

REPUBLICA



MOLDOVA

CERTIFICAT DE ÎNREGISTRARE

Societatea cu Răspundere Limitată "BIOSISTEM MLD"
— ESTE ÎNREGISTRATĂ LA CAMERA ÎNREGISTRĂRII DE STAT —

Numărul de identificare de stat - codul fiscal
1010600028048

Data înregistrării

12.08.2010

Data eliberării

12.08.2010

Svirepova Ludmila, registrator

*Funcția, numele, prenumele persoanei
care a eliberat certificatul*

L. Svirepova
semnătura

MD 0101250





AGENȚIA SERVICII PUBLICE

Departamentul înregistrare și licențiere a unităților de drept

EXTRAS

din Registrul de stat al persoanelor juridice

Nr. 531522 data 15.09.2023

Denumirea completă: **Societatea cu Răspundere Limitată "BIOSISTEM MLD"**

Denumirea prescurtată: **"BIOSISTEM MLD" S.R.L.**

Forma juridică de organizare: **Societate cu răspundere limitată,**

Numărul de identificare de stat și codul fiscal (IDNO): **1010600028048**

Data înregistrării de stat: **12.08.2010**

Sediul: **MD-2001, str. Albișoara, 16/1, ap. 7, mun. Chișinău, Republica Moldova.**

Obiectul principal de activitate:

- 1. Activitatea farmaceutică; importul și (sau) producerea articolelor de parfumerie și cosmetică**
- 2. Fabricarea, comercializarea, asistența tehnică, repararea și verificarea articolelor de tehnică și optică medicală**
- 3. Acordarea asistenței medicale de către instituțiile medico-sanitare private**
- 4. Comerțul cu ridicata al calculatoarelor, echipamentelor periferice și software-ului**
- 5. Întreținerea și repararea mașinilor de birou și a tehnicii de calcul**
- 6. Consultații în domeniul sistemelor de calcul**

Capitalul social: **5400 lei,**

Administrator: **POIATA VITALIE, IDNP 0983103892591,**

Asociații:

1. **POIATA VITALIE, IDNP 0983103892591, cota 1803,60 lei, ce constituie 33,4%**

Beneficiar efectiv:

- 1.1. **POIATA VITALIE, IDNP 0983103892591,**

2. **NASEDCHIN ALEXANDR, IDNP 2002001070747, cota 1798,20 lei, ce constituie 33,3%**

Beneficiar efectiv:

- 2.1. **NASEDCHIN ALEXANDR, IDNP 2002001070747,**

3. **KOJEVNIKOV DMITRII, IDNP 0972305012362, cota 1798,20 lei, ce constituie 33,3%**

Beneficiar efectiv:

- 3.1. **KOJEVNIKOV DMITRII, IDNP 0972305012362**

Prezentul extras este eliberat în temeiul art.34 al Legii nr.220-XVI din 19 octombrie 2007 privind înregistrarea de stat a persoanelor juridice și a întreprinzătorilor individuali și confirmă datele din Registrul de stat la data de: **15.09.2023.**

**Registrator în domeniul
înregistrării de stat**

Digitally signed by Rusu Diana
Date: 2023.09.15 16:44:17 EEST
Reason: MoldSign Signature
Location: Moldova



Rusu Diana



EB 0461494



BC "MOLDINDCONBANK" S.A.

Filiala "Invest"

Republica Moldova, MD-2068
mun. Chișinău, bd. Moscovei, 14/1
Tel. : (373-22) 43-44-81, 43-46-24
Fax : (373-22) 43-44-22
cod: MOLDMD2X329

Data 14. IAN. 2016
Nr. 03/2 - 19/23

Республика Молдова, MD-2068
мун. Кишинэу, бул. Московской, 14/1
Тел. : (373-22) 43-44-81, 43-46-24
Факс : (373-22) 43-44-22
код: MOLDMD2X329

Filiala „Invest” BC „Moldindconbank” SA confirmă existența contului curent în moneda națională al **“BIOSISTEM MLD” S.R.L. (c/f 1010600028048)**, cu **IBAN MD95ML000000002251429243**.

Codul băncii MOLDMD2X329.

Director

Nina Turcan

Director financiar



Nina Balmuș

Ex. Diana Brinza
Tel. 43-45-96

Lista fondatorilor Biosistem-mld SRL

Nr.	Nume, Prenume	IDNP
1.	Vitalie Poiata	0983103892591
2.	Alexandr Nasedchin	2002001070747
3.	Dmitrii Kojevnikov	0972305012362



Declaration of Conformity



According to the In Vitro Diagnostic Medical Devices Directive 98/79/EC

Manufacturer: Dirui Industrial Co., Ltd.
95 Yunhe Street New& High Tech. Development Zone
Changchun Jilin 130012 P.R. China

Authorized Representative : Emergo Europe
Molenstraat 15 2513 BH The Hague
The Netherlands

Medical Device : Product Name: Reagent strips for Urinalysis
IVDD-Classification: Professional use

Lot/batches/Serial mber, Type, Periods of manufacture
(where applicable)

DIRUI 1 ITEMS (GLU)	DIRUI 1 ITEMS (KET)	DIRUI 1 ITEMS (PRO)
DIRUI 2 ITEMS (PRO, GLU)	DIRUI 2 ITEMS (KET, GLU)	
DIRUI 3 ITEMS (PRO, PH, GLU)	DIRUI 3 ITEMS (PRO, KET, GLU)	
DIRUI 4 ITEMS (PRO, PH, BLD, GLU)	DIRUI 4 ITEMS (PRO, PH, SG, GLU)	
DIRUI 5 ITEMS (PRO, PH, BLD, KET, GLU)		
DIRUI 8 ITEMS	DIRUI H8	
DIRUI 9 ITEMS		
DIRUI A10	DIRUI H10	DIRUI E10
DIRUI H11	DIRUI H11-MA	DIRUI M10
DIRUI H11-800MA	DIRUI H12-800MA	DIRUI H10-800
DIRUI H13-Cr	DIRUI H14-Ca	
DIRUI H13-Cr (H-800)	DIRUI H14-Ca (H-800)	

The undersigned hereby declares that the In Vitro Diagnostic medical device as specified above conforms with the essential requirements listed in the Annex 1 of the European In Vitro Diagnostic Medical Device Directive 98/79/EC (IVDD)

This declaration of conformity is based on the European In Vitro Diagnostic Medical Device Directive 98/79/EC, Annex III.

Valid Since

May 9th, 2012
Changchun, China

(place and date of issue)

Representative:

Yu Ge

Dirui Industrial Co., Ltd.

于歌

(name and signature or equivalent
marking of authorized person)



H-Series

Urinalysis Strips User's Guide

Rev:07/2024

Intended Purpose:

This guide instructs the methods, reaction principles and points for attention for the use of DIRUI H Series Urinalysis Strips. DIRUI H Series Urinalysis Strips are made for urinalysis both qualitative and semi-quantitative, which are in vitro reagent for diagnostics. The strips are for professional use only. The results on the strips can be read visually and instrumentally. You are required to read the User's Guide before taking use of the strips. The following chart tells the type of strips and the items tested.

Products Type	Test Item
H11	Urobilinogen, Bilirubin, Ketone (acetoacetic acid), Blood, Protein, Nitrite, Leukocytes, Glucose, Specific Gravity, pH and Ascorbic Acid
H10	Urobilinogen, Bilirubin, Ketone (acetoacetic acid), Blood, Protein, Nitrite, Leukocytes, Glucose, Specific Gravity and pH
H8	Urobilinogen, Bilirubin, Ketone (acetoacetic acid), Blood, Protein, Nitrite, Glucose and pH

Sample Collecting and Preparation

Collect fresh urine in a clean and dry container. Don't centrifuge the urine. Mix the sample well before taking the test. The urine test must be taken within 2 hours. All samples must always be taken and kept under sanitary conditions.

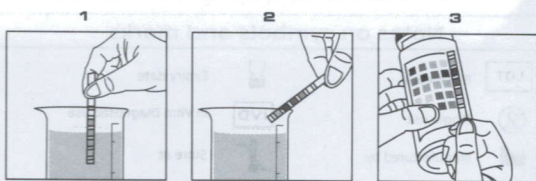
Note: Water should not be used as negative control liquid. The preservatives will not prevent the deterioration of ketones, bilirubin or urobilinogen. The growth of bacteria in the long-term storage sample may affect the test results on glucose, pH, nitrite and blood.

Test Method

Room temperature for test: (25±5)°C

Visual Reading

1. Promptly replace cap after taking out strip.
2. Immerse the reagent area of the strip in the urine and remove quickly.
3. Run the edge of the strip against the rim of the container to remove the excess urine.
4. Hold the strip horizontally and compare the result on the strip with the colour chart on the bottle label. Make note of the result. For a semi-quantitative result, read the result according to the time specified on the colour chart. For qualitative results, the strip should be read between 1-2 minutes after dipping. If a positive result is obtained, repeat the test and compare with the colour chart at the time specified. Colour changes beyond 2 minutes are of no diagnostic significance.



Instrumental Reading

Follow the directions given in the instrument user manual.

Limitation of Test Method

Like all lab tests, diagnosis result and therapeutic schedule can not be made according to any single diagnosis method. Reagent strips' application is based on clinical analysis. In clinical sample, the sensitivity depends upon several factors: the variability of color perception, specific gravity, pH and the lighting conditions change when the product is read visually. Each colour block or instrumental display value represents a range of values. Because of sample and reading variability, sample with analyte concentrations that fall between nominal levels may give results at either level. Results at levels greater

than the second positive level for the Protein, Glucose, Ketone, and Urobilinogen tests will usually be within one level of the true concentration. Exact agreement between visual results and instrumental results might not be found because of the inherent differences between the perception of the human eye and the optical system of the instruments.

Storage Condition and Validity

Storage Condition: The strips must be stored in dry place at the temperature between 2°C-30°C. Protect it from direct sunlight and chemical reagents.

Validity: Stored in dry place and avoid sunlight, with the temperature between 2°C-30°C, the sealed validity is 2 years; After opened seal, cover the tap closely, stored in dry, avoid sunlight with the temperature between 2°C-30°C, the validity is 1 month.

Reaction Principles

Glucose: The glucose oxidized by glucose oxidase catalyzes the formation of glucuronic acid and peroxide hydrogen. Peroxide hydrogen releases neo-ecotypes oxide [O] under the function of peroxidase. [O] oxidizes iodide potassium, which makes the colour changes.

Bilirubin: The direct bilirubin and dichlorobenzene diazonium produce azo dyes in a strongly acid medium.

Ketone: The acetoacetate and sodium nitroprusside cause reaction in alkaline medium, which produces violet colour.

Specific Gravity: Electrolyte (M^+X^-) in the form of salt in urine reacts with poly methyl vinyl ether and maleic acid (-COOH), which are weak acid ionic exchanger. The reaction produces hydrogenous ionogen, which reacts with pH indicator that causes the colour change.

Blood: Hemoglobin acts as peroxidase. It can cause peroxidase release neo-ecotypes oxide (O). (O) oxidizes the indicator and make the colour change subsequently.

pH: The method of pH indicator is applied.

Protein: This is based on the protein-error-of-indicator principle. Anion in the specific pH indicator attracted by cation on protein molecule makes the indicator further ionized, which changes its colour.

Urobilinogen: Urobilinogen and diazonium produce pink azo dyes under the function of strong acid medium.

Nitrite: Nitrite in the urine and aromatic amino sulphanilamide are diazotized to form a diazonium compound. The diazonium compound reacting with tetrahydro benzo(h) quinolin 3-phenol causes the colour change.

Leukocytes: Granulocyte leukocytes in urine contains esterases that catalyze the hydrolysis of the pyrrole amino acid ester to liberate 3-hydroxy 5-phenyl pyrrole. This pyrrole reacting with diazonium forms a purple colour.

Ascorbic Acid: Ascorbic acid, with 1,2-dihydroxy alkenes, under the alkaline condition, deoxidizes the blue 2,6-dichloroindophenolate into colourless N-(p-pheno)-2,6- dichloro-P-amine phenol.

Points for attention

Glucose

The test is for specificity of glucose. There is no false positive result occurred in reagent strip, caused by any substance in urine. When the ascorbic acid concentration ≥ 2.8 mmol/L or acetoacetic acid concentration ≥ 1.0 mmol/L, the sample of glucose concentration is 3 ~ 7 mmol/L may occur false negative result.

Bilirubin

Normally, even the most sensitive method can't detect bilirubin in urine. It is abnormal to have little bilirubin in urine, which requires further inspection. Medicines that dyes urine red and anything that shows red itself in an acid medium e.g., phenazopyridine may affect the test result. High concentration of the ascorbic acid may cause false negative result.

Ketone

The reagent strip reacts with acetoacetic acid in urine. It doesn't do with acetone or β -hydro butyric acid. Normal urine specimens usually conduct negative results in the test. False positive results may occur in highly pigmented urine or those containing a large amount of levodopa metabolites.

Specific Gravity

The reagent strip for Specific Gravity allows the urine specimens specific gravity between 1.000 and 1.030. In general, the mean error between the

results of the strip test and those from the refractive index method is only 0.005. To make it more accurate, 0.005 may be added to readings from urines with pH equal or greater than 6.5. Urine reading instrument can automatically make these adjustments in strip-readings. The urine nonionic constituents such as glucose or radiopaque dye won't make any changes in the test. Highly buffered alkaline urines may cause the low readings comparing with the other methods. Elevated specific gravity readings may occur in the presence of moderate quantities of protein (1-7.5g/L).

Blood

'Trace' reaction may vary among the patients. Clinical judgments are required for individual cases. The presence of green spots (intact erythrocytes) or green color (haemoglobin/myoglobin) on the reagent area within 60 seconds indicates for further diagnostic check. Blood is often found in the urine of the menstruating females. Haemoglobin 150µg/L-620µg/L is approximately equivalent to 5-15 cells/µL intact erythrocytes.

The reagent strip is highly sensitive to haemoglobin and thus can be used as a supplementary to the microscopic examination. The sensitivity of the strip might be reduced in urine with a large amount of specific gravity. The strips are equally sensitive to myoglobin as to haemoglobin. Certain oxidizing contaminants, such as hypochlorite, may lead to false positive results. Microbial peroxidase associated with urinary tract infection may also produce a false positive result. Normal Vitamine in urine may not influence the result of the test.

pH

The strip tests for pH values are generally in the range of 5.0-8.5 visually and 5.0-9.0 instrumentally.

Protein

The reagent area is more sensitive to albumin than to globulins, haemoglobin, Bence-Jones protein and mucoprotein. So a 'Negative Result' is not good enough to indicate that these proteins don't exist in urine. Normally no protein is detectable in urine with conventional methods, although a minute amount of protein is excreted through a normal kidney. It shows the protein in urine when the color is darker than mark on the chart. False positive results may be obtained in highly buffered alkaline urines. Urine specimens contaminated with quaternary ammonium compounds and cleansers containing chlorhexidine may also produce false positive results.

Urobilinogen

The reagent strips can detect urobilinogen in low amount as 3µmol/L (approximately 0.2 Ehrlich unit/dL) in urine. A result of 34µmol/L in urine indicate the critical value, representing the transition from normal to abnormal, which requires further check on patients and specimens. The negative results are not final to determine the absence of urobilinogen.

Nitrite

Gram-negative bacteria in urine converts nitrate(derived from foods) into nitrite. The reagent strip is essential to nitrite and won't react with the other substances in urine. Pink spots or edges on the strip should not be interpreted as positive result, but any degrees of uniform pink color development should be taken as positive result. The degrees of colour development the numbers of bacteria are not in direct proportion. The negative result doesn't mean the existence of bacteria in a large amount. Negative result may occur (1) when urine doesn't contain organism that caused the conversion from nitrate to nitrite. (2)when urine has not remained in the bladder long enough(four hours up)to let the nitrate covert into nitrite.(3) the nitrate in the foods is absent. Large High volume of specific gravity in urine may reduce the sensitivity of the test. 1.4mmol/L ascorbic acid or less won't interfere the test result.

Leukocytes

Test area react with esterase in leucocytes (granulocytic leukocytes). Normal urine specimens generally yield negative result; positive results (+ or greater) are clinically significant. Individually observed 'Trace' results may be of questionable clinical significance; however 'Trace' results observed repeatedly may be clinically significant. 'Positive' results may occasionally be found with random specimens from females due to contamination of the specimen by vaginal discharge. Elevated glucose concentrations (160mmol/L) or high specific gravity may cause decreased test results.

Ascorbic Acid

The test area can detect the ascorbic acid in urine. Through the ascorbic acid detection, we will know the level of ascorbic acid in the body and the effect degree that the ascorbic acid bring to the test on glucose, bilirubin, blood and nitrite. It will reduce the sensitivity when the oxidant (such as potassium permanganate, hypochlorite) in the urine.

Notes

The strips must be kept in the original bottle. Never use the products after the expiration date. Each strip can be used only once. Do not remove the desiccant(s). If strips are removed from the bottle, they must be used immediately. Cap the bottle immediately and tightly after taking out the strips. The strips should be stored in a dry place at the temperature between 2°C-30°C. Do not store the strips in refrigerator and keep them away from direct sunlight. Do not touch the reagent area of the strip. Protection against ambient moisture, light and heat is essential to guard against altered reagent reactivity. Deterioration may result in discoloration or darkening of the reagent area of the strip. If

this happens, or the test results are questionable or inconsistent with the expected results, check and make sure the strips are within the expiration date and also run a control. Please dispose the used strips as waste according to Treatment Regulations of Lab Biohazard Materials.

SENSITIVITY AND TEST RANGE OF H SERIES URINALYSIS STRIPS

Item	Sensitivity	Instrumental test range	Visual test range
Glucose (mmol/L)	2.8-5.6	Neg.-56	
Protein(g/L)	0.15-0.3	Neg.-3.0	Neg.-20.0
Ketone(acetoacetic acid) (mmol/L)	0.5-1.0	Neg.-7.8	Neg.-16
Blood (Ery/µL)	5-15	Neg.-200	
Bilirubin(µmol/L)	8.6-17	Neg.-103	
Nitrite(µmol/L)	13-22	Neg.- Pos.	
Leukocytes (leuko/µL)	5-15	Neg.-500	
Urobilinogen (µmol/L)	3.4-17	3.4-135	
Ascorbic Acid(mmol/L)	0.6-1.4	0-5.7	0-6.0
pH	—	5.0-9.0	5.0-8.5
Specific Gravity	—	1.005-1.030	1.000-1.030

REACTIVE INGREDIENTS

Protein	tetrabromphenol blue buffer nonreactive ingredients.	0.1% w/w 97.4% w/w 2.5% w/w
Blood	diisopropylbenzene dihydro peroxide tetramethylbenzidine buffer nonreactive ingredients.	26.0% w/w 1.5% w/w 35.3% w/w 37.2% w/w
Glucose	glucose oxidase (microbial,123U) peroxidase(horseradish, 203U) potassium iodide buffer nonreactive ingredients.	1.7% w/w 0.2% w/w 0.1% w/w 71.8% w/w 26.2% w/w
Ketone	sodium nitroprusside nonreactive ingredients buffer;	5.7% w/w 29.9% w/w 64.4% w/w
Leukocytes	pyrrole amino acid ester diazonium salt buffer nonreactive ingredients.	4.3% w/w 0.4% w/w 92.6% w/w 2.7% w/w
Nitrite	p-arsanilic acid-N-(1-Naphthol) -ethylenediamine tetrahydroquinoline buffer nonreactive ingredients	1.3% w/w 0.9% w/w 89.6% w/w 8.2% w/w
Specific Gravity	bromthymol blue poly(methyl vinyl ether co maleic anhydride) sodium hydroxide	4.8%w/w 90.2%w/w 5.0% w/w
pH	bromcresol green bromthymol blue nonreactive ingredients	3.3% w/w 55.0% w/w 41.7% w/w
Bilirubin	2,4-dichloroaniline diazonium salt buffer nonreactive ingredients	0.6%w/w 57.3%w/w 42.1%w/w
Urobilinogen	fast B blue buffer nonreactive ingredients	0.2%w/w 98.0%w/w 1.8%w/w
Ascorbic acid	2,6-dichloroindophenolate hydrate buffer nonreactive ingredients.	0.8%w/w 40.7%w/w 58.5%w/w

Notes on symbols and marks

LOT	Batch code	Expiry date
Single use	IVD	In Vitro Diagnostic Use
Manufactured by	Store at	
Please read package insert	CE	These test strips conform to the directive 98/79/EC(IVD-directive)
EC REP	Authorised Representative	REF
		Catalogue number

DIRUI®

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H-100

Urine Analyzer



DIRUI H-100 Semi-automatic urine analyzer offers ideal urine analysis solutions for small laboratories and hospitals.

Product features:

- ◎ Friendly interface is convenient for users' operation
- ◎ Built-in thermal printer can print results automatically
- ◎ 4 wavelength cold light source ensure the result accuracy
- ◎ Throughput is 60 samples/hour or 120 samples/hour
- ◎ 14 test items are optional
- ◎ Large capacity of data memory is convenient for reviewing
- ◎ H-100 can connect computer with RS-232

Order Information:

Product Number	Description	Pack Size
1520102001	DIRUI H-100 Urine Analyzer	1 instrument

Product Number	Description	Volume	Pack Size
2310201003	DIRUI H8	100 strips/ bottle	1 bottle
2310201002	DIRUI H10	100 strips/ bottle	1 bottle
2310201001	DIRUI H11	100 strips/ bottle	1 bottle
2310201021	DIRUI H11-MA	100 strips/ bottle	1 bottle
2310201037	DIRUI H13-Cr	100 strips/ bottle	1 bottle
2310201089	DIRUI H14-Ca	100 strips/ bottle	1 bottle