# Assessment of Smart Check Recombinant Test in Diagnosis of Pulmonary Tuberculosis In Al-Najaf Al-Ashraf Governorate

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الخلاصة

أجريت هذه الدراسة المقطعية لتقيم فحص Smart Check Recombinant TB test و هو فحص سريع يستخدم لاكتشاف الأجسام المضادة لمرض التدرن الرئوي الفعال ( فحص سيرولوجي يستخدم لأول مرة في محافظة النجف الاشرف) و هو فحص سريع لتشخيص التدرن الرئوي و مقارنته بالفحص ألمجهري للبلغم .

تضمنت الدراسة المرضى اللذين أحيلوا من قبل المراكز الصحية ، المستشفيات والعيادات الخاصة إلى مركز عيادة أمراض الجهاز التنفسي في النجف الاشرف . .

خمسون مريضا مشتبه بهم بالإصابة بمرض التدرن الرئوي اعتمادا على الأعراض السريرية ، تتراوح أعمارهم من 12سنة إلى أكثر من 70 سنة ، للفترة2006/1/1ولغاية 2005/12/31.

خمسون مريضا مشتبه به كان فحص بلغمهم سالبا، حيث اجري لهم فحص Smart Check Recombinant TB test وكانت النتيجة 7 ( 14%) حالات موجبة تم تشخيصها , بينما 43 (86%) حالة كانت سالبة

النتائج تشير بوضوح إلى أن حساسية فحص Smart Check Recombinant TB test كانت أعلى من حساسية فحص البلغم ألمجهري.

تم استخدام فحص مربع – كأي مع قيمة – ب عند 0.05– وكانت نتيجة الفحص بأنه ذو معنوية عالية

**ABSTRACT**

This cross sectional study was undertaken to evaluate the Smart Check Recombinant TB test which is a rapid membrane based screening test to detect the presence of antibodies to active M. tuberculosis (Serological test, which is used for the first time in Al - Najaf Al-Ashraf governorate) in screening for pulmonary tuberculosis as a rapid diagnostic test of pulmonary tuberculosis, in comparison with sputum smear microscopy depending on the (findings and clinical judgment). Patients involved were those who attend at Respiratory Chest Diseases Center in AL– Najaf AL-Ashraf Governorate. Fifty suspected patients, within the age groups

12 - 70 years old who were referred from primary health care centers, hospitals, and private clinics, between1/5/2006to31/6/2006. From 50 cases 7 (14 %) were diagnosed as pulmonary tuberculosis by Smart Check test and 43 (86%) all patients were negative, by direct sputum smear microscopy .
Chi-square had been applied to test, the level of significance when alpha < 0.05 and indicated there was high significant association.

## INTRODUCTION;

"Tuberculosis is curable disease; we should not let anybody die from it" (1)... It is a worldwide killer disease whose occurrence is on rise (2)…

**Kenneth et al ;( 3)** defined TB as a systemic infection manifested by evidence of an immune response in most exposed individuals… It is one of the oldest diseases known to affect human, and is caused by bacteria belonging to the Mycobacterium tuberculosis complex **(4)**…**Farmer (5)** said that one-third (2 billion) of the world's population is infected with TB bacilli… It is one of the top three infectious killing diseases in the world: HIV / AIDS kills 3 million people each year, TB kills 2million, & malaria kills 1million…Other researchers stated that it is seventh infectious cause of the death in the world **(6)**…It is directly responsible for (7%) of all death worldwide **(7)…** About 1.66 million people die annually from tuberculosis **(8).**

In Iraq 11.656 cases of tuberculosis were reported in 2003 and more than 60%are cases of pulmonary tuberculosis. Ministry of health and World health organization estimated an incidence of 130 cases per 100,000 populations putting the annual number of cases much higher than the reported figure **(9)**

In Iraq, the number of tuberculosis cases had notified 1637 in 1980 to 13123 cases in 2004 **(10)**

In AL-Najaf AL-Ashraf Governorate, the number of TB cases notified has increased from 200 in 1990 to 457 in 2005 **(11)**

**STUDY DESIGN;** Cross sectional study**.**

**THE TIME;** 1/5/2006 to 31/6/2006.

**PLACE;** Laboratory of Respiratory Chest Diseases Center in AL-Najaf AL-Ashraf.

## Materials & Methods

**STUDY POPULATION;** all suspected patients referred to the outpatient in the RCDC by Hospitals, primary health care centers, and private clinics.

**Sample size** was 50 cases, 30 (60 %) were males and 20 (40%) were females and their age range between 12 -70 years.

All suspected patients were presented with clinical features suggested of pulmonary tuberculosis chronic cough two weeks duration or more, haemoptysis , chest pain ,low grade fever , loss of weight , fatigue , night sweats , especially those who are living with pulmonary TB patients ( contacts ) , also when chest x-ray appears with significant findings , such as cavitary pulmonary TB ,and all patients were able to produce sputum .

All samples were examined routinely by using Ziehl – Neelsen's stain.

### SPECIMEN COLLECTION AND PROCESSING OF SPUTUM;

The study samples were instructed to expectorate three consecutive early morning sputa into a clean container with well – fitted cap , because a suspected PTB should submit 3 sputum specimens for microscopy , the chance of finding TB bacilli are greater with 3 samples than with two or one sample **(6)** ,Sputum ( early morning , deep cough ,on three consecutive days**.(12)**

### SPECIMEN COLLECTION AND PROCESSING OF (RAPID TEST)

We used commercial kit provides with;

***Test Device 25 Tests/Kit (13)**

Diluent's Buffer

Technical Insert

***Materials not provided with Kit;**

-Centrifuge

-Specimen collection tube

-Timing Device

-Sterile disposable syringe size 3 ml.

-Sterile test tubes.

-Micropipette.

-Gloves +face mask.

**PROCEDURE**;

1-Blood samples were drawn from patient's vein 2.5-3 ml by disposable syringe.

2- Putting the sample in the test tube (in room's temperature), then in centrifuge 3000 rpm for 15 minutes to separate between plasma and blood components.

3- Pull 20 microns plasma by micropipette from the tube and put it in the special place on the slide.

4-Cover the plasma with 3 drops of buffer.

5- Read the result after 10 minute, if the blue color appears that means positive, if does not, wait 30 minutes until the color appears or does not

**RESULTS**

Table (1) Distribution of cases according to age and sex

| | Age group | M | F | Total |
|---|---|---|---|---|
| **1** | 12-19 | 4 | 4 | **8** |
| **2** | 20-29 | 3 | 4 | **7** |
| **3** | 30-39 | 5 | 4 | **9** |
| **4** | 40-49 | 4 | 2 | **6** |
| **5** | 50-59 | 2 | 3 | **5** |
| **6** | 60-69 | 5 | 3 | **8** |
| **7** | 70 | 5 | 2 | **7** |
| **8** | **Total** | **28** | **22** | **50** |

Table (2) Distribution of cases according to clinical features and tests

| Age group | | Suspected cases | Direct Sputum Smear (+ ve) | Smart Check (+ve) |
|---|---|---|---|---|
| **1** | 12-19 | 8 | 0 | **4** |
| **2** | 20-29 | 7 | 0 | **1** |
| **3** | 30-39 | 9 | 0 | **1** |
| **4** | 40-49 | 6 | 0 | **0** |
| **5** | 50-59 | 5 | 0 | **0** |
| **6** | 60-69 | 8 | 0 | **0** |
| **7** | 70 | 7 | 0 | **1** |
| **8** | **Total** | **50** | **0** | **7** |

## DISCUSSION

Accurate diagnosis is essential for the treatment, prevention, and control of tuberculosis **(14)**

Accuracy and rapid diagnosis of TB remain to be difficult. We still have to find single ideal test that can detect potentially infectious patients who remain undetected because of the low bacillary count and other causes of misclassification **(6).**

For more than a century, microscopic examination of stained sputum smear has been the central and sometimes the only laboratory tool available for the diagnosis of TB in health clinics of diseases-endemic countries **(6).**

The serodiagosis of tuberculosis has long been the subject of investigation, but we still lack a test with widespread clinical utility**. (15)**

Fifty patients 28 (56%) were male and 22(44%) were female and their age range from 12 -70 years (table 1) , all were with negative direct sputum smear microscopy, but by the Smart Check Recombinant test were 7 (14%) cases positive and 43 (86%) cases were negative , and more age group affected was 12-39 years **(7)**

Chi-square ($\chi^2$**)** had been applied, reject H0 and there are difference between direct sputum smear and Smart check recombinant, it is high significant with (probability < 0.0025) **(17)**
**Deffenbaugh (16)** had found 80% of victims were between 15 and 49 year, the most economically productive years of their life, and our study confirmed that (75 %) of people with TB are in the economically productive age group of 15 – 54 years,

The sensitivity of Smart Check Recombinant for sputum smear negative was (14%) in comparison with (29%) for the ELISA test (in the same laboratory), smear negative **(18)** and (39%) **(19)** and > (60%) **(20)**, (67.1%) **(21)**

## CONCLUSION

The result reported in this study has provided the evidence that the Smart Check Recombinant test is useful in diagnosis of active PTB for patients with negative sputum smear examination, but the

detection of antibodies in the serum of PTB patients still less than ELISA test and other tests.

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