

Automation: Survival Tools for the Hospital Laboratory

Presented to the Second International Bayer Diagnostics
Laboratory Testing Symposium
New York City, N.Y., July 17th, 1998.

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Keywords: Automation, robotics, modular automation,
clinical laboratory.

ABSTRACT

New technologies based on manufacturing automation are now making hospital clinical laboratories into profit centers. Ever since the Japanese introduced the laboratory robotics and automation paradigm in the early 1980s, over 20 laboratories in North America and Europe have installed fully functional robotic systems.

Laboratory automation will soon be an indispensable survival tool for laboratories facing difficult market competition. Laboratory automation technology consists of integrated hardware and software designed to perform complete specimen processing and analysis. Automation hardware can be installed in the form of a complete automation system (total laboratory automation) or as discreet hardware devices that perform specific tasks (modular automation). Estimates suggest that only 8% of hospital laboratories in North America will be able to afford a total laboratory automation systems while 100% of laboratories will profit from installing small discreet automated devices. Therefore, automation vendors have begun to focus on less extensive hardware configurations called “modular automation,” to fit the smaller laboratory.

Modular automation consists of consolidated analyzers, integrated analyzers, modular workcells, and pre and post-analytical automation. Modular automation should be a technology that will last well into the next century since it is affordable by all laboratories, provides a significant

increase in laboratory productivity, can be integrated into larger automation systems, and provides an increase in the quality of laboratory services.

INTRODUCTION

The Quest Laboratory in St. Louis, MO, installed the first total laboratory automation (TLA) system in North America in 1996 under the direction of J. David Hoover (1). In that historic move, the Coulter Corporation provided the leadership that has led to 22 other installations in North America (2) and 3 in Europe. Japan started their laboratory automation era in the 1980s and thus has installed over 170 automation systems (figure 1). Laboratory directors are learning about the many facets that must be considered before purchasing and installing robotic hardware. Infrastructure remodeling, personnel team building, software interfacing are just a few of the challenges that have to be overcome before a successful project can be realized. TLA installation is one of the largest projects a laboratory can undertake. Some important installation examples are at the Beth Israel Hospital (New York) (3), Mount Sinai Hospital (New York), the University of Leiden (The Netherlands) (4), and The South Bend Medical Foundation (South Bend, Indiana) (5), and Smith Kline Beecham Laboratories (King of Prussia, Pennsylvania) (6,7). It is clear from the outcome of these projects that the majority of laboratories cannot afford to purchase and install a TLA. According to David O'Bryan (director of automation at Smith Kline Beecham, King of Prussia, Pennsylvania, USA) of the

5,200 laboratories in the USA, very few are suitable for TLA. The exclusion criteria he used for these estimates included the consolidation of laboratories, physical layout, available market, and affordability of automation. Only 441(8%) laboratories are considered suitable for TLA in North America.

Given the limited market for TLA, automation vendors had little choice but to develop modular workstations that provided the scalability to accommodate the large variety of productivity needs. Modular automation is being configured to consolidate sample handling (decapping, centrifugation, aliquotting, quality inspection) (8) and analysis into a single automation platform. Modular automation defines a broad range of approaches to providing laboratory equipment that will ultimately link to other systems to create increasing levels of integrated automation (9). However, at this time, it is doubtful that vendors will address true connectivity of modular systems due to the lack of standards in this area. While standardization efforts are underway, market demands often outpace the standards creation effort. True connectivity would allow for simple hardware interconnection, plug-and-play software interconnectivity, and the ability to accept a wide range of specimens and specimen labeling options.

DEFINITIONS

Laboratory automation can be defined broadly as any device, software or process that improves the efficiency of the laboratory. Definitions are needed to classify the wide array of hardware that is beginning to appear on the market.

Analytical Consolidation – the act of combining several analytical techniques into one instrument.

Consolidated Instrument – an analytical instrument that combines a variety of analytical techniques. For example, consolidated instruments may combine chemistry as well as immunoassay reagents to provide a broad spectrum of analytical tests.

Task integration – the act of integrating various automated tasks into a continuous process. For example, an automated centrifuge may be integrated with an analyzer.

Specimen manager – A specimen manager is a mechanical device that allows the storage and buffering of specimens prior to and after analysis. For example, racks holding

anywhere from 1-10 specimens are loaded into a specimen manager, which in turn feeds them into an analyzer. After analysis, the racks are automatically moved into an output buffer (figure 2).

Workcell – A workcell is a combination of a specimen manager with instrument(s), or consolidated instrument(s). For example, a workcell includes sample buffering prior to analysis, transportation into the analytical instrument, and finally storage in an output buffer. Workcells can be automated using hardware such as a Cartesian robot or an articulating robotic arm (figure 3).

Modular Workcell – A modular workcell differs from a conventional workcell in that the instruments used in the workcell are configured to interface directly with the specimen manager. Thus a modular workcell is defined as a workcell composed of modular components which are designed to be easily interfaced to create a working analytical system. Usually, modular workcells are

integrated pre-analytical and analytical components provided by one manufacturer. In the future, customers may be able to mix and match components from various manufacturers (Figure 4).

Pre-analytical workcell – a pre-analytical workcell automates accessioning and specimen processing tasks. For example, a pre-analytical workcell could include sample inspection for errors and bar coding, centrifugation, aliquotting, relabeling, and sample buffering (Figure 5).

Integrated workcells - a series of instruments, consolidated instruments, or workcells that are integrated with other pre-analytical or analytical workcells.

Total Laboratory Automation system – The definition of a TLA is the combination of several instruments, consolidated instruments, workcells, integrated workcells,

or integrated modular workcells that are coupled to a specimen management and transportation system as well as a process control software component to automate a large percentage of laboratory work (Figure 2).

LABORATORY INFORMATION AND AUTOMATION

The automated core laboratory should include the automation of data collection and information distribution center. Laboratory data should be evaluated by trained professionals with the aid of diagnostic software algorithms to provide diagnostic information to practicing physicians. A data collection and information distribution plan should be the foundation on which the automated laboratory is built (Figure 6). Bi-directional laboratory data handling will be performed to and from the site of generation and then useful clinical information will be provided back to hospital wards, community laboratories (e.g. family practice, geriatrics and pediatrics) as well as directly into the home. Both the home care and self-care markets are growing at a rate of 70 % per year in the

United States and thus are expected to require a significant amount of data handling.

Automated laboratories require much more decision-making capabilities than what legacy laboratory information systems can provide. Using techniques familiar to the manufacturing industry, many decisions made by technologists and laboratory directors are being made by decision-making software. Decision making software is also called process control software. For example, process control software can direct specimens to processing and work areas, download test requests, accommodate back-up, repeat, re-run and reflex testing, track progress of the samples and the results through the system, and ultimately support storage and retrieval of specimens.

AN EXAMPLE OF A MODULAR WORKCELL

A variety of automated systems are appearing on the market. It is important to choose a system with modular, scalable features that will allow room for

expansion over time. Furthermore, a laboratory is more likely to succeed at automation if a modular stepwise approach is used so that major changes do not occur all at once. One example of a scalable automation system is the ADVIA® LabCell® from Bayer® Corporation, Diagnostic Division (10). The LabCell® is an automation system that can be scaled to offer a wide variety of automation configurations. Laboratories can adopt automation in a stepwise fashion starting from a simple specimen manager and transportation device and then expand the automation to include an analytical workstation (e.g. chemistry, hematology, or coagulation (figure 7)). Ultimately, the fully configured LabCell® can become a total laboratory automation system.

Specimen transportation in a LabCell™ system is via a single tube carrier “puck” that is a weighted cylindrical carrier fitted with expandable internal “fingers” that accommodates the outside dimensions of most popular vacutainer tubes (~11.5 mm to 16.2 mm). Individual tube carriers are most efficiently used with the

LabCell transportation conveyor since the use of high speed passing lanes and low speed exit lanes is the basis for “non-linear” sample routing (figure 9). The two-lane conveyor that is sold in 2-meter increments, each of which can accommodate the input and output capabilities of an analytical instrument. The space beneath the conveyor belt system has been used to house various utility lines for the automation system as well as analytical instruments connected to the conveyor. Each conveyor section provides diverter gates that function to shunt specimens to a low speed lane where they can be stopped at an interface gate. The interface gate has several functions; it functions to position the specimen for access by an instrument’s specimen manipulator as well as provides an interface to the utilities that have been integrated underneath the conveyor lanes. The LabCell accommodates the defacto standard of presenting the specimens within 50mm of the instrument and in a standardized sampling zone.

Instruments that are designed for only manual entry will require a specimen manipulator in order to move specimens from the instrument to the LabCell conveyor. Bayer also provides an inverted cylindrical robot for this purpose. However, the LabCell can also accommodate third party systems. The specimen manager is configured with unique drawer pallets that allow 100 labeled tubes to be stored. The pallets also provide a convenient method to deliver, store, and organize large number of specimens.

STANDARDIZATION

Standardization groups such as the National Committee for Clinical Laboratory Standards (NCCLS) the American Society for Testing and Materials (ASTM) as well as the Institute of Electrical and Electronic Engineers (IEEE) are all working on standards that will impact the clinical laboratory (11). Laboratories have specific needs as well for developing standards for specimen containers, carriers, caps, bar codes, and many other features of the analytical process. Similarly, standards need to be created for automation systems.

Modular automation devices cannot achieve their true market potential until they can be linked in a vendor independent manner. There is the reality that the adoption of standards will reduce some of the competitive features of vendor's products. Ultimately, standards benefit not only the customer as well as industry because they improve the efficiency of the laboratory by reducing labor costs. Reduction in costs should increase demand for analytical systems and automation.

THE DISTRIBUTED LABORATORY

Modern concepts of laboratory automation are moving away from the highly efficient, centralized, automated laboratory. Even with the highest level of efficiency, the cost of packaging, transporting, and unpackaging the specimen will ultimately become the most expensive part of the information generation process. Steps that do not add value to the diagnostic process will soon be eliminated. Point-of-care and rapid response laboratory technology will provide the necessary sample analyses at the patient bedside. The majority of data

interpretation, tightly coupled with a quality control system, will be performed using software built into the analyzer. Final results (and especially exceptions to normal data) will be sent via the Internet to a professional for interpretation. A distributed laboratory has already been installed at The University of Virginia (12) and is reducing the cost of centralized testing by 50% (13). When one examines the most frequently ordered laboratory tests against the tests currently available at point-of-care it is not difficult to imagine that it may be more cost effective to perform high volume routine testing at the point-of-care. This is true especially when one considers that point-of-care testing costs half of centralized testing (13,14).

CONCLUSION

There is a recent trend to consolidate as much of the laboratory testing as possible in core centralized laboratories. However, with the rapid proliferation of new sensor technologies suggest that 80% of laboratory testing will soon be performed at the patient bedside within the next 5 years. Certainly, centralized core laboratories are

not going to disappear. In the future, centralized laboratories will house the center of information management, process control, and esoteric testing. Therefore, in order for laboratories to remain competitive in the marketplace through the end of this century and into the next, previously unachievable levels of efficiency will be mandatory. Clearly, automation and robotics will be a key survival tool for the esoteric core laboratory. What sets automation technology apart from so many other efficiency solutions are dramatic savings that automation brings to the clinical laboratory. Proper standardization that will allow vendor independent modular configurations will assure success of this revolutionary new technology.

ACKNOWLEDGEMENTS

I wish to thank David O'Bryan for providing data on the TLA market. Organon Teknika (Boxtel, The Netherlands) for providing grant support for the modular automated coagulation workcell project. ADVIA® and LabCell™ is a registered trademark of Bayer Corporation.

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FIGURES

WORLDWIDE INSTALLED BASE OF TLA

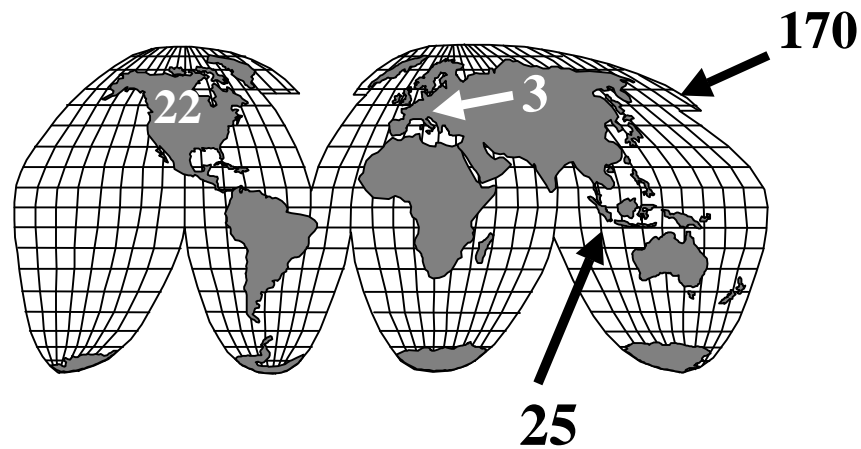


Figure 1

Figure 1. The installed base of TLA throughout the world is shown by continent. Japan has approximately 107 installed systems (presented by Dr. Kawai at the 1st Cherry Blossom Symposium, Kochi, Japan), 25 systems in the Pacific Rim, 22 in North America and 3 systems in Europe. The European systems are either already installed (University of Leiden) or soon to be completed.

TOTAL LABORATORY AUTOMATION

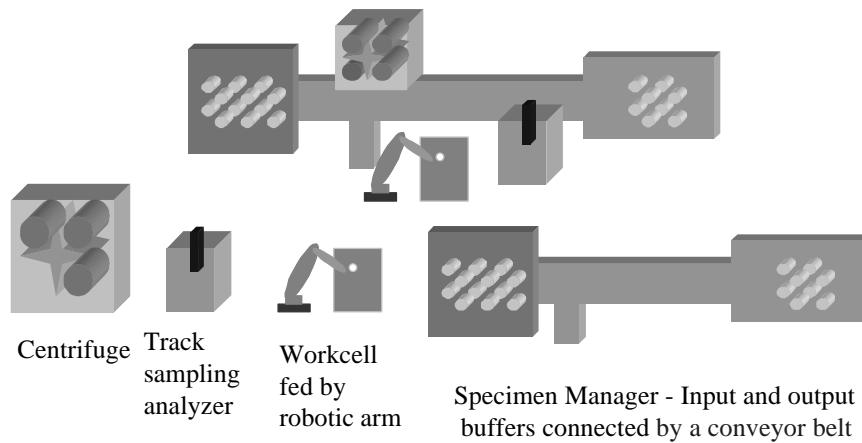


Figure 2

Figure 2. A total laboratory automation system (TLA) is a custom-designed combination of devices that perform most of the pre-analytical and analytical tasks in the laboratory. Specimens may be either sampled directly on the track by a track-sampling analyzer, or removed by a robotic arm to be placed into an analyzer. Samples are transported from the input buffer to the output buffer via conveyor belt.

THE AUTOMATED WORKCELL

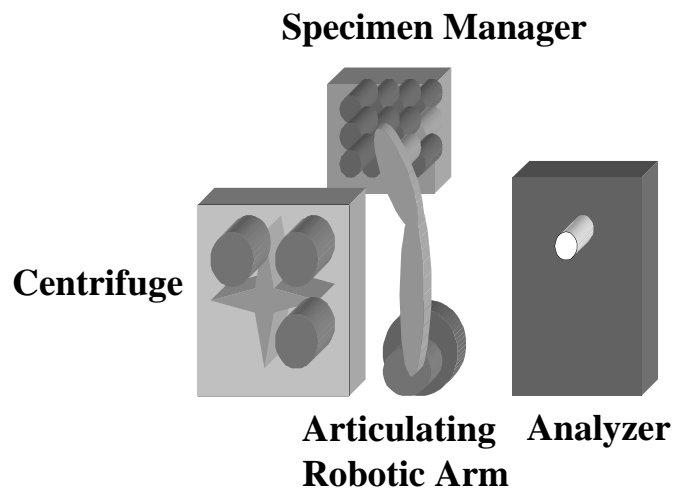


Figure 3

Figure 3. An automated workcell consists of a specimen manager, centrifuge (if required), mechanical manipulator (usually an articulating robotic arm), and an analyzer.

MODULAR ANALYTICAL WORKCELL

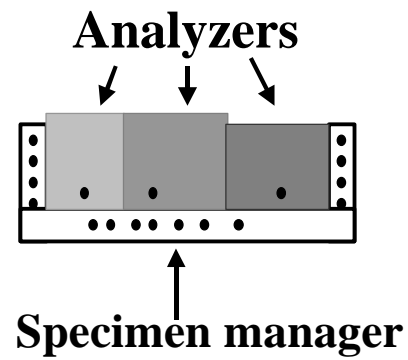


Figure 4

Figure 4. A modular workcell is usually designed by one vendor to operate in a fully integrated fashion. The specimen manager wraps around the front (or back) of the analytical modules that are designed to operate optimally as automated instruments.

MODULAR PREANALYTICAL WORKCELL

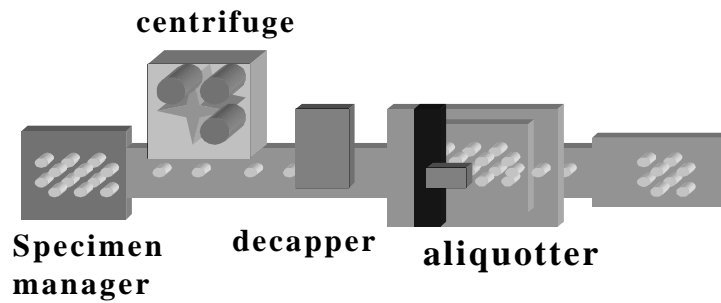


Figure 5

Figure 5. A modular pre-analytical workcell is configured with mechanical devices that perform most of the specimen preparation tasks that are required prior to analysis. Specimens are loaded into an input buffer in the specimen manager, centrifuged, decapped, aliquoted (if necessary), and stored in an output buffer. Properly designed, the modular pre-analytical workstation could also be interfaced directly to an analytical workcell.

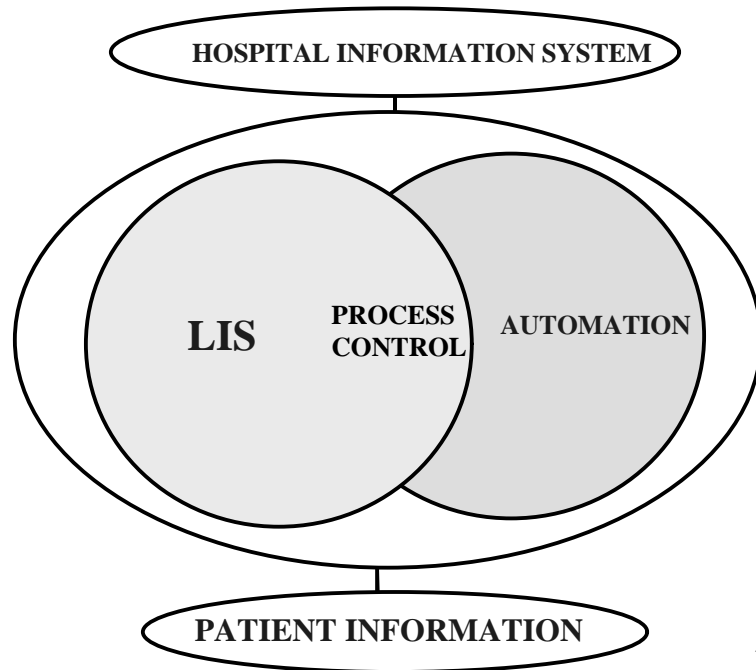


Figure 6

Figure 6. The complexity of laboratory information systems is adapting to the increasing input and output needs of an automated laboratory. Patient demographics are provided by manual input into the database of the laboratory information system (LIS) and hospital information system. Process control software regulates the function of the automated systems by storing and manipulating knowledge about system performance and status. Thus process control is a fundamental necessity for a successful automated system.

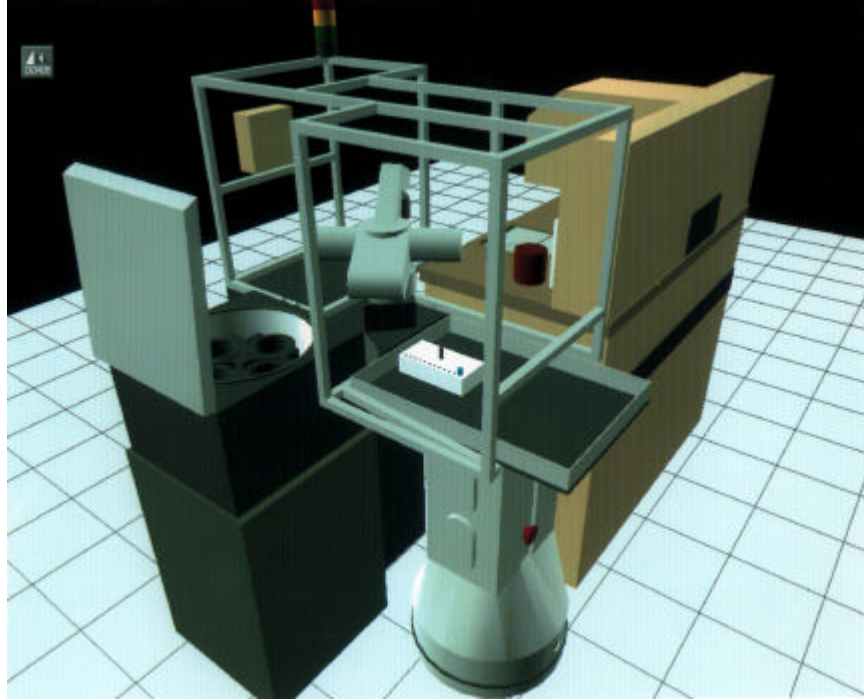


Figure 7. A hypothetical modular workcell was created in our automation center using 3 dimensional computer simulation. The Bayer LabCell platform is coupled a coagulation workcell using the MDA-180 (Organon Teknika, Boxtel, The Netherlands) that includes an automated centrifuge to achieve a throughput of at least 130 specimens per hour. Specimens may be delivered to the system either manually (not shown), or via the LabCell conveyor belt.

THE ORGANIZATIONAL PLAN FOR THE LABORATORY OF THE FUTURE

CORE LABORATORY

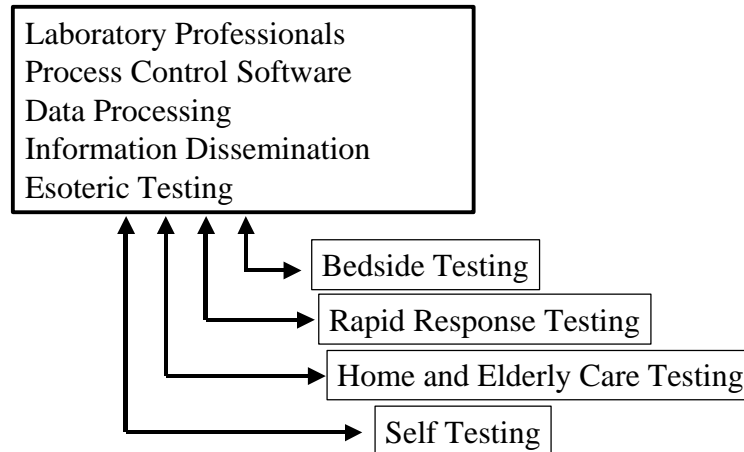


Figure 8

Figure 8. This figure shows the organizational plan for a laboratory in the future. The core laboratory, staffed with professionals, will perform the key role of disseminating information in a timely manner to physicians and patients.

In addition, the core laboratory will most likely be the site of esoteric testing. However, the majority of laboratory testing will be distributed throughout the hospital, clinic, and community.

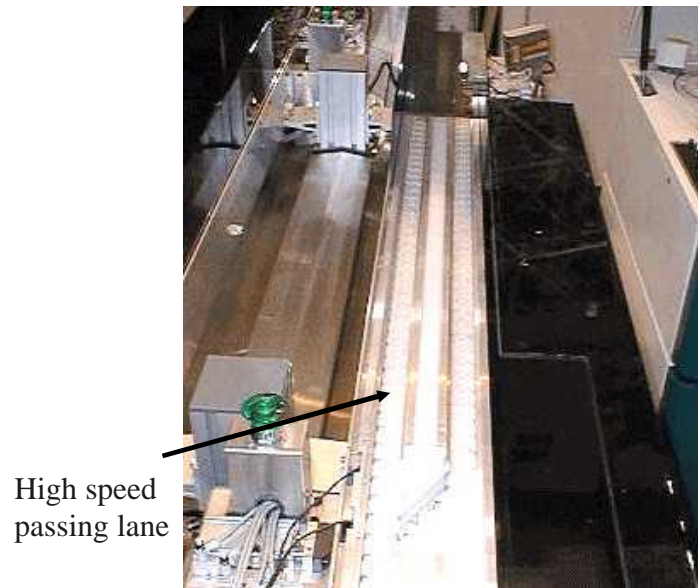


Figure 9

Figure 9. The Bayer LabCell employs the use of two conveyor lanes for the basis of non-linear processing. The high-speed lane allows specimens to bypass instruments. The low speed lane acts as a buffer to queue specimens prior to analysis.