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Dear Madam, dear Sirs,

Please find below our first results of the evaluation of the saliva test system **Rapid STAT**.

The "Roadside" Saliva test System RapidSTAT of MAVAND Solutions GmbH (Mössingen) was employed for trial in the federal State of Rheinland-Pfalz (Rhineland Palatinate). The tests have been carried out normally within routine traffic controls, mostly in the service territory of the Police Departments Ludwigshafen, Trier and Wittlich.

At the same time the saliva samples have been examined via Gas Chromatography / Mass Spectrometry (GC/MS) by the Institut für Rechtsmedizin der Johannes Gutenberg-Universität Mainz (Institute of Forensic Medicine of the Johannes Gutenberg University Mayence). The Institut für Rechtsmedizin, Mainz is accredited according to DI EN ISO/IEC 17025. The results of the RapidSTAT-Tests and the associated GC/MS saliva analysis have been compared with the results of the blood examinations ordered by the police. The GC/MS analysis of the police blood samples was carried out within the ongoing routine operations of the Institut für Rechtsmedizin. The employed blood examination procedure is validated according to the Guidelines GTFCh and ranks among the certified testing methods of the Institute. An analogue to the blood examinations GC/MS procedure was established for the analysis of the saliva samples which also was validated according the the GTFCh Guidelines.

Within the period of studies 84 RapidSTAT tests were performed. However not always sufficient saliva was available to serve as examination material for the GC/MS analysis. In these cases the result of the RapidSTAT was compared with the analysis results of the associated blood sample. In quite a few cases there was not taken a blood sample by the police. In the end there is a number of realizable data set of considerably below 84. Cocaine and Opiates have not been evaluated at all as for these drugs only one RapidSTAT test turned out positive. RapidSTAT results for Amphetamines/Methamphetamines as well as Cannabis (THC) have been evaluated.

#### Amphetamine/Methamphetamine-Assay:



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nach DIN EN ISO/IEC 17025

Regarding the Amphetamine test altogether 71 data sets have been evaluable.

|            | correct<br>positive | correct negative | False-positive | False negative |
|------------|---------------------|------------------|----------------|----------------|
| number     | 12                  | 57               | 1              | 1              |
| proportion | 16,9 %              | 80,3 %           | 1,4 %          | 1,4 %          |

Therefore for the Amphetamine Test resulted the following:

Specificity **98,3 %**

Sensitivity **92,3 %**

With the persons tested correct positive in Amphetamine by the RapidSTAT test, Amphetamine concentrations in serum of between 13 and 548 ng/mL have been found when examining the associated blood samples. The average value was 235 ng/mL and the Median was at 190 ng/mL.

#### **THC-Assay:**

With the THC test altogether 31 evaluable data sets were available.

|            | Correct<br>positive | Correct negative | False-positive | False-negative |
|------------|---------------------|------------------|----------------|----------------|
| number     | 20                  | 8                | 1              | 2              |
| proportion | 64,5 %              | 25,8 %           | 3,2 %          | 6,5 %          |

Therefore the following resulted for THC test:

Specificity **88,9 %**

Sensitivity **90,9 %**

With the persons tested correct positive in THC by the RapidSTAT test, THC concentrations in serum between 0,8 und 24,3 ng/mL have been found when examining the associated blood samples. The average value was at 7,1 ng/mL and the Median at 3,1 ng/mL. Outstanding was that with 5 of the donors tested positive by the RapidSTAT the THC serum concentration was detected in the range of the limit value of 1 ng/mL (0,8, 0,9, 1,2, 1,6, 1,7 ng/mL). This argues for a high sensitivity of the test system.

Please do not hesitate to contact me for further request or detailed explanations.

Yours sincerely

Dr.rer.nat. J. Röhrich