



Abon Biopharm (Hangzhou) Co., Ltd.
#198 12th Street East,
Hangzhou Economic & Technological
Development Area
Hangzhou, 310018, P.R.China
T: +86 571 81638000
F: +86 571 81638001

To: Department of Medical Equipment & Construction (DMEC)
138A Giang Vo str., Ba Dinh, Hanoi

AUTHORIZATION LETTER

We, **ABON Biopharm (Hangzhou) Co., Ltd.**

Address: #198 12th Street East, Hangzhou Economic & Technological Development Area, Hangzhou, 310018, P.R. China.

Tel.: +86 (571) 81638000

Fax: +86 (571) 81638001

Hereby appoint: **Asia Joint Stock Company**

Address: No. 17, L12A Trung Yen Urban Area, Yen Hoa Ward, Cau Giay District, Hanoi City, Vietnam

Tel: +84 24 37832446

Fax: +84 24 37832448

Our behalf in the name of the Registration of following products:

Product name:	MET One Step Methamphetamine Test Strip (Urine)	
Dosage forms:	Test Strip (solid state)	
Ingredient and amount of unite dose:		
Location	Ingredient	Amount
Conjugated pad	Methamphetamine (MET) antibody	0.022-0.812 μ g
	Rabbit antibody	0.011-0.487 μ g
Test line	Methamphetamine (MET) antigen	0.344-1.075 μ g
Control line	Goat antibody	0.224-0.662 μ g

at the Ministry of Health Vietnam (DMEC).

Asian Joint Stock Company - authorized facility - will be the owner of registration number and responsible to the Ministry of Health Vietnam (DMEC) on all matters related to this product in Vietnam.

Date: 2020/12/12

Authorization facility

(direct signature, full name and seal)

General manager: Mr. Frank Zhuang

Date: _____

Authorized facility

(direct signature, full name and seal)

General manager: Mr. Dao Dinh Khoi



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PRODUCT SPECIFICATION

I. PRODUCT INFORMATION

1	Product's name	MET One Step Methamphetamine Test Strip (Urine)		
2	Catalogue No.	DME-101		
3	Indication	The test is a rapid immuno-chromatographic assay for the qualitative detection of elevated levels of Methamphetamine in urine.		
4	Dosage form	Test Strip (solid state)		
5	Ingredient and amount per unit dose (test)	Location on the test	Ingredient	Amount
		Conjugated pad	Methamphetamine (MET) antibody	0.022-0.812 μ g
			Rabbit antibody	0.011-0.487 μ g
		Test line	Methamphetamine (MET) antigen	0.344-1.075 μ g
Control line	Goat antibody	0.224-0.662 μ g		
6	Product classification	In-Vitro rapid diagnostic test		
7	Specimen type	Human urine		
8	Method/ Technology	Immuno-Chromatographic Lateral Flow		
9	Cutoff	1000 ng/ml MET		
10	Assay time	5-10 minutes		
11	Dosage of use	1 test for each assay. Single use then destroy		
12	Storage	Room temperature (2-30 $^{\circ}$ C). Do not freeze		
13	Shelf life	24 months in sealed pouch.		
14	Specification	In-house		
15	Package	Each test kit contents: 1. Tests individually foil pouched: 50 2. Package insert: 1		
16	Manufacturer	ABON BIOPHARM (HANGZHOU) CO., LTD #198 12 th Street East, Hangzhou Economic & Technological Development Area, Hangzhou, 310018, P.R. China. Tel.: +86 (571) 81638000/ Fax: +86 (571) 81638001		

II. PHYSICAL SPECIFICATION

Procedures	Test Type		Grade AQL	Test Method
Pouch Package	A	Pouch mix up/printing information incorrect or missing	critical 0.15	visual check
	B	No seal	critical 0.15	visual check
	C	Damage/layer/Lack of components/Defected ink printing	major 0.65	visual check
	D	Dirty/no notch in pouch/seal method incorrect	minor 1.5	visual check
	H	Box mix up, barcode available for scan	/	visual check



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Procedures	Test Type		Grade AQL	Test Method
Box Package	K	Box label printing information incorrect or missing (product name, lot number, expiry date)	critical 0.15	visual check
	M	Incorrect or missing component in box	major 0.65	visual check
	N	Dirty/damage/ package method incorrect	minor 1.5	visual check
	P	Insert/operation card mix up, barcode available for scan	/	visual check
	R	Insert or card key information incorrect or missing	critical 0.15	visual check
Carton Package	S	Incorrect material/carton label print incorrect or missing	critical 0.15	visual check
	T	Quantity incorrect in carton	major 0.65	visual check
	U	Dirty/damage/packing method incorrect	minor 1.5	visual check

Remark: For AQL assigned as 0.15, acceptance criteria should be 0 defect.

Inspection Items		Test method	Critical	Major	Minor
Device/Strip	Assembly defect/Miscut	visual check	√	√	√
	NC Abnormal line/Streaky/dirty/damage	visual check	√	√	√
	Poor background	visual check	√	√	N/A
	Slanted C/T lines	visual check	N/A	√	√
	Invalid result	visual check	N/A	√	N/A
	Incomplete C line	visual check	N/A	N/A	√
	Strip/Panel bad stickness	visual check	N/A	N/A	√
	Cassette damage/dirty/poor printing	visual check	N/A	N/A	√
Attachment	Pouch/Canister Difficult to open	Manual operation	N/A	N/A	√

Remark: A broken C line visible ≤50% referred to as "Incomplete C line".

III. PERFORMANCE SPECIFICATION

Test line criteria:

Inspection Item	Critical Samples	Non-critical Samples	Critical Samples
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		Negative urine	-50% cutoff	+50% cutoff	3X cutoff
Inspection level		S-2	S-1	S-1	S-2
AQL		1.0	10	10	1.0
Batch size	≤35,000	13 (0, 1)	5 (1, 2)	5 (1, 2)	13 (0, 1)
	≥35,001	13 (0, 1)	10 (2, 3)	10 (2, 3)	13 (0, 1)
Test Line	MET	≥G7	≥G4	<G4	≤G3

Control line criteria:

Inspection Item		Negative Urine
Inspection level		S-1
AQL		1.5
Batch size	Any batch	8 (0, 1)
Control line	Appearance time	≤90 seconds
	Intensity	≥G8
Remark: Record the C line result of the first 8 pcs when testing the negative urine T line.		

Date: 2020/11/12
 ABON Biopharm (Hangzhou) Co., Ltd.
 (direct signature, full name and seal)

General manager: Mr. Frank Zhuang



HANGZHOU