

Title: EVALUATION OF AGREEMENT BETWEEN RAPID MOLECULAR TEST FOR TUBERCULOSIS AND CULTURE.

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Summary:

Tuberculosis is a highly infectious disease with epidemiological significance. It is related to social exclusion and marginalization of the population subjected to health in vulnerable situations. Although there was a reduction in the number of cases in recent decades, it is still a highly prevalent disease. The National Program for Tuberculosis Control has developed various activities to strengthen the diagnostic actions, surveillance and disease control. New methodologies were incorporated, such as drug ethambutol in the basic scheme of treatment, the supply of drugs in fixed-dose combination and as technological innovation to expand the diagnosis, rapid molecular test for tuberculosis (TRM-TB). While the smear has a sensitivity of 65%, TRM-TB has a sensitivity of about 90% and specificity of 99%. The test result is released in two hours and detects resistance to rifampicin, enabling identification of cases of resistance to the basic scheme. Culture for mycobacteria is still considered the method "gold standard" for diagnosis of tuberculosis, allowing an increase of 30% in the number of diagnosed cases compared to the smear. The ratio of detection rate between the rapid test and culture has not yet been evaluated. The recommendation of the Ministry of Health is that all samples submitted to TRM-TB are also subject to culture, to identify possible positive samples not identified by molecular testing. This study aimed to evaluate the agreement of the TRM-TB with the culture, the gold standard method. We evaluated all rapid tests and cultures performed on sputum samples from patients sent to the Central Laboratory of the Municipality of Salvador, from October to November 2014. In total, samples of 242 patients were submitted to the rapid test and culture for mycobacteria. About 94% of the results were concordant between the two methods. Discordant results, around 6%, were within the expected sensitivity limit of the test. Among the discordant results, 35.7% were related to false negative results of the rapid test (negative TRM-TB, with positive cultures). The TRM-TB showed a specificity of 100%. The possibility of widely to have a diagnostic test for tuberculosis easy to perform, efficient, with quick result, brings the prospect of expanding the diagnosis and the opportunity of treating the disease in Brazil. However, one must be alert to cases of false negative results of TRM-TB, not eliminating the concomitant realization of culture.

Keywords: Tuberculosis, rapid molecular test, culture.