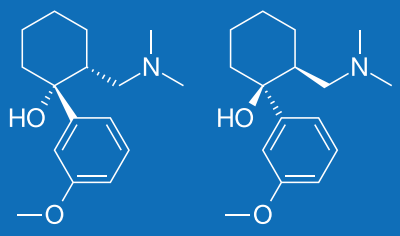


(1*R*,2*R*)-tramadol (1*S*,2*S*)-tramadol

ARK™ Tramadol Assay

The ARK Tramadol Assay is intended for the qualitative and/or semiquantitative determination of tramadol in human urine at a cutoff concentration of 100 ng/mL. The assay is intended for use in laboratories with automated clinical chemistry analyzers. This *in vitro* diagnostic device is for prescription use only.

KEY POINTS

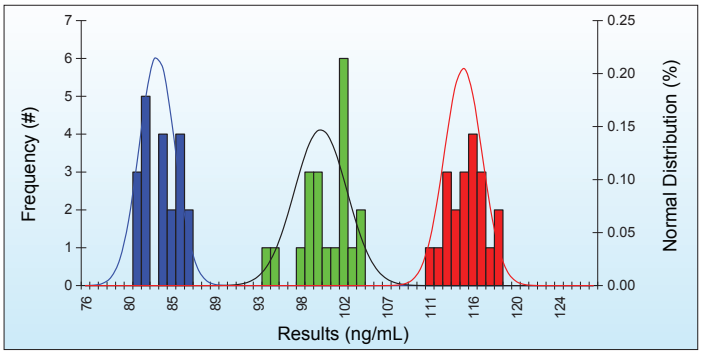
- Convenient, liquid-stable, ready-to-use homogeneous enzyme immunoassay
- Qualitative and/or semi-quantitative applications available for automated clinical chemistry systems
- 0 – 1000 ng/mL calibration range; 100 ng/mL cutoff
- Excellent sensitivity and specificity for detection of Tramadol in human urine
- Demonstrated cross-reactivity with *O*-Desmethyltramadol and *N*-Desmethyltramadol

Next Generation Assays

ARK Diagnostics, Inc.

CE Mark, FDA Cleared

QUALITATIVE PRECISION



Qualitative Control Precision vs 100 ng/mL Cutoff Calibrator

SEMI-QUANTITATIVE PRECISION

Human Urine (ng/mL)	Relative % Cutoff	# of Results	Mean (ng/mL)	Semiquantitative Precision Results
0.0	-100	160	1.7	160 Negative
25.0	-75	160	29.2	160 Negative
50.0	-50	160	53.7	160 Negative
75.0	-25	160	76.7	160 Negative
100.0	Cutoff	160	98.5	97 Negative/63 Positive
125.0	+25	160	120.5	160 Positive
150.0	+50	160	142.6	160 Positive
175.0	+75	160	165.3	160 Positive
200.0	+100	160	189.0	160 Positive

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

ACCURACY – ANALYTICAL RECOVERY

Concentration Tested (ng/mL)	Mean (ng/mL)	Recovery (%)
50	52.8	105.6
100	107.3	107.3
200	191.2	95.6
300	277.1	92.4
400	361.5	90.4
500	490.7	98.1
600	654.8	109.1
700	724.4	103.5
800	872.5	109.1
900	917.9	102.0
1000	984.1	98.4

METHOD COMPARISON

ARK Immunoassay Result	Low Negative Less than 50% below the Cutoff (< 50 ng/mL by LC-MS/MS)	Near Cutoff Negative Between 50% below the Cutoff and the Cutoff (50 – 99 ng/mL by LC-MS/MS)	Near Cutoff Positive Between the Cutoff and 50% above the Cutoff (100 – 150 ng/mL by LC-MS/MS)	High Positive Greater than 50% above the Cutoff (> 150 ng/mL by LC-MS/MS)
Negative	50	0	0	0
Positive	0	5*	4	56

**O*-desmethyltramadol was detected in these samples and contributed to the positive result obtained with the ARK Tramadol Assay.

Sample ID Number	ARK Immunoassay Result	Tramadol (ng/mL by LC-MS/MS)
01	Positive	74.0
05	Positive	98.7
06	Positive	98.9
51	Positive	75.0
52	Positive	79.0

CROSS-REACTIVITY AND INTERFERENCE

- Demonstrated cross-reactivity to Tramadol metabolites; *O*-Desmethyltramadol and *N*-Desmethyltramadol.
- No cross-reactivity to other pain medications tested.
- Tested endogenous substances do not interfere

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™ Tramadol Assay	5040-0001-00	R1 28mL, R2 14mL
	5040-0001-01	R1 115mL, R2 58mL
	5040-0001-02	R1 500mL, R2 250mL
ARK™ Tramadol Calibrator	5040-0002-00	5 x 10mL
	5040-0002-01	2 x 10mL; Negative
	5040-0002-02	2 x 10mL; 100 ng/mL Cutoff
ARK™ Tramadol Control	5040-0003-00	2 x 10mL; LOW 75 ng/mL 2 x 10mL; HIGH 125 ng/mL

ARK Diagnostics, Inc.
48089 Fremont Boulevard
Fremont, CA 94538
Tel: 510-270-6270 Fax: 510-270-6298

For Customer Support:
Call toll free: 877-869-2320
customersupport@ark-tdm.com
www.ark-tdm.com

MKT18-016 Rev 02 January 2019

ARK Diagnostics, Inc.