



Republic of the Philippines

DEPARTMENT OF SCIENCE AND TECHNOLOGY



CALL FOR STAKEHOLDER COMMENTS ON THE PRELIMINARY RECOMMENDATION OF THE HEALTH TECHNOLOGY ASSESSMENT (HTA) COUNCIL ON HUMAN IMMUNODEFICIENCY VIRUS (HIV) SELF TEST KIT, HIV/SYPHILIS DUO TEST, IN VITRO QUANTITATIVE HIV NUCLEIC ACID TEST (HIV-NAT 1), AND SILVER DIAMINE FLUORIDE 38% CLEAR TOPICAL SOLUTION

Published as of 26 May 2025

As of 26 May 2025, the Health Technology Assessment Council has completed the evidence appraisal on the assessment of the following health technologies for possible government financing:

- **HIV Self Test Kit** for screening of HIV infection in adults belonging to HIV and sexually transmitted infection key populations
- **HIV/Syphilis Duo Test** for screening of HIV and Syphilis infection in pregnant women as part of antenatal care, ideally during the first trimester
- **In Vitro Quantitative HIV Nucleic Acid Test (HIV-NAT 1)** for screening and diagnosis of HIV type 1 (HIV-1) infection in HIV-exposed infants and children
- **Silver Diamine Fluoride 38% Clear Topical Solution** for prevention and arrest of dentine caries in primary and permanent teeth among children 12 months to 10 years old

The HTA Council hereby releases its preliminary recommendation on the said health technologies **for stakeholder feedback and comments from 26 May (Monday) to 10 June (Tuesday) 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)
1	HIV Self Test Kit for screening of HIV infection in adults belonging to HIV and sexually transmitted	Positive recommendation for the screening of HIV infection in adults belonging to HIV and sexually transmitted infection key populations* HIV Self Test Kit is a standard of care based on the DOH Omnibus Health Guidelines for Adults (2023) , and DOH Omnibus Health Guidelines for Elderly (2023) as an approach to HIV testing. Likewise,

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	infection key populations	<p>the WHO Model List of Essential In Vitro Diagnostics (2022) recommends HIV self-testing to screen for or to aid in the diagnosis of HIV infection in adults.</p> <p>In selecting HIV self-tests for procurement, the WHO prequalification can be used as a technical specification as the WHO currently has no target product profile for this health technology.</p> <p>The HTAC also emphasizes that the reporting of self-test results must be ensured to facilitate appropriate follow-up services, including confirmatory testing and linkage to care.</p> <p>Each blood-based self-test kit's estimated cost is Php 400.00, which is good for 1 test. The test kit includes all materials needed to conduct the test.</p> <p><i>*key populations including:</i></p> <ul style="list-style-type: none"> • <i>Adolescents</i> • <i>high-risk individuals who have not been tested recently</i> • <i>partners, infants and children of people living with HIV</i> • <i>patients showing signs and symptoms consistent with AIDS defining illness</i> • <i>patients with sexually transmitted infections</i> • <i>patients with Hepatitis B and C</i> • <i>patients with undernutrition not responsive to interventions</i> • <i>all confirmed tuberculosis patients</i> • <i>all pregnant women regardless of risk;</i> • <i>MSM;</i> • <i>people in prisons and other closed settings;</i> • <i>people who inject drugs;</i> • <i>sex workers;</i> • <i>transgender men and women</i>
2	HIV/Syphilis Duo Test for screening of HIV and Syphilis infection in pregnant women as part of antenatal care, ideally during the first trimester	<p>Positive recommendation for the screening of HIV and Syphilis infection in pregnant women as part of antenatal care, ideally during the first trimester</p> <p>HIV/Syphilis Duo Test is a standard of care for screening of both HIV and Syphilis infection based on the WHO Model List of Essential In Vitro Diagnostics (2022). Further, the 2019 WHO Policy Brief on Dual HIV/Syphilis Rapid Diagnostic Test recommends this health technology as the first test in antenatal care setting.</p> <p>It was noted that the WHO developed a target product profile for combined and single point-of-care test for syphilis (WHO Point-of-care tests for sexually transmitted infections target product profile, 2023) which can be used as reference in the selection of HIV/Syphilis tests.</p> <p>Each test kit's estimated cost is Php 6,500.00, which is good for 25 tests, resulting in an estimated cost of Php 260.00 per test kit. Human resource cost may range from Php 63.00 - 84.00, bringing the total cost per test at Php 323.00 - 344.00.</p>
3	In Vitro Quantitative HIV Nucleic Acid Test (HIV-NAT 1) for screening and diagnosis of HIV type 1 (HIV-1) infection in	<p>Positive recommendation for the screening and diagnosis of HIV-1 infection in HIV-exposed infants and children</p> <p>In Vitro Quantitative HIV Nucleic Acid Test (HIV-NAT 1) is a standard of care for both screening and diagnosis of HIV-1 infection in infants aged <18 months based on the DOH Omnibus Health Guidelines for</p>

HIV-exposed infants and children	<p><u>Children (2023)</u> [See Annex A for algorithm for screening and diagnosis]. The <u>WHO Consolidated Guidelines on HIV Prevention, Testing, Treatment, Service Delivery and Monitoring (2021)</u> also recommends this health technology for the same indication. In selecting in vitro quantitative nucleic acid test for procurement, the <u>WHO prequalification</u> can be used as a technical specification as the WHO currently has no target product profile for this health technology.</p> <p>Each test's estimated cost based on quotation from two brands ranges from Php 850.61 (COBAS 5800) to Php 1,596.45 (Cepheid's Xpert HIV-1 Viral Load XC test), which is inclusive of the cost of leasing and using the machine, reagents, consumables, human resource, service surcharge, instrument surcharge, and supply chain surcharge.</p>
<p>4 Silver Diamine Fluoride 38% Clear Topical Solution for prevention and arrest of dentine caries in primary and permanent teeth among children 12 months to 10 years old</p>	<p>Positive recommendation for prevention and arrest of dentine caries in primary and permanent teeth among children 12 months to 10 years old</p> <p>Silver Diamine Fluoride 38% Clear Topical Solution is a standard of care to prevent and/or treat dental caries based on the DOH Omnibus Health Guidelines for Children (2023) and DOH Omnibus Health Guidelines for Adolescents (2023). Further, this health technology is included in the WHO Essential Medicines List for the same indication.</p> <p>The HTA Council noted that there are no severe and adverse health outcomes. However, the application of silver diamine fluoride results in a black stain on the arrested dentine caries lesion, which may cause aesthetic concerns. Despite this, the HTA Council noted that the benefits of silver diamine fluoride outweigh this concern.</p> <p>Each Silver Diamine Fluoride kit's estimated cost is Php 3,000.00, which can cover 50 patients, resulting in an estimated cost of Php 60.00 per patient. This estimated cost includes one 5-mL bottle of 38% Silver Diamine Fluoride and consumables.</p>

The HTA Council strongly recommends that implementation of HIV health technologies should follow the [WHO testing strategy for HIV diagnosis](#) (i.e., serial assay testing) to ensure that HIV cases are detected within the HIV diagnosis window period. Additionally, it should be coupled with information dissemination and awareness campaigns, with clear messaging pointing out the advantages and disadvantages of the test. Information on the specific use cases of these tests, especially among other populations for whom the test may be made accessible (e.g., individuals with tuberculosis but without HIV, or pregnant women without HIV) must be made clear to prevent misinterpretation, reduce stigma, and specifically for HIV self test kit, encourage reporting of results. Further, the HTA Council highlights the importance of informed consent for the implementation of these tests.

In addition to this, 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 **10 June 2025** (Tuesday), 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:



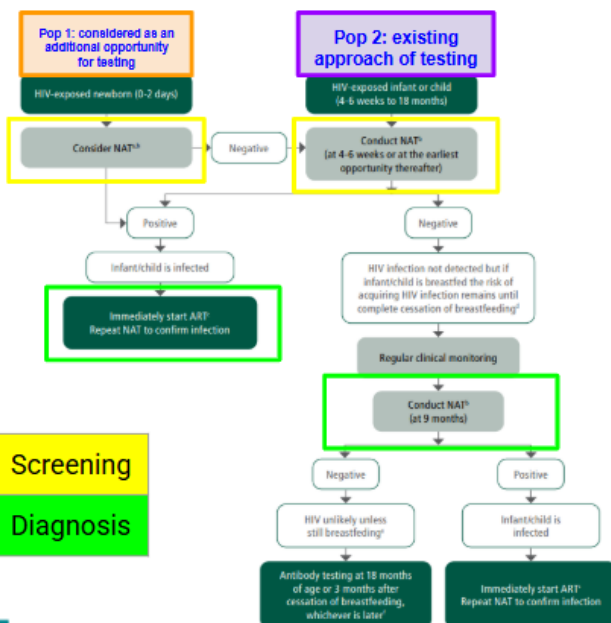
ANNE JULIENNE C. MARFORI, RPh, MSc
Division Chief, HTA Division



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Chairperson, HTA Council

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

Health technology	Clinical Practice Guidelines	WHO recommendation	Costing																												
HIV Self Test Kit for screening of HIV infection in adults belonging to HIV and sexually transmitted infection key populations	Recommended in the DOH Omnibus Health Guidelines for Adults (2023) , and DOH Omnibus Health Guidelines for Elderly (2023) <i>“HIV self-testing, with rapid diagnostic test kits, should be offered as an approach to HIV testing services (Strong recommendation)”</i>	Included in the WHO Model List of Essential In Vitro Diagnostics (2022) <table><tr><th colspan="7">I.b. Disease-specific IVDs recommended for use in community settings and health facilities without laboratories</th></tr><tr><th>Disease</th><th>IVD test</th><th>Test purpose</th><th>Assay format</th><th>Specimen type</th><th>WHO prequalified or recommended products</th><th>WHO supporting documents</th></tr><tr><td rowspan="2">HIV infection</td><td rowspan="2">Antibodies to HIV 1/2 (anti-HIV Ab)</td><td>HIV self-testing to aid in the diagnosis of HIV infection</td><td>RTD</td><td>Oral fluid Capillary whole blood</td><td rowspan="2">Public reports of WHO prequalified IVDs https://extranet.who.int/qaqs/extra-diagnostic/prequalification-reports/whoqr/field_whoqr...category=60</td><td rowspan="2">Guidelines on HIV and partner notification supplement to consolidated guidelines on HIV test services (2016) https://apps.who.int/iris/handle/10665/231605 Consolidated guidelines testing services (2018) https://apps.who.int/iris/handle/10665/246300</td></tr><tr><td>To screen for or to aid in the diagnosis of HIV infection: adults, adolescents, children and infants > 18 months of age</td><td>RTD</td><td>Oral fluid Capillary whole blood Venous whole blood¹</td></tr></table>	I.b. Disease-specific IVDs recommended for use in community settings and health facilities without laboratories							Disease	IVD test	Test purpose	Assay format	Specimen type	WHO prequalified or recommended products	WHO supporting documents	HIV infection	Antibodies to HIV 1/2 (anti-HIV Ab)	HIV self-testing to aid in the diagnosis of HIV infection	RTD	Oral fluid Capillary whole blood	Public reports of WHO prequalified IVDs https://extranet.who.int/qaqs/extra-diagnostic/prequalification-reports/whoqr/field_whoqr...category=60	Guidelines on HIV and partner notification supplement to consolidated guidelines on HIV test services (2016) https://apps.who.int/iris/handle/10665/231605 Consolidated guidelines testing services (2018) https://apps.who.int/iris/handle/10665/246300	To screen for or to aid in the diagnosis of HIV infection: adults, adolescents, children and infants > 18 months of age	RTD	Oral fluid Capillary whole blood Venous whole blood ¹	Each self-test kit's estimated cost is Php 400.00 , which is good for 1 test. The test kit includes all materials needed to conduct the test.				
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HIV/Syphilis Duo Test for screening of HIV and Syphilis infection in pregnant women as part of antenatal care, ideally during the first trimester	Recommended in the DOH Omnibus Health Guidelines for Adults (2023) Antenatal care includes the following: <i>Complete general and obstetrical examination, including:</i> <ul style="list-style-type: none">■ <i>vital signs</i>■ <i>weight gain based on pre-pregnant weight</i>■ <i>oral health check-up and prophylaxis</i>■ <i>screening for cigarette smoking, alcohol use, substance abuse, psychosocial risk factors, depression and exposure to violence, HIV and syphilis</i>■ <i>assessment of significant signs and symptoms</i>	Included in the WHO Model List of Essential In Vitro Diagnostics (2022) <table><tr><th colspan="7">I.b. Disease-specific IVDs recommended for use in community settings and health facilities without laboratories continued</th></tr><tr><th>Disease</th><th>IVD test</th><th>Test purpose</th><th>Assay format</th><th>Specimen type</th><th>WHO prequalified or recommended products</th><th>WHO supporting documents</th></tr><tr><td>Syphilis</td><td>Antibodies to Treponema pallidum</td><td>To diagnose or to aid in the diagnosis of T. pallidum</td><td>RTD</td><td>Capillary whole blood Venous whole blood¹</td><td>N/A</td><td>Laboratory diagnosis of sexually transmitted infections, including human immunodeficiency virus (2013) https://apps.who.int/iris/handle/10665/83343 https://www.who.int/news-room/fact-sheets/detail/sexually-transmitted-infections-stis</td></tr><tr><td></td><td>Combined antibodies to T. pallidum and HIV 1/2</td><td>To diagnose or to aid in the diagnosis of HIV 1/2 and/or T. pallidum</td><td>RTD</td><td>Capillary whole blood Venous whole blood¹</td><td>Public reports of WHO prequalified IVDs https://extranet.who.int/qaqs/extra-diagnostic/prequalification-reports/whoqr/field_whoqr...category=32</td><td>WHO information note on the use of dual HIV/syphilis rapid diagnostic tests (RDT) (2017) http://apps.who.int/iris/handle/10665/232845 Consolidated guidelines on HIV prevention, diagnosis, treatment and care for key populations (2016 update) https://apps.who.int/iris/handle/10665/246300</td></tr></table>	I.b. Disease-specific IVDs recommended for use in community settings and health facilities without laboratories continued							Disease	IVD test	Test purpose	Assay format	Specimen type	WHO prequalified or recommended products	WHO supporting documents	Syphilis	Antibodies to Treponema pallidum	To diagnose or to aid in the diagnosis of T. pallidum	RTD	Capillary whole blood Venous whole blood ¹	N/A	Laboratory diagnosis of sexually transmitted infections, including human immunodeficiency virus (2013) https://apps.who.int/iris/handle/10665/83343 https://www.who.int/news-room/fact-sheets/detail/sexually-transmitted-infections-stis		Combined antibodies to T. pallidum and HIV 1/2	To diagnose or to aid in the diagnosis of HIV 1/2 and/or T. pallidum	RTD	Capillary whole blood Venous whole blood ¹	Public reports of WHO prequalified IVDs https://extranet.who.int/qaqs/extra-diagnostic/prequalification-reports/whoqr/field_whoqr...category=32	WHO information note on the use of dual HIV/syphilis rapid diagnostic tests (RDT) (2017) http://apps.who.int/iris/handle/10665/232845 Consolidated guidelines on HIV prevention, diagnosis, treatment and care for key populations (2016 update) https://apps.who.int/iris/handle/10665/246300	Each test kit's estimated cost is Php 6,500.00, which is good for 25 tests, resulting in an estimated cost of Php 260.00 per test kit. Human resource cost may range from Php 63.00 - 84.00, bringing the total cost per test at Php 323.00 - 344.00 .
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In Vitro Quantitative HIV Nucleic Acid Test (HIV-NAT 1) for screening and diagnosis of HIV type 1 (HIV-1) infection in HIV-exposed infants and children	Recommended in the DOH Omnibus Health Guidelines for Children (2023) <ul style="list-style-type: none">● Offer nucleic acid testing (NAT) at or around birth (0–2 days) among HIV-exposed infants● Screen infants < 18 months of age with virologic assays (e.g., HIV RNA, HIV DNA NAT) depending on risk of perinatal or postnatal exposure, or breastfeeding status	Recommended in the WHO Consolidated Guidelines on HIV Prevention, Testing, Treatment, Service Delivery and Monitoring (2021) : <i>The addition of nucleic acid testing (NAT) at birth to existing early infant diagnosis testing approaches can be considered to identify HIV infection in HIV-exposed infants (conditional recommendation, low-certainty)</i>	Each test's estimated cost based on quotation from two brands ranges from Php 850.61 (COBAS 5800) to Php 1,596.45 (Cepheid's Xpert HIV-1 Viral Load XC test), which is inclusive of the cost of leasing and using the machine, reagents, consumables, human resource, service surcharge, instrument																												



Note: This algorithm is from WHO

evidence).

surcharge, and supply chain surcharge.

Silver Diamine Fluoride 38% Clear Topical Solution for prevention and arrest of dentine caries in primary and permanent teeth among children 12 months to 10 years old

Recommended in the [DOH Omnibus Health Guidelines for Children \(2023\)](#) and [DOH Omnibus Health Guidelines for Adolescents \(2023\)](#)

Primary care providers shall perform the following to ensure the safety of newborns and children:

- Provide the following appropriate dental interventions to prevent and/or treat dental caries but not limited:
 - Silver diamine fluoride application non-restorative treatment, arresting untreated dentin caries

Included in the [WHO Essential Medicines List](#)



Each Silver Diamine Fluoride kit's estimated cost is **Php 3,000.00**, which can cover 50 patients, resulting in an estimated cost of **Php 60.00** per patient. This cost includes one 5-mL bottle of 38% Silver Diamine Fluoride and consumables.