

TB DIAGNOSIS & TREATMENT

NTEP

CASE DEFINITIONS

- **MICROBIOLOGICAL CONFIRMED TB** : Microbiologically confirmed TB refers to a **presumptive TB case** from whom a biological specimen is
 - A. positive for acid fast bacilli
 - B. or positive for Mycobacterium tuberculosis on culture
 - C. or positive for tuberculosis through Rapid Diagnostic molecular test
- **CLINICALLY DIAGNOSED TB** : Clinically diagnosed TB refers to a **presumptive TB case** who is **not microbiologically confirmed**, but has been **diagnosed with active TB by a clinician** on the basis of :
 1. X-ray abnormalities,
 2. histopathology
 3. or clinical signswith a decision to treat the patient with a full course of Anti-TB treatment.

CLASSIFICATION OF TB BASED ON ANATOMICAL SITES

- PULMONARY TB
- EXTRAPULMONARY TB
- Miliary TB is classified as PTB because there are lesions in the lungs.
- A patient with both pulmonary and extra-pulmonary TB should be classified as a case of Pulmonary TB.

CLASSIFICATION BASED ON HISTORY

- **NEW TB PATIENT** - A TB patient who has **never had treatment for TB** or **has taken anti-TB drugs for less than one month** is considered as a new TB patient.
- **PREVIOUSLY TREATED TB** - A patient who has received one month or more of anti-TB drugs from any source in the past.
- **Recurrent TB patient** - A TB Patient **previously declared as successfully treated** (cured/treatment completed) and is subsequently found to be microbiologically confirmed TB is a recurrent TB patient.
- **Treatment after failure patients** are those who have previously been treated for TB and whose treatment failed at the end of their most recent course of treatment.
- **Treatment after lost to follow-up** - A TB patient previously **treated for TB for one month or more** and was declared lost to follow-up (LFU) in their most recent course of treatment and subsequently found to be microbiologically confirmed TB.
- **Other previously treated patients** are those who have previously been treated, who cannot be classified into any of the above.

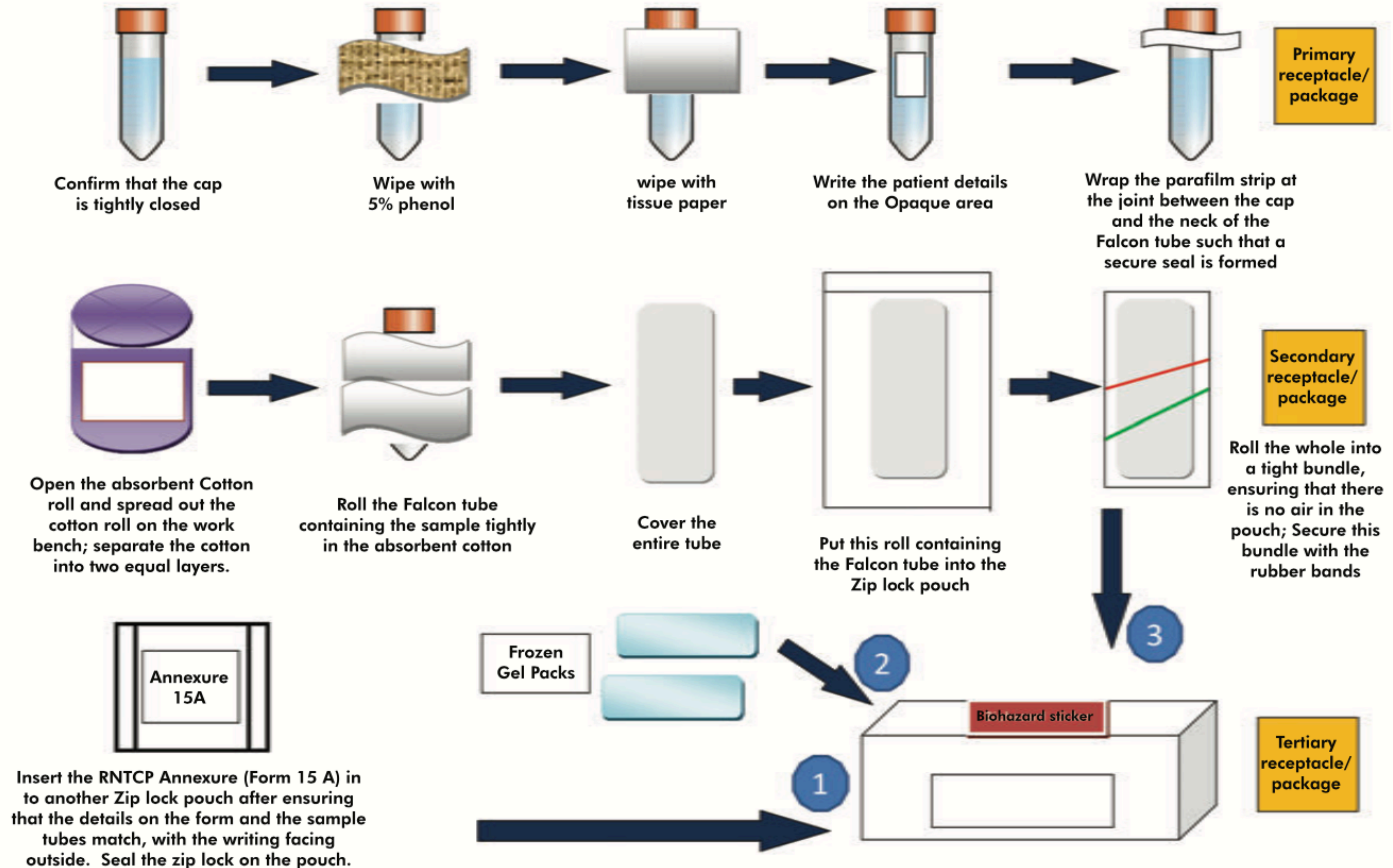
DIAGNOSIS

SPUTUM COLLECTION

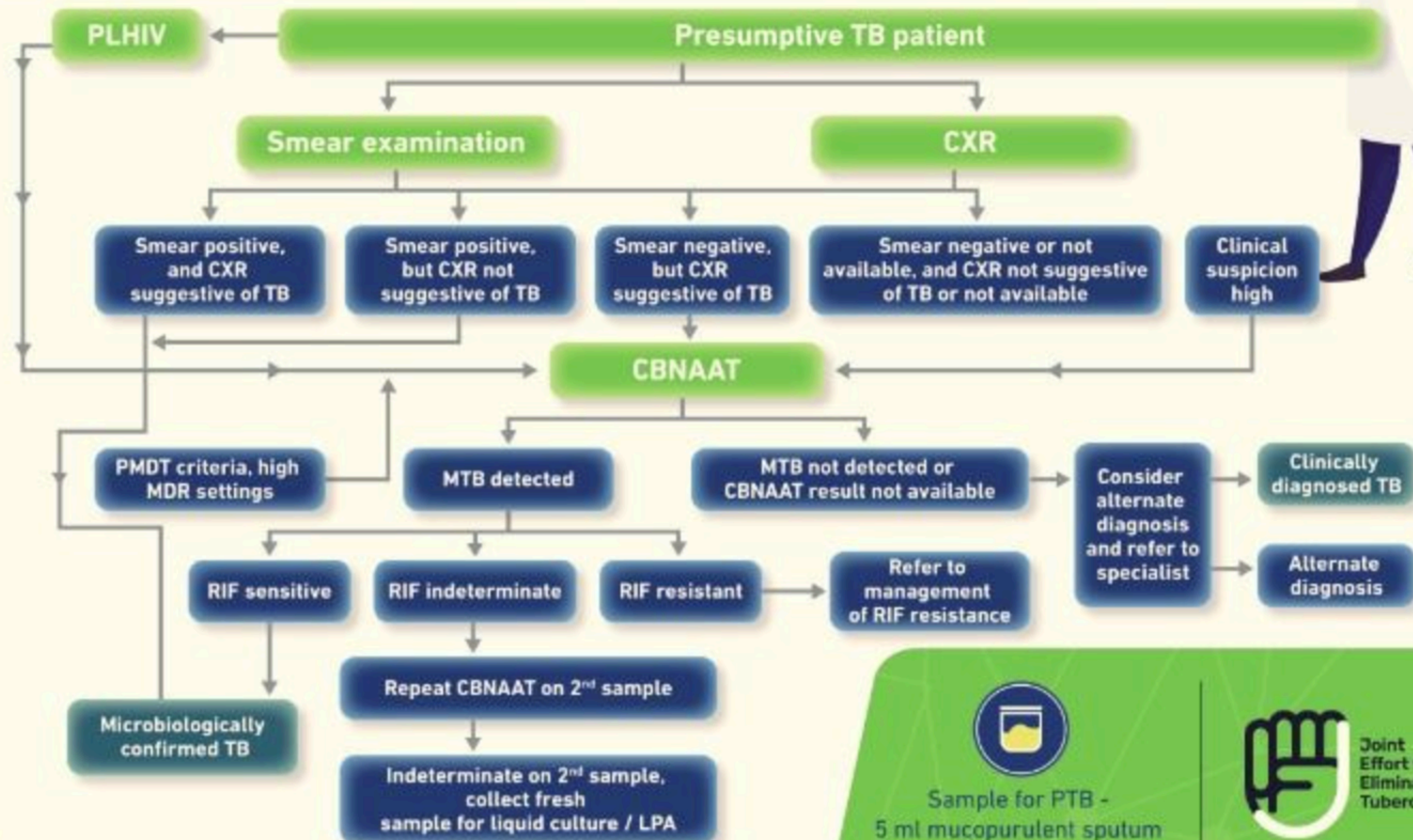
NTEP DOCUMENT

- For the diagnosis of tuberculosis, the two specimens of a patient i.e., one "SPOT-and the other an early MORNING " sample are collected. The spot sample is designated as 'A' and the early morning sample as 'B' adjacent to laboratory serial number. For follow-up sputum examination of patients, one specimen of sputum is collected. The specimen collected in the early morning is marked as 'B' and spot sample collected subsequently is marked as 'A'.
- The person collecting the specimen demonstrates how to open and close the container. The patient is instructed to inhale deeply (2–3 times), cough out sputum from the chest, spit into the container and close it.
- The person collecting the specimen should make sure that no one stands in front of the patient who is trying to collect sputum. Sputum should not be collected in closed rooms, toilets or ill-ventilated rooms.
- When a patient has only coughed up saliva or has not coughed up at least 2 l of sputum, the patient should be encouraged to give good specimen
- In case the container is soiled outside, it should be wiped dry using cotton swab and the same is disinfected in a bin containing 5% phenol solution.

Triple packaging system for sputum transportation



DIAGNOSTIC ALGORITHM FOR PULMONARY TB

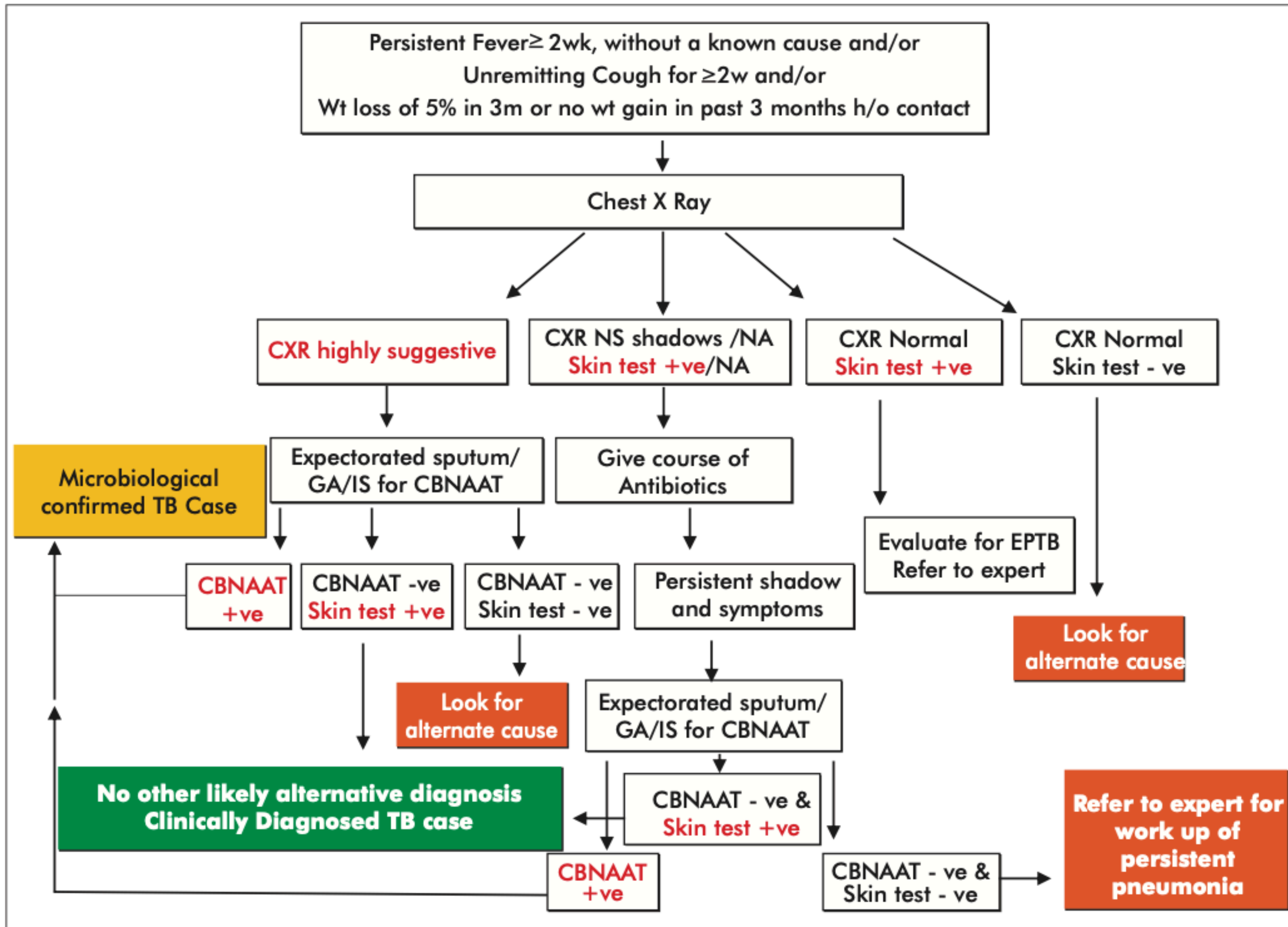


Sample for PTB -
5 ml mucopurulent sputum
without saliva or blood



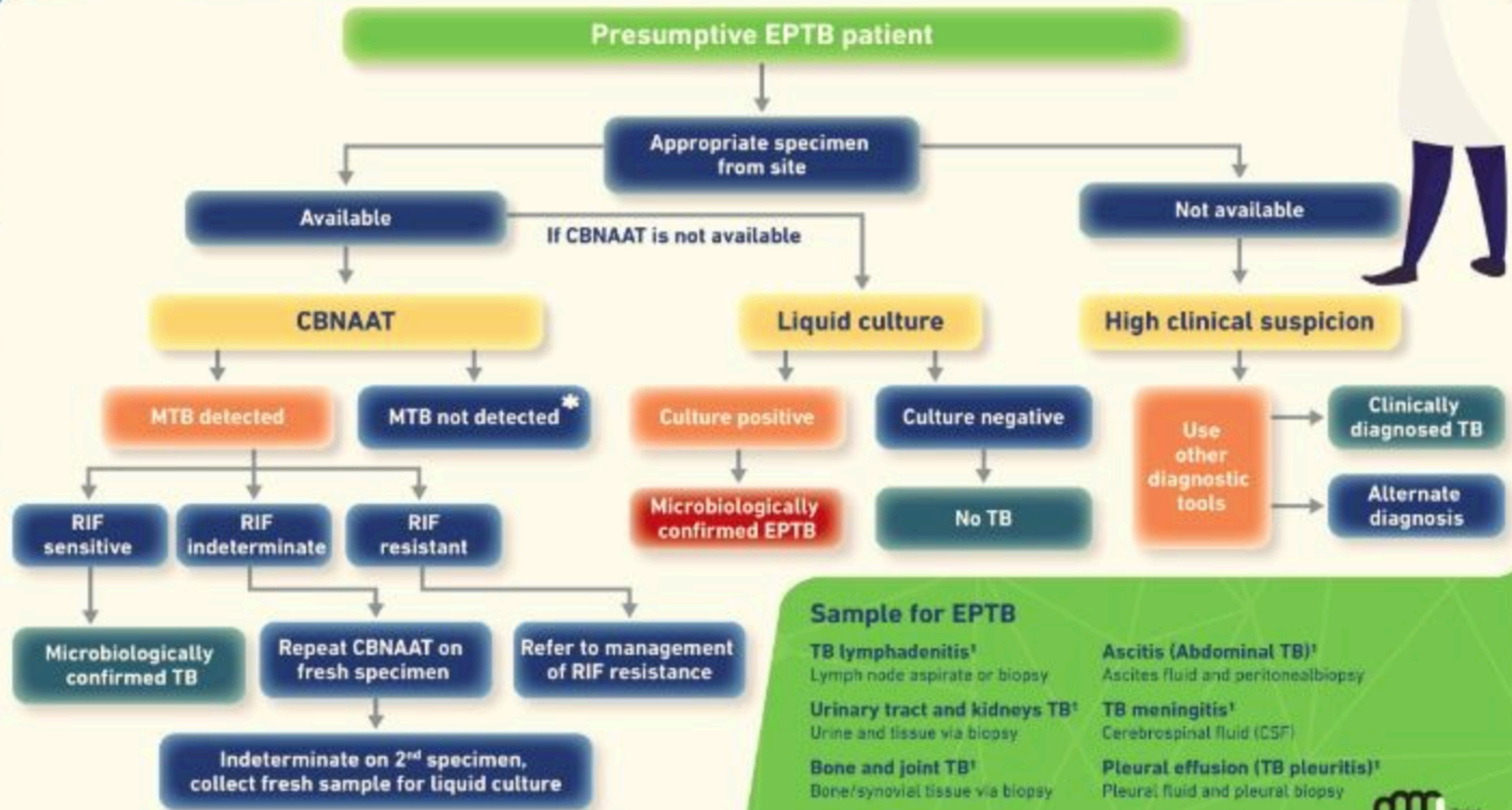
Joint
Effort for
Elimination of
Tuberculosis

Diagnostic algorithm for Paediatric Pulmonary Tuberculosis





DIAGNOSTIC ALGORITHM FOR EXTRA PULMONARY TB



Sample for EPTB

TB lymphadenitis¹

Lymph node aspirate or biopsy

Urinary tract and kidneys TB¹

Urine and tissue via biopsy

Bone and joint TB¹

Bone/synovial tissue via biopsy

Genito-urinary tract TB¹

Tissue via biopsy
(Endometrial tissue in women)

Ascitis (Abdominal TB)¹

Ascites fluid and peritoneal biopsy

TB meningitis¹

Cerebrospinal fluid (CSF)

Pleural effusion (TB pleuritis)¹

Pleural fluid and pleural biopsy



Joint Effort for Elimination of Tuberculosis

¹ Diagnosis of Tuberculosis: Importance of appropriate specimen collection, GP clinics, Let's talk TB (supplement) First edition 2014.

* If high clinical suspicion then follow high clinical suspicion flow diagram

PRESUMPTIVE DR-TB

It refers to the following patients in order of their risk:

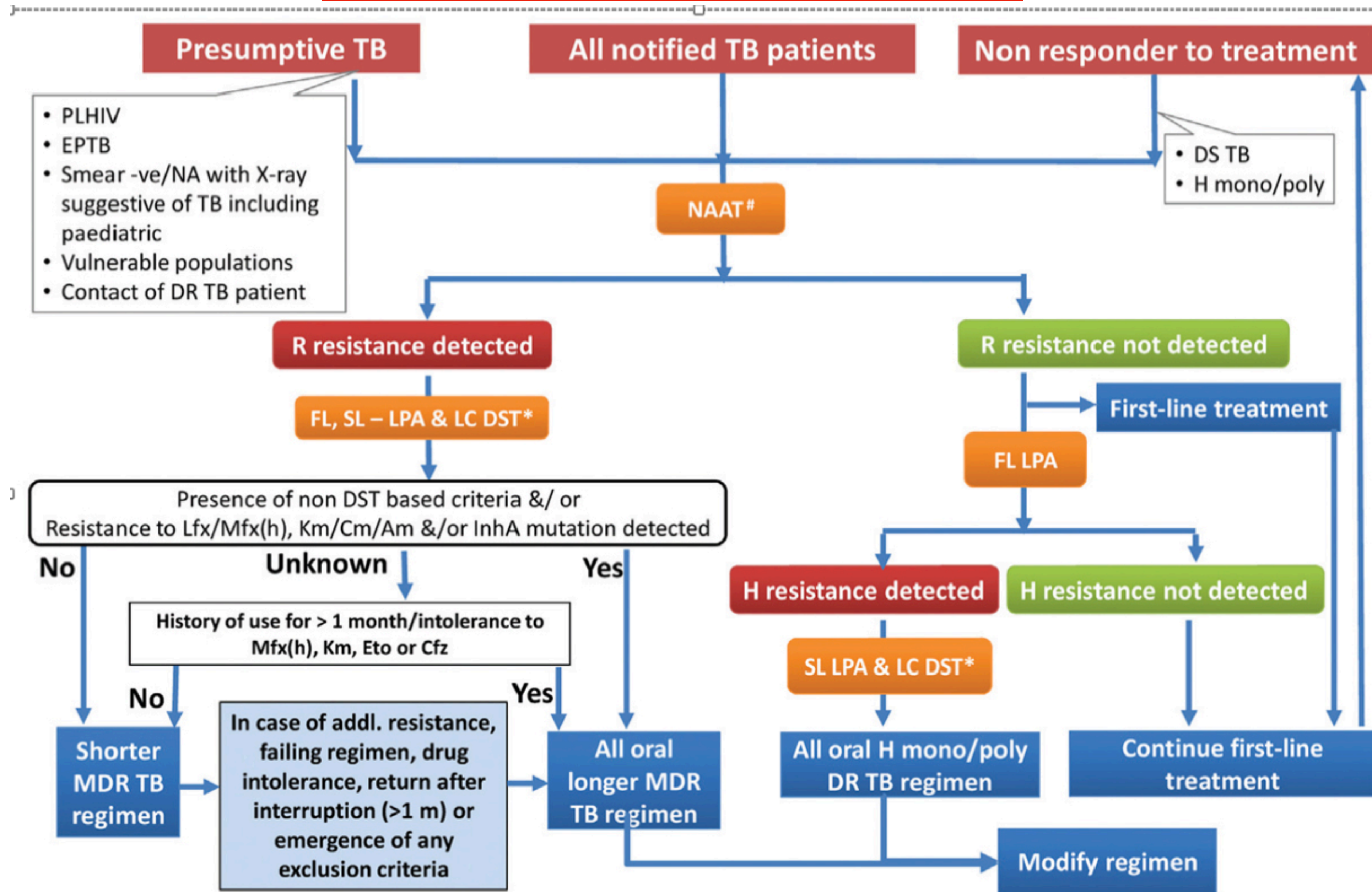
- A. TB patients found **positive on any follow-up sputum smear examination during treatment with First line drugs** including treatment failures
- B. paediatric TB non-responders;
- C. TB patients who are contacts of DR-TB
- D. previously treated TB patients
- E. new TB patients with HIV co-infection
- F. all notified new TB patients (all presumptive patients are send for CB-NAAT to know about rifampicin resistance status)

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CLASSIFICATION BASED ON DRUG RESISTANCE

1. **MONO-RESISTANCE (MR)** : Resistant to one first line Anti-TB drug only.
2. **POLYDRUG RESISTANCE** : Resistant to more than one first line Anti-TB drug other than H & R.
3. **MULTIDRUG RESISTANCE (MDR)** : Resistant to both H & R with or without resistance to other first line drugs.
4. **RIFAMPICIN RESISTANCE** : Resistant resistance to rifampicin detected with or without resistance to other anti-TB drugs excluding INH.
 - Patients, who have any Rifampicin resistance, should also be managed as if they are an MDR TB case.
5. **EXTENSIVE DRUG RESISTANCE** : MDR + resistance to FQ + 2nd line Injectables.

INTEGRATED DRUG RESISTANT TB ALGORITHM



NAAT include CBNAAT & TruNAAT

*LC DST will be done as per the diagnostic algorithm

** Refer table of exclusion criteria for shorter MDR-TB regimen

TREATMENT OF TB

NTEP

DRUG SENSITIVE TB		DRUG RESISTANT TB		
INTENSIVE PHASE	CONTINUATION PHASE	H-MONO/POLY DRUG RESISTANT	MDR-TB	
2 HRZE	4 HRE	• Z - Isoniazid • E - Ethambutol • R - Rifampicin • O - levOfloxacin	SHORTER MDR	LONGER MDR
			4 - 6 months of CHOKZEE	1. 18 - 20 Months of Bedaquiline (for 6 months)
			Followed by 5 months of COZE	2. Linezolid 3. Clofazimine 4. Cycloserine
		C - Clofazimine H - High dose Isoniazid O - mOxifloxacin high dose K - Kanamycin Z - pyraZinamide E - Ethambutol E - Ethionamide	E - Ethambutol	LONGER MDR Linezolid dose is reduced to 300mg after 6 - 8 months.

FIXED DOSE COMBINATIONS (FDC) ARE GIVEN.

Intensive phase - 4 FDC
Continuation phase - 3 FDC

Daily Dose Schedule for Adults (as per weight bands)

Weight category	Number of tablets (FDCs)		
	Intensive phase	Continuation phase	
	HRZE	HRE	
	75/150/400/275	75/150/275	
25-34 kg	2	2	
35-49 kg	3	3	
50-64 kg	4	4	
65-75 kg	5	5	
>75 kg	6	6	

During treatment if the weight of the patient increases by more than 5 kg and crosses the next weight band category then patient should be given the next higher weight band FDC drugs.

PEDIATRIC FDCs

Drug dosage for paediatric TB (24)

Weight category	Number of tablets (dispersible FDCs)			
	Intensive phase		Continuation phase	
	HRZ	E	HR	E
	50/75/ 150	100	50/75	100
4–7 kg	1	1	1	1
8–11 kg	2	2	2	2
12–15 kg	3	3	3	3
16–24 kg	4	4	4	4
25–29 kg	3 + 1A*	3	3 + 1A*	3
30–39 kg	2 + 2A*	2	2 + 2A*	2

* A=Adult FDC (HRZE = 75/150/400/275; HRE = 75/150/275). It is added in higher weight band categories i.e. > 25 kg as these children may be able to swallow tablets.

Key Product Information (for Paediatric)

- 1. Dispersible FDC, flavoured**
Rifampicin 75 mg + Isoniazid 50 mg + Pyrazinamide 150 mg
Rifampicin 75 mg + Isoniazid 50 mg
- 2. Dispersible Loose drugs**
Ethambutol 100 mg
Isoniazid 100 mg

Pyridoxine may be given at a dosage of 10 mg per day to all children receiving INH containing therapy irrespective of age group.

All adolescents up to 18 years of age and weighing less than 39 kg, are to be treated using paediatric weight bands and children weighing more than 39 kg with adult weight bands.

CHEMOPROPHYLAXIS

ISONIAZID PREVENTIVE THERAPY

1. PLHIV & CL-HIV
2. Children < 6 years of age who are close contact of TB patients
3. For all HIV infected children who either had a known exposure to an infectious TB case or are Tuberculin skin test (TST) positive (≥ 5 mm induration) but have no active TB disease
4. All TST positive children who are receiving immunosuppressive therapy
5. A child born to mother who was diagnosed to have TB in pregnancy should receive prophylaxis for 6 months.
6. Children who had completed TB treatment are also given INH prophylaxis for extra 6 months.

DOSE

ADULTS & ADOLESCENTS : @300 mg + 50 mg Pyridoxime X 6 months

CHILDREN age < 10 ys : 10 mg Isoniazid + 25 mg pyridoxine X 6 months

REFERENCE SECTION

VULNERABLE POPULATION

Clinical	Social	Geographical
Clients attending HIV Care Settings	Prisoners	Urban Slums
Substance abuse including smokers	Occupations with risk of developing TB (mines, coal industry, sand blasting industries, weaving & glass industries, stone crushers, cotton mill workers, tea garden workers, rice mill workers etc.,)	Hard to reach areas
Co-morbidities like Diabetes Mellitus, Malignancies, patients on dialysis and on long term immunosuppressant therapy	People in Congregate settings – e.g., night shelters, De-addiction centres, Old age homes	Indigenous and tribal populations
Health Care Workers		
Household & Workplace Contacts		
Patients with Past History of TB		
Malnourished		
Antenatal mothers attending antenatal clinics/MCH clinics		

TYPES OF CASE FINDINGS IN NTEP

Passive Case Finding: When the Patient Voluntarily reports symptoms to the Medical Officer.

Intensified Case Findings: When the Medical Officer searches for TB symptoms among the individual seeking care in the health facility e.g., ART Centre, Diabetic Clinics, NCD Clinics.

Active Case Finding: When the Community health workers seeks for TB symptoms among the vulnerable key population. The Programme encourages Active Case finding as an intervention for Ending TB