

## EU Declaration of Conformity

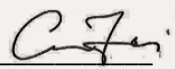
**Manufacturer:** HANGZHOU ALLTEST BIOTECH CO., LTD.  
**Address:** #550, Yin Hai Street, Hangzhou Economic & Technological Development Area, Hangzhou  
-310018, P.R. China  
**SRN:** CN-MF-000010710

<b>Product Name:</b>	Multi-Drug Rapid Test		
<b>REF:</b>	See Annex I		
<b>EMDN Code:</b>	W0102160511	<b>Classification According to IVDR Annex VIII Rule 6 :</b>	Class B
<b>Basic UDI-DI:</b>	See Annex I	<b>Conformity Assessment Procedure:</b>	IVDR Annex IX Chapters I, III and Section 4 of Chapter II
<b>Intended Purpose:</b>	See Annex II		

We, HANGZHOU ALLTEST BIOTECH CO., LTD, herewith declare that the EU declaration of conformity is issued under the sole responsibility of above manufacturer. The above mentioned product is in conformity with REGULATION (EU) 2017/746 and following Standards: EN ISO 13485:2016, EN ISO 14971:2019, EN 13975:2003, ISO 18113-1:2022, ISO 18113-2:2022, ISO 20916:2019, EN ISO 23640:2015, EN 13641:2002, EN ISO 15223-1:2021, EN 62366-1:2015

**Notified Body:** TÜV SÜD Product Service GmbH  
**Address:** Ridlerstrasse 65, 80339 Munich, Germany  
**Notified Body No.:** 0123  
**EU Quality Management System Certificate:** V12 095123 0012 Rev. 01  
**Expire date of the Certificate:** 2027-07-11  
**Start of CE Marking:** 2024-05-23

**European Representative:** MEDNET EC-REP GmbH  
**Address:** Borkstrasse 10, 48163 Muenster, Germany  
**SRN:** DE-AR-000000002

Signature:   
Name and Position: Gao Fei, General Manager

Place, Date of Issue: in Hangzhou on 2024-05-24



Annex I:

Device Name	AllTest Ref No.	Drug Combination Description	Basic UDI-DI
Multi-Drug Rapid Test	DOA-N124-001	COC300/THC50	6970277510000OY7
Multi-Drug Rapid Test	DOA-N124-002	AMP1000/COC300	6970277510000PY9
Multi-Drug Rapid Test	DOA-N124-003	MET1000/THC50	6970277510000QYB
Multi-Drug Rapid Test	DOA-N124-004	MOP300/THC50	6970277510000RYD
Multi-Drug Rapid Test	DOA-N124-005	MDMA500/THC50	6970277510000SYF
Multi-Drug Rapid Test	DOA-N124-006	AMP1000/THC50	6970277510000TYH
Multi-Drug Rapid Test	DOA-N124-007	OPI2000/COC300	6970277510000UYK
Multi-Drug Rapid Test	DOA-N124-008	AMP1000/MET1000	6970277510004DXV
Multi-Drug Rapid Test	DOA-N124-009	MOP300/MET1000	6970277510004EXX
Multi-Drug Rapid Test	DOA-N134-001	MOP300/COC300/THC50	6970277510004FXZ
Multi-Drug Rapid Test	DOA-N134-002	AMP1000/COC300/THC50	6970277510004GY3
Multi-Drug Rapid Test	DOA-N134-003	MOP300/AMP1000/MET1000	6970277510004HY5
Multi-Drug Rapid Test	DOA-N134-004	COC300/THC50/MET1000	6970277510004IY7
Multi-Drug Rapid Test	DOA-N134-005	MOP300/THC50/BUP10	6970277510004JY9
Multi-Drug Rapid Test	DOA-N134-006	MDMA500/COC300/THC50	6970277510004KYB
Multi-Drug Rapid Test	DOA-N134-007	MOP300/MTD300/BUP10	6970277510004LYD
Multi-Drug Rapid Test	DOA-N134-008	THC50/AMP1000/MET1000	6970277510004MYF
Multi-Drug Rapid Test	DOA-N134-009	MOP300/AMP1000/BUP10	6970277510004NYH
Multi-Drug Rapid Test	DOA-N134-010	MOP300/MDMA500/THC50	6970277510004OYK
Multi-Drug Rapid Test	DOA-N134-011	MOP300/COC300/BZO300	6970277510005RYU
Multi-Drug Rapid Test	DOA-N134-012	MOP300/COC300/MTD300	6970277510005SYW
Multi-Drug Rapid Test	DOA-N134-013	MOP300/COC300/BUP10	6970277510005TYY
Multi-Drug Rapid Test	DOA-N134-014	OPI2000/COC300/MTD300	6970277510005UZ2
Multi-Drug Rapid Test	DOA-N134-015	MOP300/AMP1000/THC50	6970277510005VZ4
Multi-Drug Rapid Test	DOA-N134-016	OPI2000/COC300/THC50	6970277510005WZ6
Multi-Drug Rapid Test	DOA-N134-017	COC300/AMP1000/THC50	6970277510005XZ8
Multi-Drug Rapid Test	DOA-N134-018	COC300/MET1000/THC50	6970277510005YZA
Multi-Drug Rapid Test	DOA-N134-019	COC300/THC50/BZO300	6970277510005ZZC
Multi-Drug Rapid Test	DOA-N134-020	BZO300/AMP1000/THC50	6970277510006AXV
Multi-Drug Rapid Test	DOA-N134-021	BZO300/MOP300/THC50	6970277510006BXX
Multi-Drug Rapid Test	DOA-N134-022	THC50/COC300/MET1000	6970277510006CXZ
Multi-Drug Rapid Test	DOA-N134-023	THC50/MDMA500/MET1000	6970277510006DY3
Multi-Drug Rapid Test	DOA-N134-024	BUP10/COC300/MOP300	6970277510006EY5
Multi-Drug Rapid Test	DOA-N134-025	BAR300/AMP1000/THC50	6970277510006FY7
Multi-Drug Rapid Test	DOA-N134-026	OPI2000/BAR300/THC50	6970277510006GY9

Device Name	AllTest Ref No.	Drug Combination Description	Basic UDI-DI
Multi-Drug Rapid Test	DOA-N134-027	MOP300/MET1000/THC50	6970277510006HYB
Multi-Drug Rapid Test	DOA-N134-028	THC50/AMP1000/OPI2000	6970277510006IYD
Multi-Drug Rapid Test	DOA-N134-029	MOP300/MDMA500/MET1000	6970277510006JYF
Multi-Drug Rapid Test	DOA-N134-030	BZO300/MET1000/THC50	6970277510006KYH
Multi-Drug Rapid Test	DOA-N144-001	COC300/THC50/AMP1000/MET1000	6970277510006LYK
Multi-Drug Rapid Test	DOA-N144-002	MOP300/THC50/AMP1000/BZO300	6970277510006MYM
Multi-Drug Rapid Test	DOA-N144-003	MDMA500/COC300/MET1000/THC50	6970277510006NYP
Multi-Drug Rapid Test	DOA-N144-004	OPI2000/COC300/MET1000/THC50	6970277510006OYR
Multi-Drug Rapid Test	DOA-N144-005	COC300/THC50/MTD300/MOP300	6970277510006PYT
Multi-Drug Rapid Test	DOA-N144-006	OPI2000/COC300/AMP1000/THC50	6970277510006QYV
Multi-Drug Rapid Test	DOA-N144-007	OPI2000/AMP1000/BZO300/THC50	6970277510006RYX
Multi-Drug Rapid Test	DOA-N144-008	MOP300/COC300/MET1000/THC50	6970277510006SYZ
Multi-Drug Rapid Test	DOA-N144-009	COC300/AMP1000/THC50/BZO300	6970277510006TZ3
Multi-Drug Rapid Test	DOA-N144-010	COC300/OPI2000/THC50/AMP1000	6970277510006UZ5
Multi-Drug Rapid Test	DOA-N144-011	MOP300/AMP1000/MET1000/THC50	6970277510006VZ7
Multi-Drug Rapid Test	DOA-N144-012	MOP300/COC300/AMP1000/THC50	6970277510006WZ9
Multi-Drug Rapid Test	DOA-N144-013	OPI2000/COC300/MTD300/THC50	6970277510006XZB
Multi-Drug Rapid Test	DOA-N144-014	OPI2000/AMP1000/MET1000/THC50	6970277510006YZD
Multi-Drug Rapid Test	DOA-N144-015	COC300/BZO300/MET1000/THC50	6970277510006ZZF
Multi-Drug Rapid Test	DOA-N144-016	OPI2000/MDMA500/AMP1000/THC50	6970277510007AXY
Multi-Drug Rapid Test	DOA-N144-017	MOP300/MDMA500/MET1000/THC50	6970277510007BY2
Multi-Drug Rapid Test	DOA-N144-018	OPI2000/MDMA500/COC300/THC50	6970277510007CY4
Multi-Drug Rapid Test	DOA-N144-019	COC300/THC50/OPI2000/AMP1000	6970277510007DY6
Multi-Drug Rapid Test	DOA-N144-020	OPI2000/COC300/BZO300/THC50	6970277510007EY8
Multi-Drug Rapid Test	DOA-N144-021	MOP300/COC300/BZO300/THC50	6970277510007FYA
Multi-Drug Rapid Test	DOA-N144-022	MOP300/COC300/AMP1000/MET1000	6970277510007GYC
Multi-Drug Rapid Test	DOA-N144-023	MDMA500/BZO300/MET1000/THC50	6970277510007HYE
Multi-Drug Rapid Test	DOA-N144-024	BZO300/AMP1000/MET1000/THC50	6970277510007IYG
Multi-Drug Rapid Test	DOA-N154-001	MOP300/COC300/THC50/AMP1000/MET1000	6970277510007JYJ
Multi-Drug Rapid Test	DOA-N154-002	OPI2000/COC300/THC50/AMP1000/MTD300	6970277510007KYL
Multi-Drug Rapid Test	DOA-N154-003	MOP300/THC50/AMP1000/MTD300/BUP10	6970277510007LYN
Multi-Drug Rapid Test	DOA-N154-004	MOP300/COC300/THC50/AMP1000/BZO300	6970277510007MYQ
Multi-Drug Rapid Test	DOA-N154-005	MOP300/MDMA500/THC50/MET1000	6970277510007NYS

Device Name	AllTest Ref No.	Drug Combination Description	Basic UDI-DI
		/BZO300	
Multi-Drug Rapid Test	DOA-N154-006	OPI2000/COC300/THC50/AMP1000/BZ O300	6970277510007OYU
Multi-Drug Rapid Test	DOA-N154-007	MOP300/COC300/THC50/MET1000/BZ O300	6970277510007PYW
Multi-Drug Rapid Test	DOA-N154-008	BZO300/BUP10/COC300/MOP300/MT D300	6970277510007QYY
Multi-Drug Rapid Test	DOA-N154-009	OPI2000/COC300/THC50/MET1000/BZ O300	6970277510007RZ2
Multi-Drug Rapid Test	DOA-N154-010	MOP300/COC300/AMP1000/BZO300/ BUP10	6970277510007SZ4
Multi-Drug Rapid Test	DOA-N154-011	MOP300/COC300/AMP1000/MET1000 /BAR300	6970277510007TZ6
Multi-Drug Rapid Test	DOA-N154-012	OPI2000/MDMA500/COC300/MET100 0/THC50	6970277510007UZ8
Multi-Drug Rapid Test	DOA-N154-013	OPI2000/MDMA500/COC300/AMP100 0/THC50	6970277510007VZA
Multi-Drug Rapid Test	DOA-N154-014	MOP300/COC300/AMP1000/MET1000 /THC50	6970277510007WZC
Multi-Drug Rapid Test	DOA-N154-015	OPI2000/COC300/AMP1000/MET1000 /THC50	6970277510007XZE
Multi-Drug Rapid Test	DOA-N154-016	OPI2000/PCP25/COC300/AMP1000/TH C50	6970277510007YZG
Multi-Drug Rapid Test	DOA-N154-017	OPI2000/COC300/MTD300/BZO300/A MP1000	6970277510007ZZJ
Multi-Drug Rapid Test	DOA-N154-018	MOP300/THC50/MET1000/AMP1000/ BZO300	6970277510008AY3
Multi-Drug Rapid Test	DOA-N154-019	MOP300/MDMA500/BZO300/AMP100 0/THC50	6970277510008BY5
Multi-Drug Rapid Test	DOA-N154-020	MDMA500/COC300/AMP1000/MET10 00/THC50	6970277510008CY7
Multi-Drug Rapid Test	DOA-N154-021	MOP300/MDMA500/COC300/BZO300/ THC50	6970277510008DY9
Multi-Drug Rapid Test	DOA-N154-022	COC300/BAR300/BZO300/AMP1000/T HC50	6970277510008EYB
Multi-Drug Rapid Test	DOA-N154-023	AMP1000/COC300/MET1000/MOP300 /THC50	6970277510008FYD
Multi-Drug Rapid Test	DOA-N154-024	OPI2000/MTD300/BZO300/AMP1000/ THC50	6970277510008GYF
Multi-Drug Rapid Test	DOA-N154-025	MOP300/COC300/BAR300/AMP1000/ THC50	6970277510008HYH

Device Name	AllTest Ref No.	Drug Combination Description	Basic UDI-DI
		THC50	
Multi-Drug Rapid Test	DOA-N154-026	MOP300/MDMA500/COC300/AMP1000/THC50	6970277510008IYK
Multi-Drug Rapid Test	DOA-N154-027	MOP300/OPI2000/AMP1000/MET1000/THC50	6970277510008JYM
Multi-Drug Rapid Test	DOA-N154-028	OPI2000/COC300/MTD300/BZO300/THC50	6970277510008KYP
Multi-Drug Rapid Test	DOA-N154-029	COC300/AMP1000/MET1000/OPI2000/THC50	6970277510008LYR
Multi-Drug Rapid Test	DOA-N154-030	COC300/AMP1000/MET1000/THC50/OPI2000	6970277510008MYT
Multi-Drug Rapid Test	DOA-N154-031	MOP300/COC300/MTD300/BZO300/THC50	6970277510008NYV
Multi-Drug Rapid Test	DOA-N154-032	BZO300/COC300/MTD300/MOP300/THC50	6970277510008OYX
Multi-Drug Rapid Test	DOA-N154-033	COC300/BZO300/AMP1000/MET1000/THC50	6970277510008PYZ
Multi-Drug Rapid Test	DOA-N154-034	THC50/COC300/AMP1000/OPI2000/MET1000	6970277510008QZ3
Multi-Drug Rapid Test	DOA-N154-035	THC50/COC300/AMP1000/BAR300/BZO300	6970277510008RZ5
Multi-Drug Rapid Test	DOA-N154-036	AMP1000/COC300/THC50/MOP300/MET1000	6970277510008SZ7
Multi-Drug Rapid Test	DOA-N154-037	AMP1000/COC300/MOP300/THC50/MDMA500	6970277510008TZ9
Multi-Drug Rapid Test	DOA-N154-038	AMP1000/COC300/THC50/MOP300/PCP25	6970277510008UZB
Multi-Drug Rapid Test	DOA-N154-039	MOP300/BAR300/AMP1000/MET1000/THC50	6970277510008VZD
Multi-Drug Rapid Test	DOA-N154-040	MOP300/COC300/MTD300/MET1000/THC50	6970277510008WZF
Multi-Drug Rapid Test	DOA-N154-041	MOP300/MDMA500/AMP1000/MET1000/THC50	6970277510008XZH
Multi-Drug Rapid Test	DOA-N154-042	OPI2000/PCP25/COC300/MET1000/THC50	6970277510008YZK
Multi-Drug Rapid Test	DOA-N154-043	MOP300/COC300/MTD300/AMP1000/THC50	6970277510008ZZM
Multi-Drug Rapid Test	DOA-N154-044	COC300/BAR300/BZO300/AMP1000/MET1000	6970277510009AY6
Multi-Drug Rapid Test	DOA-N154-045	MOP300/MDMA500/COC300/AMP1000	6970277510009BY8

Device Name	AllTest Ref No.	Drug Combination Description	Basic UDI-DI
		0/MET1000	
Multi-Drug Rapid Test	DOA-N154-046	THC50/MET1000/MDMA500/COC300/MOP300	6970277510009CYA
Multi-Drug Rapid Test	DOA-N154-047	MOP300/MDMA500/COC300/MET1000/THC50	6970277510009DYC
Multi-Drug Rapid Test	DOA-N154-048	OPI2000/MDMA500/AMP1000/MET1000/THC50	6970277510009EYE
Multi-Drug Rapid Test	DOA-N154-049	OPI2000/BAR300/BZO300/AMP1000/MET1000	6970277510009FYG
Multi-Drug Rapid Test	DOA-N154-050	COC300/BUP10/MET1000/MOP300/THC50	6970277510009GYJ
Multi-Drug Rapid Test	DOA-N154-051	OPI2000/MDMA500/COC300/BZO300/THC50	6970277510009HYL
Multi-Drug Rapid Test	DOA-N164-001	OPI2000/COC300/THC50/AMP1000/MET1000/BZO300	6970277510009IYN
Multi-Drug Rapid Test	DOA-N164-002	MOP300/COC300/THC50/AMP1000/MET1000/BZO300	6970277510009JYQ
Multi-Drug Rapid Test	DOA-N164-003	MDMA500/COC300/THC50/AMP1000/MET1000/MTD300	6970277510009KYS
Multi-Drug Rapid Test	DOA-N164-004	MOP300/AMP1000/MTD300/PCP25/BAR300/BUP10	6970277510009LYU
Multi-Drug Rapid Test	DOA-N164-005	MOP300/MDMA500/COC300/BZO300/MET1000/THC50	6970277510009MYW
Multi-Drug Rapid Test	DOA-N164-006	OPI2000/COC300/THC50/AMP1000/BAR300/BZO300	6970277510009NYY
Multi-Drug Rapid Test	DOA-N164-007	BUP10/COC300/MET1000/MOP300/MTD300/THC50	6970277510009OZ2
Multi-Drug Rapid Test	DOA-N164-008	MOP300/OXY100/COC300/THC50/MET1000/BZO300	6970277510009PZ4
Multi-Drug Rapid Test	DOA-N164-009	BAR300/BZO300/MET1000/THC50/COC300/OPI2000	6970277510009QZ6
Multi-Drug Rapid Test	DOA-N164-010	MOP300/MDMA500/MET1000/AMP1000/MTD300/THC50	6970277510009RZ8
Multi-Drug Rapid Test	DOA-N164-011	OPI2000/PCP25/COC300/AMP1000/MET1000/THC50	6970277510009SZA
Multi-Drug Rapid Test	DOA-N164-012	OPI2000/COC300/MTD300/AMP1000/MET1000/THC50	6970277510009TZC
Multi-Drug Rapid Test	DOA-N164-013	OPI2000/MDMA500/PCP25/COC300/AMP1000/THC50	6970277510009UZE
Multi-Drug Rapid Test	DOA-N164-014	MOP300/COC300/MTD300/BZO300/A	6970277510009VZG

Device Name	AllTest Ref No.	Drug Combination Description	Basic UDI-DI
		MP1000/THC50	
Multi-Drug Rapid Test	DOA-N164-015	MOP300/MDMA500/COC300/MTD300 /AMP1000/MET1000	6970277510009WZJ
Multi-Drug Rapid Test	DOA-N164-016	MOP300/COC300/MTD300/AMP1000/ MET1000/THC50	6970277510009XZL
Multi-Drug Rapid Test	DOA-N164-017	MOP300/PCP25/COC300/AMP1000/M ET1000/THC50	6970277510009YZN
Multi-Drug Rapid Test	DOA-N164-018	MOP300/COC300/BAR300/BZO300/A MP1000/THC50	6970277510009ZZQ
Multi-Drug Rapid Test	DOA-N164-019	OPI2000/MDMA500/COC300/MET100 0/MTD300/THC50	6970277510010AXG
Multi-Drug Rapid Test	DOA-N164-020	MOP300/MDMA500/COC300/BZO300/ AMP1000/THC50	6970277510010BXJ
Multi-Drug Rapid Test	DOA-N164-021	MDMA500/COC300/BAR300/BZO300/ AMP1000/THC50	6970277510010CXL
Multi-Drug Rapid Test	DOA-N164-022	AMP1000/BUP10/COC300/MDMA500/ MET1000/MOP300	6970277510010DXN
Multi-Drug Rapid Test	DOA-N164-023	MOP300/MDMA500/COC300/BAR300/ AMP1000/THC50	6970277510010EXQ
Multi-Drug Rapid Test	DOA-N164-024	MOP300/MDMA500/COC300/AMP100 0/MET1000/BUP10	6970277510010FXS
Multi-Drug Rapid Test	DOA-N164-025	AMP1000/BZO300/COC300/MOP300/ THC50/MTD300	6970277510010GXU
Multi-Drug Rapid Test	DOA-N164-026	MOP300/MDMA500/OXY100/AMP100 0/MET1000/THC50	6970277510010HXW
Multi-Drug Rapid Test	DOA-N164-027	MOP300/MDMA500/COC300/AMP100 0/MET1000/THC50	6970277510010IXY
Multi-Drug Rapid Test	DOA-N164-028	OPI2000/MDMA500/OXY100/COC300/ AMP1000/THC50	6970277510010JY2
Multi-Drug Rapid Test	DOA-N164-029	MOP300/BZO300/AMP1000/MET1000 /THC50/BUP10	6970277510010KY4
Multi-Drug Rapid Test	DOA-N164-030	COC300/BUP10/THC50/MTD300/MOP 300/BZO300	6970277510010LY6
Multi-Drug Rapid Test	DOA-N164-031	OPI2000/MDMA500/COC300/BZO300/ MET1000/THC50	6970277510010MY8
Multi-Drug Rapid Test	DOA-N164-032	OPI2000/COC300/BAR300/AMP1000/ MET1000/THC50	6970277510010NYA
Multi-Drug Rapid Test	DOA-N164-033	MOP300/COC300/MTD300/BZO300/M ET1000/THC50	6970277510010OYC
Multi-Drug Rapid Test	DOA-N164-034	MOP300/COC300/MTD300/BZO300/T	6970277510010PYE

Device Name	AllTest Ref No.	Drug Combination Description	Basic UDI-DI
		HC50/BUP10	
Multi-Drug Rapid Test	DOA-N164-035	OPI2000/MDMA500/BZO300/AMP1000/MET1000/THC50	6970277510010QYG
Multi-Drug Rapid Test	DOA-N164-036	OPI2000/MDMA500/COC300/BAR300/AMP1000/THC50	6970277510010RYJ
Multi-Drug Rapid Test	DOA-N164-037	MOP300/EDDP100/COC300/BZO300/THC50/BUP10	6970277510010SYL
Multi-Drug Rapid Test	DOA-N164-038	COC300/THC50/AMP1000/MET1000/BAR300/BZO300	6970277510010TYN
Multi-Drug Rapid Test	DOA-N164-039	MOP300/MDMA500/BZO300/AMP1000/MET1000/THC50	6970277510010UYQ
Multi-Drug Rapid Test	DOA-N164-040	AMP1000/BUP10/BZO300/COC300/OPI2000/THC50	6970277510010VYS
Multi-Drug Rapid Test	DOA-N164-041	AMP1000/BUP10/COC300/MTD300/OPI2000/THC50	6970277510010WYU
Multi-Drug Rapid Test	DOA-N164-042	OPI2000/MDMA500/COC300/AMP1000/MET1000/THC50	6970277510010XYW
Multi-Drug Rapid Test	DOA-N164-043	OPI2000/COC300/MTD300/BZO300/AMP1000/THC50	6970277510010YYY
Multi-Drug Rapid Test	DOA-N164-044	COC300/THC50/BZO300/AMP1000/BAR300/MOP300	6970277510010ZZZ
Multi-Drug Rapid Test	DOA-N164-045	OPI2000/COC300/MTD300/BZO300/THC50/BUP10	6970277510011AXK
Multi-Drug Rapid Test	DOA-N164-046	OPI2000/MDMA500/COC300/MTD300/AMP1000/THC50	6970277510011BXM
Multi-Drug Rapid Test	DOA-N164-047	MOP300/OPI2000/COC300/BZO300/AMP1000/THC50	6970277510011CXP
Multi-Drug Rapid Test	DOA-N164-048	OPI2000/MDMA500/COC300/BZO300/AMP1000/THC50	6970277510011DXR
Multi-Drug Rapid Test	DOA-N174-001	MOP300/COC300/THC50/AMP1000/MET1000/BZO300/BUP10	6970277510011EXT
Multi-Drug Rapid Test	DOA-N174-002	MOP300/COC300/THC50/AMP1000/MET1000/MTD300/BZO300	6970277510011FXV
Multi-Drug Rapid Test	DOA-N174-003	OPI2000/COC300/THC50/AMP1000/MET1000/MTD300/BZO300	6970277510011GXX
Multi-Drug Rapid Test	DOA-N174-004	OPI2000/COC300/THC50/AMP1000/MTD300/BZO300/BUP10	6970277510011HXZ
Multi-Drug Rapid Test	DOA-N174-005	OPI2000/OXY100/COC300/THC50/AMP1000/BZO300/BUP10	6970277510011IY3
Multi-Drug Rapid Test	DOA-N174-006	MOP300/MDMA500/COC300/THC50/	6970277510011JY5

Device Name	AllTest Ref No.	Drug Combination Description	Basic UDI-DI
		AMP1000/MET1000/PCP25	
Multi-Drug Rapid Test	DOA-N174-007	OPI2000/COC300/THC50/AMP1000/MET1000/BZO300/BUP10	6970277510011KY7
Multi-Drug Rapid Test	DOA-N174-008	OPI2000/MDMA500/COC300/BAR300/BZO300/AMP1000/THC50	6970277510011LY9
Multi-Drug Rapid Test	DOA-N174-009	MOP300/MDMA500/COC300/MTD300/AMP1000/MET1000/THC50	6970277510011MYB
Multi-Drug Rapid Test	DOA-N174-010	MOP300/COC300/MTD300/BZO300/AMP1000/THC50/BUP10	6970277510011NYD
Multi-Drug Rapid Test	DOA-N174-011	OPI2000/COC300/MTD300/BAR300/BZO300/AMP1000/THC50	6970277510011OYF
Multi-Drug Rapid Test	DOA-N174-012	MOP300/COC300/MTD300/BAR300/BZO300/AMP1000/THC50	6970277510011PYH
Multi-Drug Rapid Test	DOA-N174-013	MOP300/MDMA500/COC300/BAR300/BZO300/AMP1000/THC50	6970277510011QYK
Multi-Drug Rapid Test	DOA-N174-014	OPI2000/COC300/MTD300/BZO300/AMP1000/MET1000/THC50	6970277510011RYM
Multi-Drug Rapid Test	DOA-N174-015	OPI2000/COC300/BAR300/BZO300/AMP1000/THC50/BUP10	6970277510011SYP
Multi-Drug Rapid Test	DOA-N174-016	MOP300/MDMA500/COC300/BZO300/AMP1000/MET1000/THC50	6970277510011TYR
Multi-Drug Rapid Test	DOA-N174-017	MOP300/MDMA500/COC300/MTD300/BZO300/AMP1000/THC50	6970277510011UYT
Multi-Drug Rapid Test	DOA-N184-001	MOP300/MDMA500/COC300/MTD300/AMP1000/MET1000/THC50/BUP10	6970277510011VYV
Multi-Drug Rapid Test	DOA-N184-002	AMP1000/BAR300/BZO300/COC300/MDMA500/MTD300/OPI2000/THC50	6970277510011WYX
Multi-Drug Rapid Test	DOA-N184-003	AMP1000/BAR300/THC50/COC300/BZO300/OPI2000/MOP300/PCP25	6970277510011XYZ
Multi-Drug Rapid Test	DOA-N184-004	COC300/AMP1000/MET1000/THC50/MDMA500/OPI2000/OXY100/PCP25	6970277510011YZ3
Multi-Drug Rapid Test	DOA-N184-005	MOP300/MDMA500/OXY100/COC300/MTD300/AMP1000/MET1000/THC50	6970277510011ZZ5
Multi-Drug Rapid Test	DOA-N184-006	MOP300/MDMA500/COC300/MTD300/BZO300/AMP1000/MET1000/BUP10	6970277510012AXN
Multi-Drug Rapid Test	DOA-N184-007	MOP300/COC300/MTD300/BZO300/AMP1000/MET1000/THC50/BUP10	6970277510012BXQ
Multi-Drug Rapid Test	DOA-N184-008	MOP300/OPI2000/MDMA500/COC300/BAR300/BZO300/AMP1000/THC50	6970277510012CXS

Device Name	AllTest Ref No.	Drug Combination Description	Basic UDI-DI
Multi-Drug Rapid Test	DOA-N184-009	MOP300/MDMA500/COC300/MTD300/BZO300/AMP1000/MET1000/THC50	6970277510012DXU
Multi-Drug Rapid Test	DOA-N194-001	AMP1000/BUP10/BZO300/COC300/MDMA500/MET1000/MTD300/MOP300/THC50	6970277510012EXW
Multi-Drug Rapid Test	DOA-N194-002	OPI2000/COC300/THC50/AMP1000/MET1000/MTD300/BAR300/BZO300/BUP10	6970277510012FXV
Multi-Drug Rapid Test	DOA-N194-003	OPI2000/PCP25/COC300/MTD300/BAR300/BZO300/AMP1000/MET1000/THC50	6970277510012GY2
Multi-Drug Rapid Test	DOA-N1104-001	MOP300/OPI2000/MDMA500/COC300/THC50/AMP1000/MET1000/MTD300/BZO300/BUP10	6970277510012HY4
Multi-Drug Rapid Test	DOA-N1104-002	MOP300/MDMA500/COC300/THC50/AMP1000/MET1000/EDDP100/MTD300/BZO300/BUP10	6970277510012IY6
Multi-Drug Rapid Test	DOA-N1104-003	MOP300/OPI2000/MDMA500/COC300/THC50/AMP1000/MET1000/MTD300/BAR300/BZO300	6970277510012JY8
Multi-Drug Rapid Test	DOA-N1104-004	MOP300/OPI2000/PCP25/COC300/MTD300/BAR300/BZO300/AMP1000/MET1000/THC50	6970277510012KYA
Multi-Drug Rapid Test	DOA-N1104-005	MOP300/MDMA500/PCP25/COC300/MTD300/BAR300/BZO300/AMP1000/MET1000/THC50	6970277510012LYC
Multi-Drug Rapid Test	DOA-N1104-006	MOP300/MDMA500/OXY100/COC300/MTD300/BZO300/AMP1000/MET1000/THC50/BUP10	6970277510012MYE
Multi-Drug Rapid Test	DOA-N1104-007	OPI2000/MDMA500/PCP25/COC300/MTD300/BAR300/BZO300/AMP1000/MET1000/THC50	6970277510012NYG
Multi-Drug Rapid Test	DOA-N1104-008	MOP300/PCP25/COC300/MTD300/BAR300/BZO300/AMP1000/MET1000/THC50/BUP10	6970277510012OYJ
Multi-Drug Rapid Test	DOA-N1104-009	OPI2000/MDMA500/COC300/MTD300/BAR300/BZO300/AMP1000/MET1000/THC50/BUP10	6970277510012PYL
Multi-Drug Rapid Test	DOA-N1104-010	AMP1000/OPI2000/MDMA500/COC300/THC50/BAR300/BZO300/MOP300/B	6970277510012QYN

Device Name	AllTest Ref No.	Drug Combination Description	Basic UDI-DI
		UP10/MTD300	
Multi-Drug Rapid Test	DOA-N1104-011	MOP300/MDMA500/OXY100/EDDP100/COC300/BZO300/AMP1000/MET1000/THC50/BUP10	6970277510012RYQ
Multi-Drug Rapid Test	DOA-N1104-012	COC300/AMP1000/MET1000/MDMA500/THC50/OPI2000/MTD300/EDDP100/BUP10/BZO300	6970277510012SYS
Multi-Drug Rapid Test	DOA-N1104-013	AMP1000/COC300/THC50/MET1000/PCP25/BZO300/MTD300/BAR300/BUP10/MOP300	6970277510012TYU
Multi-Drug Rapid Test	DOA-N1104-014	COC300/AMP1000/MET1000/THC50/MTD300/MDMA500/MOP300/BAR300/BZO300/THC50	6970277510012UYW
Multi-Drug Rapid Test	DOA-N1104-015	MOP300/MDMA500/COC300/MTD300/BAR300/BZO300/AMP1000/MET1000/THC50/BUP10	6970277510012VYY
Multi-Drug Rapid Test	DOA-N1104-016	OPI2000/OXY100/COC300/MTD300/BAR300/BZO300/AMP1000/MET1000/THC50/BUP10	6970277510012WZ2
Multi-Drug Rapid Test	DOA-N1104-017	OPI2000/OXY100/PCP25/COC300/MTD300/BAR300/BZO300/AMP1000/MET1000/THC50	6970277510012XZ4
Multi-Drug Rapid Test	DOA-N1104-018	MOP300/OXY100/PCP25/COC300/MTD300/BAR300/BZO300/AMP1000/MET1000/THC50	6970277510012YZ6
Multi-Drug Rapid Test	DOA-N1104-019	OPI2000/MDMA500/PCP25/COC300/BAR300/BZO300/AMP1000/MET1000/THC50/BUP10	6970277510012ZZ8
Multi-Drug Rapid Test	DOA-N1104-020	MOP300/OPI2000/COC300/MTD300/BAR300/BZO300/AMP1000/MET1000/THC50/BUP10	6970277510013AXR
Multi-Drug Rapid Test	DOA-N1124-001	OPI2000/MDMA500/OXY100/PCP25/COC300/MTD300/BAR300/BZO300/AMP1000/MET1000/THC50/BUP10	6970277510013BXT
Multi-Drug Rapid Test	DOA-N1124-002	MOP300/OPI2000/MDMA500/PCP25/COC300/MTD300/BAR300/BZO300/AMP1000/MET1000/THC50/BUP10	6970277510013CXV
Multi-Drug Rapid Test	DOA-N1144-001	OPI2000/MDMA500/MOP300/OXY100/MTD300/PCP25/COC300/AMP1000/MET1000/BAR300/EDDP100/THC50/BZO300/BUP10	6970277510013DXX

**Annex II:**

The Multi-Drug Rapid Test is an in-vitro diagnostic rapid chromatographic immunoassay for the qualitative detection of multiple drugs and drug metabolites in human urine at the following cut-off concentrations:

Test	Analyte	Cut-off (ng/mL)
Morphine (MOP)	Morphine	300
Oxycodone (OXY)	Oxycodone	100
Opiate (OPI)	Morphine	2,000
Methylenedioxyamphetamine (MDMA)	d,l-Methylenedioxyamphetamine	500
Methadone (MTD)	Methadone	300
Methamphetamine (MET)	d-Methamphetamine	1,000
Phencyclidine (PCP)	Phencyclidine	25
Cocaine (COC)	Benzoyllecgonine	300
Secobarbital (BAR)	Secobarbital	300
Amphetamine (AMP)	d-Amphetamine	1,000
2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP)	2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine	100
Marijuana (THC)	11-nor- $\Delta^9$ -THC-9 COOH	50
Benzodiazepines (BZO)	Oxazepam	300
Buprenorphine (BUP)	Buprenorphine	10

Configurations of the Multi-Drug Rapid Test come with any combination of the above listed drug analytes. This assay provides only a preliminary test result. A more specific alternate chemical method must be used to obtain a confirmed analytical result. Gas Chromatography/Mass Spectrometry (GC/MS) or Liquid Chromatography/Mass Spectrometry (LC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

The Multi-Drug Rapid Test is used to aid in diagnose of drug dependence and drug rehabilitation. The test results can be used to provide evidence and basis for therapy and treatment plans of drug dependence and toxic psychosis.

The product is intended to be used by trained laboratory personnel. For laboratory use only.

The test is not automated. Not for self-testing use. Not for near-patient use. Not for drug concentration monitoring.

# Document Approval Record

RM-007312-DC - Ver 1

Hangzhou Alltest Biotech Co., Ltd. - Multi-Drug Rapid Test - Declaration of Conformity - EU - IVDR (2017/746)

Author: Jason Lo

## Approval Detail:

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