

ПОДТВЕРЖДАЮ

Директор

ЗАО «Медсервис»

А.Б. Бабинов

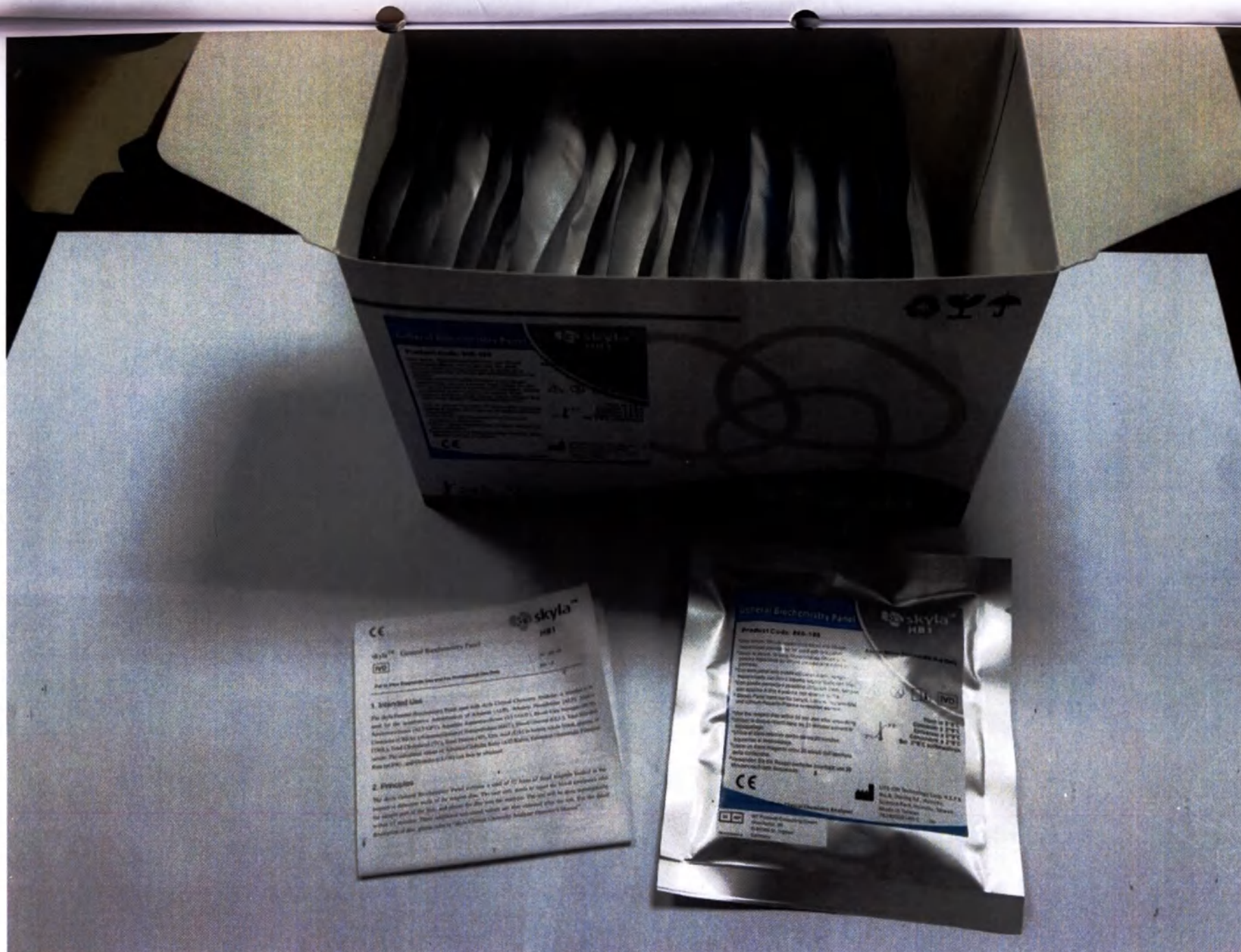
« 15 » декабря 2016 г.



Фотографическое изображение медицинского изделия

Панель биохимических реагентов для биохимического автоматического анализатора Skyla HB1 (Biochemistry Panel Skyla HB1) в вариантах исполнения

производства «Лайт-Он Текнолоджи Корпорейшн», Taiwan, R.O.C



Панель биохимических реагентов общая Skyla HB1 (General Biochemistry Panel Skyla HB1) в составе. Общий вид.



General Biochemistry Panel

skyla™
HB1

Product Code: 800-100

*Only serum, lithium heparinized blood and lithium heparinized plasma can be used with this panel.
*Seuls le sérum, le sang héparinisé au lithium et le plasma héparinisé au lithium peuvent être utilisés sur ce panneau.

*Con este panel solo puede utilizarse suero, sangre heparinizada con litio o plasma heparinizado con litio.

*Con questo pannello è possibile utilizzare siero, sangue con eparina di litio o plasma con eparina di litio.

*Dieses Panel kann nur für Serum, Lithium-Heparin-Blut und Lithium-Heparin-Plasma verwendet werden.

*Use the reagent disc within 20 minutes after unpacking.

*Utiliser le disque réactif dans les 20 minutes suivant le dépaquetage.

*Utilice el disco reactivo dentro de los 20 minutos siguientes al desembalaje.

*Usare un disco reagente entro 20 minuti dall'apertura della confezione.

*Verwenden Sie die Reagenzschibe innerhalb von 20 Minuten nach dem Auspacken.



Store at 2-8°C
Conserver à 2-8°C
Conservar a 2-8°C
Bei 2-8°C aufbewahren

CE



LITE-ON Technology Corp. U.S.A.
No. 8, Duxing Rd., Hsinchu
Science Park, Hsinchu, Taiwan
Made in Taiwan
782400014N-C 1W

For Clinical Chemistry Analyzer

2-8°C Σ 20

skyla™

General Biochemistry Panel

ALB	ALP	ALT	AST
BUN	CREA	GGT	GLU
TBIL	TC	TP	UA
A/G#	eGFR#	GLOB#	

(AEM12 or later)

LOT



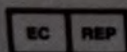
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Use by: 2017.02.17

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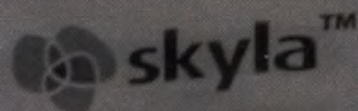
Product-Code: 800-100



MT Promed Consulting GmbH
Altenhofstr. 80
D-66386 St. Ingbert
Germany

7B24000060H-A



**HB1****skyla™ General Biochemistry Panel****IVD**

PN : 800-100

For In Vitro Diagnostic Use and For Professional Use Only

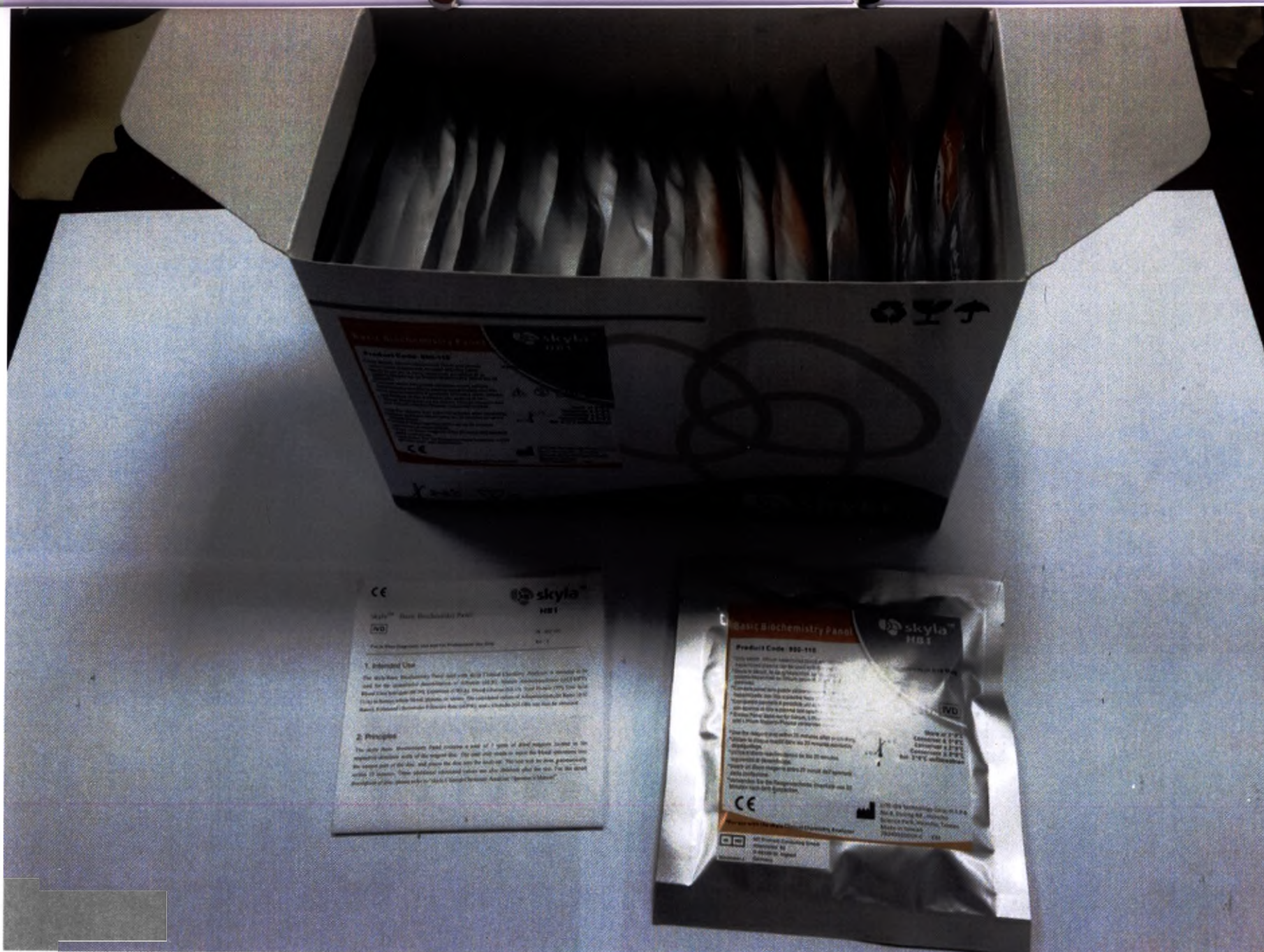
Rev : D

1. Intended Use

The skyla General Biochemistry Panel used with skyla Clinical Chemistry Analyzer, is intended to be used for the quantitative determination of Albumin (ALB), Alkaline Phosphatase (ALP), Alanine Aminotransferase (ALT/GPT), Aspartate Aminotransferase (AST/GOT), Blood Urea Nitrogen (BUN), Creatinine (CREA), γ -Gamma-Glutamyl Transpeptidase (GGT), Blood Glucose (GLU), Total Bilirubin (TBIL), Total Cholesterol (TC), Total Protein (TP), Uric Acid (UA) in human whole blood, plasma, or serum. The calculated values of Albumin/Globulin Ratio (A/G Ratio), Estimated Glomerular Filtration Rate (eGFR), and Globulin (GLOB) can then be obtained.

2. Principles

The skyla General Biochemistry Panel contains a total of 12 types of dried reagents located in the respective detection wells of the reagent disc. The user only needs to inject the blood specimens into the sample port of the disc, and places the disc into the analyzer. The test will be done automatically within 15 minutes. Three additional calculated values are also obtained after the test. For the detail description of disc, please refer to "skyla Clinical Chemistry Analyzer Operator's Manual".



Basic Biochemistry Panel

skyla™
HB1

Product Code: 800-110

*Only serum, lithium heparinized blood and lithium heparinized plasma can be used with this panel.

*Seuls le sérum, le sang héparinisé au lithium et le plasma héparinisé au lithium peuvent être utilisés sur ce panneau.

*Con este panel solo puede utilizarse suero, sangre heparinizada con litio o plasma heparinizado con litio.

*Con questo pannello è possibile utilizzare siero, sangue con eparina di litio e plasma con eparina di litio.

*Dieses Panel kann nur für Serum, Lithium-Heparin-Blut und Lithium-Heparin-Plasma verwendet werden.

*Use the reagent disc within 20 minutes after unpacking.
*Utiliser le disque réactif dans les 20 minutes suivant le dépackaging.

*Utilice el disco reactivo dentro de los 20 minutos siguientes al desembalaje.

*Usare un disco reagente entro 20 minuti dall'apertura della confezione.

*Verwenden Sie die Reagenzscheibe innerhalb von 20 Minuten nach dem Auspacken.

CE

For use with the Skyla Clinical Chemistry Analyzer

For use with the Skyla Clinical Chemistry Analyzer



Store at 2-8°C
Conserver à 2-8°C
Conserver a 2-8°C
Conserve a 2-8°C
Bei 2-8°C aufbewahren



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Science Park, Hsinchu, Taiwan
Made in Taiwan
782400005H-C CM

2-8°C Σ 20

skyla™

Basic Biochemistry Panel

ALB ALT BUN CREA
GLU TP UA A/G#
eGFR# GLOB#

(AEM12 or later)

LOT

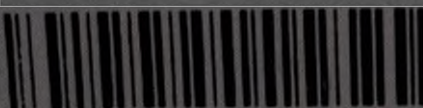


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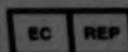
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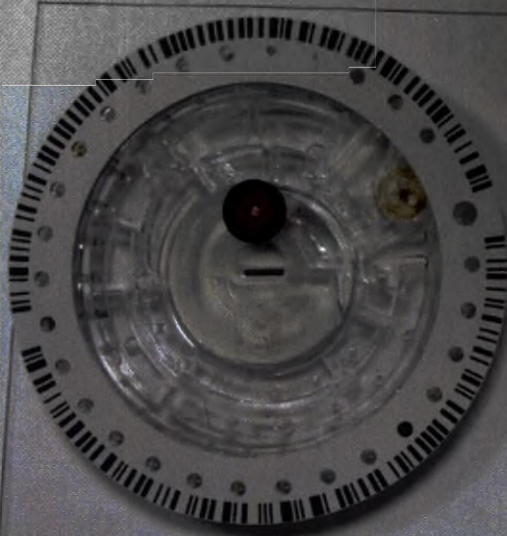


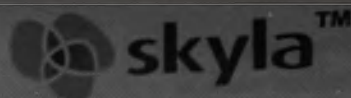
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skyla™ Basic Biochemistry Panel

HB1

IVD

PN : 800-110

For In Vitro Diagnostic Use and For Professional Use Only

Rev : D

1. Intended Use

The skyla Basic Biochemistry Panel used with skyla Clinical Chemistry Analyzer, is intended to be used for the quantitative determination of Albumin (ALB), Alanine Aminotransferase (ALT/GPT), Blood Urea Nitrogen (BUN), Creatinine (CREA), Blood Glucose (GLU), Total Protein (TP), Uric Acid (UA) in human whole blood, plasma, or serum. The calculated values of Albumin/Globulin Ratio (A/G Ratio), Estimated Glomerular Filtration Rate (eGFR), and e Globulin (GLOB) can then be obtained.

2. Principles

The skyla Basic Biochemistry Panel contains a total of 7 types of dried reagents located in the respective detection wells of the reagent disc. The user only needs to inject the blood specimens into the sample port of the disc, and places the disc into the analyzer. The test will be done automatically within 15 minutes. Three additional calculated values are also obtained after the test. For the detail description of disc, please refer to "skyla Clinical Chemistry Analyzer Operator's Manual".

Инструкция по применению – 1 шт.

Прошито и скреплено печатью

11/09/2014 листов

Директор ЗАО «МедСервис»

А.Б. Бабилов
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