

FAIR PRICING FOR CEPHEID XPRT TESTS (COVID-19, HIV, TB, HCV)

3 APRIL, 2020



Webinar Agenda

"Time for \$5" campaign

- David Branigan, TB Project Officer, Treatment Action Group

People-centered, rights-based pricing for Xpert tests for TB, COVID-19 and other diseases

- Blessina Kumar, CEO, Global Coalition of TB Activists

Cepheid's GeneXpert cartridges: a cost-of-goods analysis

- Stijn Deborggraeve, Diagnostics Advisor Infectious Diseases, MSF Access Campaign

Overall demands of diagnostics companies, not limited to Xpert

- Sharonann Lynch, HIV & TB Policy Advisor, MSF Access Campaign

Q&A

“Time for \$5” Campaign

David Branigan, TB Project Officer, Treatment Action Group

3 April, 2020



Overview:

- The “Time for \$5” campaign is a global civil society movement calling on the diagnostics company Cepheid to reduce the prices of Xpert rapid molecular tests for TB, HIV, hepatitis B & C, STIs, and now COVID-19 to US\$5, inclusive of the cost of service and maintenance.
- The \$5 ask is underpinned by an MSF-commissioned cost-of-goods (COGs) analysis, which found the cost of producing each Xpert test at annual volumes over 10 million could be as low as \$3.

Background

Public and philanthropic funding for GeneXpert

- Substantial public and philanthropic funding supported the development of GeneXpert technology and the roll-out of the Xpert MTB/RIF TB cartridge, including over \$160 million from the United States government.
- In 2012, Unitaid, the United States government and the Bill & Melinda Gates Foundation paid Cepheid \$11.1 million to buy down the price of Xpert MTB/RIF from \$16.86 to \$9.98.

Slow uptake of rapid molecular tests for TB

- In 2013, WHO recommended Cepheid's rapid molecular test Xpert MTB/RIF as the initial TB test for all, to replace smear microscopy.
- But scale-up was slow, and the \$10 price was a major barrier, along with insufficient service and maintenance provision (England et al, Public Health Action, September 2019).
- Despite reaching higher volumes and lower manufacturing costs, Cepheid did not reduce the price of its TB tests, but made higher profits while countries struggled to scale up the tests.
- In 2020, WHO released a rapid communication strengthening its earlier recommendation that Xpert TB tests should be used as an initial TB test for all rather than smear microscopy.

Past Actions

- **21 October 2019:** The first “Time for \$5” open letter called on Cepheid to reduce the price of TB cartridges to \$5, inclusive of service and maintenance (127 civil society signatories).
- **31 October 2019:** Civil society protesters interrupted a session on Xpert at the Union Conference, presented the “Time for \$5” demands to Cepheid, and distributed 500 copies of the first open letter to participants at the conference.
- **4 November 2019:** Cepheid responded to the first open letter, did not deny the manufacturing efficiencies, but said these efficiencies supported investments in tests for other diseases.
- **6 January 2020:** The second “Time for \$5” open letter expanded the \$5 ask to include other Xpert tests for HIV, hepatitis B & C, HPV, and STIs (156 civil society signatories).
- **27 March 2020:** TAG and MSF released statements calling on Cepheid to lower the price of its SARS-CoV-2 test for COVID-19 to \$5, and against the company’s profiteering from the pandemic.
 - <https://msfaccess.org/msf-calls-no-patents-or-profiteering-covid-19-drugs-tests-and-vaccines-pandemic>
 - <https://www.treatmentactiongroup.org/statement/treatment-action-group-statement-on-the-high-price-of-cepheids-xpert-test-for-covid-19/>

Join the Campaign

Join us in calling for Cepheid to lower the prices of all Xpert tests to \$5, inclusive of service and maintenance!

For more information on next steps and how to get involved, please contact:
david.branigan@treatmentactiongroup.org



People-centered, rights-based pricing for Xpert tests for TB, COVID-19 and other diseases

Blessina Kumar, CEO of Global Coalition of TB Activists

3 April, 2020

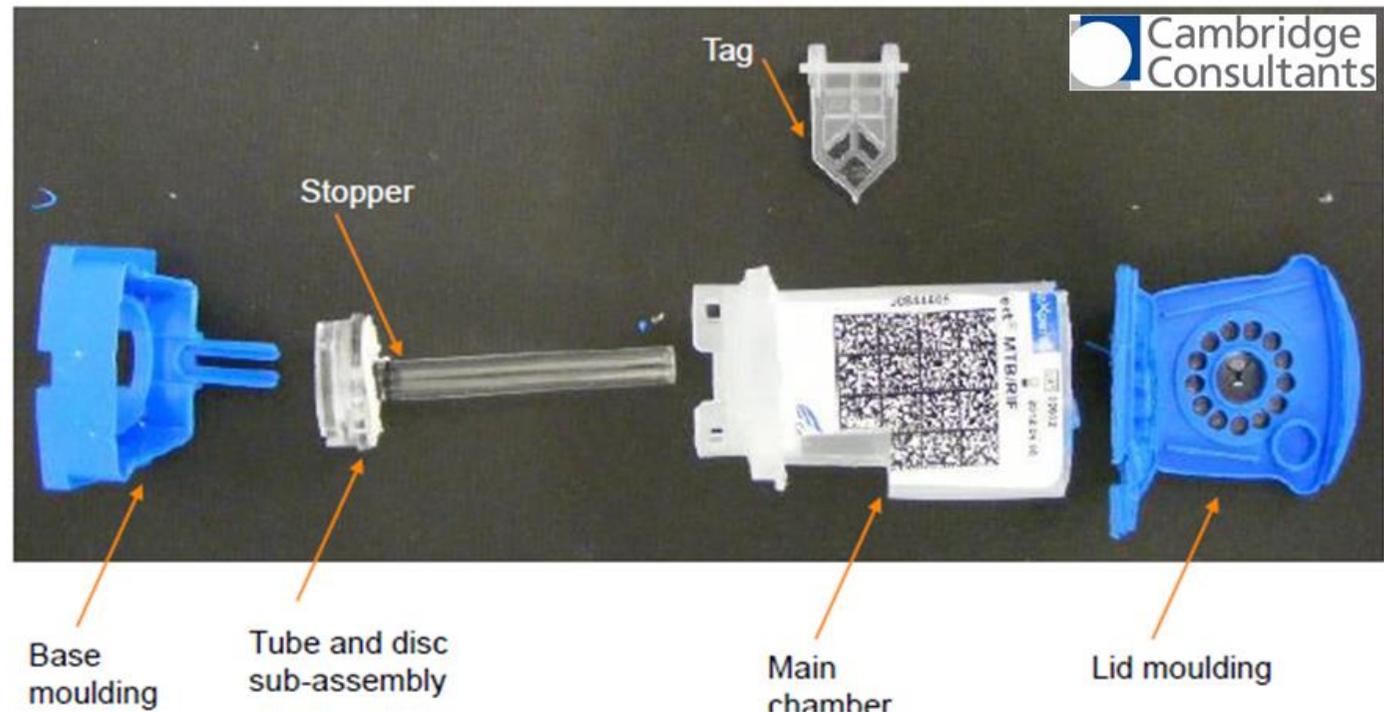
- The scale-up of Xpert TB testing in India has been slow and insufficient even with the \$10 TB test, and the current GeneXpert testing infrastructure needs strengthening.
- The \$20 price of the new Xpert COVID-19 test cannot be accepted, and civil society has to push Cepheid to reduce prices for this and other Xpert tests.
- Access to TB testing and services should not be compromised during the COVID-19 response.
- The COVID-19 crisis offers an opportunity to strengthen lab systems to test for COVID-19 as well as TB, HIV and hepatitis C.
- Equitable, needs-based global access to Cepheid's Xpert tests is needed.



Cepheid's GeneXpert: a cost-of-goods analysis

Stijn Deborggraeve, Diagnostics Advisor Infectious Diseases, MSF Access Campaign
3 April 2020

Cepheid, it's:
TIME FOR \$5
All cartridges! All inclusive services! One price!





1

2

4



16



48



2 or 4



Healthcare Associated Infections

- Xpert MRSA NxG
- Xpert MRSA/SA SSTI
- Xpert MRSA/SA BC
- Xpert SA Nasal Complete
- Xpert *C. difficile*/Epi
- Xpert *C. difficile*
- Xpert Carba-R
- Xpert Norovirus
- Xpert *vanA* for VRE

Critical Infectious Diseases

- Xpert Xpress SARS-CoV-2 (EUA)
- Xpert Xpress Strep A
- Xpert Xpress Flu/RSV
- Xpert Xpress Flu
- Xpert MTB/RIF
- Xpert-EV

Oncology/Genetics

- Xpert BCR-ABL Ultra
- Xpert FII & FV

Sexual Health

- Xpert TV
- Xpert CT/NG
- Xpert GBS
- Xpert GBS LB

WHO recommends Xpert MTB/RIF as the initial diagnostic test

Automated real-time nucleic acid amplification technology for rapid and simultaneous detection of tuberculosis and rifampicin resistance: Xpert MTB/RIF assay for the diagnosis of pulmonary and extrapulmonary TB in adults and children

Policy update



© World Health Organization 2013

Box 1. Using Xpert MTB/RIF to diagnose pulmonary TB and rifampicin resistance in adults and children

These recommendations should be read in conjunction with the remarks in section 5.1.

- Xpert MTB/RIF should be used rather than conventional microscopy, culture and DST as the initial diagnostic test in adults suspected of having MDR-TB or HIV-associated TB (strong recommendation, high-quality evidence).
- Xpert MTB/RIF should be used rather than conventional microscopy, culture and DST as the initial diagnostic test in children suspected of having MDR-TB or HIV-associated TB (strong recommendation, very low-quality evidence).
- Xpert MTB/RIF may be used rather than conventional microscopy and culture as the initial diagnostic test in all adults suspected of having TB (conditional recommendation acknowledging resource implications, high-quality evidence).
- Xpert MTB/RIF may be used rather than conventional microscopy and culture as the initial diagnostic test in all children suspected of having TB (conditional recommendation acknowledging resource implications, very low-quality evidence).
- Xpert MTB/RIF may be used as a follow-on test to microscopy in adults suspected of having TB but not at risk of MDR-TB or HIV-associated TB, especially when further testing of smear-negative specimens is necessary (conditional recommendation acknowledging resource implications, high-quality evidence).

Concessional pricing for 145 high burden developing countries (HBDC*)

Xpert MTB/RIF Ultra	\$ 9.98
Xpert MTB/RIF	\$ 9.98
Xpert HCV Viral Load	\$ 14.90
Xpert HBV Viral Load	\$ 14.90
Xpert HIV Qualitative	\$ 14.90
Xpert HIV Viral load	\$ 14.90
Xpert HPV	\$ 14.90
Xpert CT/NG 10	\$ 16.20
Xpert CT/NG 120	\$ 16.20
Xpert TV	\$ 19.00

GeneXpert IV module with desktop	\$ 17,000
GeneXpert IV module with a laptop	\$ 17,500

Warranty	1-yr	3-yr	3-yr
GeneXpert IV-2	\$1,896	\$5,184	\$4,500
GeneXpert IV-4	\$2,898	\$7,902	\$6,840
GeneXpert XVI-16	\$7,800	\$20,898	\$18,504



HBDC :	\$ 9.98	\$ 20
HIC :	\$ 40-80	\$ 36

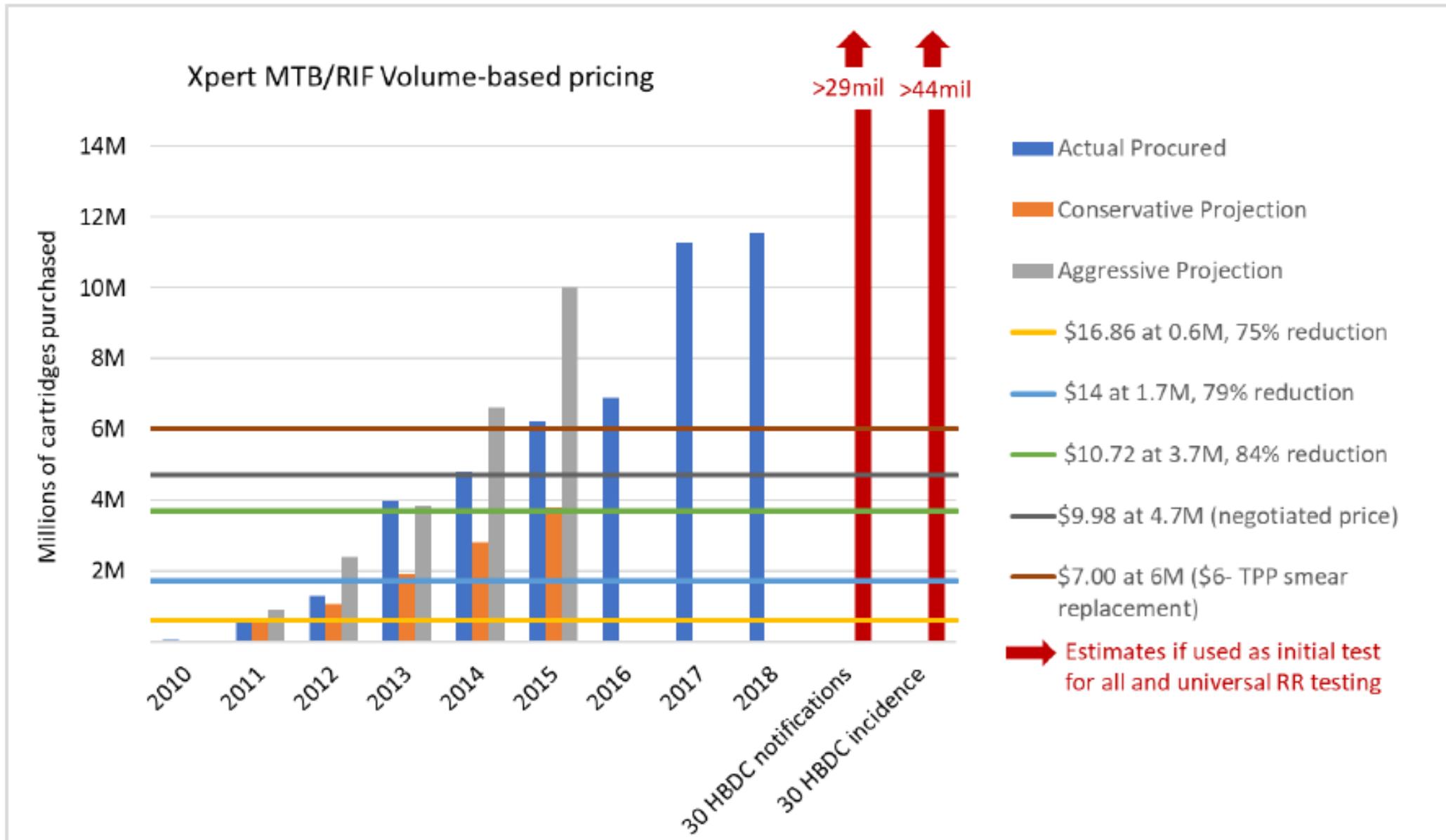
* <https://www.finddx.org/pricing/genexpert/>

10-year buy-down agreement for Cepheid' GeneXpert (2012-2022)

- **R&D:** One third of the total R&D financing for Xpert came from public funding
- **Buy down:** \$11.1 million subsidy for \$9.98 per MTB/RIF for 10y
UNITAID/WHO, USAID, OGAC, BMGF

Terms of the buy-down agreement in 2012	Status
If royalties are reduced the price should be reduced accordingly	4 royalties expired, 2 unknown
Lower price to 3 rd party will be the price for HBDCs	Countries may have received all incl. price below \$9.98
Reasonable efforts to meet the needs of private sector in HBDC	To date private sector in HBDC do not receive the same price mark
Transparency of sales volumes from public and private sector	Volumes tripled and no price reductions
Annual audits were recommended in the contract agreement	First ever audit occurred October 2019 – report kept confidential

Xpert MTB/RIF cartridge sales volumes have tripled since 2012



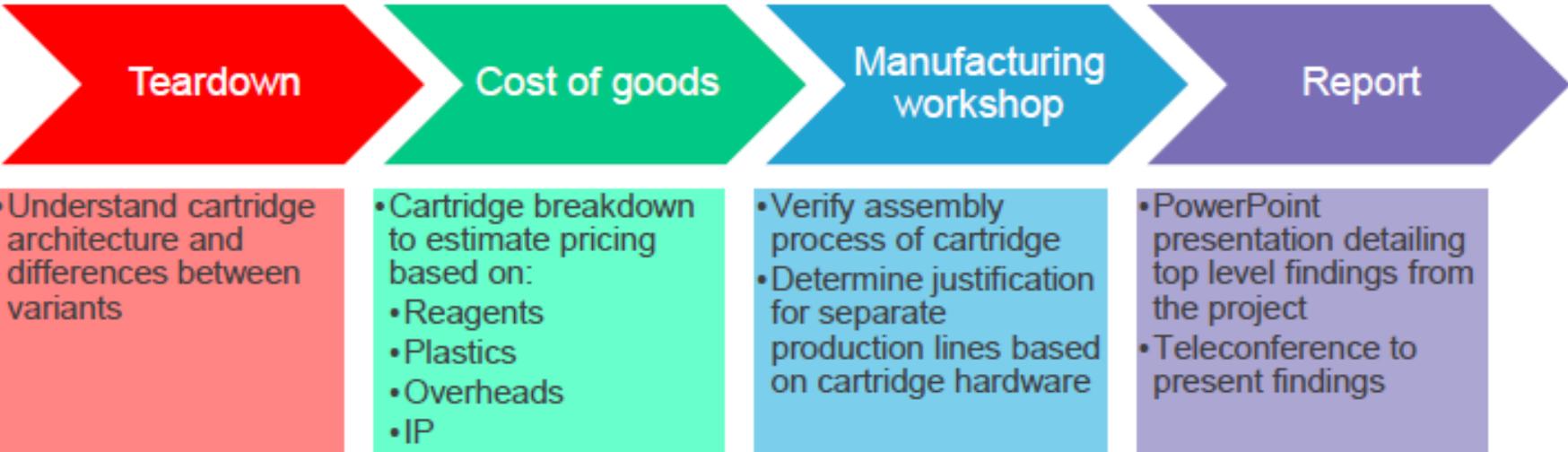
Cost of goods (COGS) of the Xpert cartridges

What

Cost of goods sold (COGS) = the direct costs of producing the goods sold by a company

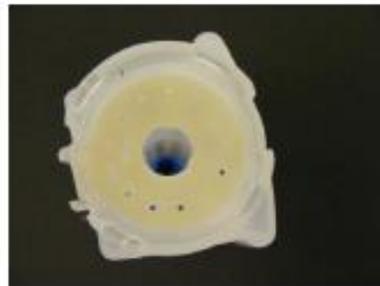
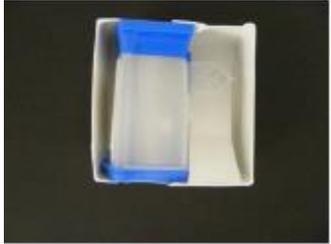
- includes the cost of the materials and labor directly used to create the good
- excludes indirect expenses e.g. distribution costs

How



- 2012: Xpert MTB/RIF
- 2015: Xpert HIV
- 2018: Xpert MTB/RIF ultra
- Xpert HCV

Teardown analysis



PLASTICS

REAGENTS

ASSEMBLY

PACKAGING

ROYALTIES

Cost of goods for Xpert MTB/RIF Ultra

PLASTICS	\$ 2.06	
REAGENTS	\$ 1.32	\$ 1.13
	Ultra	Standard
ASSEMBLY	\$ 3.50	
PACKAGING	\$ 0.15	
ROYALTIES	\$ 1.69	

**MTB/RIF
Ultra**



\$ 8.72

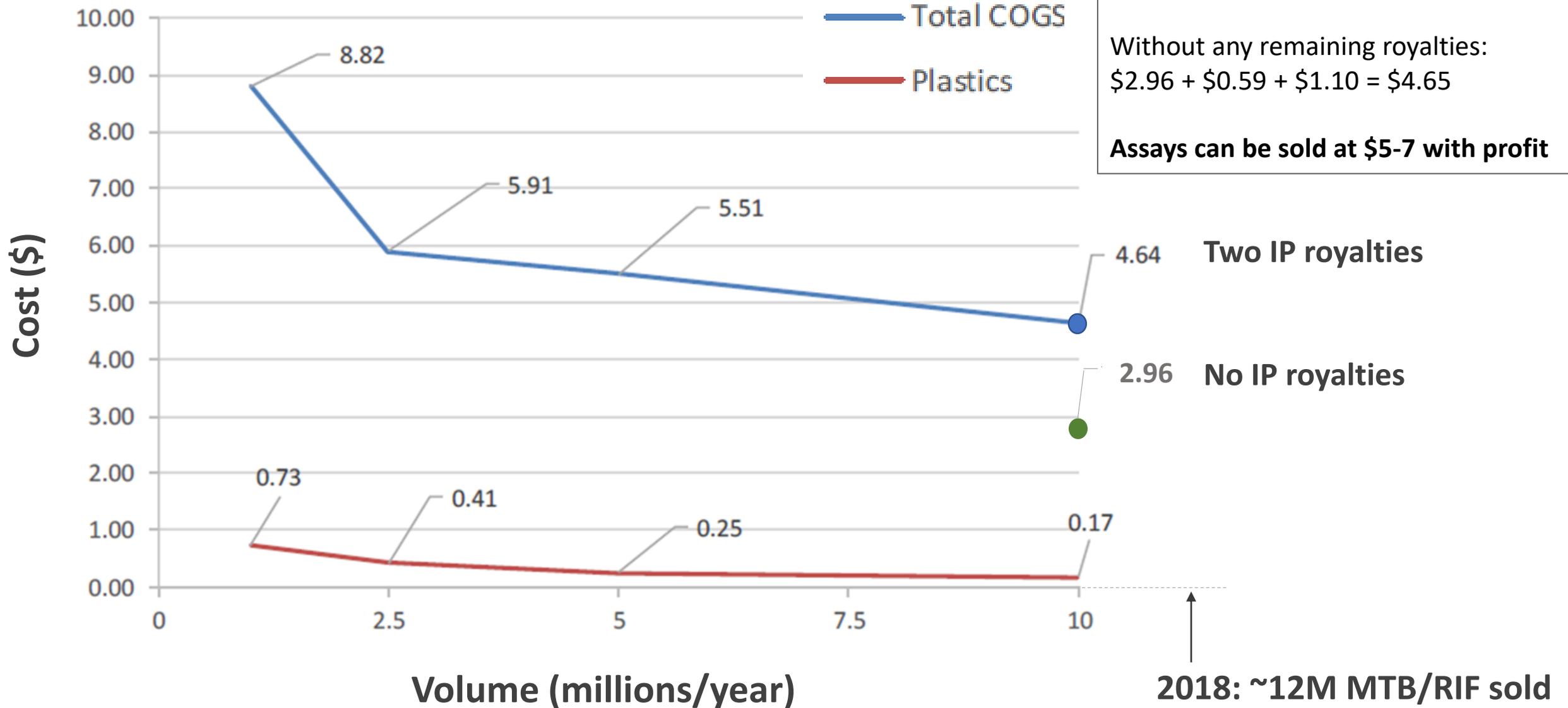
MTB/RIF



\$ 8.53

At 1,000,000 sales volumes

Volume based price variations in COGS



Is the COGS the same for bacterial and viral cartridges?

PLASTICS

Minor differences in the plastics hardware
Not warranting different production lines

REAGENTS

RNA vs DNA extraction and amplification reagents
Minor differences in cost

ASSEMBLY

No difference

PACKAGING

No difference

ROYALTIES

IP expiry unknown for viral cartridges



\$ 10.91

At 1,000,000 sales volumes

Theoretical COGS analysis of the Xpert Xpress SARS-CoV-2?



PLASTICS

No difference

REAGENTS

Both RNA viruses

Only difference are primers and probes

ASSEMBLY

No difference

PACKAGING

No difference

ROYALTIES

No other royalties than the other viral cartridges
SARS-CoV-2 viral genomes open access



Cepheid's manufacturing processes



- **Two manufacturing sites: USA and Sweden**
- **India site expected to open in 2020 for MTB cartridges**
- **MTB cartridges produced in US + Sweden, viral cartridges in Sweden**
- **Covid cartridges will be produced at both plants**
- **COGS analysis: no justification for the need of separate production lines per cartridge types**
- **Non-specific and flexible manufacturing lines, any cartridge can be produced on each line**
- **Potential rationale for separate production lines:**
 - **Some countries may not accept US manufactured products**
 - **Current Good Manufacturing Practices and risk mitigations**
 - **Minor changes in cartridge architecture, assembly and reagent storage conditions**

\$19.8 per COVID cartridge is profiteering during a global health crisis

- \$19.8 per test for HBDCs and \$36 for HICs, COGS indicates \$5 price reasonable
- Price has been copy pasted of the Ebola cartridge
- Not considering volume-based discounts available under this program
- Cepheid's nasopharyngeal swab collection kit: \$2,31/swab
- Allocations unclear and not sure LMICs will receive the volumes they need



TB, HIV, HCV, STI cartridges

AND SARS-CoV2 !

Cepheid should ensure full supply of TB & COVID cartridges



Will Cepheid push back TB cartridge production and supply?

“We also anticipate to decrease production of some other assays (MTB in particular) to provide the required minimum but will count on countries to not generate during this period large order to replenish their inventory for long periods”



**World Health Organization (WHO) Information Note
Tuberculosis and COVID-19**

Date: 20th March 2020

[COVID-19: Considerations for tuberculosis \(TB\) care services](#)

WHO is monitoring medicine supply at the global level, while The Global Fund, the Stop TB Partnership Global Drug Facility (GDF), USAID, Unitaid and other donors play an essential role in supporting countries to secure adequate and sustainable supplies of TB medicines drugs and diagnostics. Countries are advised to place their orders for 2020 delivery as soon as possible given anticipated delays in transport and delivery mechanisms.

Other near-POC COVID-19 tests in the market



<https://www.finddx.org/covid-19/pipeline/>

>100 commercialized manual PCR tests

>30 commercialized automated PCR tests

>150 commercialized immunoassays

FIND is conducting independent evaluations of COVID-19 molecular tests and immunoassays, in collaboration with WHO and other partners

	Molecular test	Immunoassay	
		Antibody based	Antigen based
How does it work?	Detects the presence of viral genetic material in a sample	Detects the presence of anti-viral antibodies in a sample	Detects the presence of viral proteins (antigens) in a sample
A positive result...	Confirms a current SARS-CoV-2 infection	Indicates a recent or past infection, and could be used to screen for current infection (tests may not be reliable in early phase of infection)	Confirms a current SARS-CoV-2 infection or suggests a potential infection (depending on test design)

https://www.finddx.org/wp-content/uploads/2020/03/FIND_COVID-19-GUIDE_24.03.2020.pdf

Cepheid's SARS-CoV-2 test versus other near-POC molecular tests

Manufacturer	Test	Price/test	Point of testing	Regulatory approval	Footprint
Cepheid	Xpert Xpress SARS-CoV-2	\$19.80*	POC	FDA EUA	23,000 machines in 145 HBDCs
Molbio	Truenat SARS-CoV-2	\$20	POC	India DCGI	India
Abbott	ID NOW COVID-19	TBD	POC	FDA EUA	USA only
Abbott	RealTime SARS-CoV-2	TBD	Central	FDA EUA	HIC
Biomérieux	BIOFIRE® COVID-19	>\$50	Central	FDA EUA	HIC
Roche	Cobas SARS-CoV2	TBD	Central	FDA EUA, CE IVD	HIC

* HBDC price, HIC price \$36/test

Antigen and antibody RDTs for COVID

Laboratory testing strategy recommendations for COVID-19

Interim guidance
22 March 2020



This document focusses solely on molecular testing as this is the current recommended method for the identification of infectious cases. The technical requirements for molecular testing are included in: [Laboratory testing for COVID-19 in suspected human cases](#). Serological assays will play an important role in research and surveillance but are not currently recommended for case detection and are not included in this document. The role of rapid disposable tests for antigen detection for COVID-19 needs to be evaluated and is not currently recommended for clinical diagnosis pending more evidence on test performance and operational utility. WHO will update this guidance as more information laboratory tests for COVID-19 becomes available.

Antigen based RDTs

- Active infection
- High specificity, moderate sensitivity

Antibody based RDTs

- Immune status
- Specificity and sensitivity unclear

- Roles in diagnostic algorithms
- Quality assured tests
- Prioritization of use

Antigen-based RDTs to be included in the first round evaluation:

Company	Assay	Country of manufacturer	Interpretation	Regulatory status
Coris BioConcept	COVID-19 Respi-Strip	Belgium	Visual	RUO
RapiGEN Inc	BIOCREDIT COVID-19 Ag	South Korea	Visual	RUO
SD BIOSENSOR, INC	STANDARD F COVID-19 Ag FIA	South Korea	Reader	CE-IVD
SD BIOSENSOR, INC	STANDARD Q COVID-19 Ag Test	South Korea	Visual	CE-IVD
Shenzhen Bioeasy Biotechnology Co, Ltd.*	BIOEASY 2019-nCoV Ag Fluorescence Rapid Test Kit (Time-Resolved Fluorescence)	China	Reader	CE-IVD



Key messages

- 1. Overall lack of transparency by Cepheid on how pricing is determined per assay**
- 2. Xpert MTB/RIF is the WHO recommended first line test for TB**
- 3. High sales volumes and public investments: price reduction are long overdue**
- 4. COGS at current volumes can be as low as \$3 per Xpert MTB-RIF cartridge**
- 5. It's time for \$5 all-inclusive price for all cartridges including service & maintenance**
- 6. 20\$ per Xpert Xpress SARS-CoV-2 cartridge is profiteering during global crisis and no COGS-based evidence for price above \$5**
- 7. Allocation prioritization: LMICs should have access to SARS-CoV-2 cartridges**
- 8. No ruptures in supply of the Xpert MTB/RIF and HIV cartridges should be guaranteed**

PRESS RELEASE | 27 MARCH 2020

MSF calls for no patents or profiteering on COVID-19 drugs, tests, and vaccines in pandemic

<https://msfaccess.org/msf-calls-no-patents-or-profiteering-covid-19-drugs-tests-and-vaccines-pandemic>

Cepheid, it's:

TIME FOR \$5

All cartridges! All inclusive services! One price!



STILL
MEDICINES SHOULDN'T BE A LUXURY

