SureScreen | Diagnostics

Ethyl Glucuronide Rapid Test Panel

(Urine)

[INTENDED USE]

[SUMMARY]

[PRECAUTIONS]

[STORAGE AND STABILITY]

Storage

Stability

[SPECIMEN COLLECTION AND PREPARATION]

Sample Preparation

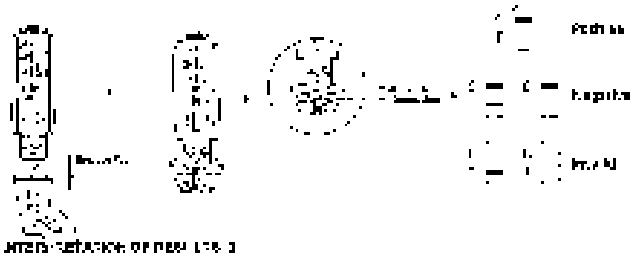
Storage

[MATERIALS]

Provided Materials

Equipment

[DIRECTIONS FOR USE]



[LIMITATIONS OF THE TEST]

[REFERENCE]

[PERFORMANCE CHARACTERISTICS]

Accuracy

Test	Cut-off	Sensitivity	Specificity	Overall
Ethyl Glucuronide Rapid Test Panel	500ng/mL	100%	100%	100%
	1000ng/mL	100%	100%	100%
	2000ng/mL	100%	100%	100%
	3000ng/mL	100%	100%	100%
	5000ng/mL	100%	100%	100%
	10000ng/mL	100%	100%	100%

Analytical Sensitivity

Ethyl Glucuronide Concentration	Positive %	n	Cut-off 500ng/mL	
			Negative	Positive
250ng/mL	0%	20	20	0
375ng/mL	5%	20	19	1
500ng/mL	50%	20	10	10
625ng/mL	95%	20	1	19
750ng/mL	100%	20	0	20
1000ng/mL	100%	20	0	20
1250ng/mL	100%	20	0	20

Analytical Specificity

Test	Cut-off	Sensitivity	
Ethyl Glucuronide	500ng/mL	100%	

Interfering Substances

Substance	Concentration (ng/mL)
Ethyl Glucuronide	1000

Precision

Ethyl Glucuronide Concentration	n	Sample A		Sample B		Sample C	
		Positive	Negative	Positive	Negative	Positive	Negative
0ng/mL	10	0	10	0	10	0	10
250ng/mL	10	1	9	0	10	0	10
375ng/mL	10	4	6	1	9	0	10
500ng/mL	10	6	4	5	5	4	6
625ng/mL	10	9	1	9	1	9	1
750ng/mL	10	10	0	10	0	10	0

Effect of Urinary Specific Gravity

Cross-Reactivity

Substance	Concentration (ng/mL)	Substance	Concentration (ng/mL)
[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]

SureScreen Diagnostics

Ethyl Glucuronide Rapid Test Panel

(Urine)

[illegible]

[illegible]

[illegible]