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# The Dräger DrugTest® 5000 Analyzer

## Part 1 – First Impressions

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Access to any forensic technology used by the police or state-run crime labs is extremely limited. Breath alcohol testing devices, as an example, typically only fall into private hands once they've been rendered obsolete by newer technology. So, when we had an opportunity to examine the new **Dräger DrugTest® 5000 Analyzer**, we designed a series of experiments to examine and challenge the performance characteristics of the device. We were curious to know if the device provided accurate and reliable results that corresponded to other biological samples. To date, we've been able to obtain readings that we will compare to forensic Gas Chromatography analysis of urine samples obtained concurrently. *This article will be the first in a series examining our findings.*

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## Experimental design

In May 2019, I travelled to Vancouver, BC to visit the offices of Acumen Law. I had been invited by lawyers Paul Doroshenko, KC, and Kyla Lee to participate in a collaborative independent assessment of the Dräger DrugTest® 5000 Analyzer. Along with long-time friend and fellow "forensic investigator", Toronto lawyer Stephen Biss, I developed a series of experiments to assess and challenge the performance of the device.

Also participating was Suzanne Perry of Salient Analytical Services Canada, an experienced veteran in chemical analysis technology. Running the whole experimental design, and in all respects acting as the coordinator, was Karly Richmond, a Doctor of Pharmacy (Pharm.D.) student from the University of Saskatchewan. Unable to join us, but most helpful in the experimental design, was another long-time collaborator and colleague, Fran Gengo, (Pharm.D.) of the Dent Neurologic Institute.

Over the course of two days, we had about 20 subjects tested on the Dräger DrugTest® 5000 Analyzer. Some of the participants were daily users of cannabis products. Some were occasional users. Ms. Richmond interviewed and assessed each user, screened them for suitability to participate, then put them into one of two groups. The first group was dosed with a marijuana cigarette. The second group was held back from the use of any cannabis containing products as a placebo group.

*Figure 1 - The Draeger 5000 (in the background), with a Sample Test Kit (in front).*

Before the dosing, I conducted a Drug Recognition Evaluation (DRE) on each participant, recording their scores. Then, divided into their two groups, they were either dosed or held back, and given about one hour to reach their **C-Max** (the maximum concentration of the dose).

After this wait period, I conducted the complete DRE assessment again, this time not knowing who had been dosed, and who had been held back as a control. In this way, uninformed, I was not able to influence, even subconsciously, the outcome of the very subjective DRE assessment.

Following the second DRE assessment, each participant was then tested on the Dräger DrugTest® 5000 Analyzer. Results of their oral swab analysis was then recorded. Finally, a mid-stream urine specimen was collected from each participant. These were immediately analyzed using the **QuickCheck Drug Screen Test Cup.** The samples were then refrigerated to - 80 Celsius (just another cold Canadian winter), and these will ultimately be further analyzed by an accredited laboratory and test facility to determine the concentration of any of the substances identified by the Dräger DrugTest® 5000 Analyzer.


*Figure 2 - A QuickCheck Drug Test Cup was used to collect a urine sample from all participants, and these will be further analyzed.*

There were numerous reasons for dividing into dosed vs. non-dosed groups:

- First, we wanted to assess the performance of the device on a person who has active THC in their system.
- Second, we wanted to assess the impact, if any, on residual THC, that is to say, consumption from a few days, or a few weeks ago, and the response of the device to that situation.
- Third, we wanted the opportunity to complete the full DRE panel of examinations on dosed vs. non-dosed subjects to see if the DRE assessments were able to discern the relative dosing difference.
- Setting up a control group (the non-dosed subjects) is critically important in any experimental design to see if there is a verifiable cause-effect relationship.
- Additionally, we tested the response of the unit to various potential interfering compounds, including poppy seed muffins, CBD oils, CBD suppositories, and herbal teas. Having non-dosed participants was vital to those investigations.

## Description of the Dräger DrugTest® 5000 Analyzer

The Dräger DrugTest® 5000 Analyzer (hereafter simply referred to as the *Dräger 5000*) can best be described as a portable electronic *screening* device that analyses oral swab saliva samples to determine the presence of a variety of commonly used *drugs of abuse*.

*Figure 3 - THE DRÄGER DRUGTEST® 5000 ANALYZER*

**An Important Note:**

We need to differentiate a *screening* device from an *evidentiary* device.

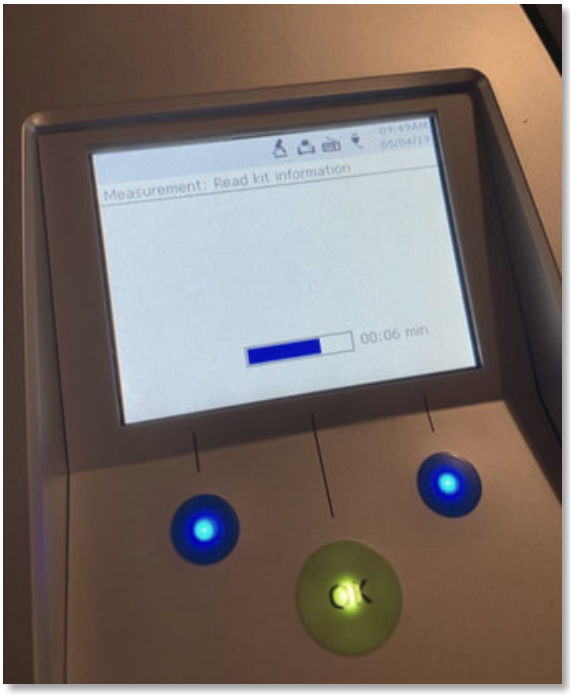
In a *screening* device, analytical results are merely qualitatively identified as, in the case of the Dräger 5000 - POSITIVE or NEGATIVE (present or not present to a sufficient amount or, as in the case of breath alcohol screening devices - Pass, Warn, or Fail).

A device is considered *qualitative* because no amount, concentration or quantity is measured – it merely detects the presence of a specific substance in the test sample.

In a more complex *evidentiary* or *quantitative* device, the amount of the thing being measured is also displayed (i.e., - 0.05 grams per 100mL, or 13 nanograms per millilitre, etc.). This degree of sophistication would require substantially more calibration and control for reliable testing.

**By identifying the Dräger 5000 as a screening device, Dräger is signifying the inherent limitations of the device, and that limitation should be respected as we examine its performance characteristics.**

The Dräger DrugTest® 5000 Analyzers are apparently configured for either *workplace health & safety* or *police criminal investigations* as the overall goal. The unit we examined was configured for police investigations. Each analyzed substance would generate a simple POSITIVE [1] reading when its concentration exceeded the level programmed into the device, through a disposable sampling cassette (the STK) used to obtain the oral saliva sample.




The unit itself can be described as being slightly larger than a bagel toaster, yet smaller than a home bread-making machine. It operated on a 12 Volt DC convertor plugged into a regular 110 Volt AC outlet, meaning that it can be used out in the field by plugging into a vehicle 12 Volt adapter (i.e. – the car charger outlet).

*Figure 4 - The color display and control buttons*

Operation of the Dräger DrugTest® 5000 Analyzer was by three simple buttons on the top of the unit, located below the color backlit LCD display screen. Once the oral swab sample in the STK was obtained, it was loaded into the front of the device behind a sliding door. Once correctly in place, analysis of the oral swab was automatic, and takes less than 10 minutes to complete. Once the analysis is completed, the results are displayed in the LCD screen. An optional external printer was available, but not configured for the unit we were examining.

[1] Throughout these essays, I will use the convention of CAPITALIZING a word or phrase to signify that it was a message or user-prompt generated by the Dräger 5000 DrugTest® Analyser.

## The heart of the matter – The Sample Test Kit

This component is referred to as the Dräger DrugTest® 5000 STK. It is a *Sample Test Kit* (I'm going to refer to these as Dräger does, simply as the "STK") that comes individually wrapped in a sealed heavy mylar-type pouch, with configuration information and an expiry date printed on the outside of the pouch. Dräger states that different versions of the STK are available to test different drugs of abuse, with their cut-off concentrations listed in ng/mL (nanograms per millilitre) of the various testable substance.

*Figure 5 - The Sample Test Kit (STK) showing a pencil for scale.*

Depending on the STK employed, the Dräger 5000 can be used to confirm the presence of the following drugs:

| CODE | Drug (Class) | Common Name |
|---|---|---|
| AMP | d-Amphetamine Sulfate | Amphetamine |
| BZO | Benzodiazepines | Diazepam |
| COC | Cocaine | Cocaine |
| MET | D-Methamphetamine | Methamphetamine |
| MTD | Methadone | Methadone |
| OPI | Opiates | Morphine |
| THC | Δ-9 THC | Delta 9-Tetrahydrocannabinol; Cannabis |

*Figure 6 - The STKs used in this study were configured to read these substances. Note that Canadian STKs use a different configuration.*

The STK consisted of a plastic sample holder with a protruding oral swab, sealed under a removable clear plastic safety cap. Also included was a blue plastic cartridge, closed on one end by a foil seal.

*Figure 7 - The swab end of the STK. The end of the swab turned blue when sufficient saliva was collected for analysis.*

Once exposed by removing the clear plastic safety cap, the sampler (an oral fluid, or saliva, sample collector) was placed in the mouth of the test subject. Saliva was then collected over the next while, anywhere from 3-5 minutes in most cases, but in one particular individual, the collection took almost 12 minutes. When enough saliva has been collected to saturate the internal test strips of the cassette, a "volume adequacy indicator" turned blue on the oral swab component of the sample collector. It was only then that the sample should be analyzed.

### An Interesting Side Note

We now had more than 30 STKs, each with a protective cap. These were stored for a little more than 6 weeks when we decided to examine the kits, and their protective caps, for traceable DNA.

Consent was taken from our identifiable test subjects, and the kits were sent for DNA analysis.

There was sufficient DNA on both the protective caps and the swabs themselves to provide unique DNA samples, suitable for comparative studies, or to identify a specific individual.

As an aside, 1 millilitre of human saliva contains about 8 million human epithelial cells, and 500 million bacterial cells.


*Figure 8 - The inside of the STK showing the analytical strips used to determine the presence of the tested-for substances. The red bands are only visible when a reading is obtained*

Inside the STK was a "piping" system that transferred saliva onto a series of five reagent test strips. Each was color coded with a dissolvable ink band, from left to right, coded purple, orange, green, red. and blue. The reagent test strips do not seem to react to anything until the liquid in the blue cap has mixed with the saliva. When activated, a series of red bands appears on the reagent test strips.

However, the appearance of a red band on the test strip did not correspond with a positive or negative reading, as one would normally see with a urinalysis reagent test strip. We thought initially that the pattern of the red stripes might indicate positive or negative results for each of the tested-for substances. When we compared three STKs, one positive for cocaine, one positive for THC and cocaine, and one negative for all substances, the pattern on the five reagent test strips was very nearly identical. Clearly, some additional colorimetric test must be being carried out within the Dräger 5000.

*A more in-depth understanding of "colorimetric immunoassay" assessment technologies and methodologies will be explained in upcoming Counterpoint articles.*

*See "Oral Fluid Testing – Examining Issues and Limitations with the Technology", Counterpoint Volume 8; Issue 1 – Article 2, March 2024.*


*Figure 9 - The red bands are apparently used for an immunoassay colorimetric test. We will explain this in the next article in this series.*

It is actually a rather sophisticated methodology being used. We will discuss immunoassay testing in an upcoming *Counterpoint* article [2]. For now, simply know that the Dräger 5000 is using the principle that any drug existing in the saliva sample is competing with the same drug on the test strip for specific antibodies. If the saliva sample has more drug, then it will bind with the antibodies, ultimately creating a colored indicator read by the device as a POSITIVE result. If there is not enough drug in the saliva to bind with the antibodies, then the drug on the test strip will do so, and the sample will read NEGATIVE. However, this does NOT connote an associated *quantitative* reading - it is merely used as a means of identifying the absence or presence of a substance.

[2] See *"Oral Fluid Testing – Examining Issues and Limitations with the Technology", Counterpoint,* Volume 8; Issue 1 – Article 2, March 2024.

## Liquid in the blue cartridge

*Figure 10 - The blue cap contained liquid used for an immunoassay colorimetric test carried out within the Dräger 5000.*

The external dimensions on the cylinder component of the blue cartridge are 10.4mm x 38.5mm. The internal dimensions are slightly less due to the thickness of the plastic – about 8.0mm x 35.0mm. This gives rise to an internal chamber size of about 1750 cubic millimetres, or 1.75 millilitres. However, when drawn directly from an unused and sealed cap, and measured using a syringe, the liquid in the blue cap was only about 0.75 mL in volume, which in turn was evenly dispersed in the sample cassette strips. The liquid measured slightly alkaline with a pH of about 8.

Once the liquid in the blue cartridge has had a chance to interact with the strips on the test cassette, the unit started to create measurements. In all, it took less than 10 minutes for the final analysis of the test results to be reported on the digital display. Once completed, the unit prompted for the removal of the STK, and the testing process was over.

We were able to retrieve test data from the onboard memory and pull up previous results.

## A preview of our results

Dräger is clear in the instruction for the STK that the results obtained must be confirmed by professional analytical assessment, preferably by GC/MS (Gas Chromatography/Mass Spectrometry) or LC/MS (Liquid Chromatography/Mass Spectrometry). *Remember, Dräger has identified the inherent limitations of the technology used and, as such, views the DrugTest® 5000 Analyzer as a qualitative screening device.* End-users of the DrugTest® 5000 must keep that limitation in mind.

*Why are these limitations necessary?* It must be acknowledged that the technology utilized in the Dräger 5000 (Immunochemical or immunoassay detection reactions) are NOT specific to a single drug (in chemistry or pharmacology, called an *analyte*), but rather, reacts to a group of drugs (analytes) with similar chemical structures. Dräger recommends that the results obtained are NOT used to quantitatively analyze the concentration of the drug, but rather, simply indicate the possible presence of the group of drugs being tested for.

It will be up to the operator of the Dräger DrugTest® 5000 Analyzer to correctly interpret the readings obtained, having full regard to the consumption history of the test subject and circumstances surrounding the sample collection. Unfortunately, if they use the same sort of testing technology for confirmatory testing (i.e. – analyst the urine sample using colorimetric testing) the false-positive reading may be re-enforced, and considered a reliable test, when clearly, they are not. Stay tuned…

We identified a series of failures of the *Dräger DrugTest® 5000*. We had positive readings from non THC users, negative readings from chronic or recent THC users, and positive hits for cocaine and opiates when herbal tea or poppy seed muffins were consumed. Cannabidiol (CBD) oil produced a false-positive THC reading in a non-user of cannabis products. The incidents of false negative and false positive readings were about the same – 25% of reported results in either group were wrong.

In upcoming issues of Counterpoint, we will look closely at the results we obtained. At this point, it appears that any supposed false-positive results appeared as a result of the identified limitations of the testing protocol – the unit is only capable of identifying a class of drugs, rather than a specific drug. This limitation in technology is not the fault of the device – all immunoassay techniques are similarly prone. Our post-dosage urinalysis samples that we captured for replicate testing, using the same competing immunoassay technology, were likewise affected.

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