Key Summary of Conference Abstract

T-SPOT®.*TB* Assay Using Extended Storage Time and Alternative Anticoagulant: A Validation Study

Background

- The T-SPOT®.*TB* assay (Oxford Immunotec) is an in vitro diagnostic test, performed with whole blood, that can detect latent *Mycobacterium tuberculosis* infection.
- After collection, specimens can be stored for a maximum of 32 hours at room temperature before processing. Storage time of whole-blood specimens plays an important role for applications of the assay, but longer storage times would be beneficial for many reasons.
- In addition, use of sodium heparin sulfate as an alternative coagulant to lithium heparin for blood collection would make the assay more accessible to patients and clinicians.
- **Objective:** The investigators assessed the effects of extended blood storage time (39 h vs 32 h) and an alternative anticoagulant for blood collection on T-SPOT®.*TB* assay performance.

Methods

- To assess the performance of the T-SPOT®.*TB* assay with an alternative anticoagulant, whole-blood specimens were collected in paired tubes containing either the previously validated (lithium heparin) or alternative (sodium heparin) anticoagulant.
  - After collection, specimens were stored for 39 hours at room temperature (18 ºC - 25 ºC). Pooled samples from the remnant blood were used for precision studies.
  - T-Cell *Xtend* reagent (Oxford), which is normally added within 32 hours of specimen collection, was then added to each specimen.
  - Specimens were processed using a modified Leucosep™ Tube method (Greiner Bio-One, Austria). Aside from storage time, other modifications to the previously validated T-SPOT®.*TB* method included duration of the initial centrifugation, the centrifugation brake setting, and cell resuspension procedures.
  - T-SPOT®.*TB* spots were developed and counted according to manufacturer instructions.
- As a reference for comparison of test results, a second set of specimens was collected in lithium heparin tubes from the same donors and processed using the previously validated T-SPOT®.*TB* method.

Results

- All precision studies (n=36) from pooled blood and comparison studies (below) had acceptable spot counts for the positive (≥20 spots) and negative (≤10 spots) controls; no invalid results were observed.
- Results for the modified and reference methods agreed for all specimens: 50 positive, 70 negative, and the 36 precision study specimens. No indeterminant results were observed.
- Results for sodium heparin and lithium heparin tubes agreed for all specimens: 25 positive and 35 negative.

Conclusions

- The longer (39 hours) storage time and use of sodium heparin anticoagulant, as well as the other modifications made to the T-SPOT®.*TB* assay in this study, did not alter the assay performance.

ePoster presentation at the ASM Microbe Online

Authors

Jian R Bao,[1] Finny P Mathew,[1] Robert S Jones,[1] Patrick W Mason,[1] Jessie M Hutchens Maxwell,[2] Ron N Master,[1] Richard B Clark,[1] Kileen L Shier[1]

Affiliations

[1] Quest Diagnostics Nichols Institute, Chantilly, VA, USA
[2] Quest Diagnostics TB, LLC, Memphis, TN, USA

ASM Microbe Online, June 22-July 20, 2020

Webpage

https://www.abstractsonline.com/pp8/#!/9103/presentation/7524