NATFORLAB 2025

Snibe Diagnostic

БОЛЬШЕ ЧЕМ АВТОМАТИЗАЦИЯ СТРЕМЛЕНИЕ К СОВЕРШЕНСТВУ

Snibe - Идеальные лабораторные решения

2025

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2 Идеальные лабораторные решения

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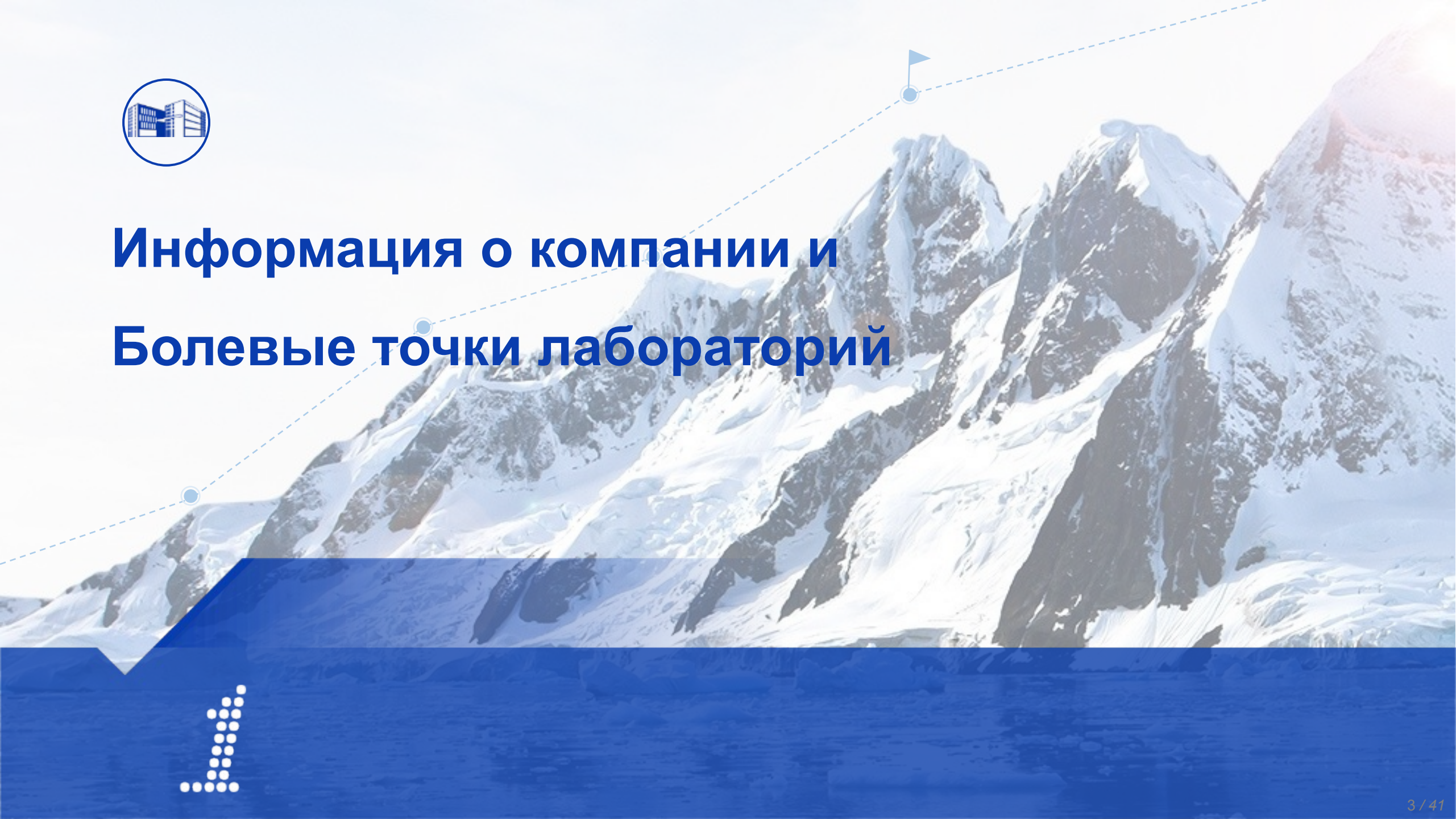
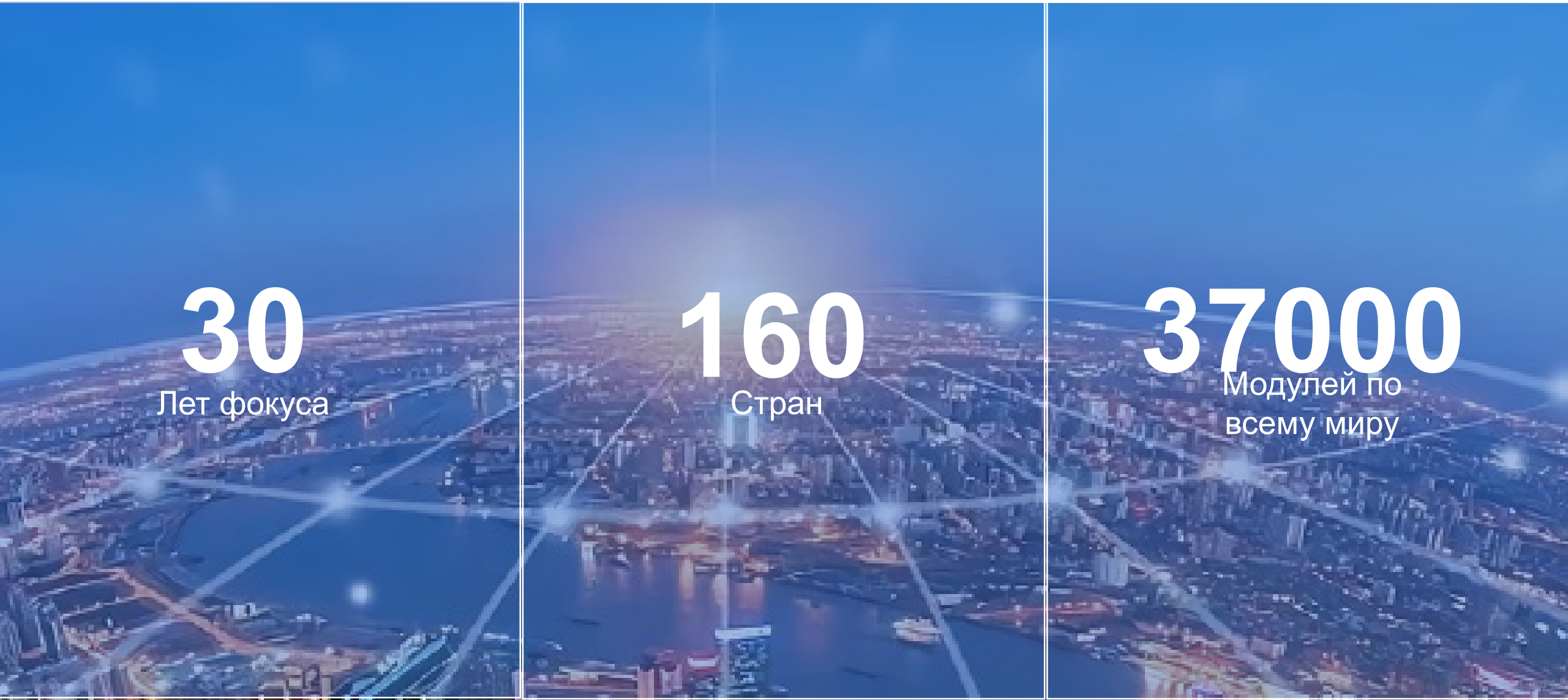


Информация о компании и

Болевые точки лабораторий

No.1 Быстрый хемилюминесцентный иммунохимический анализ в мире



Точное определение болевых точек пользователей

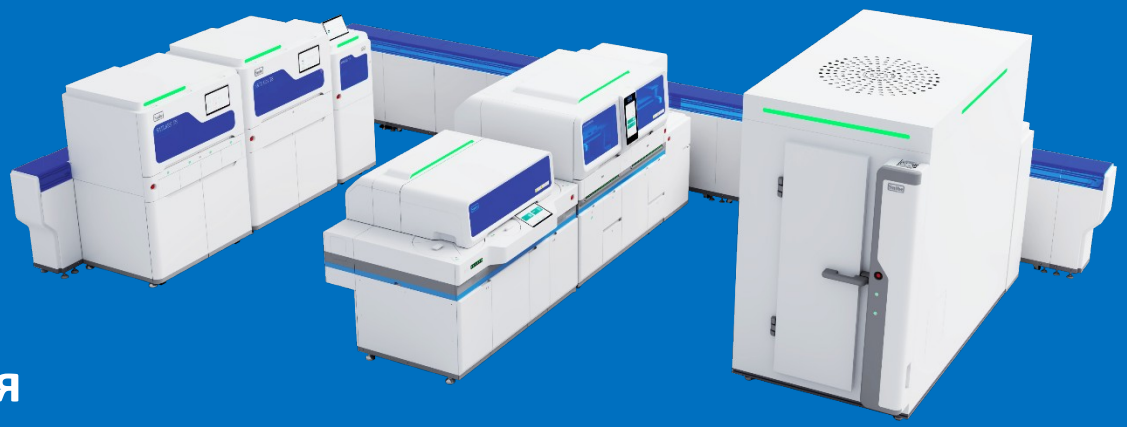
Болевые точки	Требования
Большой объем тестов	**Высокая производительность**
Низкая стабильность результатов	**Высокая эффективность**
Нехватка места в лаборатории	**Экономия места**
Высокая частота сбоев	**Высокая надежность**
Высокая стоимость реагентов и расходных материалов	**Экономическая эффективность**
Сложное ручное управление	**Высокий уровень автоматизации**
Недостаток специфических параметров	**Комплексное меню**

Snibe Идеальные Лабораторные Решения

Решения для комплексной автоматизации лабораторий

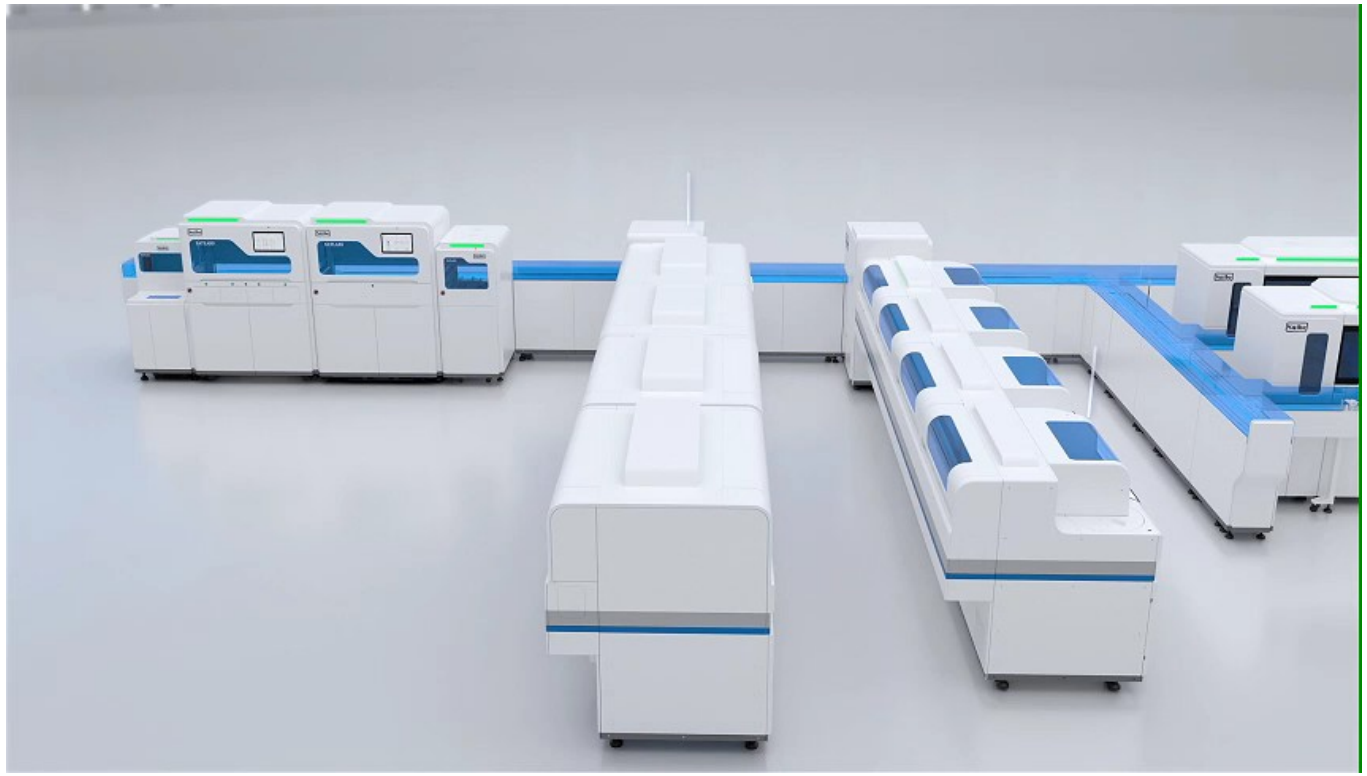
SATLARS™ T8 — Новейшее решение полной автоматизации лаборатории

SATLARS™ T8 — это мощное решение для автоматизации лабораторных процессов, обеспечивающее **высокую эффективность, надежную работу и интеллектуальные функции** для оптимизации рабочего процесса и раскрытия большего потенциала ваших лабораторий.



Решение полной автоматизации — SATLARS™ T8

Различные планировки и гибкие комбинации



Различные планировки могут быть настроены по мере необходимости.

Гибкие комбинации и неограниченные возможности расширения для удовлетворения растущих потребностей лабораторий.

- T форма
- U форма
- I формае
- F форма

Особенность 2

Беспрецедентный анализатор CLIA

MAGLUMI® X Series

Новое поколение — MAGLUMI® X Series

Одна кювета + Переработанная ОС + Улучшенное качество = Беспрецедентная группа X

ABS

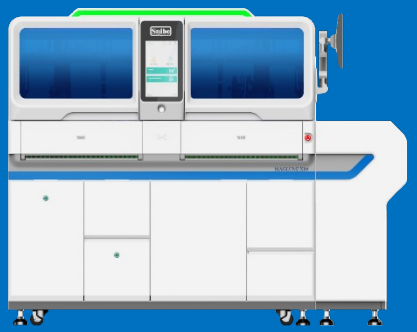
Сбалансированный и мощный

Учитывая общую ситуацию, а также изобретательную конструкцию и использование передовых на сегодняшний день технологий, анализатор демонстрирует превосходные характеристики и занимает лидирующие позиции.


MAGLUMI® X3


MAGLUMI® X6


MAGLUMI® X8


MAGLUMI® X10

Особенность 3

Комплексные продуктовые решения

Биохимия / Электролиты

Biossays® 240 Plus

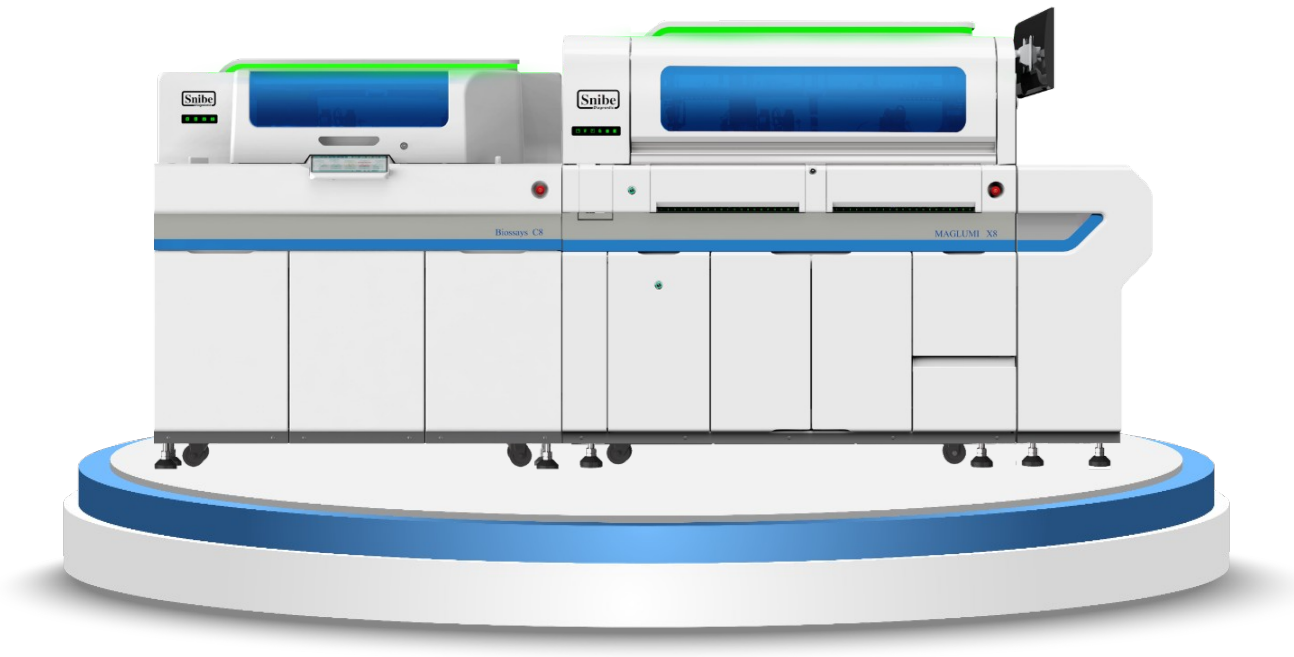
Автоматический биохимический анализатор

- Пропускная способность: **240** тестов в час
- Опциональный модуль электролитов: **200** тестов в час
- До **90** позиций образцов и реагентов, загрузка в работе
- **Низкое потребление воды** (≦2.0-3.0 Л/ч)
- **16** длин волн от 340 нм доо 800 нм

Интегрированные системы

Biolumi® CX8

Увеличьте потенциал своей лаборатории, используя всего 3,8 м²



Надежная работа

- Передовые биохимические технологии и X-tech обеспечивают точные результаты

Удобство управления

- Все устройства управляются интеллектуальным программным обеспечением
- Вспомогательные системы отображения для удобного управления испытаниями

Flexible Expansion

- Различные комбинации X8, C8 и модуля открытия образца
- Возможность подключения к TLA/LAS

Особенность 4

Широкое меню тестов ИХЛ и превосходная эффективность реагентов

Широкое меню тестов ИХЛ охватывает 23 панели заболеваний

Реагенты - легкие в использовании

Наборы реагентов совместимы со всеми анализаторами

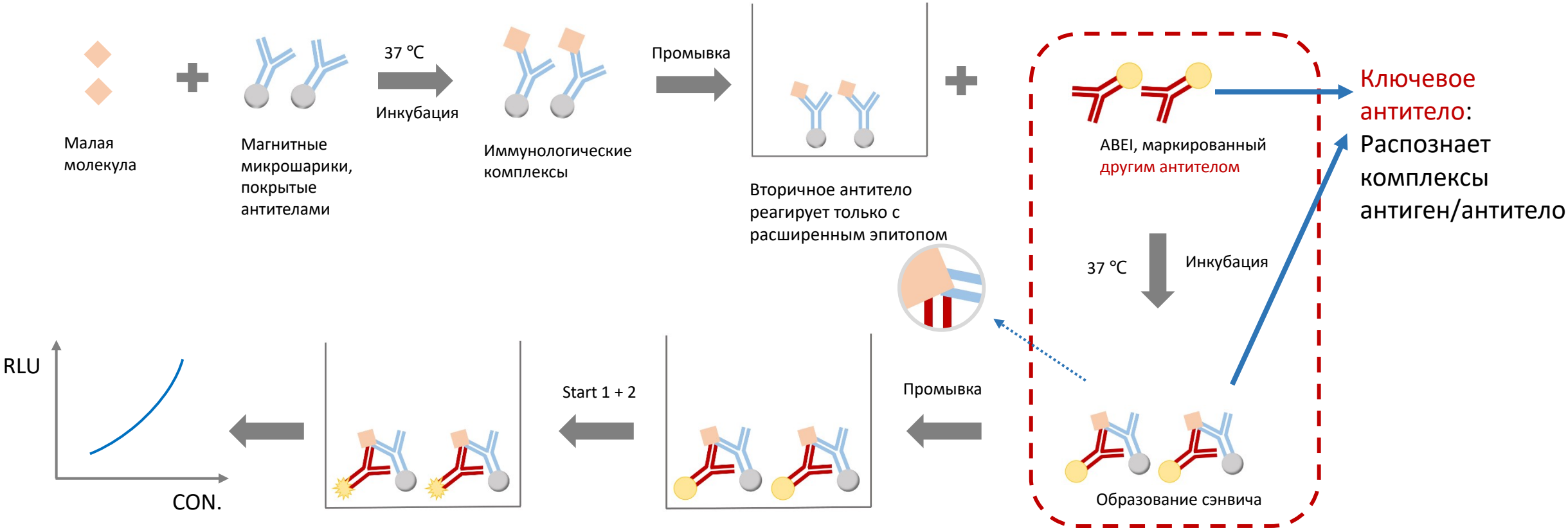
- Интегрированный набор реагентов, готовый к использованию
- RFID метка хранит всю информацию о реагенте
- Легко и быстро, загрузка/выгрузка реагентов без пауз
- 2-точечная перекалибровка для мастер-кривой
- 50/100T в упаковке, выбирайте в соответствии с потребностями вашей лаборатории

- ✓ **Внутренний контроль качества и калибраторы предоставляются бесплатно.**
- ✓ **Не беспокойтесь о проблемах с регистрацией реагентов.**

Инновационная технология измерения малых молекул

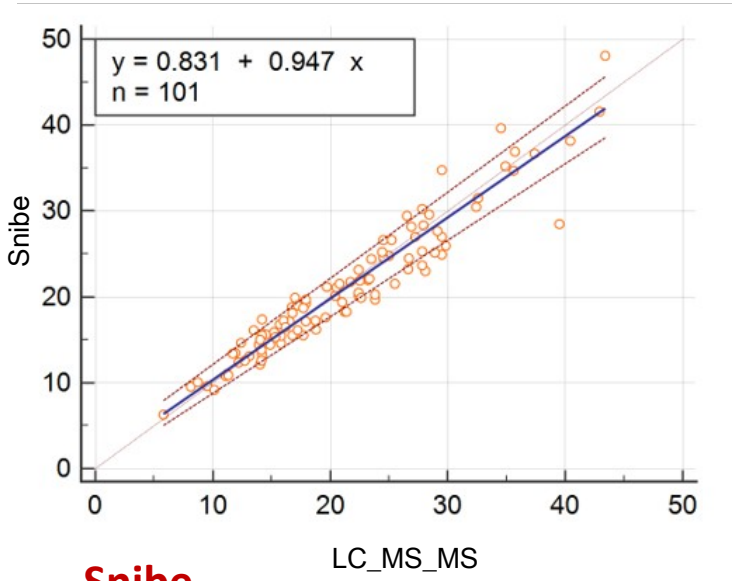
Новое решение для достижения более высокой точности, достоверности и чувствительности

Принцип

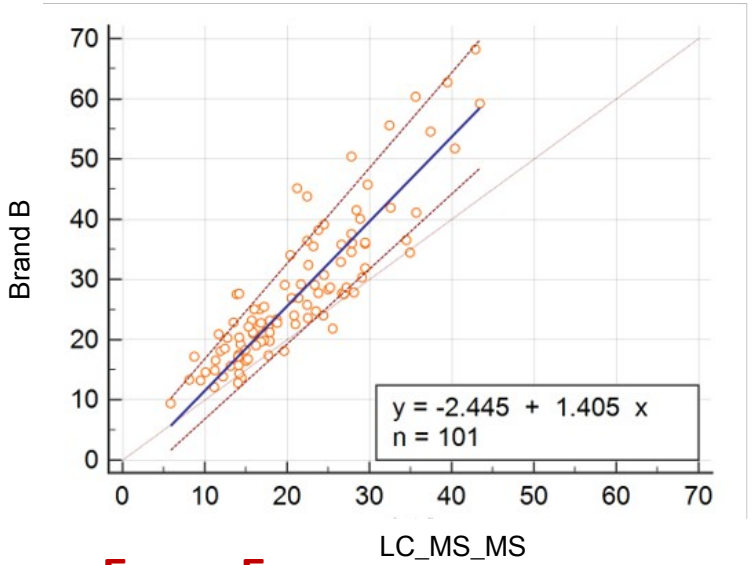


Инновационная технология измерения малых молекул

MAGLUMI® 25-OH Vitamin D — Сравнение трех систем иммуноферментного анализа и ЖХ-МС



Snibe
r=0.967



Брэнд Б
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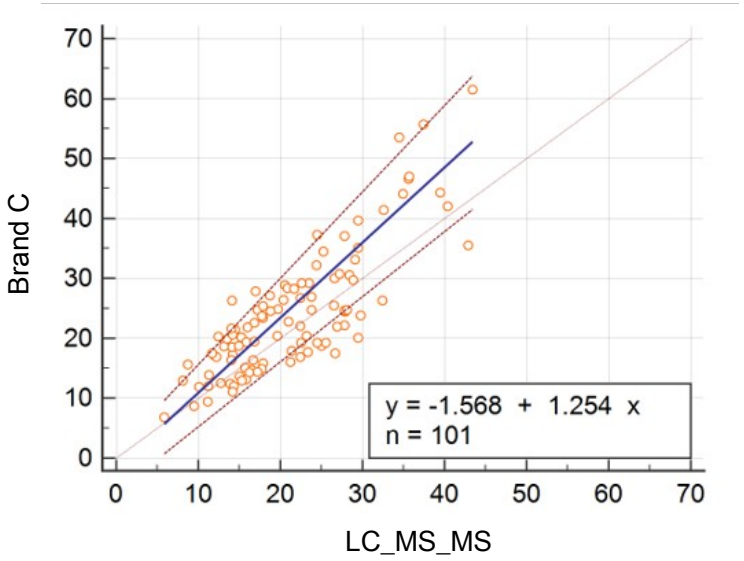


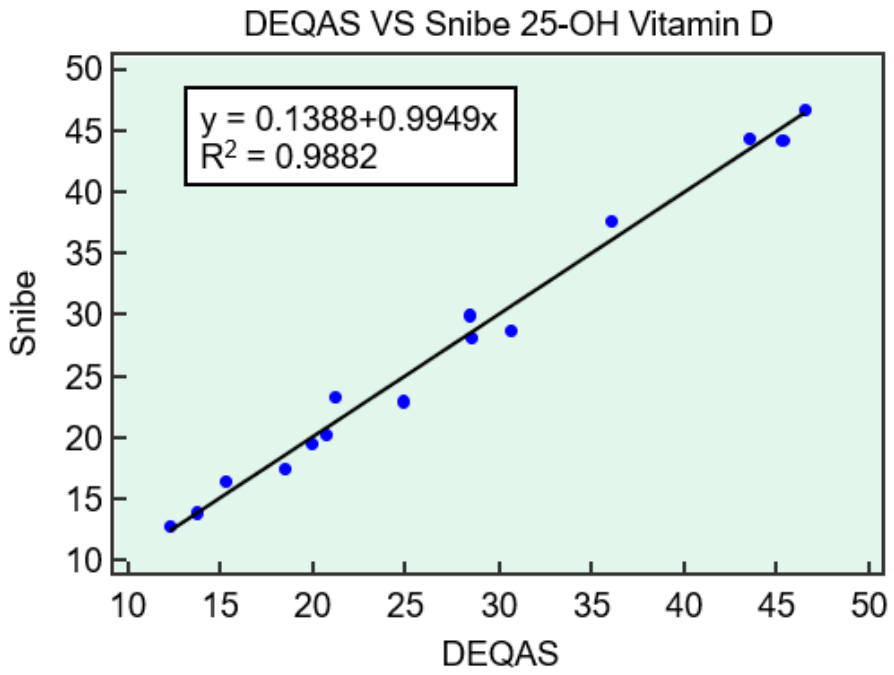
Брэнд В
r=0.777

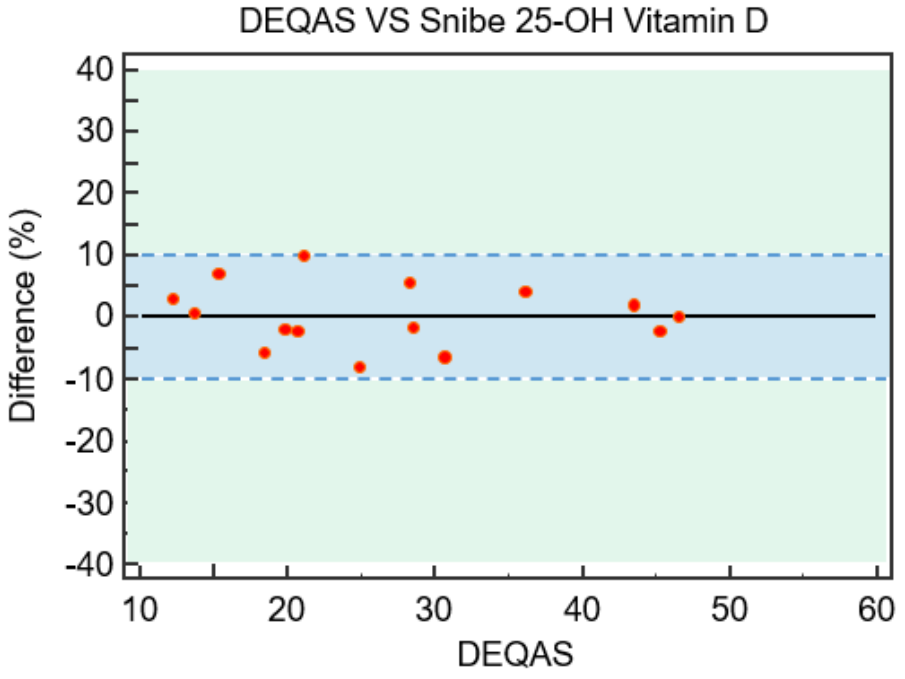
Реагент нового поколения, использующий метод сэндвича с малыми молекулами

- Высокая чувствительность, повышенная точность
- Хорошее соответствие результатов официальной референтной методике измерения (ЖХ-МС)
- Более широкий линейный диапазон (1,50–150 нг/мл)

Инновационная технология измерения малых молекул

MAGLUMI® 25-OH Vitamin D — сравнение результатов UK DEQAS





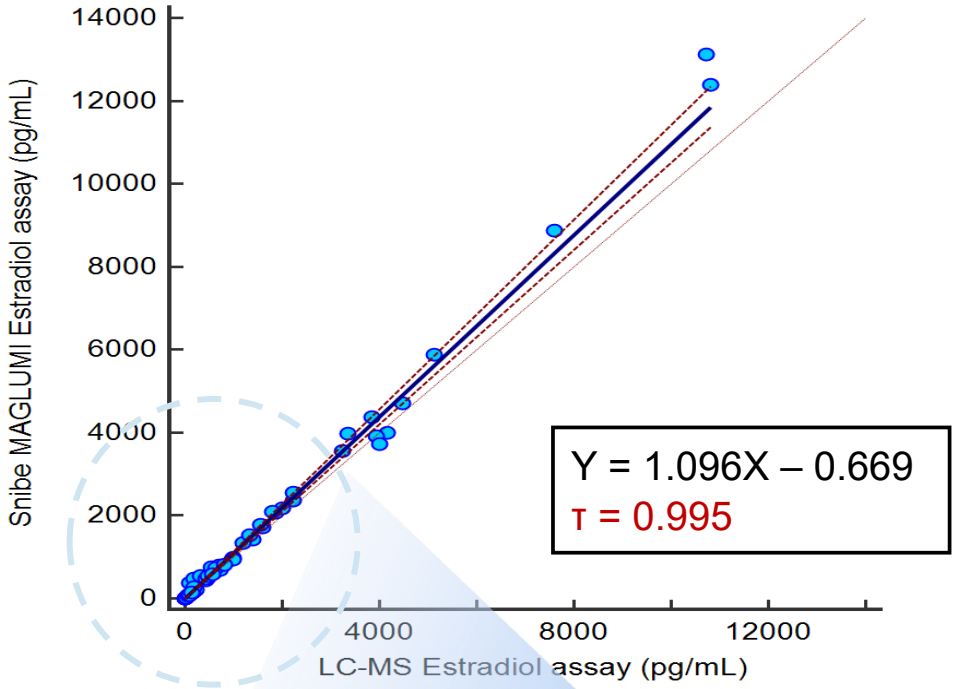
D · E · Q · A · S
Vitamin D
External Quality
Assessment Scheme

Snibe 25-OH Vitamin D в высокой степени соответствует образцам межлабораторной оценки качества DEQAS, полученным по данным масс-спектрометрии. Для каждого образца допускается систематическая погрешность в пределах 10%, при этом средняя погрешность составила 0,22%.

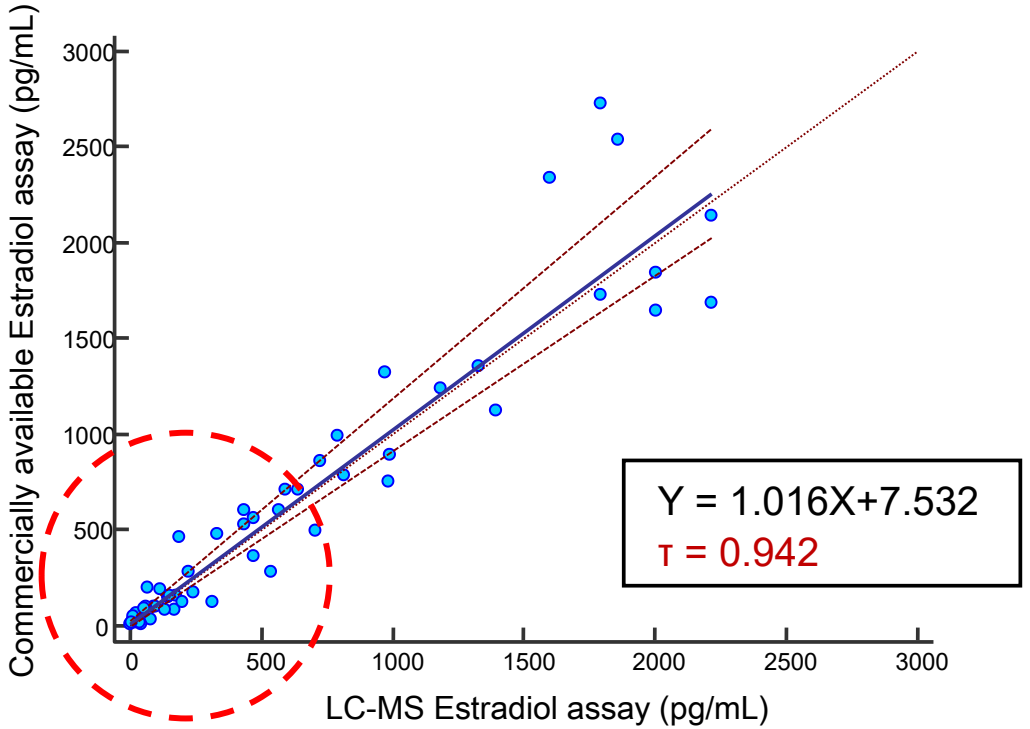
Инновационная технология измерения малых молекул

MAGLUMI® Estradiol — Точное измерение образцов с низкой концентрацией

Snibe MAGLUMI® Эстрадиол против ЖХ-МС Эстрадиол



Доступный на рынке Эстрадиол против ЖХ-МС Эстрадиол



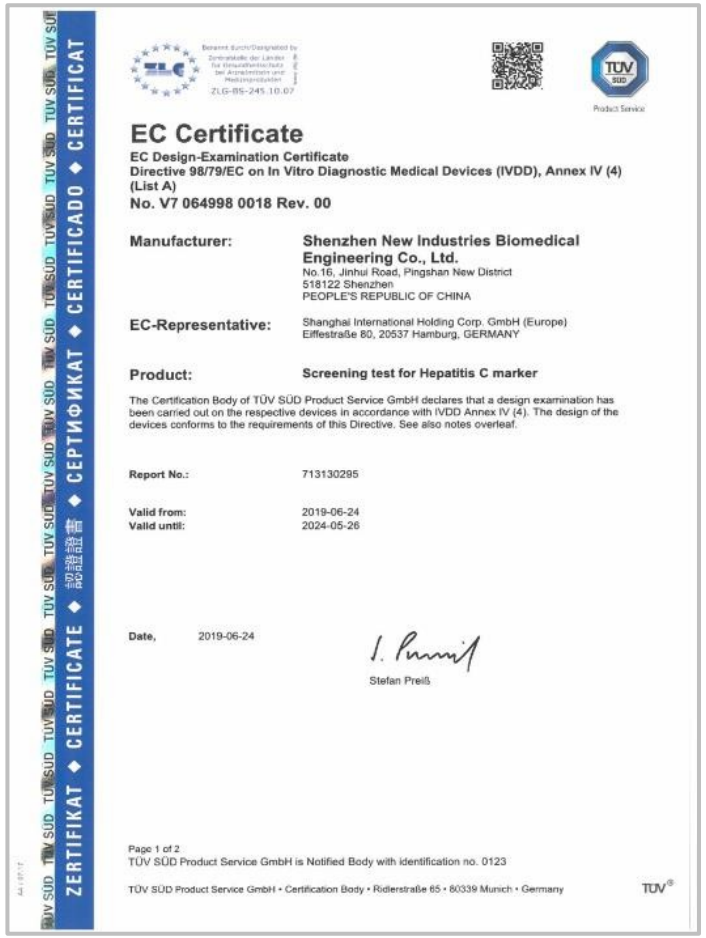
Высокая степень соответствия методу ЖХ-МС, особенно в низких концентрациях, что обеспечивает точность теста при низких концентрациях.

Особенность 5

Превосходное качество с множеством сертификатов

CE List A Сертификаты

Первый в Китае, получивший маркировку CE для тестов ИХЛ на anti-HCV



ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

ZLG-BS-245.10.07

EC Certificate

EC Design-Examination Certificate
Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV (4) (List A)
No. V7 064998 0018 Rev. 00

Manufacturer: **Shenzhen New Industries Biomedical Engineering Co., Ltd.**
No.16, Jinhui Road, Pingshan New District
518122 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

EC-Representative: Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80, 20537 Hamburg, GERMANY

Product: **Screening test for Hepatitis C marker**

The Certification Body of TÜV SÜD Product Service GmbH declares that a design examination has been carried out on the respective devices in accordance with IVDD Annex IV (4). The design of the devices conforms to the requirements of this Directive. See also notes overleaf.

Report No.: 713130295

Valid from: 2019-06-24
Valid until: 2024-05-26

Date, 2019-06-24

Stefan Preiß

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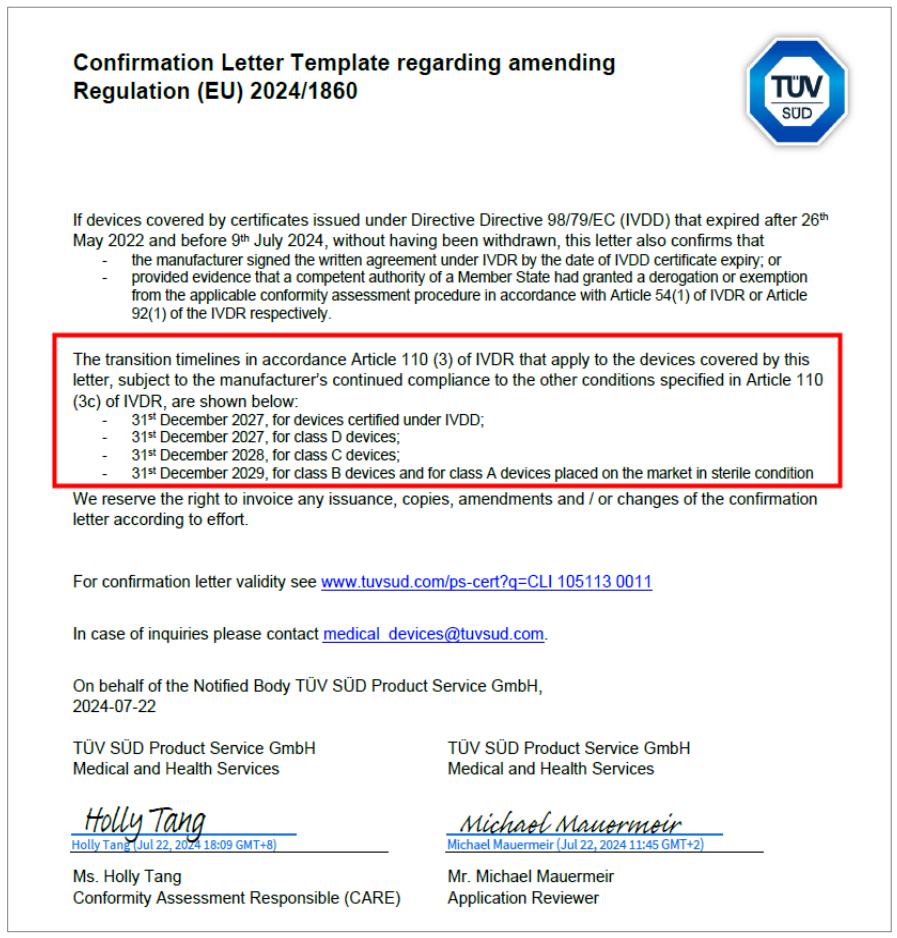
TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany



Confirmation Letter Template regarding amending Regulation (EU) 2024/1860

If devices covered by certificates issued under Directive Directive 98/79/EC (IVDD) that expired after 26th May 2022 and before 9th July 2024, without having been withdrawn, this letter also confirms that

- the manufacturer signed the written agreement under IVDR by the date of IVDD certificate expiry; or
- provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 54(1) of IVDR or Article 92(1) of the IVDR respectively.

The transition timelines in accordance Article 110 (3) of IVDR that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 110 (3c) of IVDR, are shown below:

- 31st December 2027, for devices certified under IVDD;
- 31st December 2027, for class D devices;
- 31st December 2028, for class C devices;
- 31st December 2029, for class B devices and for class A devices placed on the market in sterile condition

We reserve the right to invoice any issuance, copies, amendments and / or changes of the confirmation letter according to effort.

For confirmation letter validity see www.tuvsud.com/ps-cert?q=CLI 105113 0011

In case of inquiries please contact medical_devices@tuvsud.com.

On behalf of the Notified Body TÜV SÜD Product Service GmbH,
2024-07-22

TÜV SÜD Product Service GmbH
Medical and Health Services

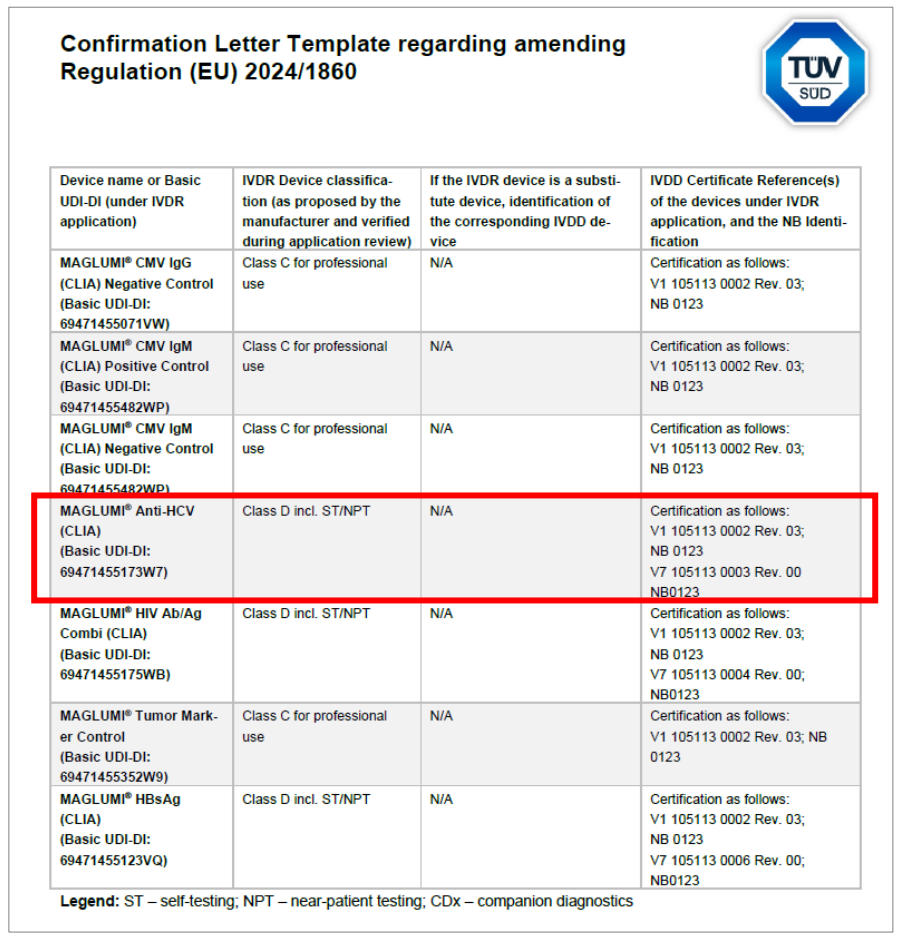
Holly Tang
Holly Tang (Jul 22, 2024 18:09 GMT+8)

Ms. Holly Tang
Conformity Assessment Responsible (CARE)

TÜV SÜD Product Service GmbH
Medical and Health Services

Michael Mauermeir
Michael Mauermeir (Jul 22, 2024 11:45 GMT+2)

Mr. Michael Mauermeir
Application Reviewer



Confirmation Letter Template regarding amending Regulation (EU) 2024/1860

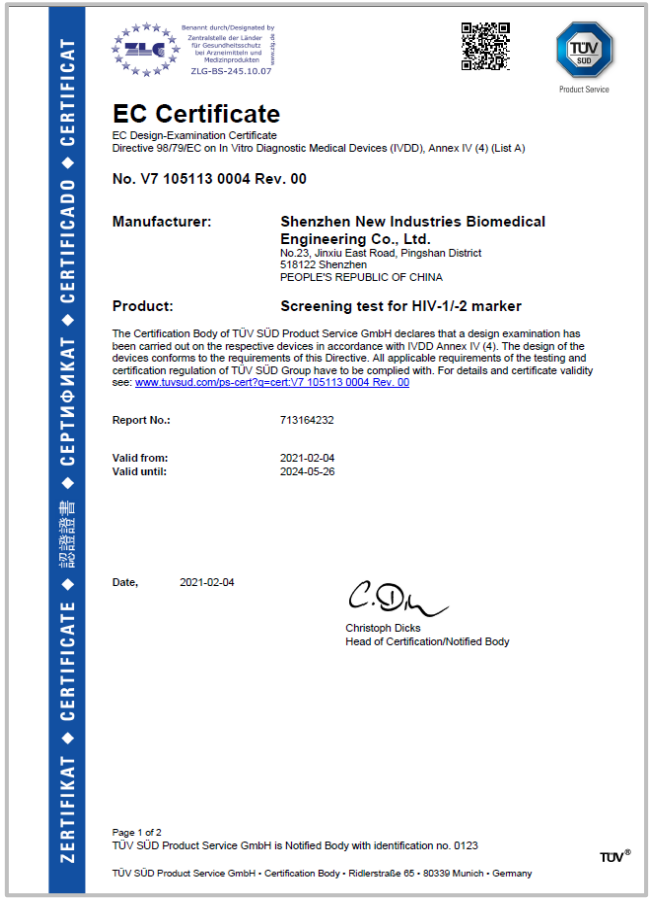
Device name or Basic UDI-DI (under IVDR application)	IVDR Device classification (as proposed by the manufacturer and verified during application review)	If the IVDR device is a substitute device, identification of the corresponding IVDD device	IVDD Certificate Reference(s) of the devices under IVDR application, and the NB Identification
MAGLUMI® CMV IgG (CLIA) Negative Control (Basic UDI-DI: 69471455071VW)	Class C for professional use	N/A	Certification as follows: V1 105113 0002 Rev. 03; NB 0123
MAGLUMI® CMV IgM (CLIA) Positive Control (Basic UDI-DI: 69471455482WP)	Class C for professional use	N/A	Certification as follows: V1 105113 0002 Rev. 03; NB 0123
MAGLUMI® CMV IgM (CLIA) Negative Control (Basic UDI-DI: 69471455482WP)	Class C for professional use	N/A	Certification as follows: V1 105113 0002 Rev. 03; NB 0123
MAGLUMI® Anti-HCV (CLIA) (Basic UDI-DI: 69471455173W7)	Class D incl. ST/NPT	N/A	Certification as follows: V1 105113 0002 Rev. 03; NB 0123 V7 105113 0003 Rev. 00 NB0123
MAGLUMI® HIV Ab/Ag Combi (CLIA) (Basic UDI-DI: 69471455175WB)	Class D incl. ST/NPT	N/A	Certification as follows: V1 105113 0002 Rev. 03; NB 0123 V7 105113 0004 Rev. 00; NB0123
MAGLUMI® Tumor Marker Control (Basic UDI-DI: 69471455352W9)	Class C for professional use	N/A	Certification as follows: V1 105113 0002 Rev. 03; NB 0123
MAGLUMI® HBsAg (CLIA) (Basic UDI-DI: 69471455123VQ)	Class D incl. ST/NPT	N/A	Certification as follows: V1 105113 0002 Rev. 03; NB 0123 V7 105113 0006 Rev. 00; NB0123

Legend: ST – self-testing; NPT – near-patient testing; CDx – companion diagnostics

CE List A Сертификаты

MAGLUMI® HIV Ab/Ag Combi

Анализ ИХЛ (4-го поколения) имеет маркировку CE (список A) — это высококачественное решение для ранней диагностики ВИЧ-инфекции.



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Benannt durch/Designated by Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten

ZLG-BS-245.10.07

TÜV SÜD Product Service

EC Certificate

EC Design-Examination Certificate
Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV (4) (List A)

No. V7 105113 0004 Rev. 00

Manufacturer: **Shenzhen New Industries Biomedical Engineering Co., Ltd.**
No.23, Jinxiu East Road, Pingshan District
518122 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

Product: **Screening test for HIV-1/-2 marker**

The Certification Body of TÜV SÜD Product Service GmbH declares that a design examination has been carried out on the respective devices in accordance with IVDD Annex IV (4). The design of the devices conforms to the requirements of this Directive. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:V7 105113 0004 Rev. 00

Report No.: 713164232

Valid from: 2021-02-04
Valid until: 2024-05-26

Date, 2021-02-04

Christoph Dicks
Head of Certification/Notified Body

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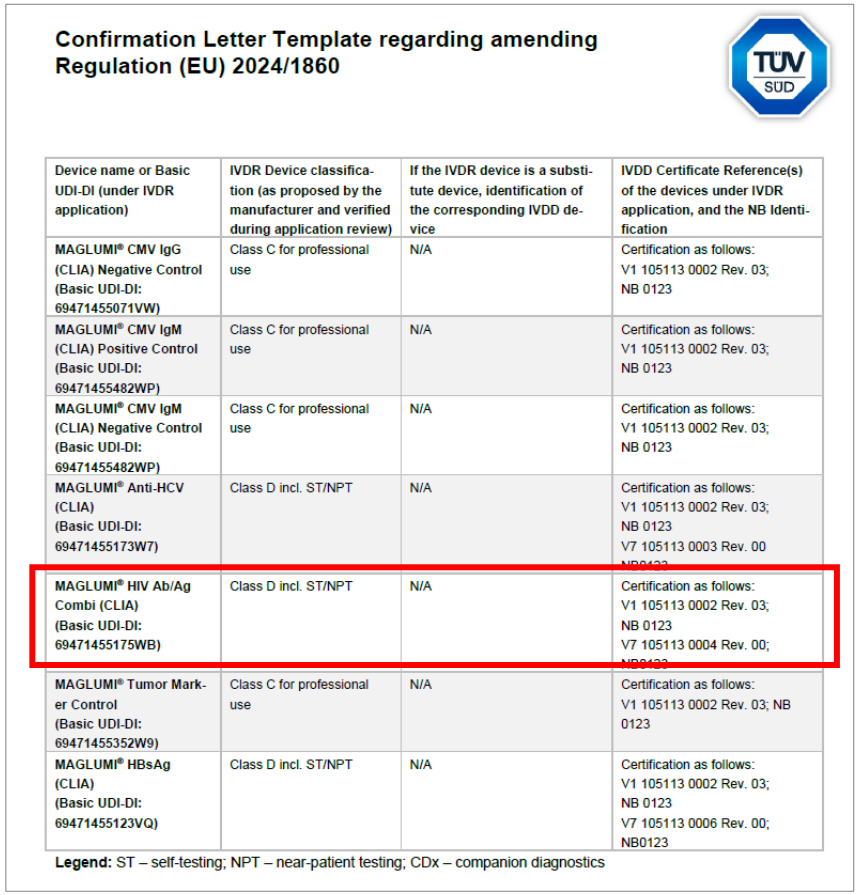
TÜV®



Confirmation Letter Template regarding amending Regulation (EU) 2024/1860

TÜV SÜD

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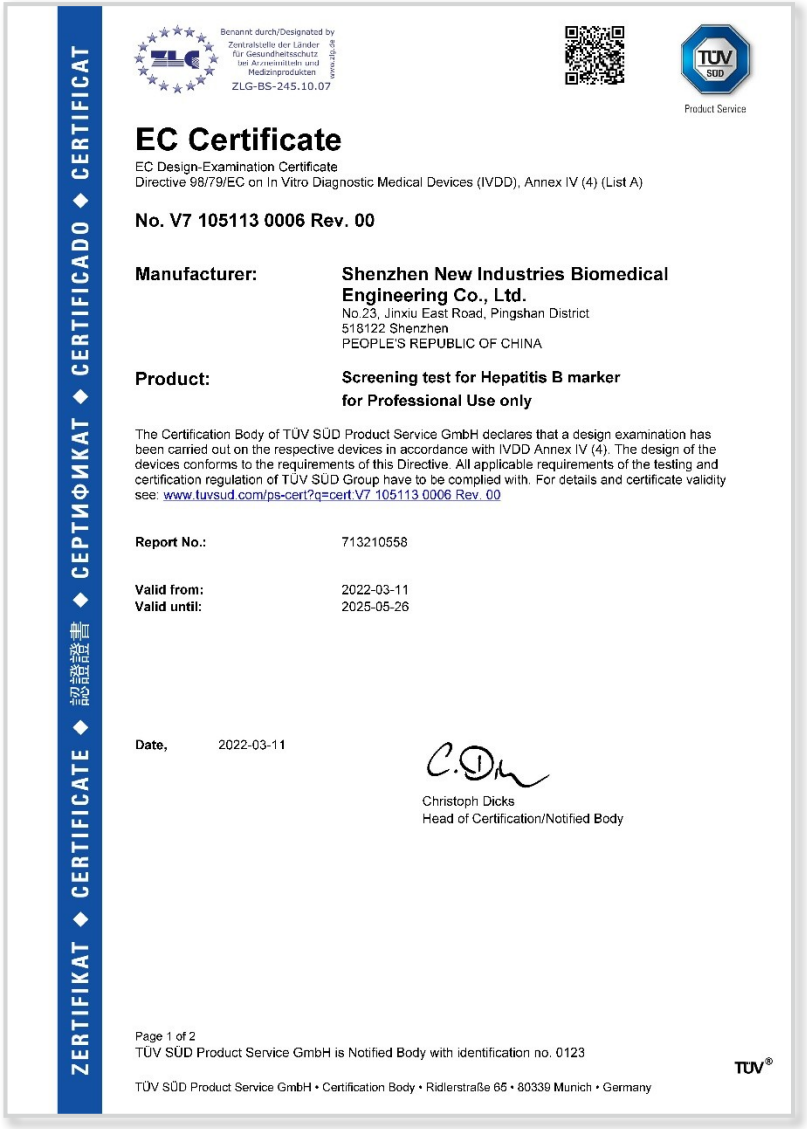

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-245.10.07

TÜV SÜD Product Service

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Manufacturer: **Shenzhen New Industries Biomedical Engineering Co., Ltd.**
No.23, Jinxiu East Road, Pingshan District
518122 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

Product: **Screening test for Hepatitis B marker for Professional Use only**

The Certification Body of TÜV SÜD Product Service GmbH declares that a design examination has been carried out on the respective devices in accordance with IVDD Annex IV (4). The design of the devices conforms to the requirements of this Directive. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:V7 105113 0006 Rev. 00

Report No.: 713210558

Valid from: 2022-03-11
Valid until: 2025-05-26

Date, 2022-03-11

Christoph Dicks
Head of Certification/Notified Body

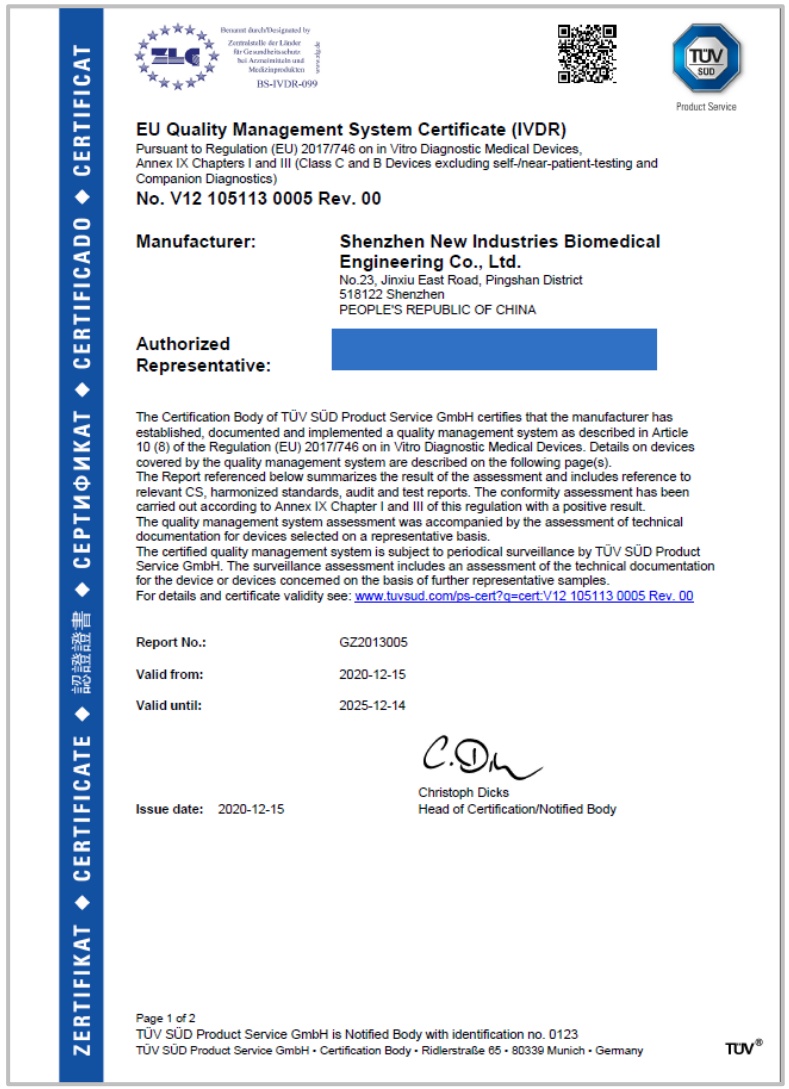
Page 1 of 2
TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV®

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

Сертификат CE List A для 6 ИХЛ анализов MAGLUMI для выявления вируса гепатита B (HBV), охватывающих HBsAg, Anti-HBs, HBeAg, Anti-HBe, Anti-HBc и Anti-HBc IgM.

IVDR CE Сертификат



ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

BS-IVDR-099

Product Service

EU Quality Management System Certificate (IVDR)

Pursuant to Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices, Annex IX Chapters I and III (Class C and B Devices excluding self-/near-patient-testing and Companion Diagnostics)

No. V12 105113 0005 Rev. 00

Manufacturer: **Shenzhen New Industries Biomedical Engineering Co., Ltd.**
No.23, Jinxiu East Road, Pingshan District
518122 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

Authorized Representative:

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (8) of the Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices. Details on devices covered by the quality management system are described on the following page(s).
The Report referenced below summarizes the result of the assessment and includes reference to relevant CS, harmonized standards, audit and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.
The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.
The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment includes an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:V12 105113 0005 Rev. 00

Report No.: GZ2013005

Valid from: 2020-12-15

Valid until: 2025-12-14

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2020-12-15

Page 1 of 2
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Первый сертификат IVDR CE для продукта ИХЛ в Азии

MAGLUMI® TSH и **MAGLUMI®** CA 19-9 получили сертификат IVDR CE от уполномоченного органа EC TÜV SÜD Product Service GmbH, что еще раз подтверждает, что качество нашей продукции соответствует международным стандартам.

IFCC-RELA Сертификаты

Множественные измерения

измеренные методом масс-спектрометрии в референтной лаборатории Snibe,

прошли схему IFCC-RELA.

IFCC-RELA организована по поручению Международной федерации клинической химии и лабораторной медицины (IFCC). Она представляет собой высший уровень измерений в области клинической химии и лабораторной медицины и признана одним из важнейших мероприятий по оценке качества в области международной клинической химии и лабораторной медицины.

Другие сертификаты

ISO 13485

ISO 9001

CE Certificate

Instrument EMC / Safety

FSC

Контроль качества третьей стороны

Первое в Китае предложение в официальной инструкции по применению BIO-RAD с заданными значениями для анализов MAGLUMI® ИХЛ

BIO-RAD

Lyphochek® Tumor Marker Plus Control
Levels 1, 2 and 3

REF				LOT		
367	Level 1	6 x 2 mL	EXP 2017-05-31	54590	Level 1	54591
368	Level 2	6 x 2 mL			Level 2	54592
369	Level 3	6 x 2 mL			Level 3	54593
368X	Trilevel MiniPak	3 x 2 mL				

INSERT UPDATE* 2015-06-11 (R.8)

METHOD
Methode // Méthode // Metodo //

ACTH
DiaSource ImmunoAssays ACTH-IRMA (2) (3)
ALPHA FETOPROTEIN (AFP)
Ortho Vitros MicroWell Series (2)
SNIBE Maglumi (CLIA) (2) (3)
BETA-2-MICROGLOBULIN (B2-M)
SNIBE Maglumi (CLIA) (2) (3)
CA 125 (4)
DiaSource ImmunoAssays CA125-IRMA (2) (3)
Ortho Vitros MicroWell Series (2)
Siemens IMMULITE 2000/2000 XPi (Lots 279 and
SNIBE Maglumi (CLIA) (2) (3)
CA 15-3 (4)
DiaSource ImmunoAssays CA15-3-IRMA (2) (3)
Ortho Vitros MicroWell Series (2)
Siemens IMMULITE 2000/2000 XPi (Revised) (2)
CA 19-9 (4)
DiaSource ImmunoAssays CA19-9-IRMA (2) (3)

BIO-RAD

SNIBE Maglumi (CLIA) (2) (3)

ichek™ Cardiac Markers Plus Control
s 1, 2 and 3

REF				LOT		
180	Trilevel	6 x 3 mL	EXP 2017-03-31	29830	Level 1	29831
181	Level 1	6 x 3 mL			Level 2	29832
182	Level 2	6 x 3 mL			Level 3	29833
183	Level 3	6 x 3 mL				
180X	MiniPak	3 x 3 mL				

http://www.myeinserts.com/29830

方法 (1)

Snibe MAGLUMI

		濃度 1 - 29831		濃度 2 - 29832		濃度 3 - 29833 (2)	
		均值	範圍	均值	範圍	均值	範圍
CK-MB ISOENZYME (MASS)							
SNIBE Maglumi Series Analyzer (3)	ng/mL	3.70	2.59 – 4.81	13.7	9.56 – 17.8	67.2	47.0 – 87.3
MYOGLOBIN							
SNIBE Maglumi Series Analyzer (3)	ng/mL	41.1	28.8 – 53.4	125	87.4 – 162	284	199 – 369
N-TERMINAL PRO-BRAIN NATRIURETIC PEPTIDE (NT-PROBNP)							
SNIBE Maglumi Series Analyzer (3)	pg/mL	137	95.6 – 177	355	248 – 461	3423	2396 – 4450

BIO-RAD

Lyphochek® Immunoassay Plus Control
Levels 1, 2 and 3

REF				LOT		
370	Trilevel	12 x 5 mL	CE 0459 IVD EXP 2017-02-28	40300	Level 1	40301
371	Level 1	12 x 5 mL			Level 2	40302
372	Level 2	12 x 5 mL			Level 3	40303
373	Level 3	12 x 5 ml				
370X	MiniPak	3 x				

http://www.

儀器 (1)

SNIBE MAGLUMI (2)
Cortisol
C-Peptide
Estradiol
Folate
Follicle Stimulating Hormone
hCG
Human Growth Hormone
Immunoglobulin E (IgE)
Insulin
Luteinizing Hormone (LH)
Prolactin

BIO-RAD

SNIBE MAGLUMI (2)

Liquichek™ Specialty Immunoassay Control
Levels LTA, 1, 2 and 3

REF				LOT		
359	Level LTA	6 x 5 mL	CE IVD EXP 2017-07-31	57450	Level LTA	57451L
364	Level 1	6 x 5 mL			Level 1	57451
365	Level 2	6 x 5 mL			Level 2	57452
366	Level 3	6 x 5 mL			Level 3	57453
359X	MiniPak	4 x 5 mL				

http://www.myeinserts.com/57450

修訂日期 2015-08-24

方法 (1)

SNIBE Maglumi Series (2)

		濃度 LTA - 57451L	
	單位	均值	範圍
25-HYDROXY VITAMIN D			
SNIBE Maglumi Series (2)	ng/mL	(4)	
ANTI-TG			
SNIBE Maglumi Series (2)	IU/mL	(4)	
ANTI-THYROPEROXIDASE (ANTI-TPO)			
SNIBE Maglumi Series (2)	IU/mL	(4)	
IGF-1/SOMATOMEDIN C			
SNIBE Maglumi Series (2)	ng/mL	(4)	
PTH (INTACT)			
SNIBE Maglumi Series (2)	pg/mL	(4)	

Контроль качества третьей стороны

Первое в Китае предложение в официальной инструкции по применению Randox с присвоенными значениями для анализов MAGLUMI® ИХЛ

RANDOX

IMMUNOASSAY PREMIUM PLUS - LEVEL 2 (IA PREMIUM PLUS 2)

Cat. No. IA3110 / IA3112 Lot No. 1662EC Size: 12 x 5 ml / 4 x 5 ml Expiry: 2019-10-28

			Range		
Analyte	unit	Target	low	high	methods
CA 15-3	U/ml	50.6	34.4	66.8	Siemens Centaur CP
CA 19-9	U/ml	713	570	856	Abbott Architect
	U/ml	159	127	191	BioMerieux Vidas
	U/ml	259	176	342	Siemens Centaur XP/XPT/Classic
	U/ml	94.1	75.3	113	Siemens Immulite 2000/2500
	U/ml	97.6	78.1	117	Siemens Immulite 1000
	U/ml	89.4	71.5	107	Beckman DxI800
	U/ml	65.7	52.6	78.8	Roche Elecsys
	U/ml	142	114	170	Diasorin Liaison
	U/ml	61.2	49.0	73.4	Roche Modular E170
	U/ml	98.2	78.6	118	Beckman Access
	U/ml	47.2	37.8	56.6	Tosoh AIA360
	U/ml	167	134	200	Vitros ECi
	U/ml	702	562	842	Abbott Architect XR/XR2 kit
	U/ml	62.1	49.7	74.5	Roche Cobas 6000/8000
	U/ml	65.7	52.6	78.8	Roche Cobas E411
	U/ml	139	111	167	Fujirebio Lumipulse G Series
	U/ml	243	165	321	Siemens Centaur CP
	U/ml	88.5	62.0	115	SNIBE Maglumi Analysers

SNIBE Maglumi Anal

朗道质控 Immunoassay Premium Plus Control 赋值结果

		IPP001/001/UL Lot No:1660EC			IPP002/001/UL Lot No:1662EC			IPP003/001/UL Lot No:1665EC		
		Immunoassay Premium Plus Control Level 1			Immunoassay Premium Plus Control Level 2			Immunoassay Premium Plus Control Level 3		
Analyte	unit	Target	low	high	Target	low	high	Target	low	high
17-OH P	ng/mL	1.70	1.19	2.21	3.05	2.14	3.97	11.7	8.19	15.2
AFP	IU/ml	11.9	8.33	15.5	53.0	37.1	68.9	191	134	248
ALD	pg/mL	<5.00			114	79.8	148	239	167	311
B2-MG	ug/mL	0.752	0.526	0.978	2.97	2.08	3.86	5.95	4.17	7.74
CA125	IU/mL	16.2	11.3	21.1	91.8	64.3	119	184	129	239
CA199	IU/mL	20.6	14.4	26.8	88.5	62.0	115	184	129	239
CEA	ng/ml	4.33	3.03	5.63	22.6	15.8	29.4	47.6	33.3	61.9
Cortisol	ng/mL	92.5	64.8	120	230	161	299	323	226	420
C-P	ng/mL	2.45	1.72	3.19	5.58	3.91	7.25	10.4	7.28	13.5
DHEA-S	ug/dL	115	80.5	150	470	329	611	740	518	962
DIGOXIN	ng/mL	0.453	0.317	0.589	2.31	1.62	3.00	3.55	2.49	4.62
E2	pg/mL	46.3	32.4	60.2	351	246	456	679	475	883
FA	ng/ml	3.05	2.14	3.97	6.82	4.77	8.87	13.1	9.17	17.0
Ferritin	ng/ml	16.7	11.7	21.7	89.3	62.5	116	287	201	373
F-PSA	ng/mL	1.15	0.805	1.50	9.72	6.80	12.6	24.7	17.3	32.1
FSH	mIU/mL	5.72	4.00	7.44	29.5	20.7	38.4	52.0	36.4	67.6
F-T	pg/mL	2.46	1.72	3.20	18.1	12.7	23.5	38.1	26.7	49.5
FT3	pg/mL	2.20	1.54	2.86	6.68	4.68	8.68	16.6	11.6	21.6
FT4	pg/mL	11.1	7.77	14.4	28.1	19.7	36.5	55.2	38.6	71.8
GH	ng/mL	2.86	2.00	3.72	10.2	7.14	13.3	23.8	16.7	30.9
HCG/B-HCG	mIU/ml	10.8	7.56	14.0	23.6	16.5	30.7	406	284	528
IgE	IU/mL	180	126	234	92.6	64.8	120	413	289	537
INS	uIU/mL	4.82	3.37	6.27	7.25	5.08	9.43	24.7	17.3	32.1
LH	mIU/mL	3.58	2.51	4.65	27.8	19.5	36.1	45.7	32.0	59.4
PRL	uIU/mL	181	127	235	704	493	915	1282	897	1667
PROG	ng/mL	1.24	0.868	1.61	9.94	6.96	12.9	27.5	19.3	35.8
PSA	ng/mL	2.15	1.51	2.80	18.0	12.6	23.4	41.9	29.3	54.5
T3	ng/mL	0.492	0.344	0.640	3.28	2.30	4.26	5.78	4.05	7.51
T4	ng/mL	31.2	21.8	40.6	131	91.7	170	199	139	259
TEST	ng/mL	0.261	0.183	0.339	4.98	3.49	6.47	8.10	5.67	10.5

朗道质控Immunoassay Speciality I Control 赋值结果

		IAC068/001/UL Lot No:1655EC			IAC069/001/UL Lot No:1689EC			IAC070/001/UL Lot No:1656EC		
		Immunoassay Speciality I Control Level 1			Immunoassay Speciality I Control Level 2			Immunoassay Speciality I Control Level 3		
Analyte	unit	Target	low	high	Target	low	high	Target	low	high
25-OH Vit D	ng/mL	13.7	9.59	17.8	24.4	17.1	31.7	37.0	25.9	48.1
C-P	ng/mL	2.29	1.60	2.98	3.64	2.55	4.73	7.57	5.30	9.84
INS	uIU/mL	6.71	4.70	8.72	11.2	7.84	14.6	37.4	26.2	48.6
PCT	ng/mL	1.07	0.749	1.39	3.09	2.16	4.02	26.2	18.3	34.1
PTH	pg/mL	50.3	35.2	65.4	216	151	281	754	528	980

Внешний контроль качества

Компания Snibe приняла участие в международном испытании EQAS на 25-OH витамин D и получала сертификат 12 лет подряд.

Vitamin D External Quality Assessment Scheme, DEQAS

Внешний контроль качества

Snibe ежегодно участвует в различных программах EQA

RCPAQAP

NGSP Certification

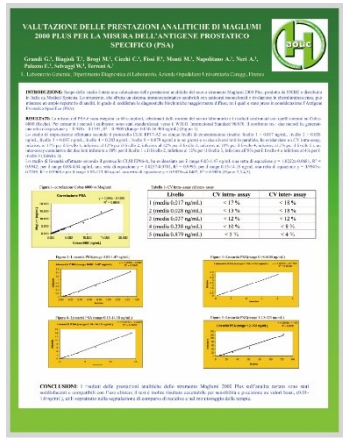
IFCC Certification

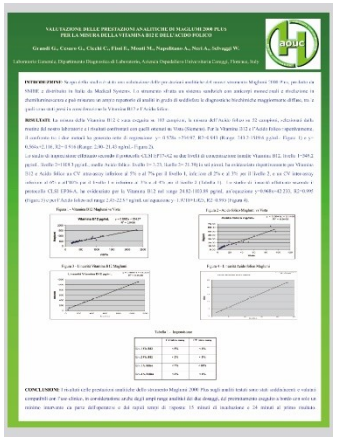
CAP Proficiency Test

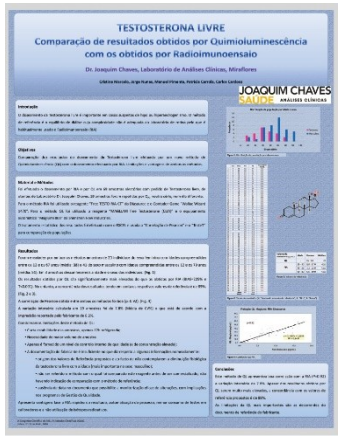
BIO-RAD External Quality Assurance Services (EQAS)

Randox International Quality Assessment Scheme (RIQAS)

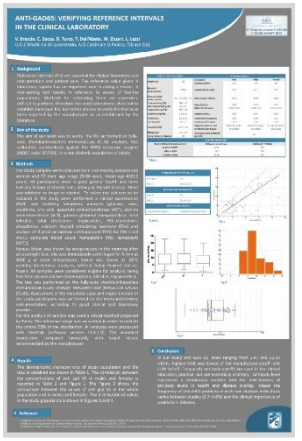
Публикации по оценке

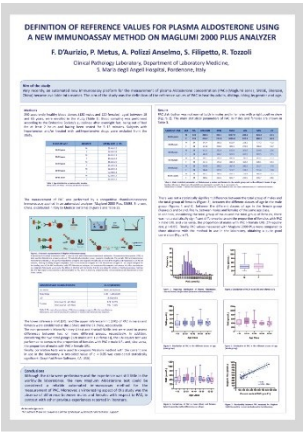

VALUTAZIONE DELLE PRESTAZIONI ANALITICHE DI MAGLUMI 2000 PLUS PER LA MISURA DELL'ANTIGENE PROSTATICO SPECIFICO (PSA)


VALUTAZIONE DELLE PRESTAZIONI ANALITICHE DI MAGLUMI 2000 PLUS PER LA MISURA DELLA VITAMINA D (I-125) DELL'ACIDO FOLICO

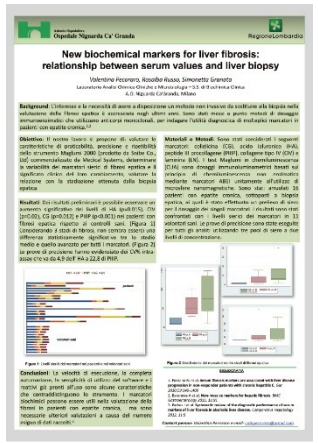

TESTOSTERONA LIVRE
Comparação de resultados obtidos por Quimioluminescência com os obtidos por Radioimunoensaio
Dr. Joaquim Chaves, Laboratório de Análises Clínicas, Miraflores

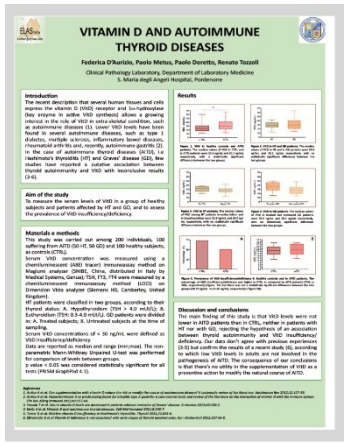

MAGLUMI 2000: NUOVO STRUMENTO IN CHEMILUMINESCENZA, COMPLETAMENTE AUTOMATIZZATO PER DOSAGGI IMMUNOMETRICI

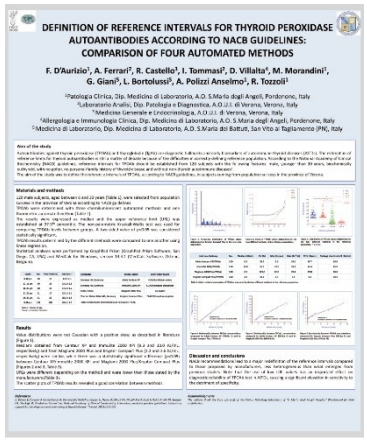

ANTI-GAD65: VERIFYING REFERENCE INTERVALS IN THE CLINICAL LABORATORY


DEFINITION OF REFERENCE VALUES FOR PLASMA ALDOSTERONE USING A NEW IMMUNOASSAY METHOD ON MAGLUMI 2000 PLUS ANALYZER
F. D'Aurizio, P. Metus, A. Polizzi Anselmo, S. Filippetto, R. Tozzoli
Clinical Pathology Laboratory, Department of Laboratory Medicine, S. Maria degli Angeli Hospital, Pordenone, Italy

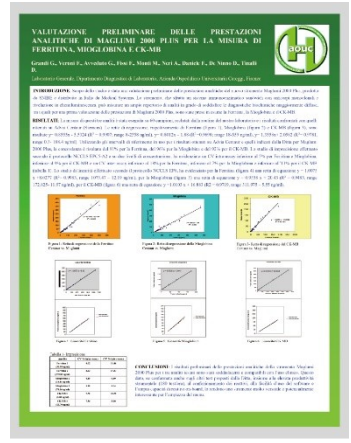

MAGLUMI 2000:
NUOVO STRUMENTO IN CHEMILUMINESCENZA, COMPLETAMENTE AUTOMATIZZATO PER DOSAGGI IMMUNOMETRICI


New biochemical markers for liver fibrosis: relationship between serum values and liver biopsy


VITAMIN D AND AUTOIMMUNE THYROID DISEASES
Federica D'Aurizio, Paolo Metus, Paolo Doretto, Renato Tozzoli
Clinical Pathology Laboratory, Department of Laboratory Medicine
S. Maria degli Angeli Hospital, Pordenone

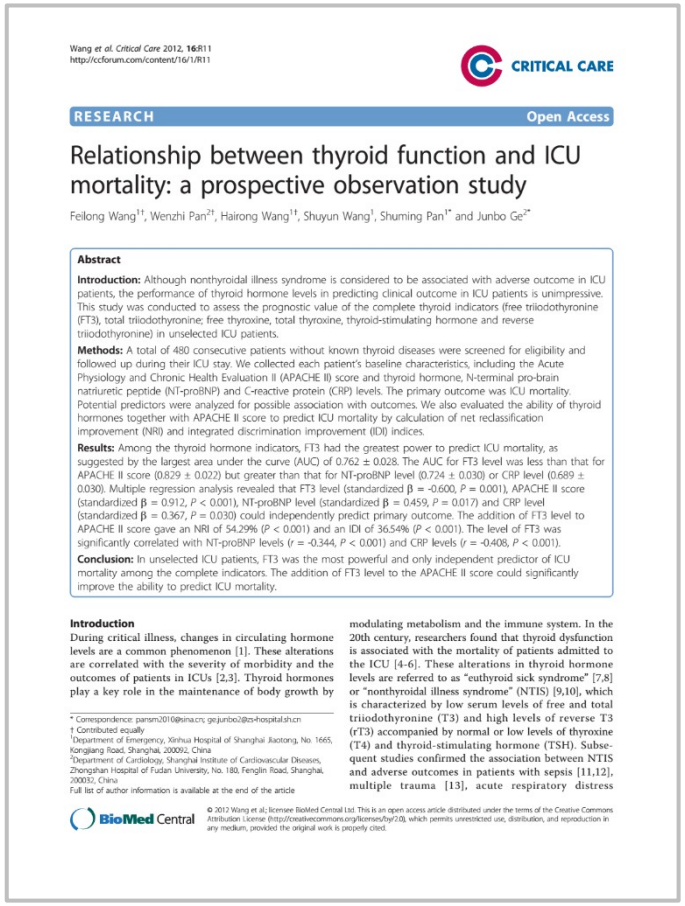

DEFINITION OF REFERENCE INTERVALS FOR THYROID PEROXIDASE AUTOANTIBODIES ACCORDING TO NACB GUIDELINES: COMPARISON OF FOUR AUTOMATED METHODS
F. D'Aurizio[1], A. Ferrari[2], R. Castello[1], I. Tommasi[2], D. Villalta[2], M. Morandini[2], G. Giani[3], L. Bortolussi[3], A. Polizzi Anselmo[3], R. Tozzoli[1]


ICCS
ESPERIENZA PRELIMINARE SU UNA NUOVA TECNOLOGIA IN CHEMILUMINESCENZA (CLIA) PER LA DETERMINAZIONE DELLA PROCALCITONINA SIERICA


VALUTAZIONE PRELIMINARE DELLE PRESTAZIONI ANALITICHE DI MAGLUMI 2000 PLUS PER LA MISURA DI FERRITINA, MIOGLOBINA E CK-MB

Публикации

Сотрудничал с известными врачами и опубликовал множество признаваемых статей в ведущих международных журналах.



Wang et al. Critical Care 2012, 16:R11
http://ccforum.com/content/16/1/R11

CRITICAL CARE

RESEARCH Open Access

Relationship between thyroid function and ICU mortality: a prospective observation study

Feilong Wang[1†], Wenzhi Pan[2†], Hairong Wang[1†], Shuyun Wang[1], Shuming Pan[1*] and Junbo Ge[2*]

Abstract

Introduction: Although nonthyroidal illness syndrome is considered to be associated with adverse outcome in ICU patients, the performance of thyroid hormone levels in predicting clinical outcome in ICU patients is unimpressive. This study was conducted to assess the prognostic value of the complete thyroid indicators (free triiodothyronine (FT3), total triiodothyronine, free thyroxine, total thyroxine, thyroid-stimulating hormone and reverse triiodothyronine) in unselected ICU patients.

Methods: A total of 480 consecutive patients without known thyroid diseases were screened for eligibility and followed up during their ICU stay. We collected each patient's baseline characteristics, including the Acute Physiology and Chronic Health Evaluation II (APACHE II) score and thyroid hormone, N-terminal pro-brain natriuretic peptide (NT-proBNP) and C-reactive protein (CRP) levels. The primary outcome was ICU mortality. Potential predictors were analyzed for possible association with outcomes. We also evaluated the ability of thyroid hormones together with APACHE II score to predict ICU mortality by calculation of net reclassification improvement (NRI) and integrated discrimination improvement (IDI) indices.

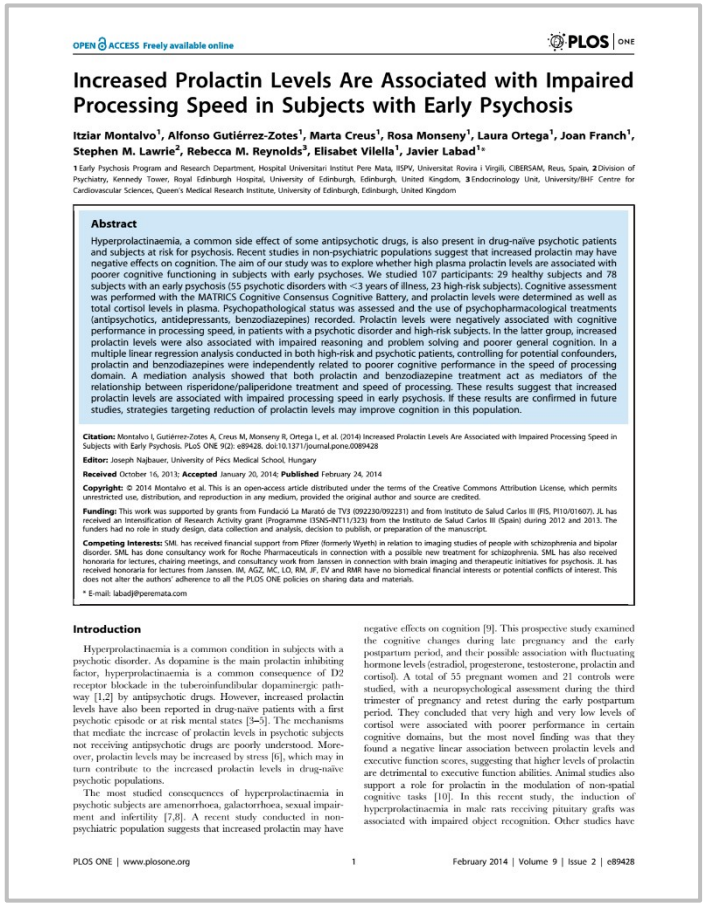
Results: Among the thyroid hormone indicators, FT3 had the greatest power to predict ICU mortality, as suggested by the largest area under the curve (AUC) of 0.762 ± 0.028. The AUC for FT3 level was less than that for APACHE II score (0.829 ± 0.022) but greater than that for NT-proBNP level (0.724 ± 0.030) or CRP level (0.689 ± 0.030). Multiple regression analysis revealed that FT3 level (standardized β = -0.600, P = 0.001), APACHE II score (standardized β = 0.912, P < 0.001), NT-proBNP level (standardized β = 0.459, P = 0.017) and CRP level (standardized β = 0.367, P = 0.030) could independently predict primary outcome. The addition of FT3 level to APACHE II score gave an NRI of 54.29% (P < 0.001) and an IDI of 36.54% (P < 0.001). The level of FT3 was significantly correlated with NT-proBNP levels (r = -0.344, P < 0.001) and CRP levels (r = -0.408, P < 0.001).

Conclusion: In unselected ICU patients, FT3 was the most powerful and only independent predictor of ICU mortality among the complete indicators. The addition of FT3 level to the APACHE II score could significantly improve the ability to predict ICU mortality.

Introduction

During critical illness, changes in circulating hormone levels are a common phenomenon [1]. These alterations are correlated with the severity of morbidity and the outcomes of patients in ICUs [2,3]. Thyroid hormones play a key role in the maintenance of body growth by modulating metabolism and the immune system. In the 20th century, researchers found that thyroid dysfunction is associated with the mortality of patients admitted to the ICU [4-6]. These alterations in thyroid hormone levels are referred to as "euthyroid sick syndrome" [7,8] or "nonthyroidal illness syndrome" (NTIS) [9,10], which is characterized by low serum levels of free and total triiodothyronine (T3) and high levels of reverse T3 (rT3) accompanied by normal or low levels of thyroxine (T4) and thyroid-stimulating hormone (TSH). Subsequent studies confirmed the association between NTIS and adverse outcomes in patients with sepsis [11,12], multiple trauma [13], acute respiratory distress

* Correspondence: pansm2010@sina.cn; gejunbo2@zs-hospital.sh.cn
† Contributed equally
[1]Department of Emergency, Xinhua Hospital of Shanghai Jiaotong, No. 1665, Kongjiang Road, Shanghai, 200092, China
[2]Department of Cardiology, Shanghai Institute of Cardiovascular Diseases, Zhongshan Hospital of Fudan University, No. 180, Fenglin Road, Shanghai, 200032, China
Full list of author information is available at the end of the article



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PLOS ONE

Increased Prolactin Levels Are Associated with Impaired Processing Speed in Subjects with Early Psychosis

Itziar Montalvo[1], Alfonso Gutiérrez-Zotes[1], Marta Creus[1], Rosa Monseny[1], Laura Ortega[1], Joan Franch[1], Stephen M. Lawrie[2], Rebecca M. Reynolds[3], Elisabet Vilella[1], Javier Labad[1]*

1 Early Psychosis Program and Research Department, Hospital Universitari Institut Pere Mata, IISPV, Universitat Rovira i Virgili, CIBERSAM, Reus, Spain, 2 Division of Psychiatry, Kennedy Tower, Royal Edinburgh Hospital, University of Edinburgh, Edinburgh, United Kingdom, 3 Endocrinology Unit, University/BHF Centre for Cardiovascular Sciences, Queen's Medical Research Institute, University of Edinburgh, Edinburgh, United Kingdom

Abstract

Hyperprolactinaemia, a common side effect of some antipsychotic drugs, is also present in drug-naïve psychotic patients and subjects at risk for psychosis. Recent studies in non-psychiatric populations suggest that increased prolactin may have negative effects on cognition. The aim of our study was to explore whether high plasma prolactin levels are associated with poorer cognitive functioning in subjects with early psychoses. We studied 107 participants: 29 healthy subjects and 78 subjects with an early psychosis (55 psychotic disorders with <3 years of illness, 23 high-risk subjects). Cognitive assessment was performed with the MATRICS Cognitive Consensus Cognitive Battery, and prolactin levels were determined as well as total cortisol levels in plasma. Psychopathological status was assessed and the use of psychopharmacological treatments (antipsychotics, antidepressants, benzodiazepines) recorded. Prolactin levels were negatively associated with cognitive performance in processing speed, in patients with a psychotic disorder and high-risk subjects. In the latter group, increased prolactin levels were also associated with impaired reasoning and problem solving and poorer general cognition. In a multiple linear regression analysis conducted in both high-risk and psychotic patients, controlling for potential confounders, prolactin and benzodiazepines were independently related to poorer cognitive performance in the speed of processing domain. A mediation analysis showed that both prolactin and benzodiazepine treatment act as mediators of the relationship between risperidone/paliperidone treatment and speed of processing. These results suggest that increased prolactin levels are associated with impaired processing speed in early psychosis. If these results are confirmed in future studies, strategies targeting reduction of prolactin levels may improve cognition in this population.

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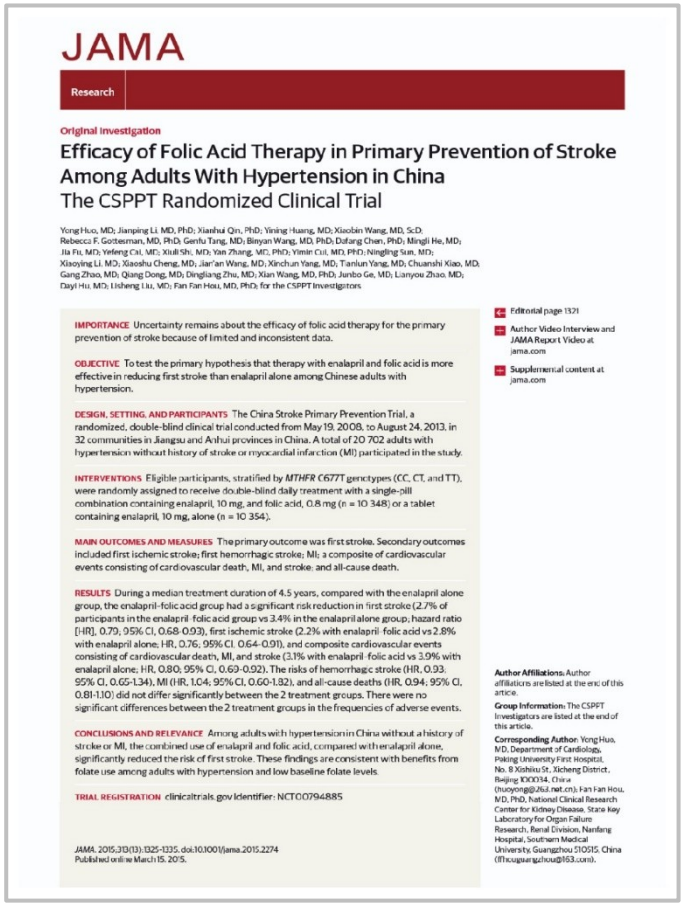
Competing Interests: SML has received financial support from Pfizer (formerly Wyeth) in relation to imaging studies of people with schizophrenia and bipolar disorder. SML has done consultancy work for Roche Pharmaceuticals in connection with a possible new treatment for schizophrenia. SML has also received honoraria for lectures, chairing meetings, and consultancy work from Janssen in connection with brain imaging and therapeutic initiatives for psychosis. JL has received honoraria for lectures from Janssen. IM, AGZ, MC, LO, RM, JF, EV and RMR have no biomedical financial interests or potential conflicts of interest. This does not alter the authors' adherence to all the PLOS ONE policies on sharing data and materials.

* E-mail: labadj@peremata.com

Introduction

Hyperprolactinaemia is a common condition in subjects with a psychotic disorder. As dopamine is the main prolactin inhibiting factor, hyperprolactinaemia is a common consequence of D2 receptor blockade in the tuberoinfundibular dopaminergic pathway [1,2] by antipsychotic drugs. However, increased prolactin levels have also been reported in drug-naïve patients with a first psychotic episode or at risk mental states [3–5]. The mechanisms that mediate the increase of prolactin levels in psychotic subjects not receiving antipsychotic drugs are poorly understood. Moreover, prolactin levels may be increased by stress [6], which may in turn contribute to the increased prolactin levels in drug-naïve psychotic populations.

The most studied consequences of hyperprolactinaemia in psychotic subjects are amenorrhoea, galactorrhoea, sexual impairment and infertility [7,8]. A recent study conducted in non-psychiatric population suggests that increased prolactin may have negative effects on cognition [9]. This prospective study examined the cognitive changes during late pregnancy and the early postpartum period, and their possible association with fluctuating hormone levels (estradiol, progesterone, testosterone, prolactin and cortisol). A total of 55 pregnant women and 21 controls were studied, with a neuropsychological assessment during the third trimester of pregnancy and retest during the early postpartum period. They concluded that very high and very low levels of cortisol were associated with poorer performance in certain cognitive domains, but the most novel finding was that they found a negative linear association between prolactin levels and executive function scores, suggesting that higher levels of prolactin are detrimental to executive function abilities. Animal studies also support a role for prolactin in the modulation of non-spatial cognitive tasks [10]. In this recent study, the induction of hyperprolactinaemia in male rats receiving pituitary grafts was associated with impaired object recognition. Other studies have



JAMA

Research

Original Investigation

Efficacy of Folic Acid Therapy in Primary Prevention of Stroke Among Adults With Hypertension in China

The CSPPT Randomized Clinical Trial

Yong Huo, MD; Jianping Li, MD, PhD; Xianhui Qin, PhD; Yining Huang, MD; Xiaobin Wang, MD, Sc.D; Rebecca F. Gottesman, MD, PhD; Genfu Tang, MD; Binyan Wang, MD, PhD; Dafang Chen, PhD; Mingli He, MD; Jia Fu, MD; Yefeng Cai, MD; Xiuli Shi, MD; Yan Zhang, MD, PhD; Yimin Cui, MD, PhD; Ningling Sun, MD; Xiaoying Li, MD; Xiaoshu Cheng, MD; Jian'an Wang, MD; Xinchun Yang, MD; Tianlun Yang, MD; Chuanshi Xiao, MD; Gang Zhao, MD; Qiang Dong, MD; Dingliang Zhu, MD; Xian Wang, MD, PhD; Junbo Ge, MD; Lianyou Zhao, MD; Dayi Hu, MD; Lisheng Liu, MD; Fan Fan Hou, MD, PhD; for the CSPPT Investigators

IMPORTANCE Uncertainty remains about the efficacy of folic acid therapy for the primary prevention of stroke because of limited and inconsistent data.

OBJECTIVE To test the primary hypothesis that therapy with enalapril and folic acid is more effective in reducing first stroke than enalapril alone among Chinese adults with hypertension.

DESIGN, SETTING, AND PARTICIPANTS The China Stroke Primary Prevention Trial, a randomized, double-blind clinical trial conducted from May 19, 2008, to August 24, 2013, in 32 communities in Jiangsu and Anhui provinces in China. A total of 20 702 adults with hypertension without history of stroke or myocardial infarction (MI) participated in the study.

INTERVENTIONS Eligible participants, stratified by *MTHFR* C677T genotypes (CC, CT, and TT), were randomly assigned to receive double-blind daily treatment with a single-pill combination containing enalapril, 10 mg, and folic acid, 0.8 mg (n = 10 348) or a tablet containing enalapril, 10 mg, alone (n = 10 354).

MAIN OUTCOMES AND MEASURES The primary outcome was first stroke. Secondary outcomes included first ischemic stroke; first hemorrhagic stroke; MI; a composite of cardiovascular events consisting of cardiovascular death, MI, and stroke; and all-cause death.

RESULTS During a median treatment duration of 4.5 years, compared with the enalapril alone group, the enalapril-folic acid group had a significant risk reduction in first stroke (2.7% of participants in the enalapril-folic acid group vs 3.4% in the enalapril alone group, hazard ratio [HR], 0.79; 95% CI, 0.68-0.93), first ischemic stroke (2.2% with enalapril-folic acid vs 2.8% with enalapril alone; HR, 0.76; 95% CI, 0.64-0.91), and composite cardiovascular events consisting of cardiovascular death, MI, and stroke (3.1% with enalapril-folic acid vs 3.9% with enalapril alone; HR, 0.80; 95% CI, 0.69-0.92). The risks of hemorrhagic stroke (HR, 0.93; 95% CI, 0.65-1.34), MI (HR, 1.04; 95% CI, 0.60-1.82), and all-cause deaths (HR, 0.94; 95% CI, 0.81-1.10) did not differ significantly between the 2 treatment groups. There were no significant differences between the 2 treatment groups in the frequencies of adverse events.

CONCLUSIONS AND RELEVANCE Among adults with hypertension in China without a history of stroke or MI, the combined use of enalapril and folic acid, compared with enalapril alone, significantly reduced the risk of first stroke. These findings are consistent with benefits from folate use among adults with hypertension and low baseline folate levels.

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Group Information: The CSPPT Investigators are listed at the end of this article.

Corresponding Author: Yong Huo, MD, Department of Cardiology, Peking University First Hospital, No. 8 Xishiku St, Xicheng District, Beijing 100034, China (huoyong@263.net.cn); Fan Fan Hou, MD, PhD, National Clinical Research Center for Kidney Disease, State Key Laboratory for Organ Failure Research, Renal Division, Nanfang Hospital, Southern Medical University, Guangzhou 510515, China (fffhou@guangzhou@163.com).

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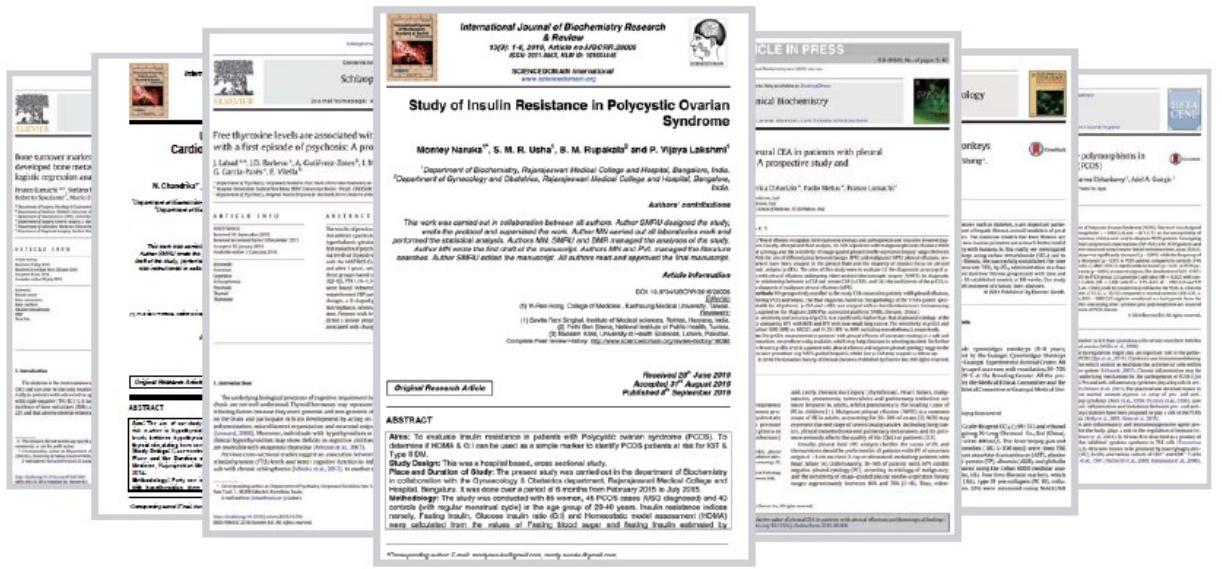

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