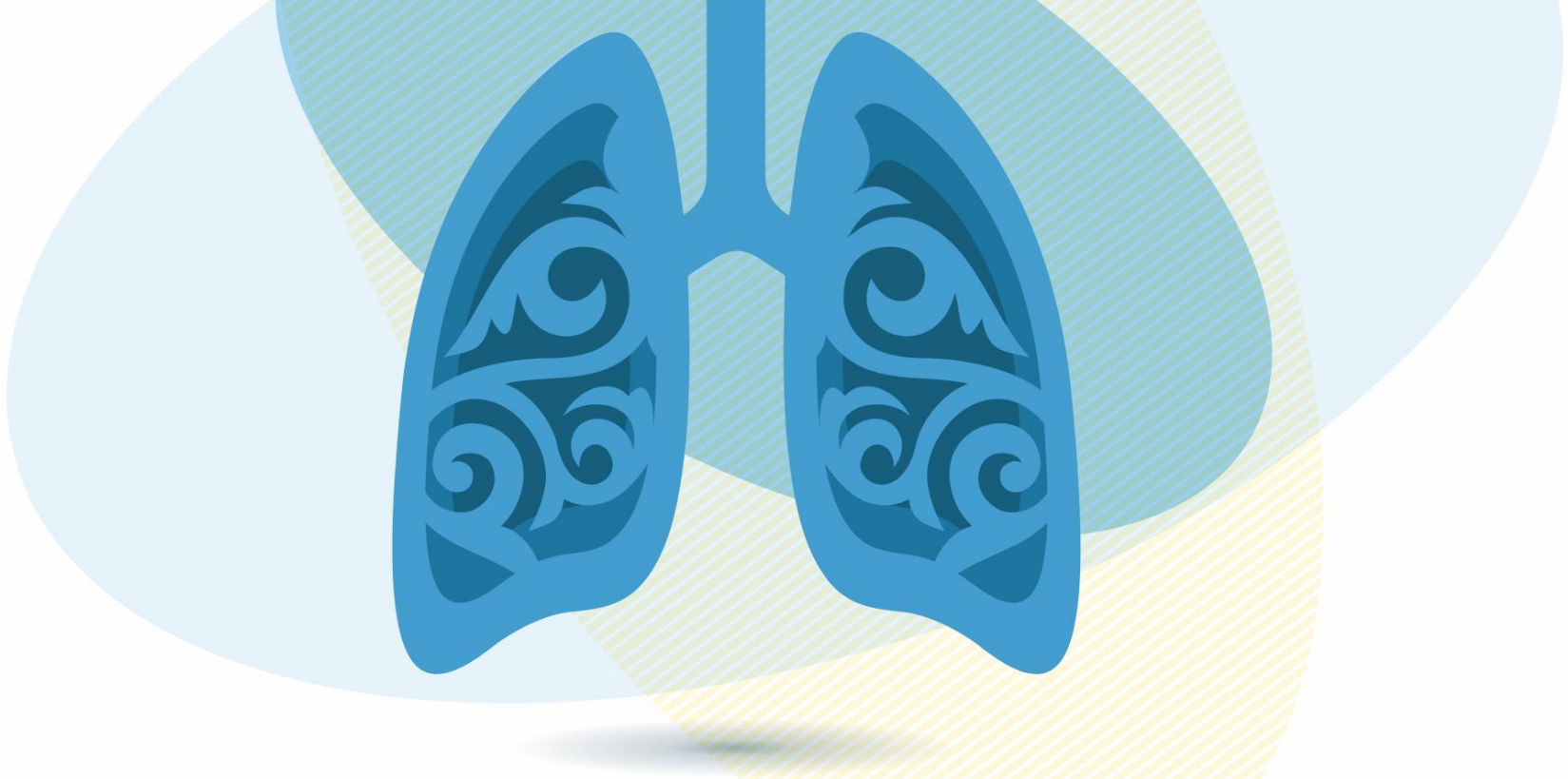

World Health Organization
European Region

Unitaid
SAVE LIVES FASTER

KNCV
TB PLUS

MEDECINS SANS FRONTIERES

# REGIONAL WORKSHOP ON ACCELERATED IMPLEMENTATION

FFL GUIDELINES ON PREVENTION, DIAGNOSIS AND TREATMENT OF TUBERCULOSIS
DRUG-RESISTANT TUBERCULOSIS (DR-TB)

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# REGIONAL WORKSHOP ON ACCELERATED IMPLEMENTATION OF WHO GUIDELINES

ON TB PREVENTION, DIAGNOSIS, AND DRUG-RESISTANT TB (DR-TB) TREATMENT

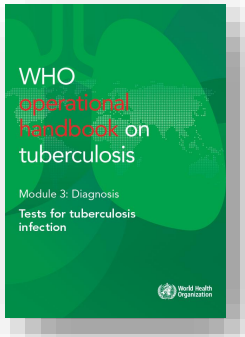
National Medical Research Centre for Phthisiopulmonology and Infectious Diseases, Ministry of Health of Russia

# Experience in the use of TB antigen-based tests for the diagnosis of tuberculosis infection

Valentina Vyacheslavovna Tinkova,

Deputy Chief Medical Officer of the National Medical Research Centre for Phthisiopulmonology and Infectious Diseases of the Ministry of Health of Russia, Candidate of Medical Sciences.

# Modern technologies for early detection of tuberculosis infection

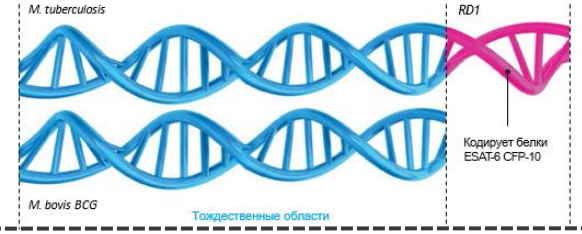



- **Determination of delayed-type hypersensitivity reaction** to virulent Mycobacterium tuberculosis pathogen (*in vivo* skin test) - test with recombinant tuberculosis allergen (Diaskintest)

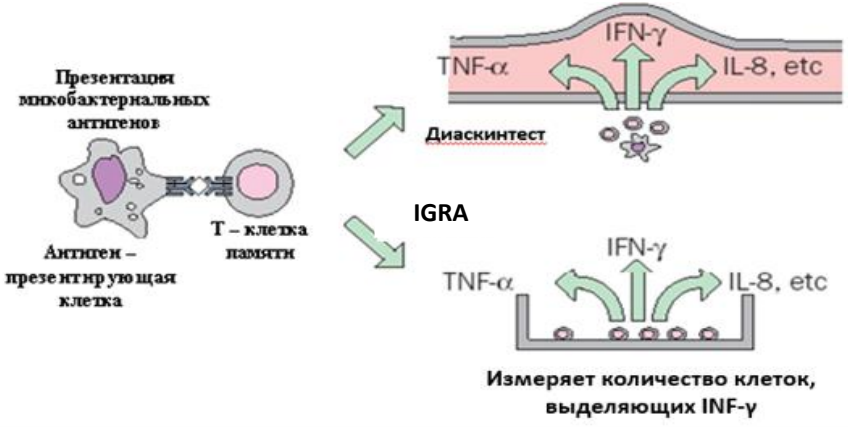
- **IGRA tests** *(interferon Gamma - release assays)*
  - ✓ Determination of effector T cells in the blood that respond to stimulation by Mycobacterium tuberculosis antigen (ELISPOT), a more accurate version of the enzyme-linked immunosorbent assay (ELISA).
  - ✓ Determination of blood levels of interferon-gamma secreted in response to stimulation with Mycobacterium tuberculosis antigen (classical ELISA)

  ( T-spot-TB, QuantiFERON®-TB Gold, Tigra-Test-TB)

**The basis of modern immunological tests:** ESAT-6 and CFP-10 proteins (produced during active reproduction of M.Tuberculosis) were isolated after complete decoding and comparison of genomes of M.Tuberculosis and M.bovis BCG and other mycobacteria.




**The essence of the tests:**




** Figures adapted from the book "Skin test with the preparation "Diaskintest" - new possibilities of identification of tuberculosis infection". Edited by M.A. Paltsev, 2011: 73-87*

# DIASKINTEST - screening test for the diagnosis of tuberculosis infection

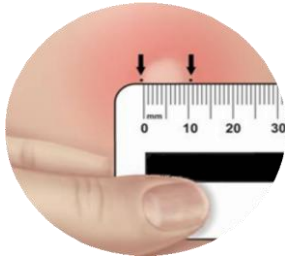

Tuberculosis recombinant allergen in standard dilution - recombinant protein (ESAT6/CFP10) produced by genetically modified culture of Escherichia coli BL21 (DE3)/

- The action of Diaskintest® is based on the detection of cellular immune response to Mycobacterium tuberculosis-specific antigens.
- When administered intradermally, Diazkintest® causes a specific skin reaction (papule) in persons with tuberculosis infection (both active and latent), which is a manifestation of delayed-type hypersensitivity.

| | |
|---|---|
| **Indications** | Diagnosis of tuberculosis infection (including LTI) in all age groups |
| **Method of administration** | Intradermally (similar to the tuberculin test) |
| **Result** | Papule measurements after 72 hours |

## Diagnostic efficacy:

- Sensitivity - 98.3%*
- Specificity - 98.5%/99.0%**
- BCG vaccination does not affect the result of the Diasquintest





РОССИЙСКАЯ ФЕДЕРАЦИЯ

ПАТЕНТ

НА ИЗОБРЕТЕНИЕ

№ 2360926

ГИБРИДНЫЙ БЕЛОК CFP10-ESAT6, ИНДУЦИРУЮЩИЙ РЕАКЦИЮ ГИПЕРЧУВСТВИТЕЛЬНОСТИ ЗАМЕДЛЕННОГО ТИПА В ОТНОШЕНИИ M.TUBERCULOSIS, КОДИРУЮЩАЯ ЕГО ХИМЕРНАЯ НУКЛЕИНОВАЯ КИСЛОТА И РЕКОМБИНАНТНЫЙ ПЛАЗМИДНЫЙ ЭКСПРЕССИРУЮЩИЙ ВЕКТОР, ЕЕ СОДЕРЖАЩИЙ, СПОСОБ ПОЛУЧЕНИЯ ГИБРИДНОГО БЕЛКА И ДОЗИРОВАННАЯ ЛЕКАРСТВЕННАЯ ФОРМА ДЛЯ ВНУТРИКОЖНОЙ ИНЪЕКЦИИ НА ЕГО ОСНОВЕ

Патентообладатель(ли): *Киселев Всеволод Иванович (RU), Пальцев Михаил Александрович (RU)*

Автор(ы): *Киселев Всеволод Иванович (RU), Пальцев Михаил Александрович (RU)*

Заявка № 2008109922

Приоритет изобретения 17 марта 2008 г.

Зарегистрировано в Государственном реестре изобретений Российской Федерации 10 июля 2009 г.

Срок действия патента истекает 17 марта 2028 г.

*Руководитель Федеральной службы по интеллектуальной собственности, патентам и товарным знакам* Б.П. Симонов


МИНИСТЕРСТВО ЗДРАВООХРАНЕНИЯ РОССИЙСКОЙ ФЕДЕРАЦИИ

Регистрационное удостоверение лекарственного препарата для медицинского применения

ДСР-006435/08

| | |
|---|---|
| Наименование держателя (владельца) регистрационного удостоверения лекарственного препарата | АО "ГЕНЕРИУМ", Россия |
| Адрес местонахождения держателя (владельца) регистрационного удостоверения лекарственного препарата | 601125, Владимирская область, Петушинский район, пос. Вольгинский, корп. 17 |
| Дата государственной регистрации лекарственного препарата | 11.08.2008 |
| Срок действия регистрационного удостоверения лекарственного препарата | бессрочно |
| Дата внесения изменений в регистрационное удостоверение лекарственного препарата (дата замены регистрационного удостоверения лекарственного препарата) | 23.01.2017 |
| Информация о зарегистрированном лекарственном препарате: | |
| Торговое наименование | Диаскинтест® |
| Международное непатентованное, или группировочное, или химическое наименование | Аллерген туберкулезный рекомбинантный в стандартном разведении |
| Лекарственная форма | раствор для внутрикожного введения |
| Дозировка | |
| Качественный состав и количественный состав действующих веществ и качественный состав вспомогательных веществ | |
| Форма выпуска (лекарственная форма, упаковка, первичная упаковка, количество лекарственной формы в первичной упаковке, количество первичной упаковки в потребительской упаковке, комплектность) | раствор для внутрикожного введения, 0,1 мл/1 доза (флакон) 1,2 мл (12 доз)/ 3 мл (30 доз) х 5 х (контурная ячейковая упаковка)] х 1/2 (пачка картонная) |
| Реквизиты нормативной документации | [раствор для внутрикожного введения, 0,1 мл/1 доза (флакон) 1,2 мл (12 доз)/ 3 мл (30 доз) х 1 х (контурная ячейковая упаковка)] х 1 пачка картонная |
| | ФСР-006435/08-110808 |

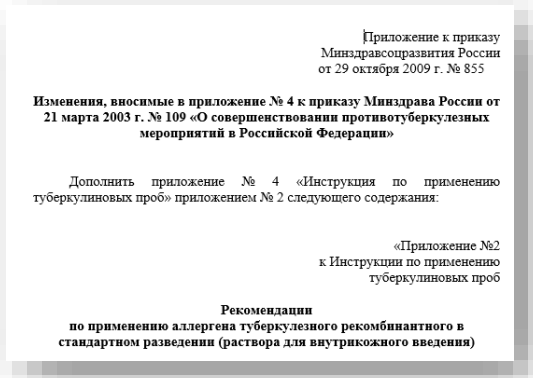
013584

**RU 11.08.2008**

**Slogotskaya L et al. PLoS ONE. 2018; 13 (12): e0208705.; **Slogotskaya L et al. Immunology. 2011; 32 (3): 116-119. ** Bogorodskaya E.M. et al. Tuberculosis and socially significant diseases, 2017, No.2. C.10-15*
**** Aksenova V.A. et al. Voprosy Practical Pediatrics, 2016, Vol. 11, No. 4, pp. 9-17 DOI:10.20953/1817-7646-2016-4-9-17*

LTI - latent tuberculosis infection

# Stages of introduction of the Diaskintest into clinical practice



Приложение к приказу
Минздравсоцразвития России
от 29 октября 2009 г. № 855

**Изменения, вносимые в приложение № 4 к приказу Минздрава России от 21 марта 2003 г. № 109 «О совершенствовании противотуберкулезных мероприятий в Российской Федерации»**

Дополнить приложение № 4 «Инструкция по применению туберкулиновых проб» приложением № 2 следующего содержания:

«Приложение №2
к Инструкции по применению
туберкулиновых проб

**Рекомендации
по применению аллергена туберкулезного рекомбинантного в
стандартном разведении (раствора для внутрикожного введения)**

МИНИСТЕРСТВО ЗДРАВООХРАНЕНИЯ
РОССИЙСКОЙ ФЕДЕРАЦИИ
(Минздрав России)

ПРИКАЗ

19 декабря 2014 г. № 951

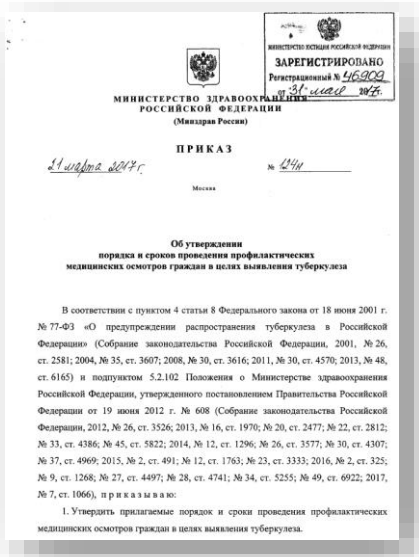
Москва

**Об утверждении
методических рекомендаций по совершенствованию диагностики
и лечения туберкулеза органов дыхания**

Во исполнение пункта 14 раздела III комплекса мер, направленных на совершенствование оказания медицинской помощи населению на основе государственной программы Российской Федерации «Развитие здравоохранения», утвержденного распоряжением Правительства Российской Федерации от 28 февраля 2013 г. № 267-р (Собрание законодательства Российской Федерации, 2013, № 9, ст. 1014) приказываю:

Утвердить прилагаемые методические рекомендации по совершенствованию диагностики и лечения туберкулеза органов дыхания.

Министр В.И. Скворцова



ЗАРЕГИСТРИРОВАНО
Регистрационный № 46909
от 31 мая 2017

МИНИСТЕРСТВО ЗДРАВООХРАНЕНИЯ
РОССИЙСКОЙ ФЕДЕРАЦИИ
(Минздрав России)

ПРИКАЗ

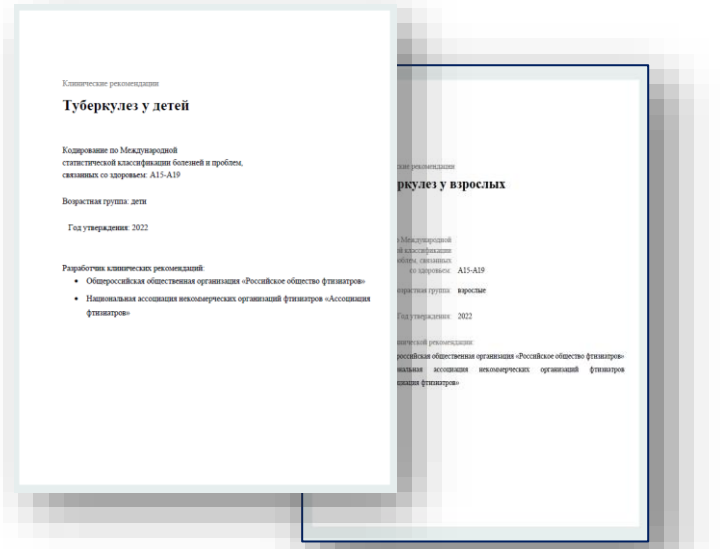
21 марта 2017 г. № 124н

Москва

**Об утверждении
порядка и сроков проведения профилактических
медицинских осмотров граждан в целях выявления туберкулеза**

В соответствии с пунктом 4 статьи 8 Федерального закона от 18 июня 2001 г. № 77-ФЗ «О предупреждении распространения туберкулеза в Российской Федерации» (Собрание законодательства Российской Федерации, 2001, № 26, ст. 2581; 2004, № 35, ст. 3607; 2008, № 30, ст. 3616; 2011, № 30, ст. 4570; 2013, № 48, ст. 6165) и подпунктом 5.2.102 Положения о Министерстве здравоохранения Российской Федерации, утвержденного постановлением Правительства Российской Федерации от 19 июня 2012 г. № 608 (Собрание законодательства Российской Федерации, 2012, № 26, ст. 3526; 2013, № 16, ст. 1970; № 20, ст. 2477; № 22, ст. 2812; № 33, ст. 4386; № 45, ст. 5822; 2014, № 12, ст. 1296; № 26, ст. 3577; № 30, ст. 4307; № 37, ст. 4969; 2015, № 2, ст. 491; № 12, ст. 1763; № 23, ст. 3333; 2016, № 2, ст. 325; № 9, ст. 1268; № 27, ст. 4497; № 28, ст. 4741; № 34, ст. 5255; № 49, ст. 6922; 2017, № 7, ст. 1066), приказываю:

1. Утвердить прилагаемые порядок и сроки проведения профилактических медицинских осмотров граждан в целях выявления туберкулеза.



Клинические рекомендации

**Туберкулез у детей**

Кодирование по Международной
статистической классификации болезней и проблем,
связанных со здоровьем: A15-A19

Возрастная группа: дети

Год утверждения: 2022

Разработчик клинических рекомендаций:

- Общероссийская общественная организация «Российское общество фтизиатров»
- Национальная ассоциация некоммерческих организаций фтизиатров «Ассоциация фтизиатров»

**2009**

Use of Diaskintest **in groups at high risk of developing tuberculosis** (tuberculosis service facilities)

**2014**

Diaskintest as a screening method for tuberculosis infection in the paediatric and adolescent population to form groups at highest risk of tuberculosis and subsequently prevent new cases (**recommended**)

**2017**

Diaskintest as a **mandatory screening test** for tuberculosis infection in the **paediatric and adolescent population** to form groups at highest risk of tuberculosis and subsequently prevent new cases of the disease (general medical network)

**2020 2022**

Clinical Guidelines:
Diaskintest as

- **A mandatory screening test in children and adolescents;**
- **in the diagnostic algorithm for tuberculosis in adults**

# Results of step-by-step introduction of Diaskintest into clinical practice

2012-2013.

- **1,830,432 children and adolescents**
- multicentre continuous retrospective study of the use of Diaskintest in Moscow, Samara and Ryazan regions

2016 г. **

- **109,207 children and adolescents**
- Study of the effectiveness of Mantoux and Diaskintest for screening for tuberculosis infection in children and adolescents in the general health care network (GHN) in Stavropol Krai.

2020 ***

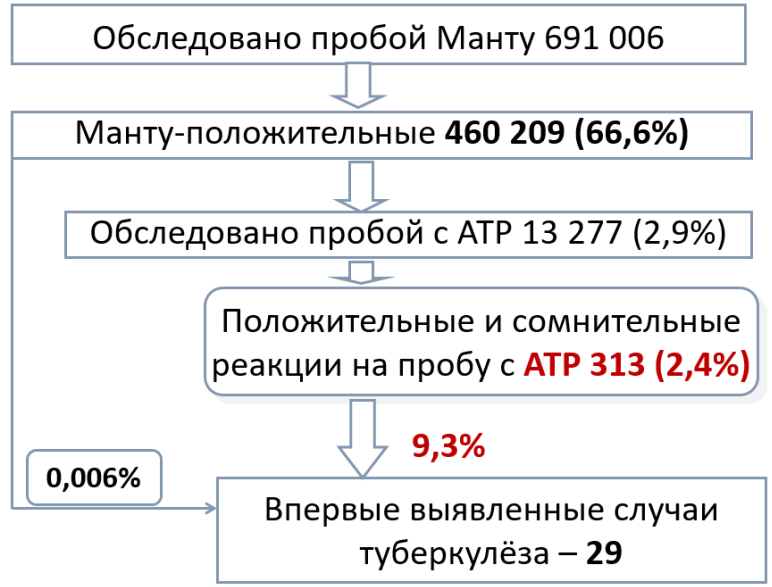
- Evaluating the effectiveness of **mass screening** for tuberculosis infection **in children aged 1-7 years old**

Results:

- in 97 per cent of cases, the diagnosis of tuberculosis was confirmed
- **There has been a 25 per cent reduction in the number of persons to be seen by a phthisiatrician**
- **more than 50 per cent reduction** in the **cost of** preventive therapy in at-risk groups
- a group of people with latent tuberculosis infection should be singled out and preventive therapy should be targeted to them.

Results:

- schoolchildren aged 8-17 years have **37 times higher detection rate of specific tuberculosis pathology** when using Diaskintest in OLS than by Mantoux test.
- **High-risk groups for tuberculosis are** targeted and much **more accurately identified**




*Aksenova V.A., Baryshnikova L.A., Klevno N.I. Modern approaches to screening of tuberculosis infection in children and adolescents in Russia. Medical Council. 2015 (4): 30-35

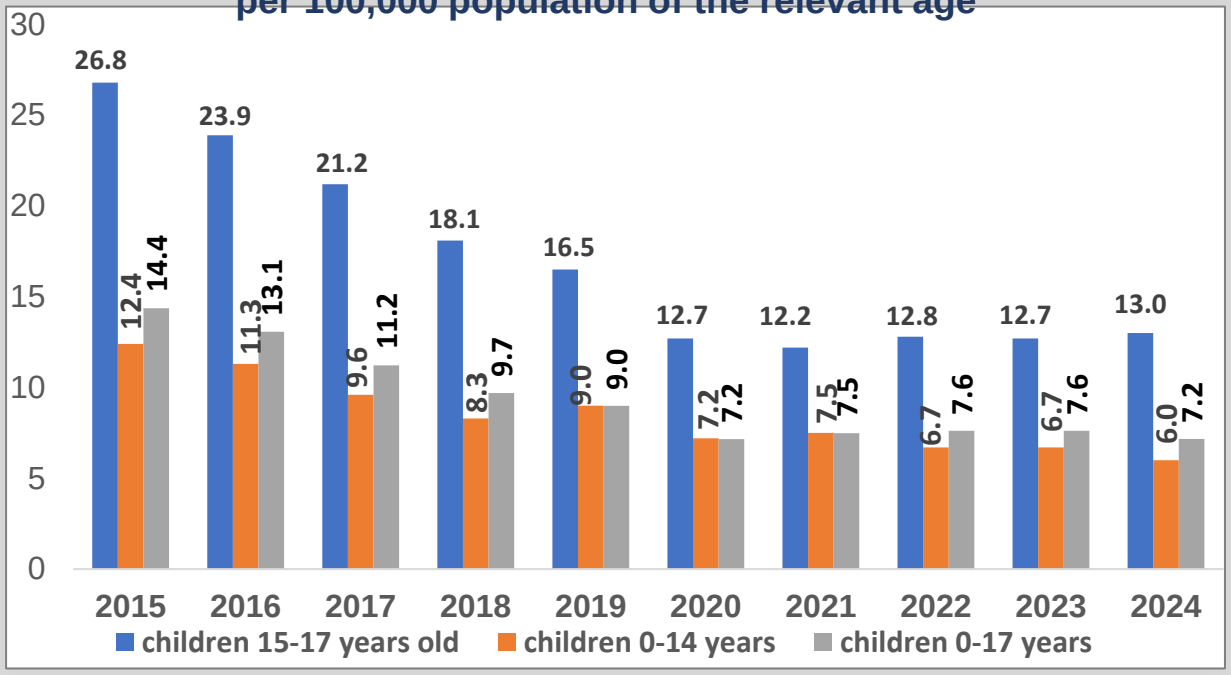
**Aksenova V.A., Moiseeva N.N., Klevno N.I., Odinets V.S., Baronova O.D. Effectiveness of various screening methods for early detection of tuberculosis in children and adolescents. Voprosy prakticheskaya paediatriya, 2016. 11(4):9-17 DOI:10.20953/1817-7646-2016-4-9-17

***Slogotskaya L. V., Bogorodskaya E. M., Shamuratova L. F., Sevostyanova T. A. Evaluation of the effectiveness of mass screening to detect tuberculosis infection in children aged 1-7 years in Moscow Tuberculosis and lung diseases. 2021. 99(12): 14-21. http://doi.org/10.21292/2075-1230-2021-99-12-14-21

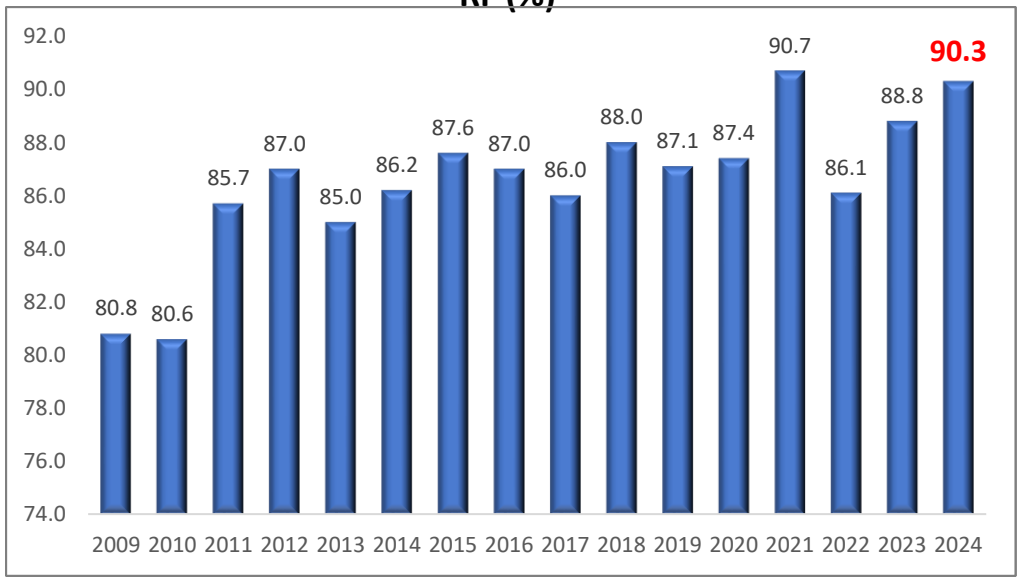
# Some epidemic indicators of tuberculosis in children aged 0-17 years on the basis of Diaskintest, RF

**21.03.2017**
**Order of the Ministry of Health of Russia**
**No. 124n - mass screening**
**in children from 8 years of age throughout the Russian Federation**
**with the use of Diaskintest**

**Incidence of tuberculosis in children in the Russian Federation**
**per 100,000 population of the relevant age**




**Percentage of actively detected TB patients in children 0-17 years of age, RF (%)**

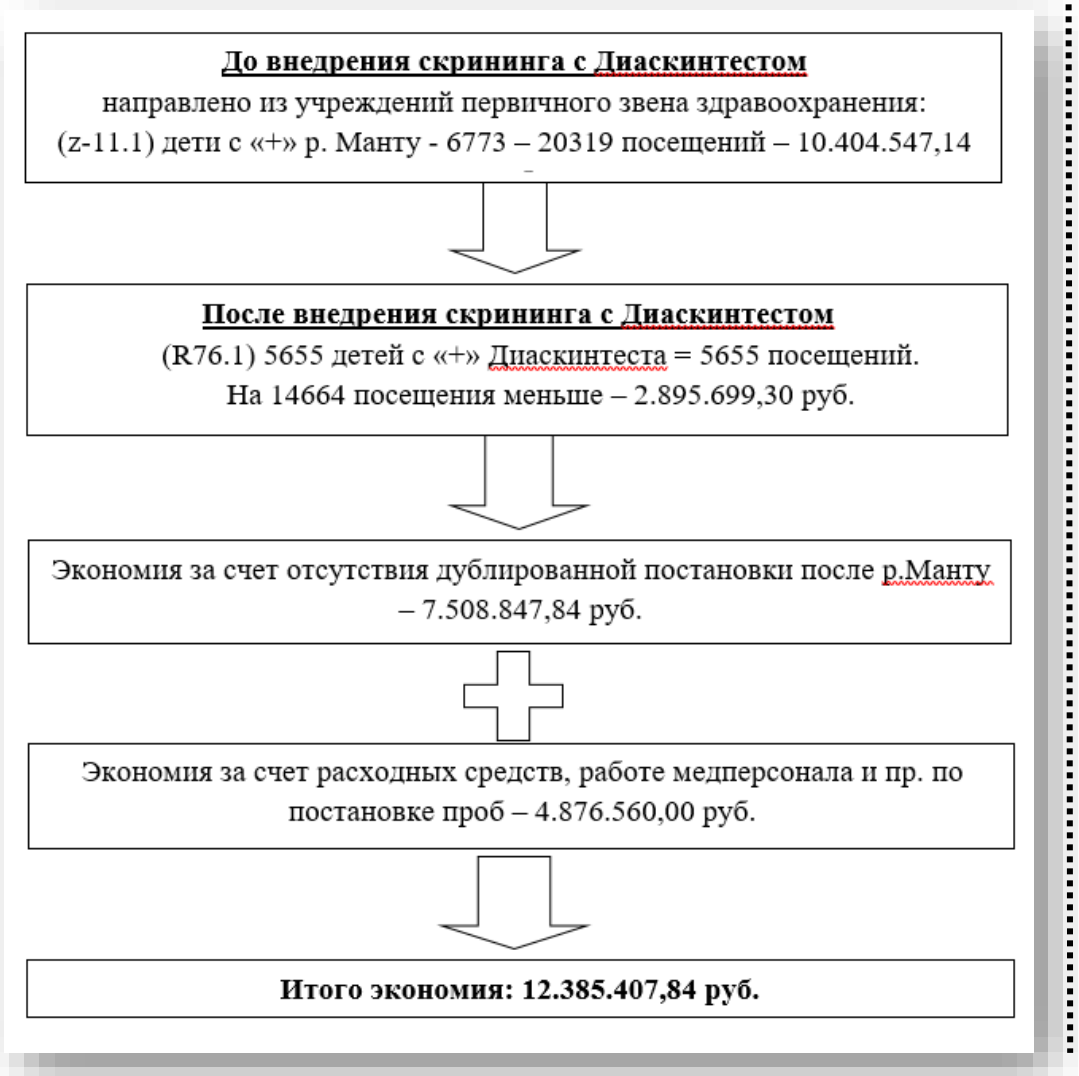



morbidity among young people (18-24 years of age) decreased 3, 4 times

There was a significant decrease in the number of deaths from tuberculosis in childhood, as well as in the proportion of CNS tuberculosis patients among first-diagnosed cases of tuberculosis among children

# Pharmacoeconomic benefit of the use of Diaskintest

**Expenditure of financial resources on screening to (in 2013) and after (in 2019) the introduction of Diaskintest in children (Sverdlovsk region)***

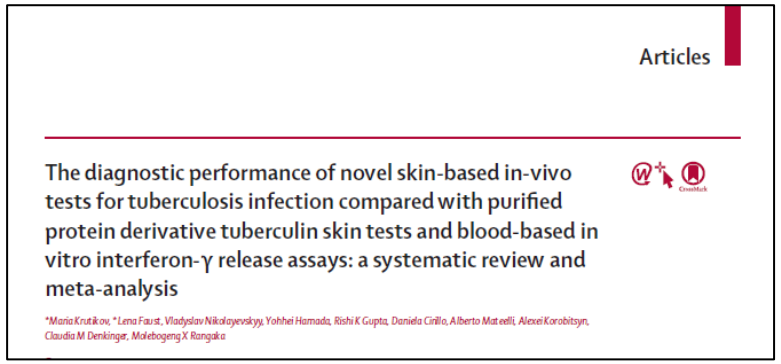



**Cost/efficiency analysis****

| Parameter | Mantoux test | Mantoux test + Diaskintest | Diaskintest |
|---|---|---|---|
| Costs per child, rub. | 209,0 | 228,0 | 182,0 |
| Diagnostic efficiency | 0,003% | 0,006% | 0,024% |
| **Costs/efficiency** | **69 666** | 38 000 | **7 583** |

**Diaskintest significantly improves the quality of mass tuberculosis screening and is cost-effective**
**more favourable compared to traditional tuberculin diagnostics.**

**Yu.P. Ugaev, N.G. Kamaeva, A.I. Tsvetkov et al. Innovative recombinant technologies for detection and diagnosis of tuberculosis in children and adolescents: achievements and problems. Paediatria named after G.N. Speransky. G.N. Speransky. 2020; 99 (6): 112-118.*
***Moiseeva N.N. Tuberculosis recombinant allergen as a screening method for early detection of tuberculosis in children and adolescents during mass preventive examinations. Author's thesis. ... cand. Med. Sciences Moscow, 2016*


Articles

The diagnostic performance of novel skin-based in-vivo tests for tuberculosis infection compared with purified protein derivative tuberculin skin tests and blood-based in vitro interferon-γ release assays: a systematic review and meta-analysis

*Maria Krutikov, *Lena Faust, Vladyslav Nikolayevskyy, Yohhei Hamada, Rishi K Gupta, Daniela Cirillo, Alberto Matteelli, Alexei Korobitsyn, Claudia M Denkinger, Molebogeng X Rangaka

# Diagnostic performance of new in-vivo skin tests for tuberculosis infection: A systematic review and meta-analysis (Lancet, 2021)

**Tests analysed:** Diaskintest (Generium, Moscow, Russia),

C-Tb (Serum Institute of India, Pune, India),

EC-skintest (recently renamed Creative-TST or C-TST, Anhui Zhifei Longcom, Hefei, China)

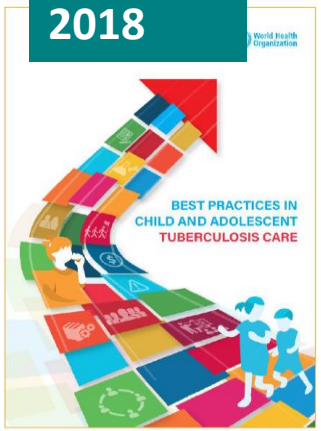
**Comparison tests:** tuberculin test, IGRA tests

| In vivo tests | Matching with IGRA test results | Coincidence with tuberculin test results | Sensitivity in comparable studies, %(95% CI ) | | | |
|---|---|---|---|---|---|---|
| | | | Test to be studied | Tuberculin test | T-SPOT.TB | QuantiFERON |
| Diaskintest | **87,16% (79,47-92,24)** | 55,45% (46,08-64,45) | **91,18% (81,72-95,98)** | 88,24% (78,20-94,01) | 90,91% (79, 95-96,16) | 89,66 (78,83-95,28) |
| C-Tb | 79,80% (76,10-83,07) | 78,92% (74,65-82,63) | 74-52% (70,39-78,25) | 78,18% (67,75-85,94) | 71,67% (63,44-78,68) | |
| EC-skintest | | | 86,06% (82,39-89,07) | | | |

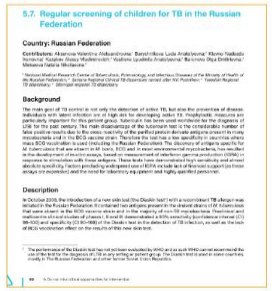
*Lancet Infect Dis October 1, 2021 https://doi.org/10.1016/ S1473-3099(21)00261-9*

# The Russian methodology of Diaskintest, successfully used in Russia for 10 years, in 2022 was highly appreciated by the WHO, which recognised the existence of a fundamentally new class of skin tests for *Mtb* antigens (TBST) for early detection of tuberculosis infection

**2018**




**Систематический скрининг детей на туберкулез в России в 2018 году под руководством В.А. Аксеновой внесен в сборник ВОЗ – лучшие практики по борьбе с туберкулезом среди детей и подростков.**


5.7. Regular screening of children for TB in the Russian Federation

Country: Russian Federation

Background

Description

**2022**

WHO operational handbook on tuberculosis

Module 3: Diagnosis

Tests for tuberculosis infection

## 1.2. Recommendation

*Mycobacterium tuberculosis* antigen-based skin tests (TBSTs) may be used to test for TB infection.
*Conditional recommendation for the intervention, very low certainty of the evidence*

The TBST class is defined as in vivo skin tests for the detection of TB infection that use *Mtb-specific* antigens (ESAT-6 and CFP-10).

### 3.2.2 Diaskintest

Diaskintest (Generium, Russian Federation) is a recombinant protein produced by genetically modified culture of *Escherichia coli* BL21 (DE3)/pCFP-ESAT, diluted with sterile isotonic phosphate buffer solution, with a preservative (phenol). One dose (0.1 mL) of the product contains 0.2 µg of CFP-10–ESAT-6 recombinant protein, and excipients – disodium phosphate dihydrate, sodium chloride, potassium dihydrogen phosphate, polysorbate 80, phenol and water for injection *(40)*.

Fig. 3.2. Diaskintest package and vial


Source: Reproduced with permission of Generium, ©2021. All rights reserved.

The manufacturer recommends administration intradermally and reading of the reaction at the injection site 48–72 hours after injection. The presence of redness and induration should be noted, although the presence and size of induration is critical to interpretation. The presence of blistering, necrosis (skin breakdown) or lymphadenitis is rarely recorded and if seen is interpreted as a "hyperergic" reaction.

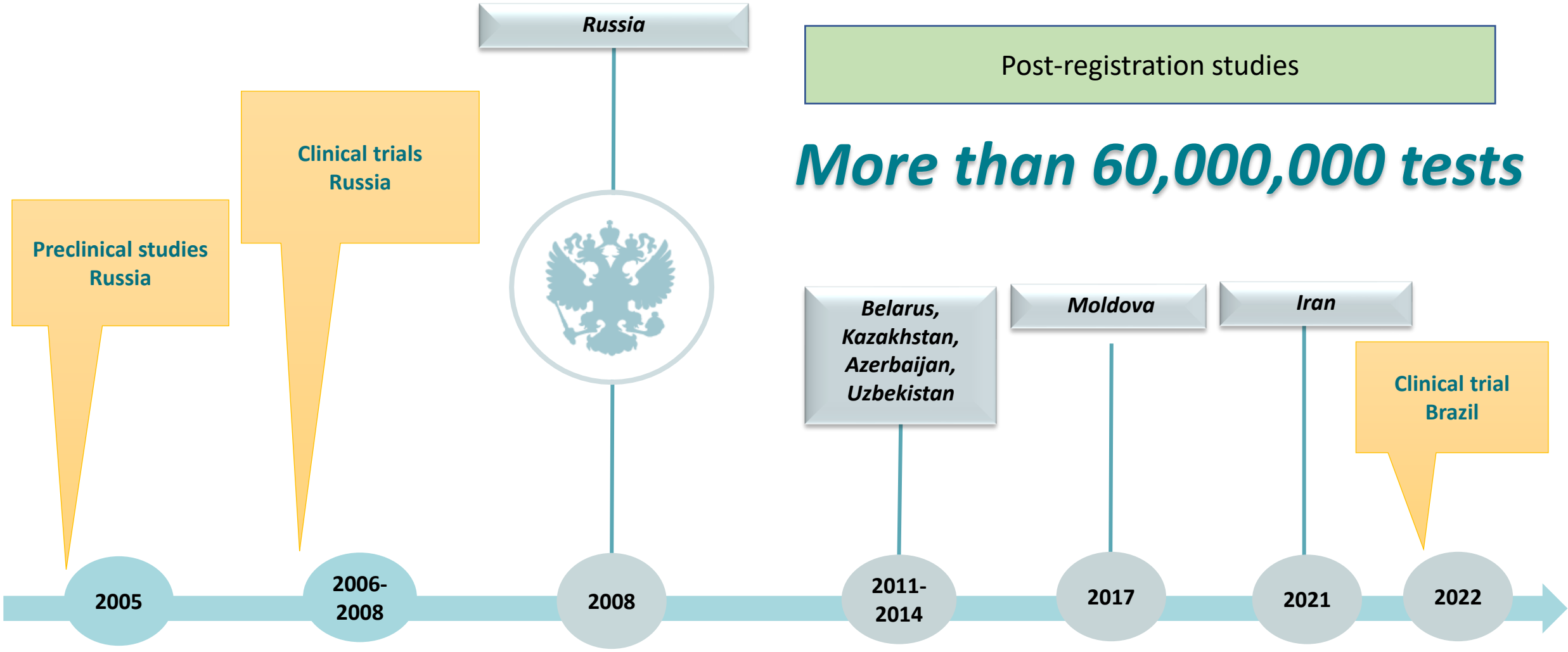
The following technologies were included in the evaluation:

- Cy-Tb (Serum Institute of India, India);
- **Diaskintest (Generium, Russian Federation);**
- C-TST (formerly known as ESAT6-CFP10 test, Anhui Zhifei Longcom, China).

Advantages of the Diaskintest methodology:

- High sensitivity and specificity
- High concordance of TVST and IGRA test results in TB-free (89%) and TB-positive individuals (86%)
- High accuracy of TVST and safety compared to tuberculin test
- Pharmacoeconomic benefit

# Registration of Diaskintest outside Russia



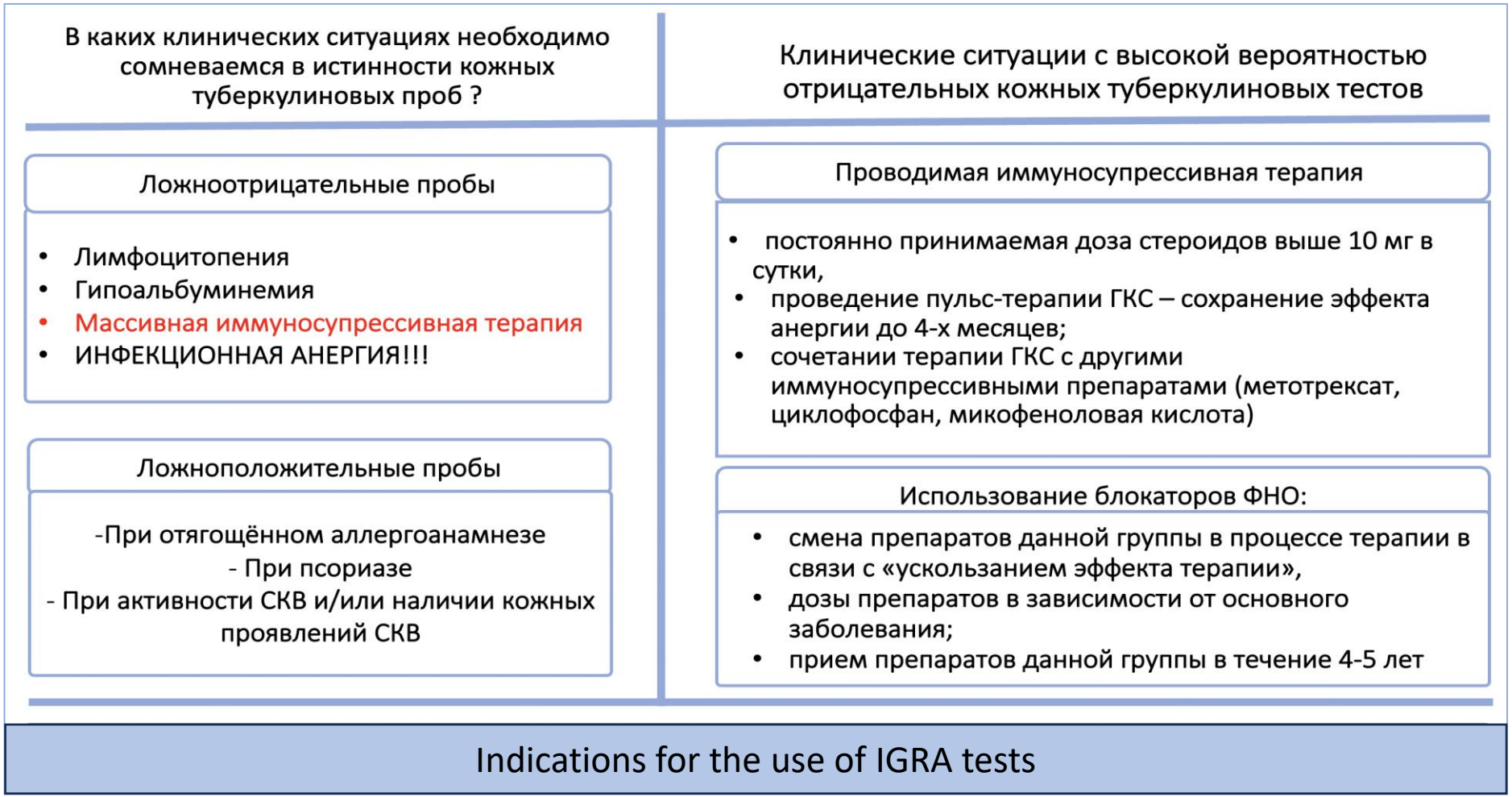
# Algorithm for the use of Diaskintest for the diagnosis of latent tuberculosis infection and differential diagnosis

| Diagnosis of latent tuberculosis infection | Persons in contact with tuberculosis patients | Examination in case of suspected tuberculosis | Differential diagnosis of tuberculosis with other diseases |
|---|---|---|---|
| - Screening and monitoring of tuberculosis infection in people receiving biological therapy<br>- In preparation for solid organ transplantation<br>In persons receiving immunosuppressive therapy | persons from family, professional, territorial and industrial contacts | - clinical minimum screening for tuberculosis<br>- screening of health and social groups at risk of tuberculosis when tuberculosis is suspected | -differential diagnosis of pulmonary and extrapulmonary localisations of tuberculosis |

- Exclusion of active tuberculosis
- Determining the need for chemoprophylaxis
- Treatment recommendations

# Indications for the use of IGRA tests

If there is no doubt about the "truth" of the results of a skin test, the choice is for the test with recombinant tuberculosis allergen - "Diaskintest".




*Ruan Q, Zhang S, Ai J, Shao L, Zhang W..1007/s10067-014-2817-6. Epub 2014 Nov 7. PMID: 25376466 ;* ***Anton C, Machado FD, Ramirez JMA, Bernardi RM, Palominos PE, Brenol CV, Mello FCQ, Silva DR. J Bras Pneumol. 2019 Apr 25;45(2):e20190023. doi: 10.1590/1806-3713/e20190023. PMID: 31038654; PMCID: PMC6733747; Thomas K, Hadziyannis E, Hatzara C, et al. Conversion and Reversion Rates of Tuberculosis Screening Assays in Patients With Rheumatic Diseases and Negative Baseline Screening Under Long-Term Biologic Treatment. Pathog Immun. 2020;5(1):34-51. Published 2020 Feb 26. doi:10.20411/pai.v5i1.349 Heubner RE, Schein MF, Bass JB Jr. Clin. Infect. Dis. 1993; 17: 968-75. Ponce de León D, Acevedo-Vásquez E, Sánchez-Torres A et al. Ann. Rheum. Dis. 2005; 64: 1360-1. Camlar SA, Makay B, Appak O et al. Clin. Rheumatol. 2011; 30: 1189-93.***

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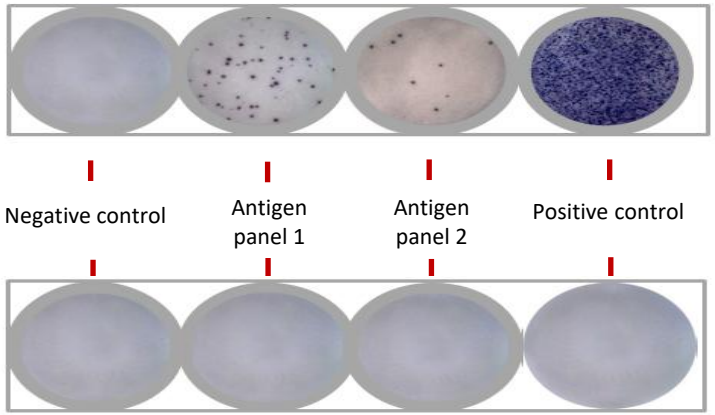
# Diagnostic performance of the ELISPOT platform for the diagnosis of tuberculosis infection (TigraTest.TV, Russia)

ELISPOT - determination of the number of activated interferon-gamma-secreting T lymphocytes in response to stimulation with specific Mycobacterium tuberculosis ESAT-6 and CFP-10 antigens. Each spot (dot) indicates one activated T cell.



- The specificity of TigerTest.TV was 97.6% (95% CI 95.25-99.95%)
- Analytical specificity - 100%
- The sensitivity of TigerTest.TV was 97.4% (95% CI 93.8-100%)
- Analytical sensitivity - 100%

- The result is independent of the level of immunosuppression[1-3]
- The result is not affected by the presence of BCG vaccination

*(ESAT-6 AND CFP-10 are absent in all BCG strains and most non-tuberculous mycobacteria)*

- One visit test (result after 24 hours)

**Indications**

- for *in vitro* diagnosis of the presence of tuberculosis infection, **including**
- **for screening among persons at high risk of developing tuberculosis infection**;
- Differential diagnosis of tuberculosis infection from postvaccine allergy due to BCG (*Mycobacterium bovis BCG*) vaccination.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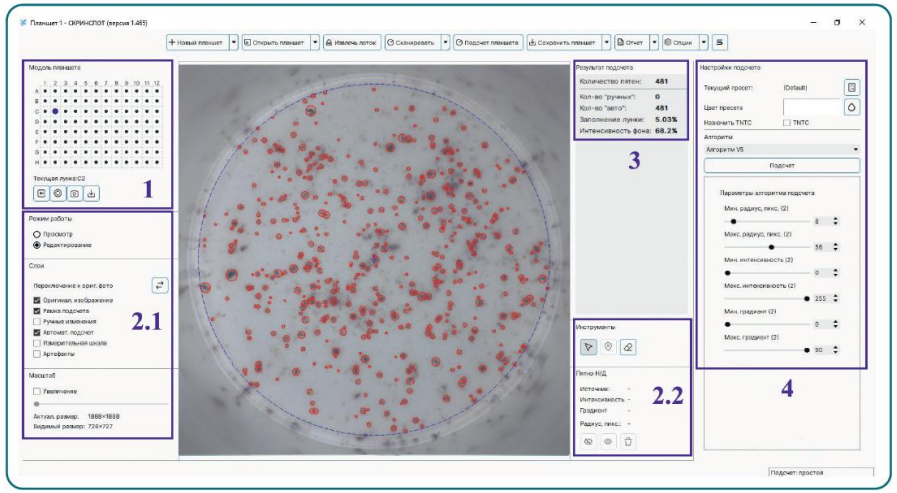
# **SCRINSPOT -** microplate analyser for reading test results based on the immunoenzyme stain method (ELISPOT)




| | |
|---|---|
| Maximum analysis time (96 wells) | 3 min. |
| Maximum time for setting the operating mode | 1 min. |
| Continuous operation time, max. | 8 hours |
| Maximum volume of saved analysis result data<br>one 96-well microplate | 500 Mb |

- The use of the analyser "SCRINSPOT" allows to increase accuracy and objectivity of the test results in comparison with manual counting with the help of usb-loupe.
- The instrument allows digital images of microplates to be captured and then analysed in detail.
- Accelerates data processing and reduces the possibility of human error (one-step evaluation

# Regulatory framework and algorithm for detection of tuberculosis infection in Russia

Order of the Ministry of Health of the Russian Federation No. 951 of 29.12.2014 "On approval of methodological recommendations on improving the diagnosis and treatment of respiratory tuberculosis", 2014

Clinical Guidelines "Latent tuberculosis infection (LTI) in children", 2016

Order of the Ministry of Health of the Russian Federation No. 124n of 21.03.2017 "On the Approval of the Procedure and timelines for preventive examinations of citizens for the detection of tuberculosis".

Clinical Guidelines "Tuberculosis in children", Moscow, 2022

Clinical Guidelines "Tuberculosis in adults", Moscow, 2022

**Children under 7 years of age**

Mantoux screening

↓

altered sensitivity to tuberculin

↓

**Diaskintest test**

↓

**determining the management of the child**

**Children 8 years and older**

**Screening with the Diaskintest test**

↓

**determining the management of the child**

**Adults**

Fluorography

↓

suspected TB

↓

**clinical minimum TB *screening** and Diaskintest/ IGRA test**

* Clinical minimum TB screening - blood, urine, chest radiological examination, sputum examination for MBT TB - tuberculosis, MBT - Mycobacterium tuberculosis

# THANK YOU!
# СПАСИБО!

World Health Organization
European Region

Unitaid
SAVE LIVES FASTER

KNCV TB PLUS

MEDECINS SANS FRONTIERES