IJBCS
ISSN: 2147-1428

Original Article

International Journal of Basic and Clinical Studies (IJBCS)
2019; 8(1): 37-45 Akalin B and Veranyurt U.

Analysis on the Errors in the Pre-analytical Process in a Clinical Microbiology Laboratory

Betul Akalin[1], Ulku Veranyurt[2]

[1]Assistant Professor, Department of Health Management, Faculty of Health Sciences, Health Sciences University, Istanbul, Turkey
[2]PhD Student, Department of Health Management, Institute of Health Sciences, Health Sciences University, Istanbul, Turkey

Abstract

Aim: To investigate the type, frequency and the role of education in preventing errors in the preanalytical process in the clinical microbiology laboratory.

Material and Methods: This study was performed by Dr. Siyami Ersek Chest and Heart Surgery Training and Research Hospital. Errors of samples from the period between 01-07.2018 and 31.12.2018 were recorded for 6 months in the clinical microbiology laboratory during the working hours of weekday. Mistakes; the test group, the type of the sample, the unit that sent the instance and the type of error. The error rates at different stages of the preanalytical process were calculated. In September, the units were given training on the preanalytical process. Correction rates were calculated. The effect of education on the type, frequency and effects of preanalytical error sources were investigated.

Results: 481 (1.2%) of 38095 samples were found to be faulty in the laboratory between 01-07.2018 and 31.12.2018. No sampling acceptance (64.66 %), false barcode adhesion (20.79%) and non-barcode sample (6.65%) are the most common causes of error. Errors have been determined to come from Surgical Intensive Care Unit - Pediatrics-1 (12.06 %), Polyclinic (12.06%) and Surgical Intensive Care Unit-B Block (9.15%). In the sample type, the highest error was Blood Culture (25.57 %), nasal culture (16.22 %) and wound culture (12.06%). Improvement studies and trainings were planned for the solution of errors by discussing the responsible persons of the related units. The number of mistakes in the weeks of new hospitalization of nurses and nurses was increased.

Conclusion: There have been increased error rates in the weeks when newly recruited resident doctors and nurses worked. In addition, there are problems with sample acceptance devices. After the data obtained, it has been proposed to give orientation training pre-analytical process such as sample request, sampling and sample transfer for newly recruited doctors and nurses.

Key Words: Microbiology laboratory, pre-analytical process, error sources

Address all correspondence to: Betul Akalin, Assistant Professor, Department of Health Management, Faculty of Health Sciences, Health Sciences University, Turkey.
Tel: +90 532 5959782, E-mail: betul.akalin@sbu.edu.tr

IJBCS
ISSN: 2147-1428

Original Article

International Journal of Basic and Clinical Studies (IJBCS)
2019; 8(1): 37-45 Akalin B and Veranyurt U.

Introduction

Today's clinical laboratory tests are very important in diagnosis and treatment in many areas of medicine. After the examination, the test results of the patients are expected to be reliable. However, some laboratory results may produce undesirable results. There are several overlooked or uncontrolled factors in the occurrence of these undesirable test results (1). Laboratory processes; it is called preanalytic, analytical and post analytic phases. The reliability of non-laboratory test results is related to the quality of these three main stages. In this process called preanalytic phase; the selection of the test, making the test request by the doctor / medical secretary, taking and collecting the sample, identifying the patient, transporting the sample to the laboratory and preparing the sample.

Preanalytical errors affect laboratory test results. The effects of preanalytical errors on laboratory test results should be known and should be considered in the evaluation of laboratory data in the light of this information. Most pre-analytical errors are related to sampling (2). Preanalytical processes are relatively more difficult to standardize than other processes because they require the involvement of units outside the laboratory. A large number of errors have been shown in various studies that occur in the pre-analytic phase (3). Errors in the clinical laboratory may occur in any of the preanalytic, analytical and post analytic processes.

Although advances in clinical laboratory aim to reduce analytical errors, 62% of all laboratory errors are found to be caused by pre-analytic process (4). Although there are many studies on the management of error sources occurring in the preanalytic phase, laboratory practices could not be standardized. Monitoring and control of this process by laboratory experts and employees is quite difficult because it takes place outside the laboratory. The responsibility for this process is not fully known and the responsibility lies between the laboratory and clinical departments. For this process, interdisciplinary cooperation and in-laboratory planning is required (5).

In this study; In the Clinical Microbiology Laboratory of a Training and Research Hospital, the type, frequency of error sources in the preanalytical process and the role of education in preventing errors were evaluated. Sample rejection rates were analyzed as preanalytical quality indicators.

Materials and methods

The examinations indicated in Table 3 that the physicians want from the patients are studied in the Microbiology laboratory. Preanalytical process starts with the arrival of the samples to the laboratory. The examination of the patient includes the process of taking the sample from the patient, transporting the patient sample to the laboratory and including the sample acceptance in the laboratory. The workflow process of the laboratory is given in Figure 1. Haydarpasa Numune Training and Research Hospital approval from the Clinical Research Ethics Committee.

IJBCS
ISSN: 2147-1428

Original Article

International Journal of Basic and Clinical Studies (IJBCS)
2019; 8(1): 37-45 Akalin B and Veranyurt U.

In our study, body fluids, blood, nose, wound, vaginal-cervix, urine, stool, tracheal aspirate, mediastinum, catheter, tissue biopsy, sputum, aspirate, culture; Screening tests such as VRE and KDE; 21 test groups (Table 3) including stool occult blood, direct parasite examination, peripheral smear, toxin, hemogram, serological tests were included.
This work; Errors of the samples that were sent to the microbiology laboratory between 01-07.2018-31.12.2018 during daytime working hours were recorded (Table 2). Mistakes; test group, sample type, sample sending unit (Table 1), error type (Table 2). Error rates at different stages of preanalytic process were determined. In September, training on preanalytic process was given. Correction rates were calculated. The effect of education on the type, frequency and errors of preanalytical error sources was investigated.

Errors in the preanalytic process; Faulty test request, faulty record, faulty sample container, improperly sampled sample, misidentified sample, no sampling acceptance, inappropriate barcode, faulty barcode, missing barcode, faulty barcode bonding, barcode-free sample, faulty sample were classified as (Table 2). The sequencing of the causes of error was done with the proportions obtained from the total number of recorded samples. Preanalytical error distribution rates, causes of errors in test groups and sample distribution of errors by months were calculated with percentages.

In the laboratory, training for hospital staff was planned to reduce the mistakes made during the preanalytical process. In September, quality trainings were given to nurses, doctors and staff in the hospital by microbiologist, biologist and education nurse. Preanalytic processes trainings; materials used in sampling (tube, container, swap), sampling techniques, patient safety and the safe transport of samples to the laboratory. In order to evaluate the effectiveness of the training, error rates calculated before and after training were evaluated. The results obtained in September were compared with the other months.

The samples that were accepted to the Microbiology Laboratory were recorded incorrectly and the Table with the causes of sample errors was created (Table 2). In this way, misunderstandings disappeared. When a faulty sample came to the sample reception unit, we checked the Table to make sure that the reason for the error was recorded and collected the correct data.

Results

Of the total 38095 samples that came to the laboratory between 01-07.2018-31.12.2018, 481 (1.2%) were found to be in error. The most common units where errors occurred were 208 (43.24%) 1-16 Floors, 58 (12.06) Surgical Intensive Care Unit- Pediatrics-1 and Polyclinic, 44 (9.15%) Surgical Intensive Care Unit-Block B (Table 1).

IJBCS
ISSN: 2147-1428

Original Article

International Journal of Basic and Clinical Studies (IJBCS)
2019; 8(1): 37-45 Akalin B and Veranyurt U.

Table 1: Unit of Error and Error Rate

Unit of Error and Error Rate	Number of Errors	% Error
Floors (1-16)	208	43.24
Emergency Outpatient Clinic	15	3.12
Operating room	5	1.04
Surgical Intensive Care Unit - Block A	8	1.66
Surgical Intensive Care Unit - Block B	44	9.15
Surgical Intensive Care Unit- Pediatrics-1	58	12.06
Surgical Intensive Care Unit- Pediatrics-2	41	8.52
Erenköy Outpatient Clinic	19	3.95
Coronary Intensive Care Unit-A	17	3.53
Coronary Intensive Care Unit-B	6	1.25
KVC-Intensive Care-B Block	2	0.42
Polyclinic	58	12.06
Grand total	481	

When the error types from the units are examined; It was seen that the most errors were sent directly from the sampling unit to the laboratory without being read with Zebex device. 311 (64.66%) samples were not accepted in the first row and 100 (20.79%) samples were found to be inaccurate. It was observed that 32 (6.65%) samples had barcode-free sample error and 20 (4.16%) samples had faulty sample container error (Table 2).

Table 2: Error Types and % Distributions

Error Type	Number of Errors	% Error
Sample without barcode	32	6.65
Empty Swap, no sample	1	0.21
Missing barcode	3	0.62
Incorrect barcode	2	0.42
Incorrect barcode sticking	100	20.79
Incorrect sample	1	0.21
Faulty sample container	20	4.16
Error test request	8	1.66
No sampling acceptance	311	64.66
Inappropriate barcode	3	0.62
Grand total	481	

IJBCS
ISSN: 2147-1428

Original Article

When the test types were examined in our study; In all of the tests in the laboratory, at least 1 and 123 samples were found to be inaccurate in a total of 481 samples. 123 (25.57%) samples were found to have the most incorrect blood culture test sent to the laboratory. 78 (16.22%) of them had nasal culture, 58 (12.06%) of them had wound culture and 47 (9.77%) of them had urine culture (Table 3).

Table 3: Test Type and Error Rates

Test Name	Number of Errors	% Error
Aspirate Culture	4	0.83
Sputum Culture	10	2.08
Throat Culture	10	2.08
Nose Culture	78	16.22
Direct interference examination (manual)	7	1.46
Tissue biopsy culture	8	1.66
Stool Culture	7	1.46
Fecal Occult Blood test	5	1.04
Urine Culture	47	9.77
Blood Culture	123	25.57
Catheter Culture	3	0.62
Carbapenem resistant enterococci	30	6.24
Culture of Mediastinum	1	0.21
Peripheral Spreading	3	0.62
Peritoneal Fluid Culture	2	0.42
Pleural Fluid Culture	6	1.25
Toxin (A-B)	1	0.21
Tracheal Aspirate Culture	15	3.12
Vaginal-Cervical Culture	13	2.70
Vancomycin resistant enterococci	47	9.77
Wound Culture	58	12.06
Grand total	481	

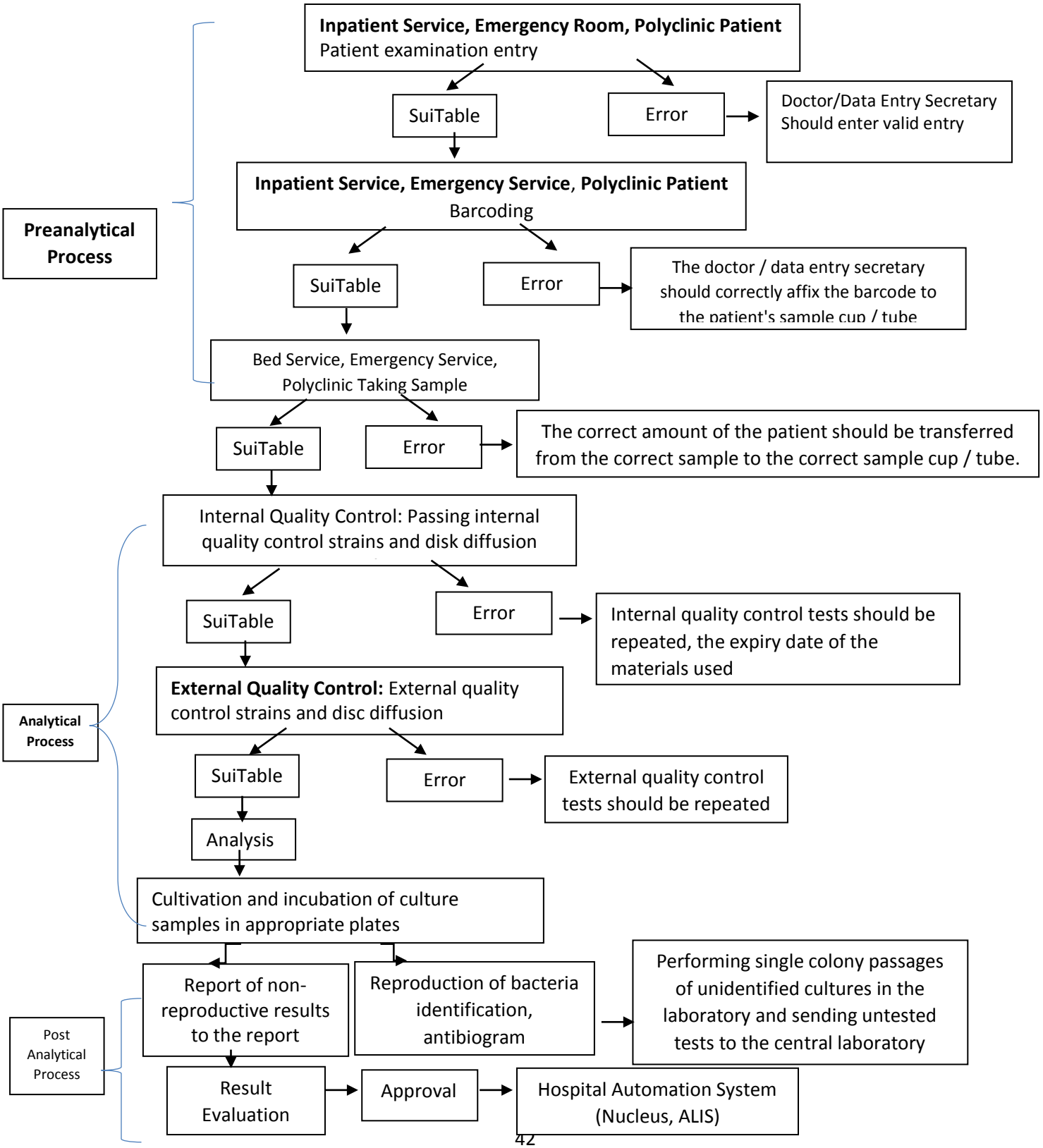
When the months are examined independently among themselves; It was observed that the sample acceptance was made in October (7398) at the most, and the sample acceptance was made in August (5144). The highest errors were observed in December (1.95%) and the least errors were in October (0.65%, Figure 2). In our study, in-service training was given to hospital staff about the preanalytic process in September. In this way, we were able to analyze error rates before, during and after the training. When the results were evaluated, the error rate increased from 1.44% to 1.77% in the months preceding the training (Figure 2). During the training period, this rate decreased slightly to 1.15%. There was a significant decrease (0.65%) in the first month after training (Figure 2). However, the error rates started to increase in the following months and the highest error rate (1.95%) was reached between December (Figure 2). When the reasons for backward range error are examined; during that month, it was seen that the sample did not accept excess errors. When the service personnel sending the faulty samples were interviewed, it was found that there was a malfunction in the Zebex device throughout the hospital.

IJBCS
ISSN: 2147-1428

Original Article

International Journal of Basic and Clinical Studies (IJBCS)
2019; 8(1): 37-45 Akalin B and Veranyurt U.

Figure 1. Clinical Microbiology Laboratory Work Flow Chart



IJBCS
ISSN: 2147-1428

Original Article

International Journal of Basic and Clinical Studies (IJBCS)
2019; 8(1): 37-45 Akalin B and Veranyurt U.

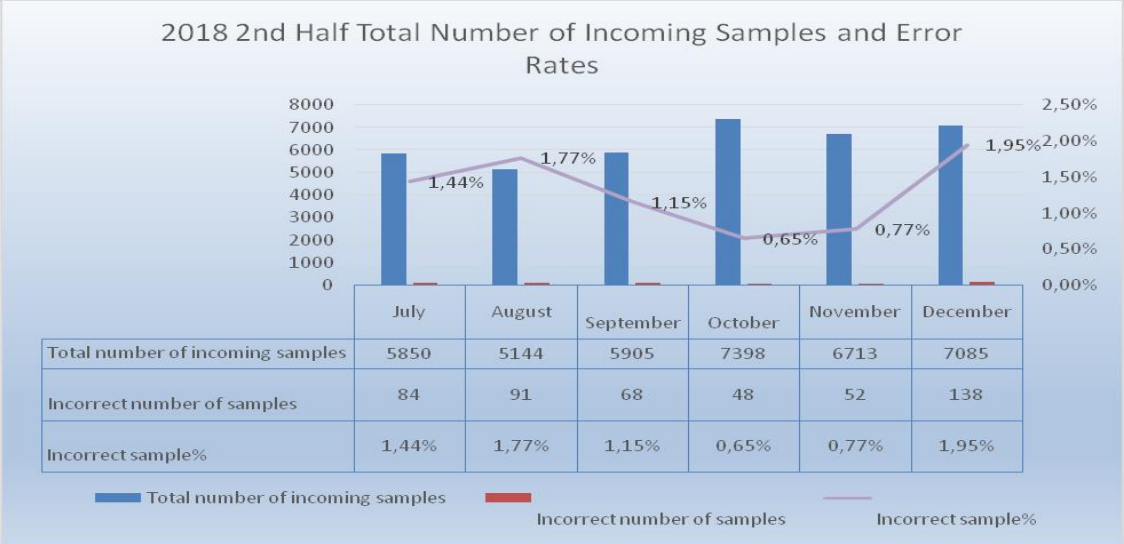


Figure 2. 2018 2nd Half Total Number of Incoming Samples and Error Rates

Discussion

Today's clinical laboratory tests are very important in diagnosis and treatment in many areas of medicine. After the examination, the test results of the patients are expected to be reliable (6). However, some laboratory results may produce undesirable results. There are several overlooked or uncontrolled factors in the occurrence of this undesirable test results. Inadequate and poor quality of the samples to be analyzed causes errors in medical decisions (7).

Laboratory services; It is based on the testing of biological samples taken from patients to help physicians in various units make decisions about diagnosis and treatment of diseases. The purpose of clinical laboratories; to analyze the tests requested from the patient and to deliver the results to the relevant physician in a timely and reliable manner (8).

Clinical laboratory process; before evaluating the types of errors and their effects, it is necessary to analyze the workflow in the laboratory process correctly, which phases it covers and the types of errors that may occur in each of these phases (9, 10). Divided into basic sections. Different methods are used in each stage. It is known that most of the errors that occur in the clinical laboratories in the preanalytic phase are made (11). Among the rejection criteria, inadequate sample barcode sticking error is noteworthy. In another study, the sample rejection rate was found to be 3.1% with a faulty barcode (12, 13). In our study, this rate was 0.42%.

In our study, in-service training was given to hospital staff about the preanalytic process in September. In this way, we were able to analyze error rates before, during and after the training. When the results were evaluated, the error rate increased from 1.44% to 1.77% in the months preceding the training. During the training period, this rate decreased to 115%. There was a significant decrease in the first month after the training (0.65%). However,

the error rates started to increase in the following months and the highest error rate (1.95%) was reached between December. When the reasons for backward range error are examined; During that month, it was observed that the maximum error was not accepted. When the service personnel sending the faulty samples were interviewed, it was found that there was a malfunction in the Zebex device throughout the hospital (Figure 2).

Of the total 38095 samples that came to the laboratory between 01-07.2018-31.12.2018, 481 (1.2%) were found to have errors. No sampling acceptance (64.66%), incorrect barcode sticking (20.79%), and sample without barcode (6.65%) are the most common causes of error. It was found that the errors were mostly from the units of Surgical Intensive Care Unit-Pediatrics-1 (12.06%), Polyclinic (12.06%) and Surgical Intensive Care Unit-Block B (9.15%). In the sample type, the most common errors were Blood Culture (25.57%), nasal culture (16.22%) and wound culture (12.06%). Improvements and trainings were planned for the solution of the errors by meeting with the responsible units of the related units. There was an increase in the number of errors in the weeks when there were assistant doctors and nurses.

Although there are many publications on the management of errors occurring in the preanalytic phase, it cannot be standardized in practice. It is a very difficult process to monitor and control by laboratory experts and employees since a significant portion of it is outside the laboratory. The responsibility of this process is not known and the responsibility is shared between laboratory and clinical departments. For this process, interdisciplinary cooperation and in-laboratory planning is required (5).

There was an increase in the error rates in the weeks of the new assistant doctors and nurses working in the hospital. In addition, it has been revealed that there are problems with the devices that are accepted for sample. After the data obtained, it was decided by the Infection Control Committee to include the orientation training for pre-analytical process including sample request, sampling, and sample transfer for new doctors and nurses.

As a result, in our study; The most repeated sample rejection in the laboratory is due to incorrect barcode sticking. Faulty Barcode was found to be the most common service samples. In-service training provided to hospital staff reduces sample rejection rates. In-service training; it should be continuous, standardized, applied and in small groups between certain periods. To reduce sample rejection rates, more corrective and preventive studies should be planned and implemented.

References

1. Hawkins, RM.D. (2012). Managing the pre –and post-analitical phase of total testing process, clinical chemistry. Ann Lab Med, 32:5-16.
2. Burtis C. & Ashwood E. (2005). Klinik kimyada temel ilkeler. Aslan D (çeviren) 3. Baskı. İstanbul. Palme, 30-54.

3. Lippi G. & Cesare G. (2007). Risk man agement in the pre-analytical phase of laboratory testing. Clinical Chemical Laboratory Medicine, 45(6):720–727.
4. Bonini P, Plebani M, Ceriotti F & Rubboli F. (2002). Errors in laboratory medicine. Clin Chem, 48: 691-8.
5. Lippi G, Salvagno G, Brocco G & Guid G. (2005). Pre-analytical variability in laboratory testing: influence of the blood drawing technique. Clin Chem Lab Med, 43(3): 319-25.
6. Lillo R, Salinas M, Lopez-Garrigos M, Naranjo-Santana Y, Gutierrez M, Marin MD, et al. (2012). Reducing preanalytical laboratory sample errors through educational and technological interventions. Clin Lab. 58.911-7.
7. Hallworth MJ. (2011). the '70% claim': what is the evidence base? Ann Clin Biochem, 48: 487-8.
8. Akın, K. Okhan (2009). "Laboratuvar Güvenliğinde Hasta Tanımlama Hatalarını Azaltmak ve Süreç Kontrolü", Kalite, Akreditasyon ve Hasta Güvenliği Dergisi, Sayı 3, Ankara.
9. Shahangian S & Snyder S. (2009). Laboratory Medicine Quality Indicators. Clin Chem, 131(3):418-31
10. Chawla R, Goswami B, Singh B, Chawla A, Gupta VK & Mallika V. (2010). Evaluating laboratory performance with quality indicators. Lab Medicine, 41(5):297-300.
11. Romero A., Cobos A., López-León A., Ortega G. & Muñoz M. (2009). Preanalytical mistakes in samples from primary care patients. *Clin Chem Lab Med*, 47(12):1549-52.
12. Ozcan O. & Gureser A. S. (2012). Analiz oncesi (pre-analitik) hata kaynakları ve egitimin hata onlemedeki rolu. Dicle Medical Journal, 39(4):524-530.
13. Plebani M, Sciacovelli L, Aita A, Pelloso M & Chiozza ML. (2015).Performance criteria and quality indicators for the pre-analytical phase. Clin Chem Lab Med. 53.943-8. https://doi. Org/10, 1515/cclm-2014-1124