Kishikawa Y, Otsuki T, Ueki M

Real-time tracking of hematological parameters in a robust mobile testing unit.

Anti-doping Research Laboratory, Japan Chemical Analysis Center, Tokyo, Japan

Abstract

A validation study of a mobile hematology test unit was conducted by estimation of uncertainty and traceability of the measurements to the permanent blood testing facility under various environmental conditions, such as temperature, humidity, vibration, distance of travel mileage etc., and possible influencing factors were sought. The results have shown traceability of the measurements between the test instruments types XE-2100 and XN-1000, and locations at the permanent facility and in the mobile unit. Accuracy depended on the type of analytes: controls or fresh blood specimens and the influence of seasonal environment changes was also evaluated. Overall the data showed acceptable results as per applicable WADA guidelines. The biggest advantage of the use of a mobile unit is the wider coverage area possible and speed of feedback of test results.

Introduction

In the beginning of hematological testing in sports, the instrument was transported to the venues and the test was conducted under the direction of the International Federation because the test was uncommon to WADA laboratories. To keep pace with the recent trends and pattern of doping, the number of blood samples tested for Athlete Biological Passport (ABP) is increasing rapidly. However, the test is still limited in certain geographical areas and category of sport due to the needs of sample collection and transportation of storage-sensitive blood specimens to the testing laboratories. The aim of our project was to allow the real-time tracking of hematological parameters on-site, thus enabling one to fill the blank areas of testing.

Experimental

The test system for the mobile ABP unit has been evaluated on two instrument platforms types XE-2100 and XN-1000, matrices of test material (fresh human blood and three levels of processed control blood), test environments (temperature, humidity, vibration, electricity), influence of weather change, and communication security. Traceability of the measurements was checked through periodical instrument calibration by the instrument supplier and by participating in PT programs provided by Quality Control Center Switzerland (CSCQ), RCPA Quality Assurance Program (QAP), and College of American Pathologists (CAP) that covers four continents. The permanent and mobile hematology test facilities of the Japan Chemical Analysis Center are ISO/IEC17025 accredited, and the mobile testing unit is approved by WADA.
Study design (Fig.1):
Instrument performance was checked before starting trials a) to c) on-site and after returning to the permanent laboratory.
a) Summer: one day/round for three days in August 241.8 km. Two way trip in between two consecutive prefectures.
b) Summer: one day/round for three days in October 1,741.2 km Round trip within two consecutive prefectures.
c) Winter: 3 days/round for three weeks in December between Tokyo and the northern tip of the Japanese mainland.
Fresh blood samples were collected on-site from five each of men and women and analyzed immediately. The same sets of the blood specimens were transported to the permanent laboratory by the return vehicle for the traceability test.
Hematological markers evaluated:
HCT: Hematocrit, HGB: Hemoglobin, RBC: Red blood cell count, RET%: The percentage of reticulocyte, RET#: Reticulo-

 ISBN 978-3-86884-040-7

cytecount, MCV: Mean corpuscular volume, MCH: Mean corpuscular hemoglobin, MCHC: Mean corpuscular hemoglobin conc., RDW-SD: Red cell distribution width (SD), IRF: Immature reticulocyte fraction.In total 1,200 tests on fresh blood samples were performed to demonstrate traceability and to the check extent of influencing factors. Analytical results on remote workstation have been transported and stored in a LIMS at the permanent office securely in real-time via a VLAN, where a second opinion on the data was given. Temperature/humidity, vibration and location/altitude were monitored by data loggers RSW-20S (Espec mic, JPN), G-MEN (Slic Co., JPN) and 62SCJ (Garmin Intl. Inc., USA), respectively.

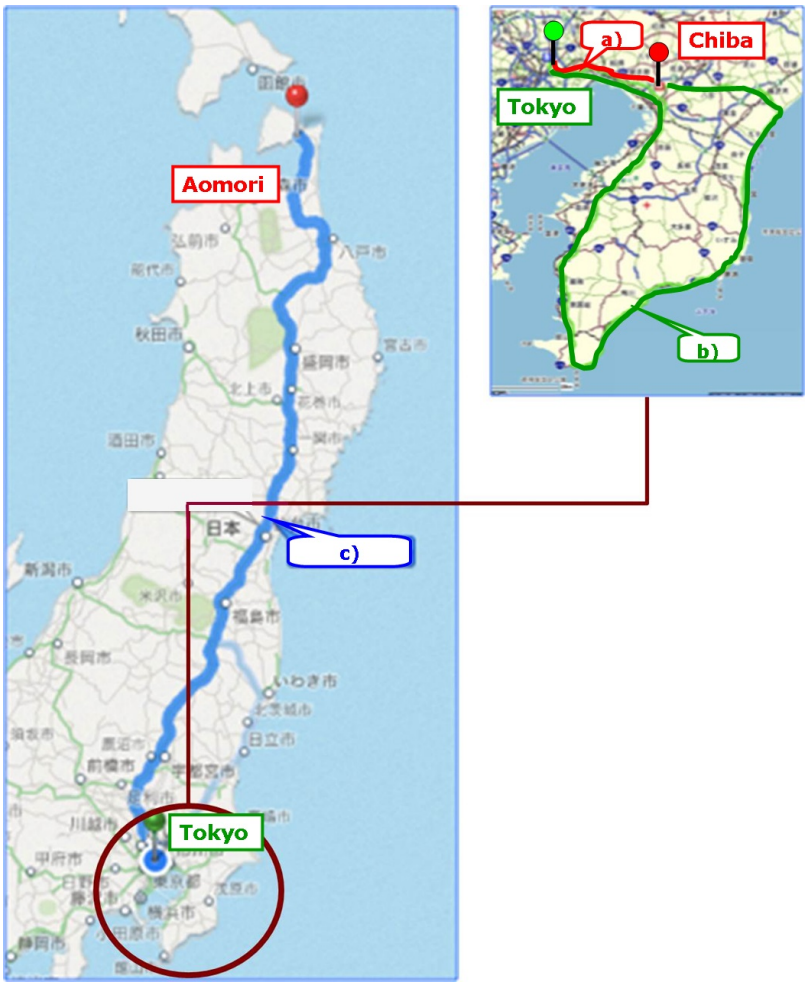

Figure 1:Route of field experiments for trial a), b) and c).

Results and Discussion

The inside temperature of the mobile unit during transportation ranged from 5.6 to 34.8°C, exceeding the recommended operation temperature of 15 to 30°C, even when the cabin was air-conditioned. The vibration, temperature and humidity of the worst case are shown in Fig.2. The room temperature of the permanent laboratory and the mobile unit during sample analysis by XE-2100 and XN-1000 was kept within the recommended operation temperature. Before each field experiment, the XE-2100 and XN-1000 were calibrated for blood parameters against Sysmex's standard instruments to check the potential change of calibration after the ground transportation. Throughout the whole field experiment period, however, the calibration was fairly stable andre- adjustment was not necessary. Overall test results obtained by the mobile unit were in excellent agreement with those obtained at the permanent laboratory without any exception (Table 1).

 ISBN 978-3-86884-040-7

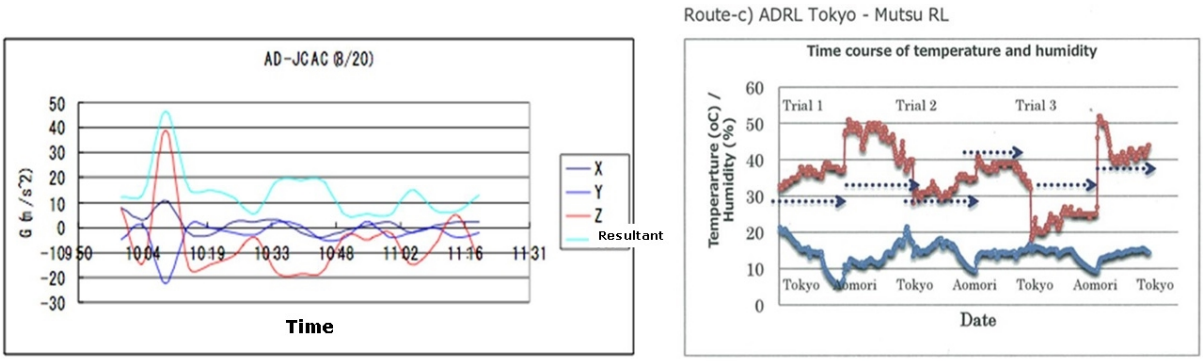

Figure 2: Worst trends of inside vibration, temperature and humidity of ABP mobile unit during transportation.

		XE-2100			XN-1000		
		y = ax			y = ax		
		a	R^2	*p*	a	R^2	*p*
HGB	[g/dL]	0.9991	0.9989	0.34	1.0028	0.9973	0.03
RET%	[%]	1.0030	0.9846	0.87	1.0070	0.9790	0.50
IRF	[%]	0.9739	0.9735	0.62	1.0040	0.9872	0.85

Table 1: Correlation of typical blood parameters between X: mobile unit and Y: permanent laboratory (n=30, 3 routes x 10 samples each)

Conclusions

Excellent traceability of the measurements between the platforms: XE-2100 and XN-1000, and between permanent and mobile laboratories has been demonstrated. Ground transportation of the instrument does not affect the reliability of thetest system when the testing system is properly maintained, calibrated and the measurement is performed under instrument supplier‘s recommended conditions.

References

Y Kishikawa, T Otsuki, M Ueki. Evaluation and ensuring robustness of mobile blood testing system for hematological moduleof WADA athlete biological passport program. (in Japanese with English summary), Report on research and developmentproject on doping test method by means of blood collection. (On demand distribution by ADRL-JCAC. March 2013, Tokyo)

Acknowledgements

This study was funded by the ministry of education, culture, sports science and technology for 2013.