

# **Time for \$5: Questions and Answers**

Want to learn more about why Médecins Sans Frontières / Doctors Without Borders (MSF) launched a <u>campaign</u> calling on diagnostics corporation Cepheid and its parent corporation Danaher to lower the price of lifesaving tests to US\$5? Read our Q&A below.

# 1. What does the "Time for \$5" campaign call for and why?

The "Time for \$5" campaign calls on US-based diagnostic corporation Cepheid and its parent corporation Danaher to prioritise people's health over profits and reduce the price of its GeneXpert tests to \$5. This price should include service provision and apply to all low- and middle-income countries (LMICs).

Cepheid's GeneXpert diagnostic testing technology has revolutionised rapid, accurate, near-point-of-care diagnosis of tuberculosis (TB), the deadliest infectious disease in the world, as well as HIV, Ebola and hepatitis C, among other diseases. MSF uses these tests routinely in medical programmes around the globe.

Yet, due to the high price of the GeneXpert test cartridges, many LMICs cannot scale up testing for all people who need diagnosis.

MSF analysis has shown that it costs Cepheid less than \$5 to manufacture one GeneXpert test, but Cepheid charges MSF and LMICs at least 2 to 4 times that price, depending on the disease.

# 2. Who are Cepheid and Danaher?

Cepheid is a diagnostics corporation based in California, USA, which manufactures GeneXpert tests for a range of infectious diseases. It was founded in 1996 following the development of the technology for the GeneXpert system at the University of California in the early 1990s. The corporation went public in 2000, and was acquired in late 2016 by Danaher Corporation, a US-based financial investment corporation, for \$4 billion. Danaher ranked 132nd on the Fortune 500 list and reported revenues of more than \$31 billion in 2023.

## 3. What is GeneXpert?

Cepheid's GeneXpert system is a closed, self-contained, fully integrated and automated platform that can run GeneXpert cartridges to test for TB, HIV, hepatitis, and sexually transmitted infections (STIs) among other diseases. Cepheid <u>received over \$250 million</u> in public funding for the development of GeneXpert.

GeneXpert's rapid molecular tests have revolutionised the way TB is diagnosed since entering the market in 2010, and are now recommended by WHO to diagnose drug-susceptible TB (DS-TB), rifampicin-resistant TB (RR-TB) and extensively drug-resistant TB (XDR-TB). Without these tests, many countries rely on sputum smear microscopy—a technology from the late 1800s—and mycobacterial culture—a method that takes weeks to yield an accurate result—for diagnosing TB and drug resistance. By detecting TB and resistance accurately and rapidly, GeneXpert's TB tests play a critical role in clinical decision-making and timely initiation of TB treatment.

## 4. How does MSF treat TB?

MSF is the largest non-governmental provider of TB treatment worldwide and has been involved in TB care for 30 years, often working alongside national health authorities to treat people in a wide variety of

settings, including conflict zones, urban slums, prisons, refugee camps and rural areas. In 2022, MSF treated more than 17,000 people with TB, including 2,300 people with DR-TB, in over 60 TB projects in 41 countries.

MSF is also involved in efforts to find shorter and safer DR-TB treatment regimens. In December 2022, WHO released updated guidance for the treatment of DR-TB, recommending use of two six-month regimens (BPaLM and BPaL) evaluated in the TB-PRACTECAL trial led by MSF in place of existing, longer regimens. Rapid and accurate diagnosis of TB and drug resistance through molecular tests such as GeneXpert's TB tests is critical to the meaningful implementation of these recommendations, and to save more lives.

#### 5. How much do low- and middle-income countries pay for Cepheid's GeneXpert tests?

GeneXpert tests entered the LMIC market at a negotiated concessional price from 2012 onwards. The price of the TB and RR-TB was set at \$9.98, the XDR-TB test at \$14.90, and HIV, HPV and hepatitis tests at \$14.90, for public purchasers and NGOs in 145 LMICs. The ceiling price of \$9.98 for the TB and RR-TB test was a result of a 10 years' "buy down" of the test by WHO and Unitaid in 2012. Other than the XDR-TB test whose price was reduced from \$19.80 to \$14.90 in January 2023, the prices of all GeneXpert tests have remained unchanged in the last 10 years.

Price of GeneXpert tests in LMICs (in US\$)	
TB and RR-TB	9.98
XDR-TB	14.90
HIV viral load	14.90
Hepatitis C viral load	14.90
Hepatitis B viral load	14.90
COVID	14.90
HIV early infant diagnosis	14.90
Human papillomavirus (HPV)	14.90
Gonorrhea and chlamydia	16.20
Trichomoniasis	19
Ebola virus disease	19.80

#### 6. Why is MSF concerned about the prices of Cepheid's GeneXpert tests?

Because of the lack of transparency from Cepheid on how much it costs to produce the GeneXpert tests, MSF commissioned an independent engineering consultancy company to estimate these costs in 2018. The analysis showed that at 10 million annual sales volumes, the cost to produce one GeneXpert test is between \$3 and \$4.6. The analysis also showed that there is no major difference between producing cartridges for TB and other diseases, and that volumes can be aggregated across cartridges for different diseases to reduce costs. Cepheid has therefore been charging MSF and LMICs more than 2-4 times what it costs to produce each test.

While the \$9.98 price of the TB and RR-TB test was set in the buy-down agreement with WHO and Unitaid in 2012 on the basis of projected annual sales of 4.7 million tests, these volumes were eclipsed within two years of the 10 years' agreement in 2014, and are at least three times higher today. Importantly, Cepheid also sold at least 45 million COVID cartridges in 2021. Despite the exponential increase in sales volumes

and the evidence that it costs the corporation less than 5\$ to produce one GeneXpert test, Cepheid continues to charge high prices to LMICs.

As a medical humanitarian organisation providing care in 75 countries, we know access to diagnostic tools can save many lives. Cepheid's irresponsible and inflated pricing acts as a barrier to scaling up lifesaving testing and treatment.

#### 7. Does Cepheid have any competitors in the market?

Because of the exponential expansion of the GeneXpert machine fleet in LMICs, largely funded with public money and supported by the buy-down agreement in 2012, Cepheid still has a monopoly on the GeneXpert system in most LMICs.

Recently, India-based diagnostic corporation Molbio introduced a similar technology, Truenat, that is recommended by WHO to detect TB and RR-TB since 2020, making it a direct competitor to Cepheid for TB testing. Molbio also has similar tests for HIV, HPV, hepatitis and several other infectious diseases. While Molbio's Truenat system has overtaken Cepheid's machine footprint in India, expanding the former's global footprint will take years as it is not yet recommended by WHO for testing diseases other than TB, and not yet included in WHO's list of prequalified diagnostics for any disease. Additionally, Cepheid is currently the only supplier of a WHO-recommended rapid molecular test that can detect XDR-TB near the point of care, and has tens of thousands of machines placed across countries. As a result, national disease programmes are highly dependent on GeneXpert cartridges, especially for TB.

Several other potential competitors have similar technologies that are close to entering the market (e.g. SD Biosensor and Bioneer) and have ambitions to supply LMICs. However, these competitors will not enter the LMIC market before 2024 and gaining market share will take years. Therefore, Cepheid will remain the dominant supplier of critical rapid molecular tests for LMICs for the next few years.

# 8. How can I participate in this campaign?

You can participate in this campaign and amplify our efforts by:

- <u>Tweeting @CepheidNews and @DanaherCorp</u> to tell them their high prices cost lives. You can write your own or use one of our tweets <u>here</u>, <u>here</u>, <u>here</u> and <u>here</u>; and
- Amplifying our campaign communications to your networks, such as our infographics, factsheets, poster and other campaign materials, found on our dedicated <u>"Time for \$5" campaign page.</u>