DRI™ Cannabinoid Assay

thermo scientific

IVD **For In Vitro Diagnostic Use**

Rx Only

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.[1,2] 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
FOR LABORATORY USE ONLY

The principal active agent in marijuana and/or hashish that produces hallucinogenic and other biological effects is generally accepted to be Δ^9-tetrahydrocannabinol (Δ^9-THC). Δ^9-THC is rapidly absorbed and almost completely metabolized by inhalation or through the gastrointestinal tract. The major metabolites of Δ^9-THC (i.e. 11-nor-Δ^9-THC-9-carboxylic acid) becomes detectable in plasma, feces and urine within hours after exposure.[3] Passive inhalation of marijuana smoke can result in an elevation of urine THC concentration as high as 10-40 ng/mL.[4,5] 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 THC Assay is a homogeneous enzyme immunoassay using ready-to-use liquid reagents.[6] The assay uses specific monoclonal antibody which can detect the major metabolite of Δ^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-Δ^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 Δ^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
1. This test is for in vitro diagnostic use only. The reagents are harmful if swallowed.
2. The assay components contain ≤0.09% sodium azide, ≤0.2% bovine serum albumin (BSA) and ≤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.
3. 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.

Specimens kept at room temperature that do not receive initial test within 7 days[7] of arrival at the laboratory may be placed into a secure refrigeration unit at 2 to 8°C for up to 4 weeks.[8] For longer storage prior to analysis or for sample retention after analysis, urine specimens may be stored at -20°C.[8, 9]

Laboratories following the SAMHSA mandatory guidelines should refer to SAMHSA "Short-Term Refrigerated Storage" and "Long-Term Storage" requirements.[10]

Samples within a pH range of 3 to 11 are suitable for testing with this assay.

To protect the integrity of the sample, do not induce foaming and avoid repeated freezing and thawing. An effort should be made to keep pipetted samples free of gross debris. It is recommended that grossly turbid specimens be centrifuged before analysis. Frozen samples should be thawed and mixed prior to 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-Δ^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 (ΔA) value equal to or greater than that obtained with the chosen cutoff calibrator is considered positive. A sample that exhibits a change in absorbance (ΔA) 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
1. 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.
2. A positive result by this assay should be confirmed by another nonimmunological method such as GC or GC/MS.
3. The test is designed for use with human urine only.
4. 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.[7] The results obtained in your laboratory may differ from these data.

Precision

The negative, 20 ng/mL, 50 ng/mL, 100 ng/mL and 200 ng/mL calibrators were assayed with a Hitachi 717 analyzer. The following results were obtained:

	Concentration (ng/mL 11-Δ^9-THC-COOH)				
Within-Run	**Negative**	**20**	**50**	**100**	**200**
Mean	233	246	268	308	382
%C.V.	0.8	0.8	1.1	1.6	1.0
n	12	12	12	12	12

Run-to-Run	**Negative**	**20**	**50**	**100**	**200**
Mean	232	243	264	308	377
%C.V.	0.7	1.2	1.5	1.7	1.3
n	12	12	12	12	12

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. *The compounds listed in the table below produced a result approximately equivalent to the cutoff calibrator.*

Compound	Concentration Tested (ng/mL)
11-Hydroxy-Δ^9-THC	200
/-11-Nor-Δ^8-THC-COOH	100
/-11-Nor-Δ^9-THC-COOH	50
8-β-Hydroxy-Δ^9-THC	200
8-β-11-diHydroxy-Δ^9-THC	200
Δ^9-THC	100
Cannabinol	1000

Table 2. *Structurally related and 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
Benzoylecgonine	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
d-11-Nor-Δ^9-THC-COOH	100
Oxazepam	500,000
Phencyclidine	1,000,000
Phenobarbital	1,000,000
Propoxyphene	1,000,000
Secobarbital	1,000,000

* It is possible that other substances and/or factors not listed above may interfere with the test and cause false results, e.g., technical or procedural.

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.
8. Fraga SG, Díaz-Flores Estévez JF, Romero CD. Stability of Cannabinoids in Urine in Three Storage Temperatures. *Annals of Clinical and Laboratory Science*, Vol. 28, No. 3, 1998.
9. C52-A2, Toxicology and Drug Testing in the Clinical Laboratory; Approved Guideline – Second Edition, *Clinical and Laboratory Standards Institute (CLSI)* (April 2007).
10. *Notice of Mandatory Guidelines for Federal Workplace Drug Testing Program: Final Guidelines; Federal Register,* Substance Abuse and Mental Health Administration (SAMHSA), (1994) 110 (June 9):11983.

Glossary:
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