Rapid Test Cassette	WB/S/P	Cassette	40 ng/mL
DMT-402	MTD Rapid Test Cassette	WB/S/P	Cassette	40 ng/mL
DOX-402	OXY Rapid Test Cassette	WB/S/P	Cassette	20 ng/mL
DPP-402	PPX Rapid Test Cassette	WB/S/P	Cassette	100 ng/mL

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DTC-402	TCA Rapid Test Cassette	WB/S/P	Cassette	300 ng/mL
DTH-402	THC Rapid Test Cassette	WB/S/P	Cassette	35 ng/mL*, 50 ng/mL
DTM-402	TML Rapid Test Cassette	WB/S/P	Cassette	50 ng/mL
DOA-425	Multi-drug 2 drugs Test Cassette	WB/S/P	Cassette	/
DOA-435	Multi-drug 3 drugs Test Cassette	WB/S/P	Cassette	
DOA-445	Multi-drug 4 drugs Test Cassette	WB/S/P	Cassette	
DOA-455	Multi-drug 5 drugs Test Cassette	WB/S/P	Cassette	
DOA-465	Multi-drug 6 drugs Test Cassette	WB/S/P	Cassette	
DOA-475	Multi-drug 7 drugs Test Cassette	WB/S/P	Cassette	
DOA-485	Multi-drug 8 drugs Test Cassette	WB/S/P	Cassette	
DOA-495	Multi-drug 9 drugs Test Cassette	WB/S/P	Cassette	
DOA-4105	Multi-drug 10 drugs Test Cassette	WB/S/P	Cassette	
DOA-4115	Multi-drug 11 drugs Test Cassette	WB/S/P	Cassette	



  
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**INSTITUTO DE SALUD PÚBLICA DE CHILE**

Santiago, 12 de julio de 2019.

  
**MCL/JPF/lps**

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