At Siemens Healthineers, our purpose is to enable healthcare providers to increase value by empowering them on their journey toward expanding precision medicine, transforming care delivery, and improving patient experience, all made possible by digitalizing healthcare.

An estimated 5 million patients globally benefit every day from our innovative technologies and services in the areas of diagnostic and therapeutic imaging, laboratory diagnostics, and molecular medicine, as well as digital health and enterprise services.

We are a leading medical technology company with over 120 years of experience and 18,000 patents globally. Through the dedication of more than 50,000 colleagues in 75 countries, we will continue to innovate and shape the future of healthcare.

Dimension Vista, Emit, Flex, and all associated marks are trademarks of Siemens Healthcare Diagnostics Inc., or its affiliates. All other trademarks and brands are the property of their respective owners.

Product availability may vary from country to country and is subject to varying regulatory requirements. Please contact your local representative for availability.

Reference:
1. Florence CS, Zhou C, Luo F, Xu L. The economic burden of prescription opioid overdose, abuse, and dependence in the United States, 2013. Med Care. 2016;54(10):901-906. doi:10.1097/MLR.0000000000000625.

Dimension Vista Intelligent Lab System

Oxycodone Assay

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The Centers for Disease Control and Prevention estimates that the total economic burden of prescription opioid misuse alone in the United States is $78.5 billion a year, including the costs of healthcare, lost productivity, addiction treatment, and criminal justice involvement.[1]

Siemens Healthineers has more than 50 years of experience in drug testing. We provide your laboratory with a high level of service, education, and training materials that enable you to keep up to date with the latest advances.

Clinical Utility

Oxycodone is a semisynthetic opioid analgesic prescribed for the relief of moderate to severe pain. Oxycodone structurally resembles codeine and morphine, with similar analgesic properties and potential for addiction and abuse. Oxycodone is a DEA schedule II drug. The drug oxycodone is prescribed in controlled-release form (OXYCONTIN), or in combination with acetaminophen (PERCOCET) or with aspirin (PERCODAN).

The Dimension Vista® Oxycodone (OXY) Flex® reagent cartridge is a homogenous enzyme immunoassay with 100 ng/mL and 300 ng/mL cutoffs. The assay is intended for in vitro diagnostic use in the qualitative and semiquantitative determination of oxycodone in human urine using the Dimension Vista Intelligent Lab System. The semiquantitative mode is for the purposes of enabling laboratories to determine an appropriate dilution of the specimen for confirmation by a confirmatory method such as liquid chromatography/ mass spectrometry (LC/MS) or to establish quality control procedures.

Oxycodone Assay Benefits

- Achieve high specificity for oxycodone and oxymorphone to provide confidence in accurate results while meeting the SAMHSA requirements for oxycodone screening.

- Reduce false results with an assay that has 93-98% agreement with LC-MS/MS for positive samples and 98-100% agreement with negatives.

- Consolidate opioid testing with other Siemens Healthineers assays, including 6-Aceytlmorphine, Buprenorphine, Methadone, and Opiates, enabling providers to screen patients on one trusted system.

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Performance Summary

|	
Assay principle	Homogeneous enzyme immunoassay
Sample type	Urine
Sample volume	7.2 µL (100 ng/mL) 2.4 µL (300 ng/mL)
Assay range	50–400 ng/mL (100 ng/mL cutoff) 75–1000 ng/mL (300 ng/mL cutoff)
Reagent stability	Until expiration date on product
Cutoff level	100 ng/mL and 300 ng/mL
Calibration range	0–500 ng/mL (100 ng/mL cutoff) 0–1000 ng/mL (300 ng/mL cutoff)
Calibration frequency	28 days
Levels	0, 100, 300, 500, 1000 ng/mL
Cutoff overlap precision	0% overlap between cutoff and ±25% controls
Onboard stability	30 days
Open well	3 days

Oxycodone Metabolite Recovery

Oxycodone metabolite cross-reactivity (100 ng/mL cutoff)

Compound	Concentration (ng/mL)	% Cross-reactivity
Oxycodone	100	102
Oxymorphone	100	83.0
Oxymorphone-3-ß-glucuronide	1500	5.6
Noroxycodone	8000	0.93
Noroxymorphone	25,000	0.31

Oxycodone metabolite cross-reactivity (300 ng/mL cutoff)

Compound	Concentration (ng/mL)	% Cross-reactivity
Oxycodone	300	102
Oxymorphone	300	80.67
Oxymorphone-3-ß-glucuronide	4000	5.68
Noroxycodone	25,000	0.88
Noroxymorphone	50,000	0.33

Overlap between the 100 ng/mL cutoff and ±25% controls

Overlap between the 300 ng/mL cutoff and ±25% controls
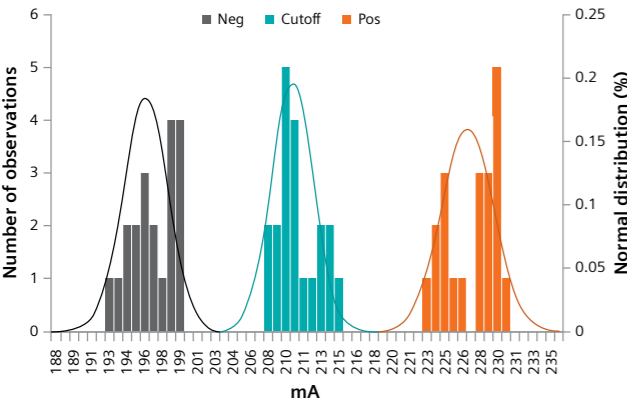
Theoretical distribution of data assuming normality.
Data for overlap charts is located in electronic notebook 106752598.
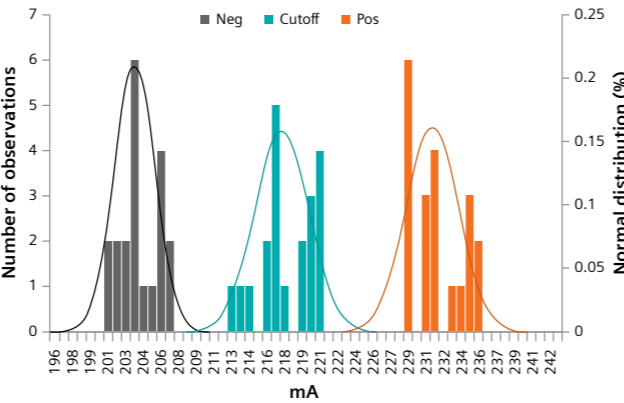
Ordering Information

SMN	Description	Contains
11533384	Dimension Vista Oxycodone (OXY) Flex reagent cartridge	2 x 60 tests, mouse monoclonal antibodies to oxycodone
10445406	Emit® Calibrator/Control Lvl 0	14 mL, human urine, negative for all drugs
10720807	Emit II Plus Specialty Multi Drug Cal/Cntrl Lvl 1	10 mL, human urine, 100 ng/mL oxycodone
10720813	Emit II Plus Specialty Multi Drug Cal/Cntrl Lvl 2	10 mL, human urine, 300 ng/mL oxycodone
10720814	Emit II Plus Specialty Multi Drug Cal/Cntrl Lvl 3	10 mL, human urine, 500 ng/mL oxycodone
10720815	Emit II Plus Specialty Multi Drug Cal/Cntrl Lvl 4	10 mL, human urine, 1000 ng/mL oxycodone
10720809	Emit II Plus Oxycodone Negative Control 100	10 mL, human urine, 75 ng/mL oxycodone
10720810	Emit II Plus Oxycodone Positive Control 100	10 mL, human urine, 125 ng/mL oxycodone
10720811	Emit II Plus Oxycodone Negative Control 300	10 mL, human urine, 225 ng/mL oxycodone
10720812	Emit II Plus Oxycodone Positive Control 300	10 mL, human urine, 375 ng/mL oxycodone

Summary of Qualitative and Semiquantitative Accuracy

Method comparison results (100 ng/mL cutoff)

		LC-MS/MS			
		Low Negative (less than 50% below the cutoff concentration)	**Near-cutoff Negative** (between 50% below the cutoff and the cutoff concentration)	**Near-cutoff Positive** (between the cutoff and 50% above the cutoff concentration)	**High Positive** (greater than 50% above the cutoff concentration)
		Qualitative Mode			
Emit	Positive	0	0	9	43
	Negative	31	13	4	0
		Agreement among positives is 52/56 = 93%		Agreement among negatives is 44/44 = 100%	
		Semiquantitative Mode			
Emit	Positive	0	0	9	43
	Negative	31	13	4	0
		Agreement among positives is 52/56 = 93%		Agreement among negatives is 44/44 = 100%	

Method comparison results (300 ng/mL cutoff)

		LC-MS/MS			
		Low Negative (less than 50% below the cutoff concentration)	**Near-cutoff Negative** (between 50% below the cutoff and the cutoff concentration)	**Near-cutoff Positive** (between the cutoff and 50% above the cutoff concentration)	**High Positive** (greater than 50% above the cutoff concentration)
		Qualitative Mode			
Emit	Positive	0	1	11	33
	Negative	42	12	1	0
		Agreement among positives is 44/45 = 98%		Agreement among negatives is 54/55 = 98%	
		Semiquantitative Mode			
Emit	Positive	0	0	11	33
	Negative	42	13	1	0
		Agreement among positives is 44/45 = 98%		Agreement among negatives is 55/55 = 100%	