Evaluation of an Automated Preanalytical Robotic Workstation at Two Academic Health Centers

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Background: Purchase of automated systems in today's clinical laboratory needs justification based on demonstrable improvements in efficiency and a sound payback model. Few studies provide information on laboratory automation that focuses on the preanalytical portion of specimen processing.

Methods: We recently evaluated an automated preanalytical processing unit (GENESIS FE500) at two academic health centers. This preanalytical unit processes blood specimens through automated specimen sorting, centrifugation, decapping, labeling, aliquoting, and placement of the processed specimen in the analytical rack. We quantified the output of the FE500 by processing >3000 barcode-labeled specimens according to a protocol designed to test all of the features of this automated specimen-processing unit.

Results: Depending on the batch size, aliquot number requested, and percentage of tubes that required centrifugation, the mean system output performance varied between 93 and 502 total tubes/h. Throughput increased when the batch size expanded from 40 or 100 samples (mean = 211 total tubes processed/h) to batch sizes of 200 and 300 tubes (mean = 474 total tube processed/h). The GENESIS FE500 processed specimen tubes differing in size from 13 × 65 mm (width × height) to 16 × 100. At one site, the FE500 was operated by one person, compared with the three individuals required to perform the same tasks manually. Finally, the specimen-processing error rate determined at one of the institutions was significantly reduced.

Conclusions: We conclude that the GENESIS FE500 effectively reduces the labor associated with specimen processing; decreases the number of laboratory errors that occur with specimen sorting, labeling, and aliquoting; and improves the integrity of specimen handling throughout the steps of specimen processing.

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Clinical laboratory automation has traditionally focused on the analytical side of the clinical laboratory operation. Automated clinical analyzers have evolved to become multifunctional, high-throughput devices that require minimal volumes of serum or plasma to rapidly complete a wide variety of analytical procedures. Until recently, several traditional manually intensive areas of the laboratory (preanalytical and postanalytical specimen processing) have not been the focus of automation. The preanalytical specimen processing area of the clinical laboratory operation is typically prone to multiple errors in specimen handling and aliquoting, and overall represents a tedious and manual section of the clinical laboratory operation. In addition, in the past 10 years, a wide variety of specimen containers have become available for the collection and transport of human blood specimens to the laboratory. This has increased the complexity of processing specimens before analysis. Furthermore, specimens requiring separation by centrifugation have historically been a bottleneck in laboratory specimen throughput because of the time required to manually balance the tubes, load them into the centrifuge, and then unload the tubes after completion of the centrifugation step (1, 2).

Automated specimen processors and transportation systems have been successfully implemented in several high-volume clinical laboratories as part of the implementation of total laboratory automation over the past 10 years (3). Laboratory automation can be classified into three major categories: total laboratory automation (TLA),3 modular laboratory automation, and workcell/workstation automation (4, 5). However, most of the laboratory automation systems available have typically

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Received August 17, 2001; accepted December 14, 2001.
been designed for the larger high-volume laboratory with substantial specimen throughput requirements (4–6). More recently, automated processing units have been designed for the preanalytical section of the small- to medium-sized laboratory as well as for laboratories that want multiple and redundant smaller processing units to achieve better flexibility and a higher processing output capacity (7–10).

The implementation of automation in the clinical laboratory has allowed for increases in laboratory productivity without the need to hire additional staff. In addition, automation helps relieve the stress on the remaining technologists brought about by a continued increase in workload. For example, Dadoun’s laboratory used a combination of process engineering followed by the application of preanalytical automation to achieve unprecedented laboratory efficiency (11). Preanalytical specimen-processing units dedicated to selected tasks, such as decapping and sorting, have also been shown to provide substantial improvements in laboratory efficiency (12).

Although existing preanalytical processing units have been cost-effective, they have been somewhat limited by low throughput and a lack of versatility in performing all or most of the tasks necessary for specimen processing. We recently carried out a clinical trial of the GENESIS FE500 preanalytical processing unit, which is designed to execute most of the tasks required between specimen receipt in the laboratory and the placement of the specimen on the analytical system. The GENESIS FE500, manufactured by TECAN AG and marketed by Abbott Diagnostics, has been shown to process sample tubes ranging in size from 13 to 16 mm in width and from 65 to 100 mm in height for most major specimen tube types. The system is also designed to read barcodes, centrifuge the specimens when required, remove the cap from the tube, label and aliquot daughter tubes, and present specimen tubes.

In the context of evaluating the FE500 in the laboratories of two academic health centers, we wanted to test the throughput and versatility of the FE500 to determine whether this specimen-processing unit is suitable for small- and medium-sized laboratories as well as for large laboratories. We therefore quantified the processing output of the FE500 under various conditions to specifically evaluate the handling of specimens under batch-loading conditions and with different aliquot tube requirements. We assessed productivity in terms of real-time specimen processing, evaluating potential labor savings and error rates as applied to aliquoting, daughter tube volume, and labeling errors. We also wanted to determine the optimal centrifuge speed necessary to produce satisfactory platelet-deficient plasma specimens.

Materials and Methods

System Description

The GENESIS FE500 preanalytical sample processor was installed in two laboratories. The first GENESIS FE500 was placed in a 1500-square foot research laboratory at the University of Virginia (UVa) Medical Automation Research Center in Charlottesville, VA, which had been established to develop and evaluate laboratory automation and to perform clinical trials. Installation was completed in 2 workdays with minimal physical plant modification. Facility modification required that 13 holes be drilled into the floor to provide anchored placement of the FE500 processor and its centrifuge. The system required a dedicated electrical circuit of 30 amps and 208 V (AC). Compressed air (water and oil free) is needed from either the laboratory facility (105 psi, 4 feet3/min) or from an independent compressor. Both study sites used the provided compressor. The completed system requires 23 feet2 (2.2 m2) of floor space and has the following dimensions: 90 inches (230 cm) wide × 36 inches (91 cm) deep. The front of the FE500 needs to remain accessible for replenishing the supply of secondary tubes and barcode labels, accessing the centrifuge, and adding and removing specimens. The back and left side of the device should remain clear to allow access by service personnel for maintenance and for removal of spent items (Fig. 1). Therefore, the total recommended floor space is 92 feet2 (8.5 m2).

The second GENESIS FE500 was installed in the specimen-processing area at the Milton S. Hershey Medical Center of The Pennsylvania State University (Hershey, PA), a university hospital laboratory that routinely processes ~2000 specimens/day. The unit was installed over a 2-day period with training of key operators over a subsequent 3-day period. After a 2-week period of trial specimen processing, the FE500 began to process actual patient specimens received into the laboratory during the day shift.

The GENESIS FE500 system contains (a) a tube-loading unit with barcode reader to route the primary specimen tubes into the system; (b) a robotically controlled brushless, refrigerated centrifuge [Rotanta 46 RSC Robotic (Hettich) Centrifuge] with a 72-tube capacity; (c) two pick-and-place robotic arms for transporting the tubes and centrifuge carriers; (d) a two-lane conveyor for intelligent routing of tubes in process; (e) an aerosol-protected decapping unit; (f) a secondary tube labeler with customized barcode capability; (g) an aliquoter with capacitance-driven clot detection and liquid level sensing; and (h) an output area (380 × 810 mm) capable of accommodating any manufacturer’s analyzer specific tube racks.

The FE500 can process a wide variety of tubes. The smallest tube that can be accepted and processed is a 13 × 65 mm tube, whereas the largest is a 16 × 100 mm tube. Any tubes within these size ranges can be accepted interchangeably by the FE500. Supplies from TECAN (www.tecan-us.com) that require replenishment on the system include secondary or daughter tubes (13 × 65 mm tubes), labels, thermo-transfer ribbons, and disposable 1000-µL pipette tips.

Operation of the FE500 is controlled through a personal computer [Pentium III processor (minimum speed >400 MHz), 128 megabyte RAM memory, and a 4 giga-
byte hard drive] with Windows NT. A Sunquest Information System, which followed the ASTM E1394-97 standard communication protocol, was interfaced with the computer through a standard RS-232 interface at both evaluation sites. The laboratory information system (LIS):FE500 interface, developed by UVa personnel in collaboration with TECAN and Sunquest, required several weeks of development and testing before becoming fully operational.

The operating software of the GENESIS FE500 (GENESIS FE) was preinstalled on the computer by the manufacturer. During this evaluation, eight system upgrades were installed (at both UVa and Hershey) by either TECAN service personnel or by our respective lead operators. Most of these upgrades were developed to enhance or correct FE500 software operation, whereas several addressed interface issues. These did not affect sample throughput or data collection. Each system upgrade required ~10–15 min to complete, and there was no additional paperwork involved with these upgrades. The latest version of the GENESIS FE used in this study was Ver. 1.00 SP2 Build 26.

**SYSTEM OPERATION**

Operation of the GENESIS FE500 begins with a system startup. During startup, hardware is initialized, and the system is checked for adequate amounts of consumable supplies. Once the startup process is complete, specimens with LIS-generated barcodes (facing forward) are placed into input racks designed for loading and placed on the tube-loading unit. The FE500 exchanges barcode information with the LIS, and then generates a work list that initiates specimen processing.

**SAMPLE LOADING AND PROCESSING**

The racks are loaded into a tray and put on the GENESIS FE500 tube-loading unit. Each rack holds 5 specimen (primary) tubes, and each tray holds up to 16 racks for a maximum of 80 specimens per tray. The barcode of each specimen is scanned to determine processing instructions, which are obtained from a database on the control computer built and tested before system operation. The double-track conveyor of the FE500 transports the specimens from the centrifuge station to the decapping unit and then on to the labeling and aliquot processing station (Fig. 1B). The inner track is used for specimen transport, whereas the outer track is reserved for specimens destined for the processing station. Specimens that require centrifugation (determined by comparing their barcode with the database) are automatically weighed and loaded into centrifuge buckets based on a computer algorithm that produces a balanced centrifuge. After all buckets are full or a user-defined timeout is exceeded (whichever comes first), the buckets are then loaded into the centrifuge. After centrifugation, the buckets are unloaded, and the centrifuged specimens are placed into barcoded sample pucks (Fig. 2).

The conveyor moves the pucks containing the centrifuged specimens to the decapping station. The decapper can remove rubber-stopper tubes, screwcap containers, and HemaGuard tubes. Once decapped, the centrifuged specimen (primary) tube is transported to the aliquot station where the required number of aliquot (secondary) tubes are labeled and placed into empty pucks behind the primary tube. The secondary tube label contains a barcode and a readable text that includes the patient’s name,

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4 Some LISs can provide a unique accession number for each sample, others cannot. For those sites where the LIS provides unique sample accession numbers, the full sorting capability of the FE500 can be realized. However, at those sites where the unique sample accession numbers are unavailable, samples must be presorted before being loaded onto the FE500 to complete their processing.
identification number, and which tests have been ordered on the specimen. At the Hershey site, the aliquot tube label also contains the type of primary tube that the specimen came from and whether the aliquot tube should be stored frozen or refrigerated after analysis is completed.

At the aliquot station, the puck and the tube barcode are read and validated to ensure proper specimen identification. If the identification of one tube in the batch does not compare as expected, all secondary tubes go to the specimen-in-question rack. This process occurs when one of the following events occurs: (a) no label on tube; (b) wrong barcode content on label; or (c) barcode not readable. The preselected aliquot volumes (determined by ordered tests) are then dispensed into secondary tubes.

All tubes (primary, noncentrifuged; primary, centrifuged; and secondary tubes) proceed to the unloading gate where they are distributed into specific analyzer racks according to the database. The analyzer-specific racks can then be manually unloaded by the technologist at any time for manual transportation to a selected analyzer. (TECAN provides a unique carrier rack for each different instrument tube rack. These tube rack carriers hold the instrument-specific tube racks in place in the output area of the FE500. A new instrument tube rack can be programmed in <5 min, using the GENESIS FE setup function to drag and drop the icon for the new rack into the output area.)

**CLINICAL EVALUATION PROTOCOL**

At UVa, the testing throughput protocol was developed to represent a typical workload experienced in a medium-sized clinical laboratory [40 batches of samples, each with a variable number (e.g., 40–300) for a total of ~3000 specimens per day]. We tested the system throughput by varying the batch sizes (40, 100, 200, or 300 specimen tubes), using an 8-min centrifugation time and 47 pucks on the system, with the first aliquot requiring 500 μL, the second aliquot requiring 400 μL, and the third and subsequent aliquots requiring 300 μL. The time to process a batch of specimens was defined as the time required from the first reading of the first specimen barcode to the time the last tube (primary or secondary) was placed in an output rack. Because some laboratories will use a preanalytical processor to sort specimens that do not require centrifugation (e.g., hematology specimens), we performed a series of timing studies under various conditions. These were divided into three categories: 100% centrifugation; 80% centrifugation and 20% sort only; and 70% centrifugation and 30% sort only. At Hershey, we also tested continuous flow operation of the FE500 (i.e., loading specimens continuously during the day) in a real-life clinical setting to assess time in motion and potential points of delay with a fluctuating clinical workload.

For the centrifugation protocols, we also studied the effects of making 0, 1, and 3 aliquots on total tube output for a series of different batch sizes (e.g., 40, 100, 200, and 300 specimen tubes/batch). The total output of processed tubes expected from each of these experiments was the sum of the number of primary (specimen) tubes plus the number of centrifuged primary tubes (percentage of tubes centrifuged × number of primary tubes) times the number of aliquot tubes (secondary) requested per primary centrifuged tube. Finally, we measured the processing time required for the FE500 to process these various centrifuged batches. The batch processing time can be obtained from run time logs accumulated by the FE500 operating software or by use of a stopwatch. Output rate, as total tubes processed per hour, was calculated using the formula:

\[
OR = \frac{[P_T + (\%C \times P_T \times A_{PT})]}{t}
\]

**Fig. 2. Sample puck with barcoded primary sample tube.**

Barcode on puck facilitates identification and tracking of puck (and corresponding primary tube carried) as it is internally processed by FE500.
where $OR$ is the output rate (tubes/h), $P_T$ the number of primary (specimen) tubes, $%C$ is the percentage of primary tubes ($P_T$) centrifuged, $A_{PT}$ is the number of aliquot tubes created per centrifuged primary tube, and $t$ is the time needed to process the batch of primary specimen tubes (hours).

System efficiency and payback were determined at Hershey through documentation. The potential savings [in full-time equivalents (FTEs)] comparing day shift staffing needs before and after installation of the FE500 was determined.

VALIDATING CENTRIFUGAL REMOVAL OF PLATELETS

The throughput of the GENESIS FE500 is influenced by the centrifugation speed used to pellet blood cells and the ratio of the number of aliquots produced per primary tube. There is a temptation to speed up the overall processing rate by increasing the centrifugation speed and reducing the centrifugation time. However, production of platelet-poor plasma required for blood coagulation studies is dependent on an optimal centrifuge speed to ensure that the majority of platelets are removed from the plasma before coagulation studies are performed. We therefore determined the optimal FE500 centrifuge speed that removed platelets from plasma to reach the reduced platelet concentration established by the NCCLS for platelet-poor plasma (e.g., $<10,000$ platelets/$\mu$L) (13).

Because the FE500 centrifuge rotor speed is fixed at 3800 rpm (2870 g), we chose to evaluate two different times, 8 and 10 min, at this rotor speed to determine which time gave the lower residual plasma platelet values.

Blood samples (~4.5 mL) were collected into 5-mL Vacutainer Tubes containing sodium citrate (product no. 369714; lot no. 0132671; Becton Dickinson) from two individuals who gave informed consent. These samples were divided into four groups: (a) reference (uncentrifuged); (b) manually processed (centrifuged at 1500 g for 10 min); (c) processed by the FE500 (centrifuged at 2870 g) for 8 min; and (d) processed by the FE500 (centrifuged at 2870 g) for 10 min. Test specimens in the last two groups and were immediately placed on the FE500 and processed. The FE500 automatically delivers the desired plasma volumes (1 mL) into $13 \times 65$ mm plastic tubes, using 1000-$\mu$L disposable tips. Aliquots of plasma were used because the hematology analyzer mixes the specimens before analysis. Whole blood (reference) samples were assayed directly, whereas manually processed (control) specimens were routinely centrifuged in the clinical laboratory. Platelet counts were determined on a Cell-Dyn hematology analyzer (Abbott Diagnostics) on either the plasma or whole blood specimens. Plasma samples were processed in triplicate, using blood collected from the two volunteers for each variable, as well as for the reference and control samples.

Results

The baseline output rate of the FE500 under conditions where the system removes the caps and centrifuges and sorts 100% of the primary tubes placed on the unit was 288 tubes/h with a 10-min centrifugation time (centrifuge completed four cycles/h). The FE500 output rate improved to 332 tubes/h when the centrifugation cycle time was decreased to 8 min (centrifuge completed 4.6 cycles/h). This time has been demonstrated to produce acceptable platelet-poor plasma according to the NCCLS protocol for coagulation studies (see platelet studies below).

We studied the effects of the number of aliquot tubes prepared from primary tubes, the length of centrifugation, and batch size on the output of the FE500 (Fig. 3). The results (output rate, in total tubes/h) from the 75 analysis runs are summarized in Fig. 3 as a function of batch size, increasing from 40 to 300 sample tubes. As the batch size increased, the processing output rate of total (primary + secondary) tubes also increased to reach a maximum of $502 \pm 11$ (mean $\pm$ SD; $n = 3$) total tubes/h (80% centrifugation with 300 tubes in a batch with 3 aliquots). The results shown in Fig. 3 indicate that for the smaller batches (e.g., 40 and 100 specimen tubes), the corresponding (i.e., similar centrifugation rate and aliquot number) output rates were always less than those for the larger batches (200 and 300 tubes).

The average output rate for smaller batches of 40 specimen tubes (including 70% and 80% centrifugation) was 211 total tubes processed/h. The average output for the largest batch of tubes (e.g., 300 tubes) that included both 70% and 80% fraction centrifuged was 474 total tubes processed/h. The extent of centrifugation (e.g., 70% vs 80%) did not influence the output rate when one aliquot was produced per centrifuged primary tube for these large batch sizes. As batch size increased from 200 to 300 tubes for 3 aliquots per centrifuged tube, the output rate increased slightly (~10%), from 452 to ~496 total tubes/h, respectively. For these larger batches, however, there was no statistical difference in output rate when one aliquot per tube was produced per centrifuged tube. The average SD was 15.5 tubes/h ($n = 75$ runs; range, 1–32 tubes/h).

We also quantified the processing times for various scenarios that represent different types of specimen tubes. For example, the FE500 can directly offload a tube in 52 s, from input into the system to racking into the analyzer-specific rack (e.g., a hematology tube). The FE500 can offload a tube in 15 min, from input into the system to racking, including an 8-min centrifugation. (i.e., a coagulation tube). The FE500 can offload a tube in 17 min and 32 s, from input into the system to racking, including an 8-min centrifugation and production of one aliquot (i.e., chemistry tube with one aliquot for reference laboratory testing). It must be emphasized that the actual system output rate depends on several variables, only some of which were controlled and measured in our studies.
PLATELET DEPLETION STUDIES
Results from the FE500 centrifuge timing studies revealed an acceptable platelet-poor preparation at either 8 or 10 min as shown in Table 1. Comparison of the platelet-poor plasma preparation against a reference whole blood specimen indicated that with an 8-min centrifuge time, ~96% of the platelets were removed. Residual platelet concentrations were 4000–4200 platelets/μL. In a 10-min centrifugation, ~98–99% of the platelets were removed. A manual preparation of platelet-poor plasma contained 4000–10 900 platelets/μL. This validates the benefits of centrifugation to prepare a platelet-poor plasma sample (Table 1).

CLINICAL STUDIES
Real-time clinical studies were carried out in a specimen-processing area of a tertiary care facility (Hershey) that receives ~2000 specimens per day. The FE500 was operated in a continuous specimen-receiving mode to accommodate the large fluctuations in numbers of specimens received throughout the day. We estimate that the number of manual processing steps for the clinical specimen volume at Hershey approximates 750 000 individual processing steps/month, with a resulting error rate of ~8000 specimen sorting and routing errors/month, ~3000 pour-off errors/month, and ~7000 labeling errors/month. These values at first inspection may seem high, but they

Table 1. Efficiency of platelet removal from blood samples by the GENESIS FE500.

<table>
<thead>
<tr>
<th>Volunteers</th>
<th>Platelet concentration (× 10^3)/μL</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Reference sample (whole blood)</td>
</tr>
<tr>
<td></td>
<td>Reference</td>
</tr>
<tr>
<td>Volunteer 1 (n = 3)*</td>
<td>159 ± 6.6</td>
</tr>
<tr>
<td>% of reference</td>
<td>100</td>
</tr>
<tr>
<td>Volunteer 2 (n = 3)*</td>
<td>180 ± 0</td>
</tr>
<tr>
<td>% of reference</td>
<td>100</td>
</tr>
</tbody>
</table>

* Data are expressed as mean ± SD of total platelets (× 10^3)/μL of whole blood.

* We performed a control run on each specimen according to NCCLS guidelines (e.g., 1500g for 10 min).

* Centrifugation speed is adequate to remove platelets to below threshold value required by NCCLS to perform coagulation studies (e.g., <10 000 platelets/μL).

* cent, centrifugation.

* Three primary specimens per volunteer.
represent a <1% error rate in the overall number of steps encountered in manually processing samples. The values represent errors for all sections of the automated testing laboratory, including stat testing. The error count was determined for all steps encountered, and one specimen, for example, might have been assigned multiple errors if the specimen was placed in the wrong analytical rack, the hand-written label on the aliquot tube was incomplete, or the specimen was short sampled for the analyzer. Many of these errors were identified and corrected immediately but were included in the overall error count. Although just an estimate, this cursory error count indicates that the potential for error is considerable when specimens are processed manually.

Before installation of the FE500, 12 FTEs were required at the Hershey facility to provide support for the hospital inpatient volume as well as to handle the volume of specimens generated from outpatient clinics and outreach laboratory services. Since the installation of the FE500, the Hershey facility has achieved close to a 95% reduction in specimen sorting and routing errors and a reduction of >98% in specimen pour-off and labeling errors (Table 2). The values are not reduced to zero because of the continued errors encountered for specimens not processed by the FE500, such as stat specimen processing. Since the placement of the FE500, the laboratory at Hershey has managed to operate the specimen-processing service area during the day shift with only 8 FTEs, vs 12 FTEs for manual processing of specimens.

Discussion

The first preanalytical specimen processing units were invented in Japan by Dr. Masahide Sasaki as part of complex laboratory automation systems called TLA (14). After the first installation of TLA in the Western Hemisphere, at the Quest Clinical Laboratory (St. Louis, MO), and the first installation of TLA in Europe, at the University of Leiden, many laboratories were convinced that TLA was the optimal solution for handling the ever-increasing work loads, labor shortages, and high laboratory labor budgets. However, for many smaller laboratories, TLA was too costly an exercise to justify an acceptable return on investment or too large to install without expensive physical renovations. Thus, modular, task-oriented automation was developed to serve the needs of reducing the high labor costs associated with the specimen-processing area of the clinical laboratory.

Preanalytical processing units can be categorized into two distinct types. Modular preanalytical processors are assembled from individual modules, such as a sample stockyard, conveyor belt transporter, centrifuge, decapper, barcode reader, aliquoter, and sorter. Current modular preanalytical processing units work as stand-alone units or serve as the preanalytical piece to a modular automated analytical system. Components of modular systems that can be easily interfaced to analytical equipment are typically available only from the vendor of the analytical piece. The second type of preanalytical processing unit is a stand-alone, independent unit that is deployed in the laboratory in the same fashion as a stand-alone chemistry analyzer. The GENESIS FE500 represents the second type, embodying a discrete, generic, preanalytical workstation used in the laboratory as an independent unit. This unit has a relatively small footprint compared with the large modular style units associated with TLA and requires only anchoring of the centrifuge to function in the laboratory.

There has been much interest in calculating the potential return on investment for laboratory automation (15, 16). Clearly, labor savings need to be considered, but enhanced throughput and specimen-handling capacity can also contribute to improved efficiencies, which can translate into cost savings. The FE500 is capable of processing a maximum of 502 total tubes/h. Mean system output performance varied between 93 and 502 total tubes/h, depending on the batch size, number of aliquot tubes needed, and percentage of tubes that required centrifugation. It is important to keep in mind that processing a 300-tube batch of specimens at a 100% centrifugation rate creates a total of 1200 tubes if three aliquots are requested for each tube. Therefore, greater laboratory efficiencies are gained by strategically locating the chemistry and immunoassay instruments as close to the processing area of the FE500 as possible and keeping the number of aliquot tubes to a minimum. One FTE assigned to general chemistry and immunoassay can monitor and replenish the FE500 and instrument reagent and supply needs, as well as move batches of completed tubes between the FE500 and the analytical instruments. The FE500 can centrifuge and decap 288–332 primary tubes/h (depending on centrifuge times of 8 or 10 min/run) and is capable of specimen processing at a rate that exceeds the rates generated by three FTEs in this area of the laboratory.

The throughput of the FE500 was calculated from 75 runs under a wide range of specimen input conditions. We examined three variables (e.g., number of specimens, percentage of specimens centrifuged, and number of aliquot tubes produced/centrifuged primary tube).

### Table 2. Effects of FE500 on specimen-processing errors.

<table>
<thead>
<tr>
<th>Error/event classification</th>
<th>Pre-FE500&lt;sup&gt;a&lt;/sup&gt;</th>
<th>Post-FE500&lt;sup&gt;c&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sorting and routing errors</td>
<td>7950</td>
<td>477</td>
</tr>
<tr>
<td>Pour-off errors</td>
<td>2612</td>
<td>96</td>
</tr>
<tr>
<td>Labeling errors</td>
<td>6668</td>
<td>33</td>
</tr>
<tr>
<td>Biohazard exposure events</td>
<td>2658</td>
<td>6</td>
</tr>
</tbody>
</table>

<sup>a</sup> Study performed at Milton S. Hershey Medical Center, Pennsylvania State University (Hershey, PA).

<sup>b</sup> Estimated for 1-month period of data collection.

<sup>c</sup> Errors recorded in this category were largely identified from specimens processed for stat testing. Stat specimens are currently not processed by the FE500 in our laboratory.
influence of these three variables on the output of the FE500 is summarized in Fig. 3 and discussed below:

NUMBER OF INPUT SPECIMENS
There was a large increase in throughput when the batch size increased from 40 or 100 samples (mean = 211 total tubes processed/h) to batch sizes of 200 and 300 tubes (mean = 474 total tube processed/h). This increase suggests a large reserve capacity to process additional tubes as batch sizes increase. However, the small difference in throughput for batches between 200 and 300 specimens suggests that the FE500 is close to achieving a steady-state operation to process additional primary specimens; the steady-state operation occurs when the percentage of centrifugation is <100%. The maximum output of the FE500 (502 total tubes processed/h) was obtained when the FE500 had been fully loaded and processed a minimum of 300 specimen tubes (Fig. 3). Thus, the best efficiencies in operating the FE500 will be obtained when it is in near-continuous operation (i.e., processing large batches of specimen tubes). However, even small batches (e.g., 40 tubes/batch) will still be processed at an average output rate of 180 total tubes/h.

FRACTION OF SPECIMEN TUBES CENTRIFUGED
For any given batch size, the extent of centrifugation partially influences the throughput rate. Initially, as the percentage of primary tubes centrifuged changes from 100% to 80%, there is an increase in throughput [i.e., comparing throughputs with 100% centrifugation (0 aliquots) for the 40-, 100-, or 200-tube batches with the corresponding output of lower fractions of centrifuged tubes (80% and 70%) for the same batch size]. However, as the rate of centrifugation decreases from 80% to 70%, the output rate moderates, even when aliquot tube numbers increase.

Decreasing the percentage of centrifuged tubes did not appear to uniformly influence throughput with the larger batch sizes tested (i.e., comparing throughputs at 70% centrifugation for the 200- and 300-specimen batch sizes, then comparing 80% centrifugation for 200- and 300-specimen batches). Thus, the throughput of processed tubes approaches a steady-state condition (e.g., reached when batch sizes reach 200–300 tubes.) Our data suggest that when large batches of mixed chemistry and hematology tubes are processed, the number of hematology tubes has only a slight influence on the sample processing rate.

ALIQUOT NUMBER
For the 40-, 100-, and 200-specimen batches, we noticed that the number of aliquot tubes had a strong positive influence on the throughput when all tubes were centrifuged (100%). This suggests that the aliquot step is much faster than the centrifugation step because throughput increases with aliquot number. For a given centrifugation rate in any of the four batches, the throughput rate was enhanced when the aliquot number increased from one to three (Fig. 3). Thus, increasing the number of aliquot tubes generated for any specified extent of centrifugation <100% enhances throughput. When the number of aliquot tubes increased from one to three in the larger batch sizes (e.g., 200 and 300 specimens), there was a significant increase in FE500 performance that yielded the maximum output rate observed (502 total tubes processed/h). However, for one aliquot, when the batch size was increased from 200 to 300 specimen tubes, there was no enhancement in throughput (Fig. 3), suggesting that the system is operating at near-maximum capacity. When the aliquot number was increased to three secondary tubes per centrifuged primary tube, there was an ~10% enhancement in the mean output rate (e.g., from 452 to 496 total tubes processed/h), suggesting that a slightly higher output might still be achieved.

Our results listed in Table 1 indicate that a centrifuge speed of 3800 rpm (2870g) for 8 min was sufficient to produce platelet-poor plasma below the NCCLS suggested threshold of 10,000 platelets/μL (12). Moreover, a 10-min centrifugation cycle further reduces the platelet content well below the NCCLS threshold (Table 1).

In our estimation, the FE500 can easily be operated by one FTE on each 8-h shift if the laboratory is set up so that the analytical equipment is nearby. We anticipate that laboratories processing 1000–3000 primary tubes/day will require one GENESIS FE500 to accommodate a peak demand of 322 primary tubes/h. From a practical viewpoint, the FE500 has several advantages over the processing of specimens manually. Labor savings in an area of the laboratory that typically has a high personnel turnover rate translate into real cost savings, as evidenced by the 33% reduction in FTEs experienced in the specimen-processing area at Hershey. Importantly, the integrity of sample handling is markedly improved over that obtained with manual processing.

The FE500 provides sample aliquots in small plastic tubes that are immediately available for analysis on nearby laboratory instrumentation. If samples are to be transported to another location for analysis, TECAN provides a tight sealing cap to prevent sample evaporation. The reference laboratories used by both UVA and Hershey have indicated that the TECAN aliquot tubes may be used to submit samples provided they have been sealed with multiribbed caps.

At Hershey, there was a noticeable decrease in laboratory errors attributable to specimen routing, sorting, aliquoting, and labeling of secondary tubes (Table 2). In addition, because the FE500 controls the volume dispensed into the aliquot tubes on the basis of specific analyzer and test request, short sampling has been markedly reduced at the analytical workstations. The FE500 also has the added benefit of reducing biohazard exposure to the individuals who process specimens because the cap removal process is shielded (Table 2). At Hershey, it was felt that the consistency and quality of specimen
processing were improved, although it is difficult to quantify these impressions.

In summary, the Genesis FE500 should be a suitable alternative for small- and medium-sized laboratories wanting to introduce preanalytical automation at a reasonable cost.

We would like to thank Abbott Diagnostics (Abbott Park, IL) for providing funding to conduct this evaluation study and TECAN US for continued technical support during the evaluation phase of the GENESIS FE500. Christopher Miceli from TECAN US provided the technical expertise to maintain the GENESIS FE500 and performed some of the timing studies. We would also like to thank Donna Crook from TECAN US and Don Rigali and Matthew Noble from Abbott Diagnostics for valuable input during the clinical trials of the GENESIS FE500. We would also like to thank Sunquest Information Systems (Tucson, AZ) for their participation with interface development.

Note Added in Proof. At UVa, the FE500 installed in the Core Laboratory has been functional for the last 6 months since its installation in July 2001. The FE500 daily maintenance is usually ~10–15 min in the morning and consists mainly of emptying waste containers and restocking the consumables. Weekly maintenance is ~15–20 min, whereas monthly maintenance is ~45 min and is done once per month.

References