

PARLIAMENTARY INQUIRY QUESTION ON NOTICE

Department of Health

Senate Select Committee on COVID-19

Australian Government's response to the COVID-19 pandemic

Written Question - 29 May 2020

PDR Number: IQ20-000290

Partnership with Minderoo Foundation

Question type: Written

Senator: Katy Gallagher

Question:

In relation to the Government's partnership with the Minderoo Foundation to procure COVID-19 test kits and equipment from the Beijing Genomic Institute:

- Did the BGI tests undergo any form of validation study in Australia?
- If so, what did that study determine?
- Were any other commercially manufactured tests subject to the same validation?
- Was the MBS rebate for private labs of around \$100 per COVID-19 PCR test set, at least in part, because private laboratories had to source test consumables from the difficult global market?
- To what extent has this supply issue been addressed by the Government's partnership with the Minderoo Foundation?
- Is the government reconsidering the MBS reimbursement for private labs PCR tests?
- As of the date of the Department's response, how many of the 10 million test kits have been:
 - o Received in Australia;
 - o Distributed to:
 - o Private providers (please provide a breakdown between Sonic, Healius and any other private providers who have received tests)
 - o States and territories (please provide a breakdown by jurisdiction)
- Is the Federal Government making any payment to the Minderoo Foundation for the tests provided by Beijing Genomics? If so, what payment terms have been agreed?
- How much does the Commonwealth pay for each test? How much do pathology providers (private/public) then pay the Commonwealth for each test?
- The Minister's announcement also stated that testing equipment from Beijing Genomics was being supplied to laboratories. How many testing platforms have been placed? Please provide a breakdown by jurisdiction and setting (private by company/public)
- Has the Department received any feedback from laboratories about the quality or performance of those devices?
- Were those devices required to undergo any form of performance validation prior to being approved by TGA?

Answer:

The Therapeutic Goods Administration approved the BGI SARS-CoV-2 RT-PCR test kit for supply in Australia by BGI Health (AU) on 10 April 2020. On 10 June 2020, the Peter Doherty Institute for Infection and Immunity completed a validation study of the BGI SARS-CoV-2 RT-PCR test kit and associated instrumentation and reagents. The full report is available on the Department of Health website at: <https://www.health.gov.au/resources/publications/post-market-validation-of-the-beijing-genomics-institute-bgi-sars-cov-2-real-time-pcr-platform>.

Information about validation of other tests is available at the same website.

The current Medicare Benefits Schedule (MBS) fees for bulk billed pathology tests for COVID-19 were set following consideration of information about input costs to testing, including consideration of international market prices for COVID-19 testing consumables. The fees are comparable to international reimbursement rates for SARS-CoV-2 detection tests.

The cost of the BGI SARS-CoV-2 RT-PCR test kit is comparable to the cost of RT-PCR test kits from other suppliers.

The Medicare items for pathology tests for COVID-19 are scheduled to cease on 30 September 2020. Developments in the COVID-19 pandemic and advice from the Australian Health Protection Principal Committee will inform whether the current items are extended.

The Minderoo Foundation sourced BGI COVID-19 test kits and associated instrumentation and reagents at a time of significant concern that Australia would face limited testing capacity because of global shortages of COVID-19 pathology testing consumables, including reagents, and disruptions to normal commercial supply chains. The Government has reimbursed the Minderoo Foundation for their costs in sourcing the equipment.

As at 27 July 2020, 4.86 million BGI test kits, equipment and reagents have arrived in Australia. The BGI equipment will be stored in the National Medical Stockpile or distributed to private pathology providers as required.

As at 17 June 2020, Sonic Healthcare and Healius Limited laboratories have received BGI test kits, equipment and reagents to support over 700,000 COVID-19 tests. Sonic and Healius have agreed to reimburse the Government at cost for the BGI tests. Sonic and Healius have validated the BGI test kits for use in their laboratories.