Meeting Protocol of the "Eurasian Community for Access to Treatment" with "Molbio"

September 28, 2023

Representatives of the organization:
Sumit Mitra - President – Global Sales and Marketing
Mani Subramani – Consultant and European Lead

Meeting commencement. Introduction of participants.

Molbio is a wholly Indian company. Our headquarters and manufacturing are located in Goa, with the research and development department situated in Bangalore. Truenat is the world's first molecular diagnostic platform designed for point-of-care use.

ABOUT US

Molbio Diagnostics, an innovative Indian In-Vitro Diagnostics (IVD) company, aims to decentralize and democratize access to high quality diagnostics across the world through novel, near patient and point-of-care solutions.

Truenat® from Molbio is the **world's first Point of Care (PoC) molecular diagnostics platform,** using PCR technology that can diagnose 30 diseases currently (with additional 30+ diseases in pipeline).

Two decades of R&D, working with healthcare institutions globally e.g. CSIR, ICMR, BIRAC, Grand Challenges Canada, BMGF, FIND to miniaturize the PCR technology, with patents approved/applied in 100+ countries.

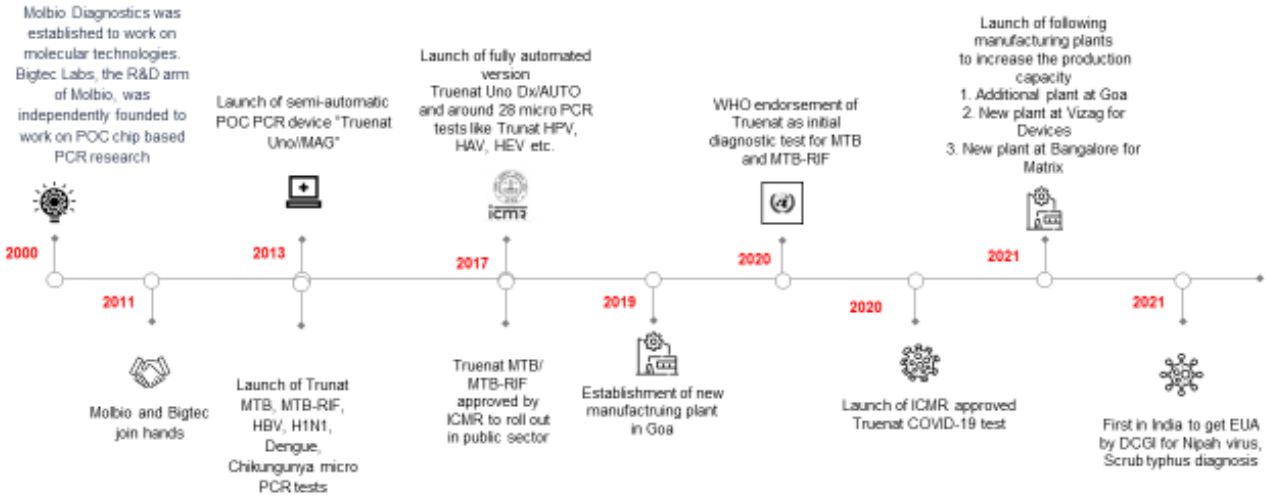
Real POC RT-PCR

For Resource Limited settings

- Fully Automated Prep and PCR
- Rapid-60 minutes
- Portable
- Battery operated
- Room temperature stable reagents
- Laboratory independent
- In built display and memory
- Wireless Data Transfer
- Affordable

Molbio entered the market in 2013 and has been operating for ten years.

EVOLUTION OF MOLBIO AND THE INNOVATIVE TRUENAT PLATFORM

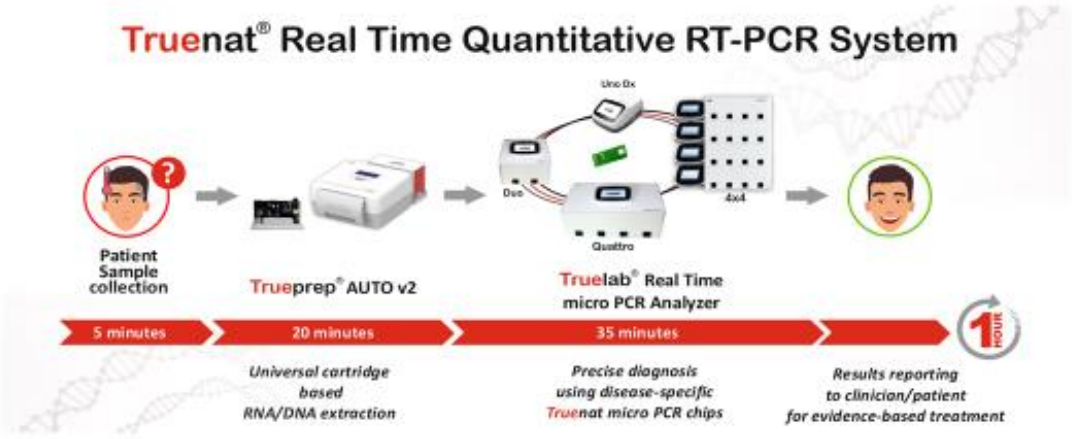


The Truenat system is innovative and unique. It is a small, lightweight device powered by a battery, allowing it to operate anywhere for an extended period. Truenat can perform tests for various diseases, including tuberculosis, with results available within an hour.

Question: How long does the GeneXpert test take?

Answer: 1 hour and 54 minutes. However, it's important to note that this time includes testing for rifampicin resistance.

MOLBIO: India's largest medical equipment & diagnostic company



World's first Point of Care PCR diagnostic equipment, capable of facilitating decentralized diagnostics, revolutionizing the way healthcare is delivered.

There are both large and small devices, and they can fit into a briefcase.

World's first commercial PoC MDx platform
implementing PCR technology for decentralising molecular diagnostics

The slide below illustrates how these devices operate directly at the point of care. Our testing stations have been set up in numerous international airports. The device simply sits in the room, and additional laboratory facilities are not required.

The slide below demonstrates that the Truenat system is a comprehensive solution that does not require additional components.

PRODUCTS

The Truelab® Real Time Quantitative micro PCR Workstation

Trueprep® AUTO v2

Cartridge Stand

Truepet® 6 µl micropipette

Microtube Stand

Pipette Stand

Truelab® micro PCR printer

The slide below showcases various international organizations we collaborate with, including WHO, FIND, and the Bill and Melinda Gates Foundation. Our testing system is WHO-approved, and soon other products from our company are expected to receive WHO approval as well.

Proven technological expertise - endorsed by leading national & international bodies

Currently, we have three long-term agreements in place. The first is with the United Nations, the second with the STOP-TB Partnership, and the third with the Global Fund. We have three products that we are implementing through these partnerships, with the goal of ensuring global access.

GLOBAL PARTNERSHIPS

Molbio continues to focus on partnering with reputed global health bodies like

- ✓ WHO (World Health Organization)
- ✓ BMGF (Bill & Melinda Gates Foundation)
- ✓ USAID (United States Agency for International Development)
- ✓ Stop TB Partnership
- ✓ United Nations

for supply of test kits and devices for diagnosis of diseases with focus on Low and Middle Income Countries and cater to Sustainable Development Goals for eradicating various diseases like TB, Hepatitis, Malaria, Cholera etc.

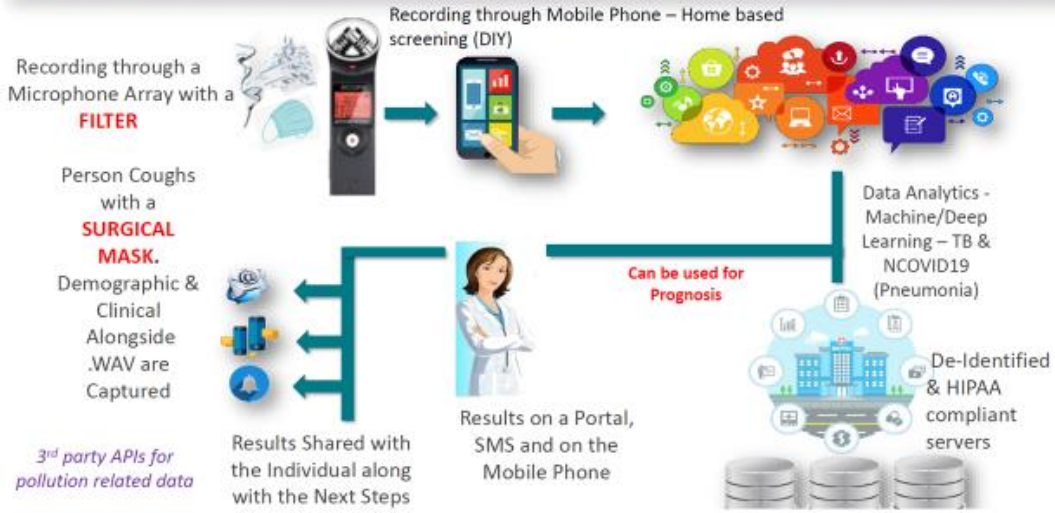
The MTB, MTB Plus, and MTB RIF DX test systems have already received WHO approval. Tests for resistance to isoniazid (INH), fluoroquinolones (FQ), and bedaquiline (BDQ) are at various stages of approval. The INH resistance test (MTB-INH) is already available on the Indian market and is expected to enter the global market. We plan to present final data for WHO evaluation soon. FQ and BDQ tests are currently unavailable, and research is ongoing. Due to their significant clinical importance, these products are being validated in several European laboratories, among other locations.

Molbio has more than 36 test systems for detecting various diseases, and an additional 32 will be available early next year. We plan to add tests for 10–12 diseases annually on the same platform.

Cepheid is a reputable company; they entered the Indian market six years before us, in 2007, and have done commendable work. However, Cepheid currently has 1700 devices in India, while we have 6000. We do not position ourselves as a cheaper alternative to Cepheid and do not consider ourselves Cepheid's primary competitors. Our context is different – we focus on small, mobile stations closer to the end user, and in this niche, we are the leaders.

Solution Workflow

Docturnal



PRODUCTS

molbio

Truenat® Real Time micro PCR Chips

PRODUCTS AVAILABLE

- MTB Screening CE
- MTB-RIF CE
- HBV with VL
- HIV-1 with EID+VL
- HCV with VL
- H1N1 CE
- Dengue CE
- HAV CE
- SARS CoV-2 CE
- Nipah CE
- Chikungunya CE
- Dengue/Chikungunya CE
- Malaria Pf CE
- Malaria Pv/Pf CE
- Salmonella CE
- Chlamydia
- HLA-B27 CE
- HEV CE
- COVID-19 CE
- Scrub Typhus CE
- Gonorrhea CE
- Chlamydia/Gonorrhea
- Trichomonas CE
- Rabies CE
- HPV-HR CE
- Influenza A/B CE
- GBS CE
- Beta CoV CE
- Leptospira CE

PRODUCTS COMING SOON

- SA/MRSA
- H3N2/H1N1
- ZIKA
- Staphylococcus aureus (SA)
- MTB/NTM
- MTB-INH
- Neisseria meningitidis (Nm)
- SA/PA
- Hemophillus influenzae B (HIB)
- Shigella
- Leishmania
- MTB-FQ
- Pseudomonas aeruginosa (PA)
- Streptococcus pneumoniae (SP)
- Sickle Cell Anemia screening
- Kysanur Forest Disease (KFD)

PRODUCTS PIPELINE

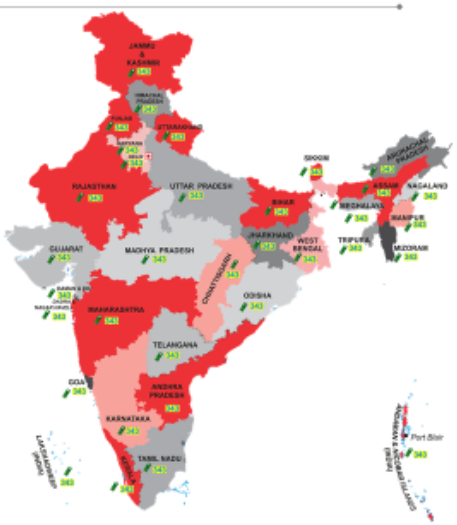
- Klebsiella
- HIV-2
- CMV
- EBV
- HSV (1/2)
- HHV-6 (A/B)
- Yellow fever virus
- Measles
- BCR-ABL for Chronic Myeloid Leukemia
- Rubella
- Rubeola
- Rubula
- H5N1
- Japanese encephalitis virus (JEV)
- Cholera
- Clostridium difficile
- Bordetella pertussis
- Toxoplasma gondii
- Rotavirus
- Syphilis
- Mumps
- MERS (Middle East Respiratory Syndrome)
- Mycoplasma

A GROWING MENU.....

For more information visit : https://www.molbiodiagnostics.com/

MOLBIO'S NATIONAL REACH

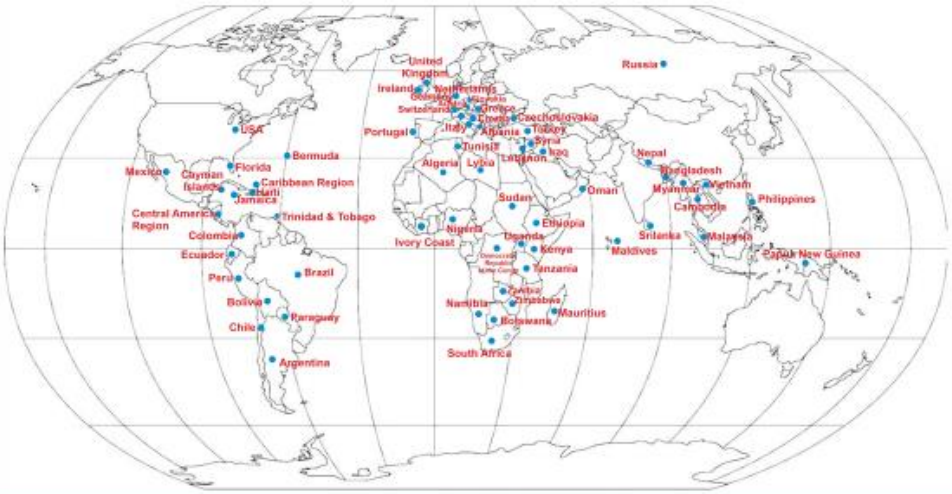
molbio



Extensive installation of Truenat Devices across India ...

- Since commercialization, Molbio has installed **6000+** Truenat devices across India
- Provided rapid molecular testing in **underserved areas and in emergency departments** of health-care facilities in India

MOLBIO'S INTERNATIONAL REACH



PROVEN DEPLOYABLE AT VARIOUS SETTINGS DURING THE PANDEMIC

COVID -19 Testing Centre at Goa International Airport

COVID -19 Testing Centre at Chandigarh International Airport

COVID - 19 Testing Centre at Colombo International Airport Sri Lanka

PHCs and CHCS

HOSPITAL EMERGENCY WARDS, ICU/CCU, OPERATION THEATRES, MATERNITY UNITS, PORTS OF ENTRY/EXIT, WORKPLACES, PUBLIC GATHERINGS, HOTELS & RESORTS

The slide below features products registered under Regulation IVDD 98/79/EC.

MOLBIO PRODUCTS REGISTERED UNDER IVDD 98/79/EC

Truenat®

1. Truenat® Chikungunya
2. Truenat® Nipah
3. Truenat® Dengue
4. Truenat® Scrub T
5. Truenat® H1N1
6. Truenat® HAV
7. Truenat® Malaria Pf
8. Truenat® HEV
9. Truenat® MTB
10. Truenat® Trich
11. Truenat® MTB-RIF Dx
12. Truenat® Beta CoV
13. Truenat® Dengue/Chikungunya
14. Truenat® Rabies
15. Truenat® Influenza A/B
16. Truenat® Salmonella
17. Truenat® LTS
18. Truenat® HLA-B27
19. Truenat® GBS
20. Truenat® Malaria Pv/Pf
21. Truenat® NG
22. Truenat® COVID-19
23. Truenat® MTB Plus
24. Truenat® SARS CoV-2
25. Truenat® HPV- *HR*

Truenat® Positive Control Kits

1. Truenat® Positive Control Kit - Panel I
2. Truenat® Positive Control Kit - Panel II
3. Truenat® Positive Control Kit - Panel III
4. Truenat® Positive Control Kit - Panel IV
5. Truenat® Positive Control Kit - Panel V

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The next slide provides the status of applications under Regulation IVDR, to which all companies are expected to transition by 2027. The transition is lengthy and challenging due to a shortage of experts.

IVDR APPLICATION STATUS

Product Name	Application Form Submission	Appendix A/B/C Status	Technical Documentation Preparation/Submission	Remark
Truenat® CT/NG	06/03/2023	Submitted	Inprocess	Technical dossier preparation is under process
Truenat®MTB-INH	06/03/2023	Submitted	Inprocess	Technical dossier preparation is under process
Truenat® HCV	06/03/2023	Submitted	Submitted	NA
Truelab® Uno Dx	NA	NA	Submitted	Review comments received

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ERPD[1]The following slide illustrates the status of WHO prequalification, Emergency Use Authorizations, and ERPD assessments.

[1] https://extranet.who.int/prequal/vitro-diagnostics/expert-review-panel-diagnostics

WHO APPLICATION STATUS

Name Of The Product	Type Of ApplicationPre Q/ EUL/ ERPD	Application Form Submission	Presubmission Call Held On	Allotment Of Number	Letter Of Agreement (LOA) With WHO	Technical Dossier Submission	Desk Assessment
Truenat®COVID-19	EUL	16/09/2022	14/09/2022	EUL 0713-240-00	20/09/2022	16/10/2022	In Process
Truenat®HCV	PreQ	09/12/2022	08/12/2022	PQDx 09329-240-00	12/01/2023	13/02/2023	In Process
Truenat®HPV-*HR*	PreQ	09/12/2022	08/12/2022	PQDx 0708-240-00	-	-	-
Truenat®MTB	PreQ	31/03/2023	08/05/2023	PQDx 10311-240-00	-	-	-
Truenat®MTB Plus	PreQ	31/03/2023	08/05/2023	PQDx 10312-240-00	-	-	-
Truenat®MTB-RIF Dx	PreQ	31/03/2023	08/05/2023	PQDx 10313-240-00	-	-	-
Truenat®MTB-INH	ERPD	-	-	-	-	13/05/2023	-
Truenat®HCV	ERPD	-	-	-	-	13/05/2023	-

The next slide provides a list of countries where the registration process is currently underway.

The following slide lists the countries where the registration process has already been completed.

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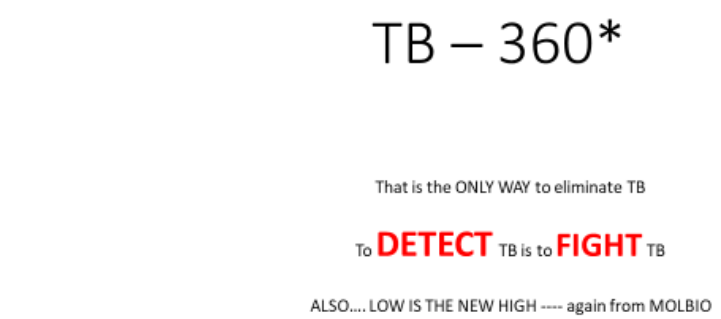
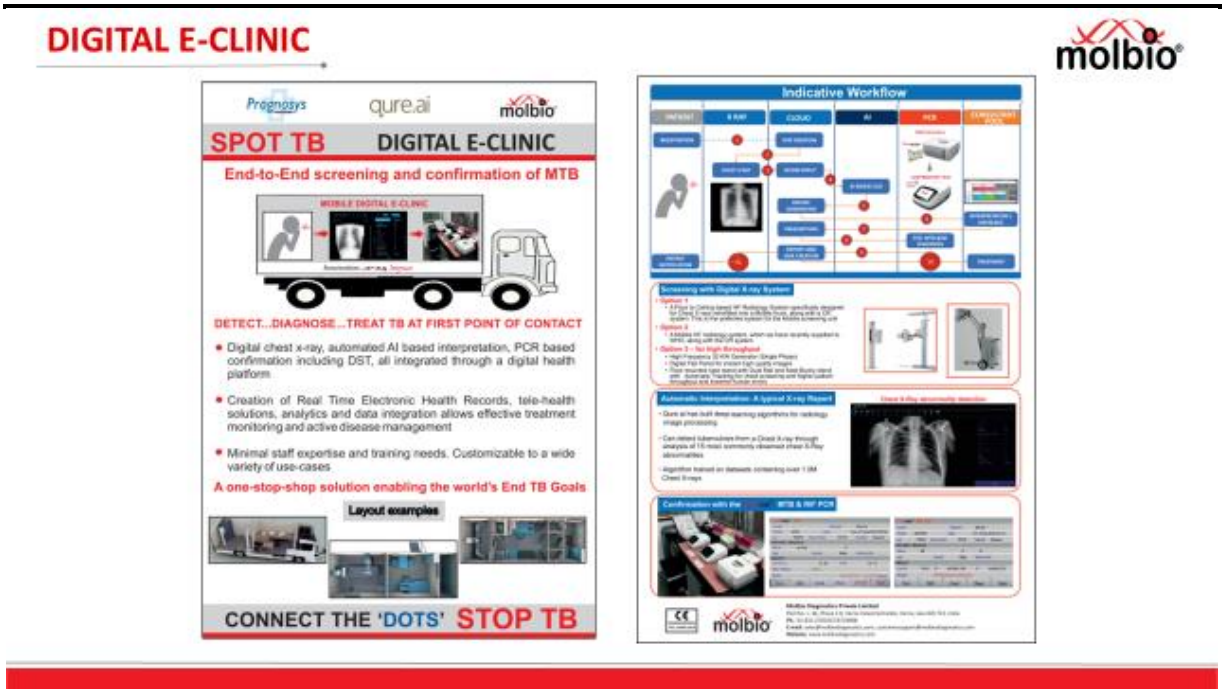
As it is known, achieving the elimination of tuberculosis requires the detection of not only symptomatic but also asymptomatic tuberculosis. We refer to this strategy as "Tuberculosis 360*," and within its framework, we propose several solutions.



The first solution is mobile testing stations, which can be either large or small vehicles, as seen in Cameroon. The key is to reach the end consumer. The slide below presents a compact version. These machines have already been purchased with USAID funding and are in use in Kenya and Congo.

The next solution involves cough signature analysis using a microphone with a sponge. A person coughs into the microphone, and artificial intelligence recognizes respiratory diseases based on the unique cough signature. This is not limited to tuberculosis but includes all respiratory diseases, including COVID-19. The system fits into a small cabin that can be easily installed in various gathering places. The analysis takes 80 seconds.



Question: How much does the device cost? How often is the sponge changed and by whom?

Answer: The sponge is changed after each testing, and it can be purchased anywhere at a very low cost. The diagnostic accuracy is high because the analysis is based on a library containing millions of cough signatures.

Question: Are you aware that there are other Indian companies doing the same?

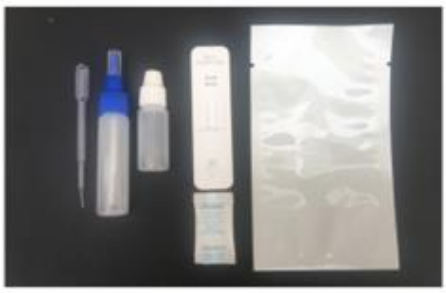
Answer: Yes, we collaborate with the Indian company DOCTURNAL (Timbre system Timbre[2]).

Another diagnostic method is a serological test. This method was developed by an Indian scientist working in New York. The method is based on detecting specific peptides that appear in the body only if a person has come into contact with mycobacteria. The test takes 15 minutes.

In each country where we operate (currently in more than 45 countries), we initially conduct training for operators and healthcare professionals. We do not sign contracts until training is completed.

[2] https://docturnal.com/timbre/ (video)

The POC TB Triage Test Kit to Detect Abs to *M. tb* specific peptides



Result	Interpretation	Outcome
Control Line Dark	Negative, Test Working Properly	Negative
Only Test Line Dark	Failed Test, No control line	Failure
Both Test/Control Dark	Positive	Positive
No Lines	Failed Test	Failure

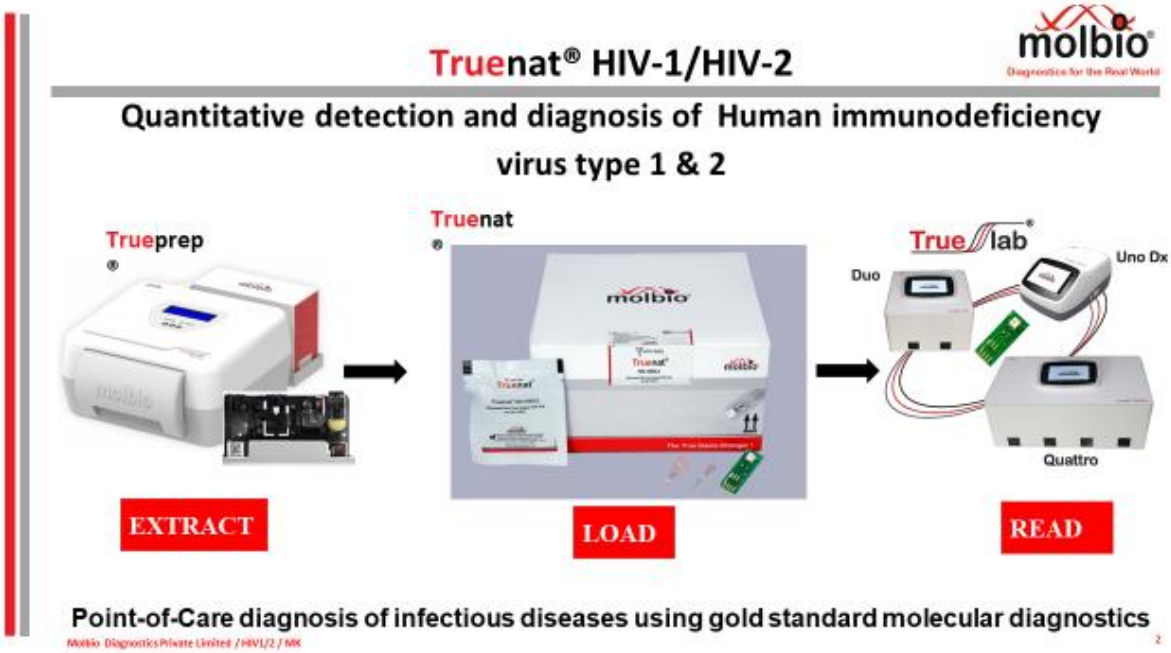
Molbio has a platform for testing HIV (HIV-1, HIV-2), viral hepatitis, papillomavirus, and other infectious diseases. The algorithm is very simple: the sample is loaded into the platform, and the result appears. Serum, whole blood, and plasma can be used. For viral load tests, plasma is the preferred choice.

Truenat® HIV-1/HIV-2

molbio
Diagnostics for the Real World

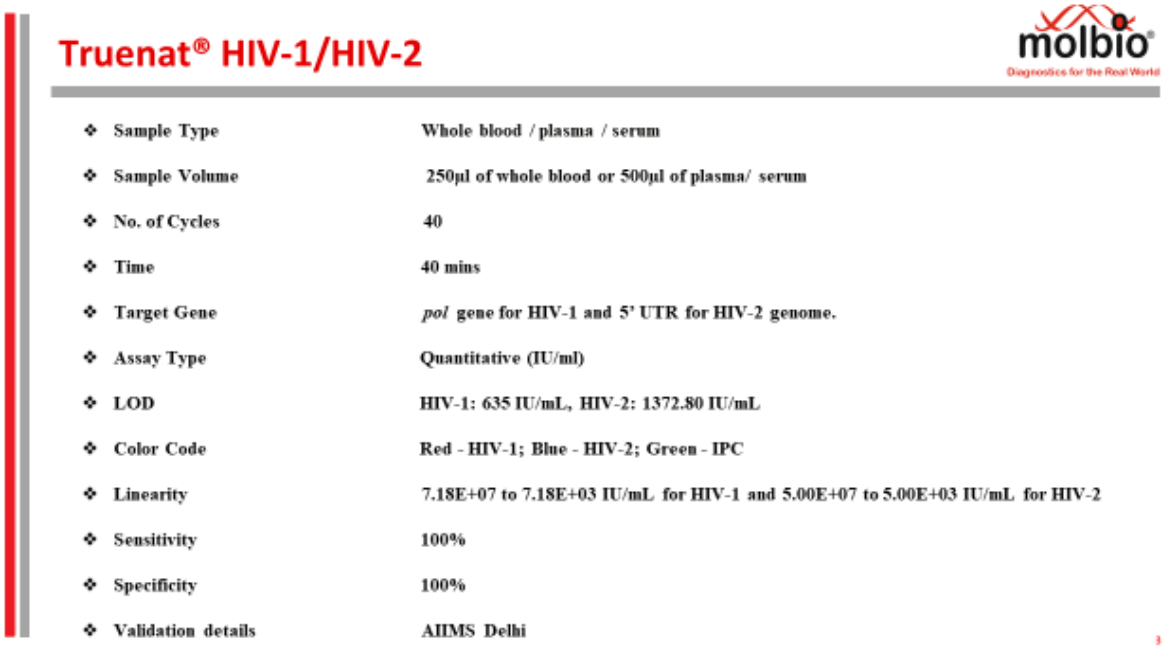
Point-of-Care diagnosis of infectious diseases using gold standard molecular diagnostics..

Truenat® HIV-1/HIV-2 (REF 601540005 / 601540020 / 601540025 / 601540050 /601540100 / 601540200) is a Chip-based Real Time Reverse Transcription Polymerase Chain Reaction (RT-PCR) test for the **quantitative detection** and differential diagnosis of infection with human immunodeficiency virus type 1 & 2 (HIV-1 & 2) in whole blood / plasma / serum and aids in the monitoring of the HIV-1 & 2 viral loads in patients with HIV-1 and/or HIV-2 infection.



Comment from a representative of the patient community: In whole blood, the virus is still inside cells in the form of proviral DNA, which can falsely increase the viral load result. Plasma, being devoid of cells, provides a result based solely on the volume of pure blood, making it more accurate.

Continuation of the response: Since we diagnose various diseases, samples can vary: plasma, blood, saliva—basically anything that can be sampled. The gold standard for HIV and hepatitis is 250 microliters of whole blood or 500 microliters of plasma/serum. The limit of detection is the minimum amount of international units per milliliter. International units are copies that allow the determination of the presence or absence of any pathogen.



The first process is extraction, taking approximately 20 minutes. The testing process itself takes 40 minutes. HIV-1 and HIV-2 follow separate channels, are compared, and the virus type is determined. It is also possible to conduct tests specifically for HIV-1 and HIV-2 separately.

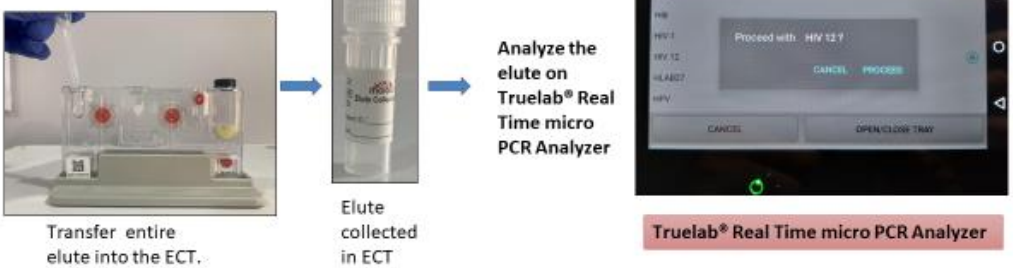
Extraction With Trueprep® AUTO v2

Blood Sample

Transfer 250µl of the contents of the culture tube into Lysis buffer

Transfer the entire content of the Lysis buffer into sample chamber of the cartridge using a 3ml transfer pipette.

Nucleic acid extraction ~20 minutes



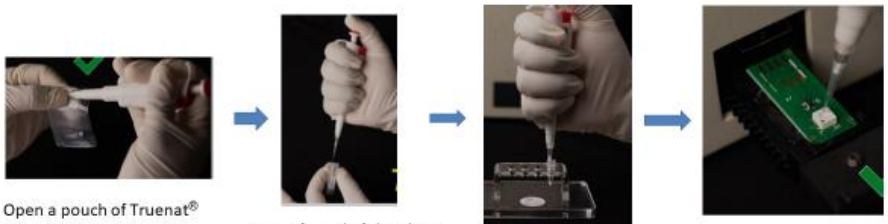
Transfer entire elute into the ECT.

Elute collected in ECT

Analyze the elute on Truelab® Real Time micro PCR Analyzer

Truelab® Real Time micro PCR Analyzer

TEST PROCEDURE



Open a pouch of Truenat® HIV-1/HIV-2 and retrieve the micro PCR chip, microtube and DNase & RNase free pipette tip

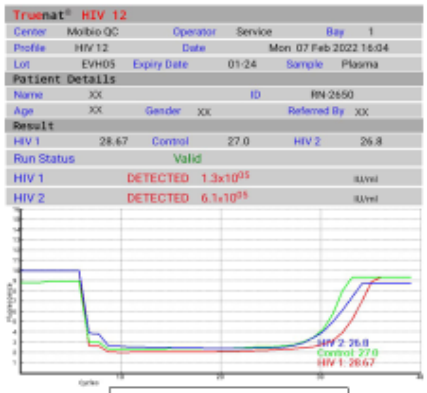
Transfer 6ul of the elute into the mastermix tube

Dispense the elute over the dried down mastermix

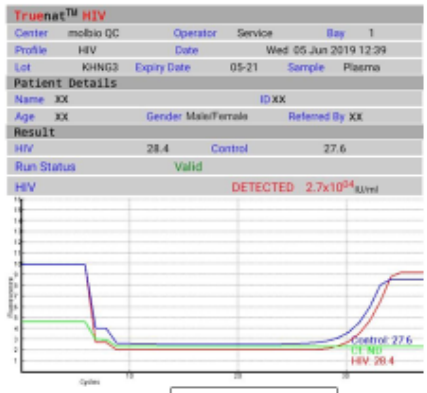
Transfer the clear solution from the mastermix tube to the white reaction well of the Truenat® chip.

Test duration (35 minutes)

Result Interpretation



Truenat® HIV-1/HIV-2

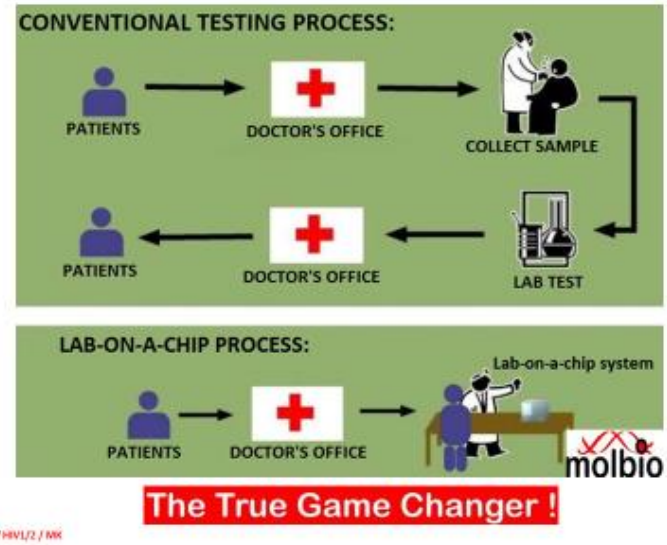


Truenat® HIV-1

At the end of the test run: Result: **"DETECTED" or "NOT DETECTED"**
Based on detection of the internal positive control (IPC), validity of test run is displayed as Run status: Valid or Invalid.

Molbio Diagnostics Private Limited / HIV1/2 / MK

RAPID RESULTS



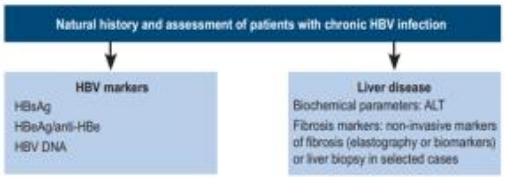
Molbio Diagnostics Private Limited / HIV1/2 / MK

The slide below provides information on Hepatitis B. The cartridges for all diseases are the same. A special small interchangeable thermocycler is used for the PCR reaction. This technology is patented. Similar to the HIV test, it takes 40 minutes for detection. Whole blood, plasma, and serum can be used. The limit of detection (LoD) is 55 international units per milliliter.

Interpretation of Serological markers

HBsAg	HBcAb	HbsAb	HBeAg	HBeAb	Interpretation
+	IgM	-	+	-	Acute Infection, high infectivity.
+	IgG	-	+	-	Chronic Infection, high infectivity.
+	IgG	-	-	+	Late acute or chronic hepatitis B, low infectivity (Resolving state).
-	IgG	+	-	+/-	Recovery (Past Infection).
-	IgM	-	-/+	-/+	Acute Infection Window Period

EASL 2017 Clinical Practice Guidelines on the management of Hepatitis B virus infection



	HBeAg positive		HBeAg negative	
	Chronic infection	Chronic hepatitis	Chronic infection	Chronic hepatitis
HBsAg	High	High/intermediate	Low	Intermediate
HBeAg	Positive	Positive	Negative	Negative
HBV DNA	>10^7 IU/ml	10^4-10^7 IU/ml	<2,000 IU/ml*	>2,000 IU/ml
ALT	Normal	Elevated	Normal	Elevated*
Liver disease	None/minimal	Moderate/severe	None	Moderate/severe
Old terminology	Immune tolerant	Immune reactive HBeAg positive	Inactive carrier	HBeAg negative chronic hepatitis

*Persistently or intermittently.

- HBV DNA levels can be between 2,000 and 20,000 IU/ml in some patients without signs of chronic hepatitis

Journal of Hepatology 2017 vol. 67:370–398

NOTE - The window period is typically associated with the acute phase of hepatitis B virus (HBV) infection. During this phase, the virus has entered the body, but standard blood tests may not yet detect it because the levels of HBV antigens and antibodies are not high enough. This can make it challenging to diagnose HBV during the window period.

Limitations

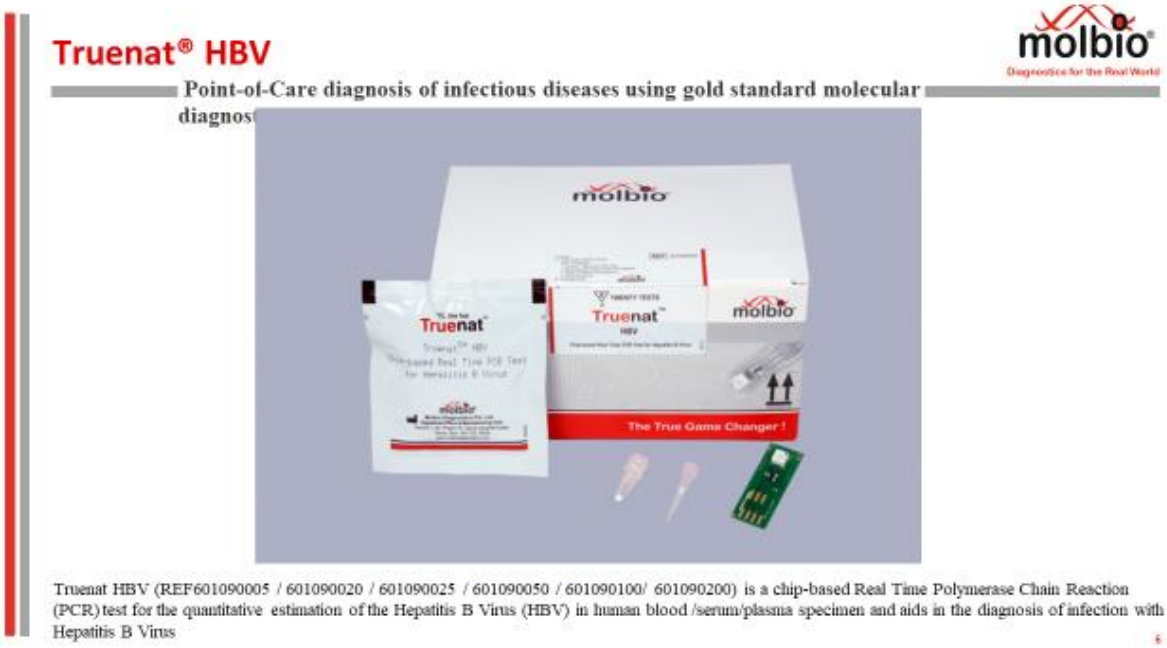
- **HBV: Difficult to grow in Cell culture**
- **ELISA:** 2-4 hours & **cross reactivity** of antibodies- false-positive reaction
  - Antibody response is late in human body i.e. **4 week later**
  - Serology based techniques have **limitations of sensitivity.**
  - Serology based tests are **qualitative**
  - Colorimetric detection
  - Cannot detect very small amount of Ag
  - **Less specific & sensitive**
- **ELISA:** Specificity varies by target; over all very good, but not great specificity
- Dipstick & RDT cannot detect extremely small amount of antigen

NOTE: Loss of HBsAg & HBeAg doesn't confirm loss of VIRUS but only RT-PCR can indicate loss of VIRUS (HBV DNA)

Molecular Method

- HBV DNA is a quantitative virological marker that reflects the level of HBV replication.
- This method has been shown to be clinically useful for assessing, managing, and treating patients with chronic HBV infection.
- It is detectable in the early stage of infection (1 month after HBV infection), increases to a peaklevel approximately 3 months after HBV exposure, then gradually declines in chronic infection or disappears during HBV recovery.
- HBV DNA viral load in serum reflects the degree of viral replication in the liver and thus facilitates in monitoring the progress of patients with chronic hepatitis receiving antiviral therapy.

Comment from a representative of the patient community: The PCR reaction consists of three stages. The first stage is the extraction of nucleic acid, the second stage involves amplifying a small piece of nucleic acid into a larger quantity that can be subsequently identified, and the third stage is the detection. The small chip on the slide is the thermocycler, where the amplification of nucleic acid takes place. Typically, this process occurs in a large box.



Question: Do we understand correctly that there is a higher risk of contamination with a larger thermocycler? If the cleaning was done poorly, could the result be distorted upon subsequent use?

Answer: Firstly, a larger thermocycler requires more energy, whereas ours operates on lithium batteries. The design of our chip practically eliminates contamination. The white part is a biological port, and the green part is electronics. The white part glows and is covered with a polymer that allows light to pass through completely. The polymer has two functions, which are important considering that only 6 microliters are used (micro-PCR technology), and considering the "hot start" technology (the temperature instantly rises to 94 degrees Celsius). The first function is that the polymer starts melting at 56 degrees, pulling the sample underneath itself to prevent evaporation. The second function is also protective. After 35-40 cycles, let's say the test shows a positive result based on billions of generated amplicons. After this, the polymer solidifies, forming protection for the amplicons. Then it is pulled out and placed in a solution. It can be spoiled only if extracted and, for example, poked with a pencil or pen.

Comment from a representative of the patient community: The amplification process involves heating and cooling. New copies are formed with each cycle, and many cycles need to be performed. This polymer allows this process to be conducted rapidly.

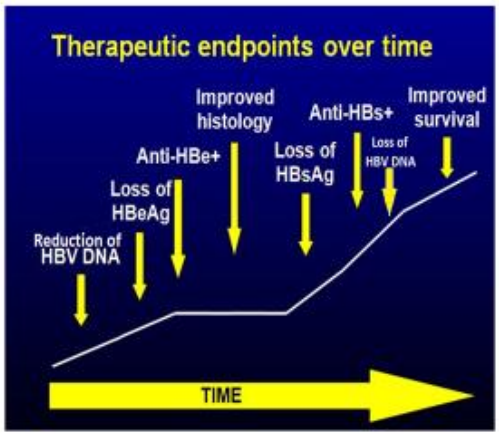
Truenat® HBV

Sample Type	Blood/Serum/ Plasma
Sample Volume	250µl of whole blood or 500µl of plasma/serum
No. of Cycles	40
Time	40 mins
Target Gene	Core/pre-core region of HBV genome.
Assay Type	Quantitative
LOD	55.92 IU/ml
Color Code	Red - Internal Positive Control, Blue - Target, Green - NA
Linearity	5.09E+09 Copies/mL to 5.09E+02 Copies/mL
Sensitivity	100%
Specificity	100%
Validation details	AIIMS, Delhi
Positive Control	II

MISDIAGNOSIS

- Misdiagnosis often leads to the unnecessary prescription of medications
  - side effects
  - costly
- People who have the hepatitis B virus **may infect others without knowing it**
- **Delay treatment of Acute HBV infection → Chronic infection**
- **Further complications like liver cirrhosis, failure and cancer**
- **Perinatal Infected child will become carrier if not treated at right time.**

Endpoints of therapy



Recommendations

- The induction of long-term suppression of HBV DNA levels represents the main endpoint of all current treatment strategies (Evidence level I, grade of recommendation 1).
- The induction of HBeAg loss, with or without anti-HBe seroconversion, in HBeAg-positive CHB patients is a valuable endpoint, as it often represents a partial immune control of the chronic HBV infection (Evidence level II-1, grade of recommendation 1).
- A biochemical response defined as ALT normalisation should be considered as an additional endpoint, which is achieved in most patients with long-term suppression of HBV replication (Evidence level II-1, grade of recommendation 1).
- HBsAg loss, with or without anti-HBs seroconversion, is an optimal endpoint, as it indicates profound suppression of HBV replication and viral protein expression (Evidence level II-1, grade of recommendation 1).

WHY CORRECT EARLY DIAGNOSIS REQUIRED?

- Early diagnosis helps in **prompt and correct treatment** in acute infection
- Early treatment prevent **Acute HBV infection** → **Chronic infection**
- **Prevent complications** viz. liver failure, cirrhosis and cancer
- Half of all people with chronic Hepatitis B **show no symptoms**
- People who have the Hepatitis B virus **may infect others without knowing it**
- People often find out they have the hepatitis B virus when it's usually too late i.e. **extensive liver damage has been done or cancer in third stage**
- **There is no cure in chronic stage**, but there are effective treatments available that can improve life

Question: We are glad that Cepheid has a competitor now, although you don't position yourself as a competitor to Cepheid. Some of our colleagues are already suggesting including Truenat in Global Fund applications, and the Global Fund is not against it. At the same time, Cepheid has built a system of service, support, and deliveries over many years. What is your price for one test for rifampicin resistance? How does it compare to the price of Cepheid? To compete with GeneXpert in our region, an attractive price for equipment needs to be offered. To work on your equipment, all healthcare workers in the country need to be retrained. What will your company do in this regard? It would be preferable for the training to be done at your expense, as it is a marketing promotion of the product.

Answer: Our presence at this meeting should be an indicator for you that we are very serious about working in the SEAR region. As our Prime Minister says: one land, one world, one heart—and we add "one health." Regarding training, as already mentioned, we do not sign agreements for product supply until we train a specific number of personnel at our facilities in India over a period of 10 to 12 days. Our team consists of individuals from a scientific

background who are highly committed to their work. We collaborate with national tuberculosis programs, universities, and the scientific community, explaining our technologies to them in simple terms.

When comparing with Cepheid, I always have a smile on my face. We don't aim to compete with Cepheid because we have a different model. Cepheid is a big, good company, but it is founded by people in the USA. Most likely, these people have not faced real-life situations that we encounter in India, you in the SEAR, our brothers in Africa, Asia, etc. It took us 12 years of hard research to achieve what we have. The Truenat project started in 2000, and we entered the market in 2013. We are not trying to replace Cepheid. In India and other countries, there are many service points with large 16-module Cepheid machines. However, very often, Truenat machines are placed next to them.

Regarding the price, all necessary information is in the Global Fund/USAID brochure. You may have read Cepheid's press release about reducing prices, but it took them 12 years, more than 35,000 machines worldwide, almost a billion tests. Only in 2022, during the Covid-19 pandemic, did the Global Fund purchase 20 million TB tests from Cepheid; this is public information. With such volumes, it's time to lower the price. We signed the first long-term agreement with the UN in 2018, in 2019—a long-term agreement with the STOP-TB Partnership. In 2020, we started the iNTP project, sponsored by USAID, aimed at implementing innovative technologies. Nine countries, 300 machines, about a million tests. Then the Global Fund requests a price reduction, even though not even two years have passed. We reduced the price by 20%. The catalog contains the new, reduced price. We do not align with Cepheid's strategy; we have our own strategy. We are grateful to you and people like you who achieve access.

Question: Please share the price for the test for rifampicin resistance. For Kyrgyzstan, an attractive price is of great importance. Cepheid is an American company with strong lobbying, but India can gain an advantage through pricing, as was the case with ARV drugs.

Answer: All prices are listed in the brochure, including separate prices for testing and services. Even with the latest price reduction from Cepheid, our price is still 7 cents cheaper.

Comment from a representative of the patient community: This is still insufficient; it would be preferable to have 70 cents or a dollar.iNTP[3],
Answer: All prices are listed in the brochure, including separate prices for testing and services. Even with the latest price reduction from Cepheid, our price is still 7 cents cheaper.

Comment from a representative of the patient community: This is still insufficient; it would be preferable to have 70 cents or a dollar.

Answer: This is a very important point. Why were there so few demands for a price reduction from Cepheid over the last 10 years? They are reducing the price now because there is a risk of losing market share. Another question is why, with such volumes of machine and test deliveries, the burden of tuberculosis has not decreased? Six to eight years ago, XDR-TB and MDR-TB were not widespread. Thirty-three percent of all people with tuberculosis live in India. According to our estimates, for every identified TB case in a laboratory with Cepheid equipment, there are approximately five missed cases. This happens because the primary test

[3] https://www.stoptb.org/sites/default/files/intp_overview_sep_2022.pdf

for TB worldwide is still the sputum test. When the World Health Organization stated the need to use another molecular test as the primary test (in smear microscopy centres), it was Molbio that responded to this request. The reason why, in our view, Cepheid's products have not had the necessary impact is their product being a central laboratory model and not a product that can be taken to the last mile.

Question: It would be interesting to learn more details about the agreement with the Global Fund for the implementation of portable PCR analyzers for the diagnosis of rifampicin and isoniazid resistance. Has the agreement been signed? What are the implementation timelines?

Answer: As mentioned earlier, it involves 9 countries, 300 machines, approximately a million tests. Detailed information is available in the brochure. We have had global-level meetings with Mark Edington. If your country is interested in purchasing Truenat, write to Mark Edington, copying us. He can assist.

Question: What registration challenges do you observe in the SEAR region, including in the EAEU countries?
Answer: In Europe, we did not encounter registration issues due to a unified regulatory system. The first agreement in the SEAR region was signed in Belarus with IVD Group, and we are willing to share contacts. We have engaged with regulators in most countries in the region, and according to their feedback, the registration process typically takes up to three months. The key requirement for equipment is compliance with CE marking (European Union), which is not a problem for us.

Question: In Russia, there is the "third extra" rule, and almost all Indian manufacturers have been pushed out of the drug market. A similar situation is now unfolding in the diagnostic field. Have you studied the Russian market and the entry mechanisms?

Answer: [Not included in the protocol at the company's request].

Question: What challenges exist in translating materials into national languages in the SEAR countries (instructions and others)?

Answer: We are very careful in choosing distributors. Translations into Spanish, French, Slovak, and Czech are always done by local distributors. So far, there have been no problems, and moreover, they do not charge extra for this service. We are aware that in all countries that have joined the IVDR regulation, there must be instructions in the national language. We also understand that translating into 15 national languages will require time, resources, etc. At this stage, we believe Russian may be sufficient, but perhaps you have a different opinion.

Comment from a representative of the patient community: The new generation of specialists in countries does not always speak Russian. Regulators often require translation into the national language.

Answer: In that case, we will need a list of languages for translating instructions and accompanying materials.IVD Group[4],

[4] https://ivd.by/contacts/

Question: How is the situation with WHO prequalification?

Answer: Our tuberculosis tests have been approved and are soon to receive WHO prequalification certification. We conducted a multi-country assessment in collaboration with the Foundation for Innovative New Diagnostics (FIND). Over 3,000 samples were examined, with GeneXpert used as the comparison system. The correlation coefficient was approximately 0.98 (very high – note by ECAT). In India, the evaluation took place over 5 years with a sample of just under 14,000 specimens (Cepheid was the comparison system). Out of these approximately 14,000 specimens (let's assume 13,500), 78 did not match. Of the 78 specimens that did not match, 74 were positive on Truenat and negative on GeneXpert, and 4 were negative on Truenat and positive on GeneXpert. To confirm the results for these 78 specimens, a third test, Next-Generation Sequencing (NGS), was used. According to the sequencing results, out of the 74 specimens with a positive result on Truenat and negative on GeneXpert, 72 showed TB sequences. Publications on this study are available on the Molbio website.

At the Global Fund summit in India, Mr. Mubangizi Deusdedit, Head of WHO Prequalification in India, openly acknowledged the presence of limitations and barriers to prequalification that slow down the process. WHO is currently planning to collaborate with regional supranational laboratories and recognize the results of their assessments as an alternative to prequalification. You can contact Mr. Deusdedit on this matter. To summarize the quality response, I want to emphasize that we have already sold several million tests worldwide, including COVID-19 tests, and the quality of Molbio products is recognized globally. Our first long-term contract with the UN was signed for the supply of COVID-19 tests, and later we supplied tests for various diseases (including COVID-19, malaria, STIs, TB – a total of 18 products) to UN missions in conflict zones.

Question: Can you share the contacts of distributors in the region?

Answer: At the moment, we have one distributor – in Belarus, and we signed a contract just yesterday. We will share the contacts.

Question: What is the lifespan of your machine? How expensive is the maintenance, and how often is it required?

Answer: Machines are electromechanical devices. Any mechanisms of this kind typically last 7–8 years on average. The lifespan depends on usage conditions and operator competence. The price of comprehensive service is specified in the Global Fund brochure. We don't make money from services; we earn from machines and reagent supplies. If your machines are operational, we make a profit through reagent deliveries, and that's sufficient for us. If you allow me a bit of humor, on September 19, Cepheid announced that they would supply tests at cost. However, even at that price, we will still make a small profit.

Company's request: We would appreciate contacts for dedicated distributors in your countries.y[5] NGS[6]

[5] https://www.molbiodiagnostics.com/uploads/publication/26_publication_2620210619.135142.pdf
[6] https://www.who.int/publications/i/item/WHO-CDS-TB-2018.19

Answer: Currently, we have one distributor - in Belarus, and we signed the contract just yesterday. We will share the contacts.

Question: What is the lifespan of your machine? How expensive is the maintenance, and how often is it required?

Answer: Machines are electromechanical devices. Typically, devices of this kind have an average lifespan of 7-8 years. The duration of service depends on usage conditions and the operators' competence. The cost of comprehensive service is outlined in the GF brochure. We do not profit from the service; our revenue comes from machine and reagent sales. If your machines are operational, we make a profit through reagent supplies, which is sufficient for us. On a lighter note, on September 19, Cepheid announced that they would supply tests at cost. However, even at that price, we will still make a small profit.

Request from the company: We would appreciate contacts with dedicated distributors in your countries.

Question: Can you lower the price for a specific category of clients, non-governmental organizations, to conduct diagnostics at the community level and gain access to people who are usually underserved? The more you reduce the price, the better you will appear. Indian company Tata is preparing to enter the market with its product and already claims that their price will be lower than Molbio's.

Answer: For all non-governmental organizations, the GF price applies. We are already working with organizations in Vietnam and Myanmar. In Myanmar, for example, there is a mobile service where NGO staff on motorcycles travel to hard-to-reach areas and test various communities within 2-3 days. All residents of India take pride in Tata. However, in diagnostics, the company faced failure. In 1991-92, Tata was already in the diagnostics field through its subsidiary Merind Diagnostics. In 1995, this company disappeared. In 2020, during the Covid-19 pandemic, many companies began to invest in diagnostics, including Tata. In conclusion, without going into details, I will simply say that in October 2023, Tata is closing its diagnostic division and is leaving the market again.

Comment from the patient community representative: We invite you to meet with community representatives at the tuberculosis conference in Paris (UNION 2023).

Answer: Molbio will participate in this conference, including organizing a workshop on AI solutions and testing technologies in point-of-care services (Truenat). We would be happy to meet.

End of the meeting.