ARK Diagnostics, Inc.

ARK™ *Hydrocodone Assay*

This ARK Diagnostics, Inc. package insert for the ARK Hydrocodone Assay must be read prior to use. Package insert instructions must be followed accordingly. The assay provides a simple and rapid analytical screening procedure for detecting Hydrocodone and its metabolites in urine. Reliability of the assay results cannot be guaranteed if there are any deviations from the instructions in this package insert.

Report any serious incident that has occurred in relation to the device to the manufacturer and the appropriate competent authority as applicable.

CUSTOMER SERVICE

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KEY TO SYMBOLS USED

LOT	Batch Code	YYYY-MM-DD	Use by/Expiration Date
REF	Catalog Number		Manufacturer
IVD	In Vitro Diagnostic Medical Device		Temperature Limitation
	Consult Instructions for Use	R1 R2	Reagent 1/Reagent 2
Rx Only	For Prescription Use Only		

Reagent Kit REF 5076-0001-00

Reagent Kit REF 5076-0001-01

Reagent Kit REF 5076-0001-02

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1 NAME

ARK *Hydrocodone Assay*

2 INTENDED USE

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.

3 SUMMARY AND EXPLANATION OF THE TEST

Hydrocodone is a semi-synthetic opioid compound derived from codeine and thebaine. It is predominantly prescribed in the United States as an analgesic to treat moderate to severe pain, and as an antitussive to treat cough[1]. Commercially, hydrocodone is typically dispensed in combination with Acetaminophen (Vicodin and Lortab), Ibuprofen (Vicoprofen), and antihistamines (Hycodan)[2]. Common side effects include nausea, dizziness, dry mouth, constipation, vomiting, and anxiety. Hydrocodone can be habit forming, causing physical and psychological dependence similar to morphine[3]. Taken orally, the onset of action is 20-30 minutes and lasts 4-8 hours[4]. Hydrocodone is rapidly metabolized in the liver by cytochrome P450 2D6 (CYP2D6) to hydromorphone, a much more potent narcotic analgesic than hydrocodone itself[5-6]. The active metabolite hydromorphone undergoes phase II glucuronidation to predominant metabolite hydromorphone-3-glucuronide. Hydrocodone and its metabolites can be found in urine up to 2-3 days[7].

4 PRINCIPLES OF THE PROCEDURE

The ARK Hydrocodone Assay is a homogeneous enzyme immunoassay. The assay uses specific antibodies that can detect hydrocodone and its metabolites without any significant cross-reactivity to other opiate compounds. The assay is based on competition between a drug labeled with recombinant glucose-6-phosphate dehydrogenase (rG6PDH) and free drug from the urine sample, for a fixed amount of specific antibody binding sites. In the absence of free drug from the sample, rabbit monoclonal anti-hydrocodone antibody binds to the drug labeled with rG6PDH and causes a decrease in enzyme activity. In the presence of hydrocodone from the specimen, enzyme activity increases and is directly related to the hydrocodone concentration. Endogenous G6PDH does not interfere because the coenzyme NAD functions only with the bacterial enzyme used in the assay. The enzyme activity is determined spectrophotometrically at 340 nm by measuring the conversion of nicotinamide adenine dinucleotide (NAD) to NADH.

5 REAGENTS

REF	Product Description	Quantity/Volume
5076-0001-00	**ARK Hydrocodone Assay** **Reagent R1 – Antibody/Substrate** Rabbit monoclonal antibodies to hydrocodone, glucose-6-phosphate, nicotinamide adenine dinucleotide, bovine serum albumin, sodium azide, and stabilizers	1 X 28 mL
	Reagent R2 – Enzyme Hydrocodone derivative labeled with recombinant glucose-6-phosphate dehydrogenase (rG6PDH), bovine serum albumin, buffer, sodium azide and stabilizers	1 X 14 mL

REF	Product Description	Quantity/Volume
5076-0001-01	**ARK Hydrocodone Assay** **Reagent R1 – Antibody/Substrate** Rabbit monoclonal antibodies to hydrocodone, glucose-6-phosphate, nicotinamide adenine dinucleotide, bovine serum albumin, sodium azide, and stabilizers	1 X 115 mL
	Reagent R2 – Enzyme Hydrocodone derivative labeled with recombinant glucose-6-phosphate dehydrogenase (rG6PDH), bovine serum albumin, buffer, sodium azide and stabilizers	1 X 58 mL

REF	Product Description	Quantity/Volume
5076-0001-02	**ARK Hydrocodone Assay** **Reagent R1 – Antibody/Substrate** Rabbit monoclonal antibodies to hydrocodone, glucose-6-phosphate, nicotinamide adenine dinucleotide, bovine serum albumin, sodium azide, and stabilizers	1 X 500 mL
	Reagent R2 – Enzyme Hydrocodone derivative labeled with recombinant glucose-6-phosphate dehydrogenase (rG6PDH), bovine serum albumin, buffer, sodium azide and stabilizers	1 X 250 mL

Reagent Handling and Storage

ARK Hydrocodone Assay reagents are provided liquid, ready to use and may be used directly from the refrigerator. When not in use, reagents must be stored at 2–8°C (36–46°F), upright and with screw caps tightly closed. If stored as directed, reagents are stable until the expiration date printed on the label. Do not freeze reagents. Avoid prolonged exposure to temperatures above 32°C (90°F). **Improper storage of reagents can affect assay performance.**

ARK Hydrocodone products contain ≤0.09% sodium azide. As a precaution, affected plumbing including instrumentation should be flushed adequately with water to mitigate the potential accumulation of explosive metal azides. No special handling is required regarding other assay components.

6 WARNINGS AND PRECAUTIONS

- For *In Vitro* Diagnostic Use. For laboratory professional use only.
- For prescription use only. Caution: US federal law restricts this device to sale by or on the order of a licensed practitioner.
- Reagents R1 and R2 are provided as a matched set and should not be interchanged with reagents from different lot numbers.
- Do not use reagents after the expiration date.
- Reagents contain ≤0.09% sodium azide.

7 SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS

- Each laboratory is responsible for supplying a valid specimen for analysis according to their quality procedures.
- Human urine is required. Treat as potentially infectious material.
- Collect urine using standard sampling cups and procedures. Care should be taken to preserve the chemical and physical integrity of the urine sample from the time it is collected until the time it is assayed, including during transport. Fresh urine specimens are suggested.
- Cap the urine sample immediately after collection, store refrigerated at 2-8°C (36–46°F) and assay within 7 days after collection. If the assay cannot be performed within 7 days, store the urine sample frozen at -20°C for up to 2 months prior to analysis[8-9].
- To protect the integrity of the sample, do not induce foaming and avoid repeated freezing and thawing.
- The presence of bubbles or foam on the sample may lead to short sample delivery and erroneous results.
- Frozen specimens must be thawed and mixed thoroughly prior to analysis.
- Centrifuge specimens with high turbidity or visible particulate matter before testing.
- The recommended pH range for urine specimens is 4.0 – 11.0[10].
- Obtain another sample for testing if adulteration of the sample is suspected. Adulteration of urine specimens can affect the test result

8 PROCEDURE

Materials Provided

ARK Hydrocodone Assay – REF 5076-0001-00, 5076-0001-01 or 5076-0001-02

Materials Required – Provided Separately

ARK Hydrocodone Calibrator (Set) – REF 5076-0002-00
ARK Hydrocodone Calibrator A (Negative) – REF 5076-0002-01
ARK Hydrocodone Calibrator D (Cutoff) – REF 5076-0002-02
ARK Hydrocodone Control (225 ng/mL and 375 ng/mL) – REF 5076-0003-00

Instruments

Many automated clinical chemistry analyzers with photometric rate determination at 340 nm are suitable. Consult the analyzer-specific application sheet for programming the ARK Hydrocodone Assay, available from your distributor or ARK Customer Service. Refer to the instrument-specific operator's manual for daily maintenance.

Reagents R1 and R2 may need to be transferred to analyzer-specific reagent containers prior to use. Avoid cross-contamination of R1 and R2

Assay Sequence

To run or calibrate the assay, see the instrument-specific operator's manual.

Qualitative Results

Use the 300 ng/mL Calibrator D as a Cutoff Calibrator to distinguish negative and positive samples. Run the Low and High Controls as Negative and Positive respectively. Report test results less than the rate (mA/min) value for the Cutoff Calibrator as Negative. Report results equal to or greater than the rate (mA/min) value for the Cutoff Calibrator as Positive.

Semi-quantitative Results

Perform a 5-point calibration procedure; test calibrators in duplicate. Verify the calibration curve with the ARK Hydrocodone Assay Low and High quality controls according to the established laboratory quality assurance plan. Specimens with sample results above the highest ARK Hydrocodone calibrator level (800 ng/mL) may be diluted in ARK Hydrocodone Calibrator A (Negative urine) and retested.

When to Re-Calibrate

- Whenever a new lot number of reagents is used
- Whenever indicated by quality control results
- Whenever required by standard laboratory protocols

Quality Control (QC) and Calibration

Laboratories should establish QC procedures for the ARK Hydrocodone Assay. All quality control requirements and testing should be performed in conformance with local, state and/or federal regulations or accreditation requirements.

Each laboratory should establish its own ranges for each new lot of controls. Control results should fall within established ranges as determined by laboratory procedures and guidelines. The ARK Hydrocodone Control is intended for use in quality control of the ARK Hydrocodone Assay.

In Qualitative Mode, the Low Control should be Negative and the High Control should be Positive relative to the 300 ng/mL Cutoff Calibrator.

9 RESULTS AND EXPECTED VALUES

A more specific confirmatory method, such as LC-MS/MS or GC-MS, is required in order to obtain a confirmed positive result

Qualitative Analysis - Negative Results

A specimen that gives a rate (mA/min) value less than the ARK Hydrocodone Calibrator D Cutoff rate (mA/min) value is interpreted as negative; either the specimen does not contain hydrocodone or hydrocodone is present in a concentration below the cutoff level of this assay.

Qualitative Analysis - Positive Results

A specimen that gives a rate (mA/min) value equal to or greater than the ARK Hydrocodone Calibrator D Cutoff rate (mA/min) value is interpreted as positive, indicating that hydrocodone is present.

Results of this test should always be interpreted in conjunction with the patient's medical history, clinical presentation and other findings.

Semi-quantitative Analysis

The actual Hydrocodone concentration cannot be determined with this assay. Semi-quantitative results for positive specimens enable the laboratory to determine an appropriate dilution of the specimen for the confirmatory method. Semi-quantitative results also permit the laboratory to establish quality control procedures and assess reproducibility. Specimens with sample results above the highest ARK Hydrocodone calibrator level (800 ng/mL) may be diluted in ARK Hydrocodone Calibrator A (Negative urine) and retested.

Results of this test should always be interpreted in conjunction with the patient's medical history, clinical presentation and other findings, particularly when the preliminary result is positive.

10 LIMITATIONS

- The assay is designated for use with human urine only.
- ARK Hydrocodone Assay reagents, ARK Hydrocodone calibrators and ARK Hydrocodone controls were developed as companion products. Performance with substituted products cannot be assured.
- A positive result using the ARK Hydrocodone Assay indicates only the presence of hydrocodone and does not necessarily correlate with the extent of physiological and psychological effects.
- **Do not use Boric Acid as a preservative.**
- Interpretation of results must take into account that urine concentrations can vary extensively with fluid intake and other biological variables.
- It is possible that substances other than those tested in the specificity study may interfere with the test and cause false results.

11 SPECIFIC PERFORMANCE CHARACTERISTICS

The following performance characteristics were collected on the Beckman Coulter AU680® automated clinical chemistry analyzer using the ARK Hydrocodone Assay.

Precision

Drug-free, negative human urine was supplemented with hydrocodone (0 to 600 ng/mL). Each level was assayed in quadruplicate twice a day for 20 days (N= 60) and evaluated qualitatively and semi-quantitatively. Results are summarized in the tables below.

Qualitative Precision

Hydrocodone (ng/mL)	Relative % Cutoff	# of Results	Results
0	-100	160	160 Negative
75	-75	160	160 Negative
150	-50	160	160 Negative
225	-25	160	160 Negative
300	Cutoff	160	50 Negative; 110 Positive
375	+25	160	160 Positive
450	+50	160	160 Positive
525	+75	160	160 Positive
600	+100	160	160 Positive

Semi-quantitative Precision

Hydrocodone (ng/mL)	Relative % Cutoff	# of Results	Mean (ng/mL)	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	459	160 Positive
525	+75	160	539	160 Positive
600	+100	160	620	160 Positive

Analytical Recovery

Drug-free, negative human urine was spiked with hydrocodone across the assay range of the semi-quantitative calibration curve. Each sample was run in replicates of 5 in semi-quantitative mode and the average was used to determine percent recovery compared to the expected value.

Expected Value (ng/mL)	Observed Value (ng/mL)	Recovery (%)
0	0	N/A
80	80	99
160	151	94
240	247	103
320	322	101
400	386	96
480	472	98
560	537	96
640	606	95
720	621	86
800	738	92

Analytical Specificity

All compounds tested were added to drug-free, negative human urine and tested with the ARK Hydrocodone Assay in both qualitative and semi-quantitative modes.

The cross-reactivity of hydrocodone and its metabolites was evaluated by spiking these compounds into drug-free, negative human urine and evaluated by dose-response to determine the approximate equivalence to the 300 ng/mL hydrocodone cutoff. These concentrations were used to determine the percent cross-reactivity according to the formula:

% Cross-reactivity = (Cutoff concentration / Concentration approximately equivalent to the 300 ng/mL cutoff) X 100

For compounds that did not produce a positive result, the highest concentration tested was used to calculate percent cross-reactivity.

Cross-reactivity of hydrocodone and its metabolites

Compound	Concentration Approximately Equivalent to the Cutoff (ng/mL)	Percent Cross-reactivity (%)
Hydrocodone	292	103
Hydromorphone	299	100
Hydromorphone-3β-Glucuronide	45,439	0.7
Norhydrocodone	2,277	13.2
Dihydrocodeine	>100,000	<0.3

Cross-reactivity of structurally related or unrelated opioid compounds

Compound	Concentration Tested (ng/mL)	POS/NEG	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

Structurally unrelated compounds

Compound	Concentration Tested (ng/mL)	POS/NEG
(+)-MDA	100,000	NEG
11-hydroxy-delta-9-THC	100,000	NEG
11-nor-9 carboxy THC	50,000	NEG
1R,2S(-)-Ephedrine	100,000	NEG
1S,2R(+)-Ephedrine	100,000	NEG
4-Bromo-2,5,Dimethoxyphenethylamine	100,000	NEG
7-Aminoclonazepam	100,000	NEG
Acetaminophen	500,000	NEG
Acetylsalicylic acid	500,000	NEG
Alprazolam	100,000	NEG
Amitriptyline	100,000	NEG
Amobarbital	100,000	NEG
Amoxicillin	100,000	NEG
Amphetamine	100,000	NEG
Atorvastatin	100,000	NEG
Benzoylecgonine	1,000,000	NEG
Benzylpiperazine	100,000	NEG
Bupropion	100,000	NEG
Butabarbital	100,000	NEG
Caffeine	100,000	NEG
Canagliflozin	50,000	NEG
Cannabidiol	100,000	NEG
Cannabinol	100,000	NEG
Carbamazepine	500,000	NEG
Carisoprodol	100,000	NEG
Chlordiazepoxide	100,000	NEG
Chlorpromazine	100,000	NEG
Cimetidine	500,000	NEG
Clobazam	100,000	NEG
Clomipramine	100,000	NEG
Clopidogrel	100,000	NEG
Cocaine	100,000	NEG
Cotinine	100,000	NEG
Cyclobenzaprine	100,000	NEG
Desipramine	100,000	NEG
Diazepam	100,000	NEG
Diphenhydramine	100,000	NEG
Doxepin	100,000	NEG
Ecgonine	100,000	NEG
Ephedrine	1,000,000	NEG
Fluoxetine	100,000	NEG
Fluphenazine	100,000	NEG
Ibuprofen	500,000	NEG
Imipramine	100,000	NEG
Ketamine	100,000	NEG
Lamotrigine	100,000	NEG
Lidocaine	100,000	NEG
LSD	100,000	NEG
Maprotiline	100,000	NEG
MDMA	50,000	NEG
Meprobamate	100,000	NEG
Metformin	100,000	NEG
Methylphenidate	250,000	NEG
Metronidazole	100,000	NEG
Naproxen	100,000	NEG
Norpseudoephedrine	50,000	NEG
Nortriptyline	100,000	NEG
Omeprazole	100,000	NEG
Ondansetron	100,000	NEG
Oxazepam	250,000	NEG
Phencyclidine	100,000	NEG
Phenobarbital	100,000	NEG
Phentermine	100,000	NEG
Phenylephrine	100,000	NEG
Phenylpropanolamine	100,000	NEG
Phenytoin	100,000	NEG
PMA	100,000	NEG
Propranolol	100,000	NEG
Protriptyline	100,000	NEG
R,R(-)-Pseudoephedrine	100,000	NEG
Ranitidine	500,000	NEG
Ritalinic Acid	100,000	NEG
S(+)-Methamphetamine	100,000	NEG
S,S(+)-Pseudoephedrine	100,000	NEG
Salicylic Acid	100,000	NEG
Secobarbital	100,000	NEG
Sertraline	100,000	NEG
Temazepam	100,000	NEG
Theophylline	50,000	NEG
Thioridazine	100,000	NEG
Trazodone	100,000	NEG
Triazolam	250,000	NEG
Trimipramine	100,000	NEG
Venlafaxine	100,000	NEG
Zolpidem	100,000	NEG

Interference – Endogenous Substances

High concentrations of the following endogenous substances were added into hydrocodone-spiked urine (± 25% of the cutoff concentration). No interference was observed when tested with the ARK Hydrocodone Assay.

Compound	Concentration Tested (mg/dL)	225 ng/mL (-25% Cutoff)	375 ng/mL (+25% Cutoff)
Acetaminophen	10	NEG	POS
Acetone	500	NEG	POS
Acetyl Salicylic Acid	10	NEG	POS
Ascorbic acid	150	NEG	POS
Caffeine	10	NEG	POS
Creatinine	400	NEG	POS
Ethanol	10	NEG	POS
Galactose	5	NEG	POS
Glucose	1000	NEG	POS
Hemoglobin	150	NEG	POS
Human Albumin	200	NEG	POS
Human γ- Globulin	500	NEG	POS
Ibuprofen	10	NEG	POS
NaCl	1000	NEG	POS
Oxalic Acid	50	NEG	POS
Riboflavin	3	NEG	POS
Urea	1000	NEG	POS

Interference – Boric Acid

One percent (1% w/v of boric acid was added into hydrocodone-spiked urine (± 25% of the cutoff concentration). Results are provided in the table below.

Compound	Concentration Tested	225 ng/mL (-25% Cutoff)	375 ng/mL (+25% Cutoff)
Boric Acid	1% w/v	NEG	NEG

Interference – Specific Gravity and pH

Urine samples with specific gravity values from 1.000 to 1.030 and pH values ranging from 3.0 to 11.0 were tested in the presence of the two levels of hydrocodone at ± 25% of the cutoff concentration. No interference was observed when tested with the ARK Hydrocodone Assay.

Method Comparison

Two hundred twenty-six (226) unaltered clinical urine specimens that are not individually identifiable were analyzed by ARK Hydrocodone Assay in both qualitative and semi-quantitative modes and the results were compared to LC-MS/MS. The overall concordance between LC-MS/MS and the ARK Hydrocodone Assay was 92.5%

Qualitative method comparison with LC-MS/MS as reference method

ARK Hydrocodone Assay Results	<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

Semi-quantitative method comparison with LC-MS/MS as reference method

ARK Hydrocodone Assay Results	<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

*Seventeen (17) samples were considered discordant due to disagreement between the methods in calling a positive or negative result relative to the 300 ng/mL cutoff. For one of these (Sample #38) the hydrocodone concentration was 306.5 ng/mL by LC-MS/MS and 277.6 ng/mL by the ARK semi-quantitative determination and negative by the qualitative protocol. For this sample the hydrocodone concentration was within 25% of the cutoff.

Discordant Result Table for the Discrepant Samples near cutoff

Sample #	ARK Qualitative (POS/NEG)	LC-MS/MS (ng/mL)			ARK Semi-quantitative (ng/mL)
		Hydrocodone	Hydromorphone	Adjusted Total	
3	POS	287.8	210.0	497.8	476.0
15	POS	226.9	150.5	377.4	390.0
18	POS	156.0	174.7	330.8	335.2
23	POS	5.4	1317.7	1323.1	387.7
38	NEG	306.5	22.4	328.9	277.6
39	POS	162.0	52.4	214.5	316.1
48	POS	200.5	61.7	262.2	358.4
51	POS	174.4	29.0	203.4	357.4
66	POS	146.7	190.3	337.0	463.1
68	POS	181.2	150.3	331.5	382.2
70	POS	Not Detected	545.7	545.7	445.7
75	POS	5.9	10524.1	10530.0	2549.1
86	POS	255.8	30.7	286.5	471.4
90	POS	106.5	214.0	320.4	335.5
97	POS	Not Detected	1769.8	1769.8	501.3
99	POS	Not Detected	706.1	706.1	657.9
101	POS	Not Detected	5461.7	5461.7	2014.2

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13 TRADEMARKS

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