Syntron Bioresearch, Inc.

QuikScreen® Multi X Drug Cup Test

ONE STEP ONSITE DRUG CUP

Catalog # 60XXX

CLIAWAIVED — Instructions — IVD

INTENDED USE

The **QuikScreen® Multi X Drug Cup test** is an immunochromatographic assay for rapid, qualitative detection of drug combinations and their principal metabolites in urine at specified cut-off concentrations. In the **QuikScreen® Multi X Drug Cup test**, X may denote any number of drugs. These drug combinations may be composed from any of the following drugs, at the noted cut-off concentrations:

DRUG CLASS	ABBREVIATIONS	SENSITIVITY
AMPHETAMINE	AMP	1000 ng/ml
BARBITURATES	BAR	300 ng/ml
BENZODIAZEPINES	BZD	300 ng/ml
COCAINE	COC	300 ng/ml
MARIJUANA	THC	50 ng/ml
METHADONE	MAD	300 ng/ml
METHAMPHETAMINE	MET	1000 ng/ml
OPIATES	OPI	2000 ng/ml
OXYCODONE	OXY	100 ng/ml
PHENCYCLIDINE	PCP	25 ng/ml
TRICYCLIC ANTIDEPRESSANT (2)	TCA	1000 ng/ml

Note: *The test provides only preliminary data which should be confirmed by other methods such as gas chromatography/mass spectrometry (GC/MS). Clinical considerations and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.*

SUMMARY AND EXPLANATION OF THE TEST

The **QuikScreen® Multi X Drug Cup test** is an easy, fast, qualitative, visually read competitive binding immunoassay method for screening without the need of instrumentation. The method employs unique mixture of antibodies to selectively identify the drugs of abuse and their metabolites in test samples with a high degree of sensitivity.

Drug abuse remains a growing social and economical concern in many developed and developing countries throughout the world. The above stated drugs are among the most frequently abused illicit drugs, according to the U.S. Substance Abuse and Mental Health Services Administration. Opiates are among a class of heavily abused prescription drugs.

The sensitivity of the **QuikScreen® Multi X Drug Cup test** is set as required for the screening immunoassays of these drugs in the reference guidelines set by the U.S. Substance Abuse and Mental Health Services Administration (SAMHSA) and the U.S. Department of Health and Human Services.

PRINCIPLE OF THE TEST

The **QuikScreen® Multi X Drug Cup test** is a competitive binding immunoassay in which drug and drug metabolites in a urine sample compete with immobilized drug conjugate for limited labeled antibody binding sites. By utilizing antibodies that are specific to different drug classes, the test permits independent, simultaneous detection of any of the drug combinations from a single sample. The approximate run time is 5 minutes.

In the assay procedure, urine mixes with labeled antibody-dye conjugate and migrates along a porous membrane. When the concentration of a given drug is below the detection limit of the test, unbound antibody-dye conjugate binds to antigen conjugate immobilized on the membrane, producing a rose-pink color band in the appropriate Test Zone for that drug. Conversely, when the drug level is at or above the detection limit, free drug competes with the immobilized antigen conjugate on the membrane by binding to antibody-dye conjugate, forming an antigen-antibody complex, preventing the development of a rose-pink color band.

Regardless of the drug levels in the sample, a rose pink-color band is produced in each Control Zone (top bands) by a parallel immunochemical reaction. These bands serve as built-in quality control measures by demonstrating antibody recognition, verifying that the reagents are chemically active.

REAGENTS AND MATERIAL PROVIDED

1. Test Devices	Contains dye-conjugated antibody and immobilized antigen in protein matrix with sodium azide.	
2. Test Instructions	*Catalog# PI-60XXX-CLIA*	
Optional:		
3. Negative Control I	Contains buffered protein solution with sodium azide. *Cat.# 4010N*	
4. Amphetamine Positive Control		*Cat.# 11120P*
5. Barbiturates Positive Control		*Cat.# 18040P*
6. Benzodiazepines Positive Control		*Cat.# 18020P*
7. Cocaine Positive Control		*Cat.# 12000P*
8. Marijuana Positive Control		*Cat.# 13020P*
9. Methadone Positive Control		*Cat.# 19020P*
10. Methamphetamine Positive Control		*Cat.# 11320P*
11. Opiates Positive Control		*Cat.# 11220P*
12. Oxycodone Positive Control		*Cat.# 19080P*
13. Phencyclidine Positive Control		*Cat.# 14020P*
14. Tricyclic Antidepressant Positive Control		*Cat.# 19092P*

MATERIALS REQUIRED BUT NOT PROVIDED

1. Clock or timer.
2. Specimen collection containers.

WARNINGS AND PRECAUTIONS

1. For *in-vitro diagnostic* use.
2. Do not use the test device beyond the expiration date.
3. Collect urine specimen directly into the test cup. Ensure that the sample amount meets the minimum level as indicated on the side of the test cup.
4. Read the results at 5 minutes. Do not interpret results after 30 minutes.

STORAGE AND STABILITY

Store test kit below 28°C; **do not freeze**. If stored at 2°-8°C, allow the test kit to reach room temperature (15°-28°C) before performing the test. Refer to the expiration date for stability.

SPECIMEN COLLECTION AND PREPARATION

Fresh urine specimens should be collected directly into the cup. The **QuikScreen® Multi X Drug Cup test** device employs a **thermal strip which should be checked immediately** after collection to validate urine specimen. SAMHSA regulations specify that any temperature below 90.5° F must be considered adulterated. No additives or preservatives are required.

Note: *Urine specimens can be transferred from a urine collection container into* ***QuikScreen®*** **Multi X Drug Cup test** *cup, if necessary.*

TEST PROCEDURE

1. Do not break the seal of the pouch until ready to begin testing.
2. Remove the test cup from the foil pouch.
3. Collect urine specimen directly into the test cup. Ensure that the sample amount meets the minimum level as indicated on the side of the test cup.
4. Read the results at 5 minutes. Do not interpret results after 30 minutes.

Note: *The result must be interpreted at five minutes. Waiting more than five minutes may cause the reading to be inaccurate. To avoid confusion, discard the test device after interpreting the result.*

INTERPRETATION OF RESULTS

Positive: A *rose-pink* band is visible in each control zone (top band). No color band appearing in the appropriate test zone (bottom band) indicates a preliminary positive result for the corresponding drug of that specific test zone. Send urine specimen to a certified laboratory for confirmation.

Negative: A *rose-pink* band is visible in each control zone and the appropriate test zone, indicating that the concentration of the corresponding drug of that specific test zone is below the detection limit of the test.

Invalid: If a color band is not visible in each of the control zones, the test is invalid. Another test should be run to re-evaluate the specimen.

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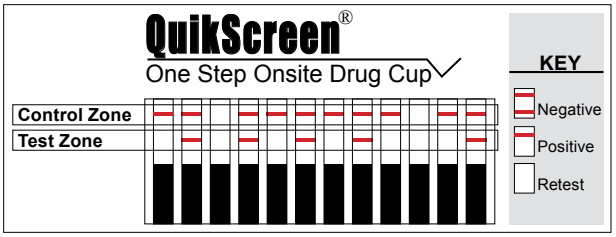
Note: There is no meaning attributed to line color intensity or width.



QUALITY CONTROL

An internal procedure control has been incorporated into the test to insure proper kit performance and reliability.

The use of an external control is recommended to verify proper kit performance. Quality control samples should be tested according to quality control requirements established by the testing laboratory.

LIMITATIONS OF THE TEST

1. This product is designed to be used for the detection of drugs of abuse and their metabolites in human urine only.
2. Although the test is very accurate, there is the possibility false results will occur due to the presence of interfering substances in the specimen sample.
3. The test is a qualitative screening assay and is not suggested for quantitative determination of drug levels in urine, or the level of intoxication.
4. Adulterants such as bleach or other strong oxidizing agents, when added to urine specimens, can cause erroneous test results regardless of the analysis method used.
5. If adulteration is suspected, obtain another urine specimen.

PERFORMANCE CHARACTERISTICS

1. **Sensitivity**. The **QuikScreen® Multi X Drug Cup test** detects drugs of abuse and their major metabolites in urine at concentrations equal to or greater than the cut-off level for the specific drug, which is suggested by the U.S. Substance Abuse and Mental Health Services Administration (SAMHSA) for the immunoassay method.
2. **Specificity**. A study was conducted with the **QuikScreen® Multi X Drug Cup test**to determine the cross-reactivity of drug-related compounds with the test. Substances listed in **Table I** produced results approximately equivalent to the cutoff levels. A separate study was conducted to determine the cross-reactivity of non-related compounds with the test at concentrations much higher than normally found in the urine of people using or abusing them. No cross reactivity was detected with the substances listed in **Table II**.

Table I: Concentrations of drug-related compounds showing positive response approximately equivalent to the cut-off set for the test:

The following Amphetamine-related substances yield positive results for Amphetamine at 1000 ng/ml cut-off level:

d-Amphetamine	*1000 ng/ml*
l-Amphetamine	*25,000 ng/ml*
Δ-l-Amphetamine	*10,000 ng/ml*
β-Phenylethylamine	*180,000 ng/ml*
Thyramine	*100,000 ng/ml*
(±) 3,4-Methylenedioxyamphetamine-HCl (MDA)	*1200 ng/ml*

The following Barbiturate-related substances yield a positive result for Barbiturates at 300 ng/ml cut-off level:

Allobarbital	*600 ng/ml*
Amobarbital	*600 ng/ml*
Barbital	*300 ng/ml*
Butabarbital	*300 ng/ml*
Butalbital	*300 ng/ml*
Pentobarbital.	*300 ng/ml*
Phenobarbital	*300 ng/ml*
Secobarbital	*300 ng/ml*

The following Benzodiazepine-related substances yield positive results for Benzodiazepines at 300 ng/ml cut-off level:

Alprazolam	*600 ng/ml*
Bromazepam	*100 ng/ml*
Chlordiazepoxide	*300 ng/ml*
Clobazam	*300 ng/ml*
Clonazepam	*300 ng/ml*
Clorazepate	*200 ng/ml*
Delorazepam	*3,000 ng/ml*
Diazepam	*300 ng/ml*
Estazolam	*300 ng/ml*
Flunitrazepam	*300 ng/ml*
Flurazepam	*150 ng/ml*
Lorazepam	*500 ng/ml*
Lormetazepam	*500 ng/ml*
Nitrazepam	*250 ng/ml*
Nordiazepam	*150 ng/ml*
Oxazepam	*300 ng/ml*
Prazepam	*1,500 ng/ml*
Temazepam	*150 ng/ml*
Triazolam	*200 ng/ml*

The following Cocaine-related substances yield positive results for Cocaine at 300 ng/ml cut-off level:

Benzoylecgonine	*300 ng/ml*
Cocaine	*300 ng/ml*

The following Marijuana-related substances yield positive results for Marijuana at 50 ng/ml cut-off level:

Cannabinol	*10,000 ng/ml*
11-nor-Δ-8-THC-9-COOH	*50 ng/ml*
11-nor-Δ-9-THC-9-COOH	*50 ng/ml*
Δ8-THC	*7500 ng/ml*
Δ9-THC	*10,000 ng/ml*
11-hydroxy-Δ-9-THC	*2500 ng/ml*

The following Methadone-related substances yield positive results for Methadone at 300 ng/ml cut-off level:

Methadone	*300 ng/ml*
Doxylamine	*50,000 ng/ml*
EDDP (2 Ethylidene-1,5-dimethy 1-3,3-Diphenylpyrrolidin)	*100,000 ng/ml*
Methadol	*25,000 ng/ml*
Perphenazine.	*75,000 ng/ml*
Protriptyline	*2,000 ng/ml*
Trimipramine.	*10,000 ng/ml*

The following Methamphetamine-related substances yield positive results for Methamphetamine at 1000 ng/ml cut-off level:

(+) Methamphetamine	*1000 ng/ml*
(±)3,4Methylenedioxymethamphetamine (MDMA).	*1000 ng/ml*
(±)3,4Methylenedioxyamphetamine (MDA).	*200,000 ng/ml*
d-Amphetamine Sulfate.	*200,000 ng/ml*
l-Amphetamine Sulfate	*200,000 ng/ml*
Δ-,l-Amphetamine Sulfate.	*200,000 ng/ml*

The following Opiates-related substances yield a positive result for Opiates at 2000 ng/ml cut-off level:

Morphine	*2000 ng/ml*
Morphine Sulfate Pentahydrate	*2000 ng/ml*
Morphine-3-β-D Glucuronide	*2000 ng/ml*
Codeine	*2000 ng/ml*
Heroin	*2000 ng/ml*
Levorphanol	*4000 ng/ml*
Ranitidine	*100,000 ng/ml*
6-Acetylmorphine	*50 ng/ml*

The following Oxycodone-related substances yield positive results for Oxycodone at 100 ng/ml cut-off level:

Oxycodone-HCl	*100 ng/ml*
Codeine	*700 ng/ml*
Hydrocodone.	*500 ng/ml*
Hydromorphone	*1,500 ng/ml*
Morphine-Sulfate	*7,000 ng/ml*
Morphine-3-b-D-Glucuronide.	*40,000 ng/ml*
Norcodeine	*40,000 ng/ml*
Oxymorphone	*300 ng/ml*

The following Phencyclidine-related substances yield a positive result for Phencyclidine at 25 ng/ml cut-off level:

Phencyclidine	*25 ng/ml*
Tenocyclidine	*2000 ng/ml*

The following Tricyclic Antidepressant-related substances yield positive results for Tricyclic Antidepressant at 1000 ng/ml cut-off level:

Amitriptyline	*1,000 ng/ml*
Cyclobenzaprine	*1,500 ng/ml*
Clomipramine	*5,000 ng/ml*
Desipramine	*600 ng/ml*
Doxepin	*1,000 ng/ml*
Imipramine	*600 ng/ml*
Notriptyline	*1,000 ng/ml*
Nordoxepin	*1,000 ng/ml*

Table II: Compounds tested and found not to cross-react with the test at a 100 µg / ml concentrate in urine.

Acetaminophen	*Ecgonine methyl ester*	*Oxazepam*
Acetone	*EDDP*	*Omega-3-Fatty Acid*
Acetyl Salicylic Acid	*+ Ephedrine*	*Penicillin G*
albumin	*- Ephedrine*	*Pentobarbital*
Amikacin	*(+/-) Epinephrine*	*Penphenazine*
Amitriptyline	*Erythromycin*	*Perphenazine*
Amobarbital	*Ethanol*	*Phenalzine*
Amphetamine	*Fentanyl*	*Phencyclidine*
D Amphatamine	*Fluxetine*	*pheniramine*
Ampicillin	*Furosemide*	*Phenobarbital*
Arterenol	*Gentisic acid*	*Phentermine*
l-Ascorbic Acid (Vitamin C)	*Glucosamine*	*l-Phenylephrine*
Aspartame	*Glucose*	*Phenylethylamine-α*
Aspirin	*Guaiacol Glyceryl Ether*	*(+/-)-Phenylpropanolamine*
Atropine	*DL-Hematropine*	*Primidone*
Benzocaine	*Hemoglobin*	*Procaine*
Benzoic Acid	*Histamine*	*Promathazine*
Benzoylecgonine	*Homatrophine*	*d-Propoxyphene*
Benzoylecgonine HCl	*Hydrochlorothiazide*	*Pseudoephedrine*
(+)- Brompheniramine	*Hydrocodone*	*Quinine*
Buprenorphine	*Hydromophone*	*Quinine antidine*
buprenorphine-3-β-d-glucuronide	*Ibuprofen*	*Quinidine*
Butabartital	*Imipramine*	*Salicylic Acid*
Caffeine	*Isoproterenol*	*Secobarbital*
Camphor	*Ketamine*	*Sodium Chloride*
(+)-Chlorpheniramine	*Lidocaine*	*Sulindac*
(+/-)-Chlorpheniramine	*Maprotiline*	*Sustiva*
Chlorprothixene	*3,4±MDA*	*Tenocyclidine*
Chloroquine	*(+/-)MDMA*	*Tetracycline*
Chlorpromazine	*Meperidine*	*Delta-9- Tetrahydocannabinol*
Cocaine	*Methadone*	*Tetrahydrozoline*
Codeinine	*Methamphetamine*	*Theophyline*
Cortisone	*Methanol*	*Thioridazine*
(-)-Cotinine	*Methaqualone*	*11-nor-Δ-THC-9-COOH (10 ug/ml)*
Creatinine	*Methylphenidate*	*11-nor-Δ-THC-9-COOH (10 ug/ml)*
r-Cyclodextrin	*Morphine*	*Tramadol*
Cyclobenzaprine	*Morphine-3-b-D-Glucuronide*	*d(+)-Trehalose*
Deoxyephedrine	*(1S,2S)-(-)-N-methyl-ephedrine*	*Trifluoperazine*
Dextromethorphan	*Naloxone*	*Trimethobenzamide*
Diazepam	*Naltrexone*	*Tyramine*
Digitoxin	*b-Naphthaleneacetic acid*	*Triprolidine Hydrochloride*
Digoxin	*(+/-) Naproxen*	
4-Dimethylaminoantipyrine	*Neomycin*	
Diphenhydramine	*Niacinamide*	
5,5-Diphenylhydantoin	*Nicotene*	
Dopamine	*Nicotinic Acid*	
Doxylamine	*Nor-Buprenorphine*	
Ecgonine	*Noscapine Hydrochloride*	
Ecgonine HCl	*Oxalic Acid*	

In order to examine potential naturally occurring interfering substances normally contained in urine. Drug free urine and drug positive urine were spiked with various potential interfering substances. Both samples were tested with QuikScreen® Multi X Drug Screen Test Cup Device. No cross-reaction was noted by any of the following substances at the concentrations list in the following table.

Table III - Natural Occurring Compounds in Urine and the Effect on QuikScreen® Multi X Drug Cup test

Analyte	Range	Effect	
		Positive*	Negative**
Ascorbic	300 mg/dl		
Bilirubin	1.0 mg/dl	None	None
Creatine	500 mg/dl	None	None
Glucose	1500 mg/dl	None	None
Hemoglobin	300 mg/dl	None	None
Potassium	110 mEq/dl	None	None
Human Serum Albumin	500 mg/dl	None	None
Globulin	1500 mg/dl	None	None
Sodium chloride	6000 mg/dl	None	None
Uric Acid	23 mg/dl	None	None
Cholesterol	500 mg/dl	None	None

*Concentration of Positive Drug Control = Amphetamine 1250 ng/ml, Methamphetamine 1250 ng/ml, Opiates 2500 ng/ml, Cocaine 375ng/ml, THC 63 ng/ml, Phencyclidine (PCP) 32 ng/ml, Benzodiazepine (450 ng/ml), Barbiturate (450 ng/ml), Methadone (450 ng/ml), TCA (1250 ng/ml), Oxycodone (100 ng/ml), Propoxyphene (300 ng/ml).

** Concentration of Drug [Drug Free urine] = 0 ng/ml

Effects of prolonged specimen exposure to the test device: In order to determine if there were any significant affects on the specimen by prolonged exposure to the test device, a study on the **QuikScreen® Multi X Drug Cup test** was performed using in-house urine control with GC/MS value assignment. The test specimens were subjected to a time zero (0) GC/MS evaluation. The test specimens were then applied to the **QuikScreen® Multi X Drug Cup test** such that the fluid level was midway between urine level marks and moderately shaken for a period of 10 minutes. The **QuikScreen® Multi X Drug Cup test** with the test specimens were stored for 50 hours at room temperature(15-30°) C.

Samples for GC/MS analysis were taken at times 0, 12, 36 and 60 hours. Statistically there was no significant change in the concentrations reported for any of the analytes at any time period. Based upon the GC/MS data, it may safe to conclude that there were no significant changes in the analyte concentrations of specimens that could be related to the device or the test strips contained in the device.

Accuracy: The accuracy of the **QuikScreen® Multi X Drug Cup test** was tested in a clinical trial of urine samples submitted to a SAMHSA certified laboratory. The laboratory used Syva® EMIT II as their screening procedure. All positive samples by either screening method were confirmed by GC/MS. The relative sensitivity results by either GCMS is summarized as follows:

3.1 Amphetamine (AMP) 1000 ng/ml Cut-Off Level

	GC/MS Positive	GC/MS Negative
QuikScreen® Positive	**47**	**2**
QuikScreen® Negative	**0**	**61**

When compared to GC/Mass the relative sensitivity was computed to be 47/47 or 100%. The relative specificity was computed to be 61/63 or 97%. The concordance of the combined data with respect to GC/Mass was 108/110 or 98%.

3.2 Barbiturates (BAR) 300 ng/ml Cut-Off Level

	GC/MS Positive	GC/MS Negative
QuikScreen® Positive	**39**	**2**
QuikScreen® Negative	**0**	**52**

When compared to GC/Mass the relative sensitivity was computed to be 39/39 or 100%. The relative specificity was computed to be 52/54 or 96%. The concordance of the combined data with respect to GC/Mass was 91/93 or 98%.

3.3 Benzodiazepine (BZD) 300ng/ml Cut-Off Level

	GC/MS Positive	GC/MS Negative
QuikScreen® Positive	**42**	**2**
QuikScreen® Negative	**0**	**52**

When compared to GC/Mass the relative sensitivity was computed to be 42/42 or 100%. The relative specificity was computed to be 52/54 or 96%. The concordance of the combined data with respect to GC/Mass was 94/96 or 98%.

3.4 Cocaine (COC) 300 ng/ml Cut-Off Level

	GC/MS Positive	GC/MS Negative
QuikScreen® Positive	**42**	**1**
QuikScreen® Negative	**0**	**53**

When compared to GC/Mass the relative sensitivity was computed to be 42/42 or 100%. The relative specificity was computed to be 53/54 or 98%. The concordance of the combined data with respect to GC/Mass was 95/96 or 99%.

3.5 Marijuana (THC) 50 ng/ml Cut-Off Level

	GC/MS Positive	GC/MS Negative
QuikScreen® Positive	**42**	**1**
QuikScreen® Negative	**0**	**53**

When compared to GC/Mass the relative sensitivity was computed to be 42/42 or 100%. The relative specificity was computed to be 53/54 or 98%. The concordance of the combined data with respect to GC/Mass was 95/96 or 99%.

3.6 Methadone (MAD) 300 ng/ml Cut-Off Level

	GC/MS Positive	GC/MS Negative
QuikScreen® Positive	**42**	**0**
QuikScreen® Negative	**0**	**52**

When compared to GC/Mass the relative sensitivity was computed to be 42/42 or 100%. The relative specificity was computed to be 52/52 or 100%. The concordance of the combined data with respect to GC/Mass was 94/94 or 100%.

3.7 Methamphetamine (MET) 1000 ng/ml Cut-Off Level

	GC/MS Positive	GC/MS Negative
QuikScreen® Positive	**41**	**1**
QuikScreen® Negative	**0**	**59**

When compared to GC/Mass the relative sensitivity was computed to be 41/41 or 100%. The relative specificity was computed to be 59/60 or 98%. The concordance of the combined data with respect to GC/Mass was 100/101 or 99%.

3.8 Opiates (OPI) 2000 ng/ml Cut-Off Level

	GC/MS Positive	GC/MS Negative
QuikScreen® Positive	**41**	**1**
QuikScreen® Negative	**0**	**54**

When compared to GC/Mass the relative sensitivity was computed to be 41/41 or 100%. The relative specificity was computed to be 54/55 or 98.2%. The concordance of the combined data with respect to GC/Mass was 95/96 or 99%.

3.9 Oxycodone (OXY) 100 ng/ml Cut-Off Level

	GC/MS Positive	GC/MS Negative
QuikScreen® Positive	**55**	**1**
QuikScreen® Negative	**0**	**43**

When compared to GC/Mass the relative sensitivity was computed to be 55/55 or 100%. The relative specificity was computed to be 43/44 or 98%. The concordance of the combined data with respect to GC/Mass was 98/99 or 99%.

3.10 Phencyclidine (PCP) 25 ng/ml Cut-Off Level

	GC/MS Positive	GC/MS Negative
QuikScreen® Positive	**40**	**4**
QuikScreen® Negative	**0**	**53**

When compared to GC/Mass the relative sensitivity was computed to be 40/40 or 100%. The relative specificity was computed to be 53/57 or 93%. The concordance of the combined data with respect to GC/Mass was 93/97 or 96%.

3.11 Tricyclic Antidepressant (TCA) 1000 ng/ml Cut-Off Level

	GC/MS Positive	GC/MS Negative
QuikScreen® Positive	**41**	**1**
QuikScreen® Negative	**0**	**42**

When compared to GC/Mass the relative sensitivity was computed to be 41/41 or 100%. The relative specificity was computed to be 42/43 or 98%. The concordance of the combined data with respect to GC/Mass was 83/84 or 99%.

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IVD = In-Vitro Diagnostic Device
EC REP = Authorized Rep in the EU Community
= Manufacturer