

## TOX DS panel evaluation

Dr. Patrick Mura, Laboratory of Toxicology and Pharmacokinetics University Hospital - Poitiers, France

### METHOD:

- Evaluation Panel : AMP, MET, COC, MTD, OPI, THC, Paracetamol, BAR, BZO, TCA
- 100 urine samples
- TOX DS results compared to CEDIA technique performed on Roche Modular
- Discrepancies analyzed by GC-MS, HPLC

### RESULTS:

Drugs	Positive on both techniques	Negative on both techniques	Discrepancy
Cannabis	64	36	0
Amphetamine	2	98	0
MET	3	97	0
Cocaine	33	66	2
Opiates	70	28	4
Methadone	94	6	0
PCP	0	0	0
TCA	2	98	0
Barbiturates	2	98	0
BZO	14	86	0
Acetaminophen	46	54	0
Total	330	667	6

- No false positive (FP) results with TOX DS and only 2 false negative (FN):  
1 FN Cocaine & 1 FN Opiates with low concentrations (443ng/ml & 576ng/ml respectively)  
The 4 other discrepancies were 3 FP Opiates and 1 FN Cocaine results with the CEDIA Modular

## Author's conclusions

In comparison with the traditional methods used in the laboratories, TOX DS technology associated with the Triage® Meter provides an easy to use test allowing patient identification, display and printout of results and data uploading to a "Data Management System" or to a "Laboratory Information Systems" (LIS). As results are automatically analyzed by the Meter and reported as Positive or Negative, **Triage® eliminates the subjectivity of visual reading, a source of errors with other rapid tests.**

Very good performances were obtained with Triage TOX Drug Screen, with only 2 false negative results and no false positives. Consequently, the Triage TOX Drug Screen test may be useful for screening drugs of abuse and therapeutic drugs in a number of applications.

- Dr. Patrick Mura



*The Triage® TOX Drug Screen device shows perfect performance in comparison to LC-MS-MS.*

Pr. Alain Verstraete

*The Triage® eliminates the subjectivity of visual reading, a source of errors with other rapid tests.*

Dr. Patrick Mura

*The performance of the method on the Triage Meter was qualitatively high, easy to use and ... (Highly safe system).*

Dr. Andre Scholer

*The TOX DS is more convenient, efficient and adds advantages...*

Dr. Gert Printzen

## TOX Drug Screen Evaluation Reports Summary

### Triage® TOX Drug Screen Evaluation

TOX DS & Triage® evaluation for Methadone by:  
**Pr. Alain Verstraete**  
Laboratory of Clinical Biology Ghent University Hospital Belgium

TOX DS panel evaluation by:  
**Dr. Patrick Mura**  
Laboratory of Toxicology and Pharmacokinetics University Hospital - Poitiers, France

# TOX Drug Screen Evaluation Reports Summary

TOX DS panel evaluation by:  
**Dr. Andre Scholer**  
Clinical Chemistry Laboratory - University Hospital Basel, Switzerland

TOX DS comparison study versus Triage® by:  
**Dr. Gert Printzen**  
Analytical Medicine Laboratory Inselspital Bern, Switzerland



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## TOX Drug Screen evaluation reports summary

### TOX DS & Triage®8 evaluation for Methadone

Pr. Alain Verstraete, Laboratory of Clinical Biology, Ghent University Hospital, Belgium

#### METHOD:

- 100 urine samples
- TOX DS & Triage®8 MTD results compared to the KIMS technique on Integra 400
- Discrepancies were analyzed by LC-MS
- In a second part, the potential cross reactivity of tramadol was evaluated on both Triage TOX DS & Triage®8

#### Methadone Performance

TOX DS (cut off set to 300 ng/ml in the MeterPro) vs LC-MS-MS			Triage®8 vs LC-MS-MS		
<b>TN</b>	54		<b>TN</b>	52	
<b>TP</b>	46		<b>TP</b>	46	
<b>FP</b>	0		<b>FP</b>	2 *	* One sample had a methadone concentratio of 137 ng/mL, lower than the cut off of 250 ng/mL.
<b>FN</b>	0		<b>FN</b>	0	
<b>n.</b>	100	<b>Sensitivity = 100 %</b> <b>Specificity = 100 %</b>	<b>n.</b>	100	<b>Sensitivity = 100 %</b> <b>Specificity = 96.3 %</b>

#### Tramadol Cross reactivity

Interference of tramadol					
TOX DS		Triage®8	LC-MS-MS (ng/mL)		
Cut off 300	Cut off 100		Methadone (ng/mL)	EDDP (ng/mL)	Tramadol (ng/mL)
Negative	Negative	Negative	0	13.6	326
Positive	Positive	Positive	392	1760	34200
Negative	Negative	Positive	0	18.1	41400

### Author's conclusions

#### **The Triage® TOX Drug Screen device shows perfect performance in comparison to LC-MS-MS.**

In comparison to the TOX DS device, Triage®8 is less specific with a specificity of 96.3%. No interference of tramadol was observed when using the TOX Drug screen device. The Triage® TOX DS combined to the MeterPro is very easy to use and does not require any extensive training. The Triage® MeterPro allows patient identification (manually or by a barcode reader), test selection and gives positive or negative results very clearly on the screen and on the automatically printed report. The Triage® Meter saves all patients results including lot reagent and can be connected to the LIS system, reduces TAT (Turn Around Time) and the risk of errors. It also ensures full traceability of the results.

- Pr. Alain Verstraete

#### Instrument & Control handling

- With this new TOX DS and in addition to the internal controls already included in each individual test, Biosite proposes two external liquid controls allowing more quality assurance which may be required by Institutions or recommended by local guidelines.
- We tested the Triage® TOX DS Control Set 2 with both screening devices. Both devices yielded positive results for all screened classes of drugs. The result for THCCOOH was very difficult to read on the Triage®8 device.

### TOX DS Panel Evaluation

Dr. Andre Scholer, Clinical Chemistry Laboratory - University Hospital - Basel, Switzerland

#### METHOD:

- Panel: AMP, MET, COC, MTD, OPI, THC, Paracetamol, BAR, BZO, TCA\* (PCP not tested)
- 50 urines samples
- TOX DS results compared to CEDIA or DRI (TCA) techniques performed on Roche Hitachi 917 and on Dade Behring EMIT for paracetamol.
- Discrepancies analyzed by LC-MS & HPLC

#### RESULTS:

Analytes	Positive on both techniques	Negative on both techniques	Discrepancy
APAP	16	31	2
AMP / MET	1	48	0
COC	11	38	0
MTD	10	39	0
OPI	10	39	0
THC	10	39	0
TCA	2	40	7
BAR	1	48	0
BZO	22	26	1
Total	83	348	10

- Paracetamol: 1 APAP FN on TOX DS with 1 sample with low APAP concentration . The second discrepancy showed a lower concentration of native APAP below the TOX DS cut-off
- TCA:
  - 1 FP on TOX DS with cross reactivity to confirm with Chlorprotixene and or Desmethyl-Mirtazapine
  - 2 samples containing Desipramine, Venlafaxin metabolites and 2-OH-Desipramine, Venlafaxin giving TCA negative on TOX and positive on DRI method
  - 4 TCA positive on DRI technique due to interferences with the DRI TCA method.
- BZO: 1 FP on CEDIA technique

### Author's conclusions

**The new TOX DS shows a good agreement with other screening tests** and after confirmation of the discrepant results there were only one false negative Acetaminophen result, one false positive TCA and 2 questionable false negative TCA tests in 50 measurements for each parameter.

The performance of the method on the Triage Meter was qualitatively high, easy to use and without the possibility to produce handling failures (Highly save system). The new toxicological screening method on the Triage Meter has some advantages compared to the manual Triage test:

- Easy performance
- Shorter process time
- No transfer of reaction mixture during process
- Printed documentation of the results

Additional method for the determination of acetaminophen (paracetamol) as a urgency parameter in case of suspected overdose.

- Dr. Andre Scholer

### TOX DS comparison study versus Triage®8

Dr. Gert Printzen, Analytical Medicine Laboratory, Inselspital Bern, Switzerland

#### METHOD:

- Result comparison of 20 urine samples selected from the daily routine
- Control samples were used to ensure analytical quality of the results

#### RESULTS:

- The 34 positive results and 126 negative results gave exactly the same data on both TOX DS and Triage®8

Parameter	Positive on both techniques	Negative on both techniques	Discrepancy
MTD	3	17	0
COC	5	15	0
AMP / MET	0	20	0
OPI	8	12	0
THC	4	16	0
TCA	1	19	0
BAR	2	18	0
BZO	11	9	0
Total	34	126	0

### Author's conclusions

**We have a 100% correlation between the 2 Biosite tests, TOX DS and Triage®8, no discrepancy.**

The TOX DS is more convenient, efficient and the following advantages are valuable:

- Easy to use with a larger panel, 3 more parameters including paracetamol with interesting implications for the ED
- No pre-incubation step and no transfer-pipetting

Objective reading, documented results (printing + memory) and possibility of LIS-connection

- Dr. Gert Printzen