# GREATER EFFICIENCY OBSERVED 12 MONTHS POST-IMPLEMENTATION OF AN AUTOMATIC TUBE SORTING AND REGISTRATION SYSTEM IN A CORE LABORATORY

VEĆA EFIKASNOST UOČENA 12 MESECI POSLE IMPLEMENTACIJE SISTEMA ZA AUTOMATSKO SORTIRANJE I REGISTROVANJE UZORAKA U CENTRALNOJ LABORATORIJI

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## Summary

**Background:** Sample classification and registration have been recognized as important and time-consuming processes in laboratories. There is increasing pressure on laboratories to automate processes due to intense workload and reduce manual procedures and errors. The aim of the present study was to evaluate the positive effects of an automatic tube registration and sorting system on specimen processing.

**Methods:** An automatic tube registration and sorting system (HCTS2000 MK2, m-u-t AG, Wedel, Germany) was evaluated. Turnaround time (TAT), rate of sample rejection and unrealized tests were examined 12 months pre- and post-implementation of the automatic tube sorting and registration system.

**Results:** The mean TAT of routine chemistry immunoassay, complete blood cell count (CBC) and coagulation samples were significantly improved ($P < 0.001$). The number of rejected samples and unrealized tests was insignificantly decreased post-implementation of the system (0.4% to 0.2% and 4.5% to 1.4%, respectively) ($P > 0.05$).

**Conclusions:** By reducing delays and errors in the preanalytical processing and sorting of samples, significant improvements in specimen processing were observed after implementation of the system. These results suggest that an automatic tube registration and sorting system may also be used to improve specimen processing in a higher-volume core laboratory.

**Keywords:** laboratory automation, specimen processing, turnaround time, preanalytical phase

## Kratak sadržaj

**Uvod:** Klasifikacija i registracija uzoraka u laboratorijama prepoznate su kao važni i dugotrajni procesi. Laboratorije su pod sve većim pritiskom da automatizuju postupke zbog velikog obima posla i smanje manuelne procedure i greške. Cilj ove studije bio je da se procene pozitivni efekti jednog sistema za automatsko registrovanje i sortiranje uzoraka na njihovu obradu.

**Metode:** Ocenjivali smo sistem za automatsko registrovanje i sortiranje uzoraka (HCTS2000 MK2, m-u-t AG, Wedel, Nemačka). Ukupno vreme za obradu uzorka (*turnaround time*), stopa odbacivanja uzoraka i nerealizovani testovi obrađeni su 12 meseci pre i posle implementacije sistema za automatsko sortiranje i registrovanje uzoraka.

**Rezultati:** Srednje ukupno vreme obrade uzoraka za rutinske hemijske imunoeseje, kompletnu krvnu sliku i koagulaciju bilo je značajno bolje ($P < 0,001$). Broj odbačenih uzoraka i nerealizovanih testova bio je smanjen, iako ne značajno, posle implementacije sistema (sa 0,4% na 0,2%, odnosno sa 4,5% na 1,4%) ($P > 0,05$).

**Zaključak:** Zahvaljujući režim slučajevima kašnjenja i režim greškama prilikom preanalitičke obrade i sortiranja uzoraka, uočena su značajna poboljšanja u obradi uzoraka posle implementacije ovog sistema. Naši rezultati pokazuju da se sistemi za automatsko registrovanje i sortiranje mogu koristiti radi poboljšane obrade uzoraka i u centralnim laboratorijama sa velikim obimom posla.

**Ključne reči:** laboratorijska automatizacija, obrada uzoraka, vreme obrade uzorka, preanalitička faza

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## Introduction

Laboratory centers are faced with variable and difficult tasks throughout the workday and are depended upon to provide reliable laboratory data. A major proportion of difficult tasks in laboratory medicine includes handling errors in patient identification, phlebotomy, sample handling, sample classification and these are critical for the downstream procedures accomplished in the analytical phase (1–3).

Registration and sorting of specimens are the initial steps and key procedures in laboratory testing. These initial steps can be done either by automatic systems or manually (4, 5). There is increasing pressure on laboratories to automate processes due to intense workload and reduce manual procedures and errors (6, 7). The turnaround time (TAT) is often used by clinicians as an indicator of laboratory performance. Non-analytical delays might be responsible for up to 96% of the total TAT (8, 9).

The laboratory evaluated in the present study is a high-volume core laboratory that accepts approximately 4,250 specimens and performs 20,657 tests per day. Samples in different tubes from six peripheral clinics are submitted to this central laboratory and, therefore, specimen traffic is busy. Prior to the purchase of the automatic tube sorting and registration system, all specimens were checked and manually sorted by three technicians. Following this, sample registration was completed by reading the tubes individually with a barcode reader. The manual system was perceived to negatively affect laboratory processing, from the start of sample registration to the device entry and subsequent test request-outcome duration. In addition, errors were observed from time to time in tube sorting due to manual operations that resulted in a considerable waste of time. Errors experienced in tube sorting with manual processing were sorting mislabelled tubes, unlabelled tubes, specimen lost, wrong destination entered for tubes and mixed tubes. These errors were resulting in a high number of unrealized tests (test not done). As a result of the initial review, laboratory management determined there was a need for an automated and quick tube sorting system to address the problems in preanalytical processes and purchased an automatic tube registration and sorting system. The benefits of total laboratory automation have been reported in various studies (10–13). However, few studies to date have focused on the outcomes of implementation of automatic tube registration and sorting systems. The aim of the present study was to evaluate the effects of an automatic tube registration and sorting system on specimen processing performance in a high-volume core laboratory.

## Materials and Methods

An automatic tube registration and sorting system (HCTS2000 MK2, m-u-t AG, Wedel, Germany)
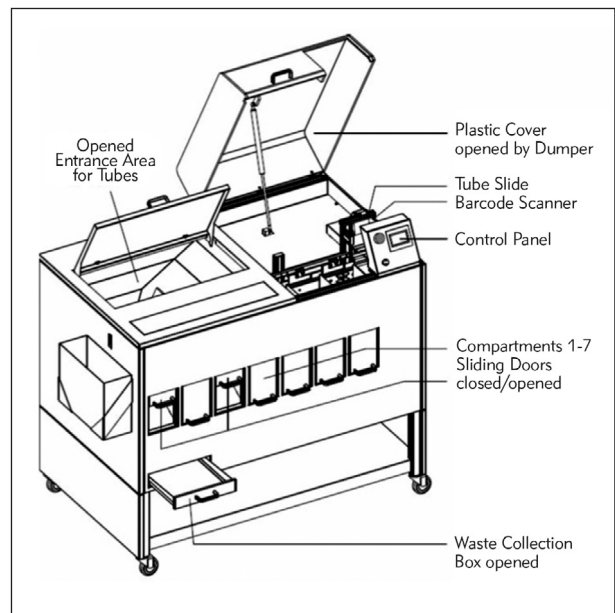


**Figure 1** Overview, illustrating placement of various components of HCTS2000 MK2 system.

(*Figure 1*) was evaluated. All data were collected from the laboratory information system (LIS) and were examined 12 months pre- and post-implementation of the automatic tube sorting and registration system. TAT, rate of rejected samples and unrealized tests (samples that reached the laboratory but requested tests were not completed for variable reasons such as sample sorting errors, wrong specimen types and mislabelled/unlabelled specimens) were compared. Pre- and post-implementation periods were subgrouped into three periods within each year. Because of the high quantity of TAT data, random sampling was performed in each period. TAT in the laboratory was defined as the interval from blood-draw to the verification of results in the LIS. The study was approved by the institutional ethics committee.

### System description of HCTS2000 MK2

The HCTS2000 MK2 was designed for clinical laboratories to complete sample registration and sort closed primary sample tubes in accordance with barcode information and through queries in the LIS. The HCTS2000 MK2 system is a registration and sorting system used before centrifugation and can process various sizes of cylindrical tubes without adjustment and several tube sizes can be mixed together in a single load. Except for sedimentation tubes with citrate, all common tubes, including chemistry, hematology and coagulation tubes (serum, EDTA, heparin, citrate), are easily processed. A limitation of this system is that it cannot process sedimentation tubes with citrate and urine samples. HCTS2000 MK2 sorts up to

2,000 tubes per hour. Each tube is separated from the others, its unique identification barcode is scanned and it is sorted into one of 7 target bins according to the barcode information. Barcodes can have up to 30 characters. Sorting rules can be defined by the scanned barcodes or querying the LIS. Up to 10 different sorting rules can be stored in the HCTS2000 MK2, making it flexible and adaptable for different sorting routines required by laboratories. Moreover, if there is a deformation of the sample barcode and/or if the barcode is pressed into a different code, or if there are cases that the LIS cannot approve, these tubes are then discarded into a box for unidentified samples. The system has not read the barcode of such tubes and sends them to an unidentified sample tubes compartment. There are no racks to be filled. Scanning, identifying and sorting into the target bins are done fully automatically. The system can be used as a stand-alone device or connected to a LIS.

### Statistical analyses

All statistical analyses were performed using the SPSS statistical software version 15.0 (SPSS, Chicago, IL, USA). Pre- and post-implementation phases were subdivided into three periods in each year. Each pre-implementation subgroup was compared with the similar period in the post-implementation subgroup. The TAT of routine chemistry immunoassay, CBC, coagulation and specific immunoassay samples was calculated as mean and standard deviation (SD) for each period. An independent t test was used to test for significance differences between the TATs of each period. The Chi-square test or Fisher's exact test, where appropriate, was used to compare the frequency of sample rejection and unrealized test in the pre- and post-implementation periods. A $P$ value < 0.05 was considered indicative of statistical significance.

### Results

The number of tests performed in the laboratory in the year prior to establishing the automated system was 3,286,346. Pre-implementation, the number of patients was 457,143, the number of sample tubes was 820,081, the number of unrealized tests was 148,886 (4.5%) and the number of rejected samples was 3,351 (0.4%). In the 12 months post-implementation, the number of tests performed in the laboratory was 4,874,670, the number of patients was 459,476, the number of sample tubes was 920,152, the number of unrealized tests was 68,874 (1.4%) and the number of rejected samples was 1,661 (0.2%). Although the frequencies of rejected samples and unrealized tests were found decreased in the post-implementation period, the differences were not statistically significant ($P$>0.05). The mean TAT of routine chemistry immunoassay, CBC and coagulation samples significantly improved ($P$<0.001). However, no significant improvement in specific immunoassay TAT was observed after implementation of the tube registration and sorting system (Table I). Box plots graphs of the TAT for routine chemistry immunoassay, CBC and coagulation samples are shown in Figure 2.

**Table I** Turnaround time of test profile groups (all data were expressed as mean±SD).
($P$ value was estimated by comparing each pre-implementation subgroup with the similar period in post-implementation subgroup).

| Test Profile | Pre-implementation | | | Post-implementation | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| | 1st period TAT (min) | 2nd period TAT (min) | 3rd period TAT (min) | 1st period TAT (min) | 2nd period TAT (min) | 3rd period TAT (min) | P |
| Routine chemistry immunoassay profile | 296±82 (n=5347) | 319±108 (n=5351) | 333±94 (n=4565) | 280±84 (n=4782) | 295±81 (n=4782) | 282±80 (n=4604) | <0.001*,<0.001**, <0.001*** |
| CBC profile | 219±99 (n=2027) | 224±98 (n=2019) | 217±75 (n=1543) | 184±66 (n=1742) | 197±79 (n=1943) | 196±85 (n=2020) | <0.001*,<0.001**, <0.001*** |
| Coagulation profile | 218±80 (n=1596) | 220±78 (n=1598) | 223±70 (n=1746) | 201±78 (n=1745) | 190±71 (n=1600) | 185±60 (n=1746) | <0.001*,<0.001**, <0.001*** |
| Specific immunoassay profile | 288±63 (n=136) | 281±86 (n=140) | 284±79 (n=144) | 264±85 (n=161) | 265±74 (n=163) | 347±127 (n=164) | 0.059*, 0.262**,0.002*** |

*P value, compared with pre- and post-implementation for 1st period
** P value, compared with pre- and post-implementation for 2nd period
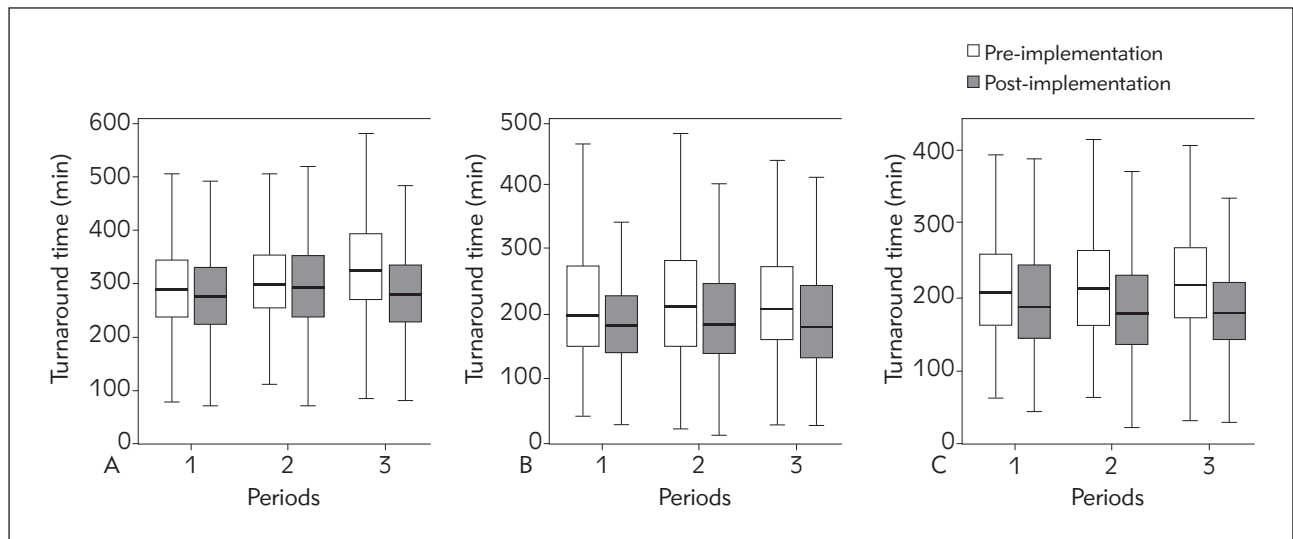*** P value, compared with pre- and post-implementation for 3rd period

**Figure 2** (A) Box plots graphs of the TAT for routine chemistry immunoassay samples; (B) TAT for CBC samples; (C) TAT for coagulation samples.

## Discussion

Implementation of the automated system had a dramatic impact on the quality, TAT and efficiency of the laboratory workload. The results of the present study showed that significant improvements in TAT were observed by reducing delays and errors in the preanalytical processing and sorting of samples after establishment of the system.

Holman et al. (10) showed that an automated preanalytical processing unit (GENESIS FE500) significantly reduced the work associated with specimen processing, decreased the number of laboratory errors due to specimen sorting, labelling and aliquoting and improved the integrity of specimen handling throughout the specimen processing steps. Different from the system mentioned above, the HCTS2000 MK2 system just included automatic registration and sorting. In the present study, similar to the findings of Holman et al, HCTS2000 MK2 system reduced the work associated with specimen processing and improved the integrity of specimen handling. The HCTS2000 MK2 system decreased specimen rejection rates and the number of unrealized laboratory tests. We also report that the number of human resourced errors, such as slow sorting of mislabelled tubes, wrong destination entered for tubes and mixed tubes, was decreased.

Most of the sample rejection criteria include factors (lipemic, hemolytic and clotted sample etc.) revealed after sample registration and sorting procedures. In the present study, the frequencies of rejected samples and unrealized tests were found decreased in the post-implementation period. However, the differences were not statistically significant. Numerical improvements in the sample rejection rate

can be related to timing in regard to rapid intervention due to mislabelled tubes, wrong destination entered tubes and mixed tubes. Mislabelled or wrong destination entered tubes staying at room temperature at wrong destinations for a long period had mostly been rejected due to stability problems before implementation. After implementation; mislabelled or wrong destination entered tubes can easily be recognized among the correctly labelled tubes. Corrections may be applied and these tubes can be transferred to the correct destination as soon as possible.

In another study, Hawker et al. (14, 15) evaluated the implementation of an automated sorting system (MDS AutoLab™ Systems) on performance results over three years in a large reference laboratory. They showed that the median TAT decreased by an estimated 7 hours and the number of lost specimens decreased by 58% after implementation of the system. In the present study, the TAT significantly decreased for routine chemistry immunoassay, CBC and coagulation samples. However, no significant improvement in specific immunoassay TAT was observed after establishment of the tube registration and sorting system. Even an increase in the mean TAT of specific immunoassays during the post-implementation period (especially in the 3rd period) was observed. This might have occurred because the specific immunoassay test workload/menu was expanded after implementation of the system. AntiTG and AntiTPO assays were added to the specific immunoassay group causing nearly a twofold increase in total test numbers for the specific immunoassay system. This significant increase could have prevented improvement in the specific immunoassay TAT.

Many studies that have been conducted aimed to shorten laboratory TAT (8, 16–21). In the present study, an automatic tube registration and sorting sys-

tem improved laboratory efficiency by decreasing turnaround time. Another major advantage of the system used in the present study is that sample registration and sorting systems can be implemented by one staff member with minimal training. Laboratories should decide to purchase such systems according to their workload and considering cost ratios. Laboratory managers need to evaluate real-life installations of the various vendors thoroughly, before they make purchase decisions (4). It is difficult to balance cost with the goals of quality, patient safety and clinical service demands (22).

There are several potential limitations to the present study. The major limitation was that due to LIS constraints, all data could not be obtained and analyzed during the 2-year period. Because of the LIS constraints, a limited amount of data was selected for analysis by random sampling. Small differences in TATs for the routine chemistry immunoassay were also observed during the three sub-periods before or after implementation of the tube registration and sorting system (*Table I*). This might suggest that unknown

factors also affected the efficiency of specimen processing and TAT. These potential small factors could not be evaluated.

In conclusion, by reducing delays and errors in the preanalytical processing and sorting of samples, significant improvements in TAT were made after establishment of the automated system. Implementation of the system also decreased specimen rejection rates and the number of unrealized laboratory tests. Technological advances in laboratory systems have made an important difference in laboratory workload and efficiency, reducing manual processes and errors as well as increasing data reliability. An automatic tube registration and sorting system might also be indicated for improvement of specimen processing in a higher-volume core laboratory.

## Conflict of interest statement

The authors stated that they have no conflicts of interest regarding the publication of this article.

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