CALL FOR STAKEHOLDER COMMENTS ON THE PRELIMINARY RECOMMENDATION OF THE HEALTH TECHNOLOGY ASSESSMENT (HTA) COUNCIL ON TUBERCULOSIS SCREENING AND DIAGNOSTIC TESTS

Published as of 19 June 2025

As of 19 June 2025, the Health Technology Assessment Council has completed the evidence appraisal on the assessment of the following health technologies for possible government financing:

- **Interferon gamma release ELISA assay (IGRA)** for screening of latent/ asymptomatic tuberculosis
- **Chip-based Reverse Transcriptase- Polymerase Chain Reaction (RT-PCR) Test** for diagnosis of drug-susceptible tuberculosis (DS-TB)
- **Cartridge-based RT-PCR test** for diagnosis of rifampicin-resistant tuberculosis (RR-TB)
- **Chip-based RT-PCR test** for diagnosis of RR-TB
- **Line probe assay (LPA)** for diagnosis of multidrug-resistant tuberculosis (MDR-TB)
- **LPA** for diagnosis of extensively drug-resistant tuberculosis (XDR-TB)
- **Cartridge-based RT-PCR test** for diagnosis of XDR-TB
- **Lateral flow urine lipoarabinomannan assay (LF-LAM)** for diagnosis of active tuberculosis infection in human immunodeficiency virus (HIV) patients

The HTA Council hereby releases its **preliminary recommendation** on the said health technologies **for stakeholder feedback and comments from 19 June (Thursday) to 04 July (Friday) 2025.**

These health technologies were reviewed against clinical practice guidelines (CPGs) *[local and approved by the DOH, such as the DOH Omnibus Health Guidelines (OHG); and/or international, but locally adopted guidelines*], and existing recommendations by the World Health Organization (WHO). Further, costing analyses of these health technologies were performed. The specific recommendations and the supporting evidence reviewed and considered by the HTA Council are shown in ***Annex A***.

Health Technology		Preliminary HTAC Recommendation *(Further details in Annex A)*
Latent/Asymptomatic Tuberculosis		
1	**Interferon gamma release ELISA assay (IGRA)** for	**Positive** recommendation for the screening of **latent/asymptomatic tuberculosis.**

	screening of latent/ asymptomatic tuberculosis	IGRA is a standard of care test for screening of latent/asymptomatic tuberculosis based on the DOH Omnibus Health Guidelines (OHG) for Children (2023), DOH OHG for Adolescents (2023), DOH OHG for Adults (2023), DOH OHG for Elderly (2023) and the DOH Tuberculosis Manual of Procedure 6th Edition for eligible individuals prior to TB treatment ***except*** for the following: ● *People living with HIV* ● *Children less than 5 years old (yo) who are household contacts of bacteriologically confirmed pulmonary tuberculosis (PTB)* ● *Individuals aged 5 yo and older who are household contacts of bacteriologically confirmed PT and with other TB risk factors* IGRA is included in the World Health Organization's (WHO) Essential Medical Device List. Currently, the WHO has no target product profile for this health technology. Per the DOH Department Circular No.2025–018 or the Interim Guidelines on the Use of IGRA for detecting TB, either IGRA or TST can be utilized for TB infection testing, particularly in high-risk groups, as aligned with the WHO Guideline. With this, consultation with the National Tuberculosis Program noted that IGRA will serve as a supplemental screening test for latent/asymptomatic TB in health facilities. Each run of the IGRA assay has an estimated cost of **Php 2,924.23.** The cost includes reagents, consumables, and human resource costs. Meanwhile, TST is estimated to cost **Php 650.00**. While it is more costly than the TST, the HTA Council considers the following: ● IGRA can serve as an alternative test for TST, considering previous supply issues encountered with TST ● While both IGRA and TST have comparable sensitivity, IGRA had a marginally higher specificity compared to TST **(**2021 Philippine CPG for the Diagnosis and Treatment of Adult Tuberculosis) ● IGRA is more objective (i.e., not operator-dependent) ● IGRA requires a single patient visit compared to TST, which requires two to three visits. This can be equated to less direct non-medical costs (e.g., transportation cost to the facility) and indirect costs (i.e., productivity loss) ● IGRA has a faster turnaround time ● IGRA can be applied to identify patients for preventive TB treatment However, the HTA Council also notes that training human resources for the implementation of IGRA is needed.
Drug Susceptible Tuberculosis		
2	**Chip-based Reverse Transcriptase-Polymerase Chain Reaction (RT-PCR) Test** for diagnosis of drug-susceptible tuberculosis (DS-TB)	**Positive** recommendation for the **diagnosis of drug-susceptible tuberculosis.** Chip-based RT-PCR test is a standard of care diagnostic test for drug-susceptible TB based on the DOH Omnibus Health Guidelines for Children (2023), Adolescents (2023), Adults (2023), and Elderly (2023) as alternative to smear microscopy. Further, Chip-based RT-PCR test is included in the World Health Organization's (WHO) Essential Medical Device List for diagnosis of active TB. A WHO Target Product Profile (TPP) for rapid tests for TB detection is available which can be used as reference for selecting RT-PCR tests for procurement. On top of compliance to the TPP, the HTA Council notes

		that in choosing, technology with the higher sensitivity is preferred for procurement since it will be used primarily for screening. The key features of Chip-based RT-PCR test which sets it apart from the current RT-PCR test (Cartridge-based) being implemented, is that it is a battery-operated, point-of-care test which does not need special infrastructure. This allows it to be a complement to the cartridge-based RT-PCR test. It can be the TB diagnostic test used in the community setting, especially in Geographically Isolated and Disadvantaged Areas (GIDA). It is also specifically useful in expanding case finding in communities/ household contacts. 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.
Rifampicin- Resistant Tuberculosis		
3	**Cartridge-based RT-PCR test** for diagnosis of rifampicin-resistant tuberculosis (RR-TB)	**Positive** recommendation for the **diagnosis of rifampicin-resistant tuberculosis.** Cartridge-based RT-PCR test is a standard of care diagnostic test for tuberculosis detection in general based on the DOH Omnibus Health Guidelines for Children (2023), Adolescents (2023), Adults (2023), and Elderly (2023). Further, the cartridge-based RT-PCR test is included in the World Health Organization's (WHO) Essential Medical Device List for detection of rifampicin resistance. A WHO Target Product Profile (TPP) for rapid tests for TB detection is available which can be used as reference for selecting RT-PCR tests for procurement. Cartridge-based RT-PCR test is the currently implemented health technology for the diagnosis of RR-TB. Each RT-PCR test is estimated to cost **Php 1,338.72.** This cost includes the cost of the test kit, consumables, machine use, and human resource.
4	**Chip-based Reverse Transcriptase-Polymerase Chain Reaction (RT-PCR) Test** for diagnosis of rifampicin-resistant tuberculosis (RR-TB)	**Positive** recommendation for the **diagnosis of rifampicin-resistant tuberculosis.** Chip-based RT-PCR test is a standard of care diagnostic test for rifampicin-resistant TB based on the DOH Omnibus Health Guidelines for Children (2023), Adolescents (2023), Adults (2023), and Elderly (2023) for those with positive TB diagnosis. Further, Chip-based RT-PCR test is included in the World Health Organization's (WHO) Essential Medical Device List for detection of rifampicin-resistance. A WHO Target Product Profile (TPP) for rapid tests for TB detection is available which can be used as reference for selecting RT-PCR tests for procurement. The key features of Chip-based RT-PCR test which sets it apart from the current RT-PCR test (Cartridge-based) being implemented, is that it is a battery-operated, point-of-care test which does not need special infrastructure. This allows it to be a complement to the cartridge-based RT-PCR test. It can be the TB diagnostic test used in the community setting, especially in GIDA. It is also specifically useful in expanding case finding in communities/ household contacts.

		Each Chip-based RT-PCR test is estimated to cost **Php 2,128.64 to 2,762.94.** This cost includes the cost of the test kit, consumables, machine use, and human resource.
Multidrug-Resistant Tuberculosis		
5	**Line probe assay (LPA)** for diagnosis of multidrug-resistant tuberculosis (MDR-TB)	**Positive** recommendation for the **diagnosis of multidrug-resistant tuberculosis.** LPA is a standard of care diagnostic test for multidrug-resistant TB based on the DOH Omnibus Health Guidelines (OHG) for Children (2023), DOH OHG for Adolescents (2023), DOH OHG for Adults (2023) and DOH OHG for Elderly (2023) as additional or alternative test for susceptibility testing. Further, LPA is included in the World Health Organization's (WHO) Model List of Essential In Vitro Diagnostics (MeDevis) for detection of resistance to first-line anti-TB drugs. A WHO Target Product Profile (TPP) for next-generation drug susceptibility testing for TB is available which can be used as reference for selecting drug susceptibility tests for procurement. LPA is the currently implemented health technology for the diagnosis of MDR-TB using donated supplies. The key features of LPA which sets it apart from the conventional test (mycobacterial culture and phenotypic drug susceptibility test), is that it is faster (LPA takes 8 hours compared to conventional test which can take 2-12 weeks) and 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.
Extensively Drug-Resistant Tuberculosis		
6	**LPA** for diagnosis of extensively drug-resistant tuberculosis (XDR-TB)	**Positive** recommendation for the **diagnosis of extensively drug-resistant tuberculosis.** LPA is a standard of care diagnostic test for extensively drug resistant TB based on the DOH Omnibus Health Guidelines (OHG) for Children (2023), DOH OHG for Adolescents (2023), DOH OHG for Adults (2023) and DOH OHG for Elderly (2023) as additional or alternative test for susceptibility testing. Further, LPA is included in the World Health Organization's (WHO) Model List of Essential In Vitro Diagnostics (MeDevis) for detection of second-line anti-TB drugs. A WHO Target Product Profile (TPP) for next-generation drug susceptibility testing (DST) for TB is available which can be used as reference for selecting drug susceptibility tests for procurement. LPA is the currently implemented health technology for the diagnosis of XDR-TB using donated supplies. The key features of LPA which sets it apart from the conventional test (mycobacterial culture and phenotypic drug susceptibility testing), are its faster turnaround time (LPA takes 8 hours compared to 2-12 weeks for conventional test) and its ability to run samples simultaneously to test for resistance to both first line and second line drugs. Each LPA is estimated to cost **Php 3,542.17.** This cost includes the cost of the device, consumables, machine use, and human resource.

7	**Cartridge-based RT-PCR test** for diagnosis of extensively drug-resistant tuberculosis (XDR-TB)	**Positive** recommendation for the **diagnosis of extensively drug-resistant tuberculosis.** Cartridge-based RT-PCR test is a standard of care diagnostic test for tuberculosis detection in general based on the DOH Omnibus Health Guidelines for Adolescents (2023), DOH Omnibus Health Guidelines for Adults (2023) and DOH Omnibus Health Guidelines for Elderly (2023) as additional test at primary and high level of care. Further, the cartridge-based RT-PCR test is included in the World Health Organization's (WHO) Essential Medical Device List for detection of resistance to rifampicin and other TB drugs. A WHO Target Product Profile (TPP) on a rapid test for TB detection and a TPP on next-generation DST are available which can be used as reference for selecting RT-PCR tests for procurement. The key feature of cartridge-based RT-PCR test which sets it apart from the current assay being implemented (LPA) is its faster turnaround time (< 90 minutes) for RT-PCR test versus 8 hours for LPA. However, this test will require a specific system to run. 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.
Active Tuberculosis Infection in HIV patients		
8	**Lateral flow urine lipoarabinomannan assay (LF-LAM)** for diagnosis of active tuberculosis infection in HIV patients	**Positive** recommendation for the **diagnosis of active tuberculosis infection in HIV patients** LF-LAM is a standard of care diagnostic test for HIV-positive patients based on the DOH Omnibus Health Guidelines for Children (2023), Adolescents (2023), Adults (2023), Elderly (2023), and WHO Policy Guidance on LF-LAM (2015). Further, LF-LAM is included in the World Health Organization's (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 . A WHO Target Product Profile (TPP) for non-sputum point-of-care test for TB is available, which can be used as a reference for selecting RT-PCR tests for procurement. The key features of LF-LAM, which set it apart from the conventional chest x-ray and currently implemented cartridge-based RT-PCR tests, are that sample collection is more convenient and it does not have the infection control risk associated with sputum-based testing. It provides a rapid, safe, and available TB test for those who: - Cannot expectorate; OR - Are critically ill; OR - With low CD4; OR - Present with multiple system affection Each LF-LAM assay is estimated to cost **Php 892.00.** This cost includes the cost of the device, consumables, machine use, and human resource.

The HTA Council recommends that the Department of Health refer to **existing and future WHO target product profiles (TPPs)** when selecting tests for procurement. In the absence of target product profiles, WHO prequalification may be used as a requirement to ensure the quality of the test to be procured.

All comments, inputs, and/or appeals on the above preliminary recommendation may be submitted until **04 July 2025** (Friday), for the consideration of the HTA Council, through email at hta@dost.gov.ph.

Please use the prescribed form for appeals indicated on the official HTA Philippines website [https://hta.dost.gov.ph/appeals-2/]. **Appeals not following the prescribed format, and those submitted beyond the deadline shall not be entertained**.

Should you have any questions or concerns regarding the preliminary recommendation, please do not hesitate to contact us through the same email address or via telephone call at (02) 8837-2071 local 4100.

Thank you very much and best regards.

On behalf of the HTA Philippines:

ANNE JULIENNE G. MARFORI, RPh, MSc
Division Chief, HTA Division

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Chairperson, HTA Council

Annex A. Summary of Evidence for the Preliminary Recommendation of Priority Topics

Health Technology	CPG Recommendation	WHO Recommendation	Key Features	Costing
Latent/ Asymptomatic Tuberculosis				
Interferon gamma release ELISA assay (IGRA) for screening of latent/ asymptomatic tuberculosis	**Recommended** in the DOH Omnibus Health Guidelines (OHG) for Children (2023), DOH OHG for Adolescents (2023), DOH OHG for Adults (2023), DOH OHG for Elderly (2023) for screening of latent/ asymptomatic tuberculosis In the DOH Tuberculosis Manual of Procedure 6th Edition for individuals prior to TB treatment *except* for the following: ● *People living with HIV* ● *Children less than 5 years old (yo) who are household contacts of bacteriologically confirmed pulmonary tuberculosis (PTB)* ● *Individuals aged 5 yo and older who are household contacts of bacteriologically*	Included in the World Health Organization's (WHO) Essential Medical Device List. No WHO target product profile for this health technology.	● 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 (2021 Philippine CPG for the Diagnosis and Treatment of Adult Tuberculosis) ● 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 (e.g.transportation cost to the facility)	Each run of the IGRA assay has an estimated cost of **Php 2,924.23.** The cost includes reagents, consumables, and human resource costs.

	confirmed PT and with other TB risk factors		and indirect costs (i.e. productivity loss) • faster turnaround time • can be applied to identify patients for preventive TB treatment • training human resources is needed	
Drug Susceptible Tuberculosis				
Chip-based Reverse Transcriptase-Polymerase Chain Reaction (RT-PCR) Test for diagnosis of drug-susceptible tuberculosis (DS-TB)	**Recommended** in the DOH Omnibus Health Guidelines for Children (2023), Adolescents (2023), Adults (2023), and Elderly (2023) as an alternative to smear microscopy for diagnosis of drug-susceptible TB	Included in the World Health Organization's (WHO) Essential Medical Device List for diagnosis of active TB. A WHO Target Product Profile (TPP) for rapid tests for TB detection is available.	• 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	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.
Rifampicin-Resistant Tuberculosis				

Cartridge-based RT-PCR test for diagnosis of rifampicin-resistant tuberculosis (RR-TB)	Recommended in the DOH Omnibus Health Guidelines for Children (2023), Adolescents (2023), Adults (2023), and Elderly (2023) for tuberculosis detection in general	Included in the World Health Organization's (WHO) Essential Medical Device List for detection of rifampicin resistance. A WHO Target Product Profile (TPP) for rapid tests for TB detection is available.	• improves TB detection in patients with very low bacterial load • allows for faster turnaround time • improves accuracy of rifampicin-resistance detection	Each RT-PCR test is estimated to cost **Php 1,338.72.** This cost includes the cost of the test kit, consumables, machine use, and human resource.
Chip-based Reverse Transcriptase-Polymerase Chain Reaction (RT-PCR) Test for diagnosis of rifampicin-resistant tuberculosis (RR-TB)	Recommended in the DOH Omnibus Health Guidelines for Children (2023), Adolescents (2023), Adults (2023), and Elderly (2023) for those with positive TB diagnosis.	Included in the World Health Organization's (WHO) Essential Medical Device List for detection of rifampicin-resistance. A WHO Target Product Profile (TPP) for rapid tests for TB detection is available.	• 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 2,762.94.** This cost includes the cost of the test kit, consumables, machine use, and human resource.
Multi-Drug Resistant Tuberculosis				
Line probe assay (LPA) for diagnosis of	Recommended in the DOH Omnibus Health Guidelines (OHG) for	included in the World Health Organization's (WHO) Model List of	• faster compared to conventional test	Each LPA is estimated to cost **Php 3,542.17.** This cost includes the cost of

multidrug-resistant tuberculosis (MDR-TB)	Children (2023), DOH OHG for Adolescents (2023), DOH OHG for Adults (2023) and DOH OHG for Elderly (2023) as additional or alternative test for susceptibility testing for diagnosis of multi-drug resistant TB	Essential In Vitro Diagnostics (MeDevis) for detection of resistance to first-line anti-TB drugs. A WHO Target Product Profile (TPP) for next-generation drug susceptibility testing for TB is available.	• can run samples for first-line and second-line drugs simultaneously	the device, consumables, machine use, and human resource.
Extensively Drug-Resistant Tuberculosis				
LPA for diagnosis of extensively drug-resistant tuberculosis (XDR-TB)	Recommended in the DOH Omnibus Health Guidelines (OHG) for Children (2023), DOH OHG for Adolescents (2023), DOH OHG for Adults (2023) and DOH OHG for Elderly (2023) as additional or alternative test for susceptibility testing for diagnosis of extensively drug resistant TB	included in the World Health Organization's (WHO) Model List of Essential In Vitro Diagnostics (MeDevis) for detection of resistance to first-line anti-TB drugs. A WHO Target Product Profile (TPP) for next-generation drug susceptibility testing for TB is available.	• 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 DOH Omnibus Health Guidelines for Adolescents (2023), DOH Omnibus Health Guidelines for Adults (2023) and DOH Omnibus Health Guidelines for Elderly (2023) as additional test at primary and high level of care for diagnosis of extensively	Included in the World Health Organization's (WHO) Essential Medical Device List for detection of resistance to rifampicin and other TB drugs. A WHO Target Product Profile (TPP) on a rapid test for TB detection and a TPP on next-generation DST are available.	• 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.

	drug-resistant TB			
Active Tuberculosis in HIV-positive individuals				
Lateral flow urine lipoarabinomannan assay (LF-LAM) for diagnosis of active tuberculosis infection in HIV patients	Recommended in the DOH Omnibus Health Guidelines for Children (2023), Adolescents (2023), Adults (2023), Elderly (2023) for HIV-positive patients	Included in the World Health Organization's (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 . A WHO Target Product Profile (TPP) for non-sputum point-of-care test for TB is available.	• sample collection is more convenient • does not have infection control risk associated with sputum-based testing • provides a rapid, safe, and available TB test for those who: ○ Cannot expectorate; OR ○ Are critically ill; OR ○ With low CD4; OR ○ Present with multiple system affection	Each LF-LAM assay is estimated to cost **Php 892.00.** This cost includes the cost of the device, consumables, machine use, and human resource.