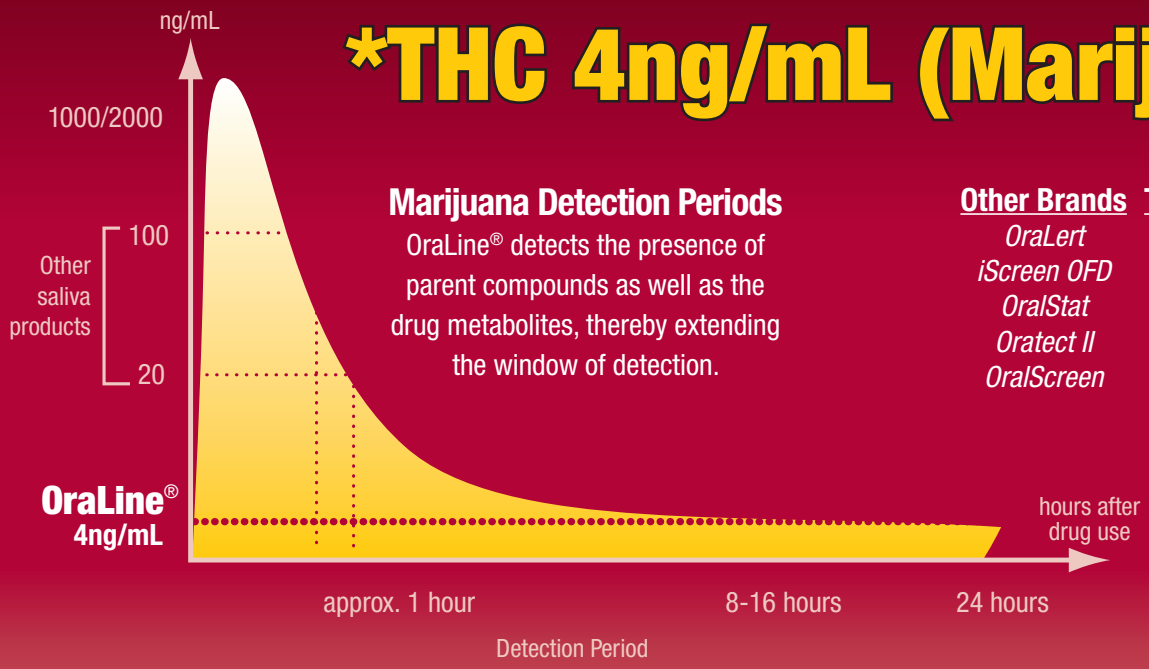
# OraLine®

## The ONLY instant oral fluid drug screen that meets the SAMHSA cutoff for THC*

## *THC 4ng/mL (Marijuana)



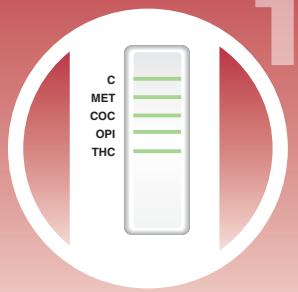

### Marijuana Detection Periods

OraLine® detects the presence of parent compounds as well as the drug metabolites, thereby extending the window of detection.

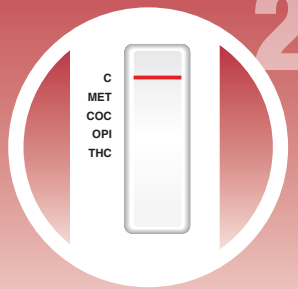
| Other Brands | THC Cutoff |
|---|---|
| *OraLert* | *12ng/mL* |
| *iScreen OFD* | *12ng/mL* |
| *OralStat* | *25ng/mL* |
| *Oratect II* | *40ng/mL* |
| *OralScreen* | *50ng/mL* |

**No additional oral fluid needed for confirmation**

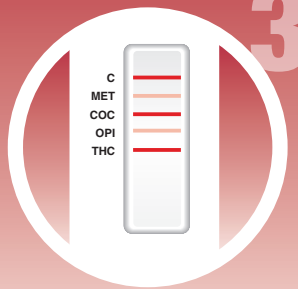

| ORALINE® Cutoffs | |
|---|---|
| *THC* | *4ng/mL* |
| *COC* | *25ng/mL* |
| *MET/AMP* | *50ng/mL* |
| *OPI* | *40ng/mL* |




5 green lines indicate device readiness.




After specimen collection, a red line opposite the control "C" symbol indicates the screen is valid.




Red lines of any intensity indicate a negative result (no drug detected).




Example above: The screen is negative for opiates and methamphetamine but positive for THC and cocaine.
**Total test time is 10 minutes.**

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# Oral fluid testing for cannabis: On-site OraLine® IV s.a.t. device versus GC/MS

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**Abstract**
Saliva or "oral fluid" has been presented as an alternative matrix to document drug use. The non-invasive collection of a saliva sample, which is relatively easy to perform and can be achieved under close supervision, is one of the most important benefits in a driving under the influence situation. Moreover, the presence of D9-tetrahydrocannabinol (THC) in oral fluid is a better indication of recent use than when 11-nor-D9-tetrahydrocannabinol-9-carboxylic acid (THC-COOH) is detected in urine, so there is a higher probability that the subject is experiencing pharmacological effects at the time of sampling. In the first part of the study, 27 drug addicts were tested for the presence of THC using the OraLine® IV s.a.t. device to establish the potential of this new on-site DOA detection technique. In parallel, oral fluid was collected with the Intercept® DOA Oral Specimen Collection device and tested for THC by gas chromatography mass spectrometry (GC/MS) after methylation for THC (limit of quantification: 1 ng/mL). The OraLine® device correctly identified nine saliva specimens positive for cannabis with THC concentrations ranging from 3 to 265 ng/mL, but remained negative in four other samples where low THC concentrations were detected by GC/MS (1–13 ng/mL). One false positive was noted. Secondly, two male subjects were screened in saliva using the OraLine® and Intercept® devices after consumption of a single cannabis cigarette containing 25 mg of THC. Saliva was first tested with the OraLine® device and then collected with the Intercept® device for GC/MS confirmation. In one subject, the OraLine® on-site test was positive for THC for 2 h following drug intake with THC concentrations decreasing from 196 to 16 ng/mL, while the test remained positive for 1.5 h for the second subject (THC concentrations ranging from 199 to 11 ng/mL). These preliminary results obtained with the OraLine® IV s.a.t. device indicate more encouraging data for the detection of THC using on-site tests than previous evaluations.


Keywords: Tetrahydrocannabinol (TCH); On-site test; DOA detection technique


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EZI-TEST P/L
85 Sheffield Road
Welshpool WA 6106

26th October 2004

Attention: Terry Snell - CEO

Dear Mr Snell

**ORALINE® SALIVA DRUG SCREEN**

Subsequent to our discussions on the Laboratory's saliva drug confirmation procedures, I also wish to confirm that the Oraline® test device has met all its specifications with regard to accuracy, sensitivity and reliability.

As I have previously mentioned many similar products, and even more sophistocated instrumental on-site screening devices, have fallen well short with respect to sensitivity.

Our work to date shows that the Oraline® screen for cannabinoids clearly correlates with our GC-MS confirmation at the 4 ng/ml level. A THC saliva concentration of 4 ng/ml should adequately serve as a screening and confirmation reporting cut-off.

It should be also heartening for you to know that using our Laboratory's GC-MS procedure, the THC in saliva limit of quantitation has been determined to be 0.4 ng/ml. This represents an order of magnitude lower than an acceptable reporting cut-off. Our Laboratory has uniquely achieved such a low level of quantitation by derivatising the extracted THC with pentafluorobenzoyl chloride prior to analysis using GC-MS in *Negative Ion Chemical Ionisation mode*.

I must admit to being more than pleasantly surprised that the Oraline® product delivers what it claims given some of the poor products I have encountered.

I look forward to our association with EZI-Test as the Oraline® test device penetrates the marketplace; as indeed it must given its outstanding performance.

Yours sincerely

Robert Hansson
Principal Chemist
Forensic Science Laboratory

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