WHO Recommendations on TB Diagnosis (2026 Update)

Testing & Diagnostics Team
Department for HIV, TB, Hepatitis, and STIs

Accelerating Progress Towards ending TB in the WHO African Region
Addis Ababa, Ethiopia 23-25, June 2026

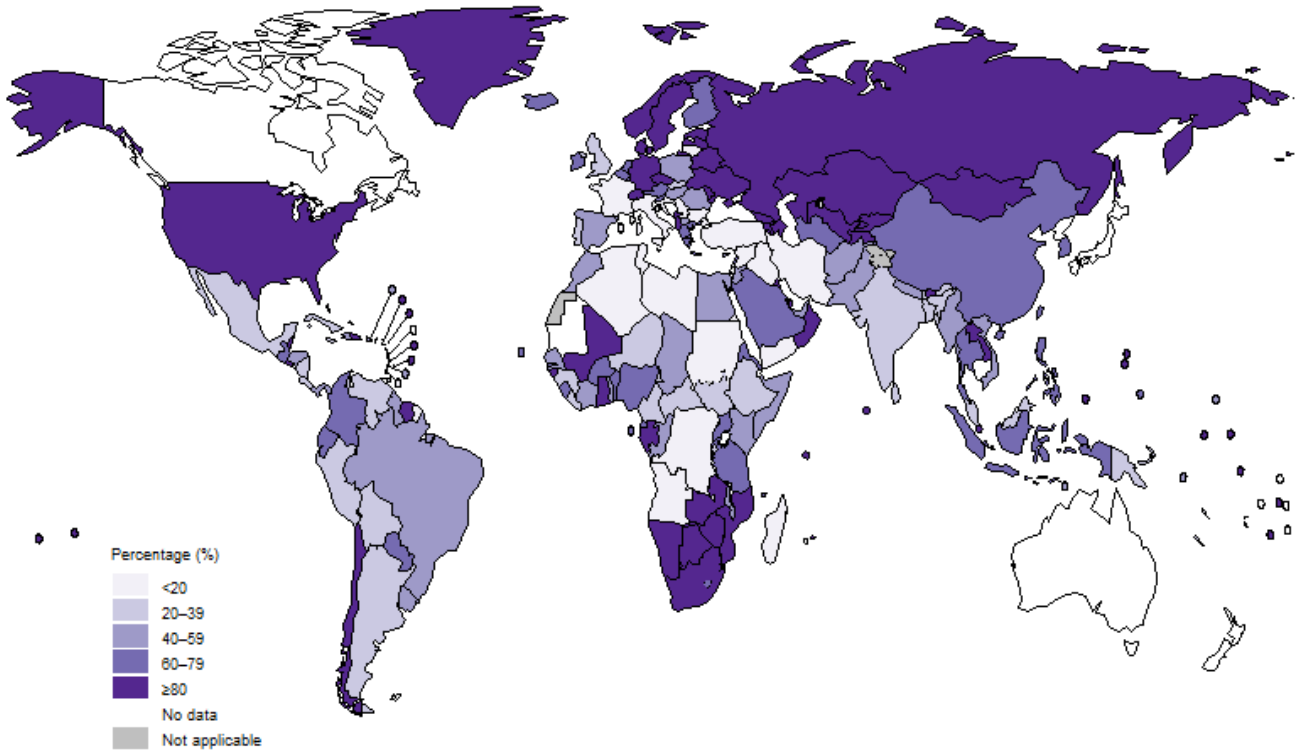
World Health Organization

Global Data Highlight Opportunities for TB Testing

WHO Global TB Report

- *~1/4 World Infected*
- *~10.8M Incident cases*
- *~8.2M Notified cases*
  - *48% notified cases tested with a WHO-recommended diagnostic*
- *~400,000 MDR/RR TB cases*
- *<50% DR-TB cases diagnosed*

Percentage of people newly diagnosed with TB initially tested with a WHO-recommended diagnostic test



[Global Tuberculosis Report 2024]

Guideline Development is a Core WHO Function

"The World Health Organization (WHO) is distinguished, compared to other global health organizations, by its unique mandate to provide independent, evidence-based normative products to improve public health and well-being."

Guideline development at WHO

Why and How Does WHO Develop Guidelines?

- To provide policy makers, practitioners and patients with clear guidance on an appropriate course of action (whether an intervention, practice, policy, medical device, diagnostic)
- Based on internationally recognized methods and standards for guideline development to ensure that its guidelines are of the highest quality
- Implementing robust WHO Conflict of Interest policy

Classes of tests for detection of TB, DR TB and TBI included in the current guidelines

Technology class	TB	RIF R	INH R	FQ R	Other R	TBI
Tests for diagnosis of tuberculosis (TB) or TB drug resistance (or both)						
Point-of-care antigen detection in a lateral flow format (biomarker-based detection) (LF-LAM)	X					
NEW: Near point-of-care nucleic acid amplification tests (NPOC-NAATs)	X					
UPDATED: Low-complexity automated nucleic acid amplification tests (LC-aNAATs)	X	X	X	X	X	
Low-complexity manual nucleic acid amplification tests (LC-mNAATs)	X					
Moderate-complexity automated nucleic acid amplification tests (MC-aNAATs)	X	X	X			
Line probe assays (LPAs)		X	X	X	X	
Targeted next-generation sequencing (NGS)		X	X	X	X	
TB culture and culture-based drug susceptibility testing	X	X	X	X	X	
Tests for TB treatment monitoring						
TB culture and culture-based drug susceptibility testing	X	X	X	X	X	
TB smear microscopy	X					
Tests for TB infection						
Mycobacterium tuberculosis (Mtb) antigen-based skin tests (TBSTs)						X
Interferon-gamma release assays (IGRAs)						X
Tuberculin skin tests (TSTs)						X

New Diagnostic Interventions

Near Point-of-Care NAATs (NPOC-NAATs)

Tongue Swabs

Pooling of Sputa for Low-Complexity automated NAAT

Potential to Increase Access & Decrease Costs

Near Point-of-Care (NPOC) Class Determination

New NPOC Technologies Differ from Low-Complexity Nucleic Acid Amplification Tests (LC-NAATs)

- Complexity:
  - Reagents
  - Skills
  - Pipetting
  - Testing procedure
- Setting of Use

Table 2.1.1.1 Class criteria for LC-aNAATs

Purpose		Detection of TB and rifampicin resistance
Principle of action		Nucleic acid amplification testing
Complexity	Reagents	Most reagents are enclosed in a disposable sealed container to which a clinical specimen is added. The disposable sealed container does not have special storage requirements
	Skills	Basic technical skills (e.g. basic pipetting, precision not critical)
	Pipetting	Either no, or only one, pipetting step in the process
	Testing procedure	• May require an initial manual specimen treatment step before transferring the specimen into the disposable sealed container for automated processing • Automated DNA extraction • Automated real-time PCR • Results generation
Type of test result reporting		Automated
Setting of use		Basic laboratory (no special infrastructure needed)

WHO consolidated guidelines on tuberculosis. Module 3: diagnosis

First-in-Class NPOC-NAAT: Pluslife MTB NAT Card

Pluslife Thermolyse

MiniDock Ultra (Model: PM001 Ultra)

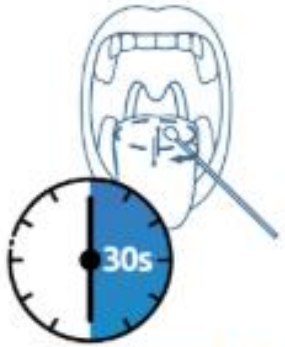
MTB Nucleic Acid Test Card

- Swab-based test (sputum or tongue)
- Lysis procedure uses chemical, heat, and mechanical disruption to lyse MTB and release nucleic acids
- Amplification procedure is based on RHAM (Rnase hybridization-assisted amplification; LAMP with enzymatic cleavage of for probe signaling)

Pluslife MTB Collection & Testing Procedure

Sample Collection

Sputum



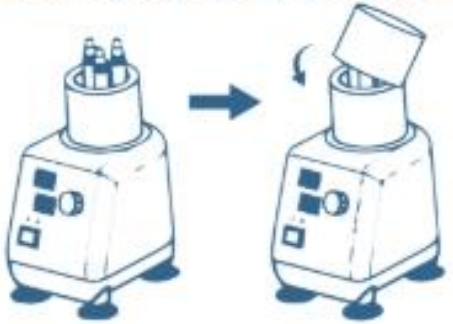
30 seconds

Tongue Swab

Mix Sample

1 Step Pretreatment

3000 rpm, 75°C, 5 minutes



Heating and vortex process in the Pluslife Thermolyse

Run Test & Result Output

5-25min

✓ MiniDock

✓ PC Software

World Health Organization

END TB

What are the NPOC-NAATs to diagnose tuberculosis?

A. culture-based tests for TB and rifampicin resistance detection
B. molecular tests for TB and rifampicin resistance detection that produce results using sputum and other samples in 2 hours in laboratories
C. molecular tests for TB detection that produce results using sputum and other samples in less than 1 hour with instruments that can be battery operated in and outside of laboratories

New: NPOC-NAATs with Sputum & Tongue Swabs

In **adults and adolescents** with signs and symptoms of pulmonary TB or who screen positive for pulmonary TB, **NPOC-NAATs on sputum** should be used as initial diagnostic tests for TB rather than smear microscopy (*Strong recommendation, moderate certainty of evidence*)

When sputum cannot be obtained, **NPOC-NAATs on tongue swabs** should be used as initial diagnostic tests for TB (*Strong recommendation, moderate certainty of evidence*)

Remarks

- Evidence was available for expectorated and induced sputum.
- Sputum remains the preferred sample and should be collected and tested whenever possible, given improved diagnostic accuracy over tongue swabs.
- TS may be collected by trained personnel or self-collected with guidance from trained personnel.
- Applies to adults and adolescents living with HIV. However, concurrent testing with an LC-aNAAT and LF-LAM is the preferred strategy for PLHIV. In the context of concurrent testing, where LC-aNAATs are not available, NPOC-NAATs may be used with LF-LAM; where a respiratory sample is unobtainable, a tongue swab may be used with LF-LAM.
- Extrapolated to children for use with sputum (expectorated or induced), but not tongue swabs or other paediatric samples. Wherever available, concurrent testing with LC-aNAATs on respiratory and stool samples (and LF-LAM among those that are HIV positive) is the preferred testing strategy for children.
- As NPOC-NAATs do not provide rifampicin resistance results, all positive tests should be referred for resistance testing.

Are NPOC-NAATs recommended for children?

A. NPOC-NAATs are recommended for children with sputum only - not with tongue swabs or other paediatric samples.
B. NPOC-NAATs are recommended for children for use with both sputum and tongue swabs.
C. NPOC-NAATs are not recommended for children.

Considerations for NPOC-NAAT Implementation

- Recommendation of NPOC-NAATs as initial diagnostics for TB does not replace the need for smear microscopy for treatment monitoring.
- When conducted outside of laboratories, sufficient training for sample collection and testing should be provided to testers without prior technical testing or laboratory experience – including practices to reduce chances of contamination.
- When providing testing services in peripheral settings:
  - linkage to appropriate treatment and care services should be ensured
  - engagement of civil society and community organizations for early communication, demand creation, delivery and monitoring are essential
  - programmes should consider developing context-specific plans with civil society
- Swab-based testing is equal in biosafety risk to smear microscopy; biosafety cabinets are not required.
- For sites using battery power, battery back-ups may be useful to prevent service interruption and clear plans for battery charging between uses should be available.
- Initial clinical management of people who cannot produce sputum and test positive for TB using tongue swabs will need to be done without culture and DST.

Advantages and Limitations for NPOC-NAATs

Advantages

- Can be done in basic peripheral laboratories (e.g. smear) and in health clinics, mobile units or community sites that do not have laboratories
- Can be done by health care workers with basic technical skills
- Can be used with both swabbed sputum and tongue swabs – expanding testing access
- Produces pre-test to post-test results in <60 minutes
- Can be used to test for multiple diseases (tests available for influenza, RSV, COVID-19, and HPV with others in development)
- Lower cost than other WHO-recommended diagnostics for the detection of TB
  - Equipment unit cost USD 335
  - Test unit cost USD 3.6
  - External quality controls unit cost USD 4.5

Limitations

- Less sensitive than LC/MC-aNAATs on sputum (85% vs 90%)
- Tongue swabs less sensitive than sputum (76% vs. 85%) among mostly sputum-producers
- Does not detect resistance, requiring reflex testing with another test type or sample referral for rapid rifampicin resistance testing (at a minimum)
- Enhanced PPE required for worker collection of tongue swabs (e.g., eye protection, N95 mask, gloves, coat and overalls)
- Instrument based; requires two instruments and battery charging with replacement mechanisms for testing sites that do not rely on stable power.
- Sample transfer between lysis and testing can lead to contamination (i.e., false positive results for serially-tested samples) if tester practices and disifection of the testing space are not done

What are advantages of NPOC-NAATs?

A. They can be done in basic peripheral laboratories (e.g. those that perform smear microscopy) and in health clinics, mobile units or community sites that do not have laboratories.
B. They can be performed by health care workers with basic technical skills (e.g. basic pipetting) because they do not require precision.
C. They produce pre-test to post-test results in <60 minutes using swabbed sputum or tongue swabs
D. Their instruments can be used to detect multiple diseases, such as influenza, RSV, COVID-19, and HPV.
E. They can detect rifampicin resistance.

Swab Considerations

- Swabs may be healthcare worker or self-collected. However, HCW collection is preferred due to limited data on self-collection.
- Where healthcare worker-collected, collection should be done in a well-ventilated space with enhanced PPE (eye protection such as goggles, N95, gloves, clothing protection such as a coat or overalls).
- Following optimization studies, nylon FLOQ swabs with built-in break points are generally recommended for both sputum and oral sampling
- Instructions for Use documents should list swab types/ product numbers compatible with their assays
- One swab per sample and test.
- Duration of tongue swab collection is important. Available evidence show that sensitivity decreases when swabbing is done for less than 30 seconds.

Is the duration of tongue swab collection important?

A. Yes, duration of tongue swab collection is important; evidence shows that sensitivity for diagnosing TB decreases when swabbing is done for less than 30 seconds.
B. Yes, duration of tongue swab collection is important; evidence shows that sensitivity for diagnosing TB decreases when swabbing is done for less than 15 seconds.
C. No, the duration of tongue swab collection is not important; swabbing time can be estimated.

LC-aNAAT Class Technologies

2025 Class Products

- Truenat MTB Plus
- Truenat MTB Rif-Dx
- Xpert MTB/RIF Ultra

2026 Class Products

- Truenat MTB Plus
- Truenat MTB Rif-Dx
- ***Now for use with tongue swabs***:
  - Xpert MTB/RIF Ultra
  - ***New***: Truenat MTB Ultima

New: Tongue Swabs with LC-aNAATs

In adults and adolescents with signs and symptoms of pulmonary TB or who screen positive for pulmonary TB, LC-aNAATs on respiratory samples should be used as initial diagnostic tests for TB rather than smear or culture (*strong recommendation, high certainty of evidence*);

When respiratory samples cannot be obtained, LC-aNAATs on tongue swabs may be used as initial diagnostic tests for TB (*conditional recommendation, low certainty of evidence*).

- *The products for which eligible data met the class-based performance criteria for tongue swabs were Xpert MTB/RIF Ultra and Truenat MTB Ultima. Diagnostic accuracy varied between products, with MTB Ultima showing higher sensitivity in the assessed population than Xpert MTB/RIF Ultra.*
- Tongue swab-based testing should be reserved for situations where sputum cannot be obtained because of the decreased sensitivity of swab-based testing compared to use of sputum and evidence on values from key interest-holders.

Should tongue swabs be used to help diagnose TB among all adults and adolescents with presumptive TB?

- Yes, tongue swabs should be used to diagnose TB among all adults and adolescents with presumptive TB.
- No, sputum is a preferred sample type for diagnosis of tuberculosis for all WHO recommended initial tests because it produces more accurate results. However, if sputum cannot be obtained, tongue swabs are recommended for use with NPOC-NAATs or LC-aNAATs.

Remarks: Tongue Swabs with LC-aNAATs

- Adult and adolescent respiratory samples include sputum (expectorated or induced), tracheal aspirate and bronchoalveolar lavage.
- Respiratory samples are preferred and should be collected and tested whenever possible, given improved diagnostic accuracy over tongue swabs.
- Tongue swabs may be collected by trained personnel or self-collected with guidance from trained personnel.
- Concurrent testing with LC-aNAATs on a respiratory sample and LF-LAM on urine is the preferred testing strategy for PLHIV. If a sputum specimen cannot be obtained, a tongue swab may be used as part of concurrent testing with LF-LAM.
- Concurrent testing with LC-aNAATs on a respiratory and a stool samples (with LF-LAM among those that are HIV positive) is the preferred testing strategy for children. Tongue swabs should not be used as part of the concurrent testing strategy for children (limited evidence).
- While no data were available on rifampicin resistance detection using tongue swabs, the recommendation was extrapolated for rifampicin resistance detection using Xpert MTB/RIF Ultra based on accuracy and equity considerations.

Considerations for LC-aNAATs on Tongue Swabs

- Initial clinical management of people who cannot produce sputum and test positive for TB using tongue swabs will need to be done without culture and DST.
- Existing LC-aNAAT instruments (i.e., GeneXpert, Molbio Truelab supported with a new TrueLyse instrument for sample processing) may be used to test swabs, respiratory samples, and other recommended sample types. Use of existing sites may therefore reduce the time required to implement swab-based testing for patients unable to produce sputum.

Which classes of TB diagnostic tests are recommended for use with tongue swabs?

A. Near point-of-care nucleic acid amplification tests (NPOC-NAATs)
B. Low-complexity automated nucleic acid amplification tests (LC-aNAATs)
C. Moderate-complexity automated nucleic acid amplification tests (MC-aNAATs)
D. Targeted Next Generation Sequencing (tNGS) solutions
E. Point-of-care lateral flow biomarker-based tests (LF-LAM)

Advantages & Disadvantages of LC-aNAATs on TS

Advantages

- Enables testing of people with signs and symptoms of TB who cannot produce sputum
- Can use existing WRD testing networks which are immediately available (no need to wait for NPOC-NAAT regulatory approval and uptake)
- The recommendation was extrapolated for resistance detection using Xpert Ultra – allowing for both TB & RR-TB detection at the same time

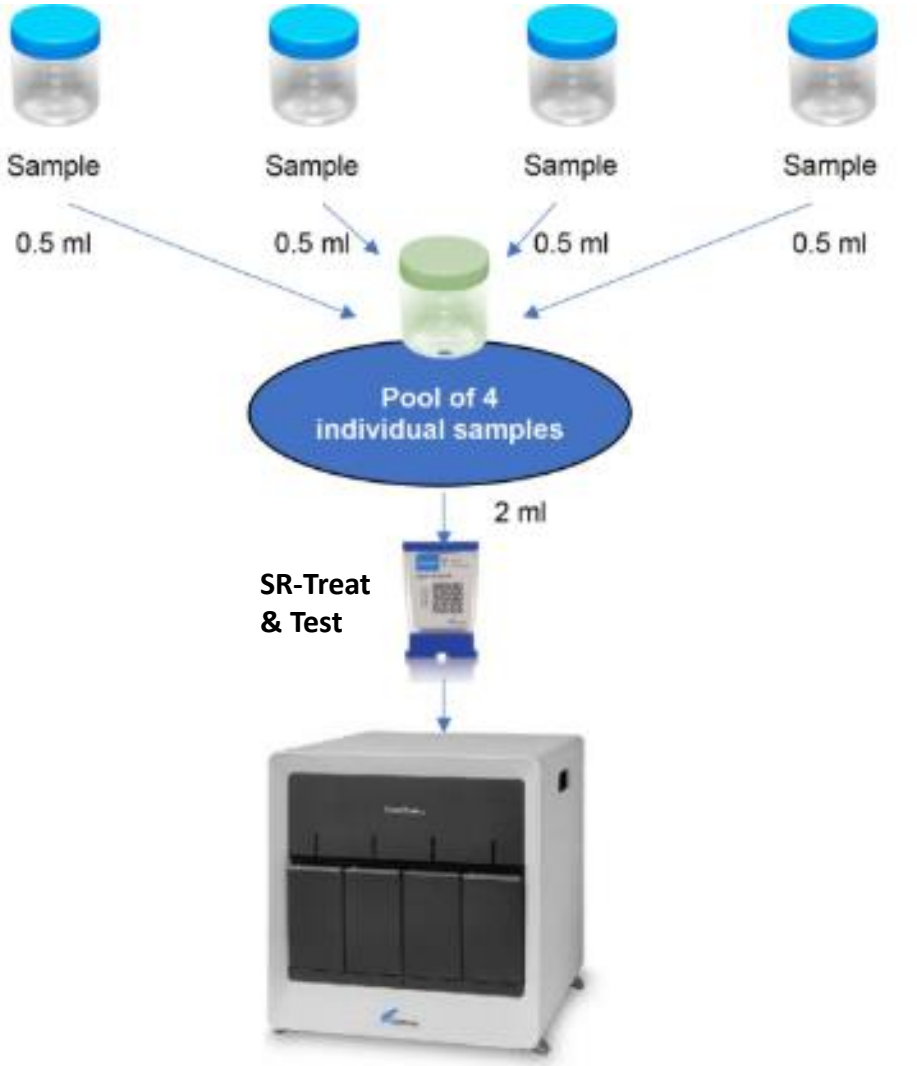
Disadvantages

- Less sensitive than LC-aNAATs on sputum (71% vs 90%)
- Diagnostic accuracy varied between the two evaluated products: Molbio Truelyse with MTB Ultima vs Xpert Ultra (76.2% vs 66.6%, respectively).
- No data were available on swab use with Molbio Truenat MTB Plus.
- Enhanced PPE required for for healthcare worker collection of tongue swabs (e.g., eye protection, N95 mask, gloves, coat and overalls)

What are advantages of using LC-aNAATs on tongue swabs?

A. Enables testing of people with signs and symptoms of TB who cannot produce sputum.
B. Allows existing WRD testing networks that are immediately available to be used (no need to wait for NPOC-NAAT regulatory approval and uptake).
C. They can be used for detection of both TB and rifampicin resistance at the same time using Xpert MTB/RIF Ultra, while NPOC-NAATs do not yet test for rifampicin resistance.
D. Tongue swabs produce more accurate results on LC-aNAATs than sputum.

Pooling of Sputum for Use with LC-aNAATs



A Two-Step Strategy

Step 1: Pooling

- ≤ 4 eligible samples identified, brought together, labeled with a unique pool identifier & treated, as usual, with sample reagent per manufacturer instructions.
- The pooled sample is then tested.
- All individual and pooled samples are stored until test results are available.

Step 2: Result-Based Testing & Resulting

- If negative, no further testing. All individual samples that contributed to the pool are reported negative for TB.
- If positive, individual samples must be tested individually to identify which is positive. One or more of the individual samples in the pool may be positive for TB.
- Results for rifampicin resistance detected for pooled samples are not reliable and should not be used for clinical management. Samples contributing to rifampicin-resistant pools should be re-tested individually to confirm possible rifampicin resistance.

Figure credit BMC Infectious Diseases 2023 Iem et al.

Can the rifampicin resistance result from a pooled sample be used for patient management?

A. No, results for rifampicin resistance detected for pooled samples are not reliable and should not be used for clinical management. Samples contributing to rifampicin-resistant pools should be re-tested individually to confirm possible rifampicin resistance.

B. Yes, results for rifampicin resistance detected for pooled samples are reliable and can be used for clinical management to speed results for patients.

New: Pooling of sputa with LC-aNAATs

When resource constraints do not allow for the testing of individual samples: In adults and adolescents with signs and symptoms for pulmonary TB or who screen positive for pulmonary TB, LC-aNAATs on (up to four) pooled sputa may be used as the initial diagnostic strategy for diagnosing TB rather than LC-aNAATs on individual samples *(conditional recommendation, high certainty of evidence).*

- Applies to within-class product: Xpert MTB/RIF Ultra
- Given relative reduced accuracy and high user value on accurate testing services, pooling should be reserved for situations where resource constraints do not allow for the testing of individual samples.
- Even in these situations, PLHIV, children, individuals at increased risk of drug resistance and other priority populations should not be tested with the pooled testing strategy but should instead be prioritized for individual testing due to the potential for reduced equity and increased harm among individuals at increased risk of TB morbidity and mortality.

Remarks: Pooling Sputum for LC-aNAATs

- Evidence was available for both induced and expectorated sputum.
- This recommendation applies to pooling of individual specimens from up to 4 individuals based on a majority of evidence for this pooling ratio.
- Pooling may result in reduced costs and increased CE for testing programs. Savings were reduced and CE was not documented in settings of test positivity above 24% (commodity costs alone, modeled evidence).
- This recommendation does not apply to PLHIV, children, or individuals at increased risk of DR-TB due to potential for reduced equity and increased harm. These and other priority populations may be prioritized for individual testing according to local risk groups.
- Diagnostic accuracy of the pooling strategy was reduced when sputum was collected in community settings (sensitivity range of 25-96%, 4 studies) compared with facility-based sputum collection (sensitivity range of 84-100%, 7 studies) and the reductions were greater than those associated with individual testing. The reasons for this variability were not directly assessed but may include bacterial load or other factors.

Is pooling of sputa recommended for children, people living with HIV, or people at risk of DR-TB?

A. No, pooling of sputa for the detection of tuberculosis is **not** recommended for people living with HIV, children or individuals at increased risk of drug resistance due to the potential for reduced accuracy and increased harm.

B. Yes, pooling of sputa for the detection of tuberculosis **does** apply to people living with HIV, but not children or individuals at increased risk of drug resistance.

C. Yes, pooling of sputa for the detection of tuberculosis **does** apply to people living with HIV, children and individuals at increased risk of drug resistance.

Advantages & Disadvantages of LC-aNAAT Pooling

Advantages

- Can yield substantial cost reductions, particularly in low-prevalence or low-positivity settings (down to 3 USD per test – lower than NPOC-NAAT)
- In settings with <25% TB positivity rates, can:
  - Reduce the number of tests needed for the same number of people – enabling more to get tested
  - Improve efficiency of instrument use, by reducing overall volumes
- Can use existing GeneXpert testing services which are immediately available

Disadvantages

- Less sensitive than LC-aNAATs on sputum (85% vs 90%)
- Evidence only available for one LC-aNAAT (Xpert Ultra)
- Not relevant to vulnerable groups (children, PLHIV, people with risk of DR-TB, other setting-specific)
- The cost saving of pooling is highly dependent on TB prevalence or test positivity rate; as prevalence increases, cost saving decreases due to the higher number of required re-tests.
- Increases complexity of sample management for testing, including labeling and preparation for testing, sample processing, pooling of individual samples while minimizing increased risk of contamination, and appropriate storage of samples until pooled results are available
- Sensitivity reduced when sputum is collected in communities vs facilities (74.1% vs 85.4%)

What are advantages of pooling of sputa for TB diagnostic testing?

A. May result in reduced costs and increased cost-effectiveness for testing programs, particularly in low-prevalence or low-positivity settings (down to 3 USD per test – lower than the current NPOC-NAAT unit cost).

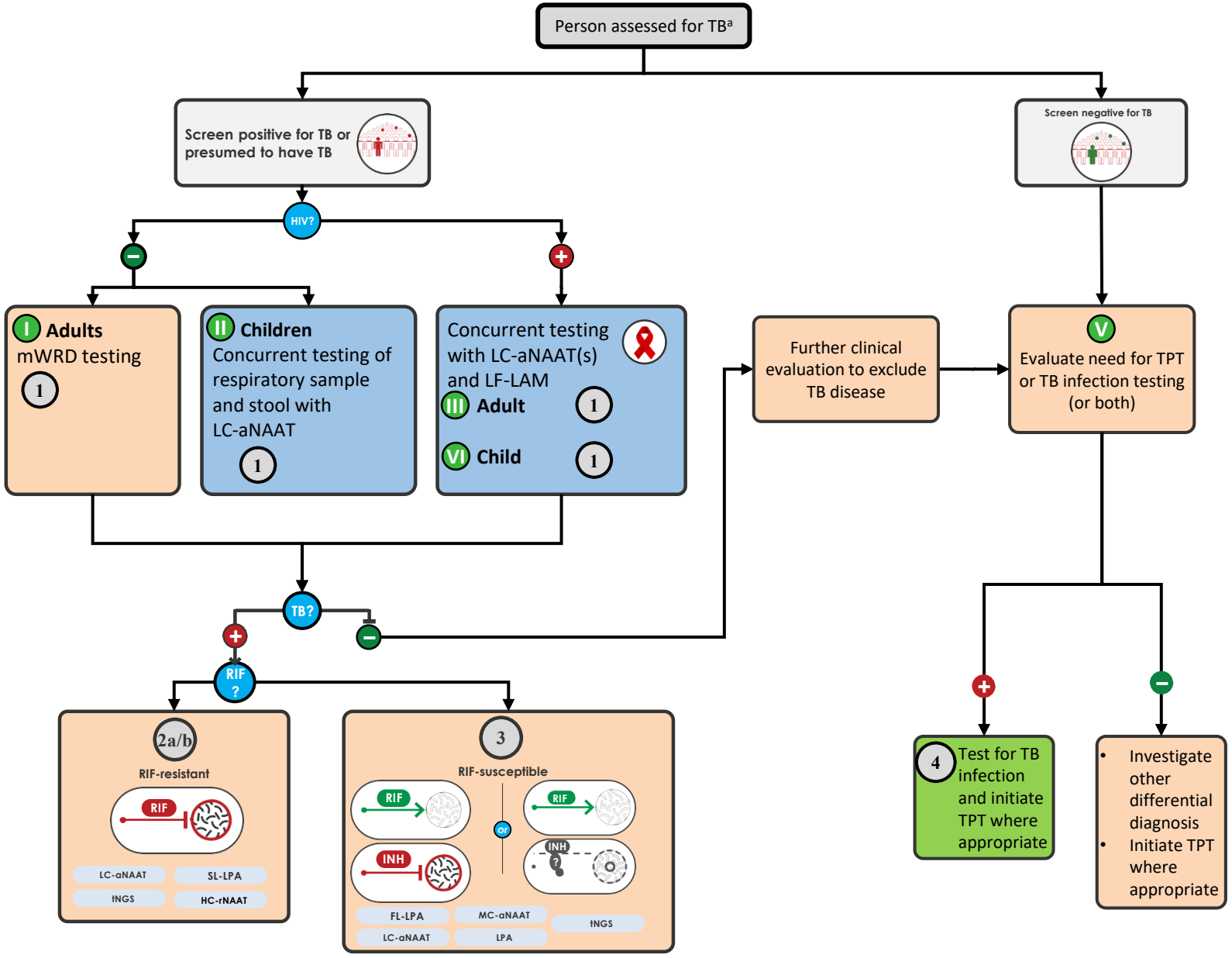
B. In settings with ≤24% TB positivity rates, pooling can reduce the number of tests needed for the same number of people – enabling more to get tested and iimproving efficiency of instrument use by reducing overall volumes.

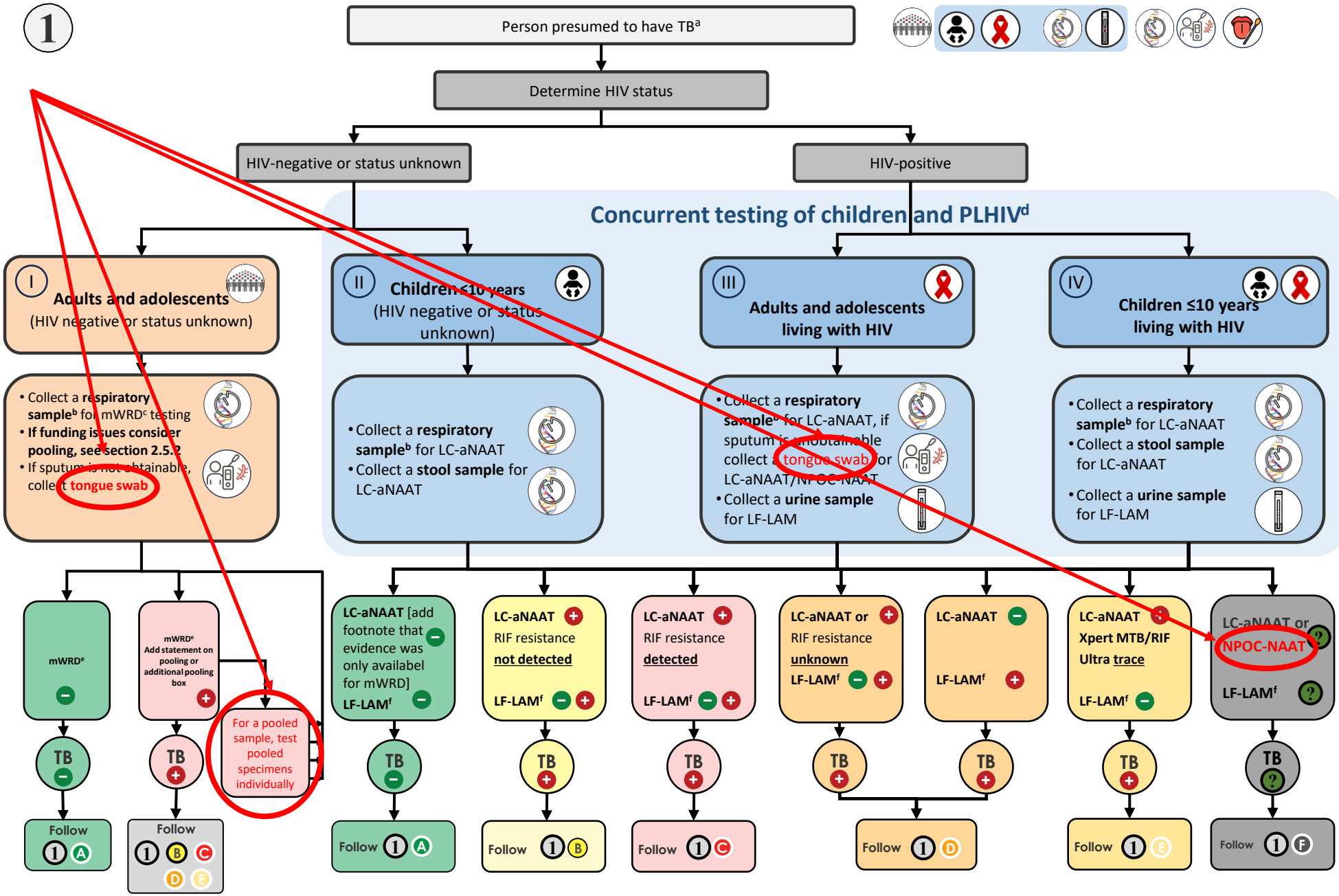
C. Can use existing GeneXpert testing services that are immediately available to save costs and improve turnaround times.

D. It is more sensitive than LC-aNAATs on individual sputum, providing clients with more accurate TB results.

Accuracy of TB Detection

	LC-aNAATs		NPOC-NAATs	LC-aNAATs	NPOC-NAATs	Reference	
				Tongue Swabs		LC-mNAATs	MC-aNAATs
	Individual Sputum	Pooled Sputum	Individual Sputum			Individual Sputum	Individual Sputum
Sensitivity	**90% (88-92)**	**85% (81 to 88)**	**85% (82–88)**	**71% (67-75)**	**76% (71–81)**	**84% (78–89)**	**93% (91–95)**
Difference	-	*- 5.6%*	*-5%*	*-19%*	*-14%*	*-6%*	*+3%*
Specificity	**95% (93–96)**	**98% (97 to 99)**	**98% (97–98)**	**99% (98-99)**	**99% (99–100)**	**96% (94–97)**	**98% (95.6–98.8)**
Difference	-	*+3%*	*+3%*	*+4%*	*+4%*	*+1%*	*+3%*


Person assessed for TB[a]
Screen positive for TB or presumed to have TB
Screen negative for TB
HIV?
I Adults
mWRD testing
1
II Children
Concurrent testing of respiratory sample and stool with LC-aNAAT
1
Concurrent testing with LC-aNAAT(s) and LF-LAM
III Adult
1
VI Child
1
Further clinical evaluation to exclude TB disease
V
Evaluate need for TPT or TB infection testing (or both)
TB?
RIF ?
2a/b
RIF-resistant
RIF
LC-aNAAT
SL-LPA
tNGS
HC-rNAAT
3
RIF-susceptible
RIF
INH
or
RIF
INH
FL-LPA
MC-aNAAT
tNGS
LC-aNAAT
LPA
4
Test for TB infection and initiate TPT where appropriate
Investigate other differential diagnosis
Initiate TPT where appropriate


1
Person presumed to have TB[a]
Determine HIV status
HIV-negative or status unknown
HIV-positive
Concurrent testing of children and PLHIV[d]
I
Adults and adolescents
(HIV negative or status unknown)
II
Children ≤10 years
(HIV negative or status unknown)
III
Adults and adolescents living with HIV
IV
Children ≤10 years living with HIV
• Collect a respiratory sample[b] for mWRD[c] testing
• If funding issues consider pooling, see section 2.5.2
• If sputum is not obtainable, collect tongue swab
• Collect a respiratory sample[b] for LC-aNAAT
• Collect a stool sample for LC-aNAAT
• Collect a respiratory sample[b] for LC-aNAAT, if sputum is unobtainable collect a tongue swab for LC-aNAAT/NPOC-NAAT
• Collect a urine sample for LF-LAM
• Collect a respiratory sample[b] for LC-aNAAT
• Collect a stool sample for LC-aNAAT
• Collect a urine sample for LF-LAM
mWRD[e]
mWRD[e] Add statement on pooling or additional pooling box
For a pooled sample, test pooled specimens individually
LC-aNAAT [add footnote that evidence was only availabel for mWRD]
LF-LAM[f]
LC-aNAAT
RIF resistance not detected
LF-LAM[f]
LC-aNAAT
RIF resistance detected
LF-LAM[f]
LC-aNAAT or
RIF resistance unknown
LF-LAM[f]
LC-aNAAT
LF-LAM[f]
LC-aNAAT
Xpert MTB/RIF Ultra trace
LF-LAM[f]
LC-aNAAT or
NPOC-NAAT
LF-LAM[f]
TB
Follow 1 A
Follow 1 B C D E
Follow 1 A
Follow 1 B
Follow 1 C
Follow 1 D
Follow 1 E
Follow 1 F

A **MTBC *not* detected**

Re-evaluate the person clinically and conduct additional testing to confirm or exclude TB in accordance with national guidelines[k]

For children evaluate clinically and consider repeat mWRD testing.

Use clinical judgement for treatment decisions

For assessing eligibility for TPT or TB infection testing follow Algorithm 4

B **MTBC detected (if Ultra, not trace result)[g]**
RIF resistance *not* detected[h]

INH susceptible or not known

Treat with first-line regimen in accordance with national guidelines[l]

Consider DST for INH and other drugs if risk of additional resistance is high[m]

Follow Algorithm 3

INH resistant[t]

Treat with Hr-TB regimen

Consider including high-dose isoniazid in the Hr-TB regimen if low-level resistance is detected

Follow Algorithm 3

C **MTBC detected (if Ultra, not trace result)[g]**
RIF resistance detected[h]

Evaluate the person for **MDR-TB risk factors[n]**

HIGH

Treat with **MDR-TB regimen** in accordance with national guidelines[q] **Follow Algorithm** 2a/b for further testing and assessment

LOW

Repeat mWRD test with a fresh specimen[o]

Follow *this* Algorithm 1 to interpret results and use the outcome as the final result

D **MTBC detected (if Ultra, not trace result)[g]**
RIF indeterminate or unknown[i]

Ultra

Evaluate **Ultra melting curve[i]**

RIF resistance detected

Follow C

RIF resistance not detected

Initiate first-line treatment

Repeat mWRD[o]

Other mWRDs or LF-LAM

Initiate first-line treatment

Perform mWRD with RIF resistance detection

Follow *this* Algorithm 1 to interpret results

If initial and repeat mWRD test with RIF detection give indeterminate RIF results, treat with **first line regimen[l]**

Promptly conduct additional investigations to **assess resistance to RIF[r]**

Review treatment based on **DST** result

E **MTBC detected with Ultra trace[j]**
RIF indeterminate

Evaluate person for pulmonary or extrapulmonary TB, HIV, age and prior TB treatment

PLHIV[p] or children being evaluated for pulmonary TB and persons being evaluated for extrapulmonary TB and **adults** being evaluated for pulmonary TB who are not at risk for HIV and who do not have a history of prior TB or TB treatment within the past 5 years

Treat with **first-line regimen[l]**

Conduct additional investigations to **assess resistance to rifampicin[r]**

Review treatment based on **DST** result

F **No result, error or invalid result(s) for all tests**

Use **clinical judgement** for treatment decisions

Conduct **additional testing to confirm or exclude TB** in accordance with national guidelines[k]

Consider repeat mWRD test[o]

Adults being evaluated for pulmonary TB who are not at risk for HIV and who have a history of prior TB or whose TB treatment ended less than 5 years ago

Recent TB treatment may generate a **false positive** result[s]

Re-evaluate person clinically[k]

Conduct **additional testing for TB and RIF resistance** in accordance with national guidelines[r]

Use **clinical judgement** for treatment decisions

Summary

- The challenging global TB epidemic necessitates the development and implementation of WHO guidelines for TB diagnosis and the development of new diagnostic tests, samples, and strategies.
- WHO is issuing new, consolidated guidelines on tuberculosis diagnosis that aim to expand access to TB diagnostic services while reducing costs during periods of increased resource constraint.
- The guidelines update process was evidence-based with data from multiple regions and countries and based on a transparent and structured process.
- WHO recommends new, near point-of-care tests for diagnosis of TB, tongue swabs for expanded access to TB diagnosis using near point-of-care and low-complexity molecular tests, and pooling of sputa for low-complexity molecular testing that increases efficiency while reducing cost.
- WHO prequalification is required for all diagnostic products recommended by WHO HTH; the prequalification process for all molecular tests for the initial detection of TB (including NPOC-NAATs) with sputum, tongue swabs, and other sample types is open and available to support quality & market expansion

Next Steps

- The updated WHO consolidated guidelines on tuberculosis. Module 3: Diagnosis. 2nd edition with the summary of findings and evidence to decision tables will be produced in conformity with the GRADE method and made available on the WHO website over coming weeks.
- The updated guidelines will be accompanied by the WHO operational handbook on tuberculosis. Module 3: Diagnosis. 2nd edition. The handbook will provide guidance on all technologies, sample types and strategies currently recommended, steps to introducing new TB diagnostics into a health programme and the model algorithms for testing and clinical management.
- The updated guidelines will also be accompanied by a WHO toolkit for near point-of-care and swab-based tuberculosis testing that will outline key steps for implementation of these new tools and provide customizable planning, readiness assessment, testing, training, and monitoring and evaluation materials to facilitate program uptake.
- The release of the new guidance will be followed by a series of WHO and partner organization webinars for different regions and audiences. Updates will also be included on the online WHO TB Knowledge Sharing Platform providing easy access to the guidelines and operational handbook in one place.

Thank You

World Health Organization

WHO Prequalification Process Available for LF-LAM and NAATs

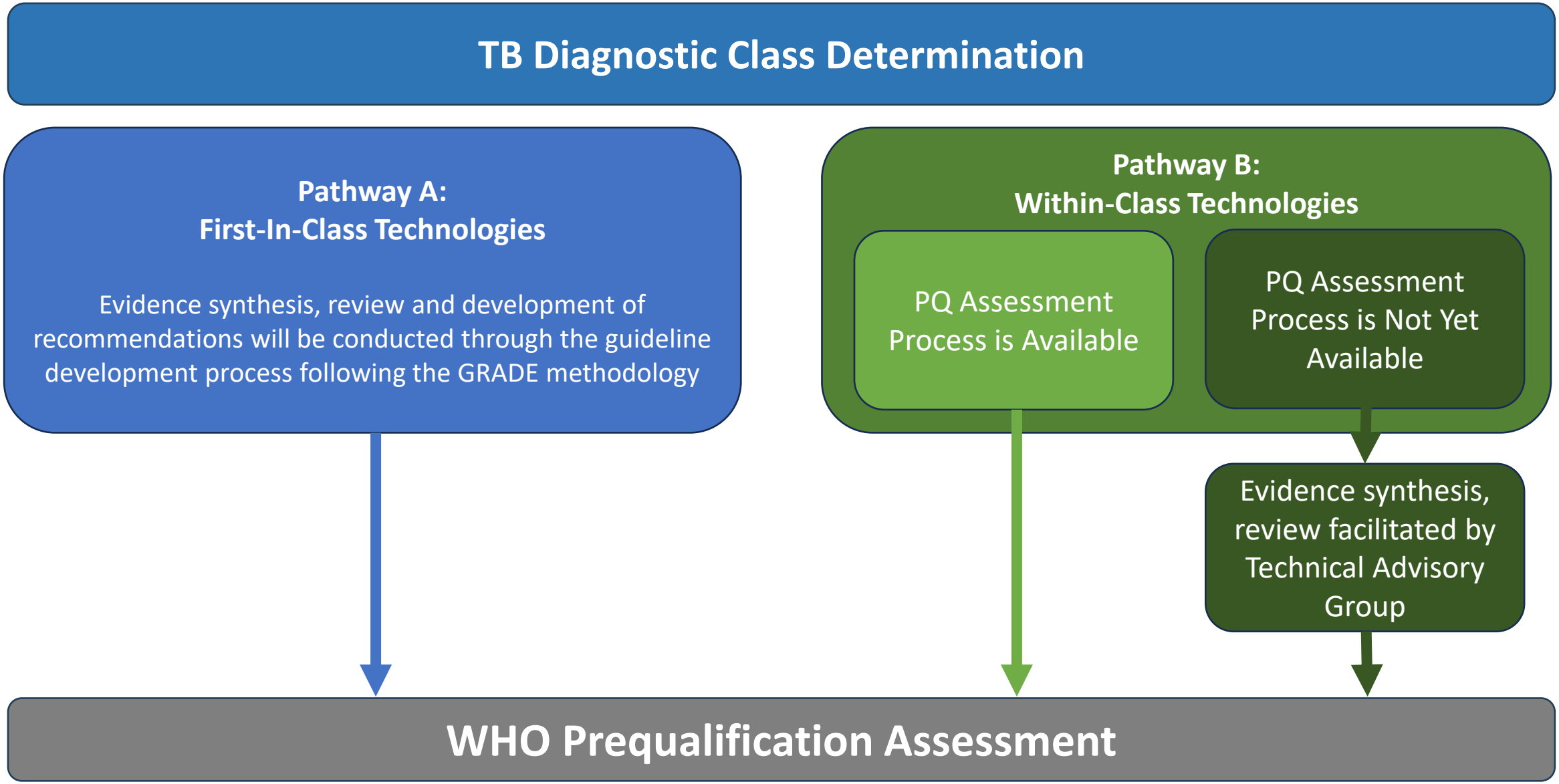
WHO launches a pilot parallel WHO Prequalification and TB policy assessment process for new TB IVDs

NEWS 29 August, 2025 - 13:44 (CEST)

ANNOUNCEMENT

- WHO PQ evaluates diagnostic products for quality, safety and performance within the manufacturer-defined intended use.
- Prequalification Technical Specification Series (TSS) and Performance Evaluation protocols (PEP) available for NAATs (2021), LF-LAMs (2025). A process for TBSTs is also available.
- NAATs Xpert MTB/RIF Ultra, Xpert MTB/XDR, Loopamp MTBC Detection Kit (TB-LAMP), and Roche cobas MTB are prequalified
- WHO PQ process for NAATs was amended in 2025 to incorporate sputum swabs and tongue swabs
- Process is available for NPOC-NAATs (sputum and tongue swabs) and for LC-aNAATs use with tongue swabs
- At least 4 additional low and moderate complexity NAATs undergoing evaluation
- Processes for IGRAs and tNGS solutions are under development

Recommendation Pathways for TB Diagnostics



Classes of tests for the detection of TB and/or DR-TB

Technology class	Included products	TB disease	RIF resistance	INH resistance	FQ resistance	Other resistance
Point-of-care antigen detection in a lateral flow format (LF-LAM)	Determine TB LAM Ag (Abbott/Alere)	X				
NEW: Near point-of-care nucleic acid amplification tests (NPOC-NAATs)	Minidock MTB Test (Guangzhou Pluslife Biotech Co. Ltd.)	X				
UPDATED: Low-complexity automated NAATs (LC-aNAATs)	Xpert MTB/RIF Ultra (Cepheid)	X	X			
	Xpert MTB/XDR (Cepheid)			X	X	X
	Truenat MTB Plus and Truenat MTB-RIF Dx (Molbio)	X	X			
	NEW: Truenat MTB Ultima (Molbio)	X				
Low-complexity manual NAATs (LC-mNAATs)	Loopamp MTBC Detection Kit (TB LAMP) (Eiken Chemical)	X				
Moderate-complexity automated NAATs (MC-aNAATs)	BD MAX MDR-TB (Becton Dickinson)	X	X	X		
	cobas MTB and cobas MTB-RIF/INH (Roche)	X	X	X		
	FluoroType MTB and FluoroType MTBDR (Bruker-Hain)	X	X	X		

Truenat MTB Ultima: A New Swab-Based Test

- Lysis procedure requires Molbio Truelyse instruments (not compatible with Trueprep devices)
- Provided, single-volume precision pipettor used to transfer lysed sample to the test chip by trained, skilled staff
- Amplification procedure (RT-qPCR) and equipment (Truelab) is the same as Truenat MTB Plus

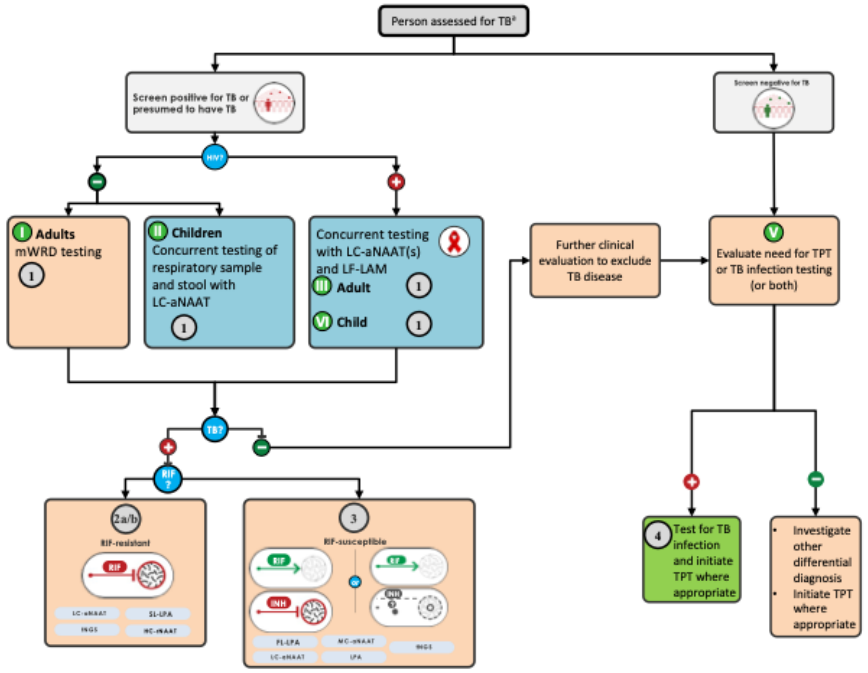
World Health Organization

Figure credit: Steadman, Amy et al. eBioMedicine, Volume 121, 105991

END TB

Model algorithms

Cascade of the algorithms



4 Algorithms

1. TB diagnosis and RIF detection
2. 2a Follow-up DST for MDR/RR-TB
   2b with and without tNGS
3. Follow-up DST for RIF susceptible TB
4. Detection of TB infection

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END TB