

Abstract

In freshly taken blood of 49 patients of a STD ambulatory, the results for antibody screening (Syphilis TP™ test from Abbott Diagnostics on Architect i2000) were compared, on one side from day to day over 72 hours, on the other side the differences between an aliquot stored in room temperature (15 – 30 °C) and one stored at 2 – 8 °C.

16 sera positive for Syphilis antibodies (s/co from 1.0 till 28.2) and 33 sera which showed negative results (s/co from 0,0 till 0,3) were measured once daily for at least 72 hours.

There was no significant decrease nor increase of the s/co results over time for ambient or cooled conditions (CV 0 – 5,46 % resp. 0 – 5,5 %), nor was there a significant difference of the s/co results between the room temperature and the cooled samples (tailed t-test with $p = 0,15$).

With a reserve due to the small number of positive sera, we interpret the results in the way that the Syphilis antibody screening for this test kit on this automate can be made from sera stored or sent at room temperature within a period of 72 hours.

Introduction

In infectious serology, for most antibodies against microbial agents, manufacturers describe a stability in ambient temperature for at least 3 days. This allows sample sending to the laboratory by post at ambient temperature. For the Syphilis TP™ Test, manufactured by Abbott Diagnostics, a stability of IgG and IgM antibodies against *Treponema pallidum* has only been studied and proven for 24 hours. To allow a postal sending of serum, there is a need to prove a stability for at least 72 hours for this testing.

Material and methods

Fresh sera from 49 patients of an STD ambulatory were collected. Immediately after centrifugation, the serum was aliquotted in two, one stored at 2 – 8 °C constantly, the other at 15 – 30 °C. Syphilis antibodies (IgG and IgM) were measured with the test kit « Syphilis TP™ » (Abbott Diagnostics, Architect i2000), once daily from days 1 to 4, integrated in the daily laboratory routine. The quantitative results were reported in s/co (sample over cut-off), and the results were compared and statistically analysed for significant increase / decrease over time and for significant differences between cooled and ambient storage of the sera.

Results

Out of 49 tested sera, 16 showed positive (s/co > 1,0) for antibodies against *Treponema pallidum* in the Syphilis TP™ test, 2 showed an s/co value of 0,3, and the other 31 negative sera showed an s/co value of 0.0 or 0,1. All samples were measured at least 3 times over at least 72 hours,

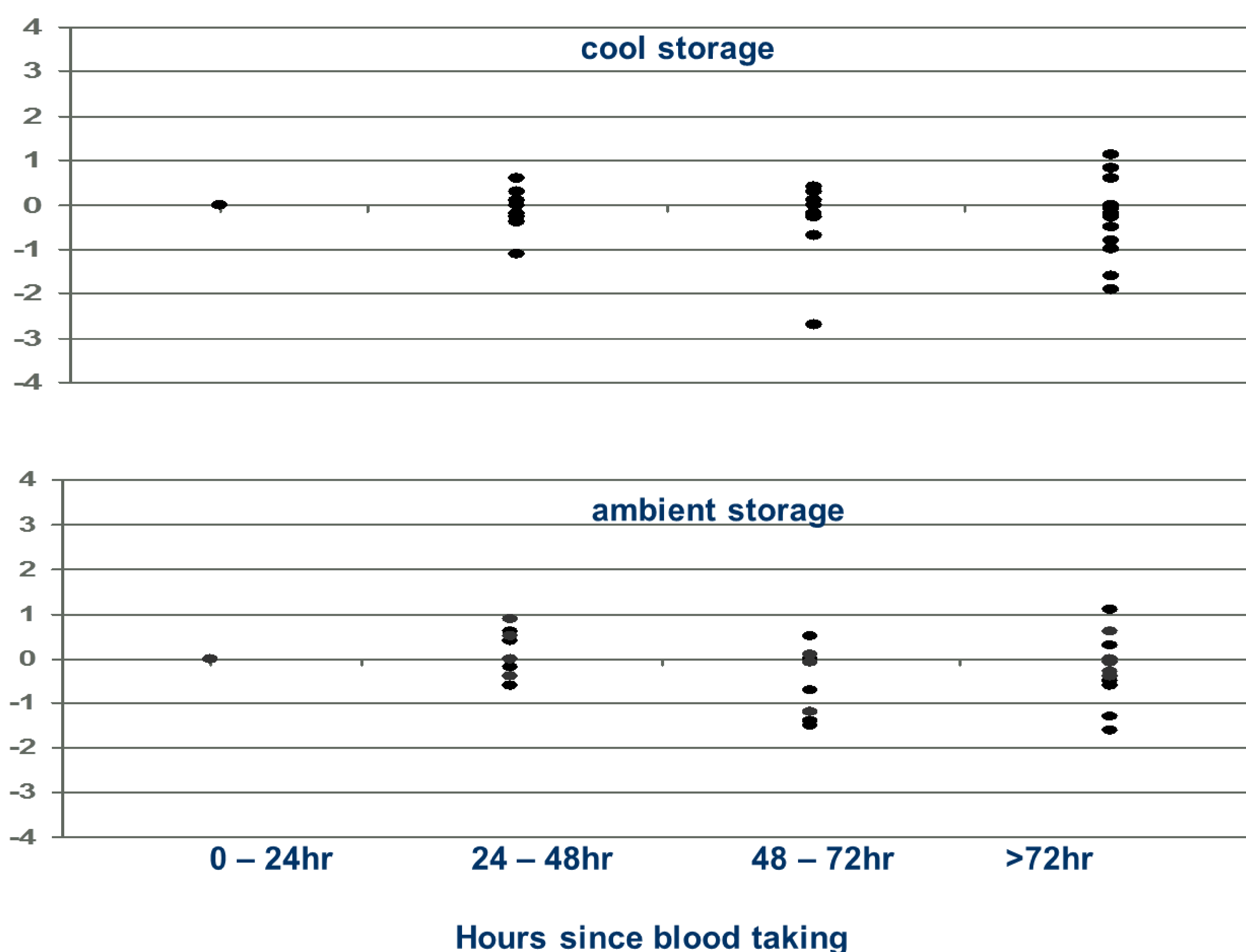
Within 72 hours, there was no change of s/co for Syphilis antibodies of more than 0.1 s/co in antibody negative sera, neither in cool nor in ambient storage conditions. The two negative sera with 0.3 s/co showed stable values as well, both sera showed the same 0.3 s/co over the whole period, in cool and ambient storage.

The positive sera showed stable s/co values. CV over 72 hours were between 0 and 5,5 % for cool storage and between 0 and 5,46 % for ambient temperature storage.

No significant differences between the values of sera stored between 2 and 8 °C and those stored at room temperature were shown in the paired t-test, at any point of the measuring period.

Raw data, statistical calculations, calibration data and lot numbers of the test kits are available upon request.

Deviation of s/co values in positive samples over time



Conclusion

Our results show no evidence that the Abbott Syphilis TP™ screening test for antibodies against *Treponema pallidum* in serum shows a significant change in s/co values if measured in sera stored at room temperature for at least 72 hours after blood taking. No results showed a change from positive to negative or vice versa, not even results near the cut-off value did so. There seems no danger of getting a false negative or false positive result due to shipping at room temperature for 3 days.

This allows the shipping of serum samples at room temperature as well as over weekends.

Only 16 tested sera were positive, therefore further investigation is needed to match criteria for putting this stability statement in the package insert.

Acknowledgement

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