ARK Diagnostics, Inc.

For Export Only – Not For Sale in USA

ARK™ *Ethyl Glucuronide Assay*

This ARK Diagnostics, Inc. package insert for the ARK Ethyl Glucuronide 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 ethyl glucuronide in urine. Reliability of the assay results cannot be guaranteed if there are any deviations from the instructions in this package insert.

CUSTOMER SERVICE

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KEY TO SYMBOLS USED

LOT	Batch code	YYYY-MM-DD	Use by/Expiration date
REF	Catalog Number		Manufacturer
EC REP	Authorized Representative	CE	CE Mark
	Consult Instructions for Use	R1 / R2	Reagent 1/ Reagent 2
	Temperature limitation	IVD	*In Vitro* Diagnostic Medical Device
Rx Only	For Prescription Use Only		

Reagent Kit REF 5036-0001-00

Reagent Kit REF 5036-0001-01

Reagent Kit REF 5036-0001-02

1 NAME

ARK™ *Ethyl Glucuronide Assay*

2 INTENDED USE

The ARK Ethyl Glucuronide Assay is intended for the qualitative and semiquantitative determination of ethyl glucuronide in human urine at cutoff concentrations of 500 ng/mL and 1000 ng/mL. The assay provides a simple and rapid analytical screening procedure for detecting ethyl glucuronide in urine and is designated for professional use on automated clinical chemistry analyzers.

The semiquantitative mode is for the purpose of (1) enabling laboratories to determine an appropriate dilution for the specimen for confirmation by a confirmatory method, or (2) permitting laboratories to establish quality control procedures.

The ARK Ethyl Glucuronide Assay provides only a preliminary analytical 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

Assessment of ethanol consumption is important for medical treatment of persons addicted to alcohol. Forensic and work place applications are also common. Ethyl Glucuronide (EtG) is a direct metabolite of ethanol, which is formed by enzymatic conjugation of ethanol with glucuronic acid.[1,2] The metabolism of ethanol leads to the time-dependent urinary excretion of ethyl glucuronide and other metabolites. Alcohol in urine is normally detected for only a few hours, whereas EtG can be detected up to several days even after complete elimination of alcohol from the body.[3] Therefore, EtG can be a useful diagnostic biomarker for determining recent alcohol use and in monitoring abstinence in alcoholics in alcohol withdrawal treatment programs.[4-7] Ethanol can be produced *in vitro* due to fermentation of glucose in urine samples containing sugars (diabetes), bacteria or yeast when samples are exposed to warm temperatures.[8] In such cases, an EtG test can confirm whether the alcohol in the sample is due to consumption of ethanol or it is formed *in vitro* as a result of fermentation. Currently EtG is monitored by GC/MS and LC-MS/MS.[9-10]

At the present time, there is no consensus cutoff for EtG. Unintentional exposure to ethanol by other means such as hand sanitizers and other products or foods containing ethanol can result in detectable levels of EtG.

The ARK Ethyl Glucuronide Assay is an *in vitro* diagnostic medical device. The determination of ethyl glucuronide in human urine aids the assessment of compliance for treatment of substance abuse due to excessive consumption of ethanol. Urinary EtG testing has also been used as a tool in the optimal selection of liver transplant candidates and in the early detection of alcohol relapse after liver transplantation.[11]

4 PRINCIPLES OF THE PROCEDURE

The ARK Ethyl Glucuronide Assay is a homogeneous enzyme immunoassay technique used for the analysis of ethyl glucuronide in human urine. The assay is based on competition between drug in the specimen and drug labeled with recombinant glucose-6-phosphate dehydrogenase (rG6PDH) for antibody binding sites. Enzyme activity decreases upon binding to the antibody, so the drug concentration in the specimen can be measured in terms of enzyme activity. Active enzyme converts nicotinamide adenine dinucleotide (NAD) to NADH in the presence of glucose-6-phosphate (G6P), resulting in an absorbance change that is measured spectrophotometrically. Endogenous G6PDH does not interfere because the coenzyme NAD functions only with the bacterial enzyme used in the assay.

5 REAGENTS

REF	Product Description	QTY/ VOL
5036-0001-00	**ARK Ethyl Glucuronide Assay** **Reagent R1 – Antibody/Substrate** Sheep monoclonal antibodies to ethyl glucuronide, glucose-6-phosphate, nicotinamide adenine dinucleotide, bovine serum albumin, sodium azide, and stabilizers	1 X 28 mL
	Reagent R2 – Enzyme Ethyl glucuronide derivative labeled with recombinant glucose-6-phosphate dehydrogenase (rG6PDH), bovine serum albumin, buffer, sodium azide and stabilizers	1 X 14 mL

REF	Product Description	QTY/VOL
5036-0001-01	**ARK Ethyl Glucuronide Assay** **Reagent R1 – Antibody/Substrate** Sheep monoclonal antibodies to ethyl glucuronide, glucose-6-phosphate, nicotinamide adenine dinucleotide, bovine serum albumin, sodium azide, and stabilizers	1 X 115 mL
	Reagent R2 – Enzyme Ethyl glucuronide derivative labeled with recombinant glucose-6-phosphate dehydrogenase (rG6PDH), bovine serum albumin, buffer, sodium azide and stabilizers	1 X 58 mL

REF	Product Description	QTY/VOL
5036-0001-02	**ARK Ethyl Glucuronide Assay** **Reagent R1 – Antibody/Substrate** Sheep monoclonal antibodies to ethyl glucuronide, glucose-6-phosphate, nicotinamide adenine dinucleotide, bovine serum albumin, sodium azide, and stabilizers	1 X 500 mL
	Reagent R2 – Enzyme Ethyl glucuronide 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 Ethyl Glucuronide 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 Ethyl Glucuronide 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 prescription use only.
- 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

- 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 at 2-8°C (36–46°F) and assay within 7 days after collection. If the assay can't be performed within 7 days, store the urine sample frozen.
- To protect the integrity of the sample, do not induce foaming and avoid repeated freezing and thawing.
- 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.
- 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 Ethyl Glucuronide Assay – REF 5036-0001-00, 5036-0001-01 or 5036-0001-02

Materials Required – Provided Separately

ARK Ethyl Glucuronide Calibrator – REF 5036-0002-00
ARK Ethyl Glucuronide Calibrator A (Negative) – REF 5036-0002-01
ARK Ethyl Glucuronide Calibrator C (500 ng/mL Cutoff) – REF 5036-0002-02
ARK Ethyl Glucuronide Calibrator D (1000 ng/mL Cutoff) – REF 5036-0002-03
Quality Controls – ARK Ethyl Glucuronide Control (375 ng/mL and 625 ng/mL) – REF 5036-0003-00 or ARK Ethyl Glucuronide Control (750 ng/mL and 1250 ng/mL) – REF 5036-0003-01

Instruments

Reagents R1 and R2 may need to be transferred to analyzer-specific reagent containers prior to use. Avoid cross-contamination of R1 and R2 . Refer to the instrument-specific operator's manual for daily maintenance. Consult the analyzer-specific application sheet for programming the assay or contact Customer Support.

Assay Sequence

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

Qualitative Results

The 500 ng/mL Calibrator C or the 1000 ng/mL Calibrator D can be used as Cutoff Calibrators to distinguish negative and positive samples depending on laboratory specific criteria. Quality Controls are available for each cutoff level. Run the Low (375 ng/mL) and High (625 ng/mL) Controls with Cutoff Calibrator C, and run the Low (750 ng/mL) and High (1250 ng/mL) Controls with Cutoff Calibrator D as Negative and Positive respectively. All qualitative testing results are expressed as enzymatic rate (mA/min). Report test results less than the rate for the applicable Cutoff Calibrator as Negative. Report results equal to or greater than the rate for the applicable Cutoff Calibrator as Positive.

Semiquantitative Results

To estimate the concentration of ethyl glucuronide, perform a 5-point calibration procedure; test calibrators in duplicate. Verify the calibration curve with ARK Low and High quality controls according to the established laboratory quality assurance plan. Specimens having concentrations of ethyl glucuronide exceeding 2000 ng/mL may be diluted in ARK Calibrator A (Negative urine), such that the result for the diluted specimen falls within the range 100 ng/mL to 2000 ng/mL.

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

A stored calibration curve was effective up to at least 28 days based on supporting data.

Quality Control (QC)

Laboratories should establish QC procedures for the ARK Ethyl Glucuronide 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. The ARK Ethyl Glucuronide Control is intended for quality control of the ARK Ethyl Glucuronide Assay when run in either the qualitative or semiquantitative mode.

In Qualitative Mode, the Low Control should be Negative and the High Control should be Positive relative to the respective 500 ng/mL and 1000 ng/mL Cutoff Calibrators used.

9 RESULTS AND EXPECTED VALUES

The actual concentration cannot be determined. A confirmatory method is required.

Qualitative Analysis - Negative Results

A specimen that gives a rate value less than the Cutoff Calibrator C or Cutoff Calibrator D rate value as applicable is interpreted as negative; either the specimen does not contain ethyl glucuronide or ethyl glucuronide is present in a concentration below the applicable cutoff level used for this assay.

Qualitative Analysis - Positive Results

A specimen that gives a rate value equal to or greater than the Cutoff Calibrator C or Cutoff Calibrator D rate value as applicable is interpreted as positive, indicating that ethyl glucuronide is present.

Semiquantitative Analysis

The semiquantitation of positive levels of ethyl glucuronide enables the laboratory to determine an appropriate dilution of the specimen for the confirmatory method. Semiquantitation also permits the laboratory to establish quality control procedures and assess reproducibility. Specimens having concentrations of ethyl glucuronide exceeding 2000 ng/mL may be diluted in ARK Calibrator A (Negative urine), such that the result for the diluted specimen falls within the range 100 ng/mL to 2000 ng/mL.

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

10 LIMITATIONS

- The assay is designated for use with human urine only.
- ARK Ethyl Glucuronide Assay reagents, calibrators and controls were developed as companion products. Performance with substituted products cannot be assured.
- A positive result using the ARK Ethyl Glucuronide Assay indicates only the presence of ethyl glucuronide and does not necessarily correlate with the extent of physiological and psychological effects.
- Boric acid is not recommended 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 investigated in the specificity study may interfere with the test and cause false results.
- To maintain sample stability, store processed patient samples frozen at -20 °C.
- Exposure to ethanol by other means such as hand sanitizers may cause a false positive result.

11 SPECIFIC PERFORMANCE CHARACTERISTICS

The data appearing in this section were collected on the Beckman Coulter AU680® clinical chemistry analyzer using the ARK Ethyl Glucuronide Assay.

Precision

Precision was determined by assaying ethyl glucuronide in human urine. Drug-free, negative human urine was supplemented with ethyl glucuronide (0.0 to 2000.0 ng/mL), and both qualitative and semiquantitative protocols were performed for 20 days, 2 runs per day in quadruplicate (N=160). Both Calibrator C (500 ng/mL) and Calibrator D (1000 ng/mL) were used as cutoffs respectively for assessment of precision in qualitative mode.

Qualitative Precision (500 ng/mL Cutoff)

Ethyl Glucuronide (ng/mL)	Relative % Cutoff	Result
0.0	-100	160 Negative
250.0	-50	160 Negative
375.0	-25	160 Negative
500.0	0	95 Negative; 65 Positive
625.0	+25	160 Positive
750.0	+50	160 Positive
1000.0	+100	160 Positive

Qualitative Precision (1000 ng/mL Cutoff)

Ethyl Glucuronide (ng/mL)	Relative % Cutoff	Result
0.0	-100	160 Negative
500.0	-50	160 Negative
750.0	-25	160 Negative
1000.0	0	98 Negative; 62 Positive
1250.0	+25	160 Positive
1500.0	+50	160 Positive
2000.0	+100	160 Positive

Analytical Recovery

Analytical recovery for the ARK Ethyl Glucuronide Assay was assessed using the semiquantitative mode. Drug-free, negative human urine was supplemented with ethyl glucuronide (0.0 to 2000.0 ng/mL). Mean drug concentration observed for six (6) replicates and percentage recovery were calculated.

Concentration Tested (ng/mL)	Mean (ng/mL)	Recovery (%)
0.0	0.0	NA
50.0	47.6	95.2
100.0	106.3	106.3
250.0	264.2	105.7
500.0	521.7	104.3
700.0	714.1	102.0
1000.0	989.4	98.9
1300.0	1338.6	103.0
1500.0	1551.2	103.4
1800.0	1749.9	97.2
2000.0	2010.4	100.5

Analytical Specificity

All compounds tested were added to drug-free, negative human urine.

The parent compound ethanol and glucuronide compounds that are commonly found in urine were negative at the concentrations tested in both qualitative and semiquantitative modes.

Compound	Concentration Tested (µg/mL)	Semi-quantitative	Qualitative	
		Mean (ng/mL)	500 ng/mL Cutoff	1000 ng/mL Cutoff
Acetaldehyde	10,000	1.5	Negative	Negative
Buprenorphine Glucuronide	10	4.2	Negative	Negative
Butanol	10,000	16.2	Negative	Negative
D-Glucose	10,000	25.7	Negative	Negative
Ethanol	100,000	33.8	Negative	Negative
Ethylene Glycol	10,000	0.0	Negative	Negative
Ethyl Sulfate	100	0.0	Negative	Negative
Glucuronic Acid	10,000	14.3	Negative	Negative
Hydroxy Coumarin Glucuronide	10	5.7	Negative	Negative
Isopropanol	10,000	0.1	Negative	Negative
Lorazepam Glucuronide	10	1.0	Negative	Negative
Methanol	10,000	0.6	Negative	Negative
Methyl Glucuronide	20	432.8	Negative	Negative
Morphine-3-Glucuronide	200	7.8	Negative	Negative
Morphine-6-Glucuronide	100	0.0	Negative	Negative
Norbuprenorphine Glucuronide	10	3.8	Negative	Negative
n-Propanol	10,000	1.0	Negative	Negative
Oxazepam Glucuronide	10	1.7	Negative	Negative
p-Nitrophenyl Glucuronide	1000	374.0	Negative	Negative
Propyl D-glucuronide	0.5	407.9	Negative	Negative
Temazepam Glucuronide	10	0.8	Negative	Negative
Trichloroethyl glucuronide	5	3.8	Negative	Negative

The following structurally unrelated compounds were negative at the concentrations tested in both qualitative and semiquantitative modes.

Compound	Concentration Tested (µg/mL)	Semi-quantitative	Qualitative	
		Mean (ng/mL)	500 ng/mL Cutoff	1000 ng/mL Cutoff
6-Acetyl Morphine	200	18.5	Negative	Negative
Acetaminophen	500	56.0	Negative	Negative
Acetylsalicylic acid	500	0.0	Negative	Negative
Amitriptyline	100	4.0	Negative	Negative
Amoxicillin	100	0.5	Negative	Negative
Amphetamine	500	31.9	Negative	Negative
Benzoylecgonine	200	8.1	Negative	Negative
Caffeine	100	4.9	Negative	Negative
Carbamazepine	500	43.9	Negative	Negative
Chlorpromazine	100	7.2	Negative	Negative
Clomipramine	100	5.1	Negative	Negative
Cimetidine	500	0.5	Negative	Negative
Codeine	200	77.6	Negative	Negative
Desipramine	500	35.9	Negative	Negative
Dextromethorphan	200	26.5	Negative	Negative
Dihydrocodeine	200	17.6	Negative	Negative
Doxepin	200	24.0	Negative	Negative
Ephedrine	500	42.7	Negative	Negative
Fentanyl	200	4.5	Negative	Negative
Fluoxetine	500	37.1	Negative	Negative
Fluphenazine	500	35.9	Negative	Negative
Heroin	200	26.4	Negative	Negative
Hydrocodone	200	13.8	Negative	Negative
Hydromorphone	200	17.1	Negative	Negative
Ibuprofen	1000	21.2	Negative	Negative
Imipramine	500	39.4	Negative	Negative
Levorphanol	500	27.1	Negative	Negative
Maprotiline	500	38.7	Negative	Negative
Meperidine	500	29.5	Negative	Negative
Methadone	500	47.0	Negative	Negative
Metronidazole	500	1.0	Negative	Negative
Morphine	200	12.7	Negative	Negative
Nalbuphine	500	37.7	Negative	Negative
Naltrexone	3000	42.9	Negative	Negative
Norcodeine	200	10.1	Negative	Negative
Normorphine	200	6.3	Negative	Negative
Nortriptyline	500	23.1	Negative	Negative
Oxazepam	500	31.4	Negative	Negative
Oxycodone	200	12.3	Negative	Negative

The following structurally unrelated compounds were negative at the concentrations tested in both qualitative and semiquantitative modes.

Compound	Concentration Tested (µg/mL)	Semi-quantitative	Qualitative	
		Mean (ng/mL)	500 ng/mL Cutoff	1000 ng/mL Cutoff
Phencyclidine	500	31.4	Negative	Negative
Phenobarbital	500	28.6	Negative	Negative
Ranitidine	500	0.2	Negative	Negative
Secobarbital	500	33.9	Negative	Negative
Talwin	500	40.7	Negative	Negative
Thebaine	100	9.4	Negative	Negative
Thioridazine	500	85.3	Negative	Negative
Tramadol	500	0.9	Negative	Negative

Interference – Endogenous Substances

High concentrations of the following endogenous substances were added to drug-free, negative human urine.

No interference was observed at the concentrations tested in both qualitative and semiquantitative modes.

Compound	Concentration Tested (µg/mL)	Semi-quantitative	Qualitative	
		Mean (ng/mL)	500 ng/mL Cutoff	1000 ng/mL Cutoff
Acetone	1000	0.0	Negative	Negative
Ascorbic Acid	2000	0.0	Negative	Negative
Creatinine	4000	0.0	Negative	Negative
Ethanol	100	0.0	Negative	Negative
Galactose	100	0.0	Negative	Negative
Glucose	30000	81.5	Negative	Negative
Hemoglobin	3000	0.0	Negative	Negative
Human Albumin	5000	0.0	Negative	Negative
Oxalic Acid	300	39.0	Negative	Negative
Riboflavin	40	0.0	Negative	Negative
Sodium Chloride	9000	0.0	Negative	Negative
Urea	10000	0.0	Negative	Negative

Interference – Specific Gravity and pH

Urine samples with specific gravity values from 1.0077 to 1.0351 and pH values ranging from 3.0 to 11.0 were tested without the presence of ethyl glucuronide. No interference was observed.

Comparative Analysis

One hundred (100) confirmed EtG-positive and one hundred one (101) confirmed EtG-negative clinical urine specimens were analyzed by ARK Ethyl Glucuronide Assay. The LC-MS/MS confirmatory method was performed by a licensed reference laboratory and used an ethyl glucuronide cutoff of 50.0 ng/mL. The ARK Ethyl Glucuronide Assay (500 ng/mL and 1000 ng/mL cutoffs) distinguished positive and negative results: 100% clinical sensitivity and 99% clinical specificity at the 500 ng/mL cutoff, and 100% clinical sensitivity and 100% clinical specificity at the 1000 ng/mL cutoff.

Qualitative Analysis – 500 ng/mL Cutoff

		LC-MS/MS	
		(+)	(-)
ARK Ethyl Glucuronide Assay	(+)	100	1*
	(-)	0	100

*Discordant Result Summary

Sample ID	ARK Qualitative (Negative/Positive)	ARK Semiquantitative (ng/mL)	LC-MS/MS Ethyl Glucuronide (ng/mL)
176	Positive	565.0	<50.0

Qualitative Analysis – 1000 ng/mL Cutoff

		LC-MS/MS	
		(+)	(-)
ARK Ethyl Glucuronide Assay	(+)	95	0
	(-)	0	106

Five (5) out of the one hundred (100) confirmed EtG-positive samples contained concentrations of ethyl glucuronide between the two cutoffs for the ARK assay. These samples were detected as positive by the ARK assay relative to the 500 ng/mL cutoff and detected as negative by the ARK assay relative to the 1000 ng/mL cutoff, as confirmed by LC-MS/MS. The results obtained for these 5 samples are summarized below.

Sample ID	ARK Qualitative (Negative/Positive)	ARK Semiquantitative (ng/mL)	LC-MS/MS Ethyl Glucuronide (ng/mL)
044	Negative	668.4	900.0
045	Negative	529.3	580.0
050	Negative	631.3	600.0
062	Negative	981.3	930.0
072	Negative	691.8	720.0

12 REFERENCES

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13 TRADEMARKS

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