

# THE RIGHT TO QUALITY TB DIAGNOSTIC TESTING

By David Branigan

Rapid molecular tests, such as Cepheid's Xpert and Molbio's Truenat, offer the potential to dramatically improve rates of diagnosing tuberculosis (TB), including drug-resistant TB, when used as the initial TB test in place of the more common, century-old technique of smear microscopy. Yet, despite clear advantages compared to smear microscopy (see table), the scale-up of rapid molecular tests since their introduction in 2010 has been slow and suboptimal,

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resulting in continued reliance on smear microscopy, and contributing to an estimated three million people with TB who go undiagnosed each year.<sup>1</sup> Reasons for this slow uptake and implementation of rapid molecular tests include "high costs," "poor sensitization of clinical staff," "insufficient service and maintenance provision," and "inadequate resources for sustainability and expansion."<sup>2</sup> Scaling up access to rapid molecular testing for all people who are evaluated for TB is necessary to improve diagnosis of TB and drug-resistant

TB. Moreover, implementing these tests is a human rights obligation under the right to science.

In its draft general comment on the right to science ([The Right to Science Finally Comes into Sight](#)), the Committee on Economic, Social and Cultural Rights (CESCR) established that under this right, everyone should have "fair access to the applications of science." An essential element of the right is "quality," defined as "the most advanced, up-to-date and generally accepted science available at the time, which is considered by the scientific community to meet certain minimum standards."<sup>9</sup> The World Health Organization (WHO) is the primary body for determining the quality of TB diagnostic tests, and since 2013 it has recommended that countries implement rapid molecular tests as the initial TB test for all people who are evaluated for TB, rather than smear microscopy.<sup>10</sup> Even after this recommendation, many countries failed to fully scale-up and implement rapid molecular tests as the initial TB test for all, failing to meet their human rights obligations under the right to science.

The reasons for this failure can ultimately be traced to insufficient country and donor budgets for procuring and implementing TB tests and also to the high prices of rapid molecular tests. Taken together, these factors limit "fair access" to quality TB diagnostic testing. Even if country and donor budgets expand, the current prices of Xpert and Truenat—both around \$10—make fully scaling up and implementing these tests too expensive,<sup>11</sup> especially in comparison to the cost

## Rapid Molecular Tests vs. Smear Microscopy for Tuberculosis Detection

TB Diagnostic Tests	Sensitivity	Specificity	Time to Results	Price per Test	WHO Target Price <sup>3</sup>
Smear microscopy <sup>4,5</sup>	50% (20-80%)	98%	< 5 min	\$0.26 to \$10.50	NA
Cepheid's Xpert MTB/RIF Ultra <sup>6</sup>	90%	96%	90 min	\$10	\$4-\$6
Molbio's Truenat MTB Plus <sup>7,8</sup>	89%	98%	60 min	\$12	\$4-\$6

Sensitivity: the proportion of people with a disease who are correctly identified by a diagnostic test as having the disease

Specificity: the proportion of people without a disease who are correctly identified by a test as not having the disease

of smear microscopy and the WHO target price for smear replacement tests (see table). The good news is that the cost of manufacturing these tests is only a fraction of their price. A 2018 cost-of-goods analysis of Xpert tests found that at annual volumes of 10 million tests—which have already been reached for TB tests—the cost of manufacturing each test may be as low as \$3. The bad news is that in spite of reaching this economy of scale, Cepheid has not lowered the price of Xpert tests and has instead continued to charge a monopoly price that takes the lion’s share as profit.<sup>12</sup> Who then, under the right to science, is responsible for addressing the predicament that the right to quality TB diagnostic testing remains unfulfilled at global and national levels?

**T**he responsibility to realize fair access to quality TB diagnostic testing rests largely on states, due to their treaty-based obligations to fulfil the right to science. According to the CESCR, governments are obligated to allocate the “maximum available resources” to fulfill the right to science, using “all appropriate means,” including “the adoption of legislative and budgetary measures,”<sup>13</sup> and to seek “business cooperation and support to implement the Covenant rights.”<sup>14</sup> Private companies, while not bound by the same treaty-based obligations as states, do bear some responsibility under the right to science to realize fair access to quality TB diagnostic testing. The United Nations Guiding Principles on Business and Human Rights establish that private companies have a responsibility to respect human rights, and that “[b]usiness enterprises should not undermine States’ abilities to meet their own human rights obligations.”<sup>15</sup> In order to realize fair access to quality TB diagnostic testing under the right to science, states would have to increase government expenditure, mobilize additional resources, and negotiate lower prices for tests with diagnostics companies. Meanwhile, diagnostics companies would have to proactively work with states to achieve fair pricing structures that support states to fulfill their human rights obligations.

**T**he diagnostics company Cepheid is failing to meet its responsibility to respect human rights by charging high prices for Xpert tests, thus undermining states’ abilities to implement these tests according to WHO recommendations. While many countries have struggled since 2010 to procure and implement rapid molecular tests due to their cost, Cepheid reaped huge profits from the sale of Xpert tests. In 2018, this amounted to approximately \$81.2 million profit from the sale of 11.6 million Xpert TB tests to high burden developing countries alone.<sup>16,17</sup> Danaher, the company that acquired Cepheid in

2016, has since enjoyed soaring stock prices and record profits, with a net income of \$3 billion in 2019.<sup>18,19</sup> Bolstered by its decade-long monopoly over the rapid molecular test market, Cepheid kept Xpert test prices high in spite of public investments in GeneXpert technology,<sup>20</sup> lower manufacturing costs, and its human rights responsibilities. Now that Molbio and other diagnostics companies are introducing new rapid molecular tests into the market, we must hold them to the same human rights standards as Cepheid.

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Realizing the right to quality TB diagnostic testing will require concerted action by all stakeholders. Countries and donors must increase investments, expand budgets, and use their combined leverage to negotiate lower prices for rapid molecular tests. Governments must use all mechanisms at their disposal—including but not limited to placing conditions on research and development funding and on procurement contracts—to apply pressure on diagnostics companies to make their cost of goods transparent and commit to volume-based price reductions. Diagnostics companies must take on a more proactive role in meeting their human rights responsibilities. They can accomplish this by setting test prices that reflect actual production costs—as well as public investments—with clear volume thresholds for price reductions based on manufacturing efficiencies, and by aligning fiscal strategies to pursue reasonable profit through high volumes rather than high prices. Activists must continue to monitor and hold countries, donors, and diagnostics companies accountable for meeting their human rights obligations and responsibilities in order to establish fair pricing structures that enable the scale-up and implementation of rapid molecular tests as the initial TB test for all.

Rapid molecular tests have been commercially available and recommended by the WHO for nearly a decade. At the United Nations General Assembly in 2018, governments made commitments to end the TB epidemic by 2030, and to close the diagnostic gap by diagnosing and treating 40 million people with TB by 2022.<sup>21</sup> It's time that government commitments to end TB translate into increased funding and action; that diagnostics companies price tests in a way that maximizes benefit to human lives; and that the right to science is fulfilled for all people at risk of TB, through universal access to rapid molecular testing as the initial TB test. We don't have another decade.

### Endnotes

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