Al Ameen J Med Sci 2025;18(2):111-117 ● US National Library of Medicine enlisted journal ● ISSN 0974-1143

ORIGINAL ARTICLE CODEN: AAJMBG

Comparison of conventional semi automated methods with advanced and semi-automated laboratory techniques: New era in clinical diagnostics

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Received: 11th January 2025; ***Accepted:*** 16th March 2025; ***Published:*** 01st April 2025

Abstract: *Aim:* The Advanced diagnostic studies often employ sophisticated technology and techniques to provide detailed information about the patient's health, which might not be obtained through conventional diagnostic methods. The need for new-generation diagnostics in the current era is essential for rapid analysis and faster treatment plans, as it provides highly detailed data allowing for more precise diagnosis and related conditions. These techniques allow a comprehensive detailing of the illness that helps in the management of chronic illnesses more effectively. These are particularly helpful in monitoring disease progression and the possible effectiveness of treatment to be made in real-time to improve patient outcomes. *Material and Methods:* 50 volunteers are selected, and blood samples are collected and processed on advanced auto and semi-auto analysers for biochemistry and hematology and 25 samples for microbiology parameters. *Results:* Both analyzers demonstrated a substantial portion of the population was classified as healthy. However, the increased percentages of individuals identified as healthy and diseased, underscore the importance of ongoing monitoring and early detection strategies in managing various diseases and related complications. Elevated levels of certain parameters in both analysers indicate potential health issues, particularly in older adults, highlighting the necessity for targeted interventions. *Conclusion:* Laboratory medicine has undergone a dramatic change, and medical laboratories must now adapt to meet new, customer-supplier needs springing from shifts in the patterns of disease prevalence, medical practice, and demographics. More recently, the resource shortages in health care and results of cost/effectiveness analysis have demonstrated that the value of a laboratory test must be ascertained not only based on its chemical or clinical performance characteristics but also by its impact on patient management. The only true assessment of the quality of testing is the quality of patient outcomes.

Keywords: Auto analysers, Cost Effectiveness, Health care, Laboratory Testing, Quality, Semi Analysers.

Introduction

Data from clinical laboratory testing is crucial for medical diagnosis. Up to 50–70% of therapeutic decisions are influenced by the timely and correct generation of test findings that are conveyed to the treating clinician and, eventually, the patient. This is a crucial part of enabling diagnostic excellence [1]. However, if this isn't accomplished, diagnostic errors may result, which could show up as missing, delayed, or incorrect diagnoses. Up to one-third of medical errors are linked to diagnostic errors, making medical errors the third most common cause of death in the US [2-3].

The era of automation characterizes modern laboratory medicine. The Auto Analyzer was the first to introduce the idea of laboratory automation. Through increased efficiency, higher throughput, larger assay menus, and fewer errors, subsequent generations of stand-alone analyzers have transformed laboratory testing operations and raised overall quality [4].

They have a wide-ranging impact, improving laboratory ordering, testing, and reporting procedures while doing away with time-consuming and tedious tasks [5]. By simplifying the usage of materials and reagents, standardizing processes, and lowering the frequency of outliers, it has ushered in a new era of increased production. Efficiency boosts output rates and enhances test results' precision and accuracy.

Therefore, in our prospective study, we used sophisticated dry chemistry analyzers, automated five-part haematology analyzers, and vitek analyzers that operate on different principles of reflectance photometry, chemiluminescence, volumetric impedance, and light-scatter techniques to analyze serum, plasma, urine, and whole blood samples for routine and some special parameters. We then compared the results on semi-analyzers to see if there were any differences in the results.

Material and Methods

Over the course of three months, from March to May 2014, this study was conducted on regular samples that were received for studies at our institutions after gaining the subjects' agreement and ethical approval. 50 samples in all, ranging in age from 5 to 56, were gathered and examined for standard biochemistry and hematology, and 25 samples were examined for microbiological characteristics. Within an hour after sample collection, two milliliters of the biochemistry sample were placed in a simple gel tube, three milliliters in a 2% EDTA tube, centrifuged, and then split and processed using both auto and semi-analyzer systems to determine the precise quantities in the samples. Important information on the health state of the population under study was revealed by the examination of the 50 samples.

A fully automated dry chemistry VITROS 4600 Biochemistry instrument that uses microslide (dry) technology was used to process the clinical biochemistry tests, which included plasma glucose, lipid profiles, liver function tests, renal profile tests, serum electrolytes, amylase, and HbA1c. Analogous tests were also conducted on an ERBA Chem 5X Semi analyzer. HbA1c was processed in BioRad D10 analyser, based on high performance liquid chromatography and results were compared with those obtained from semi analyser instrument using immunoturbidimetric method. Utilizing Chemiluminescence Immunoassay and Enzyme-Linked Immunosorbent Assays, the thyroid profile parameters, including TT3, TT4, and TSH, were examined and contrasted.

Testing for Hematology: Four milliliters of the sample were placed in a 2% EDTA tube and processed using the MINDRAY BC 6000 (5-part analyzer) and ERBA H360 (3-Part analyzer systems. Four milliliters of the material were then collected in a citrate tube for the study of the coagulation profile. HB electrophoresis was performed to look for the prevalence of any unidentified hemoglobinopathy, using electrophoresis technique.

By analyzing 25 clinical samples from pediatric samples in the age range of 5 to 10 years from a variety of resources like urine, pus, sputum, and stool, the effectiveness of culture techniques in detecting various bacterial species from clinical samples was examined, with a focus on species like Escherichia coli, Staphylococcus aureus (MRSA), Enterococcus spp., and Pseudomonas aeruginosa. Conventional detection techniques and automated system detection with VITEX 2 Compact were used to evaluate antibiotic sensitivity and resistance.

Results

Twenty-five samples were prepared for microbiological tests, and fifty samples were prepared for biochemistry and hematology parameters. Renal Function Tests (RFT), which include analytes like glucose, phosphorus, uric acid, creatine, and urea. A significant percentage of the population was categorized as healthy by both analyzers (80% with VITROS vs. 70% with ERBA).

Triglycerides, cholesterol, direct-HD, and LDL are among the analytes that are compromised by the lipid profile. The findings indicated a more prominent risk category with the ERBA analyzer (40% at risk compared to 30% with VITROS), but they also demonstrated consistency in identifying healthy individuals (40% in both analyses).

Comparative evaluation of patients' serum liver function indicators using two clinical biochemistry analyzers (total protein, total bilirubin, BUBC, and ALKP). Serum amylase were tested and compared.

Figure 1.1 shows a comparison of the serum lipid profile, amylase, liver function tests, glucose, phosphorus, uric acid, creatinine, and urea in individuals using two clinical biochemistry analyzers. The results of the HPLC and immunoturbidimetric analyses of HbA1c are displayed in figures 1.2, which showed clearer separation with D10 analyser. When compared to the data from ELISA for thyroid profile(T3,T4 and TSH), which revealed minor differences with 68% of patients healthy (34 patients), 10% at risk (5 patients), and 22% on treatment (11 patients), the TFT results obtained using CLIA showed a distribution where 72% of patients (36 individuals) were healthy, 12% (6 individuals) were at risk, and 16% (8 individuals) were on treatment as shown in figure 1.3.

Fig-1.1: Comparative analysis of serum analyte levels of glucose, phosphorus, uric acid, creatinine, and urea, lipid profile, amylase, Liver function tests) in patients across dry and semi automated chemistry analysers.

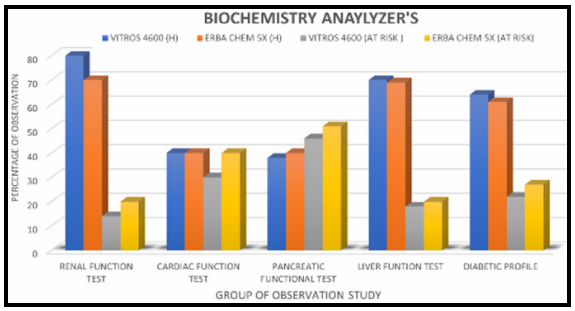


Fig-1.2: Comparitive Analysis of HbA1c using HPLC technique (D10) and using immunoturbidiemetric method (ERBA chem 5X).

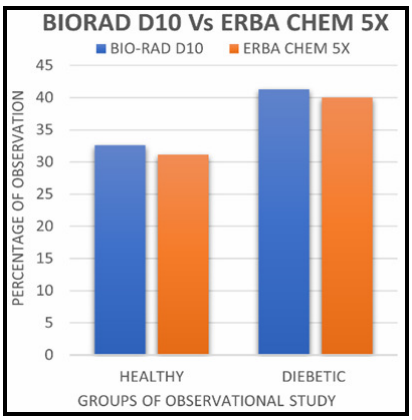
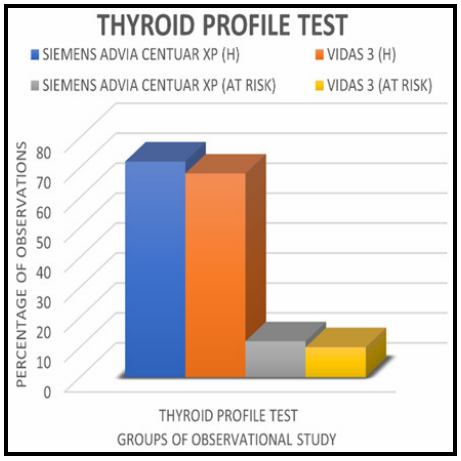


Fig-1.3: Thyroid Profile Test results: comparison of patient health status categorization using *CLIA* and *ELIA* method for thyroid profile tests.



Haematology Parameters: The distribution of the coagulation profile and routine complete blood count parameters in both pieces of equipment was as follows. Figure 2: Hematologic parameter and coagulation profile distribution utilizing 3- and 5-part analyzers. Additionally, the coagulation profile data are displayed in Fig 3. The X-axis shows the analyte levels that correlate to the patient categories of healthy, anemic, and abnormal WBC/ platelet count. The Y-axis shows the proportion of patients with hemotological abnormalities.

Sebia Minicap Flex-Piercing Capillary Electrophoresis: The analysis of the 50 patients evaluated in this test offers a thorough picture of the frequency of different hemoglobinopathies in the community under study. According to the data, half of the patients (50%) are within the normal range, which represents a sizable section of the population that does not have any observable hematological diseases.

Fig-2: Distribution of hematologic parameters using 3-Part & 5-Part analyzers.

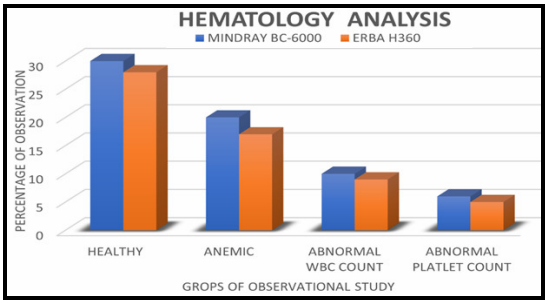
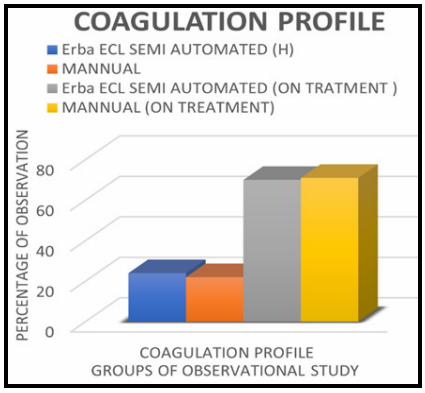
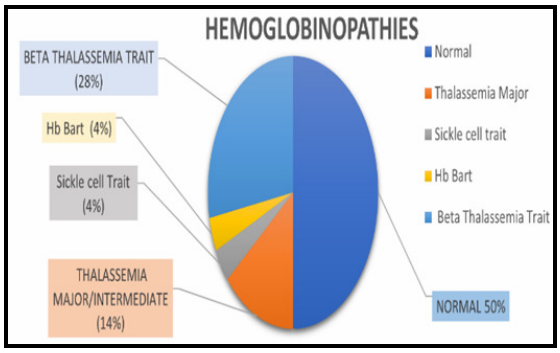


Fig-3: Comparison of coagulation test results (PT and APTT) between automated analyzer and conventional manual methods. X-axis: Represents patient categories (Healthy, at risk & on treatment) and the corresponding analyte levels. Y-axis: Represents the percentage of patients exhibiting plasma analyte levels.



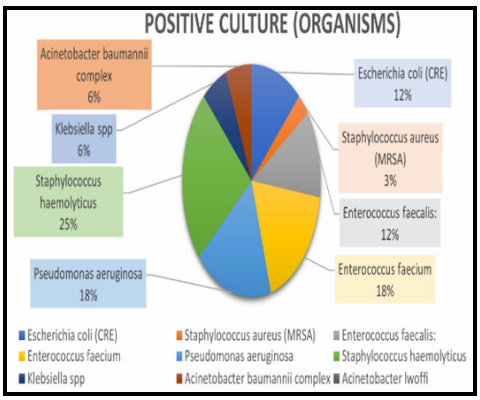
Hemoglobinopathies (Fig 4): Erba ECL Semi Automatic 105 Single Channel Coagulation Analyzer - The information gathered from this device shows how well it produces precise and reliable coagulation test results, especially for PT and APTT evaluations, compared with the traditional manual timer method.

Fig-4: Hemoglobinopathy screening using Electrophoresis method.



Microbiology Sample Analysis [Fig-5]: Negative Cultures: Five samples showed no growth during 48 hours of aerobic incubation, suggesting possible problems with sample viability or the presence of bacteria.

Fig-5: Microbiology sample analysis.



Resistance and Sensitivity to Antibiotics: Effective sensitivity to medications such as amikacin, gentamicin, tigecycline, and fosfomycin was noted for Escherichia coli (CRE). The bacteria Staphylococcus aureus (MRSA) demonstrated susceptibility to Vancomycin, Teicoplanin, Daptomycin, and Linezolid.

Resistance: A number of widely used antibiotics, such as piperacillin/ tazobactam, amoxicillin/ clavulanic acid, and several cephalosporins for Escherichia coli (CRE), were found to have high levels of resistance. Ciprofloxacin and Levofloxacin resistance was reported in Staphylococcus aureus (MRSA).

Intermediate Results: Some species, including Pseudomonas aeruginosa and Enterococcus faecalis, showed intermediate resistance to a number of antibiotics, suggesting that treatment selection should be done with caution.

The below table-1 indicates that the species detection rates in two distinct methods varied.

Table-1: Detection rates of species in two different systems

Organism	Conventional Detection Rate	Automated System Detection Rate (e.g., VITEX 2 COMPACT)
Escherichia coli (CRE)	60-70%	90-95%
Staphylococcus aureus (MRSA)	55-65%	85-95%
Enterococcus faecium (VRE)	40-50%	80-90%
Pseudomonas aeruginosa	50-60%	85-95%
Klebsiella spp.	45-55%	85-95%

The organism and the particular antibiotics tested determine the percentage of antibiotic sensitivity and resistance. Based on standard techniques, Table 2 displays the generalized estimate of antibiotic sensitivity and resistance rates for species that are often encountered in clinical settings based on conventional systems & BIOMÉRIEUX VITEK 2 COMPACT system.

Table-2: Antibiotic sensitivity and resistance of organisms

Organism Detected using conventional system	Antibiotic Sensitivity (%)	Antibiotic Resistance (%)	Organisms detected using BIOMÉRIEUX VITEK 2 COMPACT system	Antibiotic Sensitivity (%)	Antibiotic Resistance (%)
Escherichia coli (CRE)	30-40%	60-70%	*Escherichia coli* (CRE)	50-60%	40-50%
Staphylococcus aureus (MRSA)	35-45%	55-65%	*Staphylococcus aureus* (MRSA)	55-65%	35-45%
Enterococcus faecium (VRE)	25-35%	65-75%	*Enterococcus faecium* (VRE)	45-55%	45-55%
Pseudomonas aeruginosa	40-50%	50-60%	*Pseudomonas aeruginosa*	60-70%	30-40%
Klebsiella spp.	30-45%	55-70%	*Klebsiella spp.*	50-60%	40-50%
Acinetobacter species	20-35%	65-80%	*Acinetobacter* species	45-55%	45-55%
Enterococcus faecalis	50-60%	40-50%	*Enterococcus faecalis*	70-80%	20-30%

Discussion

Every clinical laboratory aims to provide high-quality diagnostic tests. Expanding laboratory capacity is crucial for addressing a variety of concerns and challenges [6]. Modern laboratory automation involves a sophisticated fusion of several technologies, including liquid handling, computers and robotics. The goal of automation is to reduce human errors and increase performance while saving time [7]. Clinical chemistry is a multidisciplinary filed that integrates routine chemistry, immunochemistry, endocrinology, toxicology, including therapeutic and drug abuse testing, to provide the necessary support to healthcare providers to improve the diagnosis and treatment of patients [8].

Our institution's use of dry chemistry analyzers for biochemistry analyzers eliminates all water-related errors, eliminates TDS checking, minimizes liquid waste, eliminates the chance of reagent contamination, and prevents the waste of dead volume of reagents that is commonly observed with liquid chemistry-based analyzers. A significant percentage of the population was categorized as healthy by both analyzers (80% with VITROS vs. 70% with ERBA). However, the higher percentages of people with diabetes (14% with VITROS vs. 20% with ERBA) highlight how crucial early detection techniques and continuous monitoring are to controlling diabetes and its complications. Both studies' elevated phosphorus and creatinine levels point to possible health problems, especially in older persons, underscoring the need for focused interventions.

Triglycerides, cholesterol, direct-HDL, and LDL are among the analytes that are compromised by the lipid profile. The findings indicated a more prominent risk category with the ERBA analyzer (40% at risk compared to 30% with VITROS), but they also demonstrated consistency in identifying healthy individuals (40% in both analyses). This disparity highlights the need for improved risk stratification instruments to enhance evaluations of cardiovascular health. Finding patients with borderline readings highlights a crucial window for preventive therapy, highlighting the significance of consistent monitoring. Both analyzers revealed a large at-risk population (46% with VITROS vs. 51% with ERBA), with the serum amylase showing stable pancreatic function in 38% (VITROS) and 44% (ERBA) of individuals. In order to treat illnesses like pancreatitis, elevated enzyme levels necessitate quick intervention techniques, highlighting the significance of early

diagnosis in halting the development of chronic illness. Elctrolytes analysis by ST-200 Electrolyte Analyser showed 30% at risk and 20% critical; 30% at risk and 16% critical for electrolyte imbalance with ERBA on the samples processed.

Four key technologies underpin the operation of dry chemistry analyzers: Microslide technology, followed by Intelicheck, Microtip, and Microsensor technologies. The lack of carry-over effects is a significant benefit that guarantees accurate and trustworthy outcomes. Additionally, it provides great stability and outstanding precision for both calibration and reagent lots, which helps to ensure consistent and repeatable readings. Additionally, samples from young or elderly patients benefit greatly from the use of very little dead volume in dry chemical analysis [9]. The HbA1c analysis by The D10showed a clearer separation, with a more refined categorization of patients into healthy, good or poor control of glucose levels or at-risk groups. This enhances its ability to precisely identify diabetes risk, making it a preferred choice for clinical setting as shown in fig 1.2).

It's shown in the study that, a more accurate picture of the patient's health status is provided by the CLIA approach (Figure 1.3).Thyroid hormones (TSH, T3, and T4) are among the very low hormone concentrations that CLIA can detect due to its much higher sensitivity that ELISA would miss [10]. Because of its complete automation, CLIA reduces human error and well-suited for high-volume testing applications. Additionally, without requiring numerous dilutions, CLIA provides a wider dynamic range, accurately measuring both low and high hormone levels in a single run. A 5-part hematology analyzer based on SF-TUBE technology makes it simple and hassle-free to identify reticulocytes, WBCs (5 kinds), NRBCs, aberrant cells (atypical lymphocytes/blast cells), and lipid particles. A considerable percentage of the cohort is categorized as healthy, according to the distribution of hematologic parameters utilizing 3-part analyzers; however, other individuals exhibit signs of anemia, increased white blood cell (WBC) counts, or low platelet counts. While 3-part analyzers work well for simple blood cell analysis, they are not always able to identify and correctly classify more complicated hematologic disorders [11].

Healthy people, patients using anticoagulant medication, and those at high risk for aberrant prothrombin time (PT) values were all correctly identified by the coagulation autoanalyzer, which showed a great capacity to distinguish between a variety of clinical circumstances. On the other hand, there were minor differences in the classification of healthy patients, anticoagulant-using patients, and high-risk persons for PT using traditional methods. The limitations of manual testing, may be due to manual handling errors, timing inconsistencies, and environmental influences. HB electrophoresis using Sebia [12], showed 28% of patients with beta Thalassemia Trait, highlighting the significance of genetic screening and counseling in at-risk groups. Furthermore, 14% of patients receive a diagnosis of Thalassemia Major or Intermedia, emphasizing the necessity of continued clinical care and assistance for these people. The fact that 4% of people have sickle cell trait and 2% have haemoglobin D trait suggests that, despite being less common.

Vitex is an identification systemfor antibiotic sensitivity and resistance that is designed to identify bacteria and yeast based on their biochemical reactions and nutrient usage.Compared to the conventional testing systems, it has high sensitivity and specificity, reduces diagnostic errors, providing reliable treatment information and delivers faster detectionresults [13]. The BacT/ALERT microbial detection system is an innovative technology applied in clinical microbiology for the quick identification of microbial growth in blood samples [14]. Every ten minutes, the BacT/ ALERT system monitors reflectance, giving regular updates on the state of development in culture bottles. The system's dependability and wide range of applications in microbiological analysis are demonstrated by the timely and accurate detection of a large diversity of bacteria and fungi made possible by this routine monitoring.

Biomérieux's, Biofire: The biofire filmarray system is a rapid multiplex-PCR (polymerase chain reaction) system, is designed to simultaneously test for multiple pathogens in a single sample providing results in hour. We

have used this for the detection of infectious diseases, which has various panels like the respiratory panel and 2, The Meningitis/ Encephalitis Panel, The pneumonia panel, the blood culture panel.

Biosafety cabinets provide a controlled environment to protect both the laboratory worker and the samples being processed. When culturing bacteria, viruses, or other microorganisms, BSCs help maintain sterility and prevent the spread of potentially harmful agents. We have used biosafety cabinet TYPE II B2, since it provides protection to both the environment and to ensure the safety of laboratory personnel, maintain the integrity of samples, and prevent contamination [15].

Conclusion

The practical use of modern diagnostic approaches, which compares the output of different automated and semi-automated tools, highlights the advantages of advanced diagnostic technologies in improving the precision and dependability of health evaluations. In contemporary healthcare, the capacity to perform thorough, quick tests that give a clear picture of a person's health status is crucial. These cutting-edge techniques enhance patient outcomes by facilitating prompt interventions and increasing diagnostic precision. Even while conventional approaches are still useful, a proactive approach to healthcare requires the incorporation of cutting-edge diagnostic methods.

Financial Support and sponsorship: Nil

Conflicts of interest: There are no conflicts of interest.

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Cite this article as: Takkalaki N, Maidargi PM, Agarwal M and Totad RD. Comparison of conventional semi automated methods with advanced and semi-automated laboratory techniques: New era in clinical diagnostics. *Al Ameen J Med Sci* 2025; 18(2): 111-117.

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