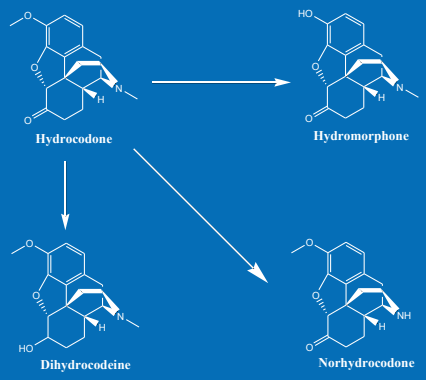


ARK™ Hydrocodone Assay

The ARK Hydrocodone Assay is an immunoassay intended for the qualitative detection and/or semi-quantitative estimation of hydrocodone and its metabolites in human urine at a cutoff of 300 ng/mL. The semi-quantitative mode is for the purpose of (1) enabling laboratories to determine an appropriate dilution of the specimen for confirmation by a confirmatory method, such as Gas Chromatography/Mass Spectrometry (GC/MS) or Liquid Chromatography/tandem Mass Spectrometry (LC-MS/MS), or (2) permitting laboratories to establish quality control procedures.

The ARK Hydrocodone Assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a confirmed positive analytical result. Gas Chromatography/Mass Spectrometry (GC/MS) or Liquid Chromatography/tandem Mass Spectrometry (LC-MS/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug test result, particularly when the preliminary test result is positive.

KEY POINTS

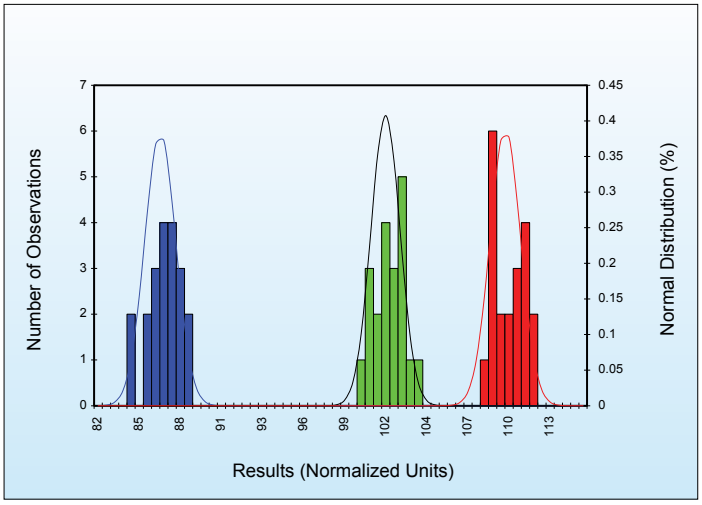
- Convenient, liquid-stable, read-to-use homogeneous enzyme immunoassay
- Applicable to many automated clinical chemistry analyzers
- 0 – 800 ng/mL semi-quantitative calibration range, 300 ng/mL Cutoff
- High specificity for hydrocodone and hydromorphone in human urine
- Nonhazardous preservatives

Next Generation Assays

ARK Diagnostics, Inc.

FDA Cleared

QUALITATIVE PRECISION



Qualitative Control Precision vs 300 ng/mL Cutoff Calibrator

SEMI-QUANTITATIVE PRECISION

Human Urine (ng/mL)	Relative % Cutoff	# of Results	Mean (ng/mL)	Semiquantitative Precision Results
0	-100	160	0	160 Negative
75	-75	160	78	160 Negative
150	-50	160	142	160 Negative
225	-25	160	229	160 Negative
300	Cutoff	160	314	24 Negative/136 Positive
375	+25	160	388	160 Positive
450	+50	160	460	160 Positive
525	+75	160	539	160 Positive
600	+100	160	620	160 Positive

Pooled Urine Samples containing Hydrocodone were assayed in quadruplicate twice a day for 20 days. CLSI Guidelines EP5-A3.

ACCURACY – ANALYTICAL RECOVERY

Concentration Tested (ng/mL)	Mean (ng/mL)	Recovery (%)
80	80	99
160	151	95
240	247	103
320	322	101
400	386	97
480	472	98
560	537	96
640	606	95
720	621	86
800	738	92

METHOD COMPARISON

ARK Immunoassay Result	<50% of cutoff concentration by LC-MS/MS (<150 ng/mL)	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration by LC-MS/MS) (150-299 ng/mL)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration by LC-MS/MS) (300-450 ng/mL)	High Positive (Greater than 50% above the cutoff concentration by LC-MS/MS) (>450 ng/mL)
Positive	8*	8*	9	66
Negative	134	0	1**	0

*Hydromorphone was detected in these samples and contributed to the positive result obtained for the ARK Hydrocodone Assay.
**For this sample, the hydrocodone concentration was within ±25% of the cutoff with a Hydrocodone value of 306.5 ng/mL (positive) by LC-MS/MS and 278 ng/mL (negative) by the ARK Hydrocodone Assay.

CROSS-REACTIVITY

Opiates/Structurally Similar Compounds

Compound	Concentration Tested (ng/mL)	Result (POS/NEG)	Percent Cross-reactivity (%)
6-Acetyl morphine	100,000	NEG	<0.3
Buprenorphine	100,000	NEG	<0.3
Buprenorphine-3β-D-glucuronide	50,000	NEG	<0.6
Codeine	100,000	NEG	<0.3
Codeine-6β-D-glucuronide	100,000	NEG	<0.3
Dextromethorphan	250,000	NEG	<0.1
EDDP	100,000	NEG	<0.3
EMDP	100,000	NEG	<0.3
Ethyl morphine	100,000	NEG	<0.3
Fentanyl	100,000	NEG	<0.3
Heroin	100,000	NEG	<0.3
Levorphanol	100,000	NEG	<0.3
Meperidine	100,000	NEG	<0.3
Methadone	100,000	NEG	<0.3
Morphine	100,000	NEG	<0.3
Morphine-3β-D-glucuronide	100,000	NEG	<0.3
Morphine-6β-D-glucuronide	100,000	NEG	<0.3
Nalbuphine	100,000	NEG	<0.3
Naloxegol	100,000	NEG	<0.3
Naloxone	100,000	NEG	<0.3
Naltrexone	100,000	NEG	<0.3
Norbuprenorphine	100,000	NEG	<0.3
Norcodeine	100,000	NEG	<0.3
Normorphine	100,000	NEG	<0.3
Noroxycodone	100,000	NEG	<0.3
Nortilidine	100,000	NEG	<0.3
Oxycodone	100,000	NEG	<0.3
Oxymorphone	100,000	NEG	<0.3
Oxymorphone-3β-D-glucuronide	50,000	NEG	<0.6
Pentazocine	100,000	NEG	<0.3
Tapentadol	100,000	NEG	<0.3
Thebaine	100,000	NEG	<0.3
Tilidine	100,000	NEG	<0.3
Tramadol	100,000	NEG	<0.3

Metabolites

Compound	Concentration Approximately Equivalent to the Cutoff (ng/mL)	Percent Cross-reactivity (%)
Hydromorphone	299	100.3
Hydromorphone-3β-Glucuronide	45,439	0.7
Norhydrocodone	2,277	13.2
Dihydrocodeine	>100,000	<0.3

SAFETY AND STABILITY

Reagent on-board stability

Up to at least 60 days

Shelf Life of Reagents, Calibrators, and Controls

18 months from date of manufacturing

Safety

Nonhazardous preservatives
Contains sodium azide ≤ 0.09%

Results shown are typical and may vary among laboratory analyzers.

ORDERING INFORMATION

ARK™ Hydrocodone Assay	5076-0001-00	R1 28mL, R2 14mL
	5076-0001-01	R1 115mL, R2 58mL
	5076-0001-02	R1 500mL, R2 250mL
ARK™ Hydrocodone Calibrator	5076-0002-00	5 x 10mL
	5076-0002-01	2 x 10mL; Negative
	5076-0002-02	2 x 10mL; 300 ng/mL Cutoff
ARK™ Hydrocodone Control	5076-0003-00	2 x 10mL; LOW 225 ng/mL
		2 x 10mL; HIGH 375 ng/mL

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MKT 24-003 Rev 01 March 2024

ARK Diagnostics, Inc.