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Automatic Control System for Quality Assurance of Clinical Pathology Examination: A Machine Learning Approach

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Abstract. The object of research is a study on a machine learning-based integrated quality control system to provide accurate test results quickly by improving the accuracy of test results and improving the utilization rate of test equipment by analyzing clinical pathology Examination data. As for the development method for research, IEC 62304, the international standard for medical S/W life cycle used in medical software development, was applied, and the S/W life cycle rule was applied to all processors by integrating agile methodology. Random Forest, XGboost (extreme Gradient Boosting), LightGBM (Light Gradient Boosting Machine), and DNN (Deep Neural Networks) to improve Rule Check accuracy to predict abnormality of inspection results, and to monitor abnormal results in real time by rule check calculation method technique was applied. In addition, to improve user convenience, automatic control and user interface technology using a dashboard function applied with machine learning technology, and automatic interlocking interface technology for various heterogeneous inspection devices were applied. Validation and verification were conducted through a qualified testing body (TTA) to ensure reliability. The following results were found through this study. As a result of implementing a module that applied big data-based machine learning technology to the algorithm used for quality control judgment of the first knowledge-based expert system, it was possible to implement a module with more than 95% accuracy. there was. Second, in order to determine whether a real-time alarm function was provided, the development module was linked to the clinical pathology information system and as a result of the experiment, it was found that it was operating normally. In addition, reliability was secured through certification by an accredited certification body. Third, as a communication support method for the interface of the inspection equipment,

stability and various technologies were secured through a number of communication tests and certification tests such as RS232C, TCP/IP, and Serial HL7. Fourth, through multiple database tests (Oracle, MSSQL, MySQL, MS Access, etc.), cost savings were secured by resolving duplicate investment by providing database neutrality and interface with other systems. Fifth, utility and user satisfaction were enhanced by providing program functions for outputting the result report in various formats and configuring the UI settings, and the UI settings were modularized to reduce the program development costs and allow the modules to be reused. Through the results of research, small and medium hospitals can improve the reliability of inspection results through the machine learning-based quality control module, and through real-time monitoring of the inspection equipment, it is possible to quickly determine whether there is a failure and improve the operation rate of the inspection equipment. In addition, by providing a module that can be linked with the existing information system, it was made easy to link, and the convenience of the user was improved by providing various UI environments. As a result, it can be expected that the hospital's competitiveness and medical service will be improved by resolving the difficulties of quality control that small and medium-sized hospitals had and providing prompt and accurate test results.

Keywords: Clinical Pathology Examination, Quality Control, Automatic Control, Big Data, Machine Learning, Laboratory Information System (LIS)

1. Introduction

Most of the people receiving treatment at the hospital undergo various clinical tests according to their own needs and the needs of the attending physician. Most of these tests are performed by Clinical Pathology Examination targeting blood, tissue, or secretions from the human body. Clinical Pathology Examination performed in laboratory medicine are an act of measuring the components of the sample (e.g., blood, body fluid) and objectifying the signs and symptoms of a disease based on the results and serve as an important measure for diagnosis and treatment (Min WG, 2009). Any small error in the laboratory can lead to a diagnostic error, in which case the patient will be unable to receive adequate treatment. Qualitative management of laboratory tests, which play a decisive role in the diagnosis and treatment of diseases, is essential for the doctor to make an accurate diagnosis and for the patient to receive appropriate treatment (Jeong JW, 2009). Therefore, it is imperative that the Department of Laboratory Medicine perform proper quality control to prevent errors that can potentially arise during a test in order to provide accurate and precise results to the medical staff and to ensure reliability. Hospitals work to maintain the accuracy and precision of Clinical Pathology Examination to provide optimal medical services and enhance their competitiveness and perform quality control in various ways to improve reliability. There are mainly two types of quality control applied by hospitals: internal quality control, which is a means to control primary variations in the equipment and records by assessing accuracy and precision based on the prescribed principles concerning the material and method used, and external quality control, which involves joining a certification body such as an academic association or a learned society and submitting the results of the tests performed on samples to have the external body conduct statistical analysis and evaluation for certification purposes. Quality control of clinical pathological examinations is mainly conducted in university hospitals or large hospitals with ample capital, facilities, and manpower, and small and medium-sized hospitals are difficult to systematically manage quality due to lack of facilities, manpower, and time. Looking at the status of quality control in domestic medical institutions, only 38.03% of small and medium hospitals implement quality control, which is very low compared to general hospitals (97.49%). Although most departments of laboratory medicine today apply various methods of quality control, they typically do not build a database on the quality control results, making it difficult to use them for research. For this reason, mathematical models are mainly used to identify the significance that applies to the group after analyzing samples using statistical analysis techniques, and this requires a decision-making system where data-based predictions are made (Yang JY, 2017). In this study, which was conducted to address the aforementioned issues of internal quality control, machine learning was applied to detect important patterns and rules from data in order to create a model that can help maintain test precision and accuracy, detect and eliminate potential causes of reduced precision in advance, track the monitoring

performance of devices and equipment, and compare and select test methods and equipment. The purpose of this study is to maintain the test equipment in advance by predicting the loss of precision of diagnostic test results using machine learning techniques, to prevent errors, to maximize the use of test equipment, and to provide accurate test results to medical staff promptly to improve hospital reliability. We present a machine learning-based integrated quality management model to improve performance and reduce management costs.

2. Literature review

2.1. Concept of Quality Control

Quality control is defined as the scientific effort to produce reliable data through early detection and prevention of the causes of errors by properly managing all processes before, during, and after analysis and the factors involved, such as personnel, equipment, and external conditions, and by minimizing the impact of errors on test results (Lee AG, 2007, Lee AG & Han JT, 2007). The quality control methods applied by clinical laboratories are largely divided into internal quality control programs (Moon JY, 1996, Hwang SY 2009), where the laboratory performs its own quality control using normal and abnormal control serums, and external quality programs (Yoon SY, 1997) for an objective assessment of whether the laboratory is performing appropriate tests and providing accurate test results. The recent trend among laboratories has been to set up a laboratory information system to perform panic check and delta check which are effective in detecting errors before and after tests (Lee GR, 1998). As for the internal quality control method for laboratory tests in Korea, quality indicators are set using the three components of Donabedian's model, which has become a general method of measuring the quality of medical care, and they are structure, process, and outcome (NANCY O. GRAHAM, 2001). Indicators of structure include the physical characteristics of the laboratory and the organizational structure of laboratory personnel, process indicators include variables related to quality control, and outcomes indicators include laboratory test results (Shin IS, 1991). Examples of an external quality control program include the External Confidence Survey carried out by the Korean Association of External Quality Assessment Service and the Laboratory Confidence Certification System implemented by the Korean Society for Laboratory Medicine to evaluate the testing process in relation to precision and reliability among other factors (Dongguk University, 2009). The Laboratory Confidence Certification System targets only hospitals with full-time laboratory medicine specialists. The qualitative management of laboratories is mainly carried out by university hospitals and general hospitals with significant capital, facilities, and manpower, whereas the participation rate of smaller medical institutions is quite low due to the lack of facilities, manpower, time, and so on.

2.2. Quality Control Method

The methods of quality control are divided into internal quality control, external quality control, panic check and delta check. Verification is performed to check for systematic errors by using quality control materials based on analysis of precision, accuracy, and reproducibility and to check for random errors using the sample measurements.

2.2.1 Internal Quality Control Techniques

Internal quality control techniques can be divided into internal quality control using control samples and internal quality control using patient samples. The former is a method of precision control that has been implemented since the late 1920s, and it involves the use of quality control serum prepared by the laboratory. The quality control materials used in this case include a reference material, calibration material, and control material. A reference material refers to the serum prepared to verify the accuracy of instrument calibration or the test method, while a calibration material, which is prepared at several different levels of concentration, is used to calculate the concentration of a sample. A control material, on the other hand, is used to monitor the accuracy of the test method and perform quality control of the test equipment, and a quality control (QC) chart labeled with concentration levels is created. Internal quality control using patient samples may involve delta and panic checks, the use of the daily mean or average of normal (AOM), arithmetic check, the use of randomized duplicate specimens, and pattern recognition.

2.2.2 Panic Check and Delta Check Techniques

Panic check is performed by creating a laboratory standard to manually check the results reported on the same day, even if an information system has not been established. It is one of the quality control methods applied to detect pre-analytical and analytical errors by re-examining any results exceeding the threshold by setting the upper value or the upper limit. It is desirable to set 1% and 99% in the distribution of test results obtained using the equipment and test method currently used in the laboratory as the upper and lower limits, respectively, for a panic check, but because this may be realistically impossible, a similar model or test method of a different laboratory may be referenced. Delta check, on the other hand, is a quality control method that uses patients' test results to help find random errors. If the patient undergoes follow-up tests or gets retested periodically, any changes in the patient's condition can be determined by comparing the latest results with the previous measurements. If the difference is significant, the possibility of occurrence of an error before, during, and/or after the test is greater compared to other samples, and in such cases, the cause of the error is identified, and the error is corrected following a retest. In the case of delta check, however, it is impossible to manually compare the previous results with the current results for all patients, so it is necessary to use a computer-based information system in combination to facilitate the process. A delta

check provides important information in determining the level of internal quality control and for tracking the patient's progress. Generally speaking, a delta check is performed using the delta difference (DD), delta percent change (DP), rate difference (RD), and rate percent change (RP). Table 1 shows the items that may be checked in a delta check.

Table 1: Checklist for Delta Check

Test registration	**Calculation method**	**Lower limit**	**Upper limit**	**Unit**
Total Protein	DD	-1.5	1.3	g/dL
Albumin	DD	0.9	0.8	g/dL
Cholesterol	DP	-39.5	45.5	%
T-Bilirubin	RD	-0.8	0.9	mg/dL/day
AST(GOT)	RP	-22.5	48.9	%/day
ALT(GPT)	RP	-19.7	56.7	%/day
ALP	RP	-10.6	21.2	%/day
Glucose	DP	-52.4	156.8	%
BUN	RP	-21.5	35.3	%/day
Cr	RD	-3.0	3.0	mg/dL/day
Uric acid	RP	-9.7	9.9	%/day
Ca	DD	-1.8	1.5	mg/dL
P	DD	-2.3	2.0	mg/dL
D-Bilirubin	RD	-1.0	1.3	mg/dL/day
Gamma-GT	RP	-100	100	%/day
Na	DD	-10	8	mmol/L
K	DD	-1.4	1.4	mmol/L
Cl	DD	-10	9	mmol/L
Triglyceride	DP	-110	200	%
HDL-cholesterol	DP	-10	15	%

※ DD: delta difference, DP: delta percent change, RD: rate difference, RP: rate percent change

2.2.3 External Quality Control Techniques

In the case of external quality control, an accredited organization, such as an international agency or a learned society, sends a sample to each laboratory to perform the prescribed test, and the submitted result is analysed to determine reliability. This is carried out for the purpose of maintaining the test quality up to the standard by evaluating the performance of certified laboratories, resolving systematic errors caused by differences in facilities, equipment, and measurement methods, and ensuring accuracy. International certification bodies include the CDC, CAP, SBCL, Mayo ML, and DADE, and domestic certification bodies include the Korean Association of External Quality Assessment Service. External quality control may be conducted by sending samples from the same batch to multiple laboratories for analysis and compare the results from individual laboratories or by sending samples from the same batch to a number of hospital laboratories and collecting the data for a distribution analysis, as part of a control survey. For external quality control, the standard deviation index (SDI) and the variance index score (VIS) are generally used. The SDI refers to the absolute value of the standard deviation of the group to which the same measurement method has been applied, and it is mainly used by the Korean Association of External Quality Assessment Service.

$$SDI = \frac{Result\ from\ individual\ labs - Average\ of\ all\ labs}{Mean\ SD\ of\ all\ labs}$$

$$\%Variation = \frac{Results\ of\ all\ participating\ labs\ -\ Average\ reference\ value\ of\ all\ labs\ (DV)}{Average\ reference\ value\ of\ all\ labs\ (DV)} * 100$$

$$VI = \frac{\%Variation}{Chosen\ coefficient\ of\ variation(CCV)} * 100$$

The method using the VIS is mainly employed by overseas institutions and services, such as the College of American Pathologists (CAP), World Health Organization (WHO), and Quality Assurance Program (QAP).

Thus, for a disaster safety system catering to the elderly and the disabled, there is a need to develop a response support system with the following characteristics in preparation for the increased risks arising from physical constraints in the event of a disaster as well as disaster alarm and evacuation support technologies in reflection of the characteristics of seniors. For this purpose, there is a need to make the following amendments to the related laws: first, taking into consideration the characteristics of elderly care facilities, in which the users face difficulties in suppressing a fire early on and evacuating independently due to aging, it should be made mandatory to install an automatic fire extinguishing system, regardless of the size of the facility; second, since seniors cannot readily perceive disasters due to deteriorated object recognition skills, it should be made mandatory to install an automatic disaster detection system

that can automatically detect disasters and issue an alarm, regardless of the size of the facility; and third, it should be made mandatory to install an automatic disaster notification system that receives disaster signals from the automatic disaster detection system in the event of a disaster and automatically notifies the fire department or related authorities of the occurrence of a disaster and the locations of the affected areas. Lastly, there is a need to develop disaster safety support technologies that are incorporated with a universal design that can be applied to elderly, disabled and non-disabled by applying ICT to disaster detection, automated systems, and evacuation guidance support among others to ensure an appropriate early response in the event of a disaster and to prevent it from developing into a massive accident.

2.3. Concept of Machine Learning

Machine learning, in its early days, was defined as a "field of study that gives computers the ability to learn without being explicitly programmed" (A. L. Samuel, 1959), but this was a concept that did not highlight the importance of data. In contrast, the current concept of machine learning includes various aspects of information and communication technology, such as cloud computing and big data. Machine learning is a technology for building an ideal learning and predictive model using various probability and combinatorial theories, mathematical optimization techniques, statistics, algorithms, and computer architecture and is being developed as convergence technology incorporated with the method of acquiring and applying empirical knowledge on the part of researchers (Oh JW, 2021). The essence of machine learning is an automated process of pattern recognition through a learning machine. Machine learning can be said to be a part of artificial intelligence (AI) that uses big data, as the computer or machine in question has to learn on their own using the complex data or problems inputted and thus exhibits capabilities comparable to those of humans (Wu, C, 2017). Deep learning is a field of machine learning that is more advanced than general machine learning. While machine learning is about giving a computer or a machine the ability to learn from data, when it comes to deep learning, the computer or machine learns by judging and executing on its own and predicting the future situation. This is possible because the data are learned through an artificial neural network (Choi, HR, 2017). Fig. 1 is a diagram showing the relationship of artificial intelligence, machine learning, and deep learning. In this study, with the rapid development of machine learning techniques, research using machine learning techniques is being conducted in various fields. However, there were no studies using machine learning techniques in the field of quality control of clinical pathology tests. Therefore, in this study, at a time when interest in machine learning is increasing, machine learning techniques. The purpose of this study is to explore ways to apply machine learning techniques to quality control through the study of quality control prediction models using clinical pathology. We analyze the factors derived from the predictive model design process and results, and present the features to be considered when applying the machine learning technique compared to

the traditional management method.

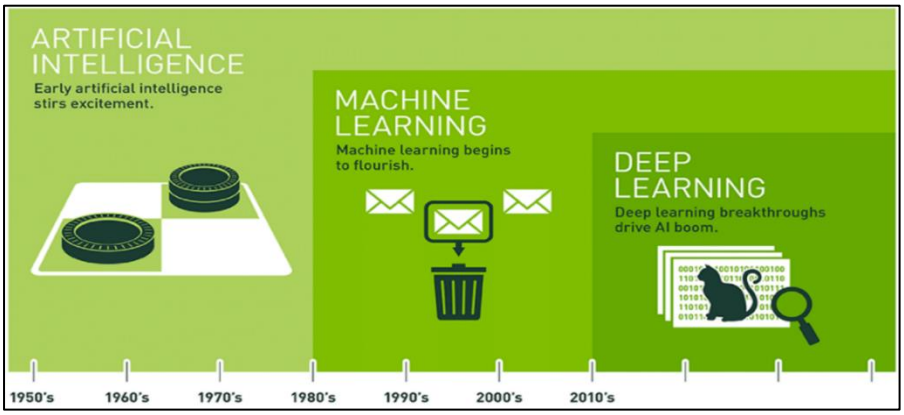

Fig. 1: Relationship of Artificial intelligence, Machine Learning, and Deep Learning

3. Research Method

3.1. System Diagram

The automatic control system for quality control of Clinical Pathology Examination is an ICT-based integrated quality control system that applies modular technology and machine learning technology to improve the accuracy and reliability of diagnostic test results. In this study, machine learning was applied to real-time monitoring and user notification technology to address the delays and inconveniences for patients resulting from testing equipment failures. By predicting failures in the equipment interface and peripherals in advance and enabling prompt action in case of failure, the system can minimize interruptions and monitor the operating status of test equipment in real time. Fig. 2 shows the components of the system examined in this study.

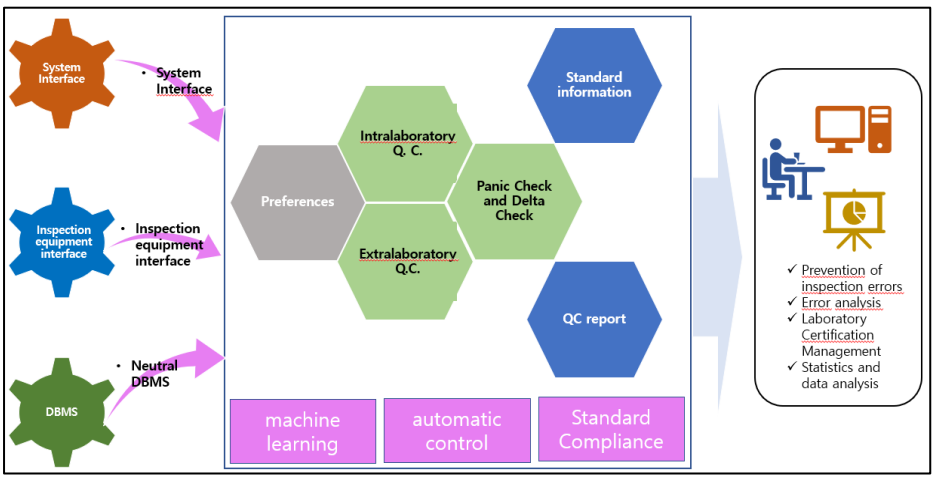

Fig. 2: System Diagram

3.2. Applied Technology

The core technologies applied to develop the ICT-based integrated quality control system incorporated with machine learning technology to improve the accuracy and reliability of diagnostic test results are a user-oriented user interface (UI), modular technology for the reporting system, packaging technology, automatic control and UI technology for the dashboard incorporated with machine learning technology, and automatic interlocking interface technology for various types of test equipment. The key functions are the rule check for user convenience, internal quality control for improving the accuracy and reliability of test results, and external quality control for external certification of the laboratory. The core technology applied to each of these modules is listed in Table 2.

As for the development method applied in this study, IEC 62304, an international standard for the life cycle requirements for medical device software, was used in the development of the software. IEC 62304 is a standard applied to the development and maintenance of medical device software, providing a life cycle process framework consisting of activities and tasks necessary to ensure a safe design and maintenance of medical device software.

Table 2: Core Technology by Module

Module	Core Technology
UI and rule check	• Material information management (lot number, test equipment, level, fixed sample number, etc.) • Test item management (test item, reference values, etc.) • Level management (Low/High, Normal/Abnormal, Positive/Negative) • Lot change management, comparison with past records, and bias calculation • Management of verification standards by equipment and test (1_2S, $1_3$3, 2_2S, R_4S, 4_1S, 6X, 10X, etc.) • User settings for the screen (control) and grid (layout)
Internal quality control	• Issuance of test orders (bar code) and fixed sample numbers (automated) • Results reporting: Descriptive type, results of applying actual measurements, notification of abnormal results, and comparison of standard ranges • Certification of test results • Trend analysis by lot number (graph) and comparative analysis of trends by level (graph) • Mean, SD, CV, and BIS trend analysis: by material and by test
External quality control	• Management of issuance of external orders • Entry of information on materials (analytical concentration range and usage history management) • Comparison of the results and BIS analysis: by laboratory and by tester • SDI management: internal quality control, peer group, etc.

Dashboard	• Real-time execution by equipment • Abnormal result (rule check) by equipment and material • User alarm settings (time, period, alarm type, etc.)
Test equipment/instruments and DBMS support	• Real-time interface support module • Support for test equipment protocol (serial, TCT/IP, HL7, etc.) • Analysis of received data and diagnostic testing system connection module • Settings for multi-database interconnection
Reports/Statistics	• Internal quality control report and external quality control report • Documentation of test results (standardized reports in Excel, PDF, or JPEG) • Test statistics (number of tests performed a month, in a designated period, etc.), etc.

Although IEC 62304 is essential for functional safety in the medical sector, it does not stipulate a specific development methodology. Therefore, agile methodology was applied in combination with IEC 62304 to all the processes of the software life cycle. In order to ensure the reliability of the research results, tests were performed at a qualified testing agency (Telecommunications Technology Association, TTA) based on a validation and verification (V&V) protocol. The performance indicators for validation were set as shown in Table 3.

Table 3: Key Performance Indicators

Key performance indicator		**Unit**	**Development target**	**Weight (%)**
Modularization and packaging	Rule check accuracy	%	95% or above	25
	Calculation method for the rule check	ea	6 or more	20
	UI settings	ea	20 or more	10
Automatic control	Real-time notification of abnormal results	sec	Within 3 seconds	10
Automatic linking	Number of communication methods supported	ea	3 or more	15
DBMS support	Number of DBMSs supported	ea	3 or more	10
Data utilization	Number of result report formats supported	ea	5 or more	10

3.3. Experimental results

3.3.1 Internal Quality Control Techniques

The experimental environment for the operation of the ICT-based integrated quality control system to which machine learning technology was applied is shown in Table 4.

Table 4: System Environment

Hardware Specification	Server	CPU: Intel® Xeon® 3.30GHz, MEM: 16GB, HDD: 1TB
	Client	CPU: Intel® Core™ i7-8700k, MEM: 16GB, HDD: 1TB
Software Specification	OS	Microsoft Windows Server 2016 Standard (64bit) * 1EA
	DBMS	Oracle 10g
	Application	.Net Framework 4.0
	Machine Learning	Random Forest, XGboost, LGBM, DNN techniques
Network environment		TCP/IP, RS 232C

3.3.2 Internal Quality Control Techniques

For the experiment, seven indicators were selected as the main indicators: accuracy of the rule check, calculation method for the rule check, UI settings, real-time notification of abnormal results, the number of communication support methods, the number of DBMSs supported, and the number of result report formats supported. Table 5 shows the number of samples required and the measurement method applied for each indicator. In the analysis, supervised learning with the application of deep learning, supervised learning without the application of deep learning, and unsupervised learning were all applied and analyzed, and four machine learning techniques, Random Forest, XGboost(extreme Gradient Boosting), LightGBM(Light Gradient Boosting Machine), and DNN (Deep Neural Networks), which are widely used for predictive model design, were applied.

Table 5: Experimental Method for Each Indicator

Indicator	**Number of samples**	**Experimental method (specification, environment, result calculation, etc.)**
Rule check accuracy	1,000	The accuracy of the rule check was checked by testing at least 1,000 samples. Accuracy was determined by applying the criteria set by the user for each test (one or more rule check methods were set for each material and test)
Calculation	60	At least six calculation methods were selected and the

method for the rule check		results of at least ten samples were checked for each method. (1_2S;Warning Rule, 1_3S;Detection of random error, 2_2S;Detection of systematic error, R_4S;Detection of random error, 4_1S;Detection of systematic error, 10X;Detection of systematic error) The target calculation accuracy was set as "95% or higher."
UI settings	20	The goal was to reflect at least 20 types of UI options set by the user (configuration of the screen (control) and grid (layout), according to the user settings, issuance of test orders (bar code) and fixed sample numbers (automated) for each material, result of applying the actual measurements, notification of abnormal results, comparison of standard ranges (rule check), certification of test results, trend analysis by lot number (graph), comparative analysis of trends by level (graph), analysis of results (mean, SD, CV, and BIS), management of issuance of external orders, comparison of the results and BIS analysis, QC report, report for each QC item, report for each QC lot, integrated QC (graph) report, report on QC measures, analysis of each QC lot, statistical data, and statistical analysis results).
Real-time notification of abnormal results	100	The goal was to display any abnormal results on the dashboard within 3 seconds upon detection.
Number of communication methods supported	3	It was checked whether various communication methods were supported by attempting connection. The goal was to support at least three communication methods (Serial HL7, RS-232C, TCP/IP).
Number of DBMSs supported	3	It was check whether various types of DBMS were supported by attempting connection. The goal was to support at least three types of DBMS(Oracle, MYSQL, MS-SQL).
Number of result report formats supported	5	The goal was to be able to output a quality control report in at least five formats (PDT, XLS, CSV, Text, Image).

3.3.3 Results

The results of this study can be summarized as follows:

First and foremost, a module with the target accuracy and at least six calculation

methods was developed by using machine learning, and reliability in the real-time notification of abnormal results was ensured through certification by an approved certification body.

Second, stability and various techniques for the communication support methods were obtained by testing various communication methods, such as RS232C, TCP/IP, and Serial HL7, and conducting certification tests.

Third, for multi-database support, tests were performed in connection with multiple databases, such as Oracle, MSSQL, MySQL, and MS Access, for database neutrality and interface with other systems to eliminate overlapping investment and reduce costs.

Fourth, utility and user satisfaction were enhanced by providing program functions for outputting the result report in various formats and configuring the UI settings, and the UI settings were modularized to reduce the program development costs and allow the modules to be reused.

The V&V results from the qualified test agency (TTA) are shown in Table 6.

Table 6: Results of Performance Evaluation by Qualified Testing Agency

Key performance indicator	**Unit**	**development target**	**Result**	**Weighted value (%)**
Number of equipment supporting web services	ea	7 or more	7 ea.(success)	20
Remote control processing speed	sec	Within 2 sec	1.455 sec, on average (success)	20
Number of data processed by the test equipment	ea	1,000 or more	1,144 ea., on average (success)	15
Number of DBMSs supported	ea	3 or more	3 ea. (success)	10
Viewer response speed	sec	Within 3 sec	Internet Explorer : 0.036 sec / Chrome : 0.033 sec / Firefox : 0.047 sec (success)	15
processing speed	sec	Within 3 sec	1.506 sec, on average (success)	10
Alarm processing speed	sec	Within 3 sec	0.707 sec, on average (success)	10

4. Conclusion

This study aims to improve the reliability of hospitals and reduce management costs by maintaining the test equipment in advance by predicting the loss of precision of diagnostic test results, maximizing the use of test equipment by preventing errors, and providing accurate test results to medical staff quickly. This is a study on the integrated quality control model based on machine learning. In recent years, laboratories carrying out Clinical Pathology Examination have been adopting high-cost cutting-edge test equipment and automating their systems. Small and medium-sized medical institutions, however, are faced with challenges in that their laboratory equipment is typically old and outdated and that they lack the human resources to manage the equipment, and this has caused delays in testing and inconveniences for patients. To address this issue, this study was conducted with the aim of developing an ICT-based integrated quality control system with the application of machine learning that would be capable of real-time monitoring and control of diagnostic test equipment. Such system would allow medical institutions to check and mitigate failures in their test equipment or peripheral devices, based on real-time monitoring and user notification functions, thereby reducing the time it takes to complete each test and minimize interruptions. With this in mind, equipment availability and operability were improved by resolving the issues of interruptions caused by equipment failures and redundant testing. Also, the system was designed to provide integrated services, including quality control, for managing the system and test equipment based on certification management to maximize the operating efficiency of the laboratory. In addition, to ensure scalability and continued utility, it was made possible to perform integrated management of the existing test equipment systems that had been developed based on data standardization. To this end, knowledge from the areas of laboratory medicine and automation, communication support technology for interconnection with diverse types of test equipment, control technology using web services, and other differentiated technologies were applied in combination. The outcomes of this study were as follows: First, the most important objective of this study, which was to develop a modularized system for automatic control of diagnostic test quality control based on machine learning, was achieved. Second, standardization technology for multiple database access and data acquisition was secured. Third, HTML5-based Universal Viewer was developed. Fourth, the system in question will reduce labor cost by reducing the time required for equipment maintenance. Fifth, the system can enable prompt response to test equipment failures and minimize related costs. Sixth, small and medium-sized medical institutions introducing this system will be able to boost profitability by offering improved medical services. However, in order for the system designed in this study to be used by small and medium-sized medical institutions, there is a need to first make technical improvements, such as adopting advanced communication, data transmission, control, and encryption technologies, apply measures to ensure system stability, ensure the ease of using the

user program, information accuracy, suitability of operation, and automatic recovery for different types of failures using web platform technology, in addition to the introduction of a new legal framework. For this reason, there should be follow-up research to reflect the test equipment and laboratory characteristics in the system design.

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