Cross Test of ICT-TB and *Genexpert* Examination in Suspected Cases of *M. tuberculosis* Infection at Bima Regency Regional Hospital

Ida Bagus Rai Wiadnya[1], Syahrul Sani[2], Lalu Srigede[3]
[1-3] Departemen of Medical Laboratory Technology, Poltekkes Kemenkes Mataram, Indonesia
*Email : s3bimapeace17@gmail.com

Article Info	ABSTRACT
	GeneXpert is able to detect specimens that are positive for *M. tuberculosis* in a shorter time and with high sensitivity and specificity. ICT-TB is used to detect the presence of antibodies produced by *M. tuberculosis* infection in the body. This response requires time to form. However, actually ICT-TB is an easier method compared to Genexpert. So this research was carried out to compare the results of the two methods. To determine the results of cross-testing of ICT-TB and Genexpert examinations on cases of suspected *M. tubeculosis* infection at the Bima Regency Hospital. This is an analytical observational study with a cross-sectional design. The samples used in this research were 52 samples and the data were analyzed descriptively. The distribution of suspected tuberculosis based on gender is 54% male and 46% female. Based on age group, Toddlers 13.5%, Children 11.5%, Teenagers 9.6%, Adults 44.2% and Elderly 21.2%. ICT-TB examination results are negative. Examination with *Genexpert* on the same patient was negative. **Conclusion:** From the results of research using ICT-TB and *GeneXpert* in patients with suspected *M. tuberculosis* infection, negative results were obtained.

INTRODUCTION

Tuberculosis (TB) is still a public health problem in the world. This disease is caused by the bacterium Mycobacterium tuberculosis and is contagious (Bloom et al., 2017). Based on the 2022 Global TB Report, the estimated number of people diagnosed with TB in 2021 globally will be 10.6 million cases, an increase of around 600,000 cases from 2020, which was estimated at 10 million TB cases (Minggarwati, Juniarti and Haroen, 2023). Based on 2018 data, the number of cases of TB sufferers (all types) in West Nusa Tenggara (NTB) Province reached 6390 people from the discovery target of 22,245 people or 28.73% (Sentana et al., 2021). Dikes data for 2021 shows that Bima Regency is ranked 4th in the discovery of new TB cases out of 10 regencies/cities in NTB Province, namely 35.57% of the discovery target of 1,549 cases. This shows that Bima district is still far from the target of achieving TB case detection.

ICT-TB (Immunochromatography Tuberculosis) is a serological test for detecting M. tuberculosis antibodies in serum using a specific antigen derived from the cytoplasmic membrane of M. tuberculosis, M.tb 38 kDa (Baghaei et al.,

2011; Buchari, 2019). The working principle of ICT-TB is the antigen reaction on the device which will bind to anti-TB from the patient's sample which is conjugated to colored fine particles, namely colloidal gold (red) as a label (Buchari, 2019). ICT-TB is a serological test that is fast, simple and easy to operate when compared to TB diagnostic work in the form of acid-fast bacilli (BTA) staining and rapid molecular tests (TCM).

Based on research by Mursalim (2021), it is stated that ICT TB has low sensitivity and sufficient specificity so it is still not good if used for initial screening detect pulmonary TB. Research by Atmayanta (2019), shows that the sensitivity of the ICT TB examination is 62.5%, meaning that the ability of the ICT TB examination in diagnosing patients with positive results and correctly suffering from pulmonary TB is 62.5%, while the specificity of the ICT TB examination is 100% , meaning that the ability of the ICT TB examination to diagnose patients with negative results and who do not actually suffer from pulmonary TB is 100%. The low sensitivity and specificity results of the ICT TB examination can be influenced by several things, such as: Immunoglobulin G not yet circulating in the patient's serum (Subroto et al., 2017).

Apart from the ICT TB method, the use of GeneXpert MTB as an initial examination for TB diagnosis has also been recommended by WHO since 2010. The GeneXpert MTB examination is a molecular examination using Nucleic Acid Amplification Technology (NAAT) technology which can diagnose TB within 2 hours (Kemenkes, 2017). Based on research by Affiyanti et al (2023), it shows that the TCM method with the GeneXpert tool is able to detect specimens that are positive for Mycobacterium tuberculosis in a shorter time and with high sensitivity and specificity. Examination of suspected pulmonary TB using the ICT TB method and GeneXpert MTB is a rapid diagnostic method with relatively high sensitivity and specificity, so it is hoped that this examination can reach peripheral health services and speed up TB diagnosis and then make it easier to monitor and supervise public health in TB disease. especially at Bima Hospital. However, there are several obstacles that are often encountered during examinations using TCM, one of which is taking sputum samples which are often difficult to obtain so that examinations are delayed and diagnosis is hampered. Therefore, it is necessary to look for other alternative examinations.

Based on the description above, the author is interested in conducting research on ICT-TB and Genexpert Cross-Examination Tests in Suspected Cases of M. tuberculosis Infection at the Bima Regency Regional Hospital.

MATERIALS/METHOD

This research is an analytical observational study with a cross-sectional design This research was conducted from January 2024 to May 2024. In this research, the samples used were sputum and blood from suspected M. tuberculosis infection. The number of respondents in this research was 52 respondents who were suspected of being infected with M. tuberculosis sent by several health service facilities in the city and district of Bima. This research was carried out at the Bima Regional Hospital Laboratory located at Jl. Langsat No. 1 Raba District, Bima City, West Nusa Tenggara Province. Next, a TCM examination is carried out for sputum samples, while for blood samples centrifugation is carried out first

to obtain serum for further examination using the ICT TB method. The examination result data will be analyzed descriptively.

RESULTS AND DISCUSSION
Table 1. Examination Result Data

NO	PETIENT CODE	GENDER (L/P)	AGE (Years)	CHECK UP RESULT	
				ICT TB	GeneXpert
1	Sm	P	52	Negatif	Negatif
2	Mh	L	52	Negatif	Negatif
3	Ms	L	31	Negatif	Negatif
4	Aw	L	9	Negatif	Negatif
5	Ar	L	57	Negatif	Negatif
6	Ma	L	5	Negatif	Negatif
7	Hs	P	47	Negatif	Negatif
8	Rt	P	16	Negatif	Negatif
9	Mm	P	48	Negatif	Negatif
10	Sf	L	50	Negatif	Negatif
11	Af	L	51	Negatif	Negatif
12	Rm	L	16	Negatif	Negatif
13	Sj	L	54	Negatif	Negatif
14	Hd	P	54	Negatif	Negatif
15	Stm	P	53	Negatif	Negatif
16	An	P	40	Negatif	Negatif
17	Ml	L	38	Negatif	Negatif
18	Rh	P	42	Negatif	Negatif
19	Sn	P	49	Negatif	Negatif
20	Am	L	67	Negatif	Negatif
21	Uw	L	5	Negatif	Negatif
22	Ab	L	63	Negatif	Negatif
23	As	L	60	Negatif	Negatif
24	Nb	P	5	Negatif	Negatif
25	Mt	L	12	Negatif	Negatif
26	Sr	P	48	Negatif	Negatif
27	Fr	L	23	Negatif	Negatif
28	Nr	P	7	Negatif	Negatif
29	Jk	L	73	Negatif	Negatif
30	Jf	L	69	Negatif	Negatif
31	Ah	L	67	Negatif	Negatif
NO	PETIENT CODE	GENDER (L/P)	AGE (Years)	CHECK UP RESULT	
				ICT TB	GeneXpert

32	Rl	P	60	Negatif	Negatif
33	Ab	L	52	Negatif	Negatif
34	Ra	P	60	Negatif	Negatif
35	Sh	P	56	Negatif	Negatif
36	Na	P	5	Negatif	Negatif
37	Ss	P	49	Negatif	Negatif
38	Is	L	64	Negatif	Negatif
39	Hn	L	35	Negatif	Negatif
40	Ks	L	56	Negatif	Negatif
41	Az	P	9	Negatif	Negatif
42	Fm	P	20	Negatif	Negatif
43	Sl	L	33	Negatif	Negatif
44	Ha	L	66	Negatif	Negatif
45	Ay	P	3	Negatif	Negatif
46	Mr	L	12	Negatif	Negatif
47	Km	P	15	Negatif	Negatif
48	Mr	P	8	Negatif	Negatif
49	Hd	L	80	Negatif	Negatif
50	Sn	P	56	Negatif	Negatif
51	Mg	L	2	Negatif	Negatif
52	Sd	P	2	Negatif	Negatif

From table 4.2 it can be seen that the ICT-TB examination results data on suspected tuberculosis infection totaling 52 respondents with negative results. Then the researchers carried out a comparison with the Genexpert TCM examination using sputum from the same patient and obtained negative examination results.

Tabel 2. Frequency distribution by gender

Gender	Frequency	Percentage (%)
Man	28	54
Woman	24	46
Total	52	100

Tabel 3. Frequency distribution by age group

Age Grup (years)	Frequency	Percentage(%)
Toddlers (1-5)	7	13,5
Children (6-12)	6	11,5
Teenagers (13-24)	5	9,6
Adults (25-59)	23	44,2
Elderly (>59)	11	21,2
Total	52	100

From Table 3 it can be seen that the highest number of suspected M. tuberculosis infections were in adults, namely 44.2%.

Immuno chromatography Test-Tuberculosis (ICT-TB) examination on samples suspected of tuberculosis infection who were referred for examination to

the Bima Regional Hospital, totaling 52 respondents. Based on data analysis, it was found that 52 respondents suspected of having tuberculosis infection were examined using immuno chromatography test-tuberculosis (ICT-TB) which showed negative results. From observing the results of the ICT-TB examination, the researchers carried out the TCM GeneXpert examination as a cross-test to confirm the results of the ICT-TB examination, because the TCM GeneXpert examination is one of the gold standard examinations in diagnosing pulmonary TB, the Rapid Molecular Test (TCM) with the GeneExpert tool uses the method RT-PCR is based on repeated amplification of a DNA target. In vitro research shows that the detection limit for Mycobacterium tuberculosis is at least 131 germs/ml of sputum (Kurniawan et al, 2016) and the results obtained from 52 respondents showed negative results, this was because the samples used were from suspected tuberculosis infections.

This ICT-TB examination uses the immuno chromatography method which is an examination to detect a significant antibody response to M. tuberculosis. This interpretation has gone through appropriate control by looking at the quality of the control which gives a red color on the special control line. If on the line
the control does not give a red color, then the inspection results are invalid or do not meet Quality Control (Meri et al, 2022).

Based on research by Mursalim et al (2020), it is explained that the sensitivity of the ICT method tool still has shortcomings, namely that it is less sensitive and specific, because the tool has less sensitivity to read the results of very small TB mycobacterium bacteria. Examination using the immuno chromatography method is still carried out because the process is relatively faster, namely around 15 minutes. The immuno chromatography method is only screening which requires subsequent confirmation tests with more accurate parameters, one of which is TCM Genexpert.

Research by Atmayanta (2019), shows that the sensitivity of the ICT TB examination is 62.5%, meaning that the ability of the ICT TB examination in diagnosing patients with positive results and correctly suffering from pulmonary TB is 62.5%, while the specificity of the ICT TB examination is 100% , meaning that the ability of the ICT TB examination to diagnose patients with negative results and who do not actually suffer from pulmonary TB is 100%.

These results are almost the same as research conducted by Nursahi et al (2018), where in this study the sensitivity value was 50% and the specificity was 95.45%. The low sensitivity and specificity results of the ICT TB examination can be influenced by several things, such as Immunoglobulin G not yet circulating in the patient's serum. When the M. tuberculosis allergen enters the patient's body, the cellular immune system (phagocytocytes and T lymphocytes) plays a more important role. At the start of an infection, the humoral immune system will synthesize Ig M first for approximately 4 – 6 weeks and then be followed by Ig G synthesis. So it is possible that Ig G will not be detected in the patient's serum because the examination is carried out early in the course of the disease before IgG circulates in the blood.

From the results of sample distribution based on gender of suspected M. tuberculosis patients, it was found that 54% were men and 46% were women, while the age group was dominated by adults (25-59 years) at 44.2%. This is in line with several research results, including research from Sunarmi and

Kurniawati (2022), showing that there is a meaningful relationship between age and gender on the incidence of pulmonary TB. Then, the results of research by Konde et al (2020), show that the group with the largest number of lung sufferers is the productive age group (15-55 years). At this age, people spend time and energy working so that energy is depleted which causes immunity to decrease.

Based on research by Marleni et al (2020), it shows that men are more susceptible to being infected with Tuberculosis compared to women because men have a heavy workload and unhealthy lifestyles such as drinking alcohol and smoking.

This research has a weakness, namely that it is difficult to get positive examination results, so it cannot provide an overview of Genexpert's TB ICT examination on positive samples.

CONCLUSIONS

Characteristics of the sample based on gender found that 54% were male and 46% female, while based on age group the largest number of samples was found at the adult age level (25 - 59 years) namely 44.2%. Of the 52 respondents, the results of the ICT-TB examination were negative. Of the 52 respondents, the results of the Genexpert examination were negative. The results of the ICT-TB and Genexpert cross-test in patients with suspected M. tuberculosis infection gave the same negative results.

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