

**IVD** For In Vitro Diagnostic Use

**REF** 10014665 (3 x 18 mL)  
0185 (100 mL Kit)  
0186 (500 mL Kit)

### Intended Use

The DRI Cannabinoid Assay is intended for the qualitative and semi-quantitative determination of cannabinoids (THC) in human urine.

*This assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.<sup>1,2</sup> Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.*

### Summary and Explanation of the Test

The principal active agent in marijuana and/or hashish that produces hallucinogenic and other biological effects is generally accepted to be  $\Delta^9$ -tetrahydrocannabinol ( $\Delta^9$ -THC).  $\Delta^9$ -THC is rapidly absorbed and almost completely metabolized by inhalation or through the gastrointestinal tract. The major metabolites of  $\Delta^9$ -THC (i.e. 11-nor- $\Delta^9$ -THC-9-carboxylic acid) becomes detectable in plasma, feces and urine within hours after exposure.<sup>3</sup> Passive inhalation of marijuana smoke can result in an elevation of urine THC concentration as high as 10-40 ng/mL.<sup>4,5</sup> In chronic users, THC may accumulate in fatty tissue faster than it can be excreted. This leads to longer detection times in urine for chronic users than for occasional users.

The DRI<sup>®</sup> THC Assay is a homogeneous enzyme immunoassay using ready-to-use liquid reagents.<sup>6</sup> The assay uses specific monoclonal antibody which can detect the major metabolite of  $\Delta^9$ -THC in urine. The assay is based on the competition of a drug labeled with enzyme, glucose-6-phosphate dehydrogenase (G6PDH), and the drug from the urine sample for a fixed amount of specific antibody binding sites. In the absence of drug from the sample, the specific antibody binds the drug labeled with G6PDH and the enzyme activity is inhibited. This phenomenon creates a direct relationship between the drug concentration in urine and the enzyme activity. The G6PDH activity is determined spectrophotometrically at 340 nm by measuring its ability to convert nicotinamide adenine dinucleotide (NAD) to NADH.

### Reagents

#### Antibody/Substrate Reagent.

Contains mouse monoclonal anti- $\Delta^9$ -THC antibodies, glucose-6-phosphate (G6P), and nicotinamide adenine dinucleotide (NAD) in Tris buffer with sodium azide as a preservative.

#### Enzyme Conjugate Reagent.

Contains  $\Delta^9$ -THC labeled with glucose-6-phosphate dehydrogenase (G6PDH) in Tris buffer with sodium azide as a preservative.

#### Additional Materials Required (sold separately):

REF	Kit Description
1664	DRI Negative Calibrator, 10 mL
1388	DRI Negative Calibrator, 25 mL
0235	DRI THC 20 ng/mL Calibrator, 5 mL
1397	DRI THC 20 ng/mL Calibrator, 25 mL
0042	DRI THC 50 ng/mL Calibrator, 5 mL
1398	DRI THC 50 ng/mL Calibrator, 25 mL
0044	DRI THC 100 ng/mL Calibrator, 5 mL
1399	DRI THC 100 ng/mL Calibrator, 25 mL
0206	DRI THC 200 ng/mL Calibrator, 5 mL
1400	DRI THC 200 ng/mL Calibrator, 25 mL

### Precautions and Warnings

- DANGER**
- This test is for in vitro diagnostic use only. The reagents are harmful if swallowed.
  - The assay components contain  $\leq 0.09\%$  sodium azide,  $\leq 0.2\%$  bovine serum albumin (BSA) and  $\leq 0.5\%$  Drug-specific antibody (Mouse). Avoid contact with skin and mucous membranes. Flush affected areas with copious amounts of water. Get immediate medical attention for eyes, or if ingested. Sodium azide may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of such reagents, always flush with large volumes of water to prevent azide build-up. Clean exposed metal surfaces with 10% sodium hydroxide.
  - Do not use the reagents beyond their expiration dates.

H317 - May cause allergic skin reaction.

H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Avoid breathing mist or vapor. Contaminated work clothing should not be allowed out of the workplace. Wear protective gloves/eye protection/face protection. In case of inadequate ventilation wear respiratory protection. If on skin: Wash with plenty of soap and water. IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing. If skin irritation or rash occurs: Get medical advice/attention. If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician. Wash contaminated clothing before reuse. Dispose of contents/container to location in accordance with local/regional/national international regulations.

### Reagent Preparation and Storage

The reagents are ready for use. No reagent preparation is required. All assay components when stored properly at 2-8°C, are stable until the expiration date indicated on the label.

### Specimen Collection and Handling

Collect urine specimens in plastic or glass containers. Testing of fresh urine specimens is suggested.

*The Mandatory Guidelines for Federal Workplace Drug Testing Programs: Final Guidelines: Notice* recommends that specimens that do not receive an initial test within 7 days of arrival in the laboratory should be placed into secure refrigeration units.<sup>2</sup> Samples within a pH of 3 to 11 are suitable for testing with this assay.

An effort should be made to keep pipetted samples free of gross debris. It is recommended that highly turbid specimens be centrifuged before analysis. Adulteration of the urine sample may cause erroneous results. If adulteration is suspected, obtain another sample and forward both specimens to the laboratory for testing.

### Handle all urine specimens as if they were potentially infectious.

### Assay Procedure

Analyzers capable of maintaining a constant temperature, pipetting samples, mixing reagents, measuring enzymatic rates at 340 nm and timing the reaction accurately can be used to perform this assay.

Refer to the specific application instructions of each analyzer for chemistry parameters before performing the assay.

### Quality Control and Calibration

Good laboratory practice suggests the use of control specimens to ensure proper assay performance. Use controls near the cutoff calibrator to validate the calibration. Control results must fall within the established range. If results fall outside of the established range, assay results are invalid. All quality control requirements should be performed in conformance with local, state and/or federal regulations or accreditation requirements.

### Qualitative analysis

For qualitative analysis of samples, use the 20 ng/mL, or 50 ng/mL, or 100 ng/mL 11-nor- $\Delta^9$ -THC-9-carboxylic acid calibrators as a cutoff level. The DRI THC Calibrators are used as cutoff references for distinguishing "positive" from "negative" samples.

### Semi-quantitative analysis

For semi-quantitative analysis, use all calibrators.

### Results and Expected Values

#### Qualitative results

A sample that exhibits a change in absorbance ( $\Delta A$ ) value equal to or greater than that obtained with the chosen cutoff calibrator is considered positive. A sample that exhibits a change in absorbance ( $\Delta A$ ) value lower than that obtained with the chosen cutoff calibrator is considered negative.

#### Semi-quantitative results

A rough estimate of drug concentration in the samples can be obtained by running a standard curve with all calibrators and quantitating samples off the standard curve.

### Limitations

- A positive result from this assay indicates only the presence of THC metabolites and does not necessarily correlate with the extent of physiological and psychological effects.
- A positive result by this assay should be confirmed by another nonimmunological method such as GC or GC/MS.
- The test is designed for use with human urine only.
- It is possible that other substances and/or factors (e.g., technical or procedural) not listed above may interfere with the test and cause false results.

### Typical Performance Characteristics

Typical performance data results obtained on a Hitachi 717 analyzer are shown below.<sup>7</sup> The results obtained in your laboratory may differ from these data.

### Precision

Within-run and run-to-run precision were evaluated using the negative and all the calibrator levels. The following results were observed:

Calibrator or Control	Within-run (n=20)		Run-to-run (n=12)	
	Mean ± SD (mA/min)	% CV	Mean ± SD (mA/min)	% CV
Negative	287 ± 2.9	1.0	287 ± 2.9	1.0
20 ng/mL	317 ± 2.9	0.9	319 ± 2.2	0.7
50 ng/mL	387 ± 3.5	0.9	388 ± 3.9	1.0
100 ng/mL	447 ± 4.0	0.9	449 ± 5.4	1.2
200 ng/mL	472 ± 2.4	0.5	473 ± 3.8	0.8

### Sensitivity

Sensitivity, defined as the lowest concentration of THC analyte that can be differentiated from the negative urine calibrator with 95% confidence, is 10 ng/mL.

### Accuracy

Five hundred and ninety-two clinical urine specimens were collected and tested with this assay, a commercial EIA assay, and a GC/MS technique for cannabinoid. A 15 ng/mL cutoff was used for GC/MS. The DRI Cannabinoid Assay showed a 100% correlation with GC/MS technique when a 50 ng/mL cutoff calibrator was used. Six GC/MS positive samples were quantitated as borderline negative by the assay when a 100 ng/mL cutoff calibrator was used. The assay also showed good correlation with a commercial EIA assay.

### Specificity

Various THC metabolites and potentially interfering substances were tested for cross-reactivity with the assay. The following table summarizes the results obtained at the concentrations tested for each potential cross-reactant when a 50 ng/mL cutoff calibrator is used.

**Table 1.** Structurally related compounds that produce a positive result at the listed concentrations.

Compound	Concentration Tested (ng/mL)
11-Hydroxy- $\Delta^9$ -THC	100
/-11-Nor- $\Delta^8$ -THC-COOH	100
/-11-Nor- $\Delta^9$ -THC-COOH	50
8- $\beta$ -Hydroxy- $\Delta^9$ -THC	100
8- $\beta$ -11-Hydroxy- $\Delta^9$ -THC	50
$\Delta^9$ -THC	50
Cannabinol	100

**Table 2.** Structurally unrelated compounds that produce a negative result at the listed concentrations.

Compound	Concentration Tested (ng/mL)
Acetaminophen	1,000,000
Acetylsalicylic acid	1,000,000
Amobarbital	1,000,000
Amphetamine	1,000,000
Benzoyllecgonine	1,000,000
Caffeine	100,000
Cannabidiol	10,000
Cocaine	200,000
Codeine	1,000,000
Dextromethorphan	1,000,000
Meperidine	1,000,000
Methadone	1,000,000
Methamphetamine	1,000,000
Morphine	200,000
$\alpha$ -11-Nor- $\Delta^9$ -THC-COOH	100
Oxazepam	500,000
Phencyclidine	1,000,000
Phenobarbital	1,000,000
Propoxyphene	1,000,000
Secobarbital	1,000,000

### References

1. Urine Testing for Drugs of Abuse. National Institute on Drug Abuse (NIDA) Research Monograph 73 (1986).
2. Mandatory Guidelines for Federal Workplace Drug Testing Program. National Institute on Drug Abuse. Federal Register Vol. 53, No. 69, p 11979 (1988).
3. Wall ME, Brine DR and M Perez-Reyes: Metabolism of Cannabinoids in Man. Brande MC and S Szara, Eds.: The Pharmacology of Marijuana. Raven Press, 93 (1976).
4. Perez-Reyes M, Di Guiseppi S, Mason AP and KH Davis: Passive Inhalation of Marijuana Smoke and Urinary Excretion of Cannabinoids. Clin Pharmacol Ther 34, 36 (1983).
5. Ferslew KE, Manno JE and BR Manno: Determination of Urinary Cannabinoid Metabolites Following Incidental Exposure to Marijuana Smoke. Res Commun Substance Abuse, 289 (1983).
6. Rubenstein KE, Schneider RS and EF Ullman: Homogeneous Enzyme Immunoassay: A New Immunochemical Technique. Biochem Biophys Res Commun 47, 846 (1972).
7. Data on file at Microgenics, a part of Thermo Fisher Scientific.



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