



Republic of the Philippines

DEPARTMENT OF SCIENCE AND TECHNOLOGY



Annex A. Summary of Evidence for TB Diagnostic Tests

Health Technology	CPG Recommendation	WHO Recommendation	Key Features	Costing
Latent/ Asymptomatic Tuberculosis				
<p>Interferon gamma release ELISA assay (IGRA) for screening of latent/ asymptomatic tuberculosis</p>	<p>Recommended in the <u>DOH Omnibus Health Guidelines (OHG) for Children (2023)</u>, <u>DOH OHG for Adolescents (2023)</u>, <u>DOH OHG for Adults (2023)</u>, <u>DOH OHG for Elderly (2023)</u> for screening of latent/ asymptomatic tuberculosis</p> <p>In the <u>DOH Tuberculosis Manual of Procedure 6th Edition</u> for individuals prior to TB treatment <i>except</i> for the following:</p> <ul style="list-style-type: none"> • <i>People living with HIV</i> • <i>Children less than 5 years old (yo) who</i> 	<p>Included in the <u>World Health Organization's (WHO) Essential Medical Device List</u>.</p> <p>No WHO target product profile for this health technology.</p>	<ul style="list-style-type: none"> • alternative test for TST, considering previous supply issues encountered with TST • comparable sensitivity for both IGRA and TST while IGRA had a marginally higher specificity vs TST (<u>2021 Philippine CPG for the Diagnosis and Treatment of Adult Tuberculosis</u>) • more objective (i.e., not operator-dependent) • requires a single patient visit compared to TST, which requires two to three visits. This can be equated to less direct medical cost 	<p>Each run of the IGRA assay has an estimated cost of Php 2,924.23. The cost includes reagents, consumables, and human resource costs.</p>

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	<p>are household contacts of bacteriologically confirmed pulmonary tuberculosis (PTB)</p> <ul style="list-style-type: none"> Individuals aged 5 yo and older who are household contacts of bacteriologically confirmed PT and with other TB risk factors 		<p>(e.g. transportation cost to the facility) and indirect costs (i.e. productivity loss)</p> <ul style="list-style-type: none"> faster turnaround time can be applied to identify patients for preventive TB treatment training human resources is needed 	
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Drug Susceptible Tuberculosis

<p>Chip-based Reverse Transcriptase-Polymerase Chain Reaction (RT-PCR) Test for diagnosis of drug-susceptible tuberculosis (DS-TB)</p>	<p>Recommended in the <u>DOH Omnibus Health Guidelines for Children (2023)</u>, <u>Adolescents (2023)</u>, <u>Adults (2023)</u>, and <u>Elderly (2023)</u> as an alternative to smear microscopy for diagnosis of drug-susceptible TB</p>	<p>Included in the <u>World Health Organization's (WHO) Essential Medical Device List</u> for diagnosis of active TB.</p> <p>A <u>WHO Target Product Profile (TPP) for rapid tests for TB detection</u> is available.</p>	<ul style="list-style-type: none"> battery-operated point-of-care test does not need special infrastructure can be a complement to the cartridge-based RT-PCR test can be the TB diagnostic test used in the community setting, GIDA useful in expanding case finding in communities/ household contacts 	<p>Each Chip-based RT-PCR test is estimated to cost Php 1,231.02 to Php 1,572.04. This cost includes the cost of the test kit, consumables, machine use, and human resource.</p>
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Rifampicin-Resistant Tuberculosis

<p>Cartridge-based RT-PCR test for diagnosis of</p>	<p>Recommended in the <u>DOH Omnibus Health Guidelines for Children (2023)</u>,</p>	<p>Included in the <u>World Health Organization's (WHO) Essential Medical</u></p>	<ul style="list-style-type: none"> improves TB detection in patients with very low bacterial load 	<p>Each RT-PCR test is estimated to cost Php 1,338.72. This cost</p>
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rifampicin-resistant tuberculosis (RR-TB)	<u>Adolescents (2023), Adults (2023), and Elderly (2023)</u> for tuberculosis detection in general	<p><u>Device List</u> for detection of rifampicin resistance.</p> <p>A <u>WHO Target Product Profile (TPP) for rapid tests for TB detection</u> is available.</p>	<ul style="list-style-type: none"> • allows for faster turnaround time • improves accuracy of rifampicin-resistance detection 	includes the cost of the test kit, consumables, machine use, and human resource.
<p>Chip-based Reverse Transcriptase-Polymerase Chain Reaction (RT-PCR) Test for diagnosis of rifampicin-resistant tuberculosis (RR-TB)</p>	Recommended in the <u>DOH Omnibus Health Guidelines for Children (2023), Adolescents (2023), Adults (2023), and Elderly (2023)</u> for those with positive TB diagnosis.	<p>Included in the <u>World Health Organization's (WHO) Essential Medical Device List</u> for detection of rifampicin-resistance.</p> <p>A <u>WHO Target Product Profile (TPP) for rapid tests for TB detection</u> is available.</p>	<ul style="list-style-type: none"> • battery-operated • point-of-care test • does not need special infrastructure • can be a complement to the cartridge-based RT-PCR test • can be the TB diagnostic test used in the community setting, especially in GIDA • useful in expanding case finding in communities/ household contacts 	Each Chip-based RT-PCR test is estimated to cost Php 2,128.64 to 2,762.04 . This cost includes the cost of the test kit, consumables, machine use, and human resource.
Multi-Drug Resistant Tuberculosis				
<p>Line probe assay (LPA) for diagnosis of multidrug-resistant tuberculosis (MDR-TB)</p>	Recommended in the <u>DOH Omnibus Health Guidelines (OHG) for Children (2023), DOH OHG for Adolescents (2023), DOH OHG for Adults (2023)</u> and <u>DOH OHG for Elderly (2023)</u> as additional or alternative test for susceptibility testing for	<p>included in the <u>World Health Organization's (WHO) Model List of Essential In Vitro Diagnostics (MeDevis)</u> for detection of resistance to first-line anti-TB drugs.</p> <p>A <u>WHO Target Product Profile (TPP) for next-generation drug</u></p>	<ul style="list-style-type: none"> • faster compared to conventional test • can run samples for first-line and second-line drugs simultaneously 	Each LPA is estimated to cost Php 3,542.17 . This cost includes the cost of the device, consumables, machine use, and human resource.

	diagnosis of multi-drug resistant TB	<u>susceptibility testing</u> for TB is available.		
<i>Extensively Drug-Resistant Tuberculosis</i>				
LPA for diagnosis of extensively drug-resistant tuberculosis (XDR-TB)	Recommended in the <u>DOH Omnibus Health Guidelines (OHG) for Children (2023)</u> , <u>DOH OHG for Adolescents (2023)</u> , <u>DOH OHG for Adults (2023)</u> and <u>DOH OHG for Elderly (2023)</u> as additional or alternative test for susceptibility testing for diagnosis of extensively drug resistant TB	included in the <u>World Health Organization's (WHO) Model List of Essential In Vitro Diagnostics (MeDevis)</u> for detection of resistance to first-line anti-TB drugs. A <u>WHO Target Product Profile (TPP) for next-generation drug susceptibility testing</u> for TB is available.	<ul style="list-style-type: none"> • faster compared to conventional test • can run samples for first-line and second-line drugs simultaneously 	Each LPA is estimated to cost Php 3,542.17 . This cost includes the cost of the device, consumables, machine use, and human resource.
Cartridge-based RT-PCR test for diagnosis of extensively drug-resistant tuberculosis (XDR-TB)	Recommended in the <u>DOH Omnibus Health Guidelines for Adolescents (2023)</u> , <u>DOH Omnibus Health Guidelines for Adults (2023)</u> and <u>DOH Omnibus Health Guidelines for Elderly (2023)</u> as additional test at primary and high level of care for diagnosis of extensively drug-resistant TB	Included in the <u>World Health Organization's (WHO) Essential Medical Device List</u> for detection of resistance to rifampicin and other TB drugs. A <u>WHO Target Product Profile (TPP) on a rapid test for TB detection and a TPP on next-generation DST</u> are available.	<ul style="list-style-type: none"> • faster turnaround time (< 90 minutes) for RT-PCR test versus 8 hours for LPA) 	Each RT-PCR test is estimated to cost Php 1,796.82 . This cost includes the cost of the test kit, consumables, machine use, and human resources.
<i>Active Tuberculosis in HIV-positive individuals</i>				
Lateral flow urine lipoarabinomannan	Recommended in the <u>DOH Omnibus Health Guidelines</u>	Included in the <u>World Health Organization's</u>	<ul style="list-style-type: none"> • sample collection is more convenient 	Each LF-LAM assay is estimated to cost Php

<p>assay (LF-LAM) for diagnosis of active tuberculosis infection in HIV patients</p>	<p><u>for Children (2023), Adolescents (2023), Adults (2023), Elderly (2023)</u> for HIV-positive patients</p>	<p><u>(WHO) Essential Medical Device List in seriously ill HIV-positive patients or HIV-positive adult patients in the outpatient setting with signs and symptoms of TB .</u></p> <p>A <u>WHO Target Product Profile (TPP)</u> for <u>non-sputum point-of-care test</u> for TB is available.</p>	<ul style="list-style-type: none"> ● does not have infection control risk associated with sputum-based testing ● provides a rapid, safe, and available TB test for those who: <ul style="list-style-type: none"> ○ Cannot expectorate; OR ○ Are critically ill; OR ○ With low CD4; OR ○ Present with multiple system affection 	<p>892.00. This cost includes the cost of the device, consumables, machine use, and human resource.</p>
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