Manufactured For:
Elka Corporation

# NOVAPLUS® X Drug Test Cup

*CLIA WAIVED* — Instructions — IVD

## INTENDED USE

The **NOVAPLUS® X Drug Test Cup** is an immuno-chromatographic assay for rapid, qualitative detection of drug combinations and their principal metabolites in urine at specified cut-off concentrations. In the **NOVAPLUS® X Drug Test Cup**, 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 |
| BUPRENORPHINE | BUP | 10 ng/ml |
| COCAINE | COC | 300 ng/ml |
| MARIJUANA | THC | 50 ng/ml |
| METHADONE | MAD | 300 ng/ml |
| METHAMPHETAMINE | MET | 1000 ng/ml |
| METHYLENEDIOXYMETHAMPHETAMINE | MDMA | 500 ng/ml |
| OPIATES | OPI | 300 ng/ml |
| OPIATES | OPI | 2000 ng/ml |
| OXYCODONE | OXY | 100 ng/ml |
| PHENCYCLIDINE | PCP | 25 ng/ml |
| TRICYCLIC ANTIDEPRESSANT | 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 **NOVAPLUS® X Drug Test Cup** is an easy, fast, qualitative, visually read competitive binding immunoassay method for screening without the need of instrumentation. The method employs a 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 **NOVAPLUS® X Drug Test Cup** 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, where applicable.

## PRINCIPLE OF THE TEST

The **NOVAPLUS® X Drug Test Cup** 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

## 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. All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
4. 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.
5. 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 **NOVAPLUS® X Drug Test Cup** 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* **NOVAPLUS® X Drug 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.

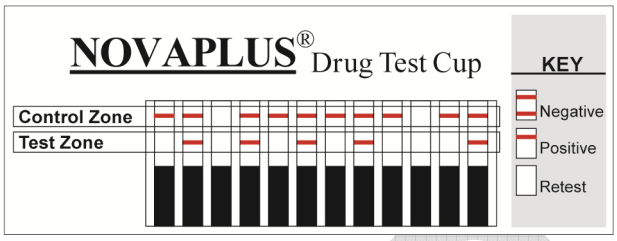
***Note:*** *The result must be interpreted at five minutes. To avoid confusion, discard the test device after interpreting the result.*

## 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. ***There is no meaning attributed to line color intensity or width.***

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

**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.




## QUALITY CONTROL

An internal procedure control has been incorporated into the test to insure proper 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 **NOVAPLUS® X Drug Test Cup** detects drugs of abuse and their major metabolites in urine at concentrations equal to or greater than the cutoff level for the specific drug, which is suggested by the U.S. Substance Abuse and Mental Health Services Administration (SAMHSA) for the immunoassay method, where applicable.

**2. Specificity**

A study was conducted with the **NOVAPLUS® X Drug Test Cup** 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 responses approximately equivalent to the cutoff set for the test**

| Compounds | Concentration (ng/ml) |
|---|---|
| **Amphetamine – 1000 (AMP)** | |
| d-Amphetamine | 1,000 |
| l-amphetamine | 25,000 |
| d-, l Amphetamine | 10,000 |
| β-Phenylethylamine | 180,000 |
| d-Methamphetamine | 400,000 |
| l-Methamphetamine | 400,000 |
| (±)3,4-Methylenedioxy-methylamphetamine-HCL ((±) 3,4 MDMA-HCl) | 400,000 |
| (±)3,4-Methylenedioxyamphetamine ((±)3,4-MDA) | 1,200 |
| Tyramine | 100,000 |
| **Barbiturates – 300 (BAR)** | |
| Allobarbital | 600 |
| Amobarbital | 600 |
| Barbital | 300 |
| Butabarbital | 300 |
| Butalbital | 300 |
| Pentobarbital | 300 |
| Phenobarbital | 300 |
| Secobarbital | 300 |
| **Benzodiazepines – 300 (BZD)** | |
| Alprazolam | 600 |
| Bromazepam | 100 |
| Chlordiazepoxide | 300 |
| Clobazam | 300 |
| **Compounds** | **Concentration (ng/ml)** |
| Clonazepam | 300 |
| Clorazepate | 200 |
| Delorazepam | 3,000 |
| Diazepam | 300 |
| Estazolam | 300 |
| Flunitrazepam | 300 |
| Flurazepam | 150 |
| Lorazepam | 500 |
| Lormetazepam | 500 |
| Nitrazepam | 250 |
| Nordiazepam | 150 |
| Oxazepam | 300 |
| Prazepam | 1,500 |
| Temazepam | 150 |
| Triazolam | 200 |
| **Buprenorphine – 10 (BUP)** | |
| Buprenorphine-3-β-D-Glucuronide | 2.5 |
| Buprenorphine | 10 |
| Nalorphine | 1000 |
| Norbuprenorphine | 15,000 |
| Norbuprenorphine-3-β-D-Glucuronide | 15,000 |
| Codeine | 12,500 |
| **Cocaine – 300 (COC)** | |
| Cocaine | 300 |
| Benzoylecgonine | 300 |

| | |
|---|---|
| **Marijuana – 50 (THC)** | |
| 11-nor-Δ8-THC-9-COOH | 50 |
| 11-nor-Δ9-THC-9-COOH | 50 |
| Δ8 –THC | 7,500 |
| Δ9 –THC | 10,000 |
| Cannabinol | 10,000 |
| 11-hydroxy-Δ9-tetrahydrocannabinol | 2,500 |
| **Methadone – 300 (MAD)** | |
| Methadone | 300 |
| Doxylamine | 50,000 |
| EDDP | 100,000 |
| Methadol | 25,000 |
| Perphenazine | 75,000 |
| Protriptyline | 2,000 |
| Trimipramine | 10,000 |
| **Methamphetamine – 1000 (mAMP)** | |
| (+) Methamphetamine | 1,000 |
| (±)3,4-Methylenedioxymethamphetamine (MDMA) | 1,000 |
| (±)3,4-Methylenedioxy-amphetamine-HCl (((±) 3,4 MDA-HCl) | 200,000 |
| d-Amphetamine Sulfate | 200,000 |
| l-Amphetamine Sulfate | 200,000 |
| Δ-l-Amphetamine Sulfate | 200,000 |
| **3,4-Methylenedioxymethamphetamine – 500 (MDMA)** | |
| Δ-Amphetamine | 1,000,000 |
| Δ-Methamphetamine | 500,000 |
| l-Methamphetamine | 500,000 |
| (±)3,4-Methylenedioxyamphetamine (MDA) | 5,000 |
| 3,4-Methylethylamphetamine (MDEA) | 5,000 |
| (±)3,4-Methylenedioxymethamphetamine (MDMA, Ecstasy) | 500 |
| p-Methoxyamphetamine (PMA) | 500,000 |
| **Opiates – 300 (OPI)** | |
| 6-Acetylmorphine | 300 |
| Codeine | 300 |
| Ethylmorphine | 5,000 |
| Hydrocodone | 6,000 |
| Hydromorphone | 6,000 |
| Morphine | 300 |
| **Opiates – 2000 (OPI)** | |
| Codeine | 2,000 |
| Heroin | 2,000 |
| Levorphanol | 4,000 |
| Morphine 3-β-D-Glucuronide | 2,000 |
| Opiate**Compounds** | **Concentration (ng/ml)** |
| Ranitidine | 100,000 |
| 6-Acetylmorphine | 50 |
| **Oxycodone – 100 (OXY)** | |
| Oxycodone-HCL | 100 |
| Codeine | 700 |
| Hydrocodone | 500 |
| Hydromorphone | 1,500 |
| Morphine-Sulfate | 7,000 |
| Morphine 3-β-D-Glucuronide | 40,000 |
| Norcodeine | 40,000 |
| Oxymorphone | 300 |
| **Phencyclidine – 25 (PCP)** | |
| Phencyclidine | 25 |
| Tenocyclidine | 2,000 |
| **Tricyclic Antidepressants – 1000 (TCA)** | |
| Amitriptyline | 1,000 |
| Cyclobenzaprine | 1,500 |
| Clomipramine | 5,000 |
| Desipramine | 600 |
| Doxepin | 1,000 |
| Imipramine | 600 |
| Nortriptyline | 1,000 |
| Nordoxepin | 1,000 |

**Table II – Compounds tested and found not to cross react with NOVAPLUS® X Drug Test Cup at a 100µg/ml concentration in urine**

| | | |
|---|---|---|
| Acetaminophen | Diphenhydramine | Naltrexone |
| Acetone | 5,5-Diphenylhydantoin | (+/-)Naproxen |
| Acetyl salicylic acid | Dopamine | Nicotine |
| Amikacin | EDDP | Noscapine Hydrochloride |
| Amitriptyline | + Ephedrine | Oxalic Acid |
| Amikacin | - Ephedrine | Omega-3-fatty acid |
| Ampicillin | +/- Epinephrine | Penicillin G |
| l-Ascorbic Acid (Vitamin C) | Erythromycin | Phenalzine |
| Aspartame | Ethanol | l-Phenylephrine |
| Aspirin | Fentanyl | (+/-)-Phenylpropanolamine |
| Atropine | Fluoxetine | Promathazine |
| Benzocaine | Furosemide | Pseudoephedrine |
| Benzoic acid | Glucosamine | Quinine |
| (+)-Brompheniramine | Guaiacol Glyceryl Ether | Quinidine |
| Caffeine | Hydrochlorothiazide | Salicylic acid |
| (+)-Chlorpheniramine | Ibuprofen | Sustiva |
| (+/-)-Chlorpheniramine | Ketamine | Sulindac |
| Chlorpromazine | Lidocaine | Theophyline |
| Cortisone | Maprotiline | Thioridazine |
| (-)-Cotinin | Meperidine | Tramandol |
| Dextromethorphan | Methanol | d(+)-Trehalose |
| 4-Dimethylaminoantipyrine | Methylphenidate | Trifluoperazine |

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 **NOVAPLUS® X Drug 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 NOVAPLUS® X Drug Test Cup**

| Analyte | Range | Effect | |
|---|---|---|---|
| | | Positive* | Negative** |
| **Ascorbic** | 300 mg/dl | None | None |
| **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 1250ng/ml, Methamphetamine 1250ng/ml, Opiates 2500ng/ml, Cocaine 375ng/ml, THC 63ng/ml, Phencyclidine (PCP) 32ng/ml, Benzodiazepine (450ng/ml), Barbiturate (450ng/ml), Methadone (450ng/ml), TCA (1250ng/ml), Oxycodone (100ng/ml), Propoxyphene (300ng/ml), Buprenorphine (12.5ng/ml)

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

**3. 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 **NOVAPLUS® X Drug Test Cup** 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 **NOVAPLUS® X Drug Test Cup** such that the fluid level was midway between urine level marks and moderately shaken for a period of 10 minutes. The **NOVAPLUS® X Drug Test Cup** with the test specimens were stored for 60 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 be 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.

**4. Accuracy**

The accuracy of the **NOVAPLUS® X Drug Test Cup** was tested in a clinical trial of urine samples submitted to a SAMHSA certified laboratory. All samples were verified by confirmed reference testing. The relative sensitivity results are summarized as follows:

**3.1 Amphetamine (AMP) 1000ng/ml Cutoff Level**

| | GC/MS Positive | GC/MS Negative |
|---|---|---|
| **NOVAPLUS® Positive** | **45** | **2** |
| **NOVAPLUS® Negative** | **0** | **56** |

When compared to GC/Mass the relative sensitivity was computed to be 45/45 or 100%. The relative specificity was computed to be 56/58 or 96.6%. The concordance of the combined data with respect to GC/Mass was 101/103 or 98.1%.

**3.2 Barbiturate (BAR) 300ng/ml Cutoff Level**

| | GC/MS Positive | GC/MS Negative |
|---|---|---|
| **NOVAPLUS® Positive** | **54** | **2** |
| **NOVAPLUS® Negative** | **1** | **46** |

When compared to GC/Mass the relative sensitivity was computed to be 54/55 or 98.2%. The relative specificity was computed to be 46/48 or 95.8%. The concordance of the combined data with respect to GC/Mass was 100/103 or 97.1%.

**3.3 Benzodiazepine (BZD) 300ng/ml Cutoff Level**

| | GC/MS Positive | GC/MS Negative |
|---|---|---|
| **NOVAPLUS® Positive** | **49** | **1** |
| **NOVAPLUS® Negative** | **1** | **52** |

When compared to GC/Mass the relative sensitivity was computed to be 49/49 or 100%. The relative specificity was computed to be 52/53 or 98.1%. The concordance of the combined data with respect to GC/Mass was 101/103 or 98.1%.

**3.4 Buprenorphine (BUP) 10ng/ml Cutoff Level**

| | GC/MS Positive | GC/MS Negative |
|---|---|---|
| **NOVAPLUS® Positive** | **49** | **0** |
| **NOVAPLUS® Negative** | **0** | **84** |

When compared to GC/Mass or LC/Mass the relative sensitivity was computed to be 49/49 or 100%. The relative specificity was computed to be 84/84 or 100%. The concordance of the combined data with respect to GC/Mass was 133/133 or 100%.

**3.5 Cocaine (COC) 300ng/ml Cutoff Level**

| | GC/MS Positive | GC/MS Negative |
|---|---|---|
| **NOVAPLUS® Positive** | **45** | **2** |
| **NOVAPLUS® Negative** | **0** | **56** |

When compared to GC/Mass the relative sensitivity was computed to be 45/45 or 100%. The relative specificity was computed to be 56/58 or 96.6%. The concordance of the combined data with respect to GC/Mass was 101/103 or 98.1%.

**3.6 Marijuana (THC) 50ng/ml Cutoff Level**

| | GC/MS Positive | GC/MS Negative |
|---|---|---|
| **NOVAPLUS® Positive** | **48** | **2** |
| **NOVAPLUS® Negative** | **0** | **53** |

When compared to GC/Mass the relative sensitivity was computed to be 48/48 or 100%. The relative specificity was computed to be 53/55 or 96.4%. The concordance of the combined data with respect to GC/Mass was 101/103 or 98.1%.

**3.7 Methadone (MAD) 300ng/ml Cutoff Level**

| | GC/MS Positive | GC/MS Negative |
|---|---|---|
| **NOVAPLUS® Positive** | **45** | **2** |
| **NOVAPLUS® Negative** | **1** | **57** |

When compared to GC/Mass the relative sensitivity was computed to be 45/46 or 97.8%. The relative specificity was computed to be 57/59 or 96.6%. The concordance of the combined data with respect to GC/Mass was 102/105 or 97.1%.

**3.8 Methamphetamine (MET) 1000ng/ml Cutoff Level**

| | GC/MS Positive | GC/MS Negative |
|---|---|---|
| **NOVAPLUS® Positive** | **46** | **2** |
| **NOVAPLUS® Negative** | **0** | **55** |

When compared to GC/Mass the relative sensitivity was computed to be 46/46 or 100%. The relative specificity was computed to be 55/57 or 96.5%. The concordance of the combined data with respect to GC/Mass was 101/103 or 98.1%.

**3.9 Methylenedioxymethamphetamine (MDMA) 500ng/ml Cutoff Level**

| | GC/MS Positive | GC/MS Negative |
|---|---|---|
| **NOVAPLUS® Positive** | **53** | **6** |
| **NOVAPLUS® Negative** | **1** | **150** |

When compared to GC/Mass the relative sensitivity was computed to be 53/54 or 98.1%. The relative specificity was computed to be 150/156 or 96.2%. The concordance of the combined data with respect to GC/Mass was 203/210 or 96.7%

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**3.10 Opiates (OPI) 300ng/ml Cutoff Level**

| | GC/MS Positive | GC/MS Negative |
|---|---|---|
| **NOVAPLUS® Positive** | **60** | **5** |
| **NOVAPLUS® Negative** | **0** | **105** |

When compared to GC/Mass the relative sensitivity was computed to be 60/60 or 100%. The relative specificity was computed to be 105/110 or 95.5%. The concordance of the combined data with respect to GC/Mass was 165/170 or 97.1%.

### 3.11 Opiates (OPI) 2000ng/ml Cutoff Level

| | | GC/MS Positive | GC/MS Negative |
|---|---|---|---|
| NOVAPLUS® | Positive | 45 | 2 |
| NOVAPLUS® | Negative | 1 | 57 |

When compared to GC/Mass the relative sensitivity was computed to be 45/46 or 97.8%. The relative specificity was computed to be 57/59 or 96.6%. The concordance of the combined data with respect to GC/Mass was 102/105 or 97.1%.

### 3.12 Oxycodone (OXY) 100ng/ml Cutoff Level

| | | GC/MS Positive | GC/MS Negative |
|---|---|---|---|
| NOVAPLUS® | Positive | 58 | 1 |
| NOVAPLUS® | Negative | 0 | 44 |

When compared to GC/Mass the relative sensitivity was computed to be 58/58 or 100%. The relative specificity was computed to be 44/45 or 97.8%. The concordance of the combined data with respect to GC/Mass was 102/103 or 99%.

### 3.13 Phencyclidine (PCP) 25ng/ml Cutoff Level

| | | GC/MS Positive | GC/MS Negative |
|---|---|---|---|
| NOVAPLUS® | Positive | 53 | 0 |
| NOVAPLUS® | Negative | 0 | 50 |

When compared to GC/Mass the relative sensitivity was computed to be 53/53 or 100%. The relative specificity was computed to be 50/50 or 100%. The concordance of the combined data with respect to GC/Mass was 103/103 or 100%.

### 3.14 Tricyclic Antidepressant (TCA) 1000ng/ml Cutoff Level

| | | GC/MS Positive | GC/MS Negative |
|---|---|---|---|
| NOVAPLUS® | Positive | 57 | 3 |
| NOVAPLUS® | Negative | 0 | 43 |

When compared to GC/Mass the relative sensitivity was computed to be 57/57 or 100%. The relative specificity was computed to be 43/46 or 93.5%. The concordance of the combined data with respect to GC/Mass was 100/103 or 97.1%.

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IVD = In-Vitro Diagnostic Device