



## The Matrix Effect of Control Serum Samples in FUJI DRI-CHEM

The data presented are from a collaboration study by FUJIFILM Corporation and Prof. Shigeo Okubo, Department of Clinical Laboratory, The University of Tokyo Hospital.

### Introduction

In line with the standardization of clinical laboratory tests in Japan, the need for precise and standardized data from external quality control increases. However, dry chemistry results are sometimes affected by the matrix effect of the control serum samples used for these surveys. To improve the understanding of our dry chemistry tests among our clients and survey institutions, Fujifilm has conducted a study in collaboration with The University of Tokyo Hospital to evaluate and demonstrate the characteristics and performance of FUJI DRI-CHEM (FDC).

### Correlation between FDC and Wet Chemistry

We verified the consistency of FDC with wet chemistry tests using human serum samples. First, materials certified in wet chemistry were measured to verify the accuracy of the wet chemistry system. Patient serum samples were later measured using both wet chemistry and FDC; the distribution of the samples was based on CLSI EP9-A2. We evaluated the consistency of FDC with wet chemistry on the basis of the 5% Medical Decision Level of linear regression results.

Nine parameters were evaluated: GLU, Ca, UN, UA, CRE,  $\gamma$ GT, ALT, CK, and T-Cho. The measurements were conducted on Hitachi 7180 for wet chemistry tests and on FDC7000 for dry chemistry tests.

Excellent correlations were obtained, with slopes of linear regression within the 5% Medical Decision Level (Table 1). These results show that the FDC results are consistent with the wet chemistry results for human serum samples.

**Table 1** The Correlation of FDC with Wet Chemistry

Parameter	n	y = ax + b	R <sup>2</sup>	Within the 5% Medical Decision level
GLU	76	y = 0.992x 0.242	0.999	Yes
Ca	70	y = 1.022x 0.341	0.988	Yes
UN	65	y = 1.010x + 0.605	1.000	Yes
UA	72	y = 0.966 + 0.068	0.997	Yes
CRE	70	y = 0.993x 0.006	0.999	Yes
$\gamma$ GT	81	y = 1.001 2.907	0.998	Yes
ALT	75	y = 0.995 + 0.651	0.995	Yes
CPK	71	y = 0.984x 0.335	0.996	Yes
T-Cho	70	y = 1.018x 6.937	0.983	Yes

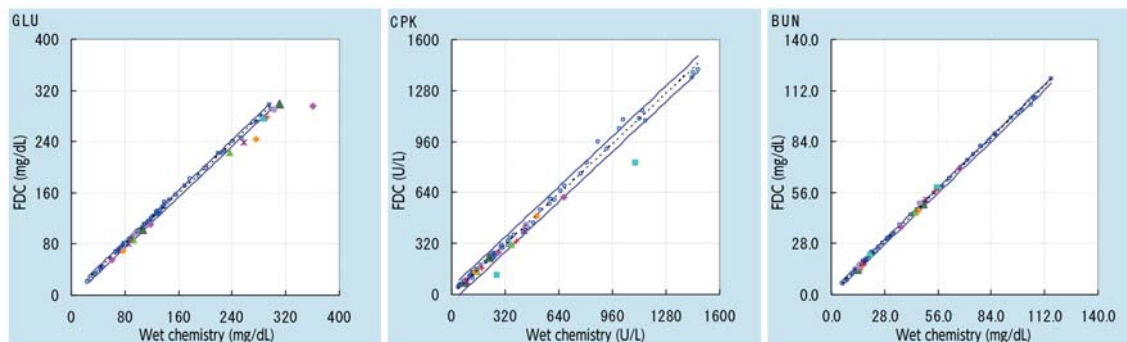
R<sup>2</sup> is the correlation coefficient.

### The Matrix Effect in Dry Chemistry

Next, we compared the measurement values of commercially available control serum samples with our human serum samples to test the matrix effect. A total of 17 control samples from 8 brands were used. The properties of these controls were examined on the basis of the same 9

parameters (fig. 1).

We found that with some parameters, there was good consistency for all controls. But none of the control samples satisfied all parameters. For a few controls, the values of FDC measurement are inconsistent with those of wet chemistry tests. The irregular behavior of control samples in some parameters can be due to differences in the composition of reagents. Thus, we can conclude that control serum samples exhibit matrix effects, which yield results that are inconsistent with the wet chemistry tests.



**Fig. 1** The test results of commercially available control serum samples for FDC GLU, CPK, and BUN parameters compared with our set of human serum samples. Blue circles are our samples, and other colors represent commercially available controls.

### Quality Control of FDC Using External Controls

Even if the FDC values of the control sera are deviated from Wet Chemistry values, as long as the matrix effect is constant, we may be able to use these controls to conduct daily quality control. To confirm the feasibility of this idea, we evaluated and found out that: 1) precision of FDC is unchanged even in control sera, 2) there is no lot variability in the slides, 3) there is no lot variability in the controls and 4) the difference between the indicated control value and FDC value remains constant despite control lot change; implying that as long as all 4 conditions are constant, commercially available controls may be used for quality control.

It is however desirable that the manufacturers of control serum samples indicate FDC values for their commercially available controls. At this point, apart from FDC's original controls, only BioRad Liquid Assayed Multiquel and BioRad Lyphochek Assayed Chemistry Control show FDC values that our clients can utilize for quality control.

*The results of this study were presented at a Luncheon Seminar at the 44th Annual Meeting of the Japan Society for Clinical Laboratory Automation, October 11–13, 2012, Yokohama, Japan.*

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