

УТВЕРЖДАЮ

Генеральный директор

ООО «Компания «БиВи»

Т.А. Носова

«15» 12 2021 г.



ПО ДОВЕРЕННОСТИ
77 АГ 5987789
КУСАЙЛО Р.В.

Фотографические изображения изделия:

Набор реагентов для количественного определения свободного тироксина (FT4 (CLIA)) в сыворотке крови на автоматическом иммунохемилюминесцентном анализаторе серии Maglumi для диагностики in vitro

Shenzhen New Industries Biomedical Engineering Co.,Ltd. («Шэньчжэнь Нью Индастриз Биомедикал Инжиниринг Ко., Лтд.»), Китай



Общий вид медицинского изделия (Набор реагентов для количественного определения свободного тироксина (FT4 (CLIA)) в сыворотке крови на автоматическом

MAGLUMI™ FT4 (CLIA)

CONTENTS

2.5 mL Magnetic Microbeads
2.5 mL Calibrator Low
2.5 mL Calibrator High
6.5 mL Buffer
6.5 mL ABEI Label

LOT 0041900501

SN 8534

2020-11-29

IVD

CE

2°C

Σ 100



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Tel: +86-755-21536601 Fax: +86-755-26292740

EC REP

Shanghai International Holding Corp. GmbH (Europe)
Eiffelstrasse 80, 20537 Hamburg, Germany
Tel: +49-40-2513175 Fax: +49-40-255726

Snibe

Картридж (100 тестов) (Набор реагентов для количественного определения свободного тироксина (FT4 (CLIA)) в сыворотке крови на автоматическом иммунохемилюминесцентном анализаторе серии Maglumi для диагностики in vitro)



Материал контрольный (Набор реагентов для количественного определения свободного тироксина (FT4 (CLIA)) в сыворотке крови на автоматическом иммунохемилюминесцентном анализаторе серии Maglumi для диагностики in vitro)

Всего прошито, пронумеровано и скреплено
печатью и подписью: 14 листа (-ов)

Генеральный директор _____ / Носова Т.А
М.П.



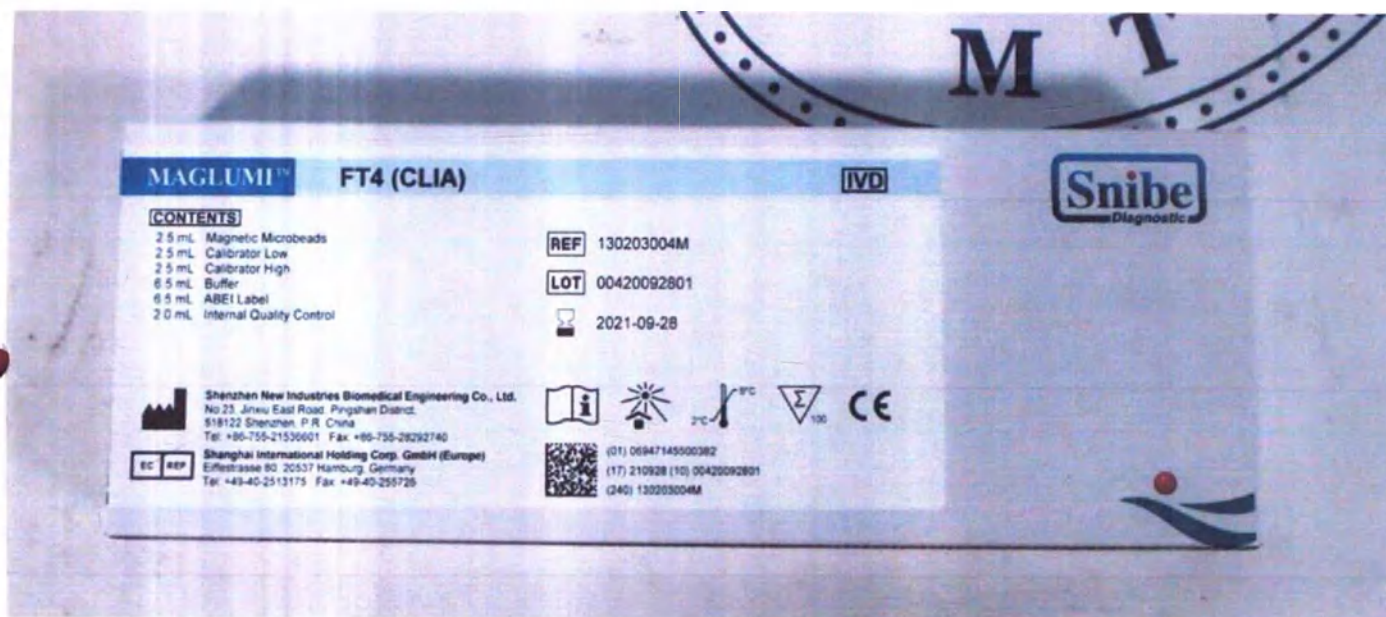
ПО ДОВЕРЕННОСТИ
77 АГ 5987789
КУСАЙЛО Р.В.

Общий вид медицинского изделия во внешней (потребительской) упаковке



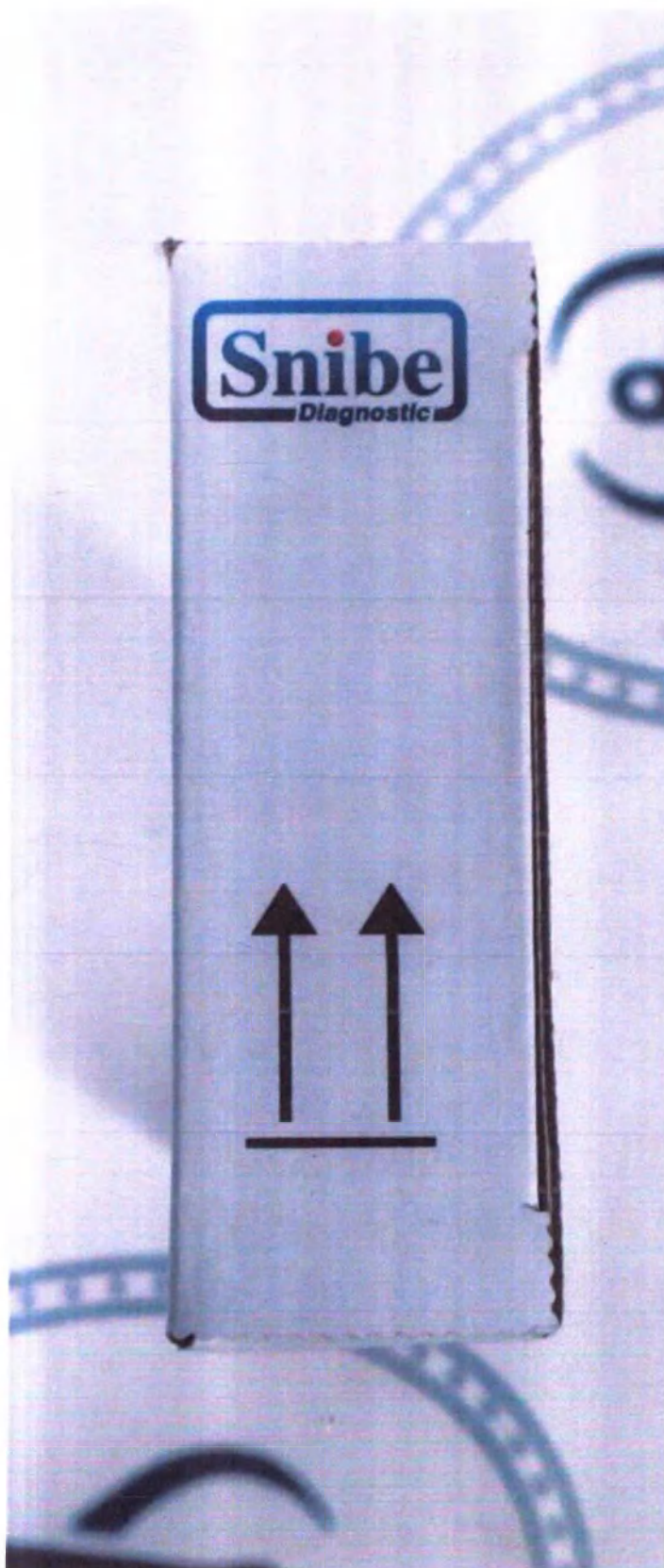


Потребительская упаковка, вид спереди.





Потребительская упаковка, вид с правой стороны.



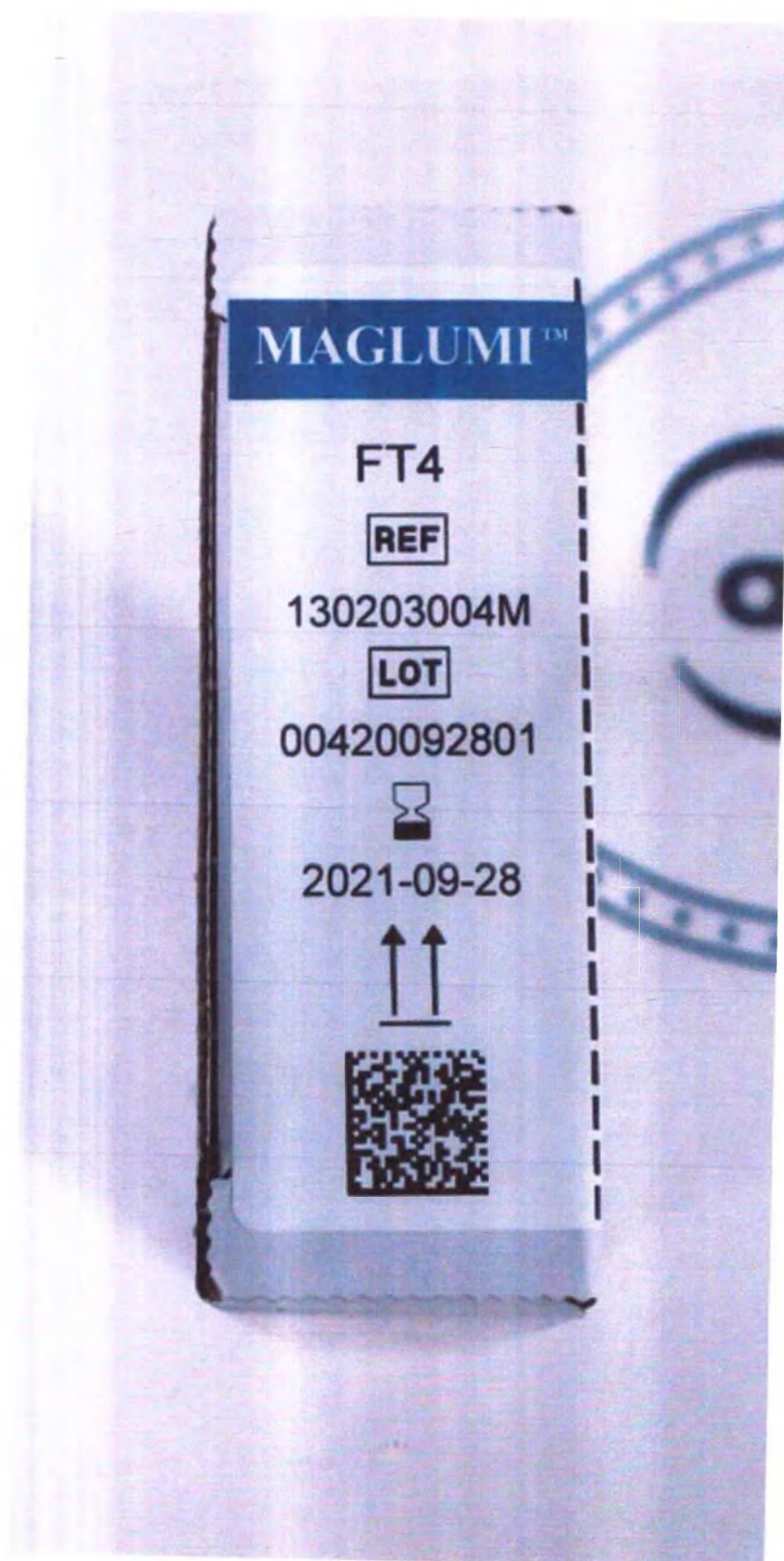


Потребительская упаковка, вид сзади.



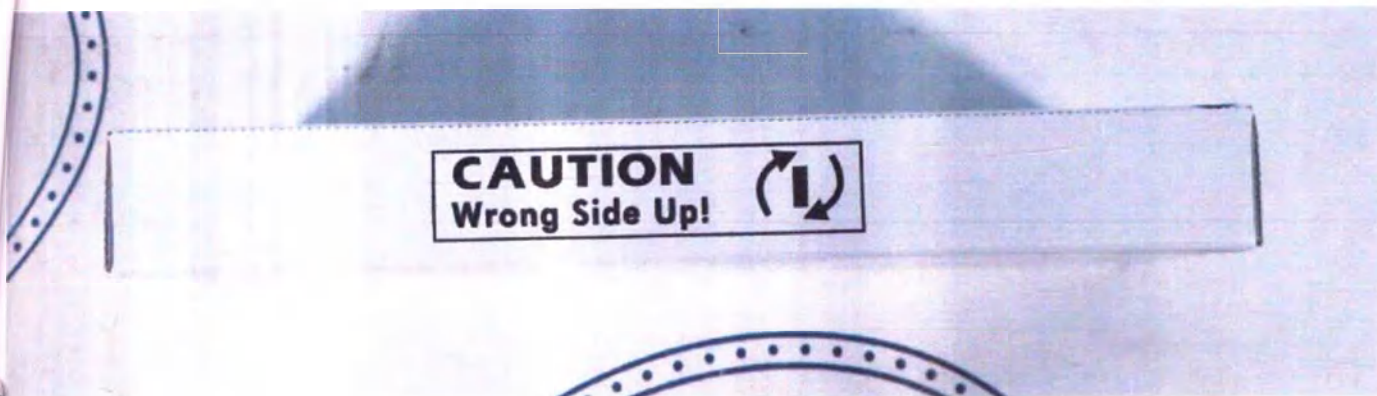


Потребительская упаковка, вид с левой стороны.

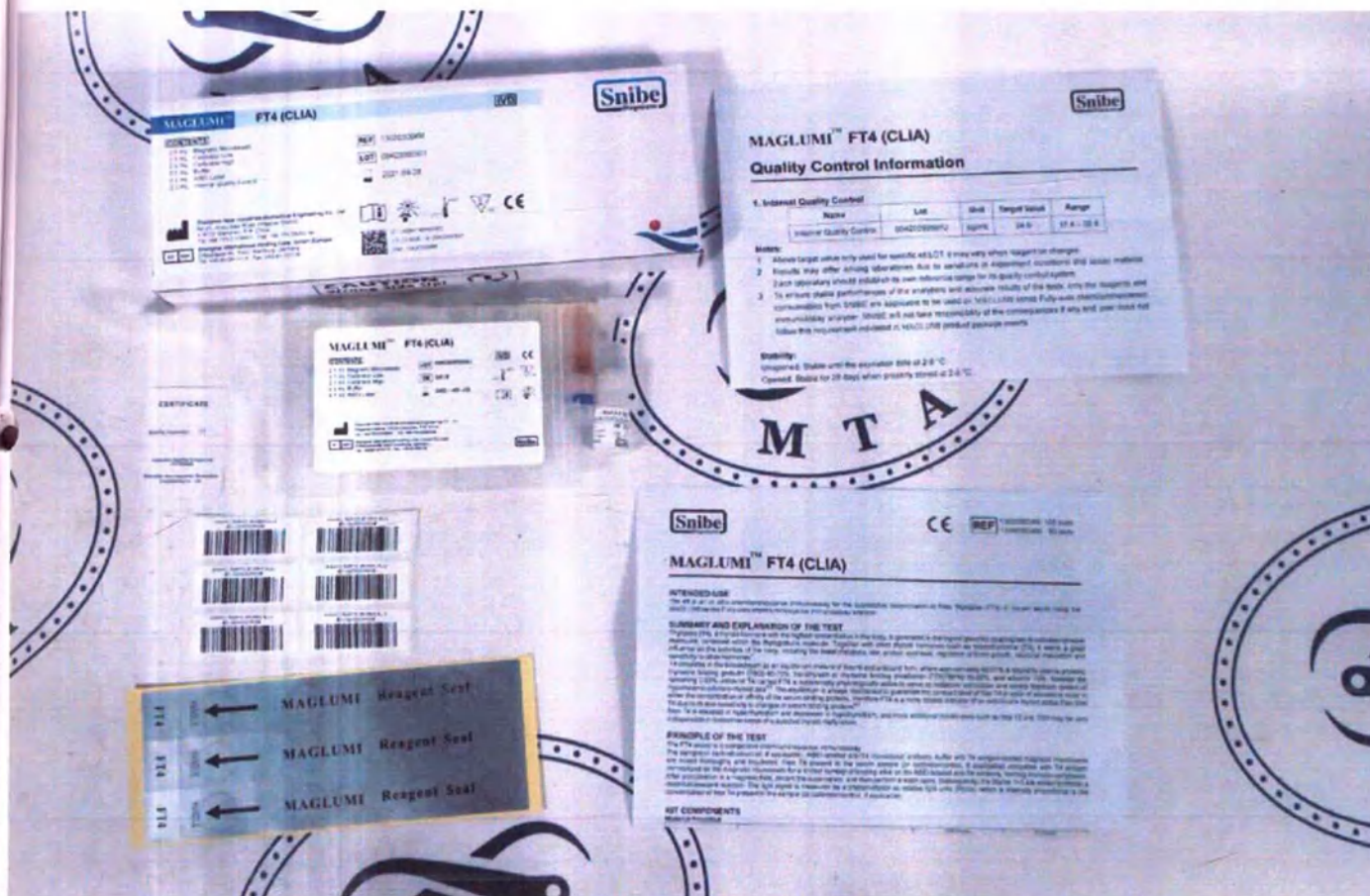




Потребительская упаковка, вид снизу.

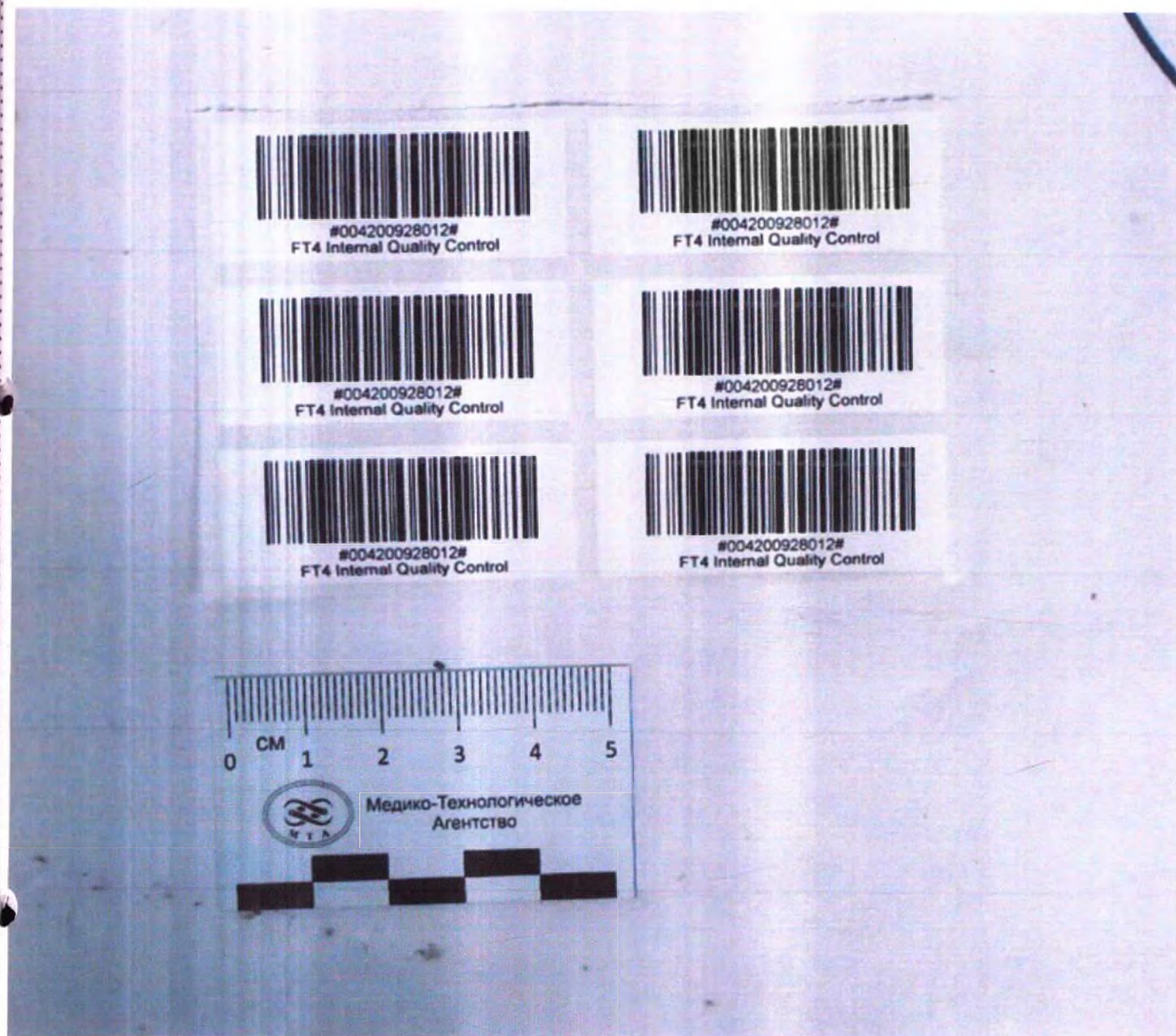


Компоненты медицинского изделия



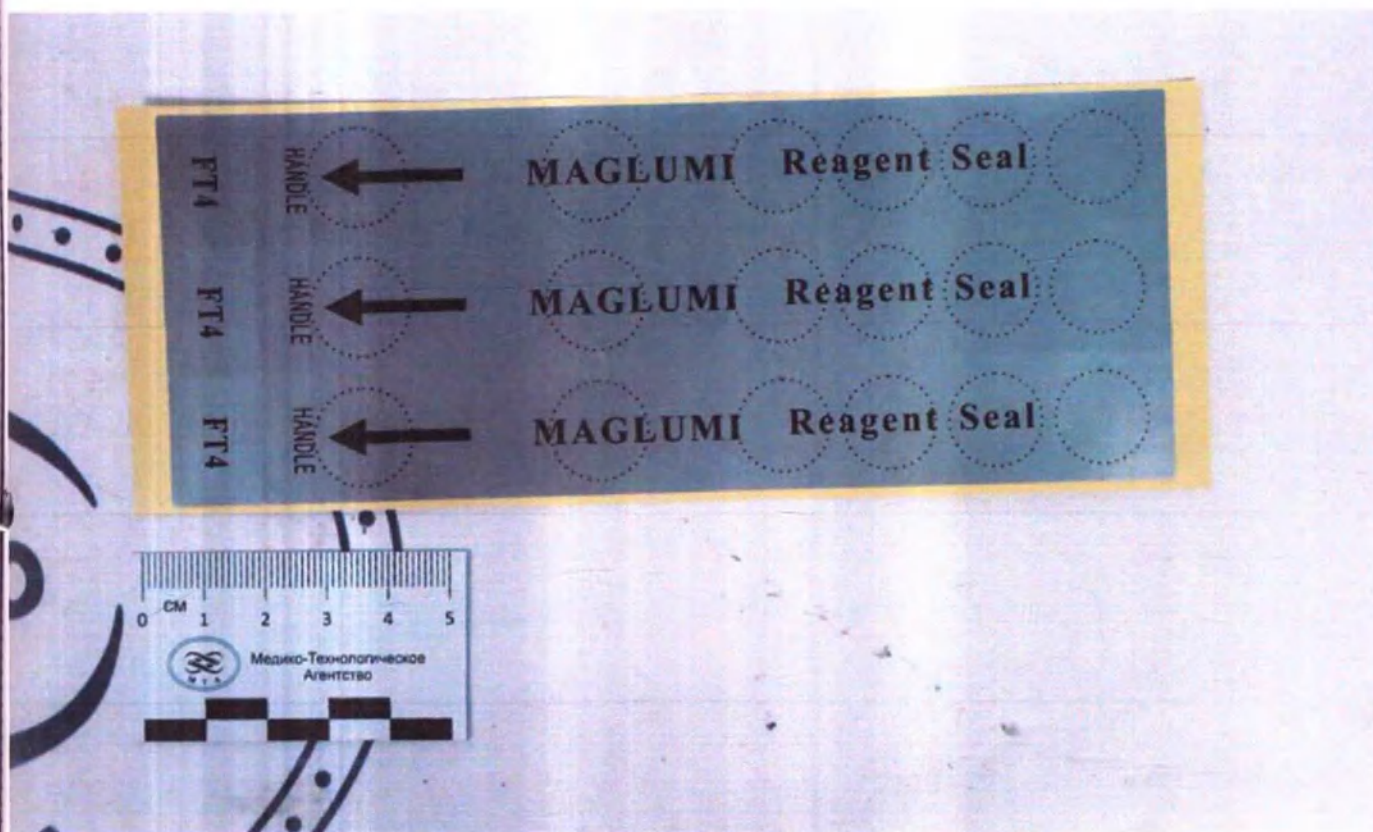


Штрих-код Internal quality control



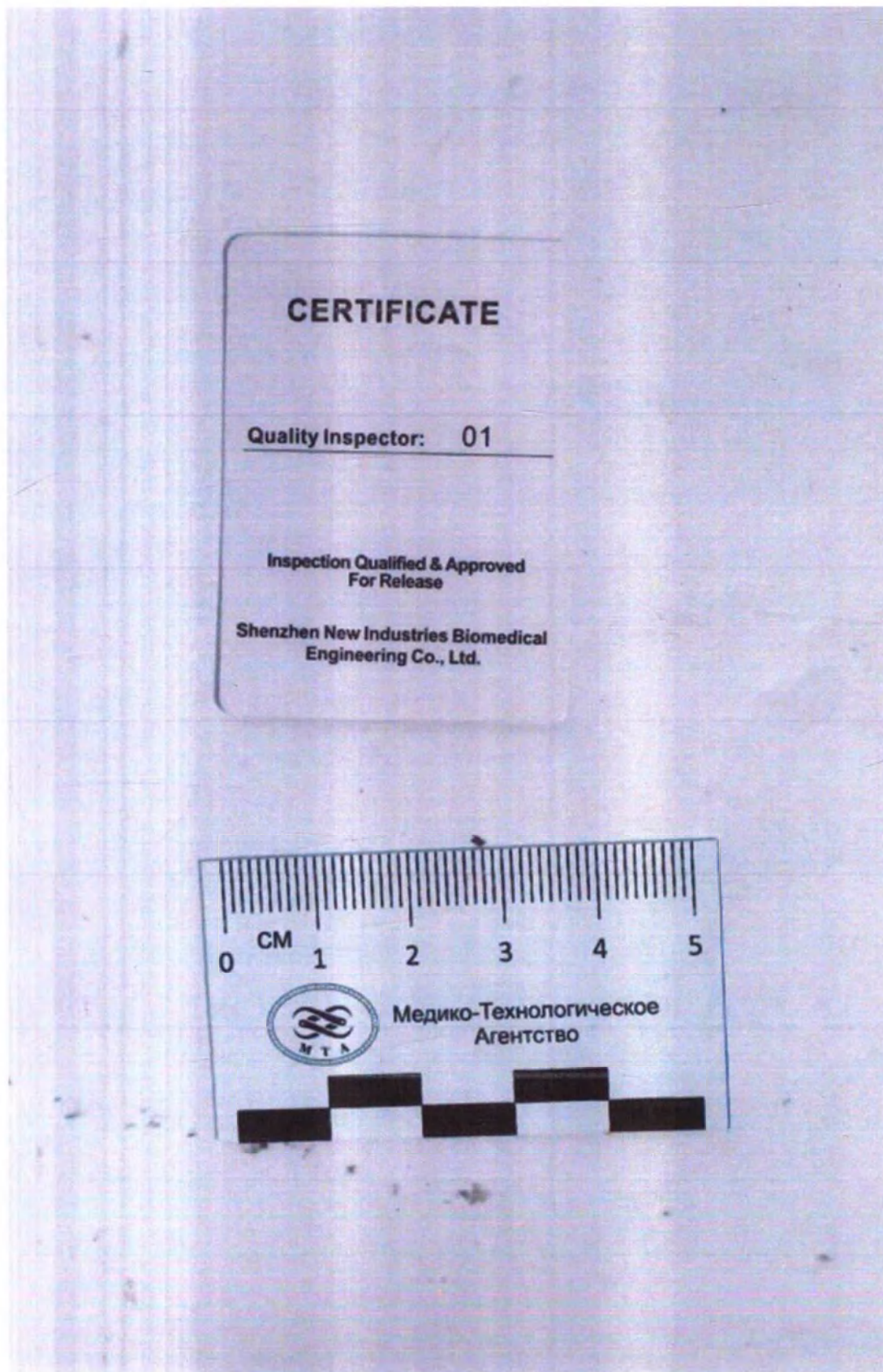


Стикер. 3шт.





Сертификат контроля качества.





Инструкция по применению.

Snibe **CE** **REF** 130293004M 100 tests
130603004M 50 tests

MAGLUMI™ FT4 (CLIA)

INTENDED USE
The kit is an in vitro chemiluminescence immunoassay for the quantitative determination of Free Thyroxine (FT4) in human serum using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer.

SUMMARY AND EXPLANATION OF THE TEST
Thyroxine (T4), a thyroid hormone with the highest concentration in the body, is generated in the thyroid gland by coupling two di-iodinated tyrosine molecules contained within the thyroglobulin molecule. Together with other thyroid hormones such as triiodothyronine (T3), it exerts a great influence on the activities of the body, including the basal metabolic rate, protein synthesis, regulation of bone growth, neuronal maturation and sensitivity to other hormones.
T4 circulates in the bloodstream as an equilibrium mixture of bound and unbound form, where approximately 99.97% is bound to plasma proteins: thyroxine binding globulin (TBG) 60-70%, transthyretin or thyroxine binding prealbumin (TRP/TBPA) 15-30%, and albumin 10%, however the remaining 0.03% unbound T4 named FT4 is substantially physiologically active to serve as metabolic stimulation and control feedback system of hypothalamic-pituitary-thyroid axis^{1,2}. The equilibrium is always maintained to guarantee the constant level of free T4 in spite of alterations occur in either the concentration or affinity of the serum binding proteins, therefore FT4 is a more reliable indicator of an individual's thyroid status than total T4 due to its less sensitivity to changes in serum binding proteins^{3,4}.
Free T4 is elevated in hyperthyroidism and depressed in hypothyroidism, and more additional thyroid tests such as free T3 and TSH may be very indispensable in borderline cases of suspected thyroid malfunction.

PRINCIPLE OF THE TEST
The FT4 assay is a competitive chemiluminescence immunoassay.
The sample (or calibrator/control, if applicable), ABEI-labeled anti-T4 monoclonal antibody, buffer and T4 antigen-coated magnetic microbeads are mixed thoroughly and incubated. Free T4 present in the serum sample (or calibrator/control, if applicable) competes with T4 antigen immobilized on the magnetic microbeads for a limited number of binding sites on the ABEI-labeled anti-T4 antibody, forming immuno-complexes. After precipitation in a magnetic field, decant the supernatant, and then perform a wash cycle. Subsequently, the Starter 1+2 are added to initiate a chemiluminescent reaction. The light signal is measured by a photomultiplier as relative light units (RLUs), which is inversely proportional to the concentration of free T4 present in the sample (or calibrator/control, if applicable).

KIT COMPONENTS

Material Provided	Contents	100 tests (REF: 130293004M)	50 tests (REF: 130603004M)
Magnetic Microbeads	Magnetic microbeads coated with purified T4 antigen, containing BSA, NaN ₃ (<0.1%).	2.5 mL	2.0 mL
Calibrator Low	Containing BSA and T4 antigen, NaN ₃ (<0.1%).	2.5 mL	2.0 mL
Calibrator High	Containing BSA and T4 antigen, NaN ₃ (<0.1%).	2.5 mL	2.0 mL
Buffer	Containing BSA, NaN ₃ (<0.1%).	6.5 mL	4.0 mL
ABEI Label	Anti-T4 monoclonal antibody labeled with ABEI, containing BSA, NaN ₃ (<0.1%).	6.5 mL	4.0 mL
Internal Quality Control	Containing BSA and T4 antigen, NaN ₃ (<0.1%).	2.0 mL	2.0 mL

All reagents are provided ready-to-use.

Accessories Required But Not Provided
MAGLUMI Series

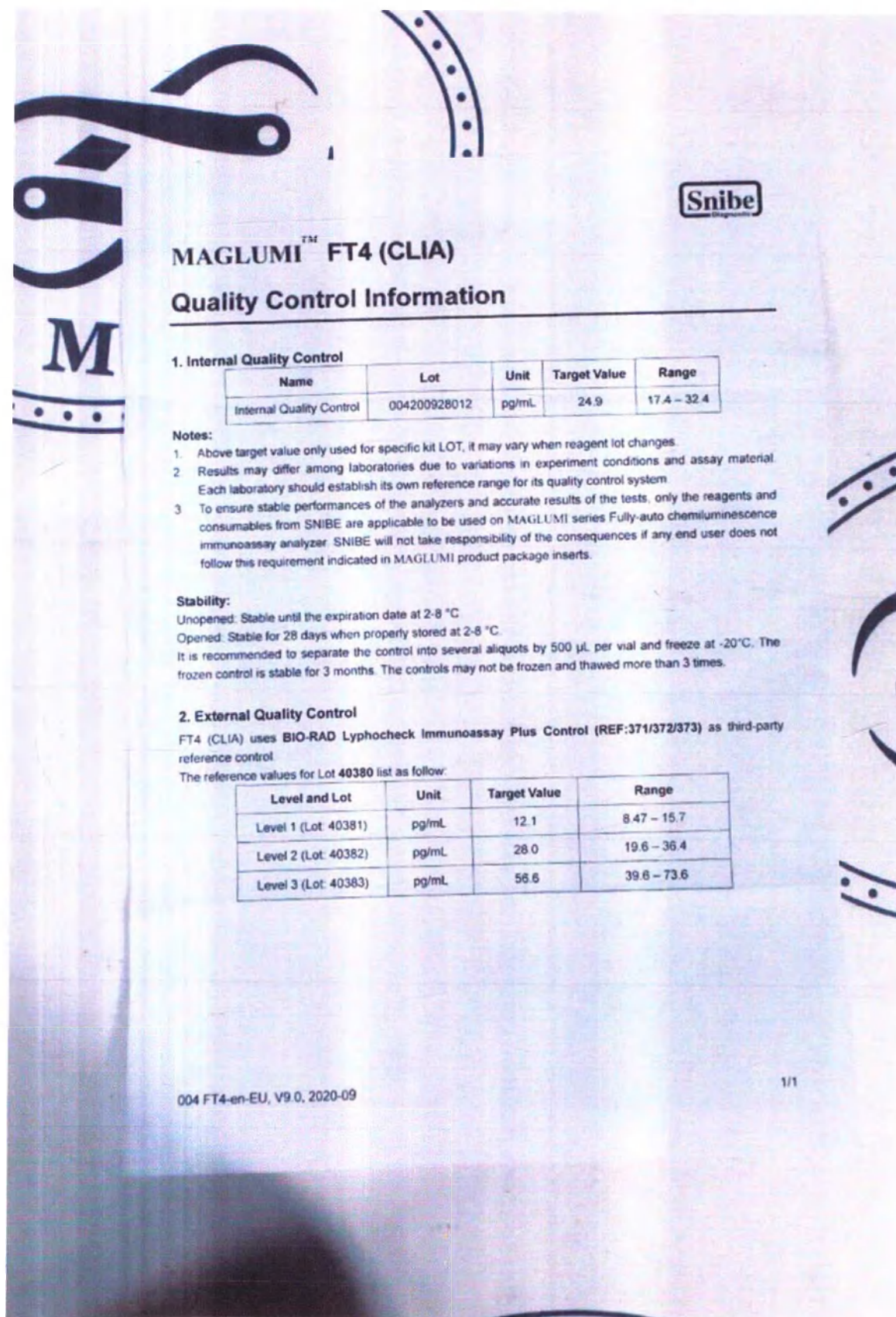
Reaction Module	REF: 830003
Starter 1+2	REF: 130293004M, 130299012M, 130299027M
Wash Concentrate	REF: 130299009M
Light Check	REF: 130299008M
Reaction Cup	REF: 130109000101

Please order accessories from Shenzhen New Industries Biomedical Engineering Co., Ltd. (SNIBE) or our authorized representatives.

CALIBRATION
Traceability: This method has been standardized against USP (United States Pharmacopoeia) Standards.
Test of assay specific calibrators allows the RLU values to adjust the assigned master curve. Results are determined via a calibration curve which is instrument-specifically generated by 2-point calibration and a master curve (10 calibrators) provided via the reagent Radio Frequency Identification (RFID) Chip.
Recalibration is recommended if any of the following conditions occurs:
• After each exchange of lots (Reagent or Starter 1+2).
• Every week and/or each time a new reagent kit is used (recommended).
• After instrument service is required.
• If controls lie outside the expected range.

QUALITY CONTROL
004 FT4-en-EU, V9.1, 2020-02

Таблица значений для контрольного материала



MAGLUMITM FT4 (CLIA)

Quality Control Information

1. Internal Quality Control

Name	Lot	Unit	Target Value	Range
Internal Quality Control	004200928012	pg/mL	24.9	17.4 – 32.4

Notes:

- Above target value only used for specific kit LOT, it may vary when reagent lot changes.
- Results may differ among laboratories due to variations in experiment conditions and assay material. Each laboratory should establish its own reference range for its quality control system.
- To ensure stable performances of the analyzers and accurate results of the tests, only the reagents and consumables from SNIBE are applicable to be used on MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer. SNIBE will not take responsibility of the consequences if any end user does not follow this requirement indicated in MAGLUMI product package inserts.

Stability:
Unopened: Stable until the expiration date at 2-8 °C
Opened: Stable for 28 days when properly stored at 2-8 °C
It is recommended to separate the control into several aliquots by 500 µL per vial and freeze at -20°C. The frozen control is stable for 3 months. The controls may not be frozen and thawed more than 3 times.

2. External Quality Control
FT4 (CLIA) uses BIO-RAD Lyphecheck Immunoassay Plus Control (REF:371/372/373) as third-party reference control
The reference values for Lot 40380 list as follow:

Level and Lot	Unit	Target Value	Range
Level 1 (Lot: 40381)	pg/mL	12.1	8.47 – 15.7
Level 2 (Lot: 40382)	pg/mL	28.0	19.6 – 36.4
Level 3 (Lot: 40383)	pg/mL	56.6	39.6 – 73.6

004 FT4-en-EU, V9.0, 2020-09

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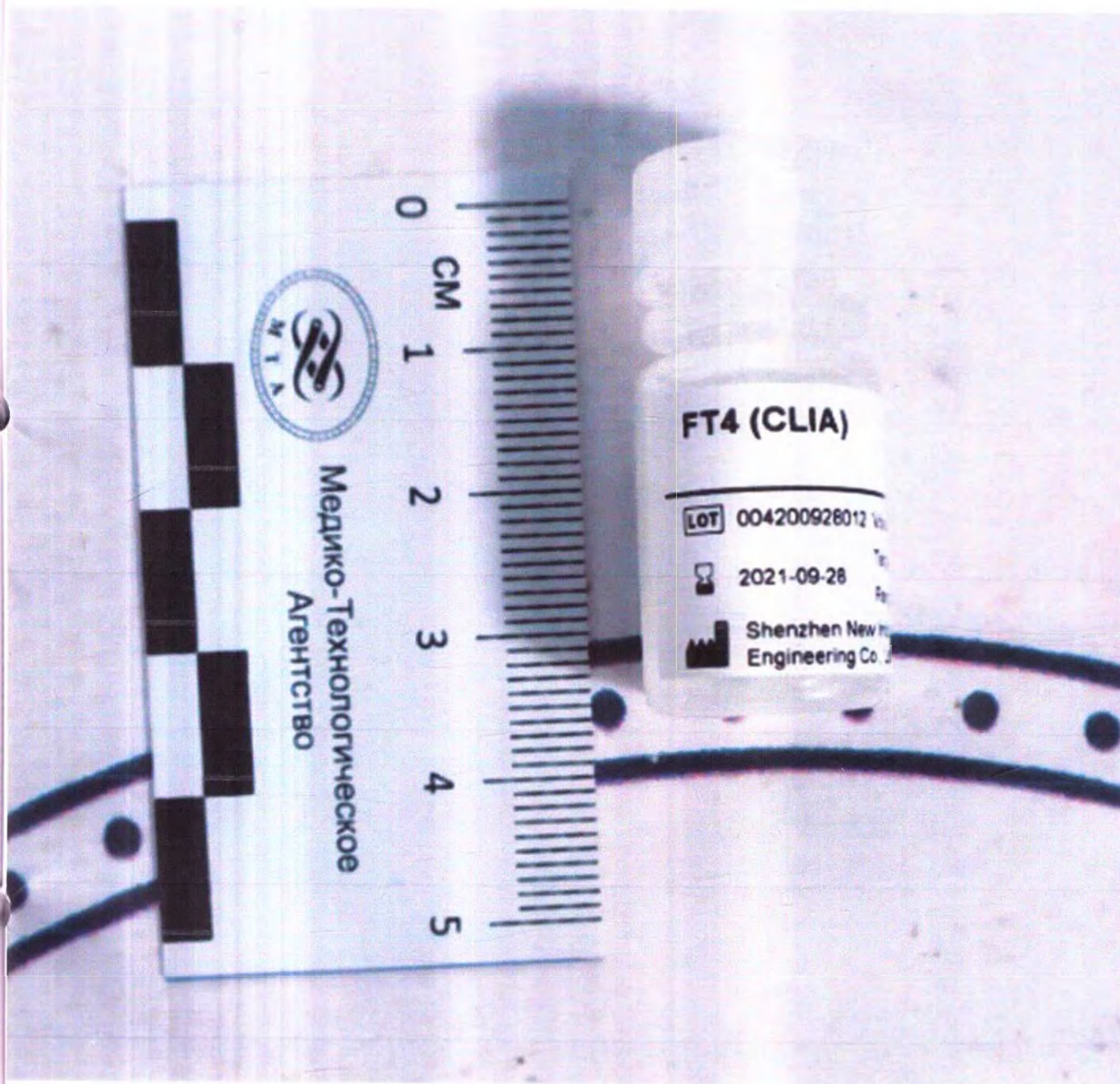


Материал контрольный. Общий вид.



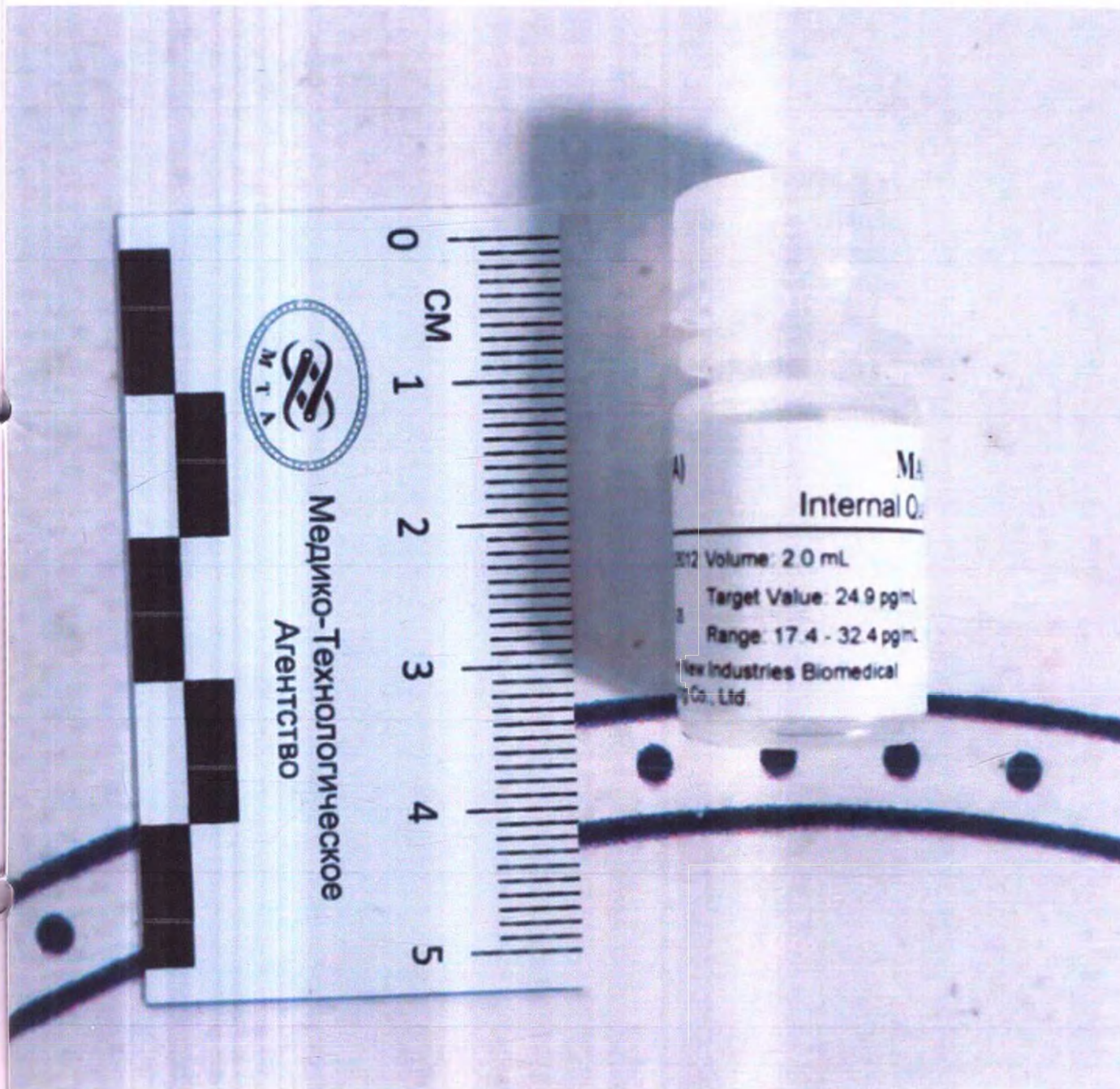


Материал контрольный. Маркировка.



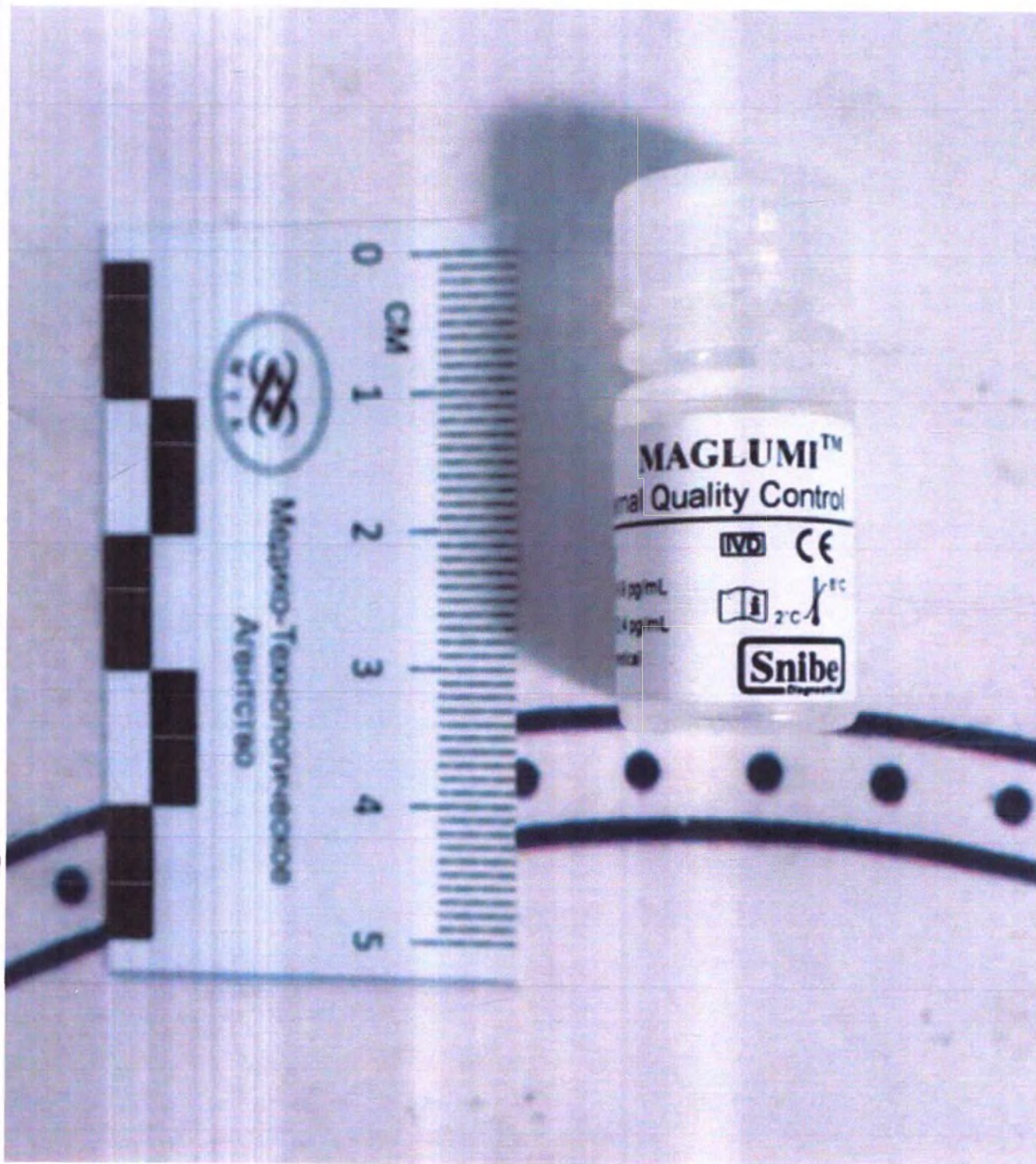


Материал контрольный. Маркировка.



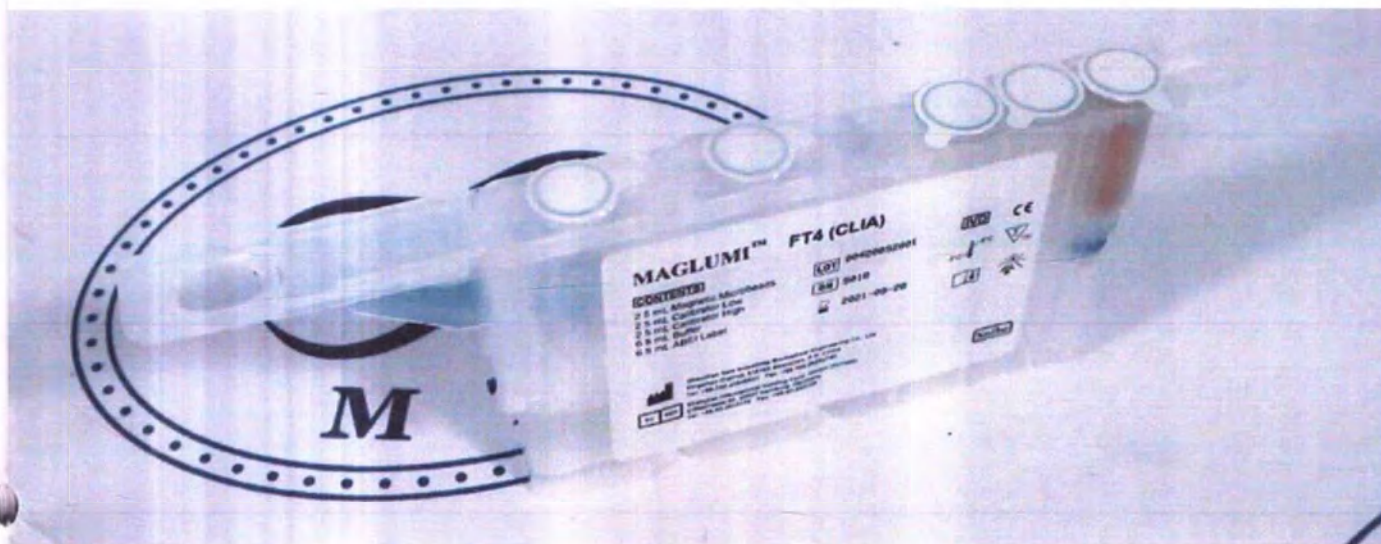


Материал контрольный. Маркировка.



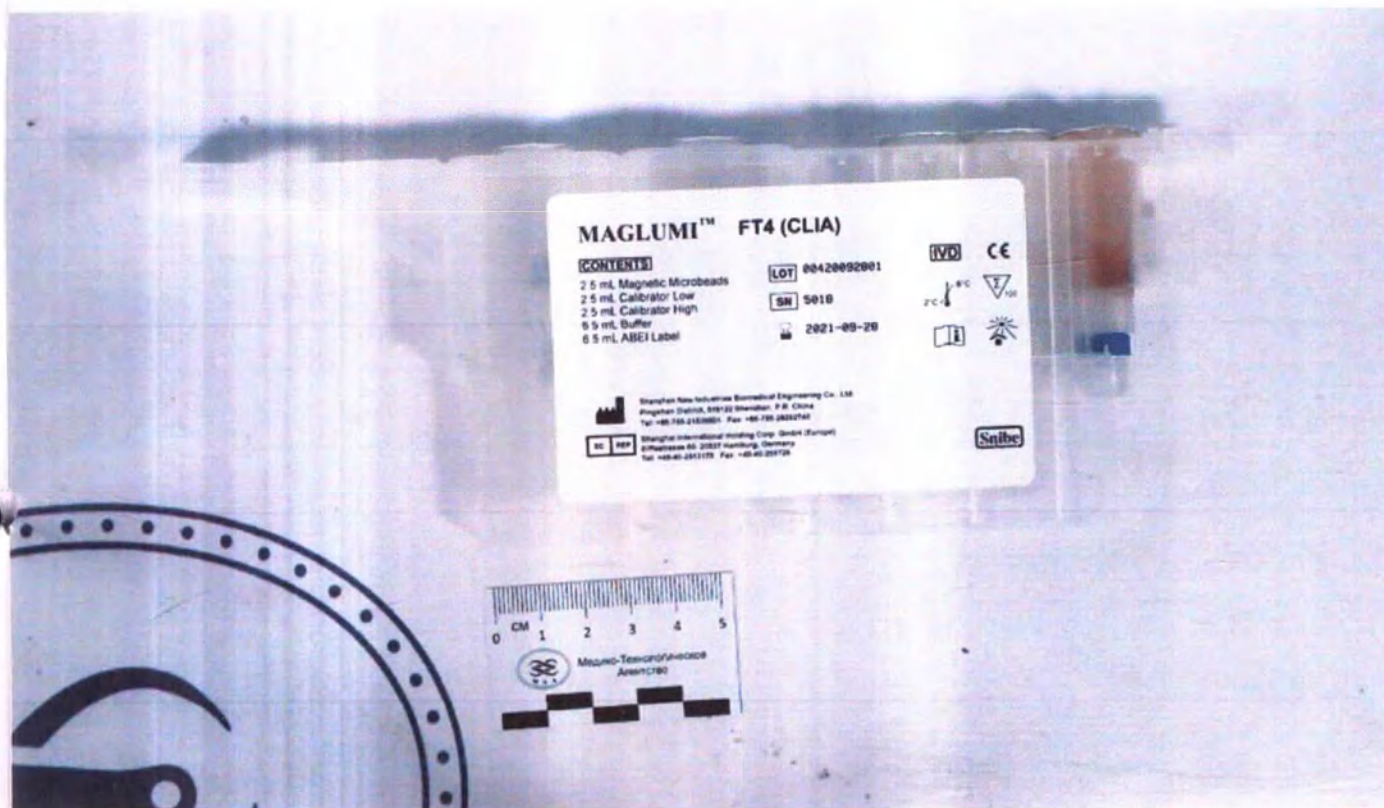


Картридж. Общий вид.



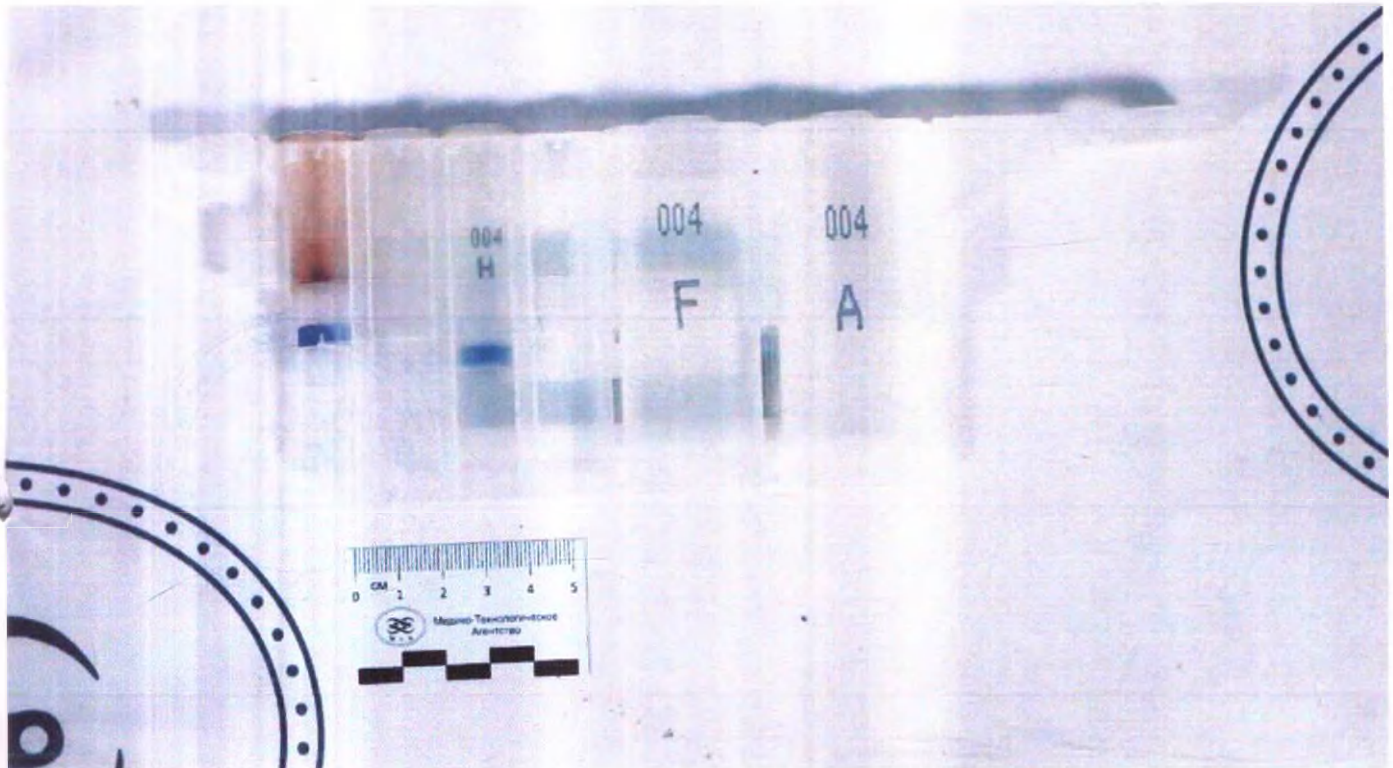


Картридж. Вид спереди.





Картридж. Вид сзади.



Всего прошито, пронумеровано и
скреплено печатью 19
(Северина)
_____ листов

Менеджер ООО «МТА»

Северина Г.А. Хромина

