



CLIA Categorization Matrix

Assay Name	Hitachi 717	CX4CE	AU400e	Beckman Coulter® AU480 [¥]	Beckman Coulter® AU680 [¥]
6-Acetylmorphine	FDA			CLIA	
510(k) # / CR #	k101195			CR190555	
Decision Date	7/6/2010			10/3/2019	
Amphetamines (1000)		FDA		CLIA	
510(k) # / CR #		k020395		CR200038	
Decision Date		6/4/2002		2/21/2020	
Amphetamines 500	510k			CLIA	
510(k) # / CR #	k102210			CR240284	
Decision Date	12/28/2010			5/29/2024	
Barbiturate	FDA			CLIA	
510(k) # / CR #	k032764			CR240503	
Decision Date	11/3/2003			9/5/2024	
Benzodiazepine	FDA			CLIA	
510(k) # / CR #	k032365			CR240605	
Decision Date	9/5/2003			11/6/2024	
Buprenorphine	FDA			CLIA	CLIA
510(k) # / CR #	k090844			CR170552	CR160659
Decision Date	7/30/2009			11/24/2017	42744
Cocaine Metabolite (300)		FDA		CLIA	
510(k) # / CR #		k020763		CR200253	
Decision Date		5/10/2002		6/17/2020	
Cocaine Metabolite 150	FDA			CLIA	
510(k) # / CR #	k113139			CR200253	
Decision Date	40869			6/17/2020	
Cotinine II				FDA	
510(k) #				k192299	
Decision Date				11/21/2019	
				CLIA	
CR #				CR190258	
Decision Date				11/29/2019	
Ecstasy (MDMA)	FDA			CLIA	
510(k) # / CR #	k033094			CR220337	
Decision Date	37974			10/12/2022	
Ethyl Alcohol	FDA			CLIA	
510(k) # / CR #	k032461			CR240426	



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Urinalysis	Decision Date	10/3/2003			8/29/2024	
	Ethyl Glucuronide III	(Forensic Use Only)				
	510(k) # / CR #				VALIDATED	
	Launch Date				3/15/2021	
	Fentanyl (Qualitative)				CLIA	FDA
	510(k) # / CR #				CR200039	k181159
	Decision Date				43886	43437
	Fentanyl (Qualitative)				CLIA	FDA
	510(k) # / CR #				CR200039	k181159
	Decision Date				2/25/2020	12/3/2018
					CLIA	CLIA
	CR #				CR200350	
	Decision Date				8/17/2020	
	Hydrocodone (100)				FDA	CLIA
	510(k) # / CR #				k141055	CR210080
	Decision Date				6/13/2014	9/15/2021
	Hydrocodone (300)				FDA	CLIA
	510(k) # / CR #				k141055	CR210080
	Decision Date				6/13/2014	9/15/2021
	Ketamine 50	(Forensic Use Only)				
						VALIDATED
	Launch Date				2/14/2023	
	Ketamine 100	(Forensic Use Only)				
						VALIDATED
	Launch Date				2/14/2023	
	Methadone II					FDA
	510(k) #					k192433
	Decision Date					43742
						CLIA
	CR #					CR190554
	Decision Date					43749
	Methadone Metabolite (EDDP) "b"				FDA	
	510(k) # / CR #				k170416	
Decision Date				6/26/2017		
Methamphetamine	FDA			CLIA		
510(k) # / CR #	k113661			CR190350		
Decision Date	40931			7/9/2019		
510(k) # / CR #						
Decision Date						
Opiate 2000	FDA			CLIA		
510(k) # / CR #	k120761			CR240079		
Decision Date	41037			3/6/2024		
Opiates "b"	FDA			CLIA		
510(k) # / CR #	k110298			CR240026		
Decision Date	7/15/2011			2/13/2024		
Oxycodone III				FDA		



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510(k) #				k202007
Decision Date				9/17/2020
				CLIA
CR #				CR200357
Decision Date				9/21/2020
Phencyclidine	FDA			CLIA
510(k) # / CR #	k020254			CR230751
Decision Date	5/10/2002			12/6/2023
Propoxyphene	FDA			CLIA
510(k) # / CR #	k023795			CR240365
Decision Date	1/21/2003			7/31/2024
Carisoprodol Metabolite (SOMA)			De Novo	
510(k) #			DEN170010	
Decision Date			43210	
			CLIA	
CR #			CR170081	
Decision Date			43217	
SPICE I (JWH-type)	<i>(Forensic Use Only)</i>			
510(k) # / CR #				
Launch Date				
SPICE II (XLR-11/UR-144)	<i>(Forensic Use Only)</i>			
510(k) # / CR #				
Launch Date				
THC (Cannabinoid)	FDA			
510(k) # / CR #	k110239			
Decision Date	40717			
Tramadol			FDA	
510(k) #			k201223	
Decision Date			43986	
			CLIA	
CR #			CR200227	
Decision Date			43994	