Siemens Healthcare Diagnostics Drug Testing, under the Cozart® brand name, has more than a 10-year legacy of providing an extensive and innovative portfolio of instruments for drug monitoring.

The Cozart DDS can be utilised within any organisation to provide peace of mind with oral fluid drug testing.
Cozart® provides peace of mind with saliva drug testing

The Cozart DDS (www.cozartgroup.com) is based around the use of the lightweight, mobile DDS reader which automates the analysis of a sample of saliva for drugs of abuse.

The DDS can be carried around for mobile testing, or it can be set up in a more permanent location. It is easy to use, and allows employees to be tested relatively quickly for the presence of drugs in their saliva, indicating recent use.

The Cozart system is used across a range of safety sensitive industries across Australia and internationally, including mining, heavy vehicle transport, manufacturing, and by the Police for roadside drug testing.

It has also recently been selected by Civil Aviation Safety Authority (CASA) as the product of choice for its Drug testing program.

All Cozart drug test kits and equipment are manufactured by Cozart under BS EN ISO 9001:2000 and ISO 13485:2003 Quality Management Systems and are CE marked (European Quality Standard).

About Cozart DDS system:

- A small saliva collection swab is used to obtain a sample of saliva from each donor under supervised collection. The collection device has a sample adequacy indicator which ensures reliable sample collection. Sample collection takes less than 1 minute.

- The DDS reader analyses the sample for 5 or 6 classes of drugs which takes 5 minutes. The use of the DDS reader removes subjectivity and operator errors. This is particularly important for in-house testing as the electronic reader removes human bias. Hard copy printouts of results ensure a record of results is available.

- The DDS comes complete with Quality Control cartridges to check instrument performance and all components are contained within a lightweight protective carry case, which enables the testing to be carried out anywhere, without special facilities.

- In the event of a positive result, a sample of saliva can then be forwarded to a laboratory for confirmatory analysis in line with the Australian Standard (AS 4760:2006) for saliva based drug testing, following all required chain of custody processes.

- The Cozart DDS can test for up to 6 drugs in the one test. Various options are available including the 2-panel (Methamphetamine/ THC), 5-panel (Methamphetamine/ Cannabis/ Opiates/ Cocaine/ Amphetamines), or 6-panel (as per 5 panel plus benzodiazepines).

- Purchase of a DDS instrument includes a 12 month warranty. Calibration and servicing of the DDS equipment is recommended on an annual basis and a 12 month warranty extension can be initiated at the time of servicing.
Intended Use: For the detection of drugs of abuse in oral fluid (saliva) samples. Samples are collected with the Cozart oral fluid collection swab. This is then applied via a dropper bottle on to a disposable cartridge.

Kit Contents: Each box contains 25 test cartridges and oral fluid collection swabs to perform 25 individual drug tests on the DDS.

Sample Type: Oral fluid (saliva)

Catalogue No.: DDS801

DDS 5 Drug Test Kit for:
- Cannabis
- Cocaine
- Opiates
- Methamphetamine
- Amphetamine

Cartridge run time: 5 minutes

Cut-off Levels: Neat oral fluid cut-off levels for this drug panel were established by fortifying negative saliva samples with the following drug levels:

<table>
<thead>
<tr>
<th>Drug Class</th>
<th>Target drug</th>
<th>Cut-off (ng/mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cannabis*</td>
<td>∆9THC*</td>
<td>*</td>
</tr>
<tr>
<td>Cocaine</td>
<td>Benzoylecgonine</td>
<td>30</td>
</tr>
<tr>
<td>Opiates</td>
<td>Morphine</td>
<td>30</td>
</tr>
<tr>
<td>Methamphetamine</td>
<td>Methamphetamine</td>
<td>50</td>
</tr>
<tr>
<td>Amphetamine</td>
<td>Amphetamine</td>
<td>50</td>
</tr>
</tbody>
</table>

*Fortifying samples with ∆9THC is difficult due to losses of material to surfaces and degradation. Validation using real samples was employed to illustrate the levels of ∆9THC found in DDS positive samples.

Fifty-five poly-drug positive samples were obtained at a drug clinic. Twenty six samples gave a DDS positive response for cannabis and were further tested by GCMS for the presence of ∆9THC in oral fluid.

All DDS screen positives were found to contain ∆9THC. Six of the twenty six samples had ∆9THC concentrations between 31 and 150 ng/mL. The remaining twenty samples had concentrations of ∆9THC ranging from 174 to 3006 ng/mL.

This illustrates that the DDS system is able to detect at least 31 ng/mL of ∆9THC.
### Specificity and Cross Reactivity

The following compounds show a negative response at 100,000 ng/ml. Concentrations that are highlighted in yellow will produce a positive result.

<table>
<thead>
<tr>
<th>Compound</th>
<th>THC</th>
<th>Cocaine</th>
<th>Opiates</th>
<th>Methamphetamine</th>
<th>Amphetamine</th>
<th>Benzodiazepines</th>
</tr>
</thead>
<tbody>
<tr>
<td>Codeine</td>
<td>100,000</td>
<td>100,000</td>
<td>55</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
</tr>
<tr>
<td>6-Acetyl Morphine</td>
<td>100,000</td>
<td>100,000</td>
<td>50</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
</tr>
<tr>
<td>Heroin</td>
<td>100,000</td>
<td>100,000</td>
<td>80</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
</tr>
<tr>
<td>Morphine</td>
<td>100,000</td>
<td>100,000</td>
<td>30</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
</tr>
<tr>
<td>MDA</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
</tr>
<tr>
<td>MDMA</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
</tr>
<tr>
<td>(+) Ephedrine</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
</tr>
<tr>
<td>Methamphetamine</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
</tr>
<tr>
<td>Amphetamine</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
</tr>
<tr>
<td>Diazepam</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
</tr>
<tr>
<td>Lorazepam</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
</tr>
<tr>
<td>Oxazepam</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
</tr>
<tr>
<td>Nitrazebepm</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
</tr>
<tr>
<td>7-Amino Flunitrazepam</td>
<td>10,000</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
</tr>
<tr>
<td>Alprazolam</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
<td>35</td>
</tr>
<tr>
<td>Midazolam</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
<td>250</td>
</tr>
<tr>
<td>Des-Methyl Flunitrazepam</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
<td>200</td>
</tr>
<tr>
<td>Triazolam</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
<td>100</td>
</tr>
<tr>
<td>Flunitrazepam</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
<td>50</td>
</tr>
<tr>
<td>Clonazepam</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
<td>50</td>
</tr>
<tr>
<td>Prazepam</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
<td>50</td>
</tr>
<tr>
<td>Flurazepam</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
<td>50</td>
</tr>
<tr>
<td>Temazepam</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
<td>15</td>
</tr>
<tr>
<td>Cocaine</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
</tr>
<tr>
<td>Cacoethylene</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
</tr>
<tr>
<td>Benzoylecgonine</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
</tr>
<tr>
<td>Colhine</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
</tr>
<tr>
<td>Amylobarital</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
</tr>
<tr>
<td>11-Hydroxy-Δ9THC</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
</tr>
<tr>
<td>Δ9THC</td>
<td>*</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
</tr>
<tr>
<td>Cannabidiol</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
</tr>
<tr>
<td>11-nor-9-Carboxy-Δ9THC</td>
<td>10</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
</tr>
<tr>
<td>Methadone</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
</tr>
<tr>
<td>Ranidine</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
</tr>
<tr>
<td>Amitriptyline</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
</tr>
<tr>
<td>Aspirin</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
</tr>
<tr>
<td>β Phenylethylamine</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
<td>100,000</td>
</tr>
</tbody>
</table>

Other drugs and drug metabolites that are not tested here may cause a positive result. Compounds for testing are under constant review, please contact Technical Services (salivadrugtesting.au@siemens.com) for any drugs not listed.
One of the key concepts of drug testing is the cut-off level at or above which a test will be reported positive.

People are generally familiar with cut-off levels in the context of drink driving laws, where prosecution will follow if a test is above the country’s decreed level and that within the regulations there can be flexibility to allow for uncertainties in measurement.

Cozart’s drug testing capability encompasses a matrix for oral fluid in Point of Care Testing (POCT) methods use a cut-off to determine positive from negative. Different cut off’s values will apply depending on the method and drug or drug groups being analysed.

Negative samples are efficiently and rapidly identified during screening against given cut-offs and on occasions the value used for a Point of Care test may vary from the laboratory cut-off for the same drug. Immunoassays provide a rapid and reliable screen to identify the negative samples. They also detect compounds of similar structure relative to the cut off and more specific drug identification is required known as Confirmation analysis. This analysis involves a chromatographic technique linked to Mass Spectrometry. The cut-off again determines whether a result is reported as negative or positive.

All Cozart’s customers are provided with details of the cut-off levels used for the screening and confirmation tests.

By using a cut off, it is possible that a sample that is reported as negative might contain the drug at a concentration that is lower than the cut off. Where a test is reported positive this merely provides evidence of use, it does not say when the drug was taken or how much was taken, and the level of drug detected cannot be accurately correlated with any degree of impairment.

<table>
<thead>
<tr>
<th>Drug Class</th>
<th>Target Drug</th>
<th>Cut-off (ng/ml)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cannabis*</td>
<td>∆9THC*</td>
<td>*</td>
</tr>
<tr>
<td>Cocaine</td>
<td>Benzoylgonine</td>
<td>30</td>
</tr>
<tr>
<td>Opiates</td>
<td>Morphine</td>
<td>30</td>
</tr>
<tr>
<td>Methamphetamine</td>
<td>Methamphetamine</td>
<td>50</td>
</tr>
<tr>
<td>Amphetamine</td>
<td>Amphetamine</td>
<td>50</td>
</tr>
<tr>
<td>Benzodiazepines</td>
<td>Temazepam</td>
<td>15</td>
</tr>
</tbody>
</table>

*Fortifying samples with ∆9THC is difficult due to losses of material to surfaces and degradation. Validation using real samples was employed to illustrate the levels of ∆9THC found in DDS positive samples.

Fifty-five poly-drug positive samples were obtained at a drug clinic. Twenty six samples gave a DDS positive response for cannabis and were further tested by GCMS for the presence of ∆9THC in oral fluid.

All DDS screen positives were found to contain ∆9THC. Six of the twenty six samples had ∆9THC concentrations between 31 and 150 ng/mL. The remaining twenty samples had concentrations of ∆9THC ranging from 174 to 3006 ng/mL.

This illustrates that the DDS system is able to detect at least 31 ng/mL of ∆9THC.
The purpose of this letter is to provide some further explanation of the THC targets versus cut-offs in relation to the Australian Standard for saliva drug testing, AS4760.

The AS4760 is different from the AS4308 (urine) as it does not specify exact cut-offs which must be used in screening or confirmation.

The concept used is Target concentrations. The target concentrations mean a level of drug sufficient to detect recent use. A degree of flexibility in the threshold applied to screening and confirmation is permitted because it is not a simple matter of the test working because the cut-off stated in the product insert meets the standard level.

The cut-off of the on-site saliva screen is an important factor, however, in the case of cannabis the other key factor is how well the saliva collection system works. This is an issue that is not commonly understood or discussed.

The saliva collection system used will have a major influence on THC detection, which is why Cozart has superior THC detection capabilities.

The term used is "recovery" - how much drug in the saliva actually gets on to the test cartridge after passing through the saliva swab. A number of saliva testing systems claim to have cut-offs even lower than Cozart, however, due to the large amount of THC being retained on the collection swab, they do not actually have good THC detection capabilities. THC is a very "sticky" drug. When smoked, the drug adheres to the mucosa of the mouth, throat and gums. This is the main method by which we are able to detect it in saliva. It also adheres to saliva collection swabs, sponges or wipes. In order to actually test a collected sample the saliva containing the drug needs to be transferred from the swab/wipe/sponge to the test cartridge. The failing of many saliva test kits is that they fail to do this. When the saliva is transferred on to the cartridge, the THC drug is retained (stuck) on the swab. Therefore positives could be missed, even if the stated cartridge "cut-off" appears low on paper.

An independent study of saliva collection systems showed up to 60% of THC was lost due to retention of THC on the swab. The Cozart system was the ONLY ONE evaluated to show acceptable recovery of THC. In fact Cozart's recovery of THC is nearly 100% due to the specific buffer solution used in both the RapiScan and DDS systems.

This has been repeatedly demonstrated in Forensic institutions around Australia. Therefore a variation from the suggested target in the standard of 5ng/ml is quite insignificant when potential losses of more than 60% of THC is lost by many other systems currently available.

The performance of Cozart is evidenced in its selection for roadside drug testing in most states of Australia. The Police relied on independent forensic evaluations of the Cozart system prior to acceptance to ensure it met the required performance criteria for an on-site screening test. This demonstrates the system is fit-for-purpose.

The standard urges selection of a saliva on-site test based on being "Fit for Purpose". This means in addition to consideration of the thresholds in use by a system, the overall performance including reliability of the sample collection procedure, integrity of the testing process and appropriate means of confirmation should also be considered.
Please read prior to beginning a test:

- Ensure that you have completed the DDS Training Programme (provided on the CD-ROM).
- Ten minutes prior to collecting the sample the donor should not eat or drink.
- Do not use the test cartridge beyond the expiration date printed on the foil.
- The cartridges and kit components are designed for single use only.
- Do not ingest the liquid contained within the sample buffer bottle.
- Do not chew or suck the Cozart® Oral Swab.
- Do not place Cozart® Oral Swab in mouth after it has been in the sample buffer solution.
- Check that the drug classes on the cartridge match those displayed on the DDS instrument.

For a copy of the cross reactivity data and full instructional manual please refer to the Cozart® DDS Training Programme CD-ROM that has been supplied with the Cozart® DDS System, or visit www.cozartgroup.com.

To collect an oral fluid sample
actively swab the Cozart® Oral Swab (a) around gums, tongue and inside cheek until the sample presence indicator turns completely blue.

To remove cap from the sample buffer bottle (b) by turning it anti-clockwise and place the Cozart® Oral Swab into the bottle bud-end first.

Snap the stem of the Cozart® Oral Swab by gently bending it at the scored break-point. Place the flip top lid (c) on the sample buffer bottle and turn it clockwise to tighten it.

Mix the contents of the bottle by gently moving it from side to side for 30 seconds, while holding the bottle upright and on a flat surface.

Ensure the DDS is now ready to begin a new test. Open the flip-top lid of the sample buffer bottle. Hold the bottle vertically and apply 4 drops of the fluid across the sample well (X) of the test cartridge (d).

As soon as the fluid appears on each of the 4 white cartridge membrane strips (this will take between 2 and 30 seconds) insert the cartridge into the DDS instrument with the arrow facing upwards.

Initiate a new test. Once completed the results will be displayed on the screen of the DDS instrument and a hard copy printout will follow if the printer is connected.

NB. This assay is for professional use only and provides a preliminary analytical test result. Clinical consideration and professional judgment must be applied to any drugs of abuse test result, particularly in evaluating a preliminary positive result. In order to obtain a confirmed analytical result a more specific alternative chemical method is required. Gas or liquid chromatography is the preferred confirmatory method.
A Summary of Scientific Papers Addressing the Detection of Drugs in Oral Fluid


This paper seeks to understand the relationship of THC concentrations in oral fluid and plasma. This is important in order to interpret oral fluid drug test results. Donors were given known doses of cannabis (low dose cigarettes), and consecutive samples of oral fluid and blood were taken at time intervals up to 24 hours after use. This study found that “THC results between oral fluid and plasma were remarkably similar” and that “THC in oral fluid followed a similar time course as plasma THC following smoked cannabis”. After 12 hours the THC level in both specimens had dropped below 1 ng/mL. The study concluded that a positive oral fluid test to THC provides credible evidence of active cannabis use.

The Involvement of Drugs in Drivers of Motor Vehicles Killed in Australian Road Traffic Crashes, Accident Analysis & Prevention, Vol 36 2004. O.H. Drummer et al

The Victorian Institute of Forensic Medicine conducted a large study on over 3000 fatally injured drivers’ blood sample results to assess the effect of drug use on culpability. A strong positive association was seen with drivers positive to THC, stimulants and alcohol. Probability calculations determined that the presence of these drugs in the driver was likely to have caused or contributed to the accident. It is important to note that the paper refers to the presence of d9-THC (active drug) in the blood, not carboxy-THC (metabolite). The paper also points out that “in cases in which THC (active) was not detected but carboxy-THC was detected, there was no increase in the likelihood of culpability compared to a drug-free driver”. In other words, the presence of cannabis metabolite in the blood did not translate into adversely affecting driver safety, only the presence of the active THC reduced driver safety.


This paper reports on the comparison of urine and oral fluid testing for Marijuana following administration of a single dose of the drug. THC (active) in oral fluid and THC-COOH (metabolite) in urine were measured immediately after administration and at regular time intervals. The data presented shows that THC in detected in oral fluid immediately, but took between 4-6 hours to be detected in urine. This means that for the casual user, there is the risk that a negative urine test could be returned in the first few hours after use. Also this study further supports others study claims that the time course of THC in oral fluid and blood are very similar, indicating that the presence of THC in saliva is a reliable indicator of active THC in the blood (see Figure 6).

Cognition and Motor Control as a function of d9-THC concentration in serum and oral fluid, Drug and Alcohol Dependence, J.G. Ramaekers et al

Subjects were administered doses of cannabis, and impairment was compared and measured to oral fluid and blood THC levels. The results showed a “strong and linear relationship between THC in serum and oral fluid”. Results did not show a strong relationship between level of impairment and levels of THC in their blood and oral fluid. This confirms the common understanding that individuals have varying tolerance to drugs such as THC and will display different levels of impairment for any given drug level. This is why detection of recent use is more relevant. In addition the paper reports that “impairment after THC was usually highest during the first hour after smoking and declined to baseline over 3-4 hours”. This time frame for acute impairment is also quoted in “The Forensic Pharmacology of Drugs of Abuse” Chapter 4; page 189 Cannabis – Duration of Action.