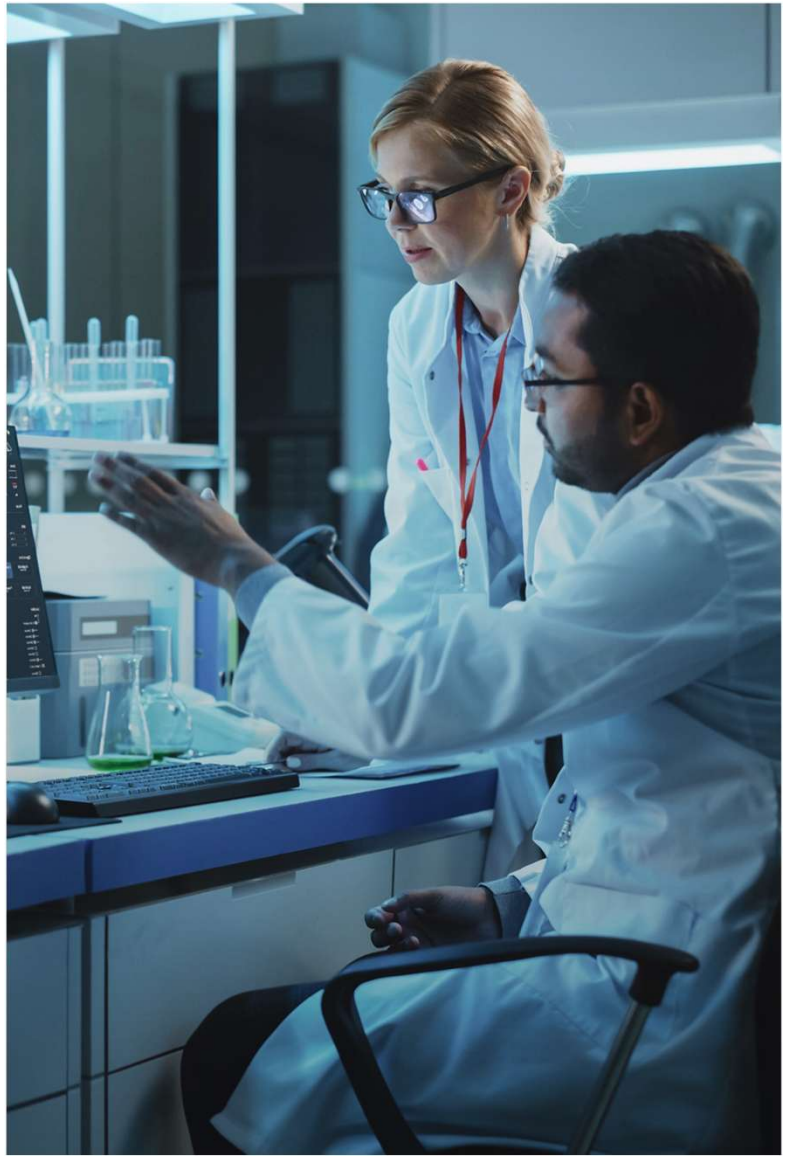
STANDARD M10 – Molecular Diagnostics

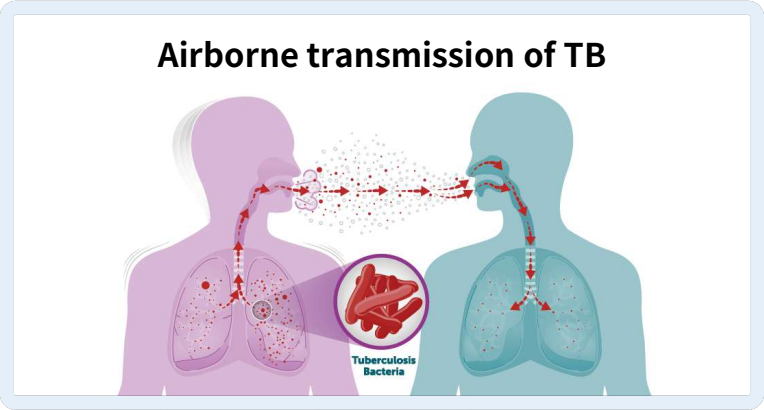
STANDARD M10

Tuberculosis (TB)



SD BIOSENSOR

Tuberculosis Diagnostic



Case overall

- [Latent TB] People infected with TB have a **5–10%** lifetime risk of falling ill with TB.
- [Active TB] Every year, about **10.6 million** people fell ill with TB [12% Children, 8.2% w/ HIV]

Death

- **1.6 million** people are killed by TB [14.9% w/HIV], by WHO

Latent TB

- TB lives but doesn't grow in the body.
- Doesn't make a person feel sick or have symptoms
- **Can't** spread from person to person
- Can advance to TB disease

- **STANDARD E TB-Feron ELISA**
- **STANDARD F TB-Feron FIA (IFN-gamma)**

Active TB

- TB is active and grows in the body.
- Makes a person feel sick and have symptoms
- **Can** spread from person to person
- Can cause death if not treated

- **STANDARD M10 MTB/NTM**
- **STANDARD M10 MDR-TB**
- **STANDARD Q TB-MPT64 Ag**

https://www.who.int/news-room/fact-

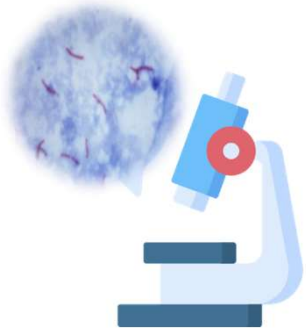
Tuberculosis diagnosis is determined by referring to **various clinical test result.**

Diagnostic Imaging

X-ray

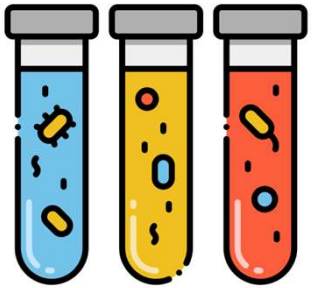
- **Screening** for those who has suspected to have TB by having respiratory symptom.

Diagnostic Testing Laboratory



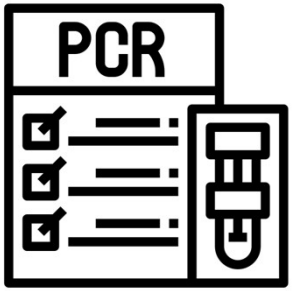
AFB Staining

- Possible to detect MTB & NTM
- Possible to perform quickly
- **Low sensitivity**



Culture

- **Gold standard** for TB diagnostic
- Divided into solid culture & liquid culture
- **Takes long time** to get the result (4-8 weeks)



PCR

- **Short** time to get the result (few hours)
- **High sensitivity**
- Divided into Low-mid-high complexity test

Tuberculosis diagnosis is determined by referring to **various clinical test result.**

Diagnostic Imaging

X-ray

- **Screening** for those who has suspected to have TB by having respiratory symptom.

Diagnostic Testing Laboratory

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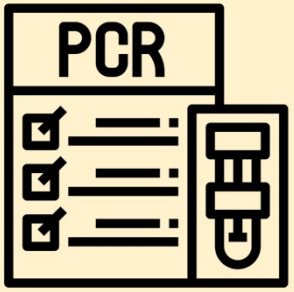

PCR

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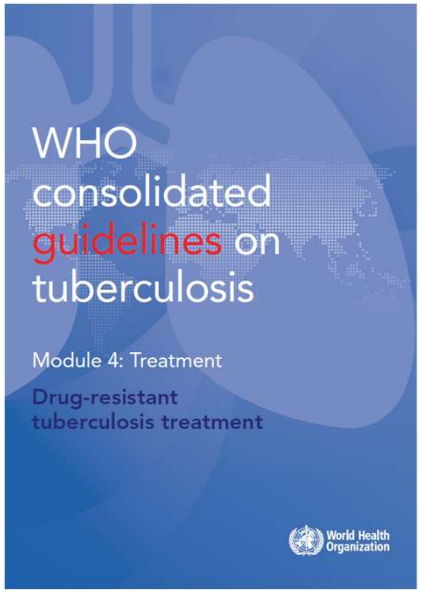
Tuberculosis Treatment

The importance of detecting resistance to both Rifampicin and Isoniazid lies in its impact on treatment decisions. According to WHO guidelines, if a patient is found to be Rifampicin-resistant, they are typically transitioned directly to second-line TB treatments, such as BPaLM, without further testing for Isoniazid resistance.



2022.12 Updated version

Drug Resistant Severity

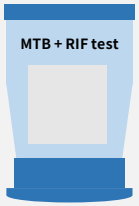
Types of TB resistance	Drugs to use		Regimen cost
	Regimen name	Composition (Detail)	
MTB	*1st line anti-TB drug* (**HREZ**)	Isoniazid(H) rifampicin(R) ethambutol (E) pyrazinamide (Z)	$55
Hr-TB	*1st line anti-TB drug + Fluoroquinolone* **REZ + Lfx**	rifampicin(R) ethambutol (E) pyrazinamide (Z) + levofloxacin (Lfx)	$76
MDR-TB/ RR-TB	*2nd lind anti-TB drug* (**BPaLM**)	Bedaquiline(B) pretomanid(Pa) linezolid (L) Moxifloxacin (M)	$5,000 ~
Pre-XDR-TB			
XDR-TB	Susceptible drugs		Depending on drugs used

Treatment Expense

Hr-TB: isoniazid-monoresistant TB, **RR-TB**: rifampicin-resistant TB, **MDR-TB**: multidrug-resistant TB, **XDR-TB**: extensively drug resistant-TB

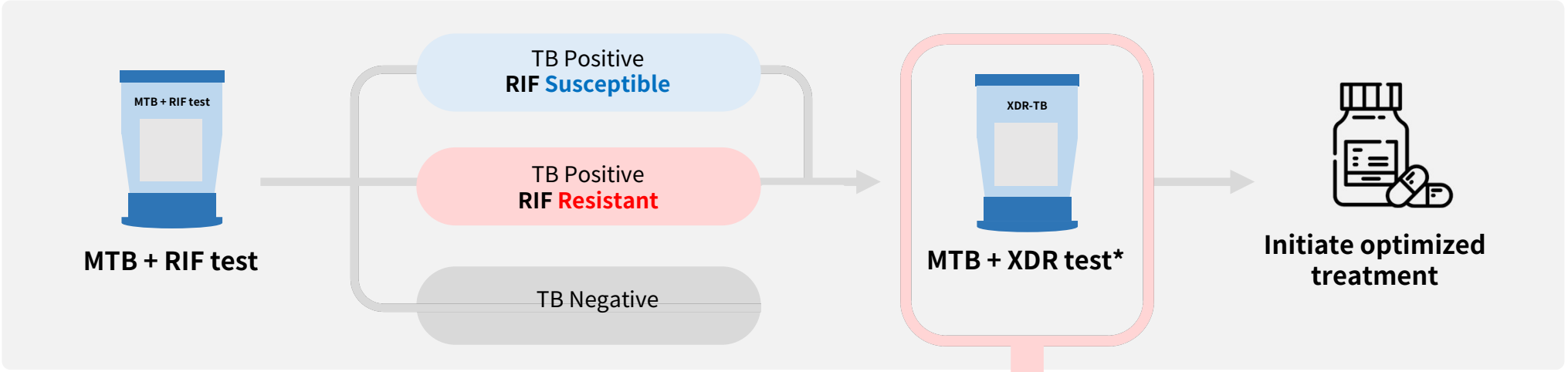
WHO consolidated guidelines on tuberculosis

Importance of RIF/INH resistant TB Dual Detection

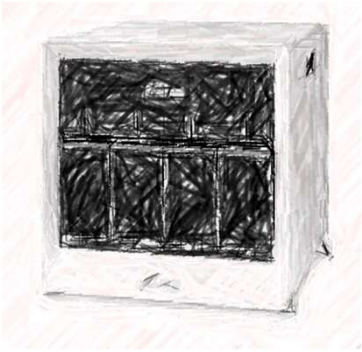
MTB + RIF ONLY test 			**STANDARD M10 MDR-TB / MTB-RIF/INH** 	
1st line anti-TB drug (**H**REZ) Possibility of further deterioration of INH resistance in case of **Hr-TB**. **Additional testing for INH resistance is required.**	Detection of INH-resistance is NOT available!	**TB Positive** RIF susceptible	**TB Positive** RIF&INH susceptible	*1st line anti-TB drug* **(HREZ)**
			Hr-TB RIF susceptible INH mono-resistant	*1st line anti-TB drug + Fluoroquinolone* **(REZ + Lfx)**
2nd lind anti-TB drug (BPaLM) Possibility of expose **RR-TB** patients to unnecessarily long and toxic therapies while excluding the possible benefits of an INH-containing regimen. **Additional testing for INH resistance is required.**	Treatment as **MDR-TB**	**TB Positive** RIF resistant	**RR-TB** RIF mono-resistant INH susceptible	**INH-inclusive regimen**
			MDR-TB RIF resistant INH resistant	*2nd lind anti-TB drug* **(BPaLM)**
-		TB Negative	TB Negative	-

Advantage of M10 Tuberculosis Assay

Existing tuberculosis diagnostic algorithm



*Old 6-Color
NO XDR-TB



New instrument is required

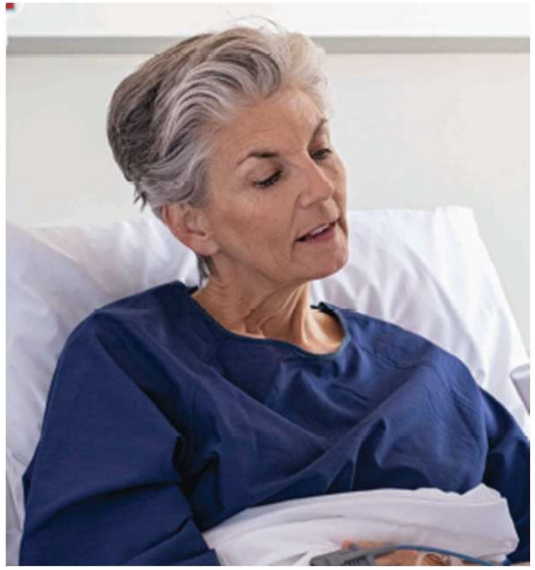
- XDR-TB assay is not compatible with old instrument.
- Installed old instrument should be replaced.
- BUT new instrument is **expensive.**

Total testing cost is more than $_____

*Manual PCR

Therefore,
users choose alternatives

SPECIFICATIONS | STANDARD M10 MTB-RIF/INH



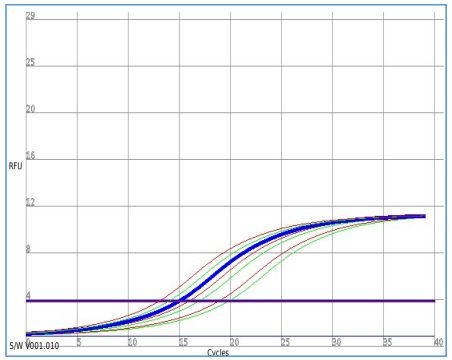
STANDARD™ M10
MTB-RIF/INH

Cat no. (11MTB30A)	Specifications
Method	**All-in-one Cartridge** Bacterial DNA Extraction : Column Method NA Amplification : Real-Time PCR + Melting curve analysis
Target	• **MTB complex** (IS1081, IS6110) • **RIF** (*rpoB1~4*) • **INH** (*katG, inhA*)
Sample type	• Sputum sediment • Sputum
	• Sputum sediment: *M. Tuberculosis* (H37Rv) – **2.25 CFU/ml** • Sputum sediment: *M. bovis* – **0.56 CFU/ml**
Testing time	**99 minutes**
Storage temp.	**2~28°C**
Test / Kit	• Cartridge x 10 • Sputum Pretreatment solution x 10 • STANDARD™ Disposable dropper (1.4 ml) x 20 • Sonication tube (2mL) x 10 • QRI

Melting Curve Analysis (MCA)

Expanding the **DST (Drug Susceptibility Testing)** product lineup through the adoption of **Melting Curve Analysis**.

Probe-based PCR



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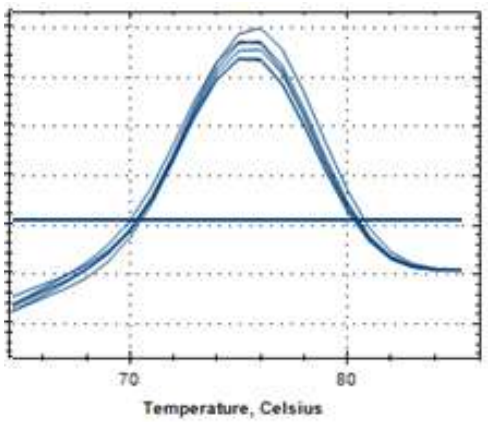
Melting curve analysis



DSTs in development

STANDARD M10 MTB-RIF/INH
STANDARD M10 preXDR-TB
STANDARD M10 XDR-TB

STANDARD M10 CT/NG/NG-AMR

PCR
Previous M10 Assay
Interpreting drug resistance results through Ct value variation

PCR + Melting
M10 MTB-RIF/INH

Interpreting drug resistance results with high sensitivity and specificity by confirming Tm (Melting Temperature) using melting curve analysis post-PCR amplification

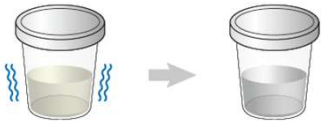
I. Procedure for sputum / sputum sediment

1. **Add Pretreatment Solution (PS)**

   Add 2 times of the vol. of the PS into the sputum or suspended sputum sediment container.
   Sputum : PS = 1 : 2 (up to 1:3)

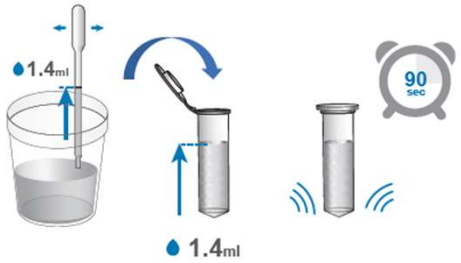
2. **Vortex and Incubate**

   Vortex for 10 seconds twice, then incubate for 15 minutes at room temperature.



3. **Transfer and Sonication**

   Transfer 1.4mL of the sample into a sonication tube and sonicate for 90 seconds.



II. Loading a sample into the cartridge

⚠ Start the test within 10 minutes of loading the sample into STANDARD M10 MTB RIF/INH cartridge.

1. **Remove Safety Clip**

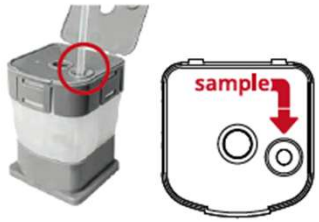
   Remove the Safety Clip from the Cartridge.

2. **Pierce Cartridge**

   Press down on the lid to pierce the sealed cartridge.

3. **Transfer Sample**

   Transfer the entire sonicated sample into the cartridge.



4. **Close Cartridge lid**

   Close the cartridge lid.

Product	STANDARD M10 MDR-TB	STANDARD M10 MTB-RIF/INH
Cat no.	**11MTB10A**	**11MTB30A**
Method	**All-in-one Cartridge** Bacterial DNA Extraction : Column Method NA Amplification : Real-Time PCR	**All-in-one Cartridge** Bacterial DNA Extraction : Column Method NA Amplification : Real-Time PCR + Melting curve analysis
Target	• **MTB complex** (IS1081, IS6110) • **RIF** (*rpoB1~4*) • **INH** (*katG, inhA*)	• **MTB complex** (IS1081, IS6110) • **RIF** (*rpoB1~4*) • **INH** (*katG, inhA*)
Sample type	• Sputum sediment, 1:2 > 1.4mL • Sputum, 1:2 > 1.4mL	• Sputum sediment, 1:2 > 1.4mL • Sputum, 1:2 > 1.4mL
Limit of Detection (LoD)	• Sputum sediment: *M. Tuberculosis (H37Rv)* – **4.2 CFU/ml** • Sputum: *M. Tuberculosis (H37Rv)* – **9.3 CFU/ml**	• Sputum sediment: *M. Tuberculosis* (H37Rv) – **2.25 CFU/ml** • Sputum sediment: *M. bovis* – **0.56 CFU/ml**
Testing time	**86 minutes**	**99 minutes**
Storage temp.	**2~28℃**	**2~28℃**
Test / Kit	10 Tests	10 Tests
Contents	• Cartridge x 10 • QRI [STANDARD M10 Sputum Pretreatment Kit] • Sputum Pretreatment solution x 10 • STANDARD™ Disposable dropper (1.4 ml) x 10 • Sputum Pretreatment tool x 10 • IFU	• Cartridge x 10 • Sputum Pretreatment solution x 10 • STANDARD™ Disposable dropper (1.4 ml) x 20 • Sonication tube (2mL) x 10 • QRI

Cat no. (11MTB40A)	Specifications
Method	**All-in-one Cartridge** Bacterial DNA Extraction : Column Method NA Amplification : Real-Time PCR
Target	• **MTB complex** (IS1081, IS6110) • **NTM** (16S rRNA / 23S rRNA / ITS)
Sample type	• Sputum sediment • Sputum
Limit of Detection (LoD)	• Sputum sediment: *M. tuberculosis* (H27Rv) – **0.65 CFU/mL** NTM (*M. Kansasii*) – 0.40 CFU/mL • Sputum: *M. tuberculosis* (H27Rv) – **2.00 CFU/mL** NTM (*M. Kansasii*) – 0.85 CFU/mL
Testing time	**69 minutes**
Storage temp.	**2~28℃**
Kit contents (10T/Kit)	• Cartridge x 10 • Sputum Pretreatment solution x 10 • STANDARD™ Disposable dropper (1.4 ml) x 20 • Sonication Tube (2mL) x 10 • QRI

Product	STANDARD M10 MTB/NTM	STANDARD M10 MTB/NTM v2.0
Cat no.	**11MTB20A**	**11MTB40A**
Method	**All-in-one Cartridge** Bacterial DNA Extraction : Column Method NA Amplification : Real-Time PCR	**All-in-one Cartridge** Bacterial DNA Extraction : Column Method NA Amplification : Real-Time PCR
Target	• **MTB complex** (IS6110) • **NTM** (ITS)	• **MTB complex** (IS1081, IS6110) • **NTM** (16S rRNA / 23S rRNA / ITS)
Sample type	• Sputum sediment, 1:2 > 1.4mL • Sputum, 1:2 > 1.4mL	• Sputum sediment, 1:2 > 1.4mL • Sputum, 1:2 > 1.4mL
Limit of Detection (LoD)	• Sputum sediment: *M. tuberculosis* – **0.3 CFU/mL** NTM – 25 ~ 81 copies/mL • Sputum: *M. tuberculosis* – **0.9 CFU/mL** NTM – 18 ~ 82 copies/mL	• Sputum sediment: *M. tuberculosis* (H27Rv) – **0.65 CFU/mL** NTM (*M. Kansasii*) – 0.40 CFU/mL • Sputum: *M. tuberculosis* (H27Rv) – **2.00 CFU/mL** NTM (*M. Kansasii*) – 0.85 CFU/mL
Testing time	**72 minutes**	**69 minutes**
Storage temp.	**2~28°C**	**2~28°C**
Test / Kit	10 Tests	10 Tests
Contents	• Cartridge x 10 • QRI [STANDARD M10 Sputum Pretreatment Kit] • Sputum Pretreatment solution x 10 • STANDARD™ Disposable dropper (1.4 ml) x 10 • Sputum Pretreatment tool x 10 • IFU	• Cartridge x 10 • Sputum Pretreatment Solution x 10 • STANDARD™ Disposable Dropper (1.4 ml) x 20 • Sonication Tube (2mL) x 10 • QRI