

AGENDA ITEM 20

Consider awarding proposals received for urinalysis drug testing for the County CSCD to the low proposal meeting specifications - American Bio Medical Corporation.

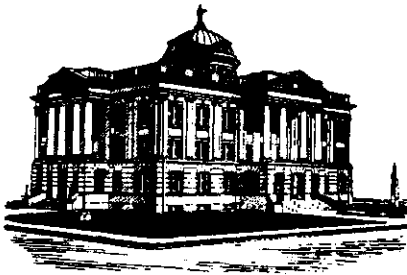
Moved: **Commissioner Boatright**

Seconded: **Judge Doerfler**

Motion: To award proposals received for urinalysis drug testing for the County CSCD to the low proposal meeting specifications - American Bio Medical Corporation.

Vote: 3 – 0. **Commissioner Limmer was absent from the dais.**

< Attachment >



**WILLIAMSON COUNTY
ADULT PROBATION
(CSCD)**

301 S.E. Inner Loop Road
P.O. Box 251
GEORGETOWN, TX 78627-0251
PHONE: (512)943-3500
www.adultprobation.net
zinsmeyer@adultprobation.net

BURT CARNES
JUDGE 368TH JUDICIAL DISTRICT

BILLY RAY STUBBLEFIELD
JUDGE 26TH JUDICIAL DISTRICT

MICHAEL JERGINS
JUDGE 395TH JUDICIAL DISTRICT

KEN ANDERSON
JUDGE 277TH JUDICIAL DISTRICT

RICK ZINSMEYER
CSCD DIRECTOR

September 17, 2003

Ginny Atkinson
Purchasing Department
County Auditor
Williamson County, Tx.

Dear Ms. Atkinson:

I have reviewed the proposals for urinalysis testing services that were received pursuant to the request for proposals last month. Attached are bid sheets submitted by the three proposers. American Bio Medica Corporation is the lowest in most categories. In the other categories, there is little difference in price. Therefore I recommend that American Bio Medica Corporation be awarded the urinalysis services proposal.

Rick Zinsmeyer
CSCD Director

*approved 9-23-03
John C. Doerfler*

American Bio Medica Corporation: Product Catalogue

Item #	Description	Qty/ Case or Package	Discount Price/ Unit	Discount Price/ case
Rapid Drug Screen: Multi-drug card only format; order sample cups separately- see below.				
2CS	COC/THC	50	\$1.90	\$95.00
2MS	METH/THC	50	\$1.90	\$95.00
3MS	COC/THC/METH	50	\$2.40	\$120.00
3XS	COC/THC/ AMP	50	\$2.40	\$120.00
3OS	COC/ THC/ OPI	50	\$2.40	\$120.00
4AS	AMP/COC/THC/OPI	50	\$3.00	\$150.00
4MS	METH/COC/THC/OPI	50	\$3.00	\$150.00
5PS	AMP/COC/THC/OPI/PCP	50	\$3.60	\$180.00
5MS	AMP/COC/THC/OPI/METH	50	\$3.60	\$180.00
5ZS	AMP/COC/THC/OPI/BZO	50	\$3.60	\$180.00
5MOS	METH/COC/THC/OPI/OXY	50	\$4.20	\$210.00
8XS	AMP/BZO/BAR/COC/METH/OPI/PCP/THC	50	\$6.35	\$317.50
9TS	AMP/BZO/BAR/COC/METH/OPI/PCP/THC/ TCA	50	\$7.10	\$355.00
10NDS	AMP/BZO/BAR/COC/METH/OPI/PCP/THC/PPX/MTD	50	\$10.00	\$500.00
Custom	Custom panels available; call for lead time and pricing	50		
<i>Opiates: Specify 300 or 2000 ng/ml cut-off</i>				

Rapid TEC®Products: Multi-drug dipsticks

2CR	Rapid TEC 2: THC/COC	50	\$1.75	\$87.50
3MR	Rapid TEC 3: THC/COC/METH	50	\$1.80	\$90.00
4OR	Rapid TEC 4: THC/COC/OPI*/METH	50	\$1.90	\$95.00
5AR	Rapid TEC 5A: THC/COC/OPI*/AMP/PCP	50	\$2.00	\$100.00
5ZR	Rapid TEC 5Z: THC/COC/OPI300/METH/BZO	50	\$2.00	\$100.00
<i>* Opiates: Specify 300 or 2000 ng/ml cut-off</i>				

Sample Integrity Tests

ADT000A	Rapid Check™: Creatinine, Specific Gravity, Glutaraldehyde, pH, Nitrite, Oxidants	25	\$0.80	\$20.00
ADT000B	Rapid Check™	50	\$0.75	\$37.50
ZKCI-070	Intect® 7	25	\$0.93	\$23.25

Oral Fluids (Saliva) Drug Screen

12-Oral-000	OralStat®: Amp/Meth/Coc/Opi/THC/PCP	25	\$13.75	\$343.75
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Alcohol Tests

AL000A	Rapid Alco TEC™: Saliva/ urine, 0.02 - 0.30%, test strip	25	\$1.75	\$43.75
AL000B	Rapid Alco TEC™: Saliva/ urine, 0.02 - 0.30%, test strip	50	\$1.50	\$75.00
ZBSA	Breathscan® Alcohol: 0.02, 0.04: Breath alcohol blow tube	100	\$1.25	\$125.00
AD000	Alcohol Detector, CA2000™ Portable Breathalyzer	1	\$275.00	\$275.00
AD001	Alcohol Detector Disposable Mouthpieces	100	\$0.24	\$24.00

Sample Cups/ Ancillaries

Tec Cup	4 oz. sample cup/ lid/ non-transport/ no temp strip	100	\$0.23	\$23.00
Non-transport	4 oz. sample cup/ lid/ non-transport/temp strip	500	\$0.30	\$150.00
Transport	4 oz. sample cup/ lid/ transport/ temp strip	300	\$0.35	\$105.00
A-Cup	RDS sample cup; transport/ temp strip/ slotted lid/ solid lid	100	\$0.75	\$75.00

For more information contact:

Anne Becknell, Director of Business Development
Office: 303-840-2607; E-mail: abecknell@abmc.com

To order call ABMC: 1-800-227-1243, option 2 or FAX: 518-758-8172

122 Smith Rd., Kinderhook, NY 12106

Federal TIN: 14-1702188

American Bio Medica Corporation: Product Catalogue

Price List for: Williamson County CSCD

Date: 9/2/2003

Item #	Description	Qty/ Case or Package	Discount Price/ Unit	Discount Price/ case
Rapid One®: Single drug test dip stick format.				
AMPD	Amphetamine (AMP)	50	\$1.15	\$57.50
BARD	Barbiturate (BAR)	50	\$1.15	\$57.50
BZOD	Benzodiazepine (BZO)	50	\$1.15	\$57.50
COCd	Cocaine (COC)	50	\$1.15	\$57.50
XTCD	Ecstasy (XTC)	50	\$2.00	\$100.00
MEDD	Methadone (MTD)	50	\$1.15	\$57.50
METD	Methamphetamine (METH)	50	\$1.15	\$57.50
OPID	Opiates (OPI) *specify 300 or 2000 cut-off	50	\$1.15	\$57.50
OXYD	Oxycodone (OXY)	50	\$2.00	\$100.00
PCPD	PCP (PCP)	50	\$1.15	\$57.50
PPXD	Propoxyphene (PPX)	50	\$2.00	\$100.00
THCD	THC (Marijuana)	50	\$1.15	\$57.50
TCAD	Tricyclic Antidepressants (TCA)	50	\$1.15	\$57.50
Single drug test strip format.				
AMPS	Amphetamine (AMP)	100	\$0.75	\$75.00
BARS	Barbiturate (BAR)	100	\$0.75	\$75.00
BZOS	Benzodiazepine (BZO)	100	\$0.75	\$75.00
COCS	Cocaine (COC)	100	\$0.75	\$75.00
XTCS	Ecstasy (XTC)	100	\$1.00	\$100.00
MEDS	Methadone (MTD)	100	\$0.75	\$75.00
METS	Methamphetamine (METH)	100	\$0.75	\$75.00
OPIS	Opiates (OPI) *specify 300 or 2000 cut-off	100	\$0.75	\$75.00
OXYS	Oxycodone (OXY)	100	\$1.40	\$140.00
PCPS	PCP (PCP)	100	\$0.75	\$75.00
PPXD	Propoxyphene (PPX)	100	\$1.40	\$140.00
THCS	THC (Marijuana)	100	\$0.75	\$75.00
TCAS	Tricyclic Antidepressants (TCA)	100	\$0.75	\$75.00
Rapid Drug Screen®: Multi-drug kit format: includes collection cup, ID label, temperature strip, evidence seal				
<i>Split: an additional split cup B: available for an extra \$.75/unit or \$15/case.</i>				
2C1	COC/ THC	25	\$2.80	\$70.00
2M1	METH/THC	25	\$2.80	\$70.00
3M1	COC/THC/METH	25	\$3.45	\$86.25
3X1	COC/THC/ AMP	25	\$3.45	\$86.25
3O1	COC/ THC/ OPI	25	\$3.45	\$86.25
4A1	AMP/COC/THC/OPI	25	\$4.35	\$108.75
4M1	METH/COC/THC/OPI	25	\$4.35	\$108.75
5P1	AMP/COC/THC/OPI/PCP	25	\$5.50	\$137.50
5M1	AMP/COC/THC/OPI/METH	25	\$5.50	\$137.50
5Z1	AMP/COC/THC/OPI/BZO	25	\$5.50	\$137.50
5MO1	METH/COC/THC/OPI/OXY	25	\$6.00	\$150.00
8X1	AMP/BZO/BAR/COC/METH/OPI/PCP/THC	25	\$9.25	\$231.25
9T1	AMP/BZO/BAR/COC/METH/OPI/PCP/THC/ TCA	25	\$12.00	\$300.00
10ND1	AMP/BZO/BAR/COC/METH/OPI/PCP/THC/PPX/MTD	25	\$13.00	\$325.00
Custom	Custom panels available; call for lead time and pricing	25		
Opiates: Specify 300 or 2000 ng/ml cut-off				

To order call ABMC: 1-800-227-1243, option 2 or FAX: 518-758-8172

122 Smith Rd., Kinderhook, NY 12106

Federal TIN: 14-1702188

Williamson County Community Corrections & Supervision Dept.

PharmView® Pricing

Packaged in Boxes of 25 Tests

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Test Type	Product Code	PharmView®	
		Prod. #	Unit Price
Single Drug Tests			
Cocaine	COC	S132 (dip)	\$0.80
Marijuana	THC	S133 (dip)	\$0.80
Amphetamine	AMP	S134 (dip)	\$0.80
Morphine	MOR	S135 (dip)	\$0.80
Phencyclidine	PCP	S136 (dip)	\$0.80
Methamphetamine	M-AMP	S137 (dip)	\$0.80
Benzodiazepines	BZO	S144 (dip)	\$0.80
Methodone	MTD	S145 (dip)	\$0.80
Barbiturates	BAR	S146 (dip)	\$0.80
MDMA/Ecstasy	MDMA	S148 (dip)	\$0.80
2-Drug Test			
2-drug (Cocaine/300/Marijuana)	COC/THC	S143 (dip)	\$1.55
3-Drug Test			
3-drug (Cocaine, Marijuana, and Opiates)	COC/THC/MOR	S158 (dip)	\$2.05
4-Drug Test			
4-drug (Cocaine, Marijuana, Opiates, and Methamphetamine)	COC/THC/MOR/ M-AMP	S150 (dip)	\$2.80
5-Drug Test			
5-Drug (300 Opiates, Cocaine, Marijuana, PCP, & Meth-amp.)	5-Drug (300)	S151 (dip)	\$3.55
5-Drug (2000 Opiates, Cocaine, Marijuana, PCP, & Meth-amp.)	5-Drug (2000)	S152 (dip)	\$3.55
5-Drug CUP			
5-Drug PharmView Cup (2000 Opiates, Cocaine, Marijuana, PCP, & Meth-amp.)	CUP	S128 CUP	\$5.55
QED Oral Fluid Alcohol Screen Packaged in boxes of 10 individual tests			
	Alcohol Screen	N401 – Semi-Quantative	\$4.60



CLIA # 45D1015868

9/3/2003

PROPOSAL

URINALYSIS DRUG TESTING FOR THE COMMUNITY SUPERVISION AND CORRECTIONS DEPARTMENT

PROPOSAL NUMBER: 03WC911

PROPOSER:

Val Walker, President/ CEO
ProResults Inc
7801 N. Lamar, Suite B-159
Austin, TX 78752
V: 512-374-9977
F: 512-374-9978
E-mail: val@proresults.us

DELIVERY:

Delivery of products specified on a Williamson County Purchasing Department purchase order shall be delivered within seven to ten working days after receipt of the purchase order.

AMP - Amphetamine
BAR - Barbiturate
BZD - Benzodiazepine
COC - Cocaine
MET - Methamphetamine

OPI - Opiates
MTD - Methadone
PCP - Phencyclidine
PPX - Propoxyphene
TCA - Tricyclic Antidepressants

THC - Marijuana
XTC - Ecstasy
AC - adulterant Check

PRODUCT AVAILABILITY:

Individual Test Devices

Test	Box Count	Minimum	Price/Box	Price/Each
AMP	50	1 Box	\$75	\$ 1.50
BAR	50	1 Box	\$75	\$ 1.50
BZD	50	1 Box	\$75	\$ 1.50
COC	50	1 Box	\$75	\$ 1.50
MET	50	1 Box	\$75	\$ 1.50
OPI	50	1 Box	\$75	\$ 1.50
MTD	50	1 Box	\$75	\$ 1.50
PCP	50	1 Box	\$75	\$ 1.50
PPX	50	1 Box	\$75	\$ 1.50
TCA	50	1 Box	\$75	\$ 1.50
THC	50	1 Box	\$75	\$ 1.50
XTC	50	1 Box	\$75	\$ 1.50

Multi-Drug Test Devices

2 Drugs				
MET, THC	25	1 Box	\$81.25	\$3.25
MET, THC, AC	25	1 Box	\$81.25	\$3.25
COC, THC	25	1 Box	\$81.25	\$3.25



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9/3/2003

3 Drugs				
COC, THC, XTC	25	1 Box	\$109.38	\$4.38
COC, THC, XTC, AC	25	1 Box	\$109.38	\$4.38
COC, OPI, THC	25	1 Box	\$109.38	\$4.38
COC, MET, THC	25	1 Box	\$109.38	\$4.38
AMP, COC, THC	25	1 Box	\$109.38	\$4.38
4 Drugs				
COC, METH, THC, XTC	25	1 Box	\$137.50	\$5.50
COC, MET, OPI, THC	25	1 Box	\$137.50	\$5.50
COC, MET, OPI, THC, AC	25	1 Box	\$137.50	\$5.50
BZD, COC, OPI, THC	25	1 Box	\$137.50	\$5.50
BAR, BZD, MTD, OPI	25	1 Box	\$137.50	\$5.50
AMP, COC, OPI, THC	25	1 Box	\$137.50	\$5.50
5 Drugs				
COC, MET, OPI, PCP, THC	25	1 Box	\$165.63	\$6.63
COC, MET, OPI, PCP, THC, AC	25	1 Box	\$165.63	\$6.63
BZD, COC, OPI, MTD, THC	25	1 Box	\$165.63	\$6.63
BZD, COC, MET, OPI, THC	25	1 Box	\$165.63	\$6.63
AMP, COC, OPI, THC, XTC	25	1 Box	\$165.63	\$6.63
AMP, COC, OPI, THC, XTC, AC	25	1 Box	\$165.63	\$6.63
AMP, COC, MET, PCP, THC	25	1 Box	\$165.63	\$6.63
AMP, COC, MOR, PCP, THC	25	1 Box	\$165.63	\$6.63
AMP, COC, MOR, PCP, THC, AC	25	1 Box	\$165.63	\$6.63
AMP, COC, MET, OPI, THC	25	1 Box	\$165.63	\$6.63
AMP, COC, MET, OPI, THC, AC	25	1 Box	\$165.63	\$6.63
6 Drugs				
COC, MET, OPI, PCP, THC, XTC	25	1 Box	\$193.75	\$7.75
COC, MET, OPI, PCP, THC, XTC, AC	25	1 Box	\$193.75	\$7.75
BAR, BZD, COC, MET, OPI, THC	25	1 Box	\$193.75	\$7.75
AMP, COC, OPI, PCP, THC, XTC, AC	25	1 Box	\$193.75	\$7.75
AMP, COC, MET, OPI, THC, XTC	25	1 Box	\$193.75	\$7.75
AMP, BZD, COC, MET, OPI, THC	25	1 Box	\$193.75	\$7.75
AMP, BZD, COC, MET, OPI, THC, AC	25	1 Box	\$193.75	\$7.75
8 Drugs				
AMP, BAR, BZD, COC, MET, OPI, PCP, THC	25	1 Box	\$250	\$10
9 Drugs				
AMP, BAR, BZD, COC, MET, OPI, MTD, PCP, THC	25	1 Box	\$278.13	\$11.13
10 Drugs				
AMP, BAR, BZD, COC, MET, OPI, MTD, PCP, TCA, THC	25	1 Box	\$306.25	\$12.25
AMP, BAR, BZD, COC, MET, OPI, MTD, PCP, THC, XTC	25	1 Box	\$306.25	\$12.25

Alcohol Tests

Alco-Screen® (Saliva) .02, .04, .06, .08, .10 graduated detection	24	1	\$75	\$3.12
Alco-Screen 02® (Saliva) .02 Pos/Neg detection	24	1	\$81.25	\$3.39
BreathScan® (Breath) Available in .02, .04, .06, .08 & .10 detections	10	1	\$46.88	\$4.69



**AMERICAN BIO MEDICA
CORPORATION**

Proposal for Williamson County

Urinalysis Drug Testing for Community Supervision and Corrections Department Proposal Number: 03WC911

**Submitted by:
American Bio Medica Corporation**

122 Smith Road
Kinderhook, NY 12106
800-227-1243

Opening: 9/3/03 @ 3:30PM

AMERICAN BIO MEDICA CORPORATION
Proposal for Williamson County/ # 03WC911/ Urinalysis Drug Testing for CSCD



Letter of Introduction

Request for Proposal (signed)

**ABMC Proposal
Discussion of Products and
Bid Specifications**

Package Inserts/ Studies

**ABMC Product Catalogue
for Williamson County**

Anne Becknell
Director of Business Development
122 Smith Road, Kinderhook, NY 12106
800-227-1243
Direct line: 303-840-2607 ♦ Fax: 303-841-3476
E-mail: abecknell@abmc.com
TIN: 14-1702188



September 2, 2003

Williamson County
Purchasing Department
Attn: Ginny Atkinson/ Rick Zinsmeyer
710 Main Street, Suite 303
Georgetown, TX 78626

Dear Ms. Atkinson and Mr. Zinsmeyer,

American Bio Medica Corporation ("ABMC") is pleased to participate in this RFP for Williamson County CSCD (the "County") for urinalysis drug testing kits. We welcome the opportunity to offer a cost effective proposal with testing options that will allow the County to determine which products best fit their testing needs. Because of our extensive portfolio of drug testing products we are certain that we will be able to meet and exceed the testing needs of the County. Our extensive portfolio allows us to offer the widest selection of drug testing options on the market, making it easy and cost effective for an agency to customize test panels to accommodate local drug testing needs. In addition, our superior training programs and customer support will provide the County agencies with a valuable resource to assist them in their efforts to reduce drug use through the utilization of this case management/ detection tool. Our products are easy to run and easy to interpret, providing an accurate, quick tool to determine the drug use status of a client/ probationer/ inmate/ parolee.

We work with many county, state and federal agencies that have found our products and services to be superior in performance, ease of use, and ease of interpretation. Our comprehensive training and support services have also influenced the decision to implement our products in many drug testing programs. There are numerous companies offering onsite drug testing for low prices, but ABMC provides much more in the way of training and on-going support than most. We consider ourselves a partner in the drug testing process and we support the customer to ensure that the products are being used in the most effective manner. Because of our extensive experience and knowledge in matters of drug testing, we can assist the customer in determining the best product configuration to make their drug testing program extremely effective both in process and cost. Our goal is to provide a drug testing system that works to meet your goals.

About American Bio Medica Corporation

American Bio Medica Corporation is a publicly traded (our common shares trade on the Nasdaq SmallCap Market under the symbol ABMC and our common share purchase warrants trade under the symbol ABMCW) biotechnology company, incorporated in 1986. ABMC develops, manufactures and markets high quality, onsite, rapid immunoassay test

kits for the detection of drugs of abuse in urine and oral fluids. ABMC products are utilized across many market segments such as physician offices, hospitals, laboratories, workplace, drug treatment, schools and criminal justice agencies throughout the world. ABMC offers one of the most comprehensive portfolios of self-contained, easy to use drug screening devices with the widest menu selection available. This allows the user to customize their drug-testing program to be more in-line with local trafficking and drug use trends as well as individual agency testing needs.

ABMC's world headquarters located in Kinderhook, New York is a 30,000 square foot medical device facility, compliant with FDA's Quality System Regulations (QSR). ABMC's research and development facility is located in Logan Township, New Jersey and is also QSR compliant. ABMC products are marketed in and outside of the United States by a direct sales organization as well as several healthcare distributors.

World Headquarters

American Bio Medica Corp
122 Smith Road
Kinderhook, New York 12101
Phone: 1-800-227-1243/ Fax: 518-758-8171

Research & Development Facility

American Bio Medica Corp
603/605 Heron Road, Unit 3
Logan Township, New Jersey 08085

Authorized Personnel to Represent ABMC Regarding this RFP:

Anne Becknell
Director of Business Development
Office: 1-800-227-1243
Direct line: 303-840-2607
Fax: 518-758-8171
abecknell@abmc.com

Melissa Decker
Administrator of Corporate Compliance
Office: 1-800-227-1243, ext. 107
mdecker@abmc.com

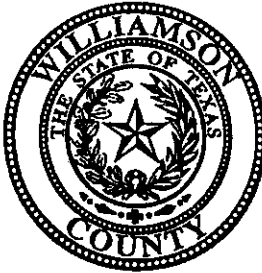
ABMC fully understands the complete terms and conditions presented in this Request for Proposal. It is clear that the onsite drug test to be used in the context of this contract is a case management tool intended to detect, deter and refer potential drug abusing inmates/offenders/clients to treatment. All of the various onsite drug and alcohol tests that ABMC has to offer the County are fast, accurate, reliable, easy to use, portable, cost effective tools. These products are also used to control and restrict contraband as well as provide for an added level of security within the confines of institutions by allowing incoming offenders to be properly segmented and categorized. Onsite drug tests have also been used in schools to ensure the health and safety of students. In the workplace, both private and public, onsite drug tests are a very cost effective way of maintaining a drug free atmosphere for employees, clients, customers and the community.

ABMC looks forward to working with Williamson County to provide a cost effective, easy drug, alcohol and sample integrity screening process that will enhance the County's drug testing program.

Sincerely,



Anne Becknell
Director of Business Development



**WILLIAMSON COUNTY AUDITOR'S OFFICE
PURCHASING DEPARTMENT
710 MAIN STREET - SUITE 303
GEORGETOWN, TEXAS 78626**

<http://www.williamson-county.org/Procurement>

REQUEST FOR PROPOSAL

URINALYSIS DRUG TESTING FOR THE COMMUNITY SUPERVISION AND CORRECTIONS DEPARTMENT

PROPOSAL NUMBER: 03WC911

PROPOSAL OPENING DATE & TIME: SEPTEMBER 3, 2003 – 3:30 PM

PROPOSAL SUBMISSION

DEADLINE: Proposals must be received in the Williamson County Auditor's Office prior to **3:30 PM on Wednesday, September 3, 2003**. At which time the proposals will be publicly acknowledged in the Williamson County Auditor's Office on the 3rd floor of the County Courthouse.

METHODS: Sealed proposals may be hand-delivered or mailed to the *Williamson County Auditor's Office, Attn: Ginny Atkinson – Purchasing, Third (3rd) floor - Suite 303, Williamson County Courthouse (on the square), 710 Main Street, Georgetown, Texas 78626.*

FAX/EMAIL: Facsimile and electronic mail transmittals are acceptable. For instructions regarding electronic submissions, please visit: <http://www.williamson-county.org/Procurement/info.html#EBids>. Failure to follow these instructions may cause your proposal to be rejected.

PROPOSAL REQUIREMENTS

TRIPLICATE: All proposals must be submitted in triplicate (1 original complete proposal set and 2 copies of the proposal set). The proposal sets must be marked "original" or "copy". A "proposal set" consists of the COMPLETED AND SIGNED Proposal Form and any other required documentation.

SEALED: All proposals must be returned in a sealed envelope with the proposal name, number, opening date and time clearly marked on the outside. If an overnight delivery service is used, the proposal name, number, opening date and time must be clearly marked on the outside of the delivery service envelope.

REFERENCES: Williamson County requires proposer to supply with this proposal, a list of at least three (3) references where like services have been supplied by their firm. Include name of firm, address, telephone number and name of representative.

LEGIBILITY: Proposals must be legible and of a quality that can be reproduced.

FORMS: All proposals must be submitted on the forms provided in this proposal document. Changes to proposal forms made by proposers shall disqualify the proposal. Proposals cannot be altered or amended after submission deadline.

LATE PROPOSAL: Proposals received after submission deadline will not be opened and will be considered void and unacceptable. Williamson County is not responsible for lateness of mail, courier service, etc.

RESPONSIBILITY: A prospective proposer must affirmatively demonstrate proposers responsibility. A prospective proposer must meet the following requirements:

- a) have adequate financial resources, or the ability to obtain such resources as required;
- b) be able to comply with the required or proposed delivery schedule;
- c) have a satisfactory record of performance;
- d) be otherwise qualified and eligible to receive an award.

Williamson County may request representation and other information sufficient to determine proposer's ability to meet these minimum standards listed above.

AWARD

THIRTY DAYS: Awards should be made approximately thirty (30) days after the proposal opening date. Results maybe obtained by contacting the Purchasing Contact.

REJECTION OR ACCEPTANCE: No more than one proposal will be awarded for any item, single department or area. Proposals may be rejected for some items, departments or areas, even though awards are made for others. The convenience of having a single source for similar items will be taken into consideration together with price in determining the lowest and best proposal.

It is understood that the Commissioners Court of Williamson County, Texas, reserves the right to accept or reject any and/or all proposals for any or all materials and/or services covered in this proposal request, and to waive informalities or defects in the proposal or to accept such proposal it shall deem to be in the best interest of Williamson County.

CONTRACT: This Proposal, when properly accepted by Williamson County, shall constitute a contract equally binding between the successful proposer and Williamson County.

The successful proposer may be required to sign an additional agreement containing terms necessary to ensure compliance with the proposal.

CONTRACT ADMINISTRATION: Under this contract, Rick Zinsmeyer, CSCD Director, Williamson County, shall be the contract administrator with designated responsibility to ensure compliance with contract requirements, such as but not limited to, acceptance, inspection and delivery. The contract administrator will serve as liaison between Williamson County Commissioner's Court and the successful proposer.

CONTRACT PERIOD(S): The Initial Contract Period is October 1, 2003 through September 30, 2004.
Possible extensions include:

October 1, 2004 through September 30, 2005
October 1, 2005 through September 30, 2006

BID CONTACTS**PURCHASING CONTACT:**

Ginny Atkinson
710 Main Street - Suite 303
Georgetown, TX 78626
(512) 943-1554
gatkenson@williamson-county.org

TECHNICAL CONTACT:

Rick Zinsmeyer
Director, Williamson County CSCD
P. O. Box 251
Georgetown, TX 78627
(512) 943-3505
rzinsmeyer@williamson-county.org

URINALYSIS DRUG TESTING FOR CSCD PROPOSAL

MISCELLANEOUS

FOB DESTINATION: All of the items listed are to be Free On Board to final destination (FOB Destination) with all transportation charges if applicable to be included in the price, unless otherwise specified in the Request for Proposal. The title and risk of loss of the goods shall not pass to the County until receipt and acceptance takes place at the FOB point.

FIRM PRICING: All of the items listed are to be on a "per unit" basis, stating a firm price per unit or unit quantity of each item. This price must be good from the date of proposal opening for a fixed period of time. Unless the Proposal expressly states otherwise, this period shall be until the end of the current fiscal year on September 30, 2004. Proposals which do not state a fixed price, or which are subject to change without notice, will not be considered. The Court may award a contract for the period implied or expressly stated in the lowest and best proposal, but for no longer than the current fiscal year.

ESTIMATED QUANTITIES: The estimated quantity of each item listed in the notice is only an estimate -- the actual quantity to be purchased may be more or less. The County is not obligated to purchase any minimum amount, and the County may purchase any reasonable amount greater than the estimate for the same unit price. Any limit on quantities available must be stated expressly in the proposal.

FUNDING: Funds for payment have been provided through the Williamson County budget approved by Commissioners Court for the October 1, 2003 thru September 30, 2004 fiscal year.

SALES TAX: Williamson County is by statute, exempt from the State Sales Tax and Federal Excise Tax.

STATEMENTS: No oral statement of any person shall modify or otherwise change, or affect the terms, conditions, plans and/or specifications stated in the various Proposal Packages and/or Proposal Instructions/Requirements.

DELIVERY: The delivery time and location for the commodity and/or service covered by this proposal shall be as stated in the various proposal packages.

PURCHASE ORDER: If required by the Williamson County Purchasing Department a purchase order(s) may be generated to the successful proposer for products and/or services. If a purchase order is issued the purchase order number must appear on all itemized invoices and/or requests for payment.

PAYMENT: Payment shall be made by check from the County upon satisfactory completion and acceptance of items and submission of the Invoice to the ordering department for work specified by this Contract Document. All payments owed will be paid no later than

thirty (30) days after the goods or services are received OR the date that the invoice is received by the Auditor's Office whichever is later. As a minimum, invoices shall include:

- (1) Name, address, and telephone number of Vendor and similar information in the event the payment is to be made to a different address
- (2) County contract, Purchase Order, and/or delivery order number
- (3) Identification of items or service as outlined in the contract
- (4) Quantity or quantities, applicable unit prices, total prices, and total amount
- (5) Any additional payment information which may be called for by the contract

Payment inquiries should be directed to the Auditor's Office, Accounts Payable Department: Donna McKittrick, 943-1558 or Kathy Blankenship, 943-1557.

CONFLICT OF INTEREST: No public official shall have interest in a contract, in accordance with Vernon's Texas Codes Annotated, Local Government Code Title 5, Subtitle C, Chapter 171.

ETHICS: The proposer shall not accept or offer gifts or anything of value nor enter into any business arrangement with any employee, official or agent of Williamson County.

DOCUMENTATION: Proposer shall provide with this proposal response, all documentation required by this proposal. Failure to provide this information may result in rejection of the proposal.

TERMINATION FOR DEFAULT: Williamson County reserves the right to enforce the performance of this

contract in any manner prescribed by law or deemed to be in the best interest of the County in the event of breach or default of this contract. Non-Performance of the proposer in terms of specifications shall be a basis for the termination of the contract by the County. The County shall not pay for commodities/services which are unsatisfactory. Vendors will be given a reasonable opportunity before termination to correct the deficiencies. This, however, shall in no way be construed as negating the basis for termination for non-performance.

SILENCE OF SPECIFICATIONS: The apparent silence of these specifications as to any detail or to the apparent omission from it of a detailed description concerning any point, shall be regarded as meaning that only the best practices are to prevail. All interpretations of these specifications shall be made on the basis of this statement.

COMPLIANCE WITH LAWS: The successful proposer shall comply with all applicable federal, state and local laws and regulations pertaining to the practice of the profession and the execution of duties under this proposal including the TEXAS HAZARD COMMUNICATION ACT and THE WILLIAMSON COUNTY HAZARD COMMUNICATION PROGRAM POLICY.

WORKER'S COMPENSATION

This contract contemplates services that do not require worker's compensation insurance coverage. However, if it becomes necessary that the proposer provide services related to the project such as delivering equipment or materials, an amended contract will be executed which fully complies with the Texas Labor Code and the Texas Worker's Compensation Commission requirements.

PROPOSAL SPECIFICATIONS

The Community Supervision and Corrections Department (CSCD) of Williamson County, Texas is requesting proposals for Urinalysis Drug Testing.

The drug testing system should provide quantitative or qualitative detection of parent compound or metabolite for at least: alcohol, THC, Cocaine, Barbiturates, Amphetamines, Opiates, PCP, and Ecstasy.

The drug testing system must:

1. Be fast, with results obtainable within 3 minutes without a timer, and readable up to 30 minutes after the test is completed.
2. Be able to be performed at any location and in the presence of the testee.
3. Provide easy to read, clearly distinguishable positive or negative results.
4. Be simple and easy to perform so that a non-technical person can capably perform the test.
5. Not require the pre-treatment of urine.
6. Be approved by the Federal Drug Administration with established and legally defensible SAMHSA cutoff detection levels.
7. Two-year stability from date of manufacture.
8. Flexibility of single or multi-panel format.

The proposer must submit the name(s) and a brief history of the company that will be providing the reagents.

WILLIAMSON COUNTY PROPOSAL FORM
URINALYSIS DRUG TESTING FOR THE
COMMUNITY SUPERVISION AND CORRECTIONS DEPARTMENT
PROPOSAL NUMBER: 03WC911

NAME OF PROPOSER: American Bio Medica Corporation

Mailing Address: 122 Smith Road

City: Kinderhook State: NY Zip: 12106

Email Address: abecknell@abmc.com

Telephone: (800) 227-1243 Fax: (518) 758-8171

The undersigned, by his/her signature, represents that he/she is authorized to bind the proposer to fully comply with the terms and conditions of the attached Request for Proposal, Specifications, and Special Provisions for the amount(s) shown on the accompanying proposal sheet(s). By signing below, you have read the entire document and agreed to the terms therein.

Anne Becknell Date of PROPOSAL: 9/2/03
Signature of Person Authorized to Sign Proposal

Printed Name and Title of Signer: Anne Becknell, Director of Business Development

DO NOT SIGN OR SUBMIT WITHOUT READING ENTIRE DOCUMENT

Signature required on awarded proposal only.

Hon. John C. Doerfler, County Judge
for the Williamson County Commissioners Court

Date

Proposal for Urinalysis Drug Testing

American Bio Medica Corporation has several options for rapid drug and alcohol testing available. Our proposal is outlined into the following sections: Drug Test Kits, Alcohol Testing, Sample Integrity Testing, Training, Evaluation and References. Our complete catalogue with all products and discount prices listed is included in this proposal. For further assistance in determining the best fit product to meet the County's needs, please contact Anne Becknell: 303-840-2607 or abecknell@abmc.com.

The term "**onsite test**" means a test which does not require laboratory instrumentation and can be administered in a location outside a laboratory such as a prison, jail, probation/parole office, community corrections, drug treatment center, half-way house or in the field. ABMC's onsite tests produce a test result within minutes in the presence of the client; eliminating uncertainty and substantially reducing the administrative burden posed by chain of custody. Rapid onsite testing is a clear deterrent to substance abuse because it greatly decreases the time between results and consequences. The use of onsite testing results in increased admissions of drug use by inmates/offenders/clients and it optimizes the rehabilitation process with immediate intervention because it quickly addresses and overcomes denial, the first step to recovery.

ABMC is prepared to demonstrate the performance capability of the entire product portfolio. We also have more to offer in terms of flexibility in testing. You will see many different options in both product line and number of drugs per panel that we are prepared to offer. Please review these additional products as some of them may meet the needs of various departments within the County. Discounted pricing for all products has been included as a separate and complete product catalogue for easy reference.

Drug Test Kits

Single Drug Tests: ABMC has a total of thirteen different single tests available: **Amphetamine, Barbiturates, Benzodiazepines, Cocaine, Ecstasy, Methamphetamine, Methadone, Opiates, Oxycodone, PCP, Propoxyphene, THC and Tricyclic Anti-depressants.** Each test is available in either the Rapid One® format that has the test strip housed in a plastic stick with a place for writing the identification of the donor, or the Rapid One Test Stick which is the drug test strip without the plastic housing. Both formats meet all of the specifications as listed in the RFP.

The tests are **easy to perform anywhere**, anytime by CSCD staff with results available in about **3 minutes** once the **control line forms indicating it is time to read** the test results. **No timing, pipetting, pouring, dispensing or pretreatment is required.** The results are **easy to read** with the presence or absence of a test line indicating a negative or positive drug result. The **results are stable for up to 60 minutes** and may be scanned or copied for a more permanent record. All of the products have **510(K) clearance from the FDA** for commercial distribution. The Amphetamine, Cocaine, THC, Opiates and PCP follow the **SAMHSA cut-off** guidelines. The Opiate test is also available at a 300 ng/ml cut-off. The other drugs follow cut-offs that are accepted as standard in the clinical marketplace. The results when compared to GC/MS were proven to **correlate greater than 99% with GC/MS** at a 95% confidence level. Our products have **18-24 month stability** from date of manufacture, and ABMC will work with the County to ensure proper ordering and storage of supplies so that a short dating problem is avoided.

Multi-drug Tests: ABMC has many multi-drug panels, from 2 – 10 drugs per panel, and we also have the ability to customize a multi-drug panel for the County or any one of its agencies or institutions. The Rapid Drug Screen® (RDS®) is available in any combination of the thirteen single drug test listed above. The RDS meets the County's specifications as listed in the RFP. The RDS multi-drug tests are available in both a kit format and a test card format. The kit format includes the sample cup with temperature strip and ID label, a test lid and a storage/shipping lid, the test card, a zip-type bag for storing the card for photocopying or scanning, tamper evident seal, interpretation guide – all packaged in a zip-type bag that can be used for easy clean disposal of the sample and testing materials. The test card format is a more cost effective option that includes just the test card; the collection cups would be purchased separately; there are several options listed in the price catalogue.

The tests are **easy to perform anywhere, anytime** by CSCD staff with results available in about **3 minutes** once the **control line forms indicating it is time to read** the test results. **No timing, pipetting, pouring, dispensing or pretreatment is required.** The results are **easy to read** with the presence or absence of a test line indicating a negative or positive drug result. The **results are stable for up to 60 minutes** and may be scanned or copied for a more permanent record. All of the products have **510(K) clearance from the FDA** for commercial distribution. The Amphetamine, Cocaine, THC, Opiates and PCP follow the **SAMHSA cut-off** guidelines. The Opiate test is also available at a 300 ng/ml cut-off. The other drugs follow cut-offs that are accepted as standard in the clinical marketplace. The results when compared to GC/MS were proven to **correlate greater than 99% with GC/MS** at a 95% confidence level. Our products have **18-24 month stability** from date of manufacture, and ABMC will work with the County to ensure proper ordering and storage of supplies so that a short dating problem is avoided.

Alcohol Testing

Rapid Alco-Tec™: This is a dip stick format that will detect alcohol in saliva or urine in two minutes. The level of alcohol is determined by comparing the color development on the test strip with a color chart on the bottle.

BreathScan®: This is a blow-tube test to determine the presence or absence of alcohol in breath. Results are read at two minutes.

Alcohol Detector: The CA2000 is a DOT approved portable breathalyzer that may be run on one 9V battery or a car adapter plug. Once the breathalyzer is turned on, the warm-up period is about 20 seconds as indicated by a countdown on the display. The donor then blows through the disposable mouthpiece until the beep, about 3-4 seconds and the result will be displayed in less than 5 seconds. Another test can be run in a little as 30 seconds.

Sample Integrity Testing

Although not included in the RFP, we also have onsite rapid tests for sample integrity. **Dilution and adulteration of urine samples are common tricks** used by offenders to circumvent the testing process. Drinking several glasses of water or other beverage can dilute a sample enough to cause a positive test to fall below the cut-off and test negative. Adulteration occurs when the donor adds a substance to the sample. There are many commercially available products that are used to try to avoid detection of a positive test,

however some household items are effective as well such as bleach, vinegar, soap, etc. By adding **Rapid Check™** to the testing process you will greatly enhance the integrity of the entire program. Our local representative will educate your staff in the area of sample tampering and can assist the County with integrating this process to improve the overall effectiveness of the drug testing program.

Training

ABMC has several training options and will work with the County to meet the training needs of all staff involved in drug testing.

Web-based: on our website, www.abmc.com, there is a training section. If the staff member completes the training and passes the test, a certificate will be available to print as evidence of the training. This is available at all times.

On-site training: This will be done at the County's request as needed at the facilities that are performing testing. This training will include information on current drug testing issues as well as how to perform the tests.

CD-ROM: A training CD-ROM will be provided to each facility or office for ongoing training of new staff or review for staff that have been trained previously.

Technical Support: Our technical support group is trained thoroughly on matters of drug testing and is available to assist with questions regarding all aspects of the drug and alcohol testing process; how to perform the ABMC tests, troubleshooting, sample integrity and drug cross-reactivities. The technical support group is available 24 hours/day, 365 days/ year, including all holidays. The phone number for the technical support is 800-227-1243, option 3.

On-going Consultation: This is part of the support ABMC provides at no charge. Anne Becknell, Director of Business Development, has many years experience in the criminal justice and drug testing fields and will be a great resource for the County. She will be the main contact for Williamson County. She will be conducting the training and will be available for consultations with staff, judges, administration, etc. if the County would find that beneficial.

Evaluation

ABMC will also offer the County onsite training along with an evaluation period (to be determined) in which ABMC shall provide the County with GC/MS confirmation of positive samples and a 5% re-screen of negative samples at a SAMHSA certified laboratory, all at no charge to the County. ABMC will write up a formal report of the results so that the County may utilize this document in court hearings where the drug test is challenged. This validation within the County departments will be a valuable tool in the support of the entire drug testing process. This report shall be in addition to any other support the County may require in relation to the challenge of a drug test.

Confirmation Testing/ Legal Resources: In addition to products listed in this bid response, we can also provide resources for lab-based testing, confirmation (GC/MS) testing and legal issues.

Package inserts for the products are included for your reference. Please direct any questions regarding this proposal to Anne Becknell; 303-840-2607.

References

United States Probation
Sandra Day O'Connor Federal Bldg. 410 W. Washington St. Phoenix, AZ 85003
Laurie Trigilio, Supervisor
602-322-7455

San Mateo County Probation
21 Tower Road San Mateo, CA 94010
Mr. Loren Buddress, Chief Probation Officer
650-312-8803 E-MAIL ADDRESS: lbuddress@co.sanmateo.ca.us

United States Probation: Western District of Texas
727 E. Durango San Antonio, TX 78206
Travis Amey, Deputy Chief Probation Officer
210-472-6590, X312

State of Michigan Department of Corrections
206 E. Michigan Ave Lansing, MI 48909
Tom Combs
517-335-4026



American Bio Medica Corporation
122 Smith Road
Kinderhook, NY 12106
(800) 227-1243

RAPID DRUG SCREEN™ and RapidOne™ Package Insert

RAPID DRUG SCREEN™ is a one-step, lateral flow immunoassay for the simultaneous detection of up to nine abused drug analytes in urine (each analyte occupies a separate channel in a test card). All configurations of the product are covered by this insert including the **RapidOne™** Single Dip Stick. **RAPID DRUG SCREEN™** and **RapidOne™** are intended for use in the qualitative detection of the following drugs of abuse in human urine at the following levels:

Compound	Abbreviation	Level
Amphetamine (d-amphetamine sulfate)	AMP	1 000 ng/mL*
Barbiturates (secobarbital)	BAR	300 ng/mL
Benzodiazepine (oxazepam)	BZO	300 ng/mL
Cocaine (benzoylecgonine)	COCAINE	300 ng/mL*
Cannabinoids (11-nor- Δ^9 -THC-9-carboxylic acid)	THC	50 ng/mL*
Methamphetamine ((+)-methamphetamine HCl)	METH	1 000 ng/mL
Opiates (morphine-3- β -D-glucuronide)	OPIATES	300 ng/mL*
		2 000 ng/mL**
Phencyclidine (phencyclidine HCl)	PCP	25 ng/mL*
Tricyclic Antidepressants (nortriptyline)	TCA	1 000 ng/mL

* Recommended screening cut-off concentrations by the Substance Abuse Mental Health Services Administration (SAMHSA).

** The test for opiates can be provided at either 300 ng/mL or 2000 ng/mL.

RAPID DRUG SCREEN™ and **RapidOne™** provide only a preliminary analytical test result.

SUMMARY AND EXPLANATION

RAPID DRUG SCREEN™ and **Rapid One™** are competitive immunoassays utilizing highly specific reactions between antibodies and antigens for the simultaneous detection of cocaine, opiates, amphetamine, cannabinoids, barbiturates, benzodiazepine, methamphetamine, phencyclidine and tricyclic antidepressants in urine.

PRINCIPLES OF THE TEST

Each **RAPID DRUG SCREEN™** and **RapidOne™** assay is a one-step immunoassay. The specifically labeled drug (drug conjugate) competes for antibody binding sites with drugs or metabolites that may be present in the urine specimen. The test device consists of a membrane strip with an immobilized drug conjugate. A colloidal gold-labeled antibody complex is dried at one end of the membrane. A control line, comprised of a different antibody/antigen reaction, is present on the membrane strip. The control line is not influenced by the presence or absence of a drug analyte in the urine specimen, and therefore, it should be present in all reactions.

In the absence of any drug in the urine specimen, the colloidal gold-labeled antibody complex moves with the urine by capillary action to contact the immobilized drug conjugate. An antibody-antigen reaction occurs forming a visible line in the 'test' area. **The formation of two visible lines occurs when the test is negative or below the cut-off for the drug.**

When a drug analyte is present in the urine specimen, the drug or metabolite will compete with the immobilized drug conjugate in the test area for the antibody binding sites on the colloidal gold-labeled antibody complex. If a sufficient amount of drug analyte is present, it will fill all of the available binding sites, thus preventing attachment of the labeled antibody to the drug conjugate. **The formation of one visible line is indicative of a positive result.**

REAGENTS AND MATERIALS SUPPLIED

Each **RAPID DRUG SCREEN™** kit box contains:

- Twenty **RAPID DRUG SCREEN™** kits consisting of the following items in a polyethylene bag:
 - Test Device:** The test device consists of a test card and desiccant in a sealed foil pouch. The test card contains independent channels for the complete immunoassay for up to 9 different drugs. Each channel contains a membrane with two attached absorbent pads and a pad containing the immobilized colloidal gold-labeled antibody complex. The upper pad acts as a reservoir for the specimen after it migrates through the membrane. The test line contains a BSA-drug conjugate for the individual analyte, dried on the membrane. A second line (control), containing an appropriate IgG, is placed above the test line on all membranes.
 - Test Cup and Caps:** Each polystyrene cup is supplied with two caps. One cap is fitted with a slot for the insertion of the test card, and a second cap is not slotted and is used for specimen transport to a confirmation laboratory, if necessary.
 - Tamper proof seal (for confirmation sample sent to laboratory)
 - Results Guide
 - Small plastic bag for storage/disposal of test card.

- Package Insert and lot number/expiration date explanation sheet

Each **RapidOne™** Test Kit box contains:

- 50 **RapidOne™** Test Sticks; this is the same device design as 1s above with only one channel
- Package Insert
- Results Guide

WARNINGS AND PRECAUTIONS

For in vitro diagnostic use

For professional use only

Follow proper handling and disposal procedures because urine specimens are potentially infectious.

Use only the specimen containers and test devices supplied. Avoid cross-contamination of urine specimens by using a new container for each urine specimen.

The foil pouch containing the test card must be completely sealed. **Do not use if foil pouch seal is not intact.**

Prior to use, ensure that the product has not expired by verifying that the date of use is prior to the expiration date embossed on the top of the foil pouch. The expiration date is the first four digits of the number embossed on the pouch. For example, 09/00 means the product expires in September 2000.

STORAGE

The **RAPID DRUG SCREEN™** and the **RapidOne™** dip stick should be stored at room temperature (15° to 30°C) or refrigerated (2° to 8°C). Allow test device to warm up to room temperature before conducting any testing.

SPECIMEN COLLECTION AND HANDLING

Use fresh urine specimens. Urine specimens do not require any special handling or pretreatment. It is best to test urine specimens immediately after collection. However, if necessary, urine specimens may be refrigerated at 2° to 8°C for two days or frozen at -20°C or colder for longer periods.

For **RAPID DRUG SCREEN™** collect enough urine in the cup to be within the blue area on the cup label. If the urine level is above or below the blue area on the cup, an invalid result may occur.

It is essential that none of the urine specimen (or other liquid) contact the test area windows of either the **RAPID DRUG SCREEN™** or the **RapidOne™** test devices.

A temperature strip is attached to the bottom of the specimen cup. For fresh urine specimens a reading between 90-100°F (32-38°C) is considered a viable sample. If the temperature strip remains black, the specimen is questionable.

Handle and dispose of urine specimens as if they were infectious and capable of transmitting infection. Avoid contact with skin.

PROCEDURES

RAPID DRUG SCREEN™ COLLECTION CUP METHOD

- Allow test card to warm up to room temperature before conducting any testing.
- Ensure urine specimen level in cup is within the blue area on the cup label or within the blue area on the test card.
- Remove test card from the foil pouch. Do not use if foil pouch seal is not intact. Label test card.
- Insert bottom end of test card into the slot in the top of the cup's cap by breaking the seal. If urine level is within the blue area noted on the cup label, push test card into the cup until it touches the bottom of the cup. If urine level in cup is above the blue area, you may pour off urine so that it is within the blue area on the cup label.
- Allow the test to proceed undisturbed until all reddish-purple control lines appear and the test background has cleared. The control line is the uppermost line in each channel in the test area. Once all control lines are visible the test is ready to be read; typically this occurs in 3-5 minutes.
- Read results as explained under Interpretation of Results.
- When interpreting results, read both sides of test card, if appropriate.

RAPID DRUG SCREEN™ ALTERNATE LOW-VOLUME PROCEDURE – PIPETTE METHOD

- Allow test card and urine specimen to warm up to room temperature before conducting any testing.
- Remove test card from the foil pouch. Do not use if foil pouch seal is not intact. Label test card.
- Lay test card flat. You may place absorbent pad under test card.
- Apply urine specimen drop-wise to each channel, allow each drop to absorb and repeat until approximately 100 microliters (about 2 to 3 drops) have been added to each channel. If testing for 8 or 9 drugs, repeat procedure on reverse side of test after testing on the first side is complete.
- Allow the test to proceed undisturbed until all reddish-purple control lines appear and the test background has cleared. The control line is the uppermost line in each channel in the test area. Once all control lines are visible the test is ready to be read; typically this occurs in 3-5 minutes.
- Read results as explained below under Interpretation of Results.
- When interpreting results, read both sides of test card, if appropriate.

RapidOne™ SINGLE DIP STICK PROCEDURE

- Allow test device to warm up to room temperature before conducting any testing.
- Remove the test device from the foil pouch. Do not use if foil pouch is not intact. Label test device.
- Insert the bottom end of the test device into the sample to the dip line on the test device.
- Hold the test device in the sample until a reddish purple color begins to appear in the test results area. When this occurs, remove the test device from the sample and lay flat. Allow the test to proceed undisturbed until a reddish-purple control line appears and the test background has cleared. The control line is the uppermost line in the test area. Once the control line is visible, the test is ready to be read; typically this occurs in 3-5 minutes.
- Read results as explained under Interpretation of Results.

INTERPRETATION OF RESULTS

The control line is the uppermost line appearing in each test area. The test line may or may not appear directly below the control line.

Once a reddish-purple control line with a clear background forms in all channels the test may be read.

A **NEGATIVE** result is the presence of two reddish-purple lines, called the test line and the control line, without regard to intensity, i.e., two lines, no matter how dark or light, indicate a negative result.

A **POSITIVE** result is the presence of **ONLY one line** (the control line).

If no control line appears after approximately 10 minutes, consider the test invalid.

RAPID DRUG SCREEN™ results are stable up to 60 minutes as long as the test card remains in the urine specimen or as long as the device is stored in a small plastic bag.

Do not read results after 60 minutes.

CONTROL LINE	TEST LINE	INTERPRETATION
No control line present	No test line present	Invalid test retest with new card
Control line present	Test line present	Negative
Control line present	No test line present	Positive

* Note If a test line appears but no control line appears, the test is also invalid.

QUALITY CONTROL

A procedural control (the control line) is built into each test channel, indicating that the reagents on the device are present and functioning properly. It is also good laboratory practice to use positive and negative controls to ensure proper test performance. Control samples are commercially available. In order to conserve the use of control materials, it is recommended that the low volume procedure be used for testing. Positive and negative controls should be used prior to using a new lot/shipment of test devices, if the product has been stored outside the recommended storage conditions, or in accordance with your laboratory defined policies.

LIMITATIONS OF PROCEDURE

The assay is designed for use with human urine only.

RAPID DRUG SCREEN™ and **RapidOne™** provide only a preliminary qualitative test result. Use a more specific alternate quantitative analytical method to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method (1). HPLC may be used as the confirmatory method for tricyclic antidepressants. Apply clinical and professional judgment to any drug of abuse test result, particularly when preliminary positive results are obtained. (2).

Other substances and/or factors not listed may interfere with the test and cause erroneous results, such as adulterants, procedural errors or cross reactivity with other drugs or agents. Refer to the Performance Characteristics section for more information. If adulteration is suspected, obtain a fresh urine specimen and repeat testing.

PERFORMANCE CHARACTERISTICS

SPECIFICITY

Interference and cross reactivity studies were performed by testing the drug analytes in the **RAPID DRUG SCREEN™** device with various other drugs. Below is the list of drugs that will give a positive result at or above the concentration stated. All of the following drugs were added to normal, drug-free urine. Note: The drugs listed are positive for only the drug test specified.

DRUG TEST	CONCENTRATION(ng/mL)
Amphetamine	
d-amphetamine	1,000
d, l-amphetamine	1,000
l-amphetamine	20,000
Phentermine (α,α -Dimethylphenethylamine)	1,250
(+/-)- Methyleneoxyamphetamine (MDA)	750
Methamphetamine	
(+/-) 3,4-Methylenedioxy-n-ethylamphetamine (MDEA)	20,000
Procaine (Novocaine)	60,000
Trimethobenzamide	20,000
+/- methamphetamine	1,000
+ methamphetamine	500
Ranitidine (Zantac)	50,000
(+/-) 3,4-Methylenedioxymethamphetamine (MDMA)	2,500
Barbiturates	
Allobarbitol (5,5-Diallylbarbituric Acid)	300
Amobarbitol (Amytal; 5-Ethyl-5-Isoamylbarbituric Acid)	1,000
Aprobarbitol	150
Barbitol (Barbitone; 5,5-Diethylbarbituric Acid; Veronal)	1,250
Butabarbital	750
Butalbital	300
Butethal	500
5,5 Diphenylhydantoin (Phenytoin)	2,500
Pentobarbital (Nembutal)	300

Phenobarbital	1,500
Secobarbital (Quinalbarbitone)	150
Talbutal	75
Benzodiazepines	
Alprazolam	75
Bromazepam	400
Chlordiazepoxide	150
Clobazam	100
Clonazepam	300
Desmethyldiazepam	100
Diazepam	100
Estazolam	500
Flunitrazepam	150
(+/-)-Lorazepam	2,200
Lometazepam	500
Nitrazepam	75
Nordiazepam	150
Oxazepam	300
Sulindac	7,500
Temazepam	100
Triazolam	1,500
Cannabinoids (Tetrahydrocannabinol, THC)	
Cannabinol	25,000
11-Hydroxy- Δ^9 -Tetrahydrocannabinol	5,000
11-Nor- Δ^8 -Tetrahydrocannabinol-9 Carboxylic Acid	50
11-Nor- Δ^9 -Tetrahydrocannabinol-9 Carboxylic Acid	50
11-Nor- Δ^9 -Tetrahydrocannabinol-9 Carboxylic Acid Glucuronide	2,500
Δ^8 -Tetrahydrocannabinol	20,000
Δ^9 -Tetrahydrocannabinol	20,000
Cocaine metabolite	
Benzoyllecgonine	300
Cocacethylene	300
Cocaine (Ecgonine Methyl Ester Benzoate)	100
Metoclopramide	80,000
Procaine (Novocaine)	75,000
Opiate 300 ng/mL	
6-Acetylmorphine	500
Codeine	100
Eserine (Physostigmine)	15,000
Ethylmorphine	100
Heroin (Diacetylmorphine)	500
Hydromorphone	2,000
Hydrocodone	1,250
Morphine	300
Morphine-3- β -D-Glucuronide	75
Nalorphine	500
Norcodeine	35,000
Oxycodone	75,000
Thebaine (Paramorphine)	13,000
Opiate 2000 ng/mL	
6-Acetylmorphine	1,000
Codeine	800
Ethylmorphine	400
Heroin (Diacetylmorphine)	10,000
Hydromorphone	2,000
Hydrocodone	5,000
Morphine	1,600
Morphine-3- β -D-Glucuronide	2,000
Oxycodone	50,000
Thebaine (Paramorphine)	26,000
Phencyclidine (PCP)	
Phencyclidine	25
4-Hydroxy phencyclidine	90
Phencyclidine Morpholine	625
RAPID DRUG SCREEN™ and RapidOne™ PCP also detects high concentrations of the cough suppressant, dextromethorphan. In young children, dextromethorphan overdoses may produce a positive result for PCP. However, adults ingesting therapeutic dosages of dextromethorphan should not produce a positive result.	
Tricyclic Antidepressants	
Amitriptyline	1,000
Clomipramine	75,000
Cyclobenzaprine	8,000
Cyproheptadine	50,000
Desipramine	1,000
Doxepin	5,000
Imipramine	1,000
Norclomipramine	2,500
Nordoxepin	500
Nortriptyline	1,000
Promazine	12,500
Protriptyline	2,000
Trimipramine	3,000

The following drugs are not detected by **RAPID DRUG SCREEN™** or **RapidOne™** at concentrations less than 100,000 ng/mL unless otherwise specified by asterisk:

Acetabulol	Chlorotrianisene	Etoposide	Acetic Acid (-) Naproxen
Acetaldehyde	(+) Chlorpheniramine	Famotidine	Methoxyphenamine
Acetaminophen (4-Acetamidophenol; N-Acetyl-p-aminophenol)	(+/-) Chlorpheniramine	Fenfluramine	5-Methoxytryptamine (Methoxamine; O-Methylserotonin)
Acetazolamide	Chlorpromazine	Fenpropofen [(+/-)-2-(3-Phenoxyphenyl) Propionic Acid]	3-Methoxytyramine
Acetone	Chlorpropamide	Fentanyl (10 ug/ml)*	2-Methyl-3-(3,4-Dihydroxyphenyl)-DL-Alanine
3-(α -acetylbenzyl)-4-hydroxycoumarin (Warfarin)	Chlorprothixene	Ferrous Sulfate	2-Methyl-3-(3,4-Dihydroxyphenyl)-L-Alanine
Acetophenetidin	Chlorthalidone	Flufenamic Acid	6 α -Methyl-17 α -Hydroxyprogesterone (Medroxyprogesterone)
Acetopromazine	Chlorzoxazone (5-Chloro-2-Hydroxybenzoxazole)	Flurazepam	Methylene Blue
N-Acetyl-L-cysteine	Cholesterol	Flurbiprofen	3,3'-Methylene-bis-(4-Hydroxycoumarin) (Dicumarol)
N-Acetylprocainamide (Acedainide)	Cimetidine	Formaldehyde	1-Methylhistamine
Acetylsalicylic Acid (Aspirin; 2-Acetoxybenzoic Acid)	Cinchonidine	Furosemide	Methylphenidate (Ritalin)
Albumin, standard	Cinoxacin	Gemfibrozil	6 α -Methylprednisolone (Medrol)
Allopurinol (4-Hydroxypyrazole(3,4-) pyrimidine)	Clemastine	Gentamicin Sulfate	Methyl Salicylate
Alprenolol	Clenbuterol	Glucoside	Methyl Viologen (Gramoxone; Paraquat Dichloride)
Amantadine (Adamantan-1-amine)	Clindamycin	(D)-(+)-Glucose (Dextrose)	Metricrane
Aminoclonide	Clobetasone Butyrate	Glybendamide	(+/-) Metoprolol
(+) Amethopterin (4-Amino-10-methylfolic acid; Methotrexate; Methylaminopterin)	Clonidine	Hexachlorocyclohexane	Metronidazole
Amikacin	Cloxacillin	Hexachlorophene	Mianserin
Amiloride	Clozapine	Hippuric Acid	Milrinone
p-Aminobenzoic Acid	Colchicine	Histamine [2 (4-Imidazolyl) Ethylamine]	Minaprine
DL-Aminoglutethimide	Cortisone	DL-Homatropine	Nabumetone
Amiodarone	β -Cortol	Hydralazine (1-Hydrazinophthalazine)	Nadolol
Ammonium Chloride	(-) Cotinine	(1S, 9R)- β -Hydrastine	Nafcilin
Amoxicillin	Creatinine	Hydrochlorothiazide	Nalbuphine
Amphotericin B	Cromolyn (Cromoglycic Acid)	Hydrocortisone	Nalidixic Acid
Ampicillin	Cyclophosphamide	Hydroflumethiazide	Nalmefene
D-Amygdalin	Cyclosporin A	Hydroxocobalamin	Naloxone
Aniline	Dantrolene	O-Hydroxyhippuric Acid	Naltrexone
Antipyrine (Phenazone)	Deferoxamine Mesylate (Deferrioxamine Mesylate)	5-Hydroxyindole-3-Acetic Acid	Naphazoline
Apomorphine	Deoxyepinephrine	5-Hydroxy-2-indole-2-Carboxylic Acid	α -Naphthalene Acetic Acid
(-) Arterenol [(-)Norepinephrine]	R-(-)-Deprenyl (Selegiline)	4-Hydroxy-3-Methoxyphenylacetic Acid (Homovanillic Acid)	β -Naphthalene Acetic Acid
L-Ascorbic Acid	N-Desmethylozapine (Normethylozapine)	5-Hydroxytryptamine (Serotonin)	α -Naphthol
ASP-PHE-Methyl-Ester (Aspartame)	Desoximetasone	3-Hydroxytyramine	Neomycin Sulfate
D-Aspartic Acid	Dexamethasone	Hydroxyzine (Atarax)	Niacinamide
DL-Aspartic Acid	Dextromethorphan	L-Hyoscyamine	Nialamide
L-Aspartic Acid	4,4'-Diaminophenyl Sulfone (Dapsone)	Ibuprofen	(+/-) Nicotine
Asterizole	Diazoxide	Imidazole-4-Acetic acid	Nicotinic Acid (Niacin)
Atenolol	Dichloromethane (Methylene Chloride)	Indapamide	Nifedipine
Atropine (Tropine tropate)	Dichlorophenamide	Indole-3-Acetic acid	Nitrofurantoin
Azathioprine	Diclofenac	Indole-3-Butyric Acid	Normifensine
Baclofen	Dicyclomine	DL-Indole-3-Lactic Acid	Norcocaine
Barbituric Acid (2,4,6-Trihydroxypyrimidine; Malonylurea)	Dieldrin	Isomethacin	Norcodeine
Bedomethasone	Diethylthiocarbamic Acid	Ipratropium Bromide	Norethindrone
Bedomethasone Dipropionate	N,N-Diethylnicotinamide (Niacin Diethylamide; Nيكهتاميد)	Iproniazid	Norfloxacin
Bendroflumethiazide	Diflurasone Diacetate	Isotonic Acid (Pyridine-4-Carboxylic Acid)	DL-Normetanephine
Benztidine (4,4 Diaminobiphenyl)	Diflucortolone pivalate	Isotonic Acid Hydrazide	Normorphine d-Norpropoxyphene
Benztic Acid β -diethylaminoethyl ester	Diflunisal	Isopropamide	Noscapine
Benzoic Acid	Digloxin	(+) Isoproterenol	Nylidrin
Benzphetamine (α -dimethylphenethylamine)	Digoxin (12 β -Hydroxydigoxin)	(-) Isoproterenol	Orotic Acid (Uracil-6-Carboxylic Acid)
Benzthiazide	DL-3,4 Dihydroxyphenyl Glycol	(+/-) Isoproterenol	Orphenadrine
Benztropine Methanesulfonate (Benztropine Mesylate)	3,4 Dihydroxyphenylacetic Acid	(+) Isoproterenol	Oxalic Acid (Ethanedioic Acid)
Benzyl alcohol	7-(2,3-Dihydroxypropyl) Theophylline (Dyphylline)	Isosuprine	Oxolinic Acid
Benzylamine	Dimethydrinate	Kanamycin	Oxprenolol
Berberine	Dimercaprol (2,3,-Dimercaptopropanol)	Ketamine	Oxybutynin Chloride
Betamethasone	4-Dimethylaminoantipyrine (Aminopyrine)	Kynurenic Acid	Oxymetazoline
Bilirubin	1,1-Dimethylbiguanide (Metformin)	Labelalol	Oxyphenbutazone
Bisacodyl	Dimethyl Isosorbide	Levorphanol	Oxypurinol
2-Bromo- α -ergocryptine (Bromocryptine mesylate)	Dimethyl Sulfoxide (DMSO)	Lidocaine	Pacitaxel
(+) Brompheniramine (Dexbrompheniramine)	1,3-Dimethyluric Acid	Lisinopril	Pancuronium Bromide
(+/-) Brompheniramine	1,7-Dimethylxanthine	Lithium Carbonate	Papaverine
Bumetanide	Diphenhydramine	Loperamide	Pargyline
Bupivacaine	Dipyridamole	Lysergic Acid Diethylamide (LSD)	Penicillin G (Benzylpenicillin)
Buprenorphine	Disopyramide	Mebendazole	Pentachlorophenol
Buspirone	Dobutamine	Medicine	Pentoxifylline (Trental)
Butacaine	Doxycycline	Medofenamic Acid	Pentylene tetrazole
2-Butynoic Acid Ethyl Ester (Ethyl-2-Butynoate)	Doxylamine	Medazepam	p-Phenylenediamine
Butyrophene	Droperidol	Mefenamic Acid	Phenazine
Caffeine (1,3,7-Trimethylxanthine)	Ecgonine	Melanin	Phenformin
(+/-) Camphor	Ecgonine Methyl Ester	Melphalan	Pheniramine
Canrenoic Acid	Emetine	(-) Menthol	Phenol
Captopril	(-) ψ -Ephedrine	Meperidine	Phenolphthalein
Carbamazepine	(+) Ephedrine	Mephensin	Phenothiazine (Thiodiphenylamine)
Carbamyl- β -methylcholine-chloride (Bethanechol Chloride)	(+/-) Ephedrine	Mephentermine	Phenoxyethylpenicillinic acid (Penicillin V)
Carboplatin	(-) Epinephrine	Meprobamate	Phentolamine
(s)-(-)-Carbidopa	(+/-) Epinephrine	6-Mercaptopurine	DL-Phenylalanine
Carisoprodol	Erythromycin	Mersalyl Acid	L-Phenylalanine
Cefaclor	Eserine (Physostigmine)	Mescaline (3,4,5-Trimethoxyphenethylamine)	Phenylephrine
Cefadroxil	β -Estradiol	DL-Metanephine	(+/-)- α -Phenylethylamine (α -Methylbenzylamine)
Cefotaxime	Estrone	Metaprotenerol	β -Phenylethylamine
Cefoxitin	Estrone- β -D-Glucuronide	Metaraminol [(-)-m-Hydroxyphenylpropanolamine]	(R)-(+)- α -Phenylethylamine
Ceftriaxone	Estrone-3-Sulfate	(+/-) Methadone	(+/-) Phenylpropanolamine (PPA)
Cefuroxime	Ethacrynic Acid	Methanol, Absolute	Phenyltoloxamine
Cephalexin	Ethambutol	Methaqualone	Phthalic acid (1,2-Benzenedicarboxylic Acid)
Cephalexidine	Ethanol, Standard	Methazocamide	Picrotoxin
Cephadrine (Cefradin)	Ethopropazine	Methotrimetaprazine	Pilocarpine
α -Chloralose	Ethosuximide (2-Ethyl-2-Methylsuccinimide)	Methoxamine	Pimozide
Chloramphenicol (Chloromycetin)	2-Ethyl-2-Phenylmalonamide	Methoxyamine	Pipemidic Acid
Chlorcyclizine	Ethylene Glycol	(S)-6-Methoxy- α -Methyl-2-Naphthalene	Piroxicam
2-(p-Chlorophenoxy)-2-Methylpropionic Acid	Ethylene diaminetetraacetic Acid (EDTA)	Acetic Acid (+) Naproxen	Potassium Chloride
Ethyl Quinone (Clobifrate)	2-Ethylidene-1,5-Dimethyl-3,3-Diphenylpyrrolidone	(S)-6-Methoxy- α -Methyl-2-Naphthalene	Potassium Iodide
Chloroquine	Etodolac		Prazepam
Chlorothiazide			Prazosin

Drugs not detected by **RAPID DRUG SCREEN™** continued

Prilocaine
 Primaquine
 Primidone (2-Desoxyphenobarbital)
 Proadifen
 Probenecid [*p*-(Dipropylsulfamoyl) Benzoic Acid]
 Procainamide
 Prochlorperazine
 Procydiline
 Promethazine
 Propionylpromazine
 d-Propoxyphene
 DL-Propranolol
 2-Propylpentanoic Acid (*Valproic Acid*)
 Protein
 d -Pseudoephedrine
 Pyridine-2-Aldoxime Methochloride (*Pralidoxime Chloride*)
 Pyridoxine
 Pyrimidine (*Mepyramine*)
 Quinidine
 Quinine
 Quinolinic Acid (2,3-Pyridinedicarboxylic Acid)
 Rescinnamine
 Reserpine
 Riboflavin
 Ritodrine
 Salbutamol (*Albuterol*)
 Salicylamide (2-Hydroxybenzamide)
 Salicylic Acid (2-Hydroxybenzoic Acid)
 (-) Scopolamine (*Hyoscine*)
 Sodium Chloride
 Sodium Formate
 (+/-) Sotalol
 Strychnine
 Succinylcholine Chloride
 Sulfamethazine
 Sulfamethoxazole
 Sulfanilamide (*p*-Aminobenzenesulfonamide)
 Sulfathiazole
 Sulfisoxazole
 (+/-) Sulfuride
 Suxibuzone
 Tamoxifen
 Tannic Acid
 Tenoxicam
 Terbutaline
 Terfenadine
 Tetracycline
 Tetraethyl Thiuram Disulfide (*Disulfiram*)
 Tetrahydrozoline
 Theobromine (3,7-Dimethylxanthine)
 Theophylline (1,3-Dimethylxanthine)
 Thiamine (*Aneurine*)
 Thimerosal (Sodium Ethylmercurithiosalicylate)
 Thioridazine
 Cis-Thiothixene
 Thymol (5-Methyl-2-Isopropylphenol)
 Timolol
 Tobramycin
 Tolazamide
 Tolbutamide
 Tolmetin
 Toluene
 Trans-2-Phenylcyclopropylamine (*Tranylcypromine*)
 Trazodone
 Triamcinolone (*Fluoxyprednisolone*)
 Triamterene
 Trichloromethiazide
 Trichloroacetic acid
 2,2,2 Trichloroethanol
 Trifluoperazine
 Trifluoromazine
 DL-Trihexyphenidyl
 Trimethoprim
 3,5,5-Trimethyloxazolidine-2,4-dione (*Trimethadione*)
 Triprolidine
 DL-Tropic Acid
 Tropine
 Tryptamine [3-(2-Aminoethyl) Indole]
 DL-Tryptophan (3 β -Indolylalanine; (+/-)- α -Amino-3-Indolepropionic Acid)
 d-Tubocurarine Chloride
 Tyramine (4-Hydroxyphenethylamine)
 DL-Tyrosine
 Urea (Carbamide)
 Uric Acid
 Vancomycin
 (+/-) Verapamil
 Vincamine
 Xylometazoline
 Yohimbine
 Zearalenone
 Zomepirac
 Zopiclone

SENSITIVITY

1) Known concentrations of drug were added to normal, drug-free urine. Ten (10) determinations were made at each serial dilution of the single analyte. Sensitivity is defined as that concentration which produced positive responses in all 10 replicates.

DRUG	AVERAGE CONCENTRATION (ng/mL)
Amphetamine	1000
Barbiturates	300
Benzodiazepine	300
Cannabinoids	50
Cocaine metabolite	300
Methamphetamine	1000
Opiates, 300 ng/ml	300
Opiates 2000 ng/ml	2000
Phencyclidine	25
Tricyclic Antidepressants	1000

SUMMARY

	Conc. (ng/ml)	Results (+/-10)
Amphetamine	500	0/10
	1000	8/10
	1250	10/10
Phencyclidine	12.5	0/10
	25	10/10
	37.5	10/10
THC	25	0/10
	50	9/10
	62.5	10/10
Cocaine	150	0/10
	300	9/10
	375	10/10
Opiates (300ng)	150	1/10
	300	10/10
	375	10/10
Opiates (2000ng)	1000	0/10
	2000	10/10
	2500	10/10
Barbiturates	150	0/10
	300	10/10
	375	10/10
Benzodiazepines	150	1/10
	300	10/10
	375	10/10
Methamphetamines	500	0/10
	1000	10/10
	1250	10/10
Tricyclic Antidepressants	500	0/10
	1000	9/10
	1250	10/10

No immunoassay that produces a single response in relation to the presence of multiple components in a mixture can reliably quantify the concentration of these components. For example, the **RAPID DRUG SCREEN™** and the **RapidOne™** Barbiturate test detects several barbiturates. Attempts to establish semi-quantitative concentrations with **RAPID DRUG SCREEN™** or **RapidOne™** are not recommended. The sensitivity of this test to detect barbiturates is at an average concentration of 300 ng/mL.

ACCURACY

The **RAPID DRUG SCREEN™** was compared to GC/MS at the claimed cut-off levels. **RAPID DRUG SCREEN™** was proven to correlate greater than 99% with GC/MS at a 95% confidence level.

	RDS Pos/Neg	GC/MS Pos/Neg
Amphetamine	>650 ng/mL 32/0 <650 ng/mL 0/58	40/0
Barbiturates	>150 ng/mL 40/0 <150 ng/mL 0/50	40/0
Benzodiazepine	>160 ng/mL 39/0 <160 ng/mL 0/51	40/0
Cannabinoids	>33 ng/mL 38/0 <33 ng/mL 0/52	40/0
Cocaine	>225 ng/mL 38/0 <225 ng/mL 0/52	40/0
Methamphetamine	>625 ng/mL 40/0 <625 ng/mL 0/50	40/0
Opiates	>225 ng/mL 40/0 <225 ng/mL 0/50	40/0
Phencyclidine	>19 ng/mL 40/0 <19 ng/mL 0/50	40/0
Tricyclic Antidepressants	>1000 ng/mL 40/0 <1000 ng/mL 0/50	40/0*

* Confirmation was done with HPLC.

REPRODUCIBILITY

Reproducibility studies were carried out using commercially available standards. Each standard was diluted in normal, drug-free urine to give the appropriate concentration. Each specimen, at each concentration of analyte, was tested four times daily, in duplicate, for five consecutive days using two different lots of **RAPID DRUG SCREEN™**. Note the following exceptions:

1. Amphetamine was tested with three clinically metabolized amphetamine urine specimens at concentrations determined by GC/MS.
2. Benzodiazepine was tested with three different lots.
3. Tricyclic Antidepressants were tested using positive control urines and negative control urines. Each was tested four times daily, in duplicate, for five days.

Drug	Concentration	#	Results	Precision
Amphetamine	0	40	40 neg	>99%
	1000	40	32 pos	>80%
	1250	40	40 pos	>99%
Barbiturates	0	40	40 neg	>99%
	225	40	40 pos	>99%
	375	40	40 pos	>99%
Benzodiazepine	0	40	40 neg	>99%
	300	40	40 pos	>99%
	360	40	40 pos	>99%
Cannabinoids	0	40	40 neg	>99%
	50	40	40 pos	>99%
	75	40	40 pos	>99%
Cocaine	0	40	40 neg	>99%
	300	40	36 pos	>90%
	375	40	40 pos	>99%
Methamphetamine	0	40	40 neg	>99%
	1000	40	40 pos	>99%
	1250	40	40 pos	>99%
Opiates, 300 ng/ml	0	40	40 neg	>99%
	300	40	40 pos	>99%
	375	40	40 pos	>99%
Phencyclidine	0	40	40 neg	>99%
	25	40	40 pos	>89%
	32	40	40 pos	>99%
Tricyclic Antidepressants	0	40	40 neg	>99%
	1000	40	36 pos	>90%
	1250	40	40 pos	>99%
Opiates, 2000 ng/ml	0	40	40 neg	>99%
	2500	40	40 pos	>99%
	2000	40	40 pos	>99%

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2. R. C. Baselt, *Disposition of Toxic Drugs and Chemicals in Man*, 2nd Ed., Biomedical Publications, Davis Ca., 1982.

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Rapid Tec®

Multiple Dip Stick

Package Insert

The **Rapid Tec** is a one-step, lateral flow immunoassay for the simultaneous detection of up to five abused drug analytes in urine (each analyte is represented by a separate test line in the test window of the dip stick). All configurations of the product are covered by this insert. **Rapid Tec** is intended for use in the qualitative detection of the following drugs of abuse in human urine at the following levels:

Compound	Abbreviation	Level
Amphetamine (d-amphetamine sulfate)	AMP	1000 ng/mL*
Cocaine (benzoylecgonine)	COCAINE	300 ng/mL*
Cannabinoids (11-nor- Δ^9 -THC-9-carboxylic acid)	THC	50 ng/mL*
Methamphetamine ((+/-)-methamphetamine)	METH	1000 ng/mL
Phencyclidine	PCP	25 ng/mL*
Opiates (morphine)	OPIATES	300 ng/mL**
(morphine-3- β -D glucuronide)		2000 ng/mL*
Benzodiazepine (oxazepam)	BZO	300 ng/mL

*Recommended screening cut-off concentrations by the Substance Abuse Mental Health Services Administration (SAMHSA).

** The test for opiates can be provided at either 300 ng/mL or 2000 ng/mL.

Rapid Tec provides only a preliminary analytical test result.

SUMMARY AND EXPLANATION

Rapid Tec is a competitive immunoassay utilizing highly specific reactions between antibodies and antigens for the simultaneous detection of cocaine, opiates, amphetamine, cannabinoids, phencyclidine, and methamphetamines.

The length of time following drug use for which a positive result may occur is dependent upon several factors including frequency and amount of drug, metabolic rate, excretion rate, drug half-life, and the drug user's age, weight, activity and diet.

PRINCIPLES OF THE TEST

Each **Rapid Tec** assay consists of a membrane strip onto which up to five different drug conjugates have been immobilized. The specifically labeled drugs (drug conjugates) compete for antibody binding sites with drugs or metabolites that may be present in the urine specimen. A multiple colloidal gold-labeled antibody complex is dried at one end of the membrane. A control line, comprised of a different antibody/antibody reaction, is present on the membrane strip. The control line is not influenced by the presence or absence of a drug analyte in the urine specimen, and therefore, it should be present in all reactions.

In the absence of any drug in the urine specimen, the colloidal gold-labeled antibody complex moves with the urine by capillary action to contact the immobilized drug conjugate. An antibody-antigen reaction occurs forming visible lines in all 'test' areas. The formation of the control line and visible lines in all test areas indicates the test is negative.

When a drug analyte is present in the urine specimen, the drug or metabolite will compete with the immobilized drug conjugate in the test area for the antibody binding sites on the colloidal gold-labeled antibody complex. If a sufficient amount of drug analyte is present, it will fill all of the available binding sites, thus preventing attachment of the labeled antibody to the drug conjugate. The absence of a visible line adjacent to a particular drug name in the test area is indicative of a positive result for that drug.

REAGENTS AND MATERIALS SUPPLIED

Each **Rapid Tec** kit box contains:

1. Fifty **Rapid Tec** test devices. The test device consists of a dipstick and desiccant in a sealed foil pouch. The dipstick contains one channel for the complete immunoassay for up to 5 different drugs. The channel contains a membrane with two attached absorbent pads and a pad containing the immobilized colloidal gold-labeled antibody complex. The upper pad acts as a reservoir for the specimen after it migrates through the membrane. The test lines contain a carrier-drug conjugate for the individual analytes, dried on the membrane. A control line, containing goat anti-mouse IgG, is placed above the test lines on the membrane.
2. Package insert

WARNINGS AND PRECAUTIONS

For In Vitro Diagnostic Use only

For professional use only

Follow proper handling and disposal procedures because urine specimens are potentially infectious.

Use only the test devices supplied. Avoid cross-contamination of urine specimens by using a new container for each urine specimen.

The foil pouch containing the dipstick must be completely sealed. Do not use if foil pouch seal is not intact.

Prior to use, ensure that the product has not expired by verifying that the date of use is prior to the expiration date embossed on the top of the foil pouch. The expiration date is the first four digits of the number embossed on the pouch. For example, 09/00 means the product expires in September 2000.

STORAGE

The **Rapid Tec** dip stick should be stored at room temperature (15° to 30°C) or refrigerated (4° to 8°C). Allow test device to warm up to room temperature before conducting any testing.

SPECIMEN COLLECTION AND HANDLING

Use fresh urine specimens. Urine specimens do not require any special handling or pre-treatment. It is best to test urine specimens immediately after collection. However, if necessary, urine specimens may be refrigerated at 2° to 8°C for two days or frozen at -20°C or colder for longer periods.

It is essential that none of the urine specimen (or other liquid) contact the test area window of the **Rapid Tec** dipstick.

Handle and dispose of urine specimens as if they were infectious and capable of transmitting infection. Avoid contact with skin.

PROCEDURES

Rapid Tec MULTIPLE DIP STICK PROCEDURE

1. Allow dipstick and urine specimen to warm up to room temperature before conducting any testing.
2. Remove test device from the foil pouch. Do not use if foil pouch seal is not intact. Label test device.
3. Insert the bottom end of the test device into the sample until the sample level is within the blue area on the test device. Do not allow the sample level to go above the blue area.
4. Hold the test device in the sample straight up for seven (7) seconds.
5. Remove the test device from the sample and lay flat. Allow the test to proceed undisturbed until a reddish-purple control line appears and the test background has cleared. The control line [C] is the uppermost line in the test area. Once the control line is visible, the test is ready to be read; typically this occurs in 3-5 minutes.
6. Read results as explained under Interpretation of Results.

Rapid Tec ALTERNATIVE LOW-VOLUME PIPETTE PROCEDURE

1. Allow dipstick and urine specimen to warm up to room temperature before conducting any testing.
2. Remove test device from the foil pouch. Do not use if foil pouch seal is not intact. Label test device.
3. Lay test device flat. You may place absorbent pad under the test device.
4. Apply urine specimen drop-wise to the bottom absorbent end of the test device. Allow each drop to absorb and repeat until approximately 100 microliters (about 2 to 3 drops) have been added.
5. Allow the test to proceed undisturbed until a reddish-purple control line appears and the test background has cleared. The control line [C] is the uppermost line. Once the control line is visible, the test is ready to be read; typically this occurs in 3-5 minutes.

INTERPRETATION OF RESULTS

The control line is the uppermost line appearing in each test area. The test lines may or may not appear below the control line [C]. Each test line will appear adjacent to the drug name on the dipstick.

Once a distinctive reddish-purple control line with a clear background forms, the test may be read.

A **NEGATIVE** result for any single drug is the presence of the reddish-purple control line and a reddish-purple line adjacent to the particular drug without regard to intensity; i.e., a line in the control area and a line adjacent to any particular drug indicate a negative result. The intensity, color and size of the test line(s) are not important.

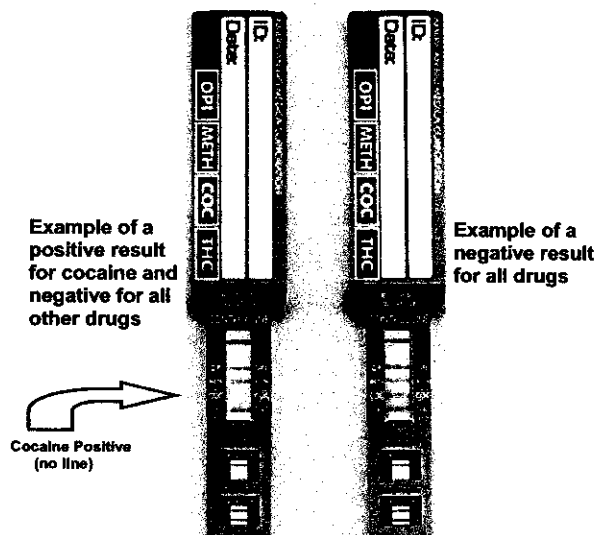
A **POSITIVE** result is the presence of the control line and no line adjacent to the particular drug or drug names.

If no control line appears after approximately 10 minutes, consider the test invalid. The test should be repeated with a new test device.

INTERPRETATION OF RESULTS (Continued)

CONTROL LINE	TEST LINES FOR EACH DRUG	INTERPRETATION
No control line present	No test line present	Invalid test
Control line present	Test line present	Negative
Control line present	No test line present	Positive
No Control line present	Test line present	Invalid test

EXAMPLES OF RESULTS



QUALITY CONTROL

A procedural control (the control line [C]) is built into each dipstick, indicating that the reagents on the device are present and functioning properly. It is also good laboratory practice to use positive and negative controls to ensure proper test performance. Control samples are commercially available. Positive and negative controls should be used prior to using a new lot/shipment of test devices.

Additional controls may be used according to guidelines or requirements of local, state, and/or federal regulations or accrediting organizations.

LIMITATIONS OF PROCEDURE

The assay is designed for use with human urine only.

Rapid Tec provides only a preliminary qualitative test result. Use a more specific alternate quantitative analytical method to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method (1). Apply clinical and professional judgment to any drug of abuse test result, particularly when preliminary positive results are obtained. (2). Other substances and/or factors not listed may interfere with the test and cause erroneous results, such as adulterants, procedural errors or cross reactivity with other drugs or agents. Refer to the Performance Characteristics section for more information. If adulteration is suspected, obtain a fresh urine specimen and repeat testing.

Rapid Tec is not for point of care use.

PERFORMANCE CHARACTERISTICS

SPECIFICITY

Interference and cross reactivity studies were performed by testing the drug analytes in the Rapid Tec device with various other drugs. Below is the list of drugs that will give a positive result at or above the concentration stated. All of the following drugs were added to normal, drug-free urine. Note: The drugs listed are positive for only the drug test specified.

DRUG TEST	CONCENTRATION (ng/mL)
Amphetamine	
d-amphetamine	1,000
d, l-amphetamine	1,000
l-amphetamine	20,000
Phentermine (α, α -Dimethylphenethylamine)	1,250
(+/-) Methyleneoxyamphetamine (MDA)	750
Benzodiazepines	
Alprazolam	75
Bromazepam	400
Chlordiazepoxide	150
Clobazam	100
Clonazepam	300
Desmethyldiazepam	100
Diazepam	100
Estazolam	500
Flunitrazepam	150
(+/-) Lorazepam	2,200
Lormetazepam	500
Nitrazepam	75
Nordiazepam	150
Oxazepam	300
Sulindac	7,500
Temazepam	100
Triazolam	1,500
Methamphetamine	
(+/-) 3,4-Methylenedioxy-n-ethylamphetamine (MDEA)	20,000
Procaine (Novocaine)	60,000
Trimethobenzamide	20,000
+/- methamphetamine	1,000
+ methamphetamine	500
Ranitidine (Zantac)	50,000
(+/-) 3,4-Methylenedioxymethamphetamine (MDMA)	1,000
Cannabinoids (Tetrahydrocannabinol, THC)	
11-Hydroxy- Δ^9 -Tetrahydrocannabinol	5,000
11-Nor- Δ^8 -Tetrahydrocannabinol-9 Carboxylic Acid	50
11-Nor- Δ^9 -Tetrahydrocannabinol-9 Carboxylic Acid	50
Δ^8 -Tetrahydrocannabinol	20,000
Δ^9 -Tetrahydrocannabinol	20,000
Cocaine metabolite	
Benzoylcegonine	300
Cocacethylene	300
Cocaine (Ecgonine Methyl Ester Benzoate)	100
Metoclopramide	80,000
Procaine (Novocaine)	75,000
Opiate 300 ng/mL	
6-Acetylmorphine	500
Codeine	100
Eserine (Physostigmine)	15,000
Ethylmorphine	100
Heroin (Diacetylmorphine)	500
Hydromorphone	2,000
Hydrocodone	1,250
Morphine	250
Morphine-3- β -D-Glucuronide	75
Nalorphine	500
Norcodeine	35,000
Oxycodone	75,000
Thebaine (Paramorphine)	13,000
Opiate 2000 ng/mL	
6-Acetylmorphine	1,000
Codeine	800
Ethylmorphine	400
Heroin (Diacetylmorphine)	10,000
Hydromorphone	2,000
Hydrocodone	5,000
Morphine	1,600
Morphine-3-b-D-Glucuronide	2,000
Oxycodone	50,000
Thebaine (Paramorphine)	26,000
Phencyclidine (PCP)	
Phencyclidine	25
4-Hydroxy phencyclidine	90
Phencyclidine Morpholine	625

Rapid Tec PCP also detects high concentrations of the cough suppressant, dextromethorphan. In young children, dextromethorphan overdoses may produce a positive result for PCP. However, adults ingesting therapeutic dosages of dextromethorphan should not produce a positive result.

The following drugs are not detected by Rapid Tec at concentrations less than 100,000 ng/mL unless otherwise specified by asterisk:

Acetabutole	Chlorpromazine	Fluphenazine	Methyl Salicylate
Acetaldehyde	Chlorpropamide	Flurandrenolide	Methyl Viologen (Gramoxone; Paraquat Dichloride)
Acetaminophen (4-Acetamidophenol; N-Acetyl-p-aminophenol)	Chlorprothixene	Flurazepam	Metricrane
Acetazolamide	Chlorthalidone	Flurbiprofen	(+/-)Metoprolol
Acetone	Chlorzoxazone (5-Chloro-2-Hydroxybenzoxazole)	Formaldehyde	Metronidazole
3-(α -acetylbenzyl)-4-hydroxycoumarin (Warfarin)	Cholesterol	Furosemide	Mianserin
Acetophenetidin	Cimetidine	Gemfibrozil	Mikronone
Acetopromazine	Cinchonidine	Gentamicin Sulfate	Minaprine
N-Acetyl-L-cysteine	Cinoxacin	Glucoside	Nabumetone
N-Acetylprocainamide (Acetaminide)	Clemastine	(D)(+)-Glucose(Dextrose)	Nadolol
Acetylsalicylic Acid (Aspirin; 2-Acetoxybenzoic Acid)	Clenbuterol	Glybenclamide	Nafclillin
Albumin, standard	Clindamycin	Griseofulvin	Nalbuphine
Alfupurinol (4-Hydroxypyrazole (3,4-) pyrimidine)	Clobetasone Butyrate	Guaiacol Glyceryl Ether	Nalidixic Acid
Alprenolol	Clomipramine	Guanethidine	Nalmefene
Amantadine (Adamantan-1-amine)	Clonidine	Halcinonide	Naloxone
Amcinonide	Cloxacillin	Haloperidol	Naltrexone
(+) Amethopterin (4-Amino-10-methylfolic acid; Methotrexate; Methyaminopterin)	Clozapine	Hemoglobin	Naphazoline
Amikacin	Colchicine	Hexachlorocyclohexane	α -Naphthalene Acetic Acid
Amiloride	Cortisone	Hexachlorophene	β -Naphthalene Acetic Acid
p-Aminobenzoic Acid	β -Cortol	Hexobarbital	α -Naphthol
DL-Aminoglutethimide	(-)-Cotinine	Hippuric Acid	Neomycin Sulfate
Amiodarone	Creatinine	Histamine[2 (4-Imidazole) Ethylamine]	Niacinamide
Amitypyline	Cromolyn (Cromoglycic Acid)	DL-Homatropine	Nialamide
Ammonium Chloride	Cyclobenzaprine	Hydralazine (1-Hydrazinophthalazine)	(+/-) Nicotine
Amobarbital (Amytal; 5-Ethyl-5-isoamylbarbituric Acid)	Cyclophosphamide	(1S,9R)- β -Hydrastine	Nicotinic Acid (Niacin)
Amoxicillin	Cyclosporin A	Hydrochlorothiazide	Nifedipine
Amphotericin B	Cyproheptadine	Hydrocortisone	Nitrofurantoin
Ampicillin	Dantrolene	Hydroflumethiazide	Normifensine
D-Amygdalin	Deferoxamine Mesylate (Deferrioxamine Mesylate)	Hydroxocobalamin	Norclonipramine
Aniline	Desoxyepinephrine	O-Hydroxyhippuric Acid	Norcocaine
Antipyrine (Phenazone)	R-(-)-Deprenyl (Selegiline)	5-Hydroxyindole-3-Acetic Acid	Nordoxepin
Apomorphine	Desipramine	5-Hydroxy-2-indole-2-Carboxylic Acid	Norethindrone
Aprobarbital	N-Desmethyldoxapine (Normethyldoxapine)	4-Hydroxy-3-Methoxyphenylacetic Acid	Nortifloxacin
(-) Arteranol [(+)-Norepinephrine]	Desoximetazone	(Homovanillic Acid)	DL-Normetanephrine
L-Ascorbic Acid	Dexamethasone	5-Hydroxytryptamine (Serotonin)	Normorphine
ASP-PHE-Methyl-Ester (Aspartame)	Dextromethorphan	3-Hydroxytyramine	d-Norpropoxyphene
D-Aspartic Acid	4,4'-Diaminophenyl Sulfone (Dapsone)	Hydroxyzine (Atarax)	Nortriptyline
DL-Aspartic Acid	Diazoxide	L-Hyoscyamine	Noscapine
L-Aspartic Acid	Dichloromethane (Methylene Chloride)	Isoproterenol	Nydrin
Astemizole	Dichlorphenamide	Imipramine	Orotic Acid (Uracil-6-Carboxylic Acid)
Atenolol	Diclofenac	Indapamide	Orphenadrine
Atropine (Tropine tropate)	Dicyclomine	Indole-3-Acetic acid	Oxalic Acid (Ethanedioic Acid)
Azathioprine	Dietlin	Indole-3-Butyric Acid	Oxolinic Acid
Baclofen	Diethylthiocarbamic Acid	DL-Indole-3-Lactic Acid	Oxprenolol
Barbital (Barbitone; 5,5-Diethylbarbituric Acid; Veronal)	N,N-Diethylnicotinamide (Niacin Diethylamide; Nikethamide)	Indomethacin	Oxybutyrim Chloride
Barbituric Acid (2,4,6-Trihydroxypyrimidine; Malonylurea)	Diflurasone Diacetate	Ipratropium Bromide	Oxymetazoline
Beclomethasone	Difluorotolone pivalate	Iproniazid	Oxyphenbutazone
Beclomethasone Dipropionate	Diflunisal	Isonicotinic Acid (Pyridine-4-Carboxylic Acid)	Oxypurinol
Bendroflumethiazide	Digoxin	Isonicotinic Acid Hydrazide	Pacitaxel
Benzydine (4,4 Diaminobiphenyl)	Digoxin (12 β -Hydroxydigoxin)	Isopropamide	Parcuronium Bromide
Benzilic Acid β -diethylaminoethyl ester	DL-3,4 Dihydroxymandelic Acid	(+)-Isoproterenol	Papaverine
Benzocaine (Ethyl-p-Aminobenzoate)	DL-3,4 Dihydroxyphenyl Glycol	(-)-Isoproterenol	Pargyline
Benzoic Acid	3,4 Dihydroxyphenylacetic Acid	(+/-)-Isoproterenol	Penicillin G (Benzylpenicillin)
Benzophetamine (α -dimethylphenethylamine)	7-(2,3-Dihydroxypropyl) Theophylline (Dyphylline)	Isoxsuprine	Pentachlorophenol
Benzthiazide	Dimenhydrinate	Kanamycin	Penicillin V
BenztropineMethanesulfonate (Benztropine Mesylate)	Dimercaprol (2,3-Dimercaptopropanol)	Ketamine	Pentoxifylline (Trental)
Benzyl alcohol	4-Dimethylaminoantipyrine (Aminopyrine)	Ketoprofen	Pentylene tetrazole
Benzylamine	1,1-Dimethylbiguanide (Metformin)	Kynurenic Acid	p-Phenylenediamine
Berberine	Dimethyl Isosorbide	Labetalol	Phenelzine
Betamethasone	Dimethyl Sulfoxide (DMSO)	Levorphanol	Phenformin
Bilirubin	1,3-Dimethyluric Acid	Lidocaine	Pheniramine
Bisacodyl	1,7-Dimethylxanthine	Lisinopril	Phenobarbital
2-Bromo- α -ergocryptine (Bromocryptine mesylate)	Diphenhydramine	Lithium Carbonate	Phenol
(+)-Brompheniramine (Dexbrompheniramine)	Dipyridamole	Loperamide	Phenolphthaleine
(+/-)-Brompheniramine	Dipyrrone	Lysergic Acid Diethylamide (LSD)	Phenothiazine (Thiodiphenylamine)
Bumetanide	Disopyramide	Mebedazole	Phenoxymethylpenicillin acid (Penicillin V)
Bupivacaine	Dobutamine	Medicine	Phentemine
Buprenorphine	Doxepin	Medofenamic Acid	Phentolamine
Bupropione	Doxycycline	Medazepam	DL-Phenylalanine
Butacaine	Doxylamine	Metenamic Acid	L-Phenylalanine
Butabarbital	Droperidol	Melanin	Phenylbutazone
Butalbital	Ecgonine	Melphalan	L-Phenylephrine
Butethal	Ecgonine Methyl Ester	(-)-Menthhol	(+/-)- α -Phenylethylamine (α -Methylbenzylamine)
2-Butynoic Acid Ethyl Ester (Ethyl-2- Butynoate)	Emetine	Meperidine	β -Phenylethylamine
Butyropheneone	(-)- ψ -Ephedrine	Mephensesin	(R)-(+)- α -Phenylethylamine
Caffeine (1,3,7-Trimethylxanthine)	(+)- ψ -Ephedrine	Mephentermine	(+/-)-Phenylpropanolamine (PPA)
(+/-) Camphor	(+/-)Ephedrine	Meprobamate	Phenyltoloxamine
Cannabidiol	(-)-Epinephrine	6-Mercaptopurine	Phthalic acid (1,2-Benzenedicarboxylic Acid)
Cannabinol	(+/-)Epinephrine	Mersalyl Acid	Picrotoxin
Canrenoic Acid	Erythromycin	Mescaline (3,4,5-Trimethoxyphenethylamine)	Pilocarpine
Captopril	β -Estradiol	DL-Metanephrine	Pimozide
Carbamazepine	Estradiol	Metaprotenerol	Pinacidil
Carbamyl- β -methylcholine-chloride (Bethanechol Chloride)	Estrone	Metaraminol[(-)-m-Hydroxyphenylpropanolamine]	Pindolol
Carboplatin	Estrone- β -D-Glucuronide	(+/-)Methadone	L-Pipecolic Acid
(S)-(-)-Carbidopa	Estrone-3-Sulfate	Methanol, Absolute	Pipemidic Acid
Carisoprodol	Ethacrynic Acid	Methaqualone	Piroxicam
Cefaclor	Ethambutol	Methazolamide	Potassium Chloride
Cafadroxil	Ethamivan (N,N-Diethylvanillamide)	Methotrimoprazine	Potassium Iodide
Cefotaxime	Ethanol, Standard	Methoxamine	Prazepam
Cefoxitin	Ethopropazine	Methoxyamine	Prazosin
Ceftriaxone	Ethosuximide(2-Ethyl-2-Methylsuccinimide)	Acetic Acid (+) Naproxen	Prednisolone (1-Dehydrocortisol)
Cefuroxime	2-Ethyl-2-Phenylmalonamide	(S)-6-Methoxy- α -Methyl-2-Naphthalene	Prednisone (Dehydrocortisone)
Cephalexin	Ethylene Glycol	Acetic Acid (-) Naproxen	5-Pregnen-3 β -OL-20-one (Epipregnanolone; Pregnenolone)
Cephadrine (Cefradin)	Ethylene Diaminetetraacetic Acid (EDTA)	Methoxyphenamine	Prilocaine
α -Chloralose	17- α -Ethinylestradiol	5-Methoxytryptamine (Methoxamine; O-Methylserotonin)	Primaquine
Chloramphenicol (Chloramycetin)	Etodolac	3-Methoxytyramine	Primidone (2-Desoxyphenobarbital)
Chlorcyclizine	Etoposide	2-Methyl-3-(3,4-Dihydroxyphenyl)-DL-Alanine	Proadifen
2-(p-Chlorophenoxy)-2-Methylpropionic Acid	Famotidine	2-Methyl-3-(3,4-Dihydroxyphenyl)-L-Alanine	Probenecid[p-(Dipropylsulfamoyl) Benzoic Acid]
Ethyl Ester (Clobetate)	Fenfluramine	6- α -Methyl-17- α -Hydroxyprogesterone (Medroxyprogesterone)	Procainamide
Chloroquine	Fenpropfen [(+/-)-2-(3-Phenoxyphenyl) Propionic Acid]	Methylene Blue	Prochlorperazine
Chlorothiazide	Fentanyl (10 ug/mL)*	1-Methylhistamine	Procyclidine
Chlorotrianisene	Ferrous Sulfate	Methylphenidate (Ritalin)	Promazine
(+)-Chlorpheniramine	Flufenamic Acid	6- α -Methylprednisolone (Medrol)	Promethazine
(+/-)Chlorpheniramine	Flunisolide		Propionylpromazine

Drugs not detected by Rapid Tec (continued)

Pyridine-2-Aldoxime Methochloride (*Pralidoxime Chloride*)
 Pyridoxine
 Pyrilamine (*Mepyramine*)
 Quinidine
 Quinine
 Quinolinic Acid (2,3-Pyridinedicarboxylic Acid)
 Rescinamine
 Reserpine
 Riboflavin
 Ritodrine
 Salbutamol (*Albuterol*)
 Salicylamide (2-Hydroxybenzamide)
 Salicylic Acid (2-Hydroxybenzoic Acid)
 (-) Scopolamine (*Hyoscyne*)
 Secobarbital (*Quinalbarbitone*)
 Sodium Chloride
 Sodium Formate
 (+/-)Sotalol
 Strychnine
 Succinylcholine Chloride
 Sulfamethazine
 Sulfamethoxazole
 Sulfanilamide (*p-Aminobenzenesulfonamide*)
 Sulfathiazole
 Sulfisoxazole
 (+/-)Sulpiride
 Suxibuzone
 Talbutal
 Tamoxifen
 Tannic Acid
 Tenoxicam
 Terbutaline
 Terfenadine
 Tetracycline
 Tetraethylthiuram disulfide (*Disulfiram*)
 Tetrahydrozoline
 Theobromine (3,7-Dimethylxanthine)
 Theophylline (1,3-Dimethylxanthine)
 Thiamine (*Aneurine*)
 Thimerosal (*Sodium Ethylmercurithiosalicylate*)
 Thioridazine
 cis-Thiothixene
 Thymol (5-Methyl-2-Isopropylphenol)
 Timolol
 Tobramycin
 Tolazamide
 Tolbutamide
 Tolmetin
 Toluene
 Trans-2-Phenylcyclopropylamine (*Tranylcypromine*)
 Trazodone
 Triamcinolone (*Fluoxyprednisolone*)
 Triamterene
 Trichloromethiazide
 Trichloroacetic acid
 2,2,2 Trichloroethanol
 Trifluoperazine
 Trifluoromazine
 DL-Trihexyphenidyl
 Trimethobenzamide
 Trimethoprim
 3,5,5-Trimethyloxazolidine-2,4-dione (*Trimethadione*)
 Trimipramine
 Triprolidine
 DL-Tropic Acid
 Tropine
 Tryptamine[3-(2-Aminoethyl) Indole]
 DL-Tryptophan (3 β -Indolylalanine; (+/-)- α -Amino-3-Indolepropionic Acid)
 d-Tubocurarine Chloride
 Tyramine (4-Hydroxyphenethylamine)
 DL-Tyrosine
 Urea (Carbamide)
 Uric Acid
 Vancomycin
 (+/-)Verapamil
 Vincamine
 Xylometazoline
 Yohimbine
 Zearalenone
 Zomepirac
 Zopiclone

SENSITIVITY

1) Known concentrations of drug were added to normal, drug-free urine. Ten (10) determinations were made at each serial dilution of the single analyte. Sensitivity is defined as that concentration which produced positive responses in all 10 replicates.

DRUG	AVERAGE CONCENTRATION (ng/mL)
Amphetamine	1000
Benzodiazepines	300
Cannabinoids	50
Cocaine metabolite	300
Methamphetamine	1000
Opiates, 300 ng/mL	300
Opiates, 2000 ng/mL	2000
Phencyclidine	25

SUMMARY

	Conc. (ng/mL)	Results (+/-10)
Amphetamine	500	6/10
	1000	10/10
	1250	10/10
Benzodiazepines	150	1/10
	300	10/10
	375	10/10
Phencyclidine	13	5/10
	25	10/10
	37	10/10
THC	25	0/10
	50	10/10
	75	10/10
Cocaine	150	8/10
	300	10/10
	375	10/10
Opiates (300 ng)	150	7/10
	300	10/10
	375	10/10
Opiates (2000 ng)	1000	7/10
	2000	10/10
	2500	10/10
Methamphetamines	500	3/10
	1000	10/10
	1250	10/10

No immunoassay that produces a single response in relation to the presence of multiple components in a mixture can reliably quantify the concentration of these components. Attempts to establish semi-quantitative concentrations with Rapid Tec are not recommended.

ACCURACY

The Rapid Tec was compared to GC/MS at the claimed cut-off levels. Rapid Tec was proven to correlate greater than 99% with GC/MS at a 95% confidence level.

	RDS Pos/Neg	GC/MS Pos/Neg
Amphetamine		
>504 ng/mL	37/0	37/0
<504 ng/mL	0/53	
Benzodiazepines		
>160 ng/mL	39/0	40/0
<160 ng/mL	0/51	
Cannabinoids		
>35 ng/mL	38/0	38/0
<35 ng/mL	0/52	
Cocaine		
>172 ng/mL	39/0	39/0
<172 ng/mL	0/51	
Methamphetamine		
>514 ng/mL	34/0	35/0
<514 ng/mL	0/56	
Opiates, 300 ng/mL		
>150 ng/mL	39/0	39/0
<150 ng/mL	0/51	
Opiates, 2000 ng/mL		
>710 ng/mL	33/0	33/0
<710 ng/mL	0/57	
Phencyclidine		
>20 ng/mL	35/0	35/0
<20 ng/mL	0/50	0/50

REPRODUCIBILITY

Reproducibility studies were carried out using commercially available standards. Each standard was diluted in normal, drug-free urine to give the appropriate concentration. Each specimen, at each concentration of analyte, was tested four times twice daily for five days.

Drug	Concentration	#	Results	Precision
Amphetamine	0	40	40 neg	>99%
	1000	40	40 pos	>99%
	1250	40	40 pos	>99%
Benzodiazepines	0	40	40 neg	>99%
	300	40	40 pos	>99%
	360	40	40 pos	>99%
Cannabinoids	0	40	40 neg	>99%
	50	40	40 pos	>99%
	75	40	40 pos	>99%
Cocaine	0	40	40 neg	>99%
	300	40	40 pos	>99%
	375	40	40 pos	>99%
Methamphetamine	0	40	40 neg	>99%
	1000	40	40 pos	>99%
	1250	40	40 pos	>99%
Opiates, 300 ng/mL	0	40	40 neg	>99%
	300	40	40 pos	>99%
	375	40	40 pos	>99%
Opiates, 2000 ng/mL	0	40	40 neg	>99%
	2000	40	40 pos	>99%
	2500	40	40 pos	>99%
Phencyclidine	0	40	40 neg	>99%
	25	40	40 pos	>99%
	38	40	40 pos	>99%

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Rapid Alco-Tec™

Two Minute Saliva Test for Blood Alcohol

INTENDED USE

Rapid Alco-TEC saliva alcohol test is intended for use as a rapid, non-invasive and highly selective method to detect the presence of alcohol in saliva. It provides a semi-quantitative estimation of blood alcohol concentration. It is a screening test only. A positive Rapid Alco-TEC result must be verified by an accepted quantitative alcohol test such as gas chromatography. It requires no instrumentation and special training except the careful following of instructions.

SUMMARY

Alcohol may be categorized as the oldest drug known to man and has played a prominent role in every culture of the world. At the same time excessive consumption of alcohol has contributed to many social ills such as road accidents, anti social behavior and medical conditions such as multiple trauma, metabolic disturbances and coma.

Alcohol diffuses rapidly throughout the organism due to its high solubility in water and lipids. Therefore, it can be, and has been determined in every type of biological fluids: blood, urine, saliva, breath, etc. Alcohol testing in these fluids depends upon the circumstances and settings of the individuals. The blood alcohol concentration (BAC) at which a person's mental status is altered depends upon age, gender, physical size, weight, activity etc. The BAC has been correlated with alcohol concentrations in other fluids and many types of detection devices are in use. It has been well documented that alcohol saliva levels has a high correlation with blood plasma/serum alcohol concentration (1, 2, and 3).

TEST PRINCIPLE

Rapid Alco-TEC alcohol test employs a sequential enzymatic reaction to detect presence of alcohol in saliva. The detection reagents are immobilized in a small square pad. When the pad comes into contact with the alcohol containing liquid, it changes colors from beige to green to

blue to brown depending upon the alcohol concentration of the sample. The alcohol concentration can be estimated by comparing the color developed on the pad with the color block printed on the color chart.

TEST COMPOSITION (per test unit)

Alcohol Oxidase (EC 1.1.3.1.3) 0.35 IU
Peroxidase (EC 1.11.1.7) 15.5 IU
Buffer 0.8 mg
Stabilizers 2.8mg
Tetramethylbenzidine 0.05 mg

STORAGE AND STABILITY

Rapid Alco-TEC should be stored at room temperature between 15-30°C (59-86°F). If the product has been kept in the refrigerator, it should be brought back to room temperature prior to opening the package.

REAGENTS AND MATERIALS SUPPLIED

Rapid Alco-TEC test consists of a plastic strip with a reactive pad glued to the tip. It is contained in a package with a desiccant and a color chart printed on the outside.

TEST PROCEDURE

1. Do not allow the donor to ingest any food, non-alcoholic beverages, mouthwash, cough syrup, breath spray, or chewing tobacco for 15 minutes prior to the test.
2. Open the foil package and remove the test strip. The original base color of the reagent pad is beige. If the pad appears discolored (dark edges), use another strip.
3. Saturate the reactive pad with saliva by inserting into the donor's mouth or insert it into a sputum cup containing the saliva. Start timer.
4. Observe the color change (if any) exactly at 2 minutes. The color development on the pad indicates the presence of alcohol in the sample. Estimate the alcohol concentration by comparing

the color of the reagent pad against the color blocks on the color chart printed on the package. Semi-quantitative estimation of alcohol concentration will be erroneous if the results are read before or after 2 minutes.

INTERPRETATION OF RESULTS

Rapid Alco-TEC reagent pad reacts with alcohol in the test sample. The color blocks, indicating different concentrations of alcohol from negative to 0.3%, are printed on the package. If the color developed on the reagent pad falls between two adjacent color blocks, then approximate the alcohol concentration between the values of the adjacent color blocks.

QUALITY CONTROL

The integrity of Rapid Alco-TEC may be qualitatively verified by using a test solution prepared by adding 5 drops 80 proof distilled spirits to 8 ounce (1 glass) of water. This solution should provide a color reaction equal to or higher (darker) than the 0.04% color block. Alternatively, if the strip is dipped in beer, a dark blue color develops immediately and turns dark brown. The reaction of Rapid Alco-TEC with alcohol in saliva is somewhat slower and less intense than with alcohol in aqueous solution.

LIMITATIONS

The results should be read at exactly two minutes after saturating the reactive pad with saliva. Reading before or after 2 minutes may give erroneous semi-quantitative estimation because Rapid Alco-TEC is an enzymatic reaction.

Rapid Alco-TEC is sensitive to interfering substances such as food, drinks, mouthwash, cough syrup, breath spray, chewing tobacco etc that may be put in the mouth. Therefore the testing process should be conducted at least 15 minutes after ingestion of anything by mouth.

Rapid Alco-TEC may be used to detect the presence of alcohol in fluids other than saliva. However, when used in this manner, the color chart in this package does not apply. If alcohol is present in any fluid, a color change ranging from light green to dark brown or black will develop on the reagent pad depending upon the alcohol concentration in the fluid.

PERFORMANCE CHARACTERISTICS

Specificity

Rapid Alco-TEC reacts with primary alcohols (methanol, ethanol) and the reactivity decreases with increasing chain length. It does not react with secondary and branched chain alcohols (rubbing alcohol), or ethylene glycol to any appreciable extent.

Interferences

Production of false positive and false negative may occur with interferents such as color enhancing agents (oxidizers), color inhibiting agents (reducing agents such as ascorbic acid, oxalic acid, uric acid) and bilirubin, L-dopa and L-methyl dopa when present in the sample. Since saliva contains no such substances in appreciable quantities, interference is negligible. However, it should be ascertained that such substances are not taken in the mouth before conducting the test.

BIBLIOGRAPHY

1. McColl K.E.L., Whiting B, Moore MR, Goldberg A, Clin. Sci., 56,283-286, 1979
2. Porter WH, in Tietz Textbook of Clinical Chemistry, 3rd edition, CA Burtis and ER Ashwood editors, WB Saunders company pp 906, 1999
3. Jones AW, J. Anal. Toxicol., 19, 169-174, 1995

Manufactured for:

American Bio Medica Corporation
800-227-1243

By: ChemProbe, Inc.

888 E. Belvidere Road
Grayslake, IL 60030

A simple 2 minute saliva test for the estimation of blood alcohol levels

Rapid Alco-TEC™

Instructions:

Do not place anything in mouth for 15 minutes prior to conducting test.

1. Saturate the test pad at the end of the strip with saliva.
2. Hold the strip for 2 minutes in horizontal position with pad facing up.
3. Compare color developed color on the pad to the color block below to estimate alcohol level.

Store at 15 - 30 °C (59 - 86 °F)

Any decision based on the results of this test will be the sole responsibility of the user.

The color chart below is not applicable for detecting alcohol in fluids other than saliva. Please contact the manufacturer for more information.

Interpretation:

NEGATIVE No color development on pad

POSITIVE Color develops on pad within 2 minutes.

American Bio Medica
Corporation
122 Smith Road
Kinderhook, NY 12106



0.02%



0.04%



0.08%



0.30%



Lot No

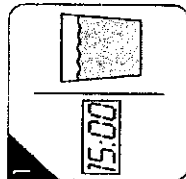
Exp. Date

Made and Printed in U.S.A.

BreathScan®

ALCOHOL DETECTOR

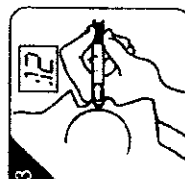
INSTRUCTIONS



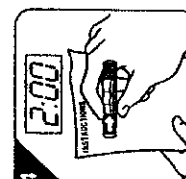
1. Wait 15 minutes after last alcoholic drink (alcohol takes about 15 minutes to have an effect on your system) OR drink a glass of water before taking the test



2. Squeeze middle of the outer plastic tube between thumb and forefinger to break inner glass ampule containing yellow crystals. SQUEEZE ONLY ONCE. DO NOT CRUSH OR BEND TUBE. Use tester immediately



3. Take a deep breath and blow, in one continuous breath, for 12 seconds through the end of the tube designated by arrow. BLOW VERY HARD. EXHALE THROUGH THE TUBE. DO NOT INHALE. Shake tester to distribute crystals evenly, wait two minutes. Identify color change of majority of crystals.



4. The crystals in the .02 tester will become white or ash at an alcohol level of .02 or greater. Testers measuring for .04 or higher will develop a aqua (bluish green/greenish blue) cast at levels at or above the level designated by the tester. For best results compare to unused tester.

BREATHSCAN® Alcohol detector is available in several configurations. Check your *BreathScan®* tester for its configuration. It is indicated by a specific fraction of a percentage point such as .02%, .04% etc. on the left side of the tester. Check the legal limit for intoxication in your state.

Note: Accuracy of test results may not be reliable if test is not conducted according to instructions

BreathScan®

ALCOHOL DETECTOR

BreathScan® brand detector is a disposable breath alcohol indicator designed for one-time use. The BreathScan® detector contains indicator chemistry which will undergo a color change in the presence of alcohol contained in the breath of the subject. This product provides a reliable indication of alcohol present in the exhaled breath of the test subject when the instructions for use of the BreathScan® indicator are rigidly followed. The manufacturers, suppliers, agents, distributors and retailers make no warranty, expressed or implied, as to the ability of this device to determine or detect intoxication of the subject or to accurately indicate the subject's blood alcohol level. Decisions and/or actions based on the use of this product by any person shall be at such person's own risk. The manufacturers, suppliers, agents, distributors and retailers assume no responsibility for consequences of subjects who test negative using this device but who later show that they are under the influence of or their judgment has been impaired by alcohol.

WARNING: This product should be used only as a screening device and is only an indication of the possible presence of alcohol in the blood of the test subject. Correlation between breath alcohol content and blood alcohol content depends on many variables, including altitude. The exact concentration of alcohol in the blood of the test subject

cannot be accurately determined by using this device.

This device is not intended to legally determine blood alcohol presence or level. No inference of intoxication is to be made from a positive indication. *BreathScan®* is guaranteed to be free from manufacturer's defects. This warranty is expressly made in lieu of any and all other warranties expressed or implied including the warranties of merchantability and fitness for a particular purpose or use. There are no warranties expressed beyond the description of the product contained on this package. The warrantor expressly disclaims liability for incidental, special, or consequential damages of any nature.

Use immediately after breaking glass vessel. Do not use if glass vessel containing crystals is ruptured prematurely or if crystals are not yellow.

Store at room temperature.

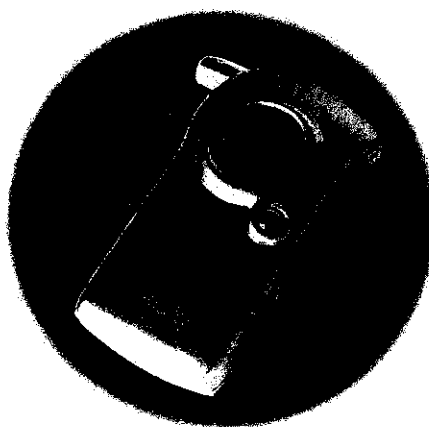
Keep out of reach of children.
Do not immerse in liquid.

DO NOT INGEST.

If ingested, induce vomiting and contact your physician.

BreathScan® is a registered trademark of WNCX, Inc.
Patented under U.S. Patent #4,740,475
MADE IN U.S.A.

Alcohol Detector (CA 2000™)



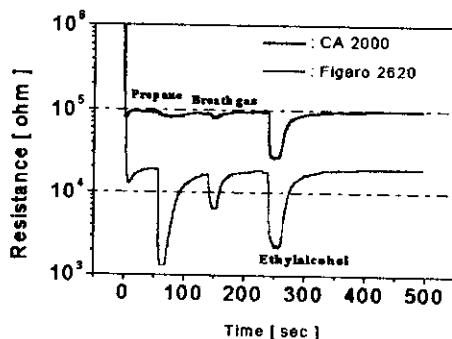
By GRIMEXTUR,LDA.

CA 2000™**HIGHLY RELIABLE, ACCURATE & QUICK
BREATH ALCOHOL ANALYZER****● PRODUCT SYNOPSIS**

CA 2000 is an unique & highly-sophisticated alcohol analyzer utilizing the variation of electrical property value of the oxide-semiconductor when the alcohol substance is detected. And, with the development of new ceramic material combined with relevant catalyst, it can selectively analyze the alcohol concentration to the ppm unit existing in the human breath. Our laboratory made it in developing the highly-selective semi-conductive sensor (**CA2000**) reactive to alcohol substance only, which can be differentiated from the other semi-conductive sensor products (which are often affected by the other substances like smokes and smells of food). Furthermore, it did improve to the large extent the standby, response & recovery time which could be crucial in measuring gas concentration.

- Detection mechanism of our unique semi-conductive sensor

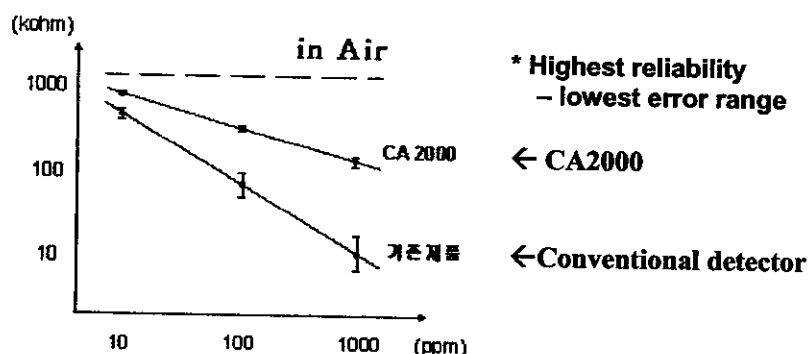
When the oxide having the property of n-type conductivity is open to the atmosphere, it decreases the number of electron affecting on electrical property by the adsorbed oxygen and results in increasing the resistance. And, afterwards, if the specific gas (reducing gas) exists in the atmosphere, it reacts with the adsorbed oxygen and increase the electron in the oxide, resulting in decreasing the resistance. So to speak, the electrical property of the oxide is getting changed when a specific gas is exposed from the outside and our sensor can analyze the gas concentration from the variation of quantity.



*** Highly selective semi-conductive sensor**

← CA2000

← Conventional detector



● FEATURES

1) **Highly reliable accuracy by the most sophisticated sensor**

CA 2000 adopts a highly-selective semiconductor sensor (reactive to only alcohol substance) designed by KAIST (Korea Advanced Institute of Science and Technology). CA 2000 is a unique breath tester adopting this most sophisticated technology of sensor.

2) **Stable testing data**

It allows you to get stable data for successive testing.

3) **Digital type** ; It displays by 3 digits (0.xx% BAC/BRAC).

4) **Wide detection range** : 0.00 ~ 0.40% BAC or 0.00 ~ 2.00 BRAC.

5) **Long-term stability**

CA 2000 can analyze very precisely even after long time of uses.

6) **Compact & light weight hand-held device**

7) **Short warm-up & response Time**

After power on, less than 20sec. of warming up countdown (200 to 000) is needed to make it ready for testing. And, exhaling just for a few seconds will reach you to instantly read the testing numeric digits.

8) **Longer life time** : 3,000 times testing

9) **Quick Recovery Time**

The sensor of CA 2000 can be purged in 30seconds for another time of testing. You don't need to be too patient to do consecutive testing.

10) **Power**

9V Alkaline battery & one cigar Jack DC adapter included

11) **Sanitary Testing**

CA 2000 includes 5pcs of mouthpiece for sanitary direct testing.

12) **Alarm Sound**

If you are out of legal limit range, alarm sound will be automatically beeping. It could be customized depending on the countries.

13) **Compact design and elegant outlook**

● HOW-TO-USE

1) Turn on the PWR On/Off switch

- Soon after the power on, CA 2000 will start the countdown 200 to 000 on the display window. - It is a "Warm-up" process to make the sensor and circuit be ready for testing.

2) When you hear beep sound & green lighting is on **READY**, please blow into for 3.5 seconds till you would hear another time of "Beep" sound.

N.B. : 1. In this stage, if you don't blow within 30 seconds, it automatically shows OFF display for turn-off
2. In case you drink quite a little (if actual concentration would be below 0.01%BAC/0.05mg/l)

BRAC), it may not be activated. However, it shows still 0.00% and you're said to be in safe range.

- 3) Then, after 3.5 seconds while both READY and WARN lamps are flickering, the test result (BAC or BRAC) will be displayed by 3 digits for 15 seconds.

N.B. : 1. If the BAC / BRAC data would be over 0.05% / 0.25 mg/l (default setting) respectively, red **WARN** lamp will be flickering along with "Alarm" sound.

2. The "Alarm" level is adjustable pursuant to the local legal limit.

- 4) Finally, it shows "OFF" for turn-off.

- 5) For the successive testing, try again from No.1 to No. 3.

● To get more accurate testing data

- After drinking, it is recommended to test after 30 min.

It is because it takes 30 min. approximately for alcohol to be absorbed into blood from the digestive organs. And residual alcohol remaining in the mouth may cause inaccurate data.

- To avoid testing under strong wind or in the closed room with contaminated air.
- When the "BAT LOW" lamp is lighting on, it's advisable to replace 9V alkaline battery.
- To attain more accurate data, please repeat testing about 3 times.

● TECHNICAL SPECIFICATION

Size	120 x 60 x 25 mm
Weight	135 grams including battery
Housing	Shock resistant, molded plastic
Sensor	Highly selective semi-conductive oxide alcohol sensor
Response time	3 sec.
Warm up time	20 sec.
Recovery time (sensor purge)	30 sec.
Battery life	Over 300 tests
Battery	9V alkaline
External power supply	12V DC adapter
Accuracy	$\leq \pm 0.01\%$ at 0.10% BAC $\leq \pm 0.05\text{mg/liter}$ at 0.50mg/liter BRAC
Detection range	0.00 ~ 0.40% BAC 0.00 ~ 2.00 mg/liter BRAC
Calibration	BAC simulator (Model 34C/Guth Laboratory, USA)
Digital display	Three digits in numeric readout
Packing	Tester, 9V alkaline, Cigar-Jack DC adapter, 5 pcs of mouthpieces, User's manual, Carrying Bag
Warranty	1 year

● COMPARISON TABLE

	Electro-chemical Sensor	The other semi-conductive sensor	CA 2000
Measuring method	Variation of Electromotive force	Variation of Electro-Conductivity	Variation of Electro-Conductivity

Dinovo, E. C., et. Al, "Comparison of opiate test results obtained from the LX20, AxSYM, REMEDi HS and the RapidOne Oxy testing systems with prescribed medications" *Clinical Chemistry*, 49 (6) A77 (2003).

Comparison of opiate test results obtained from the LX20, AxSYM, REMEDi HS and the RapidOne Oxy testing systems with prescribed medications.

E. C. Dinovo¹, M. Singh¹, S. W. Renner¹, A. M. Baria¹, B. Schieffer¹, S. Korobkin¹, B. D. Naliboff². ¹VA Greater Los Angeles Health Care System, 11301 Wilshire Blvd, Los Angeles, CA 90073, CA, ²University of California, Los Angeles, CA.

Random urine samples obtained from patients enrolled in the Greater Los Angeles VA Healthcare System Pain Management Clinic were tested for opiates using the Beckman LX20, the Abbott AxSYM, the BioRad's REMEDi HS and the American BioMedica RapidOne Oxy testing systems. Comparison of test results with prescribed medication allowed unequivocal validation of test results. Out of the total 158 urine samples, 43 samples were found to be negative and 76 samples were found to be positive by all four testing systems – all in concordance with prescribed medications. Of the remaining samples, results for 32 were discrepant among the four testing systems and 7 had incomplete data for full analysis. Of the 32 samples with discrepant results, 23 (72%) involved oxycodone, five morphine, two codeine, one hydrocodone and one methadone prescriptions. Of the 23 samples involving oxycodone, 11 (47%) were found positive by the LX20 opiate screen, 13 (56%) were picked up by the REMEDi HS; 16 (80%) of 20 tested positive by the AxSYM; and all 23 (100%) were positive by the RapidOne OXY test cartridge. Clearly, the routine drugs of abuse screening method fail to consistently pick up oxycodone. Only the new RapidOne OXY test demonstrated 100% reliability for returning positive results for all oxycodone patients. The overall sensitivity, specificity, positive predictive value and negative predictive value calculations for opiate testing are as follows:

	TP FP	FN TN	Sensitivity	Specificity	Pos PV	Neg PV
LX20 Opiate Screen	93 0	16 43	85%	100%	100%	73%
AxSYM Opiates	98 1	7 43	93%	98%	99%	86%
REMEDi HS	89 0	19 43	82%	100%	100%	69%
RapidOne OXY	108 0	1 43	99%	100%	100%	98%

SAMHSA Study of Onsite Devices

In the following study done for DHHS, all onsite devices included in the study are listed. Each device was given a letter for purposes of reporting the results.

Rapid Drug Screen is letter G. It ranked third in overall accuracy as represented in Table 6 comparing all products to GC/MS. It was the highest rated multi-drug test in the study. The top three or four devices all scored relatively close and showed good correlation with traditional laboratory screening and GC/MS.

**Substance Abuse and Mental Health Services Administration
Center for Substance Abuse Prevention
Division of Workplace Programs**

Subject: An Evaluation of Non-Instrumented Drug Test Devices

Date: January 29, 1999

Note: A printed copy of this report may be obtained by contacting the Division of Workplace Programs, 5600 Fishers Lane, Rockwall II, Suite 815, Rockville, Maryland 20857, Phone: 301-443-6014, Fax: 301-443-3031, email: wvogl@samhsa.gov

Background

The Department of Health and Human Services (HHS) published in the Federal Register on April 11, 1988, the Mandatory Guidelines for Federal Workplace Drug Testing Programs. The Mandatory Guidelines detail comprehensive standards for laboratory procedures, specified drugs for which Federal employees can be tested, and established appropriate standards and procedures for periodic review of laboratories and criteria for certification of laboratories engaged in urine drug testing for Federal agencies. The Mandatory Guidelines were revised on June 9, 1994, but the basic requirement for laboratory testing was not changed. In addition to covering the testing of Federal employees in the Executive Branch of the Federal government, the Department of Transportation requires its regulated industries to use HHS certified laboratories.

During the past few years, there has been a rapid expansion in the private sector to test for the presence of illicit drugs in other biological specimens (such as, sweat, oral fluid, and hair) as well as the use of on-site urine drug test devices. Approximately 2 years ago, the Division of Workplace Programs (DWP) began a review of the testing of alternative specimens and the use of on-site test devices. As part of the review, DWP funded Duo Research, Incorporated, to conduct a study to evaluate the performance of on-site drug test devices currently being marketed. This study was actually a second study of 15 new or modified on-site test devices that had been originally evaluated for the Administrative Office of the U.S. Courts in 1996. As in the first study, this study focused on the testing of specimens clustered above and below the cutoffs, specimens that were clearly negative or positive, and known quality control samples.

This study is not intended to make recommendations for specific products, but to provide a general assessment of the performance of currently available non-instrumented drug test devices.

Device Evaluation

All known non-instrumented drug test manufacturers and device distributors were contacted to obtain devices. Of these, 15 devices were provided by the manufacturers or distributors. A Behring Diagnostics' ETS instrument using Emit d.a.u. reagents served as a reference device. Other available instrumented systems were not included in the study.

The study was designed to test each device with 90 selected clinical specimens and 10 control samples for each drug. The specimens were selected from routine specimens submitted by Federal Probation Offices to PharmChem Laboratories under its contract with the Administrative Office of the U.S. Courts. They had been tested on an Hitachi 747 analyzer using Diagnostic Reagents, Inc (DRI) enzyme immunoassay test kits. The immunoassay rate data were compared to spiked control values to classify specimens into four categories: negative, below cutoff (ranging from about 25% below cutoff to cutoff),

above cutoff (ranging from cutoff to about 25% above the cutoff), and high (greater than 25% above the cutoff). Approximately 60 specimens had responses in the below and above cutoff categories. Specimens testing negative were selected and stored frozen until needed. Positive specimens were selected from previously confirmed positives that were ready for disposal. For phencyclidine, a sufficient number of unique clinical specimens in the desired range was not available, so dilutions (with negative urine) of positive clinical specimens were performed. The accuracy of these dilutions was checked on the ETS prior to inclusion in the study and by gas chromatography/mass spectrometry (GC/MS) following the study.

Each day, 20 to 30 specimens for a given drug were thawed and tested on all the study devices. Specimens were identified to the operators only by bar coding. All devices in this study indicate a negative result by the appearance of a colored line at the area designated for each drug. Positive results are indicated by the absence of a line.

The performance of the devices was assessed in terms of their "Positive Predictive Values" (PPV) and "Negative Predictive Values" (NPV) and percentages of false positive and false negative results. These are standard analytical measures of the certainty of obtaining a correct positive and negative result, respectively. Thus, a high percentage or high PPV indicates that there is a high certainty that a positive result from the device will be confirmed as positive, or as negative for a high NPV.

This differs from the percentage of true positives, called sensitivity, and percentage of true negatives, called specificity. These measures indicate the percentage of all specimens confirmed positive by GC/MS that were identified as positive by the device, or of those confirmed as negative by GC/MS that were negative by the device. Also, specimens confirmed as positive but identified as negative by the device are false negative results, and for specimens confirmed as negative but identified as positive by the device are false positive results. The combination of all correct negative and positive results represents an estimate of the overall accuracy for both positive and negative results for each device.

The definitions used for this study are given below. Tables 1 through 5 show the PPV, NPV, and accuracy data for each test device versus GC/MS at the HHS cutoffs and with all borderline readings scored as negative (many devices give equivocal results, which were scored initially as "borderline") for each drug. Table 6 gives the combined results for all drugs for each test device. Figures 1 through 5 are the bar-graphs showing the sensitivity, false negatives, false positives, and specificity as percentages for each drug class for each test device ("PD" is used to represent the performance of a "Perfect Device"). Figure 6 gives the combined results for all drugs for each test device. It must be noted that the results for opiates were based on the 300 ng/mL cutoffs. None of the specimens included in the study would have been positive at 2,000 ng/mL.

Note: Codes have been used in the tables and figures contained in this report to conceal the identities of the test devices. However, each manufacturer has received a report that identifies the results for its test device.

The evaluation of the 15 devices was conducted with a majority of the specimens grouped around the screening cutoffs. It was found, as expected, that many devices gave a fair number of false positive and false negative results. It is also expected, based on experiences in the field, that specimens encountered in most workplace testing situations will have fewer specimens with drug concentrations near the cutoff. This means that a much higher percentage of confirmed positive results and fewer false negative results should occur during actual testing in the field.

The favorable performance of the devices was encouraging considering the simplicity of their design

and operational requirements. Some devices were able to identify more positive specimens, but this was accompanied by a higher percentage of false positive results. Other devices were more conservative, giving few false positive results but missing many true positives.

Test Devices Evaluated

Dipro 10 Panel

Each device is packaged in a sealed pouch. The device consists of a flat plastic card that has five dipsticks extending from one edge. Two of these are connected back-to-back providing for ten separate test strips. The strips are covered with a protective cap. Storage does not require refrigeration, but 36° to 86°F is recommended. Expiration dates are stamped on the pouches. The devices are well labeled, with clear result designations and areas for donor ID and date. The device includes a "control" or validity check. The test requires the removal of the cap, insertion of the dipsticks into the specimen for about 10 seconds. The cap can be replaced. The endpoint for a positive results if the absence of a line at the test band windows. Manufactured by American Biomedical, Inc.

Distributor: Dipro Diagnostics
3415 Hycliffe Avenue
Louisville, KY 40207
Phone: 502-899-3108

Drug Check Cup

Each device is packaged in a sealed bag. Expiration dates are stamped on the bags. The devices are well labeled, with clear result designations. The device includes a "control" or validity check. The device is a self-contained collection and storage cup, that has the drug test strips imbedded in its side. The cup is closed with a screw-cap lid after specimen collection. The test begins as soon as the urine is added to the cup. There is no other activation step required. Results can be read within 5 to 9 minutes. The endpoint for a positive result is the absence of a line at the test band.

Distributor: Job Services, Inc.
32107 West Lindero Canyon Road
Westlake Village, CA 91361
Phone: 818-599-2512

Dtx 520

Each cassette-style device is packaged in a sealed pouch with an attached pipette. Storage does not require refrigeration, but 36° to 86°F is recommended. Expiration dates are stamped on the pouches. The devices are well labeled, with clear result designations. The device includes a "control" or validity check. The test requires the addition of 4 to 5 drops of urine to a well at one end of the device. Results can be read within 3 to 8 minutes, but should be read within 8 minutes. The endpoint for a positive results is the absence of a line at the test band. Manufactured by Forefront Diagnostics, Inc.

Distributor: Universal Drug Testing Company
467 Route 51
Large, PA 15025
Phone: 888-822-7120

Genie Cup

Each device is packaged in a sealed bag. Expiration dates are stamped on the bags. The devices are well labeled, with clear result designations. The device includes a "control" or validity check. The device is a self-contained collection and storage cup, that has the drug test strips imbedded in its side. The cup is closed with a screw-cap lid after specimen collection. At the time of testing, the lid is turned to its fully closed position. This depresses a plunger to trap a portion of the specimen in the test chamber. Results can be read as soon as a line appears in the "test valid" area. The endpoint for a positive result is the absence of a line at the test band. Timing is said not to be important. Manufactured by American Biomedical, Inc.

Distributor: Point of Care Technologies
6 Taft Court, Suite 150
Rockville, MD 20850
Phone: 888-713-8700

InstaCheck

Each cassette-style device is packaged in a sealed pouch with an attached pipette. Storage does not require refrigeration, but 36° to 86°F is recommended. Expiration dates are stamped on the pouches. The devices are well labeled, with clear result designations. The device includes a "control" or validity check. The test requires the addition of 4 to 5 drops of urine to a well at one end of the device. Results can be read within 3 to 8 minutes, but should be read within 8 minutes. The endpoint for a positive result is the absence of a line at the test band. Manufactured by Forefront Diagnostics, Inc.

Distributor: Forefront Diagnostics, Inc.
23561 Ridge Route Drive, Suite D
Laguna Hills, CA 92653
Phone: 949-595-0673

PharmScreen Drug Screen Card

Each device is packaged in a sealed pouch. The device consists of a flat card that has five dipsticks extending from one edge. The strips are covered with a protective cap. Storage does not require refrigeration, but 36° to 86°F is recommended. Expiration dates are stamped on the pouches. The devices are well labeled, with clear designations and areas for donor ID and date. The device includes a "control" or validity check. The test requires the removal of the cap, insertion of the dipsticks into the specimen for about 10 seconds. The cap can be replaced. The endpoint for a positive result is the absence of a line at the test band windows. Manufactured by American Biomedical, Inc.

Distributor: PharmChem Laboratories, Inc.
1505A O'Brien Drive
Menlo Park, CA 94025
Phone: 800-446-5177

PharmScreen Drug Screen Multi

Each cassette-style device is packaged in a sealed pouch. Storage does not require refrigeration, but 36° to 86°F is recommended. Expiration dates are stamped on the pouches. The devices are well labeled,

with clear result designations and areas for donor ID and date. The device includes a "control" or validity check. The test requires the addition of 4 to 5 drops of urine to a well at one end of the device. Results can be read within 3 to 8 minutes, but should be read within 8 minutes. The endpoint for a positive result is the absence of a line at the test band windows. Manufactured by American Biomedical, Inc.

Distributor: PharmChem Laboratories, Inc.
1505A O'Brien Drive
Menlo Park, CA 94025
Phone: 800-446-5177

Rapid Drug Screen

The device is a cup and a separate card containing the individual test strips. It is packaged in a sealed pouch. Expiration dates are stamped on the pouches. The devices are well labeled, with clear result designations and areas for donor ID and date. The device includes a "control" or validity check. The test requires the insertion of the test card through a slit in the lid and into the specimen. Results can be read within 3 minutes, but should be read within 8 minutes. The endpoint for a positive result is the absence of a line at the test band windows. Manufactured by American Bio Medica Corporation.

Distributor: Integrated Corporate Solutions, Inc.
3121 Sunnybrook Road
Mogadore, OH 44260
Phone: 330-677-2441

Status DS-5

Each cassette-style device is packaged in a sealed pouch with an attached pipette. Storage does not require refrigeration, but 35° to 86°F is recommended. Expiration dates are stamped on the pouches. The devices are well labeled, with clear result designations. The device includes a "control" or validity check. The test requires the addition of 3 drops of urine to a well at one end of the device. Results can be read within 3 to 5 minutes, but should be read within 10 minutes. The endpoint for a positive result is the absence of a line at the test band. Manufactured by Princeton BioMeditech.

Distributor: Orion Diagnostica, Inc.
71 Veronica Avenue
Somerset, NJ 08873
Phone: 800-526-2125

Syva Rapid Test

Each cassette-style device is packaged in a sealed pouch with an attached pipette. Storage does not require refrigeration, but 35° to 86°F is recommended. Expiration dates are stamped on the pouches. The devices are well labeled, with clear result designations. The device includes a "control" or validity check. The test requires the addition of 3 drops of urine to a well at one end of the device. Results can be read within 3 to 5 minutes, but should be read within 10 minutes. The endpoint for a positive result is the absence of a line at the test band. Manufactured by Princeton BioMeditech.

Distributor: Dade Behring, Inc.

3403 Yerba Buena Road
San Jose, CA 95135
Phone: 800-729-7982

TesTcup 5

Each device is packaged in a sealed bag. Storage does not require refrigeration, but 65° to 85°F is recommended. Expiration dates are stamped on the bags. The devices are well labeled, with clear result designations. The device includes a "control" or validity check. The device is a self-contained collection and storage cup, that has the drug test strips imbedded in its side. The cup is closed with a screw-cap lid after specimen collection. At the time of testing, the lid is turned to its "test" position, the cup tilted until the urine covers 1/2 to 3/4 of the lid (do not invert fully). It is held in this position for 10 seconds, then returned to its upright position. Results can be read as soon as the "TEST VALID" window develops a blue color, usually within 5 minutes. The endpoint for a positive result is the absence of a line at the test band. Timing is said not to be important. An adhesive covering strip is removed from the test display windows and placed on a small "breather" hole on the back of the cup. The lid should then be returned to the sealed position if the specimen is to be stored or sent for confirmation. Manufactured by Roche Diagnostic Systems, Inc.

Distributor: Roche Diagnostic Systems, Inc.
1080 U.S. Highway 202
Somerville, NJ 08876-3771
Phone: 800-526-1247

Accutest

Each cassette-style device is packaged in a sealed pouch with an attached pipette. Storage does not require refrigeration, but 36° to 86°F is recommended. Expiration dates are stamped on the pouches. The devices are well labeled, with clear result designations. The device includes a "control" or validity check. The test requires the addition of urine from a pipette marked for about 0.2 mL to a well at one end of the device. Results can be read within 3 to 8 minutes, but should be read within 8 minutes. Manufactured by Jant Pharmacal Corporation.

Distributor: Jant Pharmacal Corporation
16255 Ventura Boulevard, Suite 505
Encino, CA 91436
Phone: 818-986-8530

One Step

Each device is packaged in a sealed pouch with an attached pipette. Storage does not require refrigeration, but can be if desired, or a room temperature, 65° to 85°F. Expiration dates are stamped on the pouches. The devices are well labeled. The device includes a "control" or validity check. The test is in the form of a dipstick, requiring the dipping of the strip into the urine, preferably a small aliquot in a test tube. Results can be read within 3 minutes, but must be read within 5 minutes. The endpoint for a positive result is the absence of a line at the test band. Manufactured by Technical Chemicals & Products, Inc.

Distributor: Technical Chemicals & Products, Inc.

P.O. Box 9748
Ft. Lauderdale, FL 33310
Phone: 954-979-0400

QuickScreen

Each cassette-style device is packaged in a sealed pouch with an attached pipette. Storage does not require refrigeration, but 40° to 86°F is recommended. Expiration dates are stamped on the pouches. The devices are well labeled. The device includes a "control" or validity check. The test requires the slow addition of 4 drops of urine to a well at one end of the device. Results can be read within 10 minutes. The endpoint for a positive result is the absence of a line at the test band. Manufactured by PhamaTech.

Distributor: PhamaTech
9265 Activities Road
San Diego, CA 92126
Phone: 619-635-5840

TesTstik

Each device is packaged in a sealed pouch with an attached pipette. Storage does not require refrigeration, but 36° to 86°F is recommended. Expiration dates are stamped on the pouches. The devices are well labeled. The device includes a "control" or validity check. The test requires the dipping of the device into a urine samples up to a mark on the device for 5 to 7 seconds. Results can be read within 5 minutes, but should not be read after 30 minutes. The endpoint for a positive results is the absence of a line at the test band. Manufactured by Roche Diagnostic Systems, Inc.

Distributor: Roche Diagnostic Systems, Inc.
1080 U.S. Highway 202
Somerville, NJ 08876-3771
Phone: 800-526-1247

Definitions

True Positive (TP)

A positive result by the test device and a positive result by GC/MS (the reference method).

False Negative (FN)

A negative result by the test device and a positive result by GC/MS.

False Positive (FP)

A positive result by the test device and a negative result by GC/MS. This includes both "unconfirmed" positives, i.e., samples with drugs present below the cutoff and samples

with no drugs detected.

True Negative (TN)

A sample negative by the test device and negative by GC/MS.

Sensitivity

The number of True Positive results for a test device out of all GC/MS positives in the study expressed as a percentage ($TP \times 100 / (TP + FN)$).

Specificity

The number of True Negative results for a test device out of all GC/MS negatives in the study expressed as a percentage ($TN \times 100 / (TN + FP)$).

Prevalence

The percentage of positive specimens in a given population of specimens.

Positive Predictive Value (PPV)

The probability that a positive result for a test device will be a True Positive in a population with a known or estimated prevalence of positive specimens (that is, a value calculated for a device as to its ability to produce correct positive results, which is dependent upon the prevalence of positive specimens).

$$PPV = [Sensitivity \times Prevalence] / [(Sensitivity \times Prevalence) + ((1 - Prevalence) \times (1 - Specificity))]$$

Negative Predictive Value (NPV)

The probability that a negative result for a test device will be a True Negative in a population with a known or estimated prevalence of positive specimens (that is, a value calculated for a device as to its ability to produce correct negative results which is dependent upon the prevalence of positive specimens).

$$NPV = [Specificity \times (1 - Prevalence)] / [((1 - Sensitivity) \times Prevalence) + (Specificity \times (1 - Prevalence))]$$

Table 1. PPV, NPV, and Accuracy Values for Test Results versus GC/MS using HHS Cutoffs (All borderline results as negative)

Amphetamines

Device	PPV	NPV	Accuracy
Perfect Device	1.000	1.000	1.000

Ja	0.818	0.873	0.867
Ga	0.786	0.895	0.878
Da	0.714	0.942	0.889
La	0.556	0.827	0.800
Ea	0.545	0.896	0.809
Aa	0.500	0.981	0.789
Ha	0.476	0.870	0.778
Nm	0.467	0.840	0.778
Ca	0.432	0.943	0.733
Nm	0.400	0.843	0.744
Km	0.360	0.846	0.711
Bam	0.327	0.947	0.589
Pm	0.313	0.811	0.722
Lm	0.281	0.828	0.633
Im	0.278	0.833	0.611
Fam	0.267	0.841	0.551
Dm	0.258	0.814	0.622
Cm	0.213	0.793	0.400
Qm	0.091	0.772	0.689

Note: "a" is amphetamine specific, "m" is methamphetamine specific, "am" is sensitive to both amphetamines

Table 2. PPV, NPV, and Accuracy Values for Test Results versus GC/MS using HHS Cutoffs (All borderline results as negative)

Cannabinoids

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Device	PPV	NPV	Accuracy
Perfect Device	1.000	1.000	1.000
P	1.000	0.474	0.556
H	0.935	0.576	0.700
B	0.933	0.567	0.689
E	0.848	0.544	0.656
M	0.833	0.556	0.667
D	0.810	0.583	0.689
N	0.784	0.641	0.722
J	0.774	0.649	0.722
I	0.757	0.509	0.611
G	0.721	0.773	0.733
Q	0.705	0.500	0.600
L	0.697	0.929	0.733
K	0.697	0.929	0.733
C	0.693	0.867	0.722
F	0.667	0.619	0.656
A	0.628	0.426	0.522

Table 3. PPV, NPV, and Accuracy Values for Test Results versus GC/MS using HHS Cutoffs (All borderline results as negative)

Cocaine

Device	PPV	NPV	Accuracy
Perfect Device	1.000	1.000	1.000

C	1.000	0.667	0.856
H	1.000	0.591	0.800
B	1.000	0.578	0.789
M	0.966	0.774	0.900
A	0.963	0.667	0.844
I	0.953	0.511	0.722
Q	0.953	0.511	0.722
P	0.933	0.733	0.867
G	0.933	0.511	0.722
K	0.932	0.710	0.856
J	0.932	0.710	0.856
E	0.925	0.913	0.922
N	0.906	0.769	0.867
D	0.892	0.760	0.856
L	0.886	0.900	0.889
F	0.813	0.800	0.811

Table 4. PPV, NPV, and Accuracy Values for Test Results versus GC/MS using HHS Cutoffs (All borderline results as negative)

Opiates

Device	PPV	NPV	Accuracy
Perfect Device	1.000	1.000	1.000
B	0.481	0.968	0.820
J	0.464	0.968	0.811

N	0.597	0.797	0.693
A	0.591	0.798	0.689
P	0.569	0.734	0.658
Q	0.551	0.726	0.642
L	0.545	0.873	0.680
D	0.538	0.830	0.669
K	0.537	0.849	0.642
I	0.532	0.726	0.627
F	0.513	0.814	0.610
C	0.509	0.862	0.637

American Bio Medica Corporation: Product Catalogue

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Price List for: Williamson County CSCD

Date: 9/2/2003

Item #	Description	Qty/ Case or Package	Discount Price/ Unit	Discount Price/ case
Rapid One®: Single drug test dip stick format.				
AMPD	Amphetamine (AMP)	50	\$1.15	\$57.50
BARD	Barbiturate (BAR)	50	\$1.15	\$57.50
BZOD	Benzodiazepine (BZO)	50	\$1.15	\$57.50
COC	Cocaine (COC)	50	\$1.15	\$57.50
XTCD	Ecstasy (XTC)	50	\$2.00	\$100.00
MEDD	Methadone (MTD)	50	\$1.15	\$57.50
METD	Methamphetamine (METH)	50	\$1.15	\$57.50
OPID	Opiates (OPI) *specify 300 or 2000 cut-off	50	\$1.15	\$57.50
OXYD	Oxycodone (OXY)	50	\$2.00	\$100.00
PCPD	PCP (PCP)	50	\$1.15	\$57.50
PPXD	Propoxyphene (PPX)	50	\$2.00	\$100.00
THCD	THC (Marijuana)	50	\$1.15	\$57.50
TCAD	Tricyclic Antidepressants (TCA)	50	\$1.15	\$57.50
Single drug test strip format.				
AMPS	Amphetamine (AMP)	100	\$0.75	\$75.00
BARS	Barbiturate (BAR)	100	\$0.75	\$75.00
BZOS	Benzodiazepine (BZO)	100	\$0.75	\$75.00
COC	Cocaine (COC)	100	\$0.75	\$75.00
XTCS	Ecstasy (XTC)	100	\$1.00	\$100.00
MEDS	Methadone (MTD)	100	\$0.75	\$75.00
METS	Methamphetamine (METH)	100	\$0.75	\$75.00
OPIS	Opiates (OPI) *specify 300 or 2000 cut-off	100	\$0.75	\$75.00
OXY	Oxycodone (OXY)	100	\$1.40	\$140.00
PCPS	PCP (PCP)	100	\$0.75	\$75.00
PPXD	Propoxyphene (PPX)	100	\$1.40	\$140.00
THCS	THC (Marijuana)	100	\$0.75	\$75.00
TCAS	Tricyclic Antidepressants (TCA)	100	\$0.75	\$75.00
Rapid Drug Screen®: Multi-drug kit format: includes collection cup, ID label, temperature strip, evidence seal				
<i>Split: an additional split cup B: available for an extra \$.75/unit or \$15/case.</i>				
2C1	COC/ THC	25	\$2.80	\$70.00
2M1	METH/THC	25	\$2.80	\$70.00
3M1	COC/THC/METH	25	\$3.45	\$86.25
3X1	COC/THC/ AMP	25	\$3.45	\$86.25
3O1	COC/ THC/ OPI	25	\$3.45	\$86.25
4A1	AMP/COC/THC/OPI	25	\$4.35	\$108.75
4M1	METH/COC/THC/OPI	25	\$4.35	\$108.75
5P1	AMP/COC/THC/OPI/PCP	25	\$5.50	\$137.50
5M1	AMP/COC/THC/OPI/METH	25	\$5.50	\$137.50
5Z1	AMP/COC/THC/OPI/BZO	25	\$5.50	\$137.50
5MO1	METH/COC/THC/OPI/OXY	25	\$6.00	\$150.00
8X1	AMP/BZO/BAR/COC/METH/OPI/PCP/THC	25	\$9.25	\$231.25
9T1	AMP/BZO/BAR/COC/METH/OPI/PCP/THC/ TCA	25	\$12.00	\$300.00
10ND1	AMP/BZO/BAR/COC/METH/OPI/PCP/THC/PPX/MTD	25	\$13.00	\$325.00
Custom	Custom panels available; call for lead time and pricing	25		
Opiates: Specify 300 or 2000 ng/ml cut-off				

To order call ABMC: 1-800-227-1243, option 2 or FAX: 518-758-8172

122 Smith Rd., Kinderhook, NY 12106

Federal TIN: 14-1702188

American Bio Medica Corporation: Product Catalogue

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Item #	Description	Qty/ Case or Package	Discount Price/ Unit	Discount Price/ case
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Rapid Drug Screen: Multi-drug card only format; order sample cups separately- see below.

2CS	COC/THC	50	\$1.90	\$95.00
2MS	METH/THC	50	\$1.90	\$95.00
3MS	COC/THC/METH	50	\$2.40	\$120.00
3XS	COC/THC/ AMP	50	\$2.40	\$120.00
3OS	COC/ THC/ OPI	50	\$2.40	\$120.00
4AS	AMP/COC/THC/OPI	50	\$3.00	\$150.00
4MS	METH/COC/THC/OPI	50	\$3.00	\$150.00
5PS	AMP/COC/THC/OPI/PCP	50	\$3.60	\$180.00
5MS	AMP/COC/THC/OPI/METH	50	\$3.60	\$180.00
5ZS	AMP/COC/THC/OPI/BZO	50	\$3.60	\$180.00
5MOS	METH/COC/THC/OPI/OXY	50	\$4.20	\$210.00
8XS	AMP/BZO/BAR/COC/METH/OPI/PCP/THC	50	\$6.35	\$317.50
9TS	AMP/BZO/BAR/COC/METH/OPI/PCP/THC/ TCA	50	\$7.10	\$355.00
10NDS	AMP/BZO/BAR/COC/METH/OPI/PCP/THC/PPX/MTD	50	\$10.00	\$500.00
Custom	Custom panels available; call for lead time and pricing	50		
<i>Opiates: Specify 300 or 2000 ng/ml cut-off</i>				

Rapid TEC® Products: Multi-drug dipsticks

2CR	Rapid TEC 2: THC/COC	50	\$1.75	\$87.50
3MR	Rapid TEC 3: THC/COC/METH	50	\$1.80	\$90.00
4OR	Rapid TEC 4: THC/COC/OPI*/METH	50	\$1.90	\$95.00
5AR	Rapid TEC 5A: THC/COC/OPI*/AMP/PCP	50	\$2.00	\$100.00
5ZR	Rapid TEC 5Z: THC/COC/OPI300/METH/BZO	50	\$2.00	\$100.00
<i>* Opiates: Specify 300 or 2000 ng/ml cut-off</i>				

Sample Integrity Tests

ADT000A	Rapid Check™: Creatinine, Specific Gravity, Glutaraldehyde, pH, Nitrite, Oxidants	25	\$0.80	\$20.00
ADT000B	Rapid Check™	50	\$0.75	\$37.50
ZKCI-070	Intect® 7	25	\$0.93	\$23.25

Oral Fluids (Saliva) Drug Screen

12-Oral-000	OralStat®: Amp/Meth/Coc/Opi/THC/PCP	25	\$13.75	\$343.75
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Alcohol Tests

AL000A	Rapid Alco TEC™: Saliva/ urine, 0.02 - 0.30%, test strip	25	\$1.75	\$43.75
AL000B	Rapid Alco TEC™: Saliva/ urine, 0.02 - 0.30%, test strip	50	\$1.50	\$75.00
ZBSA	Breathscan® Alcohol: 0.02, 0.04: Breath alcohol blow tube	100	\$1.25	\$125.00
AD000	Alcohol Detector, CA2000™ Portable Breathalyzer	1	\$275.00	\$275.00
AD001	Alcohol Detector Disposable Mouthpieces	100	\$0.24	\$24.00

Sample Cups/ Ancillaries

Tec Cup	4 oz. sample cup/ lid/ non-transport/ no temp strip	100	\$0.23	\$23.00
Non-transport	4 oz. sample cup/ lid/ non-transport/temp strip	500	\$0.30	\$150.00
Transport	4 oz. sample cup/ lid/ transport/ temp strip	300	\$0.35	\$105.00
A-Cup	RDS sample cup; transport/ temp strip/ slotted lid/ solid lid	100	\$0.75	\$75.00

For more information contact:

Anne Becknell, Director of Business Development
Office: 303-840-2607; E-mail: abecknell@abmc.com

To order call ABMC: 1-800-227-1243, option 2 or FAX: 518-758-8172

122 Smith Rd., Kinderhook, NY 12106

Federal TIN: 14-1702188

AGENDA ITEM 21

Consider awarding bids received for cave gating services for the County Parks & Recreation Department to the low bidder meeting specifications - Mike Wharton and Associates.

Moved: **Commissioner Boatright**

Seconded: **Judge Doerfler**

Motion: To award bids received for cave gating services for the County Parks & Recreation Department to the low bidder meeting specifications - Mike Wharton and Associates.

Vote: **3 – 0. Commissioner Limmer was absent from the dais.**

< Attachment >



Williamson County

Parks and Recreation Department

Memorandum

TO: John Doerfler, Judge
Commissioners
Williamson County

FROM: Jim Rodgers *JMR*
Parks and Recreation

DATE: September 10, 2003,

RE: Bid Award Bid # 03WC525

Cave gating services (Bid # 03WC525) for the seven caves with endangered species in the Regional Park on CR175 were advertised and bids were opened August 21, 2003 by the purchasing department. Specifications denoted design and construction of the gates on site to meet United States Fish and Wildlife (USFW) approval. We received bids from Mike Wharton of Cedar Park and Associates and from Steelco of Waxahachie. The attached spreadsheet indicates the results of the evaluation criteria. I am recommending award of bid to Mike Wharton and Associates due to the following reasons. Wharton and Associates has experience in designing and constructing 250 cave gates in the area, his references, all for the construction of cave gates and most for the construction of endangered species cave gates, were praiseworthy of his design, construction, and acceptance by USFW. A USFW collections permit is held by Wharton and Associates and Mike is recognized as the expert in the field of cave gates.

Steelco has no experience in cave gate design or construction; their references while good were not of cave gates but of fences, security gates and a variety of welding projects. Steelco has no collections permit and when I spoke with Mr. Clifford Fischer he said he was trying to get into the business. Both entities can be finished in an acceptable time.

I visited with Steve Paulsen with aci consulting our cave expert about the risks of selecting a non-experienced builder. Steve's comments reflected our concerns in that "our credibility with Fish and Wildlife is at stake" and that "Wharton has the proven ability to meet Fish and Wildlife's complex demands"

While there is a sizable difference in price I believe that Wharton and Associates price is the acceptable bid. I called three references for each contractor and received good reports from all six. It was evident that Wharton and associates has very credible endangered species cave gate experience. I believe that Steelco is a good welding firm but is not a qualified cave gate designer or builder and his price reflects the lack of qualifications for bidding in this area.