DRI® Methaqualone Assay

thermo scientific

IVD **For In Vitro Diagnostic Use**

Rx Only

REF 0514 (100 mL Kit)
0515 (500 mL Kit)

Intended Use
The DRI® Methaqualone Assay is intended for the qualitative and semiquantitative determination of methaqualone 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] 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
Methaqualone is a sedative hypnotic agent. Abuse of methaqualone may lead to habituation or addiction. When methaqualone is ingested, it is metabolized and excreted into urine in forms of metabolites.[2,3] Detection of methaqualone or its metabolites in urine indicates use of methaqualone.

Various assay techniques such as thin layer chromatography, gas chromatography, liquid chromatography/mass spectrometry (GC/MS) and radioimmunoassay are available for methaqualone determination.[4-8] However, these test methods are laborious and not suitable for a high volume screening test application.

The DRI Methaqualone Assay is a homogeneous enzyme immunoassay using ready-to-use liquid reagents.[9] The assay uses specific antibody, which can detect methaqualone in urine. The assay is based on the competition of a drug labeled with enzyme, glucose 6-phosphate dehydrogenase (G6PDH), and the free drug from the urine sample for a fixed amount of specific antibody binding sites. In the absence of free 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 monoclonal anti-methaqualone antibodies, glucose-6-phosphate (G6P) and nicotinamide adenine nucleotide (NAD) in Tris buffer with sodium azide as a preservative.
Enzyme Conjugate Reagent.
Contains methaqualone 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
1589	DRI Multi-Drug Calibrator 1, 25 mL
1591	DRI Multi-Drug Calibrator 2, 10 mL
1592	DRI Multi-Drug Calibrator 2, 25 mL
1595	DRI Multi-Drug Calibrator 3, 25 mL
1598	DRI Multi-Drug Calibrator 4, 25 mL
100200	MGC Primary DAU Control Set, 3 x 5 mL each (high and low)

⚠ Precautions and Warnings
This test is for in-vitro diagnostic use only. The reagents are harmful if swallowed.

DANGER: The reagents contain ≤0.2% bovine serum albumin (BSA) and ≤0.5% Drug-specific antibody (anti-methaqualone). Avoid contact with skin and mucous membranes. Avoid inhalation. May cause skin or inhaled allergic reaction. Refer to SDS for additional precautions, handling instructions, and accidental exposure treatment.
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.

Reagents used in the assay components contain ≤0.09% sodium azide. 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.

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

In the case of accidental spill, clean and dispose of material according to your laboratory's SOP, local, and state regulations.

In the case of damaged packaging on arrival, contact your technical support representative (refer to end of this PI).

Specimen Collection and Handling
Collect urine specimens in plastic or glass containers.

Fresh urine specimen should be used. If the sample cannot be analyzed immediately, specimens can be stored at room temperature for up to 7 days[10], after which they may be placed into a secure refrigeration unit at 2 to 8°C for up to 4 weeks.[10] For longer storage prior to analysis or for sample retention after analysis, urine specimens may be stored at -20°C.[11]

Laboratories following the SAMHSA mandatory guidelines should refer to SAMHSA "Short-Term Refrigerated Storage" and "Long-Term Storage" requirements.[12]

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
Qualitative analysis
For qualitative analysis of samples, use Calibrator 2, which contains 300 ng/mL of methaqualone, as a cutoff level. The DRI® Multi-Drug Urine Calibrator 2, which contains 300 ng/mL methaqualone, is used as a cutoff reference for distinguishing "positive" from "negative" samples.

Semiquantitative analysis
For semiquantitative analysis, use all calibrators.

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.

Results and Expected Values
Qualitative results
A sample that exhibits a change in absorbance (ΔA) value equal to or greater than the value obtained with the cutoff calibrator is considered positive. A sample that exhibits a change in absorbance (ΔA) value lower than the value obtained with the cutoff calibrator is considered negative.

Semiquantitative 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 methaqualone or its 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, TLC or GC/MS.
3. The test is designed for use with human urine only.
4. It is possible that other substances and/or factors (eg, technical or procedural) not listed in the specificity table may interfere with the test and cause false results.

Typical Performance Characteristics

Typical performance data results obtained on the Beckman Olympus AU640 analyzer are shown below.[10] The results obtained in your laboratory may differ from these data.

Precision

Low Control, Cutoff Calibrator, and High Control were tested in qualitative and semiquantitative mode. The samples were tested in replicates of 6, twice per day for 5 days, total n=60. The results are presented in the following tables:

Qualitative

Level	Low Control	Cutoff Calibrator	High Control
Mean Rate (mA/min)	274	345	419
Within-Run SD (mA/min)	1.0	1.3	1.0
Within-Run CV (%)	0.4	0.4	0.2
Total SD (mA/min)	2.0	2.9	1.6
Total CV (%)	0.7	0.8	0.4

Semiquantitative

Level	Low Control	Cutoff Calibrator	High Control
Mean (ng/mL)	177	298	457
Within-Run SD (ng/mL)	1.7	2.3	2.1
Within-Run CV (%)	1.0	0.8	0.5
Total SD (ng/mL)	2.5	3.1	2.7
Total CV (%)	1.4	1.0	0.6

Accuracy

One hundred and thirty urine specimens were tested with a commercially available EIA assay and DRI Methaqualone Assay. Sixty-seven were negative and sixty-three were positive by DRI Methaqualone Assay while sixty-eight were negative and sixty-two were positive by the commercial assay. A total of three discordant samples were found to contain borderline concentrations of methaqualone. The positive samples were confirmed by the GC/MS technique to contain methaqualone.

Specificity

Various potentially interfering substances were tested for cross-reactivity with the assay. The compounds listed in the table below produced a positive result at the concentration tested.

Compound	Concentrations Tested (ng/mL)
Methaqualone	300
Mecloqualone	500
3′-Hydroxy methaqualone	500
4′-Hydroxy methaqualone	500
2′-Hydroxy methaqualone	3,000

Various structurally unrelated compounds were tested for cross-reactivity with the assay. The compounds listed in the table below produced a negative result at the concentration tested.

Compound	Concentrations Tested (ng/mL)
Acetaminophen	1,000,000
Acetylsalicylic acid	1,000,000
Amphetamine	1,000,000
Benzoylecgonine	1,000,000
Caffeine	1,000,000
Codeine	1,000,000
Dextromethorphan	1,000,000
Meperidine	1,000,000

Table continued

Compound	Concentrations Tested (ng/mL)
Methadone	500,000
Morphine	1,000,000
Oxazepam	1,000,000
Phencyclidine	1,000,000
Phenobarbital	1,000,000
Promethazine	1,000,000
Propoxyphene	1,000,000
Secobarbital	1,000,000

Please refer to the Drugs of Abuse: Cross Reactivity Guide for DRI Methaqualone found at www.thermofisher.com/diagnostics for additional cross-reactivity data.

References

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10. Data on file at Microgenics, a part of Thermo Fisher Scientific.
11. C52-A2, Toxicology and Drug Testing in the Clinical Laboratory; Approved Guideline – Second Edition, *Clinical and Laboratory Standards Institute (CLSI)* (April 2007).
12. *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:

http://www.thermofisher.com/symbols-glossary

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