

# The Status of LC-5000 (Pentra 60) Automated Hematology Analyzer Use in the Clinical Testing Department of the Kitasato University Higashi Hospital

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Automated Hematology Analyzers are being introduced into all types of medical facilities, regardless of size, as a device directly related to medical care. These devices analyze blood, raw cells as it were, so an Automated Hematology Analyzer must battle with time to quickly report highly precise test results. The ability to achieve this can contribute to accurate diagnoses and effective medical treatment. In this paper, we discuss the practical application and current status of the Horiba LC-5000 (Pentra 60) Automated Hematology Analyzer, which is being used in emergency cases during daytime hours and for testing during nighttime and holiday hours at the Kitasato University Higashi Hospital.

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### 1

#### Introduction

The Kitasato University Higashi Hospital is located in close proximity, approximately 600 meters, from the main university hospital. This 580-bed university hospital opened in April 1986, with a digestive organ disease treatment center, nerve and locomotor disease treatment center, and psychoneurotic disease treatment center as core facilities for the hospital. The laboratory has a total staff of 30, including 12 *in vitro* testing personnel -- two working in blood testing, two in immune serum testing, two in transfusion testing, two in general testing, two in bacterial testing, one in emergency testing and one in test receiving (eight of whom are full-time employees, two are temporary employees and two are part-time employees), 15 physiological testing personnel - four working in ultrasonic testing, two in respiratory system testing, three in circulatory system testing, one in organum vestibulocochlear testing, one in nerve and muscle testing, and four in electroencephalography (13 of whom are full-time employees and two are temporary employees), and three temporary employees stationed at the clinical trial center.

In the daily hematology tests performed at our laboratory, we sort out samples flagged for urgent testing from those for normal testing, and the tests are performed accordingly. Our laboratory uses the Horiba LC-5000 automatic blood cell counter (Pentra 60) to perform complete blood cell counts and the differentiation of white blood cells when urgent tests are requested. This is our second hematology analyzer for emergency testing manufactured by ABX Diagnostics S.A., a member of the Horiba Group, and with these two units, we have been using Horiba products for 10 years. The Horiba LC series is compact, yet instills one with a sense of high precision, and has a design that seems somehow "French" Featuring maintenance-free design and easy operation, these products can be used even by people who are not adept at operating machines. In particular, for emergency testing, a product must provide simple operation, rapid results, and excellent precision, without complex parameter settings. Therefore, as I will describe in the following pages, the LC-5000 is being used as an emergency tester for daytime shifts, nighttime shifts, and holiday shifts.

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## The Testing and Test Result Reporting System

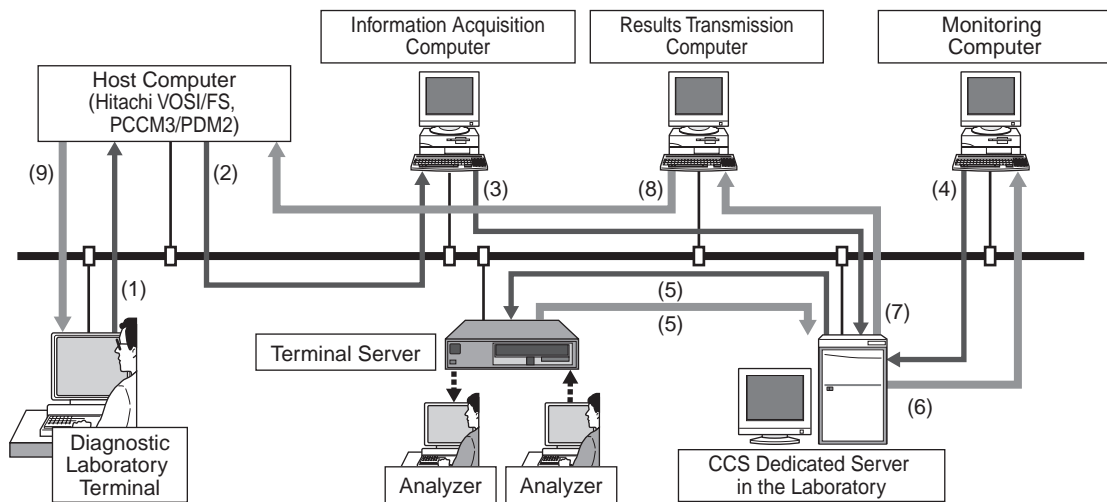
An overview and structural diagram of the *in vitro* testing CSS system used at our laboratory is provided below (Fig.1).

Test results from "urgent" samples are transferred from the laboratory computer terminal to the host computer for data storage and to the label printer for hardcopy printout. With online processing, it can be difficult to know whether or not results have been output, but an advantage of this system is that the printout provides notification that the results are ready.

Now, samples taken during nighttime and holiday shifts are from patients who are in serious condition, so abnormal values

are not uncommon. Therefore, because the test results are immediately reflected in the patient's treatment, diligent care must be used when reporting the test results. It is best to compare the results with previous results, and to set the standards for retesting. Table 1 shows the standards for retesting our laboratory uses with the LC-5000.

Also, using the graphic printer included with the system, we can print out matrices and histograms to check the test results whenever necessary. An asterisk (\*) or exclamation point (!) next to a printed value indicates that the measured value may be unreliable and that retesting is needed. The measured values from a retest are suffixed with "/T" and "/R".



### Testing Operation Flow

- (1) Information about the doctor's orders and process cancellation are stored in the queue file of the host computer (Hitachi VOS1/FS) (host program).
- (2) The stored data is sent to the CSS dedicated server in the laboratory (client program).
- (3) The transmitted data is processed and added to the CSS database and analyzer communication database (client program).
- (4) In accordance with a command from the monitoring computer in the laboratory issued to the laboratory's CSS dedicated server, the test request information in the analyzer communication database is sent to the analyzer (client/server program, socket communication).
- (5) Communication between the laboratory CSS dedicated server and terminal server (Seiko NS-2230) is handled by RS-232C-TCP/IP in order to send and receive information about test requests and test results (server program, socket communication).
- (6) The system can monitor erroneous value results and the status of communication between the monitoring computer and the analyzer (client/server program, socket communication).
- (7) If the results reported from the analyzer are within the normal range, the results are sent to the results transmission computer so that the results can be sent to the host computer, without any additional instructions from the medical technologist. If a result is outside the normal range, that result is reported in accordance with the instructions from the medical technologist for sending results (client/server program, socket communication).
- (8) The results transmission computer sends the result sent from the laboratory's CCS dedicated server to the host computer (client/server program, socket communication).
- (9) The results can be referenced from the host computer.

Fig.1. In Vitro Diagnostics CSS System at Kitasato University Higashi Hospital.

	Initial Test	When Compared to Previous Test
WBC	2000 or less, or 15000 or higher	Marked change
Hgb	10.0 or less, or 18.0 or higher	Change of 1.0 or more
MCV	70.0 or less, and "/R" attached to the PLT value	Change of 5.0 or more
MCHC	30.0 or less, or 35.6 or higher	30.0 or less, or 35.6 or higher (regardless of previous value)
PLT	100.0×10 <sup>3</sup> or less (displayed value of 100)	Change from normal range (decrease)

Table 1. Our Standards for Retesting With the LC-5000.

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Daily Maintenance and Quality Control

Because our instruments run for 24 hours a day, an automatic cleaning followed by a shutdown and startup are conducted early in the morning. The product is set to perform automatic cleaning every 30 tests, and, considering the large number of samples tested, we run a concentrated cleaning twice a week.

For quality control, internal quality control is performed by making double measurements twice a day using three levels of control bloods, controlling the precision as X-R. For calibration, the values displayed by the LC-5000 are checked using the control bloods assayed for the LC-5000. As we use different instruments for normal testing and emergency testing, we test the correlation between the two systems with six samples taken the previous day.

As for the external quality control, we participate in quality

control surveys of the Japan Medical Association, Japan Association of Medical Technologists and Kanagawa-ken Association of Medical Technologists, through which we can evaluate our laboratory. We also participate in the quality control surveys conducted by the manufacturers.

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Within-Run Precision and Correlation With Other Instruments

Making a series of 10 measurements with the LC-5000 using one sample from the same patient and then checking the within-run precision, we found the following favorable coefficients of variation: WBC-CV=1.85%, RBC-CV=1.03%, HGB-CV=0.81%, HCT-CV=1.03%, PLT-CV=3.72%. This evaluation assessed the clinical performance of the LC-5000 compared to the Coulter STKS automatic hematology analyzer, using 115 specimens taken from daily patients. The correlation between the two systems is shown in Fig.2.

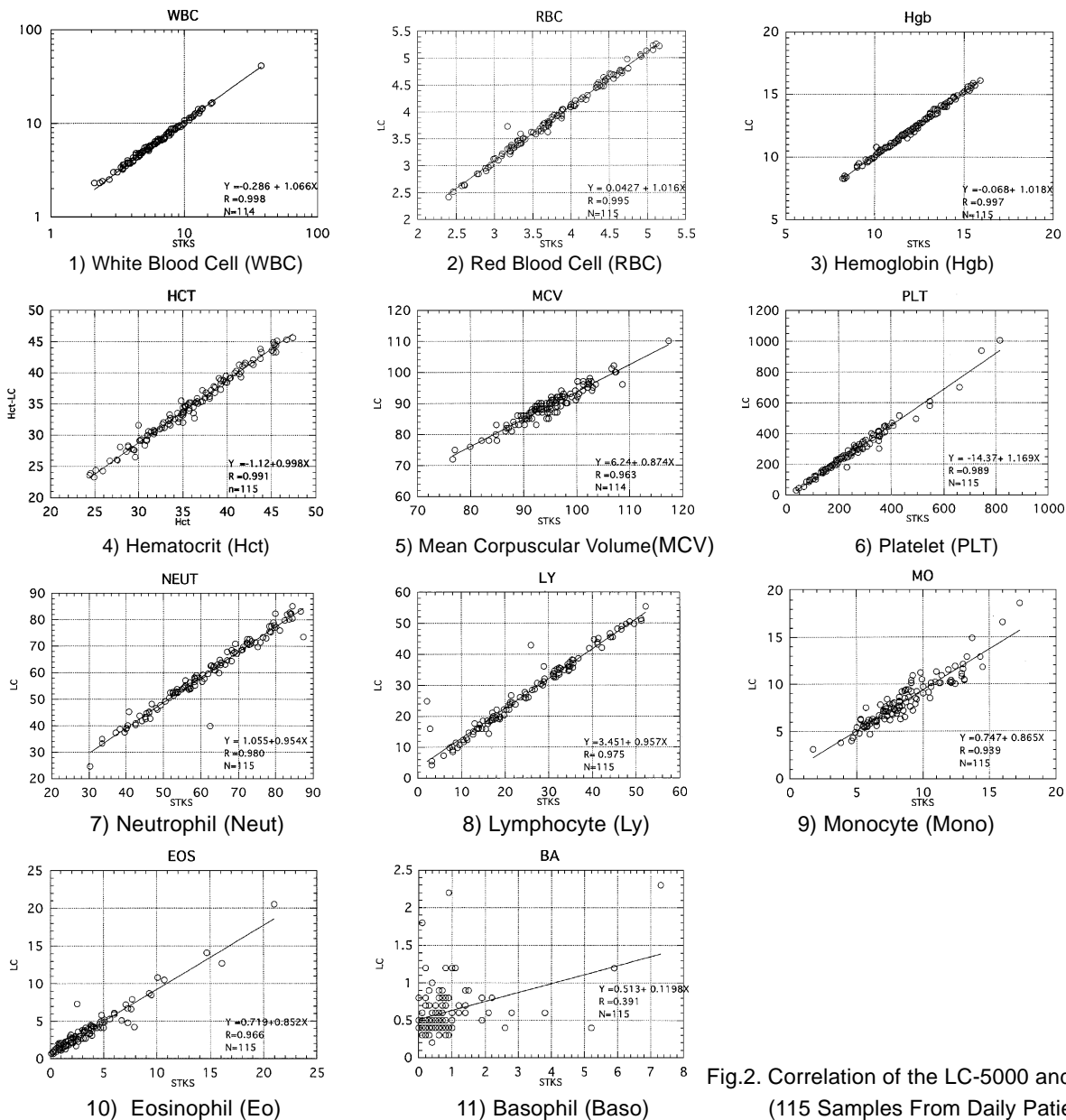


Fig.2. Correlation of the LC-5000 and STKS (115 Samples From Daily Patients).

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## Running the LC-5000 During Daytime Hours, Holidays, and Nighttime Hours

In regard to daily operation, STKS is used for processing large quantities of samples for outpatients and inpatients other than emergency cases, and the LC-5000 is used for emergency testing for more than 100 samples a day (OPE emergencies, outpatient emergencies, and hospital ward emergencies). During daytime hours, the technologists rotate daily to operate the various kinds of analyzers, and order reception (sample arrival), testing, results verification, and results reporting are done using a computer.

Holiday and nighttime hours are handled in rotation by a staff of 30 technicians, with each technician covering a holiday/nighttime shift approximately twice a month. With our work shift system, one person who is on duty during a weekday daytime shift continues working the night shift from 5:10 p.m. to 8:30 a.m. the next morning, and is then relieved from work at 10:00 a.m. The daytime shift is from 8:30 a.m. to 5:10 p.m., and the technologists rotate the night shift, which is covered by one person.

In our laboratory, a technologist covers the following tests simultaneously: full set of blood tests, blood gas, urine chemistry, and transfusion-related work. The LC-5000 is used to process approximately 10 tests during nighttime hours and 30 tests during daytime hours.

and precision that is quite sufficient for use, as at our laboratory, in emergency situations during daytime hours and during nighttime and holiday hours, as well as for daily use at hospitals that test comparatively few samples.



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## Conclusion

Instruments for diagnostics are best operated by a technologist specifically assigned to work with the system, who is well-versed in the measurement principles, highly knowledgeable in hematology, and who has received training in maintenance.

However, even if such technologists are available during daytime hours, holiday and nighttime shifts are covered by a large number of technologists in rotation as a result of a work shift system that differs from regular daytime hours. Furthermore, in medium and small size hospitals, people usually cover several areas of work, and as a result, there comes to be a wide variety of ways in which even simple work is done. Thus, as the number of people working in clinical testing increases, so does the need to utilize a system supported by manuals and documented procedures.

Therefore, what is needed is not large-scale measurement instruments requiring complex operations, rather, we first need simple operation, and second, we must have a high level of precision that provides reliable measurement values. On these points as well, the LC-5000 provides outstanding operation