





Number: Effective Date: © 2023 VivaChek Diagnostics, Inc.

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### **Multi-Drug Test**

### About VivaChek

### **Milestones**



The Global leader in Blood Glucose Meter Innovation and Manufacturing is creating its base in the U.S with launch of VivaChek USA based in Sacramento, CA. VivaChek specializes in OEM, ODM and Custom Manufacturing of various Drugs of Abuse Tests in various standard and tailor-made configurations.

We aspire to become a trusted partner in manufacturing for the U.S to cater the Professional and OTC market for DOA products with strategically placed warehouses in the U.S.

2022 CLIA Waived & OTC approved

202  $\bigcirc$ Revenue reached 180+ million USD

2019 Blood Ketone+ BGM dual system 510(k) cleared

10(k) cleared

2013



#### **O** 2023

Products Available in 120+ countries, 150+ patents

DOA urine cup of 15 Drugs: 510(k) cleared,

ivaChek established

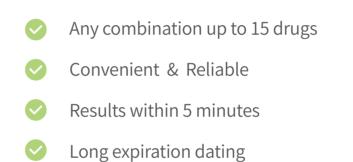


### **Product Catalogue •**

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### Urine Drug Test 510 (k) Cleared, CLIA Waived & OTC Approved

- Multi-Drug Urine Test Cup/Panel
- Marijuana Single Dip Panel/Strip



	FDA U.S. FOOD & DRUG
	ADMINISTRATION
	4
DA U.S. FOOD & DRUG	November 10, 2022
ADMINISTRATION	Visit de National de Carlos
	Vivachek Biotech (Hangzhou) Co., Ltd % Joe Shia
	76 JOE Shia Director
VivaChek Biotech (Hangzhou) Co., Ltd	LSI International
% Joe Shia	540 E Diamond Avenue, Suite I
Director	Gaithersburg, MD 20877
LSI International Inc	
504 E Diamond Ave., Suite H Gaithersburg, Maryland 20877	
Gaithersburg, Maryland 20877	Re: K222667
	Trade/Device Name: Wisdiag Multi-Drug Urine Te
Re: K231978	Regulation Number: 21 CFR 862.3100
Trade/Device Name: BioSieve <sup>TM</sup> Marijuana Test Panel 50; BioSieve <sup>TM</sup> Marijuana Test Strip 50;	Regulation Name: Amphetamine test system
BioSieve™ Dx Marijuana Test Strip 20; BioSieve™ Dx Marijuana Test Strip 50;	Regulatory Class: Class II
BioSieve <sup>TM</sup> Dx Marijuana Test Panel 20; BioSieve <sup>TM</sup> Dx Marijuana Test Panel 50	Product Code: NFT, NGL, PTH, NFV, NFY, PTG,
Regulation Number: 21 CFR 862.3870	Dated: September 2, 2022
Regulation Name: Cannabinoid Test System Regulatory Class: Class II	Received: September 6, 2022
Product Code: NFW	Dear Joe Shia:
Dated: June 27, 2023	
Received: July 3, 2023	We have reviewed your Section 510(k) premarket notific
	above and have determined the device is substantially eq
Dear Joe Shia:	enclosure) to legally marketed predicate devices markete
	enactment date of the Medical Device Amendments, or t
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the	with the provisions of the Federal Food, Drug, and Cosn
enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the	premarket approval application (PMA). You may, theref
enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance	controls provisions of the Act. Although this letter refers
with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a	some cleared products may instead be combination prod
premarket approval application (PMA). You may, therefore, market the device, subject to the general	located at https://www.accessdata.fda.gov/scripts/cdrh/cl
controls provisions of the Act. Although this letter refers to your product as a device, please be aware that	product submissions. The general controls provisions of
some cleared products may instead be combination products. The 510(k) Premarket Notification Database	listing of devices, good manufacturing practice, labeling, adulteration. Please note: CDRH does not evaluate infor
located at <a href="https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm">https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm</a> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration,	remind you, however, that device labeling must be truth
product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and	renning you, nowever, that device labeling must be truth
adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We	
remind you, however, that device labeling must be truthful and not misleading.	If your device is classified (see above) into either class I
5,7,7, 5 5	subject to additional controls. Existing major regulations
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be	Federal Regulations, Title 21, Parts 800 to 898. In additi
subject to additional controls. Existing major regulations affecting your device can be found in the Code of	concerning your device in the Federal Register.
Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements	
concerning your device in the Federal Register.	Please be advised that FDA's issuance of a substantial eq
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA	has made a determination that your device complies with
has made a determination that your device complies with other requirements of the Act or any Federal	statutes and regulations administered by other Federal ag
	U.S. Food & Drup Administration
U.S. Food & Drug Administration 10902 New Hampible Avenue	10903 New Hampshire Avenue
Shur Spring, MD 20003	Silver Spring, ND 20993
www.tht.dv	

#### Panel /Strin

un Wisdiag Multi-Drug Urine Test Cun Rx

G, QBF, QAW, NFW, LCM

on of intent to market the device referenced absel (for the indications for use stated in the interstate commerce prior to May 28, 1976, the event of the state of the state of the state of the state A (c) (A) that do not require approval of a market the device, subject to the general your product as a device, please be aware that  $K \approx 100k$ ) Premarket Notification Database  $k \propto 100k$  and the state of the state of the state  $K \approx 100k$  (remarket the State) for the state  $K \approx 100k$  (remarket the State) for the state  $K \approx 100k$  (remarket) for an and registration, d probabilities against milleranding and used are initialized.

pecial Controls) or class III (PMA), it may be lecting your device can be found in the Code of FDA may publish further announcements

alence determination does not mean that FDA her requirements of the Act or any Federal cies. You must comply with all the Act's DA U.S. FOOD & DRUG

November 10, 2022

Vivachek Biotech (Hangzhou) Co % Joe Shia Director LSI International 540 E Diamond Auguna Suite I

Be: K222667

Trade/Device Name: Wisding Multi-Drug Urine Test Cup, Wisding Multi-Drug Urine Test Cup Rx Regulation Namer: 21 (CFR 862.3100 Regulation Name: Ampletamine test system Regulation Class: Class III

Product Code: NFT, NGL, PTH, NFV, NFY, PTG, NGG, QBF, QAW, NFW, LCM Dated: September 2, 2022 Received: September 6, 2022

ear Joe Shia:

We have reviewed your Section 510(b) premadent ontification of intent to market the device referenced above and have determined the device is substantially quarihead (the the indications for more tated in the meshaner) to legally marketed predicate devices marketed in internative commerce prior to May 24, 1976, the substantiant date of the Medical Device Amendments, we to device that have been reclosified in accordance premater approach application (PMA). You may, therefore, market the device, updeet to the general control, provision of the Act. Although this itter refress to your product a advecce, places the same that some clared products may instand be combination products. The 510(k) Premater Aborification Database clared at general second and an according of the same second and the same second and some clared applications (PMA). You may, therefore, market the device, updeet to the general located at general second and an according of the same second and the same second second application (PMA). You may, therefore, market the device, updeet to the general located at general second and and according the same second and the same second second applications. The same second and the same second second second second application of the same second second applications and the same second and the same second second

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Trile 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the <u>Federal Register</u>.

Please be adviced that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

U.S. Food & Drug Administr 19903 New Hampshire Aver Silver Spring, MD 20993

# Multi-Drug Urine Test Cup

- 510 (k) Cleared, CLIA Waived & OTC Approved

#### **Products Information**

Drug Test	Cut-off (ng/mL)
2-ethylidene-1,5dimethyl-3,3-diphenylpyrrolidine (EDDP)	300
Amphetamine(AMP)	500,1000
Buprenorphine(BUP)	10
Cocaine (COC)	150, 300
Marijuana (THC)	50
Methylenedioxymethamphetamine (MDMA)	500
Methadone(MTD)	300
Methamphetamine(MET)	500, 1000
Morphine(MOP)	300
Morphine(OPI)	2000
Nortriptyline (TCA)	1000
Oxazepam(BZO)	300
Opiate (OPI)	2000
Oxycodone (OXY)	100
Phencyclidine (PCP)	25
Propoxyphene(PPX)	300
Secobarbital (BAR)	300



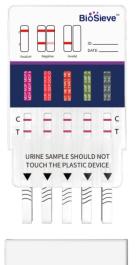
### Multi-Drug Urine Test Panel

- 510 (k) Cleared, CLIA Waived & OTC Approved

#### **Products Information** Information

Drug Test	Cut-off (ng/mL)
2-ethylidene-1,5-dimethyl-3, 3-diphenylpyrrolidine (EDDP)	300
Amphetamine (AMP)	500, 1000
Barbiturates (BAR)	300
Buprenorphine (BUP)	10
Cocaine (COC)	150, 300
Ecstasy (MDMA)	500
Marijuana (THC)	50
Methadone (MTD)	300
Methamphetamine (MET)	500, 1000
Morphine (MOP/OPI)	300, 2000
Nortriptyline (TCA)	1000
Oxazepam (BZO)	300
Oxycodone (OXY)	100
Phencyclidine (PCP)	25
Propoxyphene (PPX)	300





BioSieve™





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## Marijuana Single Dip Panel/Strip

### Urine Drug Test - FUO



#### **Products Information •**

Drug Test	Cut-off (ng/mL)
6-MAM	10
7-Aminoclonazepam (7-ACL)	100, 200, 300
AB-Pinaca (ABP)	10
Acetaminophen (ACE)	5000
Alprazolam (ALP)	100
Caffeine (CAF)	1000
Cathine (CAT)	150
Carfentanyl (CFYL)	500
Clonazepam (CLO)	150, 400
Cannabinol (CNB)	500
Cotinine (COT)	10, 50, 100, 200
Diazepam (DIA)	300
Ethyl Glucuronide (EtG)	500, 1000
Fentanyl (FYL)	10, 20
Gabapentin (GAB)	2000

#### **Product Information ()**

**Drug Test** Marijuana (THC)

Cut-off (ng/mL) 20 - 510 (k) Cleared, CLIA Moderate 50 - 510 (k) Cleared, CLIA Waived & OTC Approved





γ-Hydroxybutyric acid (GHB)	10 µg/mL
Synthetic Marijuana (K2)	25, 30, 50
Ketamine (KET)	100, 300, 500, 1000
LSD	20
Methcathinone (MCAT)	500
Tenamfetamine (MDA)	500
MDPV	1000
Mephedrone HCI (MEP)	100
Methylphenidate (MPD)	300, 1000
Meperidine (MPRD)	100
Methaqualone (MQL)	300
Pregabalin (PGB)	50000
Tramadol (TML)	100,300
Tropicmide (TRO)	350
Trazodone (TZD)	200
Urine Alcohol	0.02%
Xylazine (XYL)	500
Zolpidem (ZOL)	50
$\alpha$ -Pyrrolidinovalerophenone ( $\alpha$ -PVP)	300, 500, 1000

## **Oral Fluid Drug Test - FUO**



#### **Products Information •**

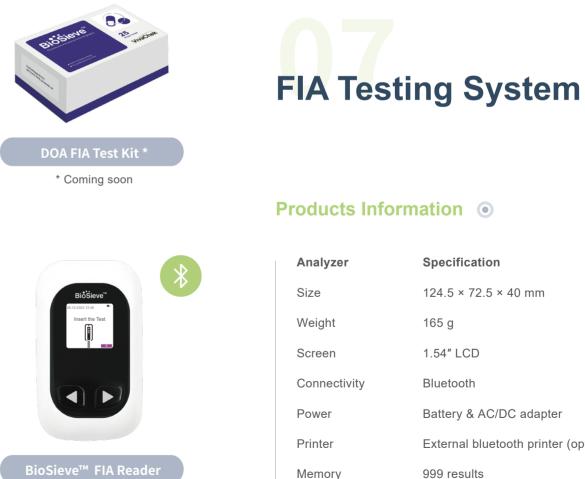
Drug Test	Cut-off (ng/mL)
AB-Pinaca (ABP)	10
Amphetamine (AMP)	300, 500
Benzodiazepines (BZO)	100, 200
Cannabinoids (THC)	25, 50
Clonazepam (CLO)	100
Cocaine (COC)	100, 150
Cotinine (COT)	200
EDDP	100
Ethyl Glucuronide (EtG)	500
Fentanyl (FYL)	200

Ketamine (KET)	1000
MDPV	1000
Methamphetamine (MET)	300, 500
Methadone (MTD)	200, 300
Methaqualone (MQL)	300
Methylphenidate (MPD)	300
Monoacetylmorphine (6-MAM)	10
Morphine (MOP/OPI)	100
Pregabalin (PGB)	1000
Synthetic Cannabisnoid (K2)	50
Tramadol (TML)	100, 200, 300

### **Accessories & Related Products**



BioSieve™ **DOA Controls** - 2 x 10 mL/box





#### BioSieve™

Adulteration Test Strips

- 25 strips/box

nalyzer	Specification
ze	124.5 × 72.5 × 40 mm
eight	165 g
creen	1.54" LCD
onnectivity	Bluetooth
ower	Battery & AC/DC adapter
inter	External bluetooth printer (optional)
emory	999 results