iSCREEN ACCURACY DATA

AMPHETAMINE (AMP) DRUG SCREEN

Accuracy: The performance of the the *iSCREEN* amphetamine drug screen was compared to the laboratory initial screen and a leading commercially available amphetamine rapid test. Testing was performed on 300 clinical specimens. **At least ten percent of the specimens evaluated were between –25% or +25% of the cut-off concentration of 1,000 ng/ml**. Presumptive positive results were confirmed by GC/MS.

When compared to GC/MS at 500 ng/mL, the results are provided in the table below:

Method		GC/MS		Total Results
iSCREEN Test Device	Results	Positive	Negative	
	Positive	142	0	142
	Negative	9	149	158
Total Results		151	149	300

Relative Sensitivity: 94% Relative Specificity: >99% Accuracy: 97%

Note: The FDA requires on-site test devices to be accurate within +25% of the drug screen's cut-off level. The *iSCREEN* detected 100% of the GC/MS positive specimens within 25% of the screen's 1000ng cut-off.

The only GC/MS positive specimens not identified as positive by the *iSCREEN* were close to or below the *iSCREEN 's* 1000 ng/ml cut-off. Specimens whose results differed between GC/MS and the *iSCREEN* contained the following concentration levels in ng/ml:
(781,862, 878, 898, 898, 1000, 1032, 1137, and 1204).

METHAMPHETAMINE (mAMP) DRUG SCREEN

Accuracy: The performance of the the *iSCREEN* methamphetamine drug screen was compared to the laboratory initial screen and a leading commercially available amphetamine rapid test. Testing was performed on 300 clinical specimens. **At least ten percent of the specimens evaluated were between –25% or +25% of the cut-off concentration of 1,000 ng/ml**. Presumptive positive results were confirmed by GC/MS.

When compared to GC/MS at 500 ng/mL, the results are provided in the table below:

Method		GC/MS		Total Results
iSCREEN Test Device	Results	Positive	Negative	
	Positive	145	0	145
	Negative	1	154	155
Total Results		146	154	300

Relative Sensitivity: >99% Relative Specificity: >99% Accuracy: >99%

Note:. The *iSCREEN* detected 100% of the GC/MS positive specimens at or above the screen's 1000ng cut-off.

The only GC/MS positive specimen not identified as positive by the *iSCREEN* was below the *iSCREEN 's* 1000 ng/ml cut-off. The discrepant specimen contained d-methamphetamine at a concentration of 954 ng/ml.

MARIJUANA (THC) DRUG SCREEN

Accuracy: The performance of the the *iSCREEN* amphetamine drug screen was compared to the laboratory initial screen and a leading commercially available marijuana rapid test. Testing was performed on 300 clinical specimens. **At least ten percent of the specimens evaluated were between –25% or +25% of the cut-off concentration of 50 ng/ml**. Presumptive positive results were confirmed by GC/MS.

When compared to GC/MS at 15 ng/mL, the results are provided in the table below:

Method		GC/MS		Total Results
iSCREEN Test Device	Results	Positive	Negative	
	Positive	143	0	143
	Negative	7	150	157
Total Results		150	150	300

Relative Sensitivity: 95% Relative Specificity: >99% Accuracy: 98%

Note: The FDA requires on-site test devices to be accurate within 25% of the drug screen's cut-off level. The *iSCREEN* detected all but two of the GC/MS positive specimens within +25% of the screen's 50ng cut-off.

The only GC/MS positive specimens not identified as positive by the *iSCREEN* were close to or below the *iSCREEN 's* 50 ng/ml cut-off. Specimens whose results differed between the GC/MS and the *iSCREEN* contained the following concentration levels in ng/ml: (15, 15, 16, 32, 51, 73, and 79)

iSCREEN ACCURACY DATA

COCAINE DRUG SCREEN

Accuracy: The performance of the the *iSCREEN* cocaine drug screen was compared to the laboratory initial screen and a leading commercially available amphetamine rapid test. Testing was performed on 300 clinical specimens. **At least ten percent of the specimens evaluated were between –25% or +25% of the cut-off concentration of 300 ng/ml**. Presumptive positive results were confirmed by GC/MS.

When compared to GC/MS at 150 ng/mL, the results are provided in the table below:

Method		GC/MS		Total Results
iSCREEN Test Device	Results	Positive	Negative	
	Positive	136	0	136
	Negative	13	151	164
Total Results		149	151	300

Relative Sensitivity: 91% Relative Specificity: >99% Accuracy: 96%

Note: The FDA requires on-site test devices to be accurate within 25% of the drug screen's cut-off level. The *iSCREEN* detected all but one of the GC/MS positive specimens within 25% of the screen's 300ng cut-off.

The only GC/MS positive specimens not identified as positive by the *iSCREEN* were close to or below the *iSCREEN 's* 300 ng/ml cut-off. Specimens whose results differed between GC/MS and the *iSCREEN* contained the following concentration levels in ng/ml: (153, 158, 188, 202, 228, 233, 243, 254, 265, 270, 298, 358 and 381)

OPIATES-2000 (OPI) DRUG SCREEN

Accuracy: The performance of the the *iSCREEN* opiates drug screen was compared to the laboratory initial screen and a leading commercially available opiates rapid test. Testing was performed on 300 clinical specimens. **At least ten percent of the specimens evaluated were between –25% or +25% of the cut-off concentration of 2,000 ng/ml**. Presumptive positive results were confirmed by GC/MS.

When compared to GC/MS at 2000 ng/mL, the results are provided in the table below:

Method		GC/MS		Total Results
iSCREEN Test Device	Results	Positive	Negative	
	Positive	134	16	150
	Negative	0	150	150
Total Results		134	166	300

Relative Sensitivity: >99% Relative Specificity: 90% Accuracy: 95%

Note: The *iSCREEN* correctly identified 100% of the specimens determined to be positive by GC/MS.

The specimens identified as positive by the *iSCREEN* but below 2000 ng/ml by GC/MS were all at or above 1500 ng/ml. Therefore the *iSCREEN* performed at >99% accuracy within +/- 25% of the screens 2000 ng/ml cut-off.

PCP DRUG SCREEN

Accuracy: The performance of the the *iSCREEN* PCP drug screen was compared to the laboratory initial screen and a leading commercially available PCP rapid test. Testing was performed on 212 clinical specimens. **At least ten percent of the specimens evaluated were between –25% or +25% of the cut-off concentration of 25 ng/ml**. Presumptive positive results were confirmed by GC/MS.

When compared to GC/MS at 25 ng/mL, the results are provided in the table below:

Method		GC/MS		Total Results
iSCREEN Test Device	Results	Positive	Negative	
	Positive	50	5	55
	Negative	0	157	157
Total Results		50	162	212

Relative Sensitivity: 100% Relative Specificity: 97% Accuracy: 98%

Note: The *iSCREEN* correctly identified 100% of the specimens determined to be positive by GC/MS.

The specimens identified as positive by the *iSCREEN* but below 25 ng/ml by GC/MS were all at or above 15 ng/ml. Therefore; the *iSCREEN* detected 5 positive specimens that were below the 25 ng/ml GC/MS cut-off, but there were no false-positive results.

iSCREEN ACCURACY DATA

BARBITURATES (BAR) DRUG SCREEN

Accuracy: The performance of the the *iSCREEN* barbiturates drug screen was compared to the laboratory initial screen and a leading commercially available barbiturates rapid test. Testing was performed on 292 clinical specimens. **At least ten percent of the specimens evaluated were between –25% or +25% of the cut-off concentration of 300 ng/ml**. Presumptive positive results were confirmed by GC/MS.

When compared to GC/MS at 300 ng/mL, the results are provided in the table below:

Method		GC/MS		Total Results
iSCREEN Test Device	Results	Positive	Negative	
	Positive	122	4	126
	Negative	10	156	166
Total Results		132	160	292

Relative Sensitivity: 92% Relative Specificity: 98% Accuracy: 95%

Note: The FDA requires on-site test devices to be accurate within 25% of the drug screen's cut-off level. The *iSCREEN's* accuracy within 25% of the screen's 300ng cut-off was 97%

The specimens identified as positive by the *iSCREEN* but below 300 ng/ml by GC/MS were all at or above 218 ng/ml. Therefore; the *iSCREEN* detected 4 positive specimens that were below the 300 ng/ml GC/MS cut-off, but there were no false-positive results.

BENZODIAZEPINE (BZO) DRUG SCREEN

Accuracy: The performance of the the *iSCREEN* benzodiazepines drug screen was compared to the laboratory initial screen and a leading commercially available benzodiazepines rapid test. Testing was performed on 300 clinical specimens. **At least ten percent of the specimens evaluated were between –25% or +25% of the cut-off concentration of 300 ng/ml**. Presumptive positive results were confirmed by GC/MS.

When compared to GC/MS at 300 ng/mL, the results are provided in the table below:

Method		GC/MS		Total Results
iSCREEN Test Device	Results	Positive	Negative	
	Positive	129	7	136
	Negative	5	159	164
Total Results		134	166	300

Relative Sensitivity: 96% Relative Specificity: 96% Accuracy: 96%

Note: The FDA requires on-site test devices to be accurate within 25% of the drug screen's cut-off level. The *iSCREEN* detected all but one of the GC/MS positive specimens within +25% of the screen's 3000ng cut-off.
The only GC/MS positive specimens not identified as positive by the *iSCREEN* were close to or below the *iSCREEN 's* 300 ng/ml cut-off. Specimens whose results differed between the GC/MS and the *iSCREEN* contained the following concentration levels in ng/ml: (323,326, 334, 335, and 540)
The *iSCREEN* detected 5 positive specimens that were below the 300 ng/ml GC/MS cut-off, but there were no false-positive results.

METHADONE (MTD) DRUG SCREEN

Accuracy: The performance of the the *iSCREEN* methadone drug screen was compared to the laboratory initial screen and a leading commercially available methadone rapid test. Testing was performed on 300 clinical specimens. **At least ten percent of the specimens evaluated were between –25% or +25% of the cut-off concentration of 300 ng/ml**. Presumptive positive results were confirmed by GC/MS.

When compared to GC/MS at 200 ng/mL, the results are provided in the table below:

Method		GC/MS		Total Results
iSCREEN Test Device	Results	Positive	Negative	
	Positive	132	0	132
	Negative	1	167	168
Total Results		133	167	300

Relative Sensitivity: >99% Relative Specificity: >99% Accuracy: >99%

Note:. The *iSCREEN* detected >99% of the GC/MS positive specimens at +/- 25% of the screens 300 ng/ml cut-off.

The only GC/MS positive specimen not identified as positive by the *iSCREEN* contained methadone at a concentration of 534 ng/ml.

The *iSCREEN* did not detect any specimens as positive that did not confirm by GC/MS at 200 ng/ml.

iSCREEN ACCURACY DATA

TRICYCLIC ANTIDEPRESSANT (TCA) DRUG SCREEN

Accuracy: The performance of the the *iSCREEN* TCA drug screen was compared to the laboratory initial screen and a leading commercially available TCA rapid test. Testing was performed on 200 clinical specimens. **At least ten percent of the specimens evaluated were between –25% or +25% of the cut-off concentration of 1,000 ng/ml**. Presumptive positive results were confirmed by HPLC.

When compared to HPLC at 300 ng/mL, the results are provided in the table below:

Method		HPLC		Total Results
	Results	Positive	Negative	
***iSCREEN* Test Device**	Positive	60	0	60
	Negative	0	140	140
Total Results		60	140	200

Relative Sensitivity: >99% Relative Specificity: >99% Accuracy: >99%

Note: The *iSCREEN* correctly identified 100% of the specimens determined to be positive by GC/MS, and all specimens identified as positive by the *iSCREEN* were confirmed positive by HPLC at or above a 300 ng/ml concentration level.

There is no DHHS specified confirmation level for TCA