

Bettina Tuerk <sup>1,2</sup>, Dietmar Leichtfried <sup>2</sup>, Lydia Halwachs <sup>1</sup>, Rainer W. Schmid <sup>1</sup>

<sup>1</sup> Inst. f. Medical & Chemical Labdiagnostics, University Hospital - Medical University of Vienna, Austria (rainer.schmid@meduniwien.ac.at)

<sup>2</sup> Greiner Bio-One, Kremsmuenster, Austria

## Introduction

In drug of abuse testing, saliva has many advantages as alternative sample matrix to urine: Easy availability, non-invasive, stress-free and pain-free collection. Currently many saliva sampling techniques are plagued with a number of practical problems, from low and variable sample volumes in case of dry mouth (xerostomia), to hygienic questions and analyte absorption onto the collection device.

A novel saliva collection technique based on a liquid carrier system (Saliva Collection System – SCS, Greiner Bio-One, Fig. 1) has been developed. The validity of this new technique was studied, comparing opiates levels in saliva and blood with a modified CEDIA urine test (Microgenics).

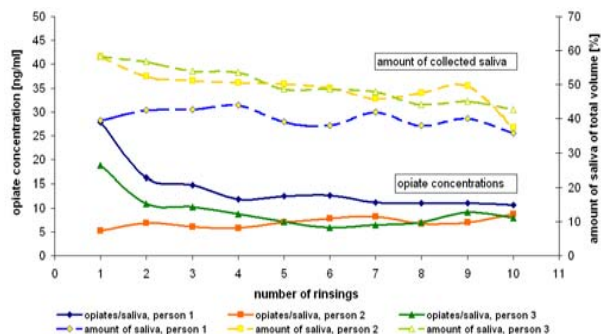


Fig. 2: Effect of consecutive rinsing with Saliva Extraction Solution (pH 4.2) on the amount of collected saliva and the opiate concentrations in 3 test persons.

## Results

The new saliva collection device allows an uncomplicated, hygienic and reproducible oral fluid sampling. An important advantage over other techniques is that collection can be done repeatedly for many times, indicated by constant morphine levels and saliva recovery (Fig. 2).

After poppy seed consumption salivary opiates concentrations peak in average after 30 minutes at 10-20 ng/mL and drop below 5 ng/mL within 3-7 hours (Fig 3).

The amount of oral fluid in the collected fluid, analysed automatically with a clinical analyser, is in average 65% (Fig. 4).

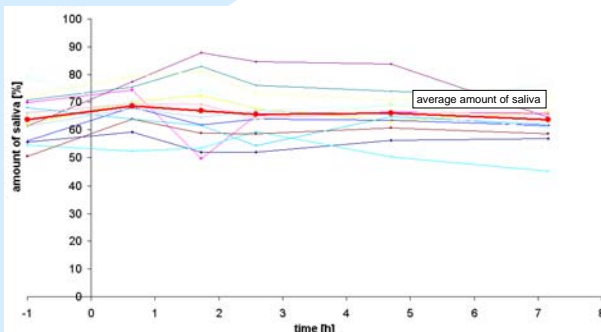


Fig. 4: Amount of saliva obtained with the new saliva collection device (at pH 4.2) in 12 test persons after poppy seed consumption. Red line shows average concentration.



Fig. 1: The Greiner Bio-One Saliva Collection System

## Methods

The SCS is composed of a non-toxic, colored saliva extraction solution, a collection beaker and an evacuated saliva collection tube. To obtain saliva, the non-toxic extraction fluid is kept in the mouth by the individual for a short period of time (2 min), emptied into the collection beaker and then transferred into the evacuated collection tube. After centrifugation the clear supernatant can be directly used for many applications in drug of abuse testing or therapeutic drug monitoring.

The exact amount of the collected (dissolved) oral fluid in the extracted saliva solution is determined by photometric quantification of the non-toxic dye in the extraction solution.

To test the usability of the new saliva collection system for routine DOA analysis volunteers were consuming commercially available poppy seeds, naturally containing morphine (240 mg/kg). Saliva was collected with the new SCS device over a period of 8 hours and opiate concentrations were determined with a modified urine CEDIA-immunoassay, adapted for the low level measurements in oral fluid. The sensitivity of the CEDIA opiate assay was extended into the measuring range of down to 5 ng/mL by modification of analyte and reagent volumes and measurement kinetics.

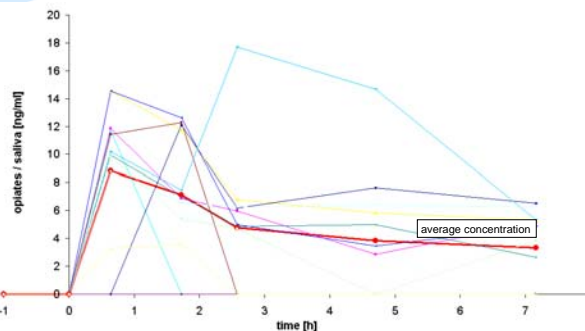


Fig. 3: Opiate concentration in saliva of 12 test persons after poppy seed consumption. Red line shows average concentration.

## Conclusions

- 1) The new collection technique provides a hygienic and easy to apply procedure for oral fluid collection and thus is an ideal alternative to urine routine DOA testing.
- 2) Saliva samples collected with the new device can be directly utilized in automatized immunoassay analysis without further sample manipulation.
- 3) There is always sufficient sample volume available for DOA testing and confirmation analysis.
- 4) With minor modifications, the commercially available urine CEDIA assay can be utilized to measure opiate concentrations in the collected oral fluid.
- 5) In combination with a sensitive, portable drug detection system, the new saliva collection system also will be useable in on-site drug testing situations.