He C, Zhang L, Jing J, Yang S, Dong Y, Xu Y, Wang X

Investigation of the ‘not satisfactory’ results in CSCQ performance test

National Anti-Doping Laboratory, China Anti-Doping Agency, Beijing, China

Abstract

To investigate the root cause of ‘not satisfactory’ results in CSCQ performance test in our lab last May, we analyzed the performance test samples received from CSCQ and National Centre for Clinical Laboratory of China and dozens of fresh blood samples anonymously provided by hospitals. The samples were respectively analyzed by use of Sysmex XE (XE2100 and XE5000) and XT (XT2000i and XT4000) series following relevant WADA Guidelines. Calibrators and quality control samples were offered by Sysmex Corporation. We found that 1) there are significant differences in HGB, MCH, MCV and PLT between XEand XT series (XE2100, XE5000 and XT4000 models) in CSCQ 1305WA1 sample, 2) there are no significant differences between XE and XT series when 45 fresh blood samples were analyzed by the same operator, 3) due to an upregulation of the RET% on XE2100 using a new product of calibrators, there are significant differences between XE2100 and XE5000 models, 4) all the results were satisfactory in another EQAS performance test assigned by National Centre for Clinical Laboratory of China.

Introduction

Our laboratory took part in the CSCQ EQAS for WADA approved laboratories 12 times a year and the National Center for Clinical Laboratories (NCCL) EQAS for Chinese clinical laboratories twice a year. This study was carried out to investigate the root cause of some ‘not satisfactory’ results for CSCQ sample 1305WA1 by use of Sysmex XE2100 in May 2013.

Experimental

The performance test samples were received from CSCQ and National Centre for Clinical Laboratory of China. 45 fresh whole blood samples (anti-coagulated in an EDTA-K syringe) were anonymously provided by hospitals and analyzed within 48 hours of sample collection according to WADA Guidelines for blood sample collection [1] and Athlete Biological Passport Operating Guidelines [2].Calibrators and qualitycontrol (QC) samples were offered by Sysmex Corporation. The samples wererespectivelyanalyzed by Sysmex XE (XE2100 and XE5000)and XT (XT2000i and XT4000) series. All the samples were stored at approximately 4°C before analysis. Statistics were carried out with SPSS and/or Microsoft Office Excel.

Results and Discussion

1) The CSCQ sample 1305WA1 was analyzed on Sysmex XE2100, XE5000 and XT4000 models, respectively. Significant differences for HGB, MCH, MCV and PLT variables were found between XE and XT series. The results observed in XT4000 were closer to the target values provided by CSCQ survey report (most of the participants utilize XT2000i). It indicates that there might be some differences between XE and XT series (Fig. 1).

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2) The QC samples and calibrators of the XE2100 are in good order (Fig. 2). The operators were trained well. The results in survey report of CSCQ test were all 'satisfactory' in April and June 2013. We also participated in another EQAS performance test for haematological parameters assigned by National Centre for Clinical Laboratory of China in April 2013. Compared with more than nine hundred other participants using XE2100 model, all of the results we submitted were satisfactory.

3) 45 fresh blood samples were analyzed on XE and XT series, respectively. No differences were observed. Although it was not clear about the components of these EQAS samples, there were indeed some differences from fresh blood samples. It seems that these differences, for example matrix effects, between fresh blood and artificial samples might cause different results in some situations.

4) A comparison test between XE2100 and XE5000 models was implemented by engineers from Sysmex Corporation last June. Two models of equipment were adjusted at the same time with a new product of calibrator including RET% for XNseries. After an up regulation of RET% on XE2100 for matching with the target value of calibrator, the result of RET% from fresh blood samples by XE2100 were significantly higher than XE5000 ($P<0.05$). Hence the monthly mean value of internal QC was quite different between May and June 2013 on SNCS system (Fig. 3). But the internal QC chart shows that the observed values are closer to the target value after regulation (Fig. 2). It indicates that the calibrators were not suitable for all kinds of Sysmex series.

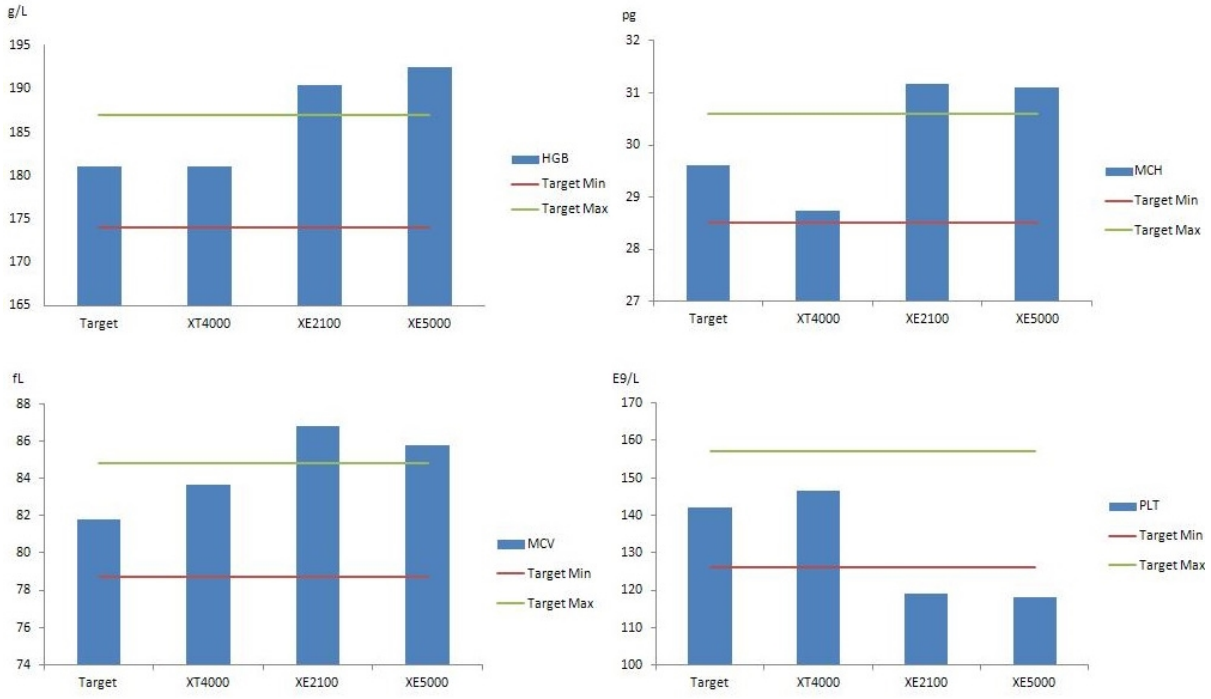

Figure 1. Comparison of several parameters from CSCQ EQAS sample 1305WA1 by Sysmex XT and XE series.

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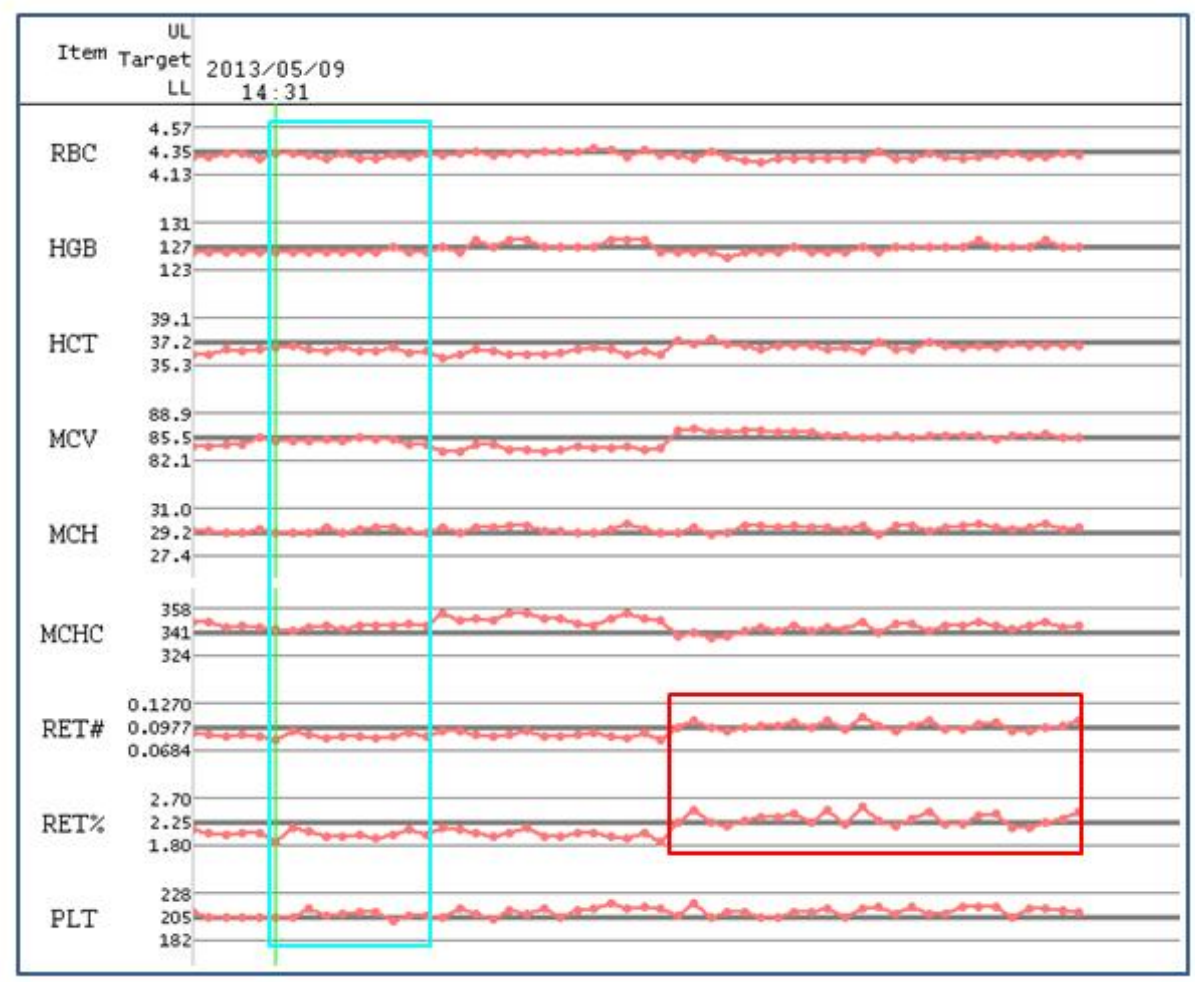

Figure 2. E-CHECK QC Level2 on Sysmex XE2100. The blue marked area is the QC sample analyzed before and after the CSCQ EQAS 1305WA1. The red area shows the result of RET% after regulation.

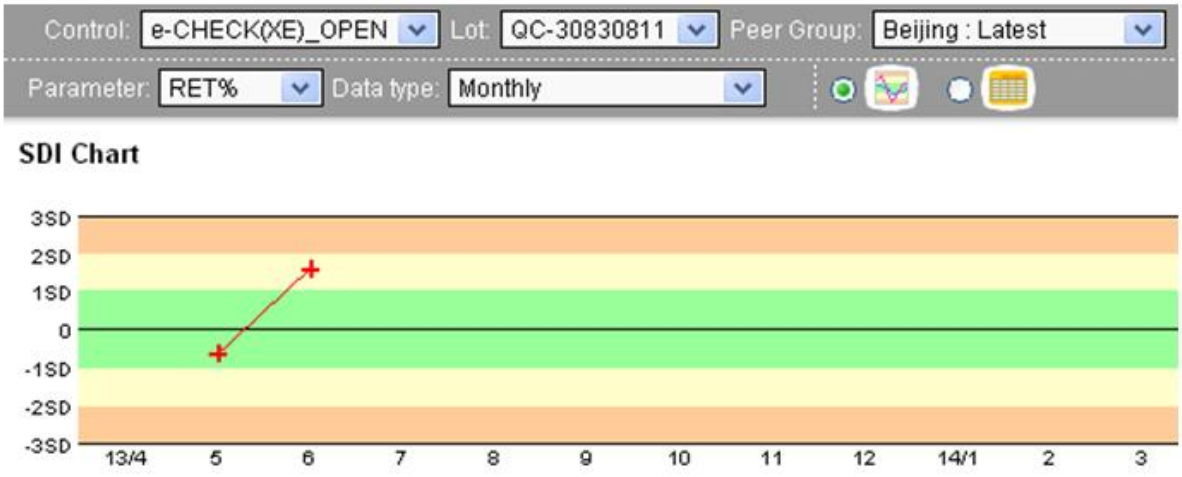

Figure 3. The change of the monthly mean value for RET% of the QC sample analyzed on XE2100 at SNCS systerm.

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Conclusions

The differences between human fresh blood samples and artificial blood products might cause variable results on Sysmex XE and XT series in some conditions. A universal calibrator including RET% for all kinds of Sysmex hematology analyzers is expected. Further investigation need to be implemented.

References

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