

## Razvoj programa za bilježenje prijeanalitičkih pogrešaka

### Development of a preanalytical errors recording software

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#### Sažetak

**Uvod:** Iako je doprinos laboratorijskoj dijagnostici od integralne važnosti u procesu donošenja kliničkih odluka, kvaliteta rada i sigurnost tijekom dijagnostičkih analiza od ključnog su značaja za unaprjeđenje zdravstvene zaštite koja je na visokom stupnju što se kvalitete i sigurnosti tiče. Unatoč izvanrednom napretku u kvaliteti cjelokupnog procesa laboratorijske analize, prijeanalitička varijabilnost predstavlja vodeći izvor pogrešaka i nesigurnosti. Uvođenje sistematične politike bilježenja prijeanalitičkih pogrešaka uvelike bi poboljšala definiranje ključnih aktivnosti tog procesa, planiranje i praćenje učinkovitih radnji s ciljem poboljšanja cjelokupnog procesa. U ovom članku želimo dati opis kompjuterskog programa razvijenog za bilježenje prijeanalitičkih pogrešaka u našem laboratoriju.

**Materijali i metode:** Naš smo program razvili na temelju Microsoftovog programa Access. Glavna polja uključena u program obuhvaćala su brojač za progresivno brojanje uzoraka, datum primitka uzorka, identifikacijski broj uzorka, ime bolesnika, tip pretrage, odjel s kojeg je bolesnik upućen, matriks uzorka, tip nesukladnosti, radnja koja je poduzeta kako bi se riješio problem, drugo polje za moguće radnje koje su dodatno poduzete, identifikacijski broj operatera. Baza podataka nalazi se na središnjem računalu unutar našeg laboratorijskog informatičkog sistema, tako da se do nje može doći s bilo kojeg računala u laboratoriju, što omogućuje kontinuirani i standardizirani unos podataka.

**Rezultati i rasprava:** Uvođenje kompjuterskog programa za sistematično bilježenje prijeanalitičkih pogrešaka donosi velika poboljšanja, kao što su harmonizacija protokola za bilježenje incidenata, jednostavnost digitalnog bilježenja, eliminaciju rukom pisanih izvješća, uključivanje mjera učinkovitosti ključnih segmenata laboratorijskog rada, jednostavna prilagodba korisniku (laboratoriju), korištenje tablica s podacima za opsežne statističke analize, poboljšano pretraživanje i obrada podataka kao i poboljšana izrada statističkih izvješća.

**Ključne riječi:** pogreške; ispitivanje laboratorija; kompjuterski program; informatika; izvananalitička faza

#### Abstract

**Background:** Although the contribution of laboratory diagnostics is integral to the clinical decision making, quality and safety in diagnostic testing are essential to furthering the goal of high-quality and safe healthcare. Despite remarkable advances in the quality of the total testing process, the preanalytical variability is the leading source of errors and uncertainty. As such, the implementation of a systematic policy for recording preanalytical errors would grant major benefits for identifying critical activities of this process, planning and monitoring effective actions for improvement. The aim of this article is to describe the software developed for the recording of preanalytical errors in our laboratory.

**Materials and methods:** We have developed error recording software based on Microsoft Access. The main fields included in the software comprehend a numerator for progressive enumeration of the samples, the date of receipt of the specimen, the Sample ID, the patient's name, the type of request, the referring ward, sample matrix, the type of non-conformity, the action undertaken to solve the problem, a second field for possible additional actions undertaken, and the operator ID. The database is stored on a common repository in our laboratory information system, so that it can be accessed by any computer in the laboratory, allowing continuous and standardized input of the data.

**Results and discussion:** The implementation of a software for systematic recording of preanalytical errors grants major benefits, including harmonization of incident reporting practices, simplicity of digital recording, elimination of handwritten reports, inclusion of validated measures of laboratory performance, handily customization, exportation on worksheets for comprehensive statistical analyses, improved data searching and processing, as well as production of improved statistical reports.

**Keywords:** errors; laboratory testing; computer program; informatics; extra-analytical phase

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## Uvod

Oduvijek je doprinos laboratorijske dijagnostike bio od integralne važnosti u donošenju kliničkih odluka, pružajući značajan doprinos probiru, dijagnozi, praćenju i kontroli bolesnika. U tom su procesu kvaliteta i sigurnost laboratorijskih analiza od ključne važnosti u unapređenju zdravstvene zaštite, koja je na visokom stupnju što se tiče kvalitete i sigurnosti (1). Iako se u zadnjih nekoliko desetljeća postotak pogrešaka u kliničkim laboratorijima značajno smanjio, trenutno dostupni dokazi pokazuju da se pogreške češće događaju u prije- i poslijeanalitičkoj fazi cjelokupnog procesa laboratorijske analize nego u samoj analitičkoj fazi (2). Prijeanalitička varijabilnost je glavni izvor pogrešaka, budući da se 70% pogrešaka koje se događaju tijekom cjelokupnog dijagnostičkog procesa događaju upravo u toj fazi te može imati neželjen utjecaj na nalaze, zdravlje bolesnika i organizaciju rada u laboratoriju (3-5). Ako pogledamo s praktične strane, možemo reći da se smanjenje pogrešaka može postići primjenom sustava za upravljanje kvalitetom, koji obuhvaća integrirani pristup i višestranu strategiju za analizu procesa i rizika, koja se temelji na pouzdanim indikatorima kvalitete za analitičku i izvananalitičku fazu (6). Sve to čini prikladan, djelotvoran i višestran pristup za sprečavanje, otkrivanje, bilježenje, analizu i upravljanje pogreškama (7,8). Informatička znanost pruža veliku pomoć laboratorijskim stručnjacima u otkrivanju, kontroliranju i smanjenju postotaka pogrešaka u cjelokupnom procesu laboratorijske analize, uključujući prije- i poslijeanalitičku fazu (9). Uvođenje kompjuterskog programa za sistematično bilježenje pogrešaka, posebno u laboratorije koji nemaju laboratorijski informatički sustav (engl. *laboratory information system*, LIS) donijelo bi velike prednosti u usporedbi s klasičnim vođenjem pisanih tabličnih evidencija, uključujući mogućnost izrade odgovarajućih statističkih analiza i izvješća o prijeanalitičkim pogreškama. Cilj je ovog članka opisati kompjuterski program razvijen za bilježenje prijeanalitičkih pogrešaka u našem laboratoriju.

## Materijali i metode

Prema prihvaćenim preporukama Radne skupine za Izvananalitičku varijabilnost pri otkrivanju nesukladnih uzoraka i njihovim upravljanjem u kliničkim laboratorijima koja je proizašla iz suradnje tri talijanskih društava: Društva za kliničku biokemiju (engl. *Society of Clinical Biochemistry and Clinical Molecular Biology*, SIBioC), Talijanskog društva za laboratorijsku medicinu (engl. *Italian Society of Laboratory Medicine*, SIMeL) i Talijanskog povjerenstva za standardizaciju hematoloških i laboratorijskih metoda (engl. *Italian Committee for Standardization of Hematological and Laboratory Methods*, CISMEL) (10), razvili smo kompjuterski program za bilježenje pogrešaka koji se temelji na

## Introduction

Ever since, the contribution of laboratory diagnostics is integral to the clinical decision making, providing a substantial contribution to screen, diagnose, monitor and follow-up of the patients. In this scenario, quality and safety in laboratory testing are essential to furthering the goal of high-quality and safe healthcare (1). Although a significant decrease of the error rate in clinical laboratories has occurred over the past decades, currently available evidence demonstrates that the pre- and post-analytical activities of the total testing process are more error-prone than the analytical phase (2). Preanalytical variability, in particular, is a major source of concern because it accounts for up to 70% of the errors occurring within the entire diagnostic process, it can adversely impact on test results, patient's health and laboratory organization (3-5). From a practical point of view, error reduction can be achieved through a total quality management system, encompassing an integrated approach and a multifaceted strategy for process and risk analysis funded on reliable quality indicators for both the analytical and extra-analytical phases of testing (6), and a suitable, effective and multifaceted approach for prevention, identification, recording, analysis and management of errors (7,8). Information technology provides a valuable aid to laboratory professionals for identifying, controlling and decreasing the error rate in the total testing process, including the preanalytical and postanalytical phase (9). As such, implementation of a software for systematical recording of errors, especially for those laboratories that do not have a laboratory information system (LIS), would carry great advantages over classical paper datasheets, including the possibility to produce proper statistics and reports on preanalytical errors. The aim of this article is to describe the software developed for the recording of preanalytical errors in our laboratory.

## Materials and methods

Following the consensus recommendations of the Italian Inter-society SIBioC-SIMeL-CISMEL (Society of Clinical Biochemistry and Clinical Molecular Biology - Italian Society of Laboratory Medicine - Italian Committee for Standardization of Hematological and Laboratory Methods) Study Group on Extra-analytical Variability for detection and management of unsuitable samples in clinical laboratories (10), we have developed an error recording software based on Microsoft Access for facilitating and standardizing the practice of recording unsuitable samples in our laboratory. Microsoft Access was chosen for several reasons. First, it is widely available on most personal computers and laptops, then it is relatively easy to use and does not require peculiar informatics skill to be

Microsoftovom programu za baze podataka Access, kako bi omogućili i standardizirali praksu bilježenja nesukladnih uzoraka u našem laboratoriju. Microsoft Access smo odabrali iz nekoliko razloga. Prvi je da je u širokoj primjeni na većini osobnih i prijenosnih računala. Nadalje, relativno je jednostavan za uporabu i ne zahtjeva posebne informatičke vještine programiranja te naposljetku, dozvoljava prenošenje podataka u različite programe za statističku obradu podataka (npr. Excel).

Glavna polja uključena u program obuhvaćaju brojač za progresivno brojanje uzoraka, datum primitka uzorka, identifikacijski broj uzorka, ime bolesnika, tip pretrage (hitna/rutinska pretraga), odjel s kojeg je bolesnik upućen, matriks uzorka (npr. EDTA puna krv, serum, EDTA plazma, citratna plazma, mokraćna, itd.), tip nesukladnosti (npr. uzorak hemoliziran; uzorak zgrušan, itd.), radnja koja je poduzeta kako bi se riješio problem (npr. zatražen dodatni uzorak; poništen rezultat, itd.), drugo polje za moguće radnje koje su dodatno poduzete (npr. zatraženi drugi uzorak/uzorci; poništen rezultat; obaviješten odjel), identifikacijski broj operatera (Tablica 1.). Grafički izgled polja za unos prikazan je na slici 1. Baza podataka smještena je na središnjem računalu u našem laboratorijskom informacijskom sustavu, tako da se do nje može doći s bilo kojeg računala u laboratoriju, što omogućuje kontinuirani i standardizirani unos podataka.

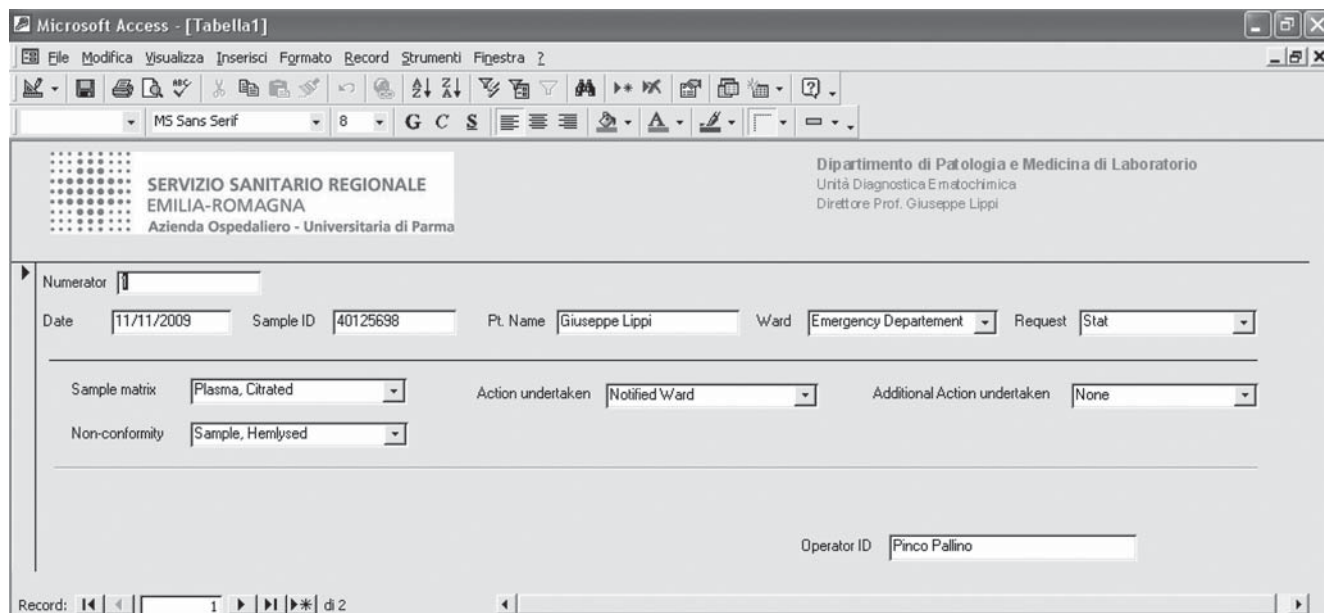
programmed and, finally, it allows exportation or download of data on several statistics platforms (e.g., Excel).

The main fields included in the software comprehend a numerator for progressive enumeration of the samples, the date of receipt of the specimen, the Sample ID, the patient's name, the type of request (stat/routine), the referring ward, sample matrix (e.g., whole blood EDTA; serum; EDTA plasma; citrated plasma, urine, etc.), the type of non-conformity (e.g., sample hemolyzed, sample clotted, etc.), the action undertaken to solve the problem (e.g., request additional specimen, results suppressed, etc), a second field for possible additional actions undertaken (e.g., other sample/s requested; results suppressed; notified ward), and the operator ID (Table 1). The definitive graphical layout is shown in figure 1. The database is stored on a common repository in our laboratory information system, so that it can be accessed by any computer in the laboratory, allowing continuous and standardized input of the data.

**TABLICA 1.** Polja i sastav baze podataka

**TABLE 1.** Fields and composition of the database

Field	Category	Option	Items
Numerator	Numerical	Progressive enumeration	-
Date	Date	Free text	-
Sample ID	Numerical	Free text	-
Patient name	Text	Free text	-
Type of request	Text	Predetermined list	Routine/Stat/Emergency
Sample matrix	Text	Predetermined list	Whole blood EDTA; Serum; EDTA Plasma; Heparin Plasma; Citrated Plasma; Urine; CSF; etc...
Hospital ward	Text	Predetermined list	e.g., Emergency Department; Intensive Care Unit; Surgery 1; Surgery 2, etc.
Type of non conformities	Text	Predetermined list	Sample not received; Sample collected in wrong conditions; Sample lost in the laboratory; Sample improperly labeled; Test request missing or unintelligible; Identification Error; Inappropriate or wrong container; Sample hemolyzed, Sample clotted; Sample insufficient; Sample contaminated; Sample with inadequate blood/anticoagulant ratio; Samples damage in transport; Sample improperly stored.
Action undertaken	Text	Predetermined list	Other sample/s requested; Results suppressed; Notified ward; Notified supervisor.
Additional action undertaken	Text	Predetermined list	Other sample/s requested; Results suppressed; Notified ward; Notified supervisor.
Operator ID	Text	Free text	



**SLIKA 1.** Grafički izgled kompjuterskog programa za bilježenje prijeanalitičkih pogrešaka

**FIGURE 1.** Graphical layout of the preanalytical errors recording software

## Rezultati i rasprava

Općenito se smatra da je potrebno poboljšati i integrirati pitanje sigurnosti kroz sve razine zdravstvene zaštite, što omogućuje proaktivno djelovanje i smanjenje velikog broja medicinskih i dijagnostičkih pogrešaka. Budući da pitanja kvalitete rada i sigurnosti pojavljuju jedno uz drugo u tom kontekstu, pojačava se potreba za smanjenjem laboratorijskih pogrešaka. Sve veća svjesnost da se pogreške češće događaju u izvananalitičkoj nego u analitičkoj fazi laboratorijskog rada, pokrenula je važne inicijative za smanjenje nesigurnosti na tom području (11), kao što je usmjeravanje pažnje na sakupljanje podataka o učestalosti pojedinih postupaka izvananalitičke faze laboratorijskog rada u nekim Europskim zemljama (12,13).

Sistematično otkrivanje i bilježenje prijeanalitičkih pogrešaka od ključne je važnosti, budući da će doprinijeti usmjeravanju određenih odgovornosti, obavještanju o stanju prijeanalitičkih procesa na odjelima ili zavodima na kojima se pogreške češće događaju, rješavanju problema, i time pruža idealnu podlogu za uklanjanje uskih grla i slabih točaka te pomaže u reorganizaciji strukture čitavog sustava dijagnostičkog analiziranja kako bi postao sigurniji i djelotvorniji. Informatika služi kao podrška tom procesu te se smatra djelotvornim sastavnim dijelom u poboljšanju kvalitete i sigurnosti u laboratorijskoj dijagnostici (14). Uvođenje programa za bilježenje prijeanalitičkih pogrešaka u dnevnom radu laboratorija može stoga uvelike koristiti budući da omogućuje harmoniza-

## Results and discussion

It is generally assumed that we need to improve and internalize the culture of safety throughout all levels of healthcare, for being proactive and reducing the large burden of medical and diagnostic errors. As quality and safety movements gallop along, the need to reduce laboratory errors spreads contextually. The growing awareness that extra-analytical activities of the total testing process are more vulnerable to errors than the analytical ones has led to important initiatives for reducing the uncertainty in this area (11), such as the focus currently being placed on collecting information on self reported routines and procedures for the extra-analytical phases of laboratory practice in some European countries (12,13).

As such, the systematic identification and recording of preanalytical errors is essential, since it would help streamline specific responsibilities, produce useful information on the local development of preanalytical processes, on wards or departments more prone to errors, troubleshoot faults, thus providing the ideal root for eliminating bottlenecks and flaws, and redesigning the structure of the entire system of diagnostic testing more safely and efficiently. Process-supporting information technology has been heralded as an effective building block to improve the quality and safety of laboratory diagnostics (14). The implementation of a software for recording preanalytical errors in the daily practice would thereby grant major benefits, in that it would enable to



ciju postupaka kod prijave incidenata te olakšava digitalno bilježenje (15). Dodatne prednosti kompjuteriziranog sustava koji smo razvili obuhvaćaju jednostavnu primjenu (program se temelji na Microsoftovom Accessu kojeg možemo naći na svakom osobnom i prijenosnom računalu pa čak i na *smart phone* uređajima), obustavu pisanih izvješća, moguće prijevode na razne jezike, uključivanje niza mjera učinkovitosti ključnih segmenata laboratorijskog rada, kao što su indikatori kvalitete koje je predložila Radna skupina Laboratorijske pogreške i sigurnost bolesnika (engl. *Laboratory Errors and Patient Safety*, WG-LEPS) koja djeluje u sklopu Međunarodne federacije za kliničku kemiju i laboratorijsku medicinu (engl. *International Federation of Clinical Chemistry and Laboratory Medicine*, IFCC) (16), spretnu prilagodbu laboratoriju i njegovim potrebama, kao i standardizaciju formata između raznih laboratorija, što bi međulaboratorijske usporedbe učinilo realnijima. Baza podataka može se linkom povezati s Excelom, ili se njeni podaci mogu prebaciti u Excel tablicu, što stvara dodatnu prednost nad tradicionalnim tablicama podataka, jer je na ovaj način moguće napraviti opsežnu statističku analizu tipova i učestalosti pogrešaka, uključujući niz podataka (npr. brojanje uzoraka, datum prijema uzorka, identifikacijski broj uzorka, ime bolesnika, tip pretrage (hitna/rutinska), odjel, matriks uzorka), moguće je poboljšano pretraživati i obraditi podatke, napraviti bolja statistička izvješća i promatrati djelotvornost promjena, koje se po potrebi trebaju uvesti u određene faze laboratorijske analize. Svi ti aspekti mogu vjerodostojno podržati napore za poboljšanje kvalitete rada u laboratorijskoj dijagnostici, pogotovo u dijelu izvananalitičkih faza (17).

Sustav u našem laboratoriju funkcionira odnedavno, tako da do sada još nismo mogli sakupiti statistički značajne podatke. Sljedeći korak je usporediti tu analizu s prethodnom praksom, odnosno s izvješćima o pogreškama iz prijašnje evidencije. Međutim, već možemo primijetiti da se praksa sistematičnog izvještavanja u našem laboratoriju značajno poboljšala, uvelike je pojednostavljena i standardizirana unutar raznih odjela i stručnjaka. Iako neki laboratorijski informatički sustavi za upravljanje (engl. *laboratory information management systems*, LIMS) kao što su Swisslab (F. Hoffmann-La Roche, Basel, Švicarska), Starlims (STARLIMS Corporation Hollywood, FL, SAD) imaju već integriranu mogućnost praćenja i bilježenja kvalitete uzorka i prebacivanja tih podataka u standardni program za izradu opsežnih statističkih analiza, program koji smo mi razvili ima prednosti za one laboratorije koji nemaju LIS niti LIMS s mogućnošću bilježenja pogrešaka ili za one koji žele nastaviti koristiti postojeći laboratorijski informacijski sustav te ne žele preći na skuplji LIMS.

harmonize procedures of incident reporting and facilitate digital recording (15). The additional advantages of the computerized system that we have developed encompasses easy of use (the software is based on Microsoft Access, which is integrated in the software of most office computers, laptops and even smart phones), elimination of handwritten reports, possible translation into different languages, inclusion of a variety of validated measures of laboratory performance such as the quality indicators proposed by the Working Group, "Laboratory Errors and Patient Safety (WG-LEPS) of the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) (16), handy customization to suit local needs as well as standardization of formats among different laboratories which would make both comparison and benchmarking more viable. The database can also be linked to or imported in an Excel worksheet, thereby carrying additional advantages over traditional paper datasheets, that are the possibility to perform comprehensive statistical analyses on errors type and frequency including a variety of data (e.g., enumeration of the samples, the date of receipt of the specimen, the Sample ID, the patient's name, the type of request - stat/routine -, the referring ward, the sample matrix), improved data searching and processing, production of better statistical reports, and to monitor the effectiveness of changes eventually introduced throughout the different activities of the total testing process. All these aspects might trustworthily support the ongoing efforts to improve the quality of laboratory diagnostics, especially the quality of the extra-analytical activities (17).

The system has been established in our lab very recently, so no statistically significant information could be collected thus far. As such, the next necessary step is to benchmark this analysis with the previous practice that was reporting errors on traditional datasheets. As yet, however, we can comment that practice of systematical error reporting in our laboratory was substantially increased, greatly eased and standardized among the different sections and professionals. Although some laboratory information management systems (LIMS) e.g. Swisslab (F. Hoffmann-La Roche, Basel, Switzerland), Starlims (STARLIMS Corporation Hollywood, FL, USA) have already the capability to monitor and record sample quality and to export these data to standard software for comprehensive statistical analysis, the software we have developed may be advantageous for those clinical laboratories that do not have a LIS or LIMS with error-recording options, or which want to remain on the old LIS without moving to a more expensive LIMS.

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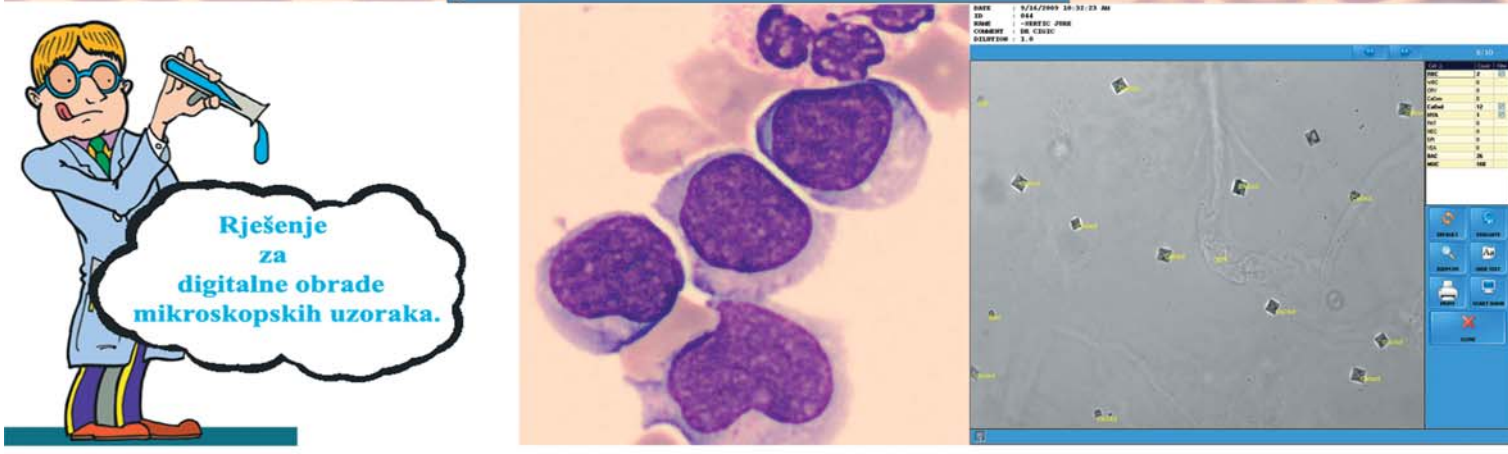
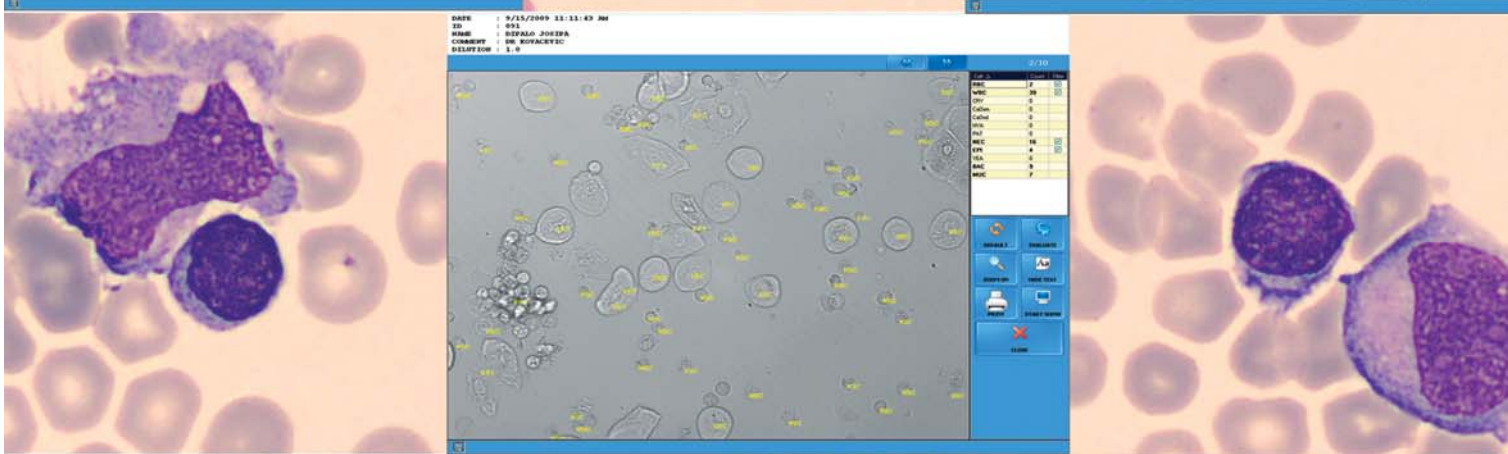
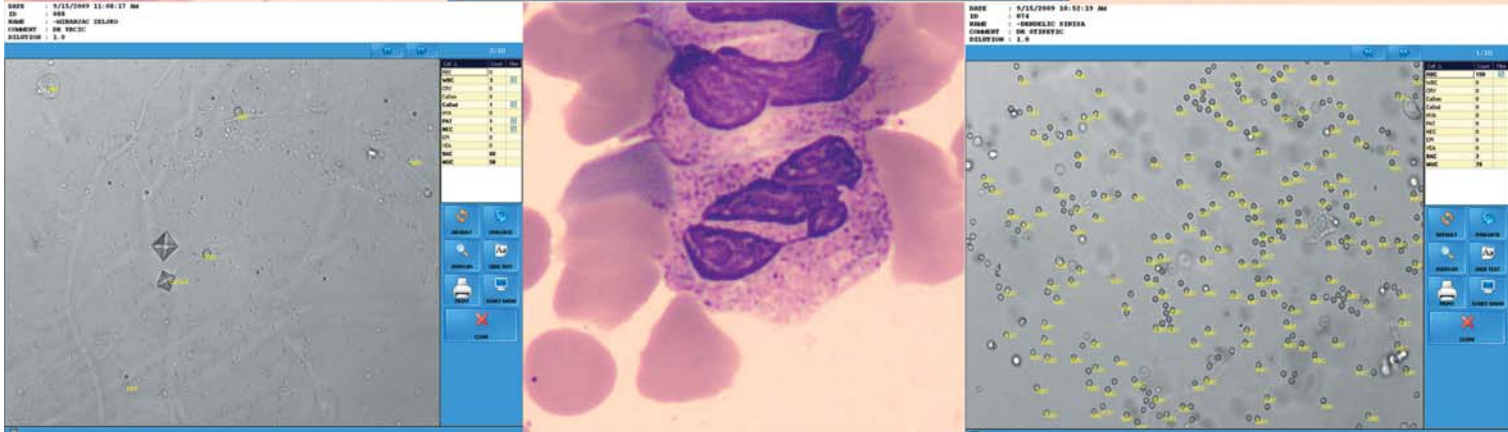
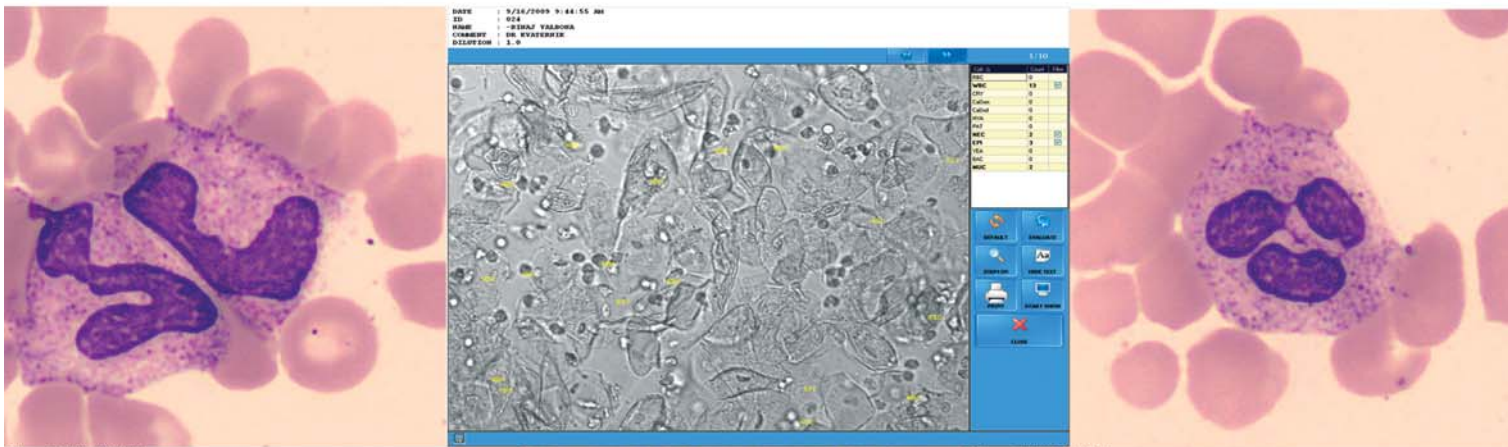




CELLAVISION

**RANDOX** RIQAS

77 Elektronika Kft.



Rješenje za digitalne obrade mikroskopskih uzoraka.