

## Sensitivity of CBNAAT in Diagnosis of Tuberculosis Infection and Rifampicin Resistance in Pulmonary and Extra pulmonary Sample

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**Abstract:** Background:

Tuberculosis is still one of the major health problem in the INDIA. India accounts for almost a quarter of TB cases world wide. According to the Globle TB Report 2017, 28 lakh new cases were reported in India. Approximately 4.5 lakh people die every year due to TB. Drug Resistant TB is one of the major cause of mortality in India, we can rule out drug resistance in TB bacilli with help of CBNAAT for both pulmonary and Extra-pulmonary TB. Here in this study we had taken the extrapulmonary sample in our college for the purpose of TB bacilli detection and resistance to Rifampicin to detect the resistance tuberculosis in them.

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### I. Introduction

CBNAAT (Gene-Xpert) is now a day most widely used, easily available, cheap, sensitive and specific test for diagnosis of tuberculosis which is one of the most prevalent infectious disease in India with high mortality. By this test we can easily and rapidly diagnose tuberculosis not only from sputum but also from various sample such as gastric aspirate, pus from any swelling, ascitic fluid, lymph node swelling, pleural fluid, urine, FNAC fluid, etc. It is also very much helpful in detecting first line anti TB drugs resistance (MDR TB) which is increasing now a days and has great influence on the treatment and outcome. According to the Programmatic Management Of Drug Resistant TB (PMDT) in India, all extra-pulmonary samples like lymphnode aspiration, bone abscess, pus, CSF (cerebrospinal fluid), pleural fluid, gastric leakage, Endotracheal secretion, ascitic fluid, ICD (intercostals drainage) fluid, Broncho-Alveolar lavage, should go for CBNAAT to rule out Drug Resistance TB bacilli.

### II. Material And Methods

Total number of specimen run for CBNAAT test (sputum, gastric aspirate, pus, fluid, etc) in Designated Microscopy Centre (DMC) Bhavnagar, from 01/01/2018 to 20/06/2018 were studied. Samples were collected for CBNAAT in the FALCON TUBE.

**Study Design:** Retrospective, observational study

**Study Location:** This was a tertiary care teaching hospital based study done in Department of Respiratory Medicine, Sir. T Hospital, Jail road, Bhavnagar.

**Study Duration:** January 2018 to June 2018.

**Sample size calculation:** The sample size was estimated on the basis of a single proportion design. Confidence interval of 10% and confidence level of 95% was assumed.

**Inclusion criteria:**

Pulmonary and extrapulmonary sample send for CBNAAT.

**Exclusion criteria:**

Blood and stool,

Sample containing food particles,  
 Inadequate sample,  
 Indeterminate result of test,  
 Sample not properly processed.

**Procedure methodology.**

Results of the CBNAAT sample were taken from the Laboratory and compiled. Results were in the form of MTB detected or not and Rifampicin resistance detected or not .

**III. Result**

MONTH Sample	JANUARY (total/mtb detected/rif resistance)	FEB (total/mtb detected/rif resistance)	MARCH (total/mtb detected/rif resistance)	APRIL (total/mtb detected/rif resistance)	MAY (total/mtb detected/rif resistance)	JUNE (total/mtb detected/rif resistance)
Sputum	111 /87/9	128 /78/6	153 /112/8	141/108/16	148/114/13	70/53/8
Gastric Aspirate	13/5/0	13/2/0	16/3/0	16/5/0	15/6/0	6/3/0
Lymph node+ Pus	3/2/0	6/3/0	4/1/0	6/4/0	7/2/0	2/1/1
Pleural ICD fluid +	2/1/0	3/0/0	3/0/0	8/4/0	2/0/0	4/1/0
Ascitic fluid	1/0/0	0/0/0	1/0/0	0/0/0	0/0/0	0/0/0
CSF	0/0/0	3/0/0	3/0/0	0/0/0	1/0/0	1/1/1

Above result showed 80-85% of sputum sample, 35-40% of gastric aspirate, 60 to 70% of fluid sample were positive for mycobacterium tuberculosis infection.

Respiratory secretion (Sputum):

	Sensitivity	Specificity
AFB Smear +Ve	95%	98%
AFB Smear -Ve	48%	95%

**IV. Discussion**

The CBNAAT/ Xpert MTB/Rif test/ Gene-Xpert is a cartridge-based fully automated NAAT (Nucleic Acid Amplification Test) for TB case detection and Rifampicin resistance testing. It purifies, concentrates, amplifies (by rapid, real-time PCR) and identifies targeted nucleic acid It sequences in the TB genome (rpo b), and provides results from unprocessed sputum samples in less than 2 hours. Easily available in government as well as private set up. Government set up also runs various sample received from private doctors free of cost.

**Sample for CBNAAT test:**

- Sputum, BAL fluid,
- Gastric lavage (with out food particles),
- Pleural fluid. ICD fluid
- Pus from various swellings and lymph node
- Incision and drainage sample
- Ascitic fluid
- CSF
- Aspiration (from Para-vertebral swelling, para-spinal collection,) / BIOPSY material
- Mid stream urine
- Stool & blood are not recommended

**Sample collection:**

- Collect 1 -4 ml specimen
- Collect the sample in the tube called FALCON tube.
- Specimen should be held at 2-8C wherever possible

- Do not leave the specimen at room temperature for more than 3 days.

**Running a CBNAAT test:**



**WHO approved diagnostic options:**

Year	Technology	Turn around time	Sensitivity gain
<b>Before 2007</b>	ZN microscopy Solid Culture	2-3 days 30-60 days	Baseline
<b>2007</b>	Liquid Culture Rapid speciation	15-30 days	+10% compared to LJ
<b>2008</b>	Line Probe Assay (1st line, Rif & INH)	2-4 days	At this time for S+ only
<b>2009</b>	LED-based FM	1-2 days	+10% compared to ZN
<b>2010</b>	Integrated NAAT (TB, Rif)	120 minutes	+40% compared to ZN

**Multi-centre FIND Validation Studies by WHO:**

Four geographically and epidemiologically diverse settings (India, Southafrica, Ajarbijan, Peru )

**Study result:**

Overall sensitivity of a single Xpert test 92.2%.  
 Smear-negative/ Culture-positive:  
 single Xpert test - 72.5% sensitivity;  
 Two tests 85.1%; Three tests 90.2%  
 Three tests 90.2%  
 Rifampicin resistance detection  
 sensitivity 98%; specificity 99%  
 detection of drug resistance by 60%  
 detection of TB infection in HIV patients by 50%

**Multi-centre FIND Demonstration Studies**

9 district, sub-district laboratories and microscopy centers in 6 countries

**Study results:**

Sensitivity  
 PULMONARY TB  
 Smear pos. /Culture pos. 99 %  
 Smear neg. / Culture pos. >80%  
 HIV-positive 86% sensitivity  
 HIV-negative 92% sensitivity  
 RIFAMPICIN RESISTANCE  
 Sensitivity 95.1%  
 Specificity 98.4%

**TB and HIV.**

Sputum smear microscopy has a particularly low sensitivity for detecting TB among PLHIV. This is because people in later stages of HIV infection and with compromised immune systems often release fewer organisms

into their sputum, at concentrations below the threshold for detection of mycobacterium tuberculosis by smear examination. (2 sample CBNAAT).

For previously treated patient, at starting of AKT its now compulsory to send sample for CBNAAT.

### **V. Conclusion**

- CBNAAT- a easily available, cheap, rapid, reliable, sensitive and specific test for diagnosis of mycobacterium tuberculosis infection as well as resistance to first line anti-Tubercular drugs(MDR-TB) which is increasing now-a-days and India is facing problem in elimination of Tuberculosis due to resistance cases.
- Send gastric aspirate from children for diagnosis of TB.
- Send sample from biopsy or any swelling in which you are suspecting tuberculosis except blood stained and stool sample.
- Send any sample any time when you are doubting about tubercular infection, also when you are suspecting resistance tuberculosis in your patient who is already on treatment and not improving.
- Send sample in FALCON tube after filling proper form.
- Properly diagnose and treat the TB patient for reducing the burden of TB and come forward to eliminate the Tuberculosis infection from India..

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