

REF	CONTENT	Analyzer(s) on which cobas c pack(s) can be used
05179459 190	DRI [®] Oxycodone (140 tests) System-ID 07 7433 2	COBAS INTEGRA 400 plus COBAS INTEGRA 800
05201284 190	DRI Oxycodone Calibrator 0 (1 x 10 mL)	
05178517 190	DRI Oxycodone Calibrator 100 (1 x 10 mL)	
05178525 190	DRI Oxycodone Calibrator 300 (1 x 10 mL)	
05178533 190	DRI Oxycodone Calibrator 500 (1 x 10 mL)	
05178541 190	DRI Oxycodone Calibrator 1000 (1 x 10 mL)	
05178568 190	DRI Oxycodone Control Set 100 Positive Control 125 ng/mL (1 x 10 mL) Negative Control 75 ng/mL (1 x 10 mL)	
05178550 190	DRI Oxycodone Control Set 300 Positive Control 375 ng/mL (1 x 10 mL) Negative Control 225 ng/mL (1 x 10 mL)	
04908856 160 ^a	Open/Close tool (5 pieces)	

a) Catalog number is for USA only. Open/Close tool is available upon request in other countries.

English

System information

Test OXY1S, test ID 0-309 for semiquantitative assay, 100 ng/mL

Test OXY3S, test ID 0-310 for semiquantitative assay, 300 ng/mL

Test OXY1Q, test ID 0-307 for qualitative assay, 100 ng/mL

Test OXY3Q, test ID 0-308 for qualitative assay, 300 ng/mL

Intended use

DRI Oxycodone assay (OXY) is an in vitro diagnostic test for the semiquantitative and qualitative detection of oxycodone and its metabolite, oxymorphone, in human urine at cutoff concentrations of 100 ng/mL and 300 ng/mL on COBAS INTEGRA systems.

Semiquantitative test results may be obtained that permit laboratories to assess assay performance as part of a quality control program. Semiquantitative assays are intended to determine an appropriate dilution of the specimen for confirmation by a confirmatory method such as gas chromatography/mass spectrometry (GC/MS).

DRI Oxycodone provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. 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

Oxycodone is a semi-synthetic opioid prescribed for pain management in patients with moderate to severe pain. It is similar to codeine and morphine in its analgesic properties but it is more potent than morphine and has higher dependence potential. The drug oxycodone is supplied as OxyContin (Oxycodone HCl) or in combination with aspirin (Percodan) or acetaminophen (Percocet).² Drug abusers crush the pills into powder and snort them for faster effect which may result in a potentially fatal outcome. According to Drug Abuse Warning Network (DAWN), there has been a dramatic increase in oxycodone related deaths.^{3,4} Oxymorphone, noroxycodone and noroxymorphone are the only known metabolites of oxycodone.³ The metabolite, oxymorphone, is a potent narcotic analgesic, while the other two metabolites are relatively inactive. From 33-61 % of a single dose of oxycodone is excreted in urine within 24 hours as unconjugated oxycodone (13-19 %), conjugated oxycodone (7-29 %), and conjugated oxymorphone (13-14 %).⁵

Test principle

The assay is supplied as a liquid ready-to-use homogeneous enzyme immunoassay. The assay uses specific antibodies that can detect oxycodone and oxymorphone without any significant cross-reactivity to other opiate compounds. The assay is based on competition between a drug labeled with glucose-6-phosphate dehydrogenase (G6PDH), and 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 causes a decrease in enzyme

activity. This phenomenon creates a direct relationship between the drug concentration in urine and enzyme activity. The enzyme activity is determined spectrophotometrically at 340 nm by measuring the conversion of nicotinamide adenine dinucleotide (NAD) to NADH.

Reagents - working solutions

- R1** Antibody/Substrate
Anti-oxycodone derivative antibody (mouse monoclonal), glucose-6-phosphate (G6P), and nicotinamide adenine dinucleotide (NAD) in Tris buffer with sodium azide as a preservative
- SR** Enzyme Conjugate Reagent
Oxycodone derivative labeled with glucose-6-phosphate dehydrogenase (G6PDH) in Tris buffer with sodium azide as a preservative

Precautions and warnings

Pay attention to all precautions and warnings listed in Section 1 / Introduction of this Method Manual.

For USA: For prescription use only.

Reagent preparation and cobas c pack MULTI assembly

Reagent handling

Ready for use

Labeling the cobas c pack MULTI

Turn the barcode labeled side of a new **cobas c** pack MULTI toward you. Affix the supplied OXY barcode label directly over the existing barcode label.



Filling the cobas c pack MULTI

1. Turn the **cobas c** pack MULTI toward you as shown above.
2. Position A of the **cobas c** pack is now in the center, position B on the left side, position C on the right side of the **cobas c** pack.

OXY**Oxycodone****cobas®**
Drug abuse testing

- Unscrew the screw cap of the bottle in position B on the left side of the **cobas c** pack MULTI using the Open/Close tool.
 - Pour the content of bottle 1 (12 mL) into the opened bottle of the **cobas c** pack (position B).
 - Close the bottle tightly using the Open/Close tool.
 - Unscrew the screw cap of the bottle in position C on the right side of the **cobas c** pack MULTI using the Open/Close tool.
 - Pour the content of bottle 2 (12 mL) into the opened bottle of the **cobas c** pack (position C).
 - Close the bottle tightly using the Open/Close tool.
 - Leave position A empty.
- The OXY **cobas c** pack is now ready for use.

NOTE: Solutions must be at the reagent compartment storage temperature of the analyzer before performing assays.

Note

Use only the **cobas c** pack MULTI. Always use a new **cobas c** pack MULTI when preparing fresh reagent. Never reuse accessories designed for single use, as this may result in reagent contamination and could affect test results. If the **cobas c** pack MULTI bottles are not filled correctly, this may result in faulty reagent pipetting and could cause erroneous results.

Storage and stability

Shelf life at 2-8 °C:	See expiration date on cobas c pack label
COBAS INTEGRA 400 plus analyzer	
On-board in use at 10-15 °C	8 weeks
COBAS INTEGRA 800 analyzer	
On-board in use at 8 °C	8 weeks

The on-board in use stability period begins at the time of **cobas c** pack puncture. Do not freeze reagents. Reagents that have been frozen should be discarded.

Specimen collection and preparation

Only the specimens listed below were tested and found acceptable.

Urine: Collect urine samples in clean glass or plastic containers. Fresh urine samples do not require any special handling or pretreatment, but an effort should be made to keep pipetted samples free of gross debris. Samples within a pH range of 3-11 are suitable for testing with this assay. No additives or preservatives are required. It is recommended that urine specimens be stored at 2-8 °C and tested within 5 days of collection.⁶

For prolonged storage, freezing of the sample is recommended.

Centrifuge highly turbid specimens before testing.

Adulteration or dilution of the sample can cause erroneous results. If adulteration is suspected, another sample should be collected. Specimen validity testing is required for specimens collected under the *Mandatory Guidelines for Federal Workplace Drug Testing Programs*.⁷

Caution: Specimen dilutions should only be used to interpret results of HIGH ABS alarms or as an estimation for GC/MS and are not intended for patient values. Dilution procedures, when used, should be validated.

Materials provided

See "Reagents – working solutions" section for reagents.

Three barcode labels: one to overlabel the existing barcode of the **cobas c** pack MULTI. Two extra labels are supplied if needed.

cobas c pack MULTI

Funnels

Assay

For optimum performance of the assay follow the directions given in this document for the analyzer concerned. Refer to the appropriate operator's manual for analyzer-specific assay instructions.

Applications for urine**COBAS INTEGRA 400 plus test definition****100 ng/mL and 300 ng/mL cutoffs**

Semiquantitative Qualitative

Measuring mode	Absorbance	Absorbance
Abs. calculation mode	Kinetic	Kinetic
Reaction mode	R1-S-SR	R1-S-SR
Reaction direction	Increase	Increase
Reaction start	SR	SR
Wavelength A/B	340/409 nm	340/409 nm
Test range	0-1000 ng/mL	0-3000 OXY1Q 0-1400 OXY3Q
Calc. first/last	24/30	24/30
Unit	ng/mL	

Pipetting parameters

OXY1S, OXY3S, OXY3Q		Diluent (H ₂ O)
R1	50 µL	5 µL
Sample	6 µL	5 µL
SR	50 µL	5 µL
Total volume	121 µL	

OXY1Q		Diluent (H ₂ O)
R1	50 µL	5 µL
Sample	8 µL	5 µL
SR	50 µL	5 µL
Total volume	123 µL	

COBAS INTEGRA 800 test definition**100 ng/mL and 300 ng/mL cutoffs**

	<i>Semiquantitative</i>	<i>Qualitative</i>
Measuring mode	Absorbance	Absorbance
Abs. calculation mode	Kinetic	Kinetic
Reaction mode	R1-S-SR	R1-S-SR
Reaction direction	Increase	Increase
Reaction start	SR	SR
Wavelength A/B	340/409 nm	340/409 nm
Test range	0-1000 ng/mL	0-3000 OXY1Q 0-1400 OXY3Q
Calc. first/last	55/65	55/65
Unit	ng/mL	

Pipetting parameters

OXY1S, OXY3S, OXY3Q		Diluent (H ₂ O)
R1	50 µL	5 µL
Sample	6 µL	5 µL
SR	50 µL	5 µL
Total volume	121 µL	

OXY1Q		Diluent (H ₂ O)
R1	50 µL	5 µL
Sample	8 µL	5 µL
SR	50 µL	5 µL
Total volume	123 µL	

Calibration

Calibrators	<i>Semiquantitative applications</i>
<i>OXY1S, 0-309;</i>	DRI Oxycodone Calibrator 0,
<i>OXY3S, 0-310</i>	DRI Oxycodone Calibrator 100,
	DRI Oxycodone Calibrator 300,
	DRI Oxycodone Calibrator 500,
	<i>and</i>
	DRI Oxycodone Calibrator 1000
	0, 100, 300, 500, 1000 ng/mL
	(OXY3Q, system-ID 07 7436 7)
	<i>Qualitative applications</i>
<i>OXY1Q, 0-307</i>	DRI Oxycodone Calibrator 0
	0 ng/mL
	<i>and</i>
	DRI Oxycodone Calibrator 100
	100 ng/mL
	(100 cutoff, OXYQ1, system-ID 07 7434 0)
	For qualitative applications, the cutoff of 100 ng/mL is assigned a value of 1000.
<i>OXY3Q, 0-308</i>	DRI Oxycodone Calibrator 0
	0 ng/mL
	<i>and</i>
	DRI Oxycodone Calibrator 300
	300 ng/mL
	(300 cutoff, OXYQ3, system-ID 07 7435 9)
	For qualitative applications, the cutoff of 300 ng/mL is assigned a value of 1000.
Calibration mode	<i>Semiquantitative applications</i>
	Logit/Log 4
	<i>Qualitative applications</i>
	Linear regression
Calibration replicate	Duplicate recommended
Calibration interval	COBAS INTEGRA 400 plus analyzer: Each lot, every 28 days, and as required following quality control procedures
	COBAS INTEGRA 800 analyzer: Each lot, every 28 days, and as required following quality control procedures

A calibration curve is generated using the calibrators. Calibrators must be placed from the highest concentration first to the lowest last on the CAL/QC rack. This curve is retained in memory by the COBAS INTEGRA systems and recalled for later use.

Traceability: This method has been standardized against a primary reference method (GC/MS).

Quality control

Quality control	<i>100 ng/mL cutoff</i>
	DRI Oxycodone Control Set 100
	Positive Control 125 ng/mL
	(OXY1P, system-ID 07 7445 6)
	Negative Control 75 ng/mL
	(OXY1N, system-ID 07 7446 4)

300 ng/mL cutoff

DRI Oxycodone Control Set 300
Positive Control 375 ng/mL
(OXY3P, system-ID 07 7447 2)
Negative Control 225 ng/mL
(OXY3N, system-ID 07 7448 0)

Control sequence User defined

Control after calibration Recommended

For quality control, use control materials as listed in the "Order information" section. In addition, other suitable control material can be used.

Drug concentrations of DRI Oxycodone Control Set 100 and 300 have been verified by GC/MS.

The control intervals and limits should be adapted to each laboratory's individual requirements. Values obtained should fall within the defined limits. Each laboratory should establish corrective measures to be taken if values fall outside the defined limits.

Follow the applicable government regulations and local guidelines for quality control.

Results

COBAS INTEGRA systems report results with the following test flags:

Semiquantitative result reporting

<i>OXY1S (100 ng/mL cutoff)</i>		
Flag	COBAS INTEGRA	Value range
No flag	Negative	< 100 ng/mL
<TEST RNG	Negative	< 0 ng/mL
>TEST RNG	Positive	> 1000 ng/mL
POS 100	Positive	≥ 100 ng/mL

Value ranges listed above are based on a cutoff value of 100 ng/mL.

<i>OXY3S (300 ng/mL cutoff)</i>		
Flag	COBAS INTEGRA	Value range
No flag	Negative	< 300 ng/mL
<TEST RNG	Negative	< 0 ng/mL
>TEST RNG	Positive	> 1000 ng/mL
POS 300	Positive	≥ 300 ng/mL

Value ranges listed above are based on a cutoff value of 300 ng/mL.

Qualitative result reporting

<i>OXY1Q (100 ng/mL cutoff)</i>		
Flag	COBAS INTEGRA	Value range
No flag	Negative	< 1000
<TEST RNG	Negative	< 0
>TEST RNG	Positive	> 3000
POS 1000	Positive	≥ 1000

Value ranges above are based on assigning the cutoff of 100 ng/mL a value of 1000.

<i>OXY3Q (300 ng/mL cutoff)</i>		
Flag	COBAS INTEGRA	Value range
No flag	Negative	< 1000
<TEST RNG	Negative	< 0
>TEST RNG	Positive	> 1400
POS 1000	Positive	≥ 1000

Value ranges above are based on assigning the cutoff of 300 ng/mL a value of 1000.

The semiquantitation of preliminary positive results should only be used by laboratories to determine an appropriate dilution of the specimen for confirmation by a confirmatory method such as GC/MS. It also permits the laboratory to establish quality control procedures and assess control performance.

Note: If a result of HIGH ABS alarm is obtained, the cause is either the presence of a high concentration of a 340 nm light absorbing compound or the presence of a high concentration of the analyte in the sample (see "Limitations - interference" section). Make an appropriate dilution of the sample using the 0 ng/mL calibrator and rerun the sample. When running in the semiquantitative mode, multiply the result by the dilution factor. In case of a near cutoff result, once the dilution factor is applied, the result should be assessed in terms of dilution and accuracy of the assay.

Dilutions should only be used to interpret results of HIGH ABS alarms or when estimating concentration in preparation for GC/MS.

Limitations - interference

See the "Analytical specificity" section of this document for information on substances tested with this assay. There is the possibility that other substances and/or factors, especially substances that absorb light at 340 nm, may interfere with the test and cause HIGH ABS alarms or erroneous results (e.g., technical or procedural errors). Samples flagged with HIGH ABS alarms should be manually diluted (see "Results" section).

A preliminary positive result with this assay indicates the presence of oxycodone and/or its metabolite, oxymorphone, in urine. It does not measure the level of intoxication.

The potential interference of pH and endogenous physiologic substances on recovery of oxycodone using the DRI Oxycodone assay was assessed by spiking known amounts of potentially interfering substances into the low (225 ng/mL) and high (375 ng/mL) controls for the 300 ng/mL cutoff. No interference was observed by the addition of the compounds up to the concentrations listed below.

Compound	Concentrations (mg/dL)
Acetone	1000
Ascorbic Acid	1500
Creatinine	500
Ethanol	1000
Galactose	10
Glucose	3000
Hemoglobin	300
Human Serum Albumin	500
Oxalic Acid	100
Riboflavin	7.5
Sodium Chloride	1000
Urea	2000
pH	3-11

For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

ACTION REQUIRED

Special Wash Programming: The use of special wash steps is mandatory when certain test combinations are run together on COBAS INTEGRA analyzers. Refer to the CLEAN Method Sheet for further instructions and for the latest version of the Extra wash cycle list.

Where required, special wash/carry-over evasion programming must be implemented prior to reporting results with this test.

Specific performance data

Representative performance data on the COBAS INTEGRA analyzers are given below. Results obtained in individual laboratories may differ.

Precision

Precision was determined in an internal protocol using a series of oxycodone calibrator and controls in replicates of 6, twice a day, for 5 days. The following results were obtained on a COBAS INTEGRA 800 analyzer.

Semiquantitative precision - 100 ng/mL cutoff			
	Mean ng/mL	SD ng/mL	CV %
Repeatability			
Level 1 (75 ng/mL)	73	3	3.5
Level 2 (100 ng/mL)	94	2	2.4
Level 3 (125 ng/mL)	123	3	2.4
Intermediate precision			
Level 1 (75 ng/mL)	73	3	4.2
Level 2 (100 ng/mL)	94	3	3.3
Level 3 (125 ng/mL)	123	4	2.9

Semiquantitative precision - 300 ng/mL cutoff			
	Mean ng/mL	SD ng/mL	CV %
Repeatability			
Level 1 (225 ng/mL)	208	3	1.2
Level 2 (300 ng/mL)	286	3	1.1
Level 3 (375 ng/mL)	340	4	1.1
Intermediate precision			
Level 1 (225 ng/mL)	208	3	1.6
Level 2 (300 ng/mL)	286	4	1.3
Level 3 (375 ng/mL)	340	5	1.4

Qualitative precision			
100 ng/mL cutoff			
300 ng/mL cutoff			
Cutoff (x)	Number tested	Correct results	Confidence level
0.75x	60	60	> 95 % negative reading
1.25x	60	60	> 95 % positive reading

Limit of Blank

4.6 ng/mL (100 ng/mL cutoff assay)

6.3 ng/mL (300 ng/mL cutoff assay)

The Limit of Blank was determined in accordance with the CLSI (Clinical and Laboratory Standards Institute) EP17-A requirements.

The Limit of Blank is the 95th percentile value from $n \geq 21$ measurements of analyte-free samples over several independent series. The Limit of Blank corresponds to the concentration below which analyte-free samples are found with a probability of 95 %.

Accuracy

Qualitative assay

A total of 186 urine samples were assayed with the DRI Oxycodone assay on the Roche/Hitachi 717 and the COBAS INTEGRA 800 analyzers. A sensitivity of 100 % (86 out of 86 preliminary positive samples) and a specificity of 100 % (100 out of 100 negative samples) were observed between the two analyzers.

100 ng/mL cutoff			
		COBAS INTEGRA 800 analyzer	
		+	-
Roche/Hitachi 717 analyzer	+	86	0
	-	0	100

A total of 186 urine samples were assayed with the DRI Oxycodone assay on the Roche/Hitachi 717 and the COBAS INTEGRA 800 analyzers. A sensitivity of 100 % (50 out of 50 preliminary positive samples) and a specificity of 100 % (136 out of 136 negative samples) were observed between the two analyzers.

300 ng/mL cutoff			
		COBAS INTEGRA 800 analyzer	
		+	-
Roche/Hitachi 717 analyzer	+	50	0
	-	0	136

Semiquantitative assay

A total of 186 urine samples were assayed with the DRI Oxycodone assay on the Roche/Hitachi 717 and the COBAS INTEGRA 800 analyzers. A sensitivity of 100 % (86 out of 86 preliminary positive samples) and a specificity of 100 % (100 out of 100 negative samples) were observed between the two analyzers.

100 ng/mL cutoff			
		COBAS INTEGRA 800 analyzer	
		+	-
Roche/Hitachi 717 analyzer	+	86	0
	-	0	100

A total of 186 urine samples were assayed with the DRI Oxycodone assay on the Roche/Hitachi 717 and the COBAS INTEGRA 800 analyzers. A sensitivity of 100 % (50 out of 50 preliminary positive samples) and a specificity of 100 % (136 out of 136 negative samples) were observed between the two analyzers.

300 ng/mL cutoff			
		COBAS INTEGRA 800 analyzer	
		+	-
Roche/Hitachi 717 analyzer	+	50	0
	-	0	136

Analytical specificity

The cross-reactivity of oxycodone metabolites, oxymorphone, noroxymorphone, and noroxycodone, was evaluated, on a Roche/Hitachi 717 analyzer, by adding known amounts of each metabolite to oxycodone free urine. As indicated by the results in the table below, oxymorphone exhibits 103 % cross-reactivity with oxycodone; noroxymorphone and noroxycodone show no evidence of significant cross-reactivity.

Compound	Concentration Tested (ng/mL)	Recovery (ng/mL)	Approximate Percent Cross-reactivity
Oxycodone	300	300	100
Oxymorphone	300	308	103
Noroxymorphone	500000	303.5	< 0.1
Noroxycodone	50000	41.5	< 0.1

Cross-reactivity with structurally related opiate compounds and structurally unrelated compounds

The potential cross-reactivity posed by drugs commonly coadministered with oxycodone was evaluated by adding each substance to oxycodone free urine at the concentration indicated. A drug was considered to cross-react if the observed oxycodone concentration exceeded 100 ng/mL, the lowest cutoff for the DRI Oxycodone assay. As shown in the tables below, all of the pharmacologic compounds evaluated, including a number of the opiate compounds, exhibited no cross-reactivity, on a Roche/Hitachi 717 analyzer, at the concentrations listed.

Structurally related opiate compounds that tested negative at 100 ng/mL cutoff

Compound	Concentrations (µg/mL)
6-Acetyl morphine	50
Codeine	500
Dihydrocodeine	100
Heroin	300
Hydrocodone	75
Hydromorphone	30
Levorphanol	200
Morphine	350
Morphine-3-glucuronide	900
Naloxone	200
Naltrexone	500
Norcodeine	1000
Normorphine	1000

Structurally unrelated compounds that tested negative at 100 ng/mL cutoff

Compound	Concentrations (µg/mL)
Acetaminophen	1000
Acetylsalicylic acid	1000
Amitriptyline	500
Amoxicillin	500
Amphetamine	2000
Benzoylcegonine	2000
Caffeine	1000
Carbamazepine	1000
Chlorpromazine	2000
Clomipramine	1000
Cimetidine	1000
Desipramine	1000
Dextromethorphan	200
Doxepin	200
Ephedrine	2000
Fentanyl	200
Fluoxetine	1000
Fluphenazine	500
Ibuprofen	1000
Imipramine	1000
Maprotiline	1000
Meperidine	1000
Methadone	1000

OXY**Oxycodone**

Metronidazole	2000
Nalbuphine	1000
Nortriptyline	500
Oxazepam	500
Phencyclidine	1000
Phenobarbital	1000
Ranitidine	3000
Secobarbital	1000
Talwin	500
Thebaine	20
Thioridazine	1000
Tramadol	500

Any modification of the instrument as set forth in this labeling requires validation by the laboratory.




References

- 1 Karch SB, ed. Drug Abuse Handbook. Boca Raton, FL: CRC Press LLC 1998.
- 2 Anderson DT, Fritz KL, Muto JJ. Oxycontin: The concept of a "ghost pill" and the postmortem tissue distribution of oxycodone in 36 cases. J Anal Toxicol 2002 Oct;26(7):448-459.
- 3 Jannetto PJ, Gock SB. Clinical & Forensic Toxicology News, Oxycodone: Recognition and Pharmacogenomics March 2003.
- 4 Cone EJ, Fant RV, Rohay JM, et al. Oxycodone Involvement in Drug Abuse Deaths: A DAWN-Based Classification Scheme applied to an Oxycodone Postmortem Database Containing over 1000 Cases. J Anal Toxicol 2003 Mar;27(2):57-67.
- 5 Oxycodone. In: Baselt RC and Cravey RH. Disposition of toxic drugs and chemicals in man, 4th ed. Chemical Toxicology Institute, Foster City, California 1995;572-574.
- 6 Toxicology and Drug Testing in the Clinical Laboratory; Approved Guideline. 2nd ed. (C52-A2). Clinical and Laboratory Standards Institute 2007;27:33.
- 7 Mandatory Guidelines for Federal Workplace Drug Testing Programs. Fed Regist 2008 Nov 25;73:71858-71907.

A point (period/stop) is always used in this Method Sheet as the decimal separator to mark the border between the integral and the fractional parts of a decimal numeral. Separators for thousands are not used.

Symbols

Roche Diagnostics uses the following symbols and signs in addition to those listed in the ISO 15223-1 standard:

	Contents of kit
	Volume after reconstitution or mixing
	Global Trade Item Number

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Drug abuse testing



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