Thermo Scientific DRI Hydrocodone Assay

Qualitative / Semi-Quantitative Detection of Hydrocodone and its Metabolites

- Specifically detects Hydrocodone and major metabolites
- Qualitative and semi-quantitative
- Superior assay precision
- Excellent correlation to LC-MS/MS
- Liquid ready to use
- Applications available on a range of clinical analyzers

Hydrocodone, a semi-synthetic opioid, is an antitussive (cough suppressant) and narcotic analgesic agent for the treatment of moderate to severe pain. Hydrocodone is the most frequently prescribed opiate in the United States. There are several hundred brand name and generic combinations of hydrocodone products marketed. The most frequently prescribed combination is hydrocodone and acetaminophen (Vicodin®, Lortab®). The 2013 National Survey on Drug Use and Health (NSDUH) reports that 24.4 million people, aged 12 and older, used hydrocodone for nonmedical purposes in the US. Hydrocodone is the most abused prescription drug in the United States.

The Thermo Scientific™ DRI® Hydrocodone Assay is a homogeneous enzyme immunoassay based on the competition of an enzyme glucose-6-phosphate dehydrogenase (G6PDH) labeled drug and the drug from the urine sample for a fixed amount of specific antibody binding sites. In the absence of free drug from the sample, the enzyme-labeled drug is bound by the specific antibody and the enzyme activity is inhibited. This phenomenon creates a direct relationship between drug concentration in urine and the enzyme activity. The enzyme G6PDH activity is determined spectrophotometrically at 340 nm by measuring its ability to convert nicotinamide adenine dinucleotide (NAD) to NADH.

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Precision

Samples were prepared by spiking hydrocodone into drug free urine at the cutoff (100%), 25%, 50%, and 75% above and below the cutoff and tested in both qualitative and semi-quantitative modes using a Clinical Laboratory and Standards Institute (CLSI) protocol. Results presented to the right were generated by testing all samples in replicates of 2, twice per day for 20 days, total n=80.

Total Precision (n=80)				
Hydrocodone Spike Concentration (ng/mL)	% of Cut-off 300 ng/mL	LC-MS/MS (ng/mL)	Number of Determinations	Immunoassay Results
0	-100%	0	80	80 Neg
75	-75%	87	80	80 Neg
150	-50%	170	80	80 Neg
225	-25%	255	80	80 Neg
300	100%	345	80	46 Neg / 34 Pos (qualitative) 40 Neg / 40 Pos (semi-quantitative)
375	25%	442	80	80 Pos
450	50%	535	80	80 Pos
525	75%	561	80	80 Pos
600	100%	664	80	80 Pos

Accuracy

One hundred patient samples were analyzed by the Thermo Scientific™ DRI® Hydrocodone Assay in both qualitative and semi-quantitative modes and the results were compared to LC-MS/MS. At 300 ng/mL cutoff, the overall concordance between the DRI Hydrocodone Assay and LC-MS/MS was 93%.

Qualitative/ Semi-Quantitative		LC-MS/MS	
		+	-
DRI Hydrocodone Assay	+	49	6*
	-	1	44

* 2 samples have oxycodone > 37,000 ng/mL

Cross-reactivity

The cross-reactivity of hydrocodone and its metabolites was evaluated by adding known amounts of each metabolite to drug-free urine. As indicated by the results in the table below, hydromorphone and hydromorphone glucuronide exhibited >100% cross reactivity. Norhydromorphone and 6-Hydrocodol showed significantly less cross reactivity.

Analyte	Concentration tested (ng/mL)	% Cross-reactivity
Hydrocodone	300	102
Hydromorphone	250	122
Hydromorphone Glucuronide	250	122
6-Hydrocodol (Dihydrocodeine)	11,000	2.7
Norhydrocodone	10,000	3.1

The potential cross-reactivity posed by drugs commonly coadministered with hydrocodone was evaluated by adding each substance to drug-free urine at the concentration indicated.

Ordering

Part Number	Description	Size
	Reagent	
10018054	DRI Hydrocodone Assays	3 x 18 mL
10018053	DRI Hydorcodone Assays	500 mL
	Calibrators	
1664 **1388**	DRI Negative Calibrator	10 mL 25 mL
10018079	DRI Hydrocodone Calibrator; 100 ng/mL	10 mL
10018080	DRI Hydrocodone Calibrator; 300 ng/mL	10 mL
10018081	DRI Hydrocodone Calibrator; 500 ng/mL	10 mL
10018082	DRI Hydrocodone Calibrator; 1000 ng/mL	10 mL
	Controls	
10018149	DRI Hydrocodone Control Kit; 225 and 375 ng/mL	10 mL

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