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A Study on the Expert System Automation Module for Comprehensive Evaluation of Clinical Pathology Results

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Abstract

Background/Objectives: The purpose of this study is to implement a rule-based automated diagnostic test result interpretation module to automate the process of presenting the findings based on the diagnostic test results for accurate diagnosis and treatment of health screening examinees.

Methods/Statistical analysis: This study involved a comparative analysis of the findings presented by laboratory medicine specialists and the findings presented by a rule-based intelligent system based on health screening results. Test results were classified by case, and the findings were classified accordingly. Rules were predicted for a total of 204 cases, which were classified into 22 types under 5 different groups in order to implement a rule-based automation module and to validate the module. The inference engine used for this purpose was Neuron Data's Intelligent Rules Element, which is capable of dynamic object creation and simultaneous forward and backward inferences, while Visual C++ and Neuron Data's Open Interface Element were used as the interface between the system that was developed and the user.

Findings: The predictability of the rule-based automation module and the feasibility of applying the module in a clinical setting were examined by using the diagnostic test results of health screening examinees. First, with respect to the inference result on quality control, the findings regarding the test results of patients detected at the Δ check value or panic value check showed 100% predictive power. Second, with respect to the results of individual diagnostic tests, the findings on glucose, virus, morphology, and bacteria matched 100%, but the inference results related to the suspicion of specific diseases matched in 25 of 28 cases, indicating a match rate of 84%. Third, the analysis of the association between the test results showed a match rate of 94.4%, on average. Fourth, in the case of ordering additional tests, there was an 81.3% match rate, the lowest predictive power among all the items examined, and it was deemed that the reliability of the prediction was still low. This study revealed the need to set a standard reference value for each test in the rule-based automation module, taking into account several variables, such as when results related to other test items are displayed and when processing a single test item.

Improvements/Applications: The results of this study showed that the rule-based automation module developed can improve the quality of medical services by utilizing the accumulated knowledge from ordering tests to drafting a written opinion on the findings through comprehensive and efficient management of test results and patient information.

Keywords**:** clinical pathology result, LIS(Laboratory Information System), HIS(Hospital Information System), rule-based system, expert system, quality control

1. Introduction

The laboratory medicine department is a medical support department that runs a wide variety of tests on specimens collected from patients, and the diagnostic results obtained through this process have a significant impact on medical decision making. Diagnostic tests are essential medical procedures to ensure rational treatment, especially in clinical medicine and preventive medicine [1]. As such, there is a need for specialists in laboratory medicine capable of analyzing test results, which make up an important part of patient treatment, and presenting comprehensive findings based on clinical pathology test information. In the current medical environment, however, there are shortages of medical specialists who can provide such comprehensive findings, and there is a need for sufficient time to systematically implement the integrated information system for diagnostic test results to be and analyze the results in order to ensure satisfactory comprehensive verification. However, many small- and medium-sized hospitals lack the resources to provide comprehensive findings from a laboratory

medicine specialist. Many do not even have a laboratory medicine specialist on staff, and they lack the information necessary for systematic judgment of the diagnostic test results. It is deemed that providing comprehensive findings on diagnostic tests based on specialized knowledge will allow accurate treatment planning and speed up the treatment process for improved medical service quality and patient health. The laboratory medicine department must be able to quickly report the test results to the doctor that ordered the test, and at the same time maximize reliability by increasing the accuracy and precision of the test results. The department must also manage the test results that have accumulated over several months to years through integrated management and be able to meet the requests to retrieve various data for research support purposes. Diagnostic test results are an important measure for patient diagnosis and treatment, which is why a laboratory information system (LIS) is recognized as an important component of the hospital information system (HIS). As clinical doctors demand increasingly diverse and specialized diagnostic tests, it has necessitated an information system that can interpret test results and support decision-making by doctors. However, there has yet to be an information system for digitizing test data as smart test data or one that integrates the main computer system of the hospital and a smart laboratory medicine department. Accordingly, there is a need for an automated module for rule-based judgment of diagnostic test results that can improve productivity and directly help doctors in laboratory medicine. The significance of this study is that it examines an automated module for rule-based judgment of diagnostic test results for accurate diagnosis based on health screening results and diagnostic tests performed for accurate diagnosis and treatment.

2. Theoretical Consideration

2.1. *Concept of Laboratory Information System*

As an information system that can ensure efficient delivery and management of all test information handled by the Department of Clinical Pathology throughout the entire process from the ordering of a diagnostic test to the reporting of the results, the laboratory information system (LIS) is a critical part of the hospital information system (HIS). The data it holds are greater in volume and diversity than any other information system, and accuracy and speed are especially vital in information generation and delivery. It must ensure that the diagnostic test results are readily available wherever they are needed by producing, processing and reporting the related information for efficient treatment of outpatient and inpatients at the hospital [2]. The LIS(laboratory information system) is arguably where data standardization is needed most among all other components of the HIS(hospital information system). Clinical pathology can be broadly divided into diagnostic blood test, clinical chemistry test, clinical microbiology test, the blood bank, and immune serum test [3]. This study specifically examined clinical chemistry tests in which samples are automatically tested using equipment. Clinical chemistry tests are categorized into general chemistry test, special chemistry test, urine chemistry test, 24-hour urine fluid test, and blood gas test. In clinical chemistry, all tests involve the use of automated equipment, and specimens and test results are registered automatically at the interface of each automated equipment, so the information on the test equipment must be entered into the system [4]. The flowchart of a general LIS(laboratory information system) is shown in Figure 1 [5].

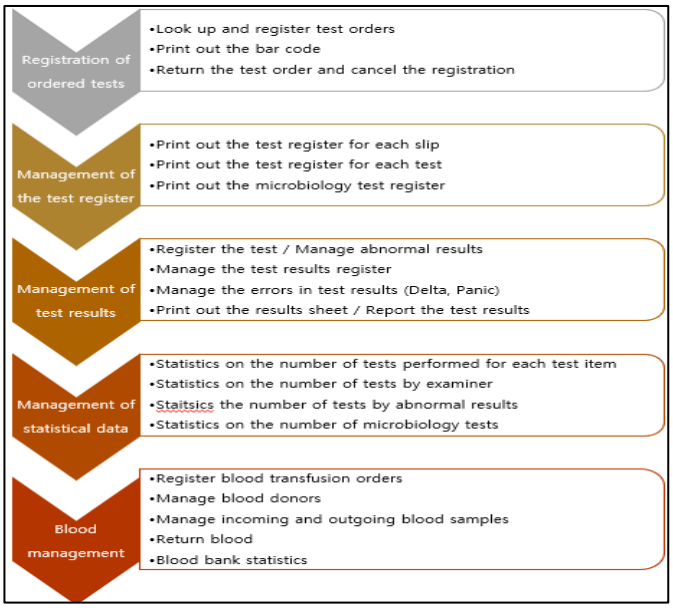

Figure 1. Flow chart of Laboratory Information System(LIS)

2.2. *Concept of clinical pathology Quality Control System*

Quality control features using patient specimens include Delta check and panic value is a method of re-examining and checking a specimen when the change in the patient's condition is clearly known by comparing the patient's last test result with the current test result and the breadth of the change always deviates from a certain range. That is, if the current test result is significantly different from the last test result, there is a greater possibility that the error occurred before, during, or after the test than other specimens, and the error is corrected by identifying the cause of the error and performing the test again. If measurement is actually accurate, any significant changes between measurements become important information that the clinician needs to know as soon as possible. Therefore, the Δ check value is important in both internal quality control at the laboratory and the tracking of patient's progress. There are four categories in checking the changes in measurement values [6, 7, 8].

Δ difference (delta difference) = Present test result – Previous test result
Δ percent change (delta percent change) = (Δ difference / Previous test result) * 100
Δ difference per period (rate difference) = Δ difference / Δ time (delta time)
Δ percent change per period (rate percent change)= Δ percentage change / Δ time (delta time)

Panic value check involves setting a test criterion for which early reporting is important for a quick clinical decision to be made regarding the patient and reporting the result through re-examination and early reporting for any values exceeding the criterion. The Delta check and panic value are the most effective methods for finding random errors as a quality control measure using patient specimens. Such quality control decisively enhances the reliability of test results, and with accumulation of data, it contributes to the advancement of the pathophysiological understanding of diseases.

2.3. *Concept of Expert System*

An expert system, one of the most popular applications in the field of artificial intelligence (AI) technology, refers to a computer system with the expertise or empirical knowledge of human experts in a specific domain that is capable of solving problems without the help of human experts or assisting

experts in solving problems [9]. When an AI system can test the decision-making ability of an expert, it is called an expert system [10, 11, 12]. Data processing involves calculating certain data and showing the result to an expert so that the expert can make decisions, whereas knowledge processing even presents a solution to the problem based on inference using knowledge from the knowledge base and even uses the result of data processing in the process. An expert system is needed in the following cases: first, it is when the related knowledge is becoming obsolete or the information that needs to be shared is scattered; second, it is when the decision-making is complicated or there is a large amount of data that needs to be considered; third, it is when the demand for experts is greater than the supply and training experts is costly and time-consuming; and fourth, it is when inference based on knowledge, rather than simple numerical calculations, is needed. The reason for developing an expert system is that it presents a number of advantages, such as permanence, ease of delivery of information, consistency, and low maintenance cost [13]. Unlike the conventional algorithm-based programs, an expert system is comprised of a knowledge base, in which specialized knowledge in a specific field is stored in the form of facts and rules, an inference engine that draws decisions based on the knowledge base, and a working memory that contains the inputted facts and inferred results. Expert systems developed and used in the medical field can be divided into decision support systems that use statistical or probabilistic methods and AI models for medicine that are based on clinical findings of diseases and various test results [14].

Expert systems began to be used in laboratory medicine in the early 1980s. A system called EXPERT, consisting of 82 rules and 38 conclusions, was developed for the first time to interpret serum protein electrophoresis patterns, and it was applied to cardiac isoenzyme pattern analysis and thyroid function test. Also, for early diagnosis of AIDS, rule-based inference and case-based inference were used, and hybrid model was developed by combining the two [15]. Studies using rule-based inference include one that aimed to diagnose hyperlipidemia and hemoglobin disorders [16].

Expert systems have various applications including sequential laboratory testing, test scheduling, endocrine diagnosis, diagnosis and therapy of coagulation disorders, erythrocyte antibody identification, coding of medical knowledge, case-finding, narrative pathologic diagnosis, instructions in pathophysiology, residency training, and general clinical diagnosis and management [17].

The main techniques applied in relation to expert systems include expert system development tools, knowledge acquisition techniques, knowledge representation techniques, inference control techniques, user interface design techniques, and explanation module design techniques. The most essential part of an expert system is arguably the knowledge base, which consists of textbook knowledge, beliefs and empirical knowledge. Here, empirical knowledges mean experiences acquired by skilled medical specialists, which are represented by a knowledge engineer in such a way that a computer can understand to build the knowledge base (as shown in Figure 2).

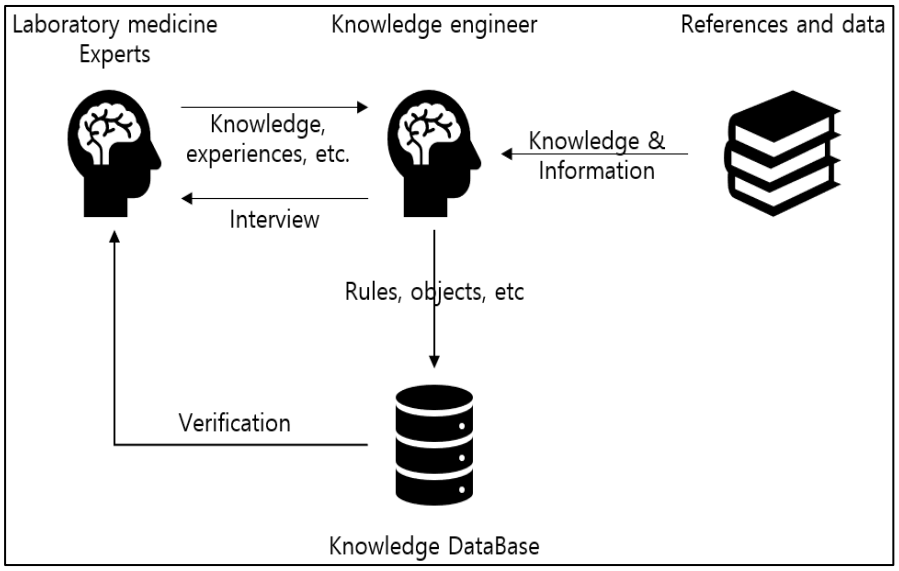

Figure 2. Build a knowledge base

An expert system is developed through a process of defining the problem to be solved, acquiring the knowledge necessary for solving the problem, expressing the acquired knowledge in a form that can be systemized, systematizing the knowledge using an appropriate development tool, and verifying and correcting the examples presented by the system [18]. Therefore, it is effective to create a system that can perform basic functions at first and then gradually improve the system configuration and knowledge expression in a systematic manner so as to progressively improve the system. The development process for an expert system is shown in Figure 3.

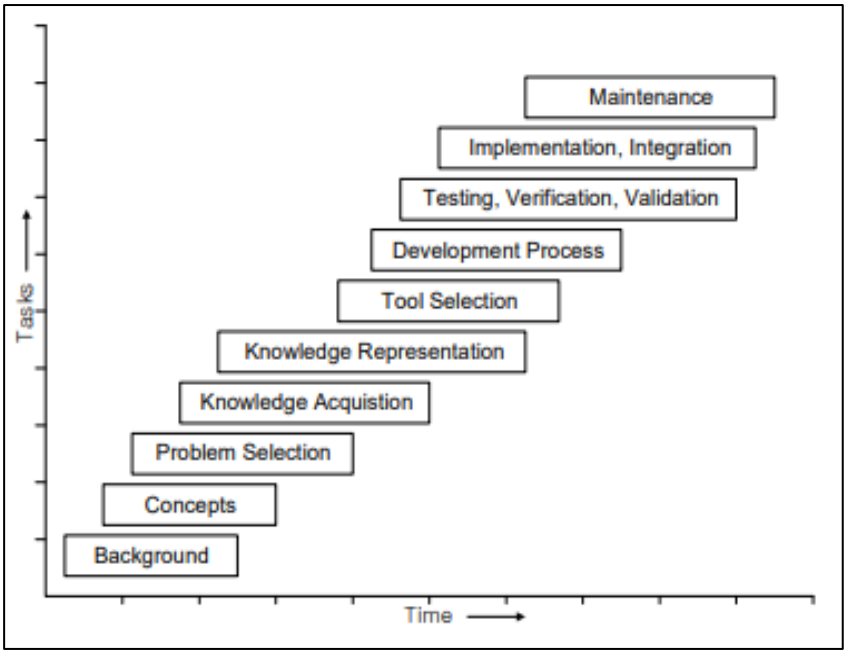

Figure 3. Expert system development process

2.4. *Concept of Rule-Based System*

A rule-based system represents knowledge in the rule form of “if” and “then” clauses, stores data representing the current situation in the working memory, and executes the rules that satisfy the current

condition by comparing the conditions for the rule and the acquired data in the inference engine to draw conclusions [19, 20]. A rule-based system is composed of a memory, a working memory, and an inference engine (as shown in Figure 4).

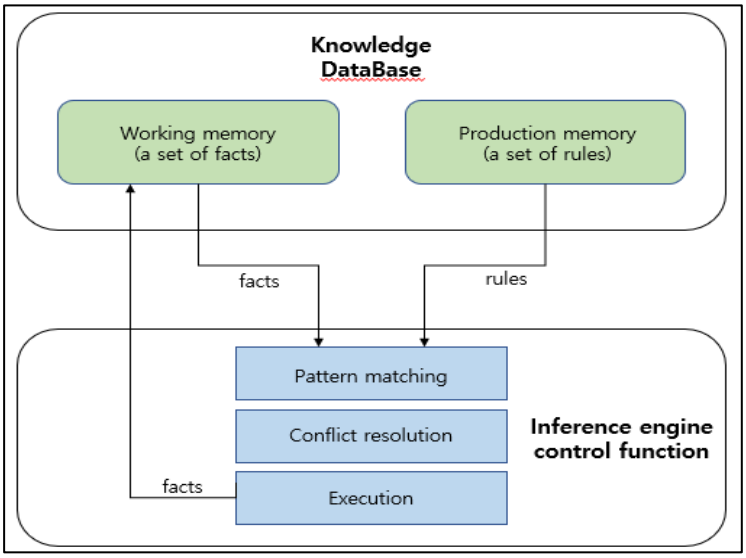

Figure 4. Configuration diagram of rule-based system

The inference engine is the part responsible for control and inference in a rule-based system. It turns the current state into the target state by repeatedly performing the steps of pattern matching → conflict resolution → execution to make inferences. First, the pattern matching step involves creating a rule-fact pair by comparing the facts in the memory with the conditional part in the memory and if there is a fact that matches the condition, assigning a specific value from the data to a variable in the conditional part of the rule. In the second step, which is conflict resolution, the method of selecting the optimal rule among the rule-fact conditions created in the pattern matching step is decided. The third step is the execution step which involves executing the rule where the actual conclusion part from the selected rules and facts, after which the result is returned to the working memory for some of the contents of the memory to be changed and used for the next inference process. When the rule is no longer satisfied by repeatedly executing the rule that checks whether the condition is met, the inference process is finished.

3. Research Method

3.1. *Research Subject*

In this study, a comparative analysis was carried out on the findings reported by a laboratory medicine specialist and the findings reported by a rule-based intelligent system regarding the test results from health screenings conducted from January to December 2019. There were 90 examinees examined in this study, but considering that one examinee might have multiple findings, the diagnostic findings were classified on a case by case basis. Rules for a total of 162 cases were predicted, and they were ultimately classified into 23 types falling under 5 different groups to verify the validity of the rule-based automation module. The inference engine used for this purpose was Intelligent Rules Element manufactured by Neuron Data that is capable of dynamic object creation and simultaneous forward and backward inferences, while Visual C++ and Neuron Data's Open Interface Element were used as the interface between the developed

system and the user.

3.2. *Analysis Procedure*

In order to acquire the knowledge of laboratory medicine specialists and clinicians and build a knowledge base for this study, problem recognition, conceptualization, formalization, implementation, and verification processes were carried out.

In order to predict proper diagnosis for the purpose of building a knowledge base, related information was divided into classes, objects, and attributes. The attributes and values of classes and objects were defined, and the inter-class, class-object, and inter-object associations were represented. Finally, based on the classes and objects, a knowledge base was built by creating rules using a rule editor which was a mix of object-oriented techniques and rules.

In order to validate the rule base, validation was performed using data from the hospital information system (HIS) and laboratory information system (LIS). In order to validate the rule-based automation module, the congruence between the diagnostic result concluded by a laboratory medicine specialist and the inference result made through the automation module was measured through the diagnostic prediction diagram

3.3. *Research Result*

This study was implemented by taking into account the degree of informatization of medical institutions and analysis required for laboratory medicine specialists to draw up the findings based on diagnostic test results. To ensure efficient utilization of the system, an interface was implemented to connect the basic patient information and the information on prior visits that need to be linked with the HIS(Hospital Information System).

3.3.1. System Configuration

The system under this study was organized as shown in Figure 5. The tasks related to the expert system were analyzed and designed by dividing it into laboratory medicine and automated reading and interpretation module, basic patient information analysis module, and order information module. The system was developed in consideration of integrating it with the existing LIS in order to draw accurate findings using information from the health examinations conducted by the medical institution in question.

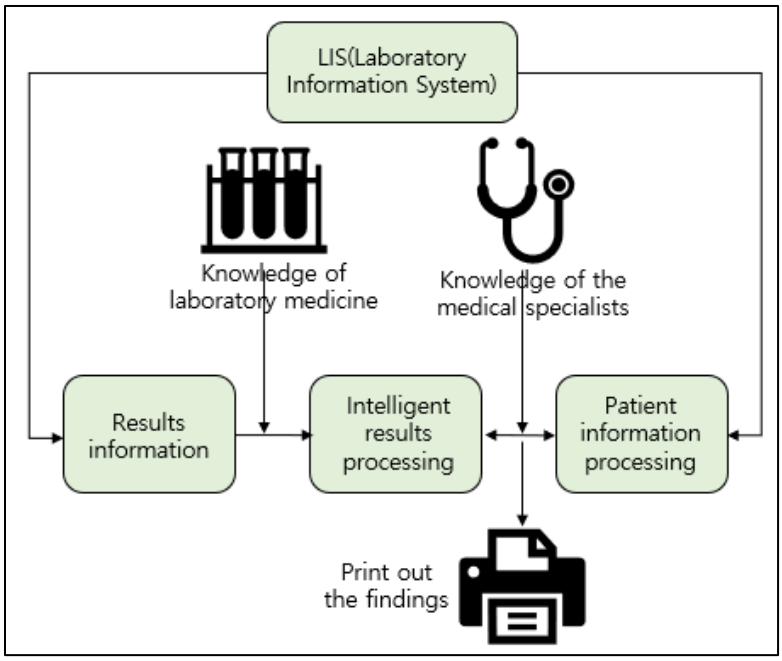

Figure 5. Configuration of intelligent comprehensive judgment system

3.3.2. DBMS Design for the System

A database containing the subject characteristics and knowledge information was built for the purpose of drafting a written opinion on the findings based on the test results so that it could be used as reference information for the knowledge acquisition model. For the database design, eighteen tables were created regarding patient information, registration information, test equipment information, test standard values, diagnostic test results, basic patient information and so on by collecting and analyzing user requirements. Eight tables were created for the management of the test equipment and tests (test equipment, tests, standard reference values, quality control, tests carried out using each equipment, test type settings, and specimen settings by test type). Since there are differences in the test equipment used by each medical institution, these matters need to be modified and supplemented according to what is suitable for the equipment of the medical institution in question. The patient management table is composed of patient information and test registration tables. Basic patient information needs to have an interface with the hospital information system, and the test registration information includes information on whether or not a test needs to be processed. The test information management table is comprised of blood, biochemistry, immune and serum tests carried out by the laboratory medicine department as well as the management of physical body measurements and other data and quality control information with respect to each test performed.

3.3.3. System Implementation

The system was implemented by using the rule-based expert system technology for the efficient performance of the tasks of laboratory medicine. After analyzing laboratory medicine information and basic patient knowledge, a knowledge base was built by categorizing objects and rules. Using the knowledge base, the relevant knowledge was systematically classified and developed in the form of reference information for flexible application according to changes in the templates for findings. First, in order to apply diagnostic knowledge for automatic reading of diagnostic test results, the standard reference values in the system can be set in various ways, and a function is provided for the user to set the level for each sample and patient's age. Second, the findings that can be presented according to the

diagnostic test results are endocrine disease, liver disease, kidney disease, heart disease and other types of disease that can easily be distinguished based on the results of just one test or four or five tests, and there is also a function for requesting additional tests necessary to present the findings regarding a suspected disease. Third, for situations where it is difficult to present an accurate finding solely based on diagnostic test results, a knowledge base was created using the knowledge and experiences of medical specialists and prior studies focusing on general matters such as physical body measurements and diseases such as hypertension, diabetes and liver dysfunction. Fourth, a rule structure was designed. Rules are generally applied in the form of "if" and "then" clauses, but in this study, the association between each rule created using a rule editor and the rules in the knowledge base was represented as a rule graph for users to comprehend it more easily. The expert system tool allows users to select and view each rule, the rules in a specific group, and the rules in the knowledge base, and the knowledge base module was designed and implemented by using this function with efficiency. As such, in order to facilitate data input and the presentation of system conclusions, the expert system was designed so that it would be easy to use for users. Also, the system flow and functions were defined according to the operating procedures, and the necessary information was derived and implemented.

3.3.4. Validation Results

The predicted results were assessed by comparing the inference results from the LIS and the findings presented by laboratory medicine specialists(as shown in table 1). First, with respect to the quality control inference results, the findings regarding the test results of patients detected at the delta check or panic value showed 100% predictive power. Second, in regard to the results of individual diagnostic tests, the findings on glucose, virus, morphology, and bacteria matched 100%, but the inference results related to the suspicion of specific diseases matched in 25 of 28 cases, indicating a match rate of 89.2%. Third, the analysis of the association between the test results showed a match rate of 94.5%, on average. Fourth, in the case of ordering additional tests, there was an 81.25% match rate, the lowest predictive power among all the items examined, and it was deemed that the reliability of the prediction was still low. This study showed the need to set the standard reference values for each test in the rule-based automation module by considering several variables such as when results related to other test items are shown and when a single test item is dealt with. In particular, there was room for improvement as it was found that there was a possibility that errors might occur due to a lack of connection between the test results and the patient treatment results. However, the findings match rate was 92% overall, so if the system is made more detailed and accurate, it will contribute greatly to patient treatment.

Table 1: Diagnosis predictive power by rule-based reasoning

Opinion classification	Findings	Number of cases	Number of matching cases (Prediction rate)
quality control check	Delta check	16	16(100%)
	Panic value	3	3(100%)
Single item	Suspected specific disease	28	25(89.2)
	Glucose	10	10(100)
	Virus	6	6(100)
	Morphology	2	2(100)
	Bacteria	2	2(100)

Analysis of correlation of test results	LFT& Virus	18	16(88.9)
	CBC & Coagulation	11	10(90.9)
	Diff & ESR	14	13(92.9)
	T3,T4,TSH & Immunoglobulin	4	4(100)
	Diff & Reticulocyte	9	8(88.9)
	Widal Test & Blood Culture	2	2(100)
	U/A & ABG	3	3(100)
Additional prescription management	Virus related	5	4(80.0)
	Liver, kidney, heart related	10	7(70.0)
	Immunology related	1	1(100)
	CBC & Coagulation related	4	3(75.0)
Validation of test results	Chemistry	8	8(100)
	Hematology	2	2(100)
	Selology & Immunology	1	1(100)
	U/A & Blood Bank	2	2(100)
	Microbiology	1	1(100)
sum		162	149(92.0)

4. Conclusion

This study was aimed at developing a rule-based automation module by comprehensively using clinical pathology test results, physical body measurements, and medical questionnaire information collected on health screening examinees and validating the module by determining its predictability and applicability in the clinical setting. A database was built based on the treatment-related knowledge and experiences of laboratory medicine specialists and clinicians and a literature review, and rule-based inference methods were applied. For knowledge modeling, it was linked with the DBMS of hospital information system, and object-oriented knowledge representation was made possible.

The application of the rule-based automation module helped improve the collection of test results for each field and the inspection of abnormal results, which are traditionally carried out manually to a certain extent. It was also found that it was possible to identify abnormal test results that are difficult for a doctor to detect and to shorten the time it takes to prepare a written opinion on the findings. Moreover, the necessary information related to the diagnostic test results of patients was collected according to the needs based on the findings before the system application, but the step was integrated afterwards. Thus, it was found that it was possible to simplify the related processes by using the rule-based automation module.

An evaluation of the rule-based model showed a 92.0% match rate with the findings presented by laboratory medicine specialists and the findings presented by the model matching in 149 out of 162 cases. The rule-based automation module ensures comprehensive and efficient management of test results and patient information, making it easy to access a wide range of patient information, and it handles all processes from ordering tests to reporting findings in a fast and accurate way. By using the information accumulated from such processes in patient treatment and research, it will help improve medical services. The results of this study showed that the rule-based automation module developed can improve the quality of medical services by utilizing the accumulated knowledge from ordering tests to drafting a written opinion on the findings through comprehensive and efficient management of test results and patient information.

As for the limitations of this study, the number of rules used was relatively inadequate compared to the number of rules used in the rule-based expert system in a medical setting, so the tests performed in

laboratory medicine were not sufficiently utilized. The prediction accuracy was less than 95%, which was lower than that of other studies. In the future, there is a need to perform accurate clinical validation by collecting and supplementing more knowledge to build a systematic database with improved predictive power to perform inferences at the level of experts.

5. Acknowledgment

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