Single blood collection method of QFT-Plus

Introduction

I would like to introduce an article published recently on single blood collection method of QuantiFERON®-TB Gold Plus (QFT-Plus).

The single blood collection method (single tube collection) of QFT-Plus is an option in the workflow for blood collection. This is a method using one lithium heparin (LiHep) tube as the primary blood collection tube (BCT), after which 1 mL of whole blood is dispensed into each of the four QFT-Plus tubes (Nil, TB1, TB2, and Mitogen). The whole blood sample collected in the LiHep BCTs can be stored in refrigerator (4° C, 2–8° C) for up to 48 hours prior to transfer to the four QFT-Plus tubes. In addition, there are up to 3 hours that the LiHep tube specimens can be stored at room temperature (22 ± 5° C) before refrigeration and up to 2 hours after the removal of the LiHep tube from refrigeration to perform the blood transfer to the four QFT-Plus tubes. i.e.a cumulative maximum of 53 hours from blood collection to incubation. The QFT-Plus single tube collection was approved by the US FDA and the Japanese Ministry of Health, Labor and Welfare based on QIAGEN's data.

Recently, Uwamino et al. reported the results of a study on single tube collection (1). Blood samples were collected from 40 outpatients (median age 63 years IQR : 43–71.5, male 13 female 27), including patients undergoing treatment for active or LTBI, human immunodeficiency virus (HIV) infection, history of diabetes mellitus (DM), history of hematologic malignancies, and usage of steroid and immunosuppressants.

Blood was collected from each patient using two LiHep BCTs (5 mL), and a blood sample from one LiHep BCT was immediately dispensed into QFT-Plus tubes and incubated (control). The blood sample from the other LiHep blood collection tube was stored in a refrigerator set at 4° C for 48 hours, returned to room temperature (22 ± 5° C), dispensed into QFT-Plus tubes, and incubated (refrigerated samples). Thereafter, the ELISA was performed on all tubes according to the package insert.

The results were shown in Table 1 (see below). Of the 22 control positive cases, 20 were positive of refrigerated samples and the 18 control negatives were all negative of refrigerated samples. The concordance rate of results between control and refrigerated samples was 95%, and the kappa coefficient κ was 0.90. Two cases with positive control were negative by refrigerated samples and were discrepant cases. According to characteristics and QFT-Plus measurement data of participants with inconsistent results, no specific factor causing the inconsistency was found.

Table. QFT-Plus test results using samples stored in refrigerated LiHep tube

		Control		
		Positive	**Negative**	
Srored at refrigerated (4° C for 48 hr)	Positive	20	0	20
	Negative	2	18	20
		22	18	40

Concordance rate : 95.0% (38/40) κ = 0.90
Modified the table in J Infect Chemother 26 (2020) 312-314

The available sample size was noted as a limitation of this study, which may be resolved by future studies using a larger sample size. However, the authors conclude that blood samples for the QFT-Plus test can be refrigerated for 48 h in lithium-heparin tubes without affecting the test results.

Single tube collection for the previous generation of the QuantiFERON-TB test, QFT (QFT-3G), using the LiHep tube with refrigerated storage for up to 32 hours has also been approved by the Japanese Ministry of Health, Labor and Welfare. According to report of Fukushima et al (2) on QFT-3G, as a result of analysis of 27 people between two groups, 10 healthy people (male 6 female 4, average age 49.5, 23–63) and 17 people who had active TB or are after treatment of TB (male 7 female 10, average age 57.8 22-91), the correlation coefficient between two group is r=0.982 (P<0.01), the overall concordance rate between the control and refrigerated samples (4° C, 32 h) was 88.9% (24/27), and the positive concordance rate was 88.2% (15/17), the negative concordance rate was 90.0% (9/10).

Currently, not only domestic clinical labs but the largest US commercial clinical labs use the single tube collection method for QFT-Plus testing, including the available 48h hold time in a refrigerator (3) (4). The QFT-Plus single tube blood collection option has the advantages of improving flexibility of preanalytical time from collection to incubation. This allows the commercial labs to perform the QFT-Plus assay on samples transported from customers at long-distance sites. It also may reduce preanalytical errors since the blood transfer, tube mixing and QFT-Plus tubes are fully controlled by the laboratory.

We expect this blood collection method to improve the flexibility and process control available to commercial laboratories in Japan.

Mr. QFT

References

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