



## CLIA Categorization Matrix

Assay Name	Hitachi 717	CX4CE	AU400e	Beckman Coulter® AU480 <sup>†</sup>	Beckman Coulter® AU680 <sup>†</sup>
6-Acetylmorphine	FDA			CLIA	
510(k) # / CR #	<a href="#">k101195</a>			CR190555	
Decision Date	7/6/2010			10/3/2019	
Amphetamines (1000)		FDA		CLIA	
510(k) # / CR #		<a href="#">k020395</a>		CR200038	
Decision Date		6/4/2002		2/21/2020	
Amphetamines 500	510k			CLIA	
510(k) # / CR #	<a href="#">k102210</a>			<a href="#">CR240284</a>	
Decision Date	12/28/2010			5/29/2024	
Barbiturate	FDA			CLIA	
510(k) # / CR #	<a href="#">k032764</a>			CR240503	
Decision Date	11/3/2003			9/5/2024	
Benzodiazepine	FDA			CLIA	
510(k) # / CR #	<a href="#">k032365</a>			CR240605	
Decision Date	9/5/2003			11/6/2024	
Buprenorphine	FDA			CLIA	CLIA
510(k) # / CR #	<a href="#">k090844</a>			CR170552	CR160659
Decision Date	7/30/2009			11/24/2017	42744
Cocaine Metabolite (300)		FDA		CLIA	
510(k) # / CR #		<a href="#">k020763</a>		CR200253	
Decision Date		5/10/2002		6/17/2020	
Cocaine Metabolite 150	FDA			CLIA	
510(k) # / CR #	<a href="#">k113139</a>			CR200253	
Decision Date	40869			6/17/2020	
Cotinine II				FDA	
510(k) #				k192299	
Decision Date				11/21/2019	
				CLIA	
CR #				<a href="#">CR190258</a>	
Decision Date				11/29/2019	
Ecstasy (MDMA)	FDA			CLIA	
510(k) # / CR #	<a href="#">k033094</a>			CR220337	
Decision Date	37974			10/12/2022	
Ethyl Alcohol	FDA			CLIA	
510(k) # / CR #	<a href="#">k032461</a>			CR240426	
Decision Date	10/3/2003			8/29/2024	
Ethyl Glucuronide III	(Forensic Use Only)				
510(k) # / CR #				<b>VALIDATED<sup>†</sup></b>	
Launch Date				3/15/2021	
Fentanyl (Qualitative)				CLIA	FDA
510(k) # / CR #				CR200039	k181159



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Decision Date				43886	43437
Fentanyl (Qualitative)				CLIA	FDA
510(k) # / CR #				CR200039	<a href="#">k181159</a>
Decision Date				2/25/2020	12/3/2018
				CLIA	CLIA
CR #				CR200350	
Decision Date				8/17/2020	
Hydrocodone (100)				FDA	CLIA <del>Y</del>
510(k) # / CR #				k141055	CR210080
Decision Date				6/13/2014	9/15/2021
Hydrocodone (300)				FDA	CLIA <del>Y</del>
510(k) # / CR #				<a href="#">k141055</a>	CR210080
Decision Date				6/13/2014	9/15/2021
Ketamine 50	(Forensic Use Only)				
				<del>VALIDATED<del>Y</del></del>	
Launch Date				2/14/2023	
Ketamine 100	(Forensic Use Only)				
				<del>VALIDATED<del>Y</del></del>	
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 #				<a href="#">k170416</a>	
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			<a href="#">CR240079</a>	
Decision Date	41037			3/6/2024	
Opiates "b"	FDA			CLIA	
510(k) # / CR #	<a href="#">k110298</a>			CR240026	
Decision Date	7/15/2011			2/13/2024	
Oxycodone III				FDA	
510(k) #				k202007	
Decision Date				9/17/2020	
				CLIA	
CR #				CR200357	
Decision Date				9/21/2020	
Phencyclidine	FDA			CLIA	
510(k) # / CR #	<a href="#">k020254</a>			CR230751	
Decision Date	5/10/2002			12/6/2023	
Propoxyphene	FDA			CLIA	
510(k) # / CR #	<a href="#">k023795</a>			CR240365	
Decision Date	1/21/2003			7/31/2024	
Carisoprodol Metabolite (SOMA)			De Novo		



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510(k) #			<b>DEN170010</b>		
Decision Date			<b>43210</b>		
			<b>CLIA</b>		
CR #			<b>CR170081</b>		
Decision Date			<b>43217</b>		
<b>SPICE I (JWH-type)</b>	<i>(Forensic Use Only)</i>				
510(k) # / CR #					
Launch Date					
<b>SPICE II (XLR-11/UR-144)</b>	<i>(Forensic Use Only)</i>				
510(k) # / CR #					
Launch Date					
<b>THC (Cannabinoid)</b>	<b>FDA</b>				
510(k) # / CR #			<b>k110239</b>		
Decision Date			<b>40717</b>		
				<b>CLIA</b>	
CR #				CR240707	
Decision Date				12/23/2024	
<b>Tramadol</b>	<b>FDA</b>				
510(k) #				<b>k201223</b>	
Decision Date				<b>43986</b>	
				<b>CLIA</b>	
CR #				CR200227	
Decision Date				43994	