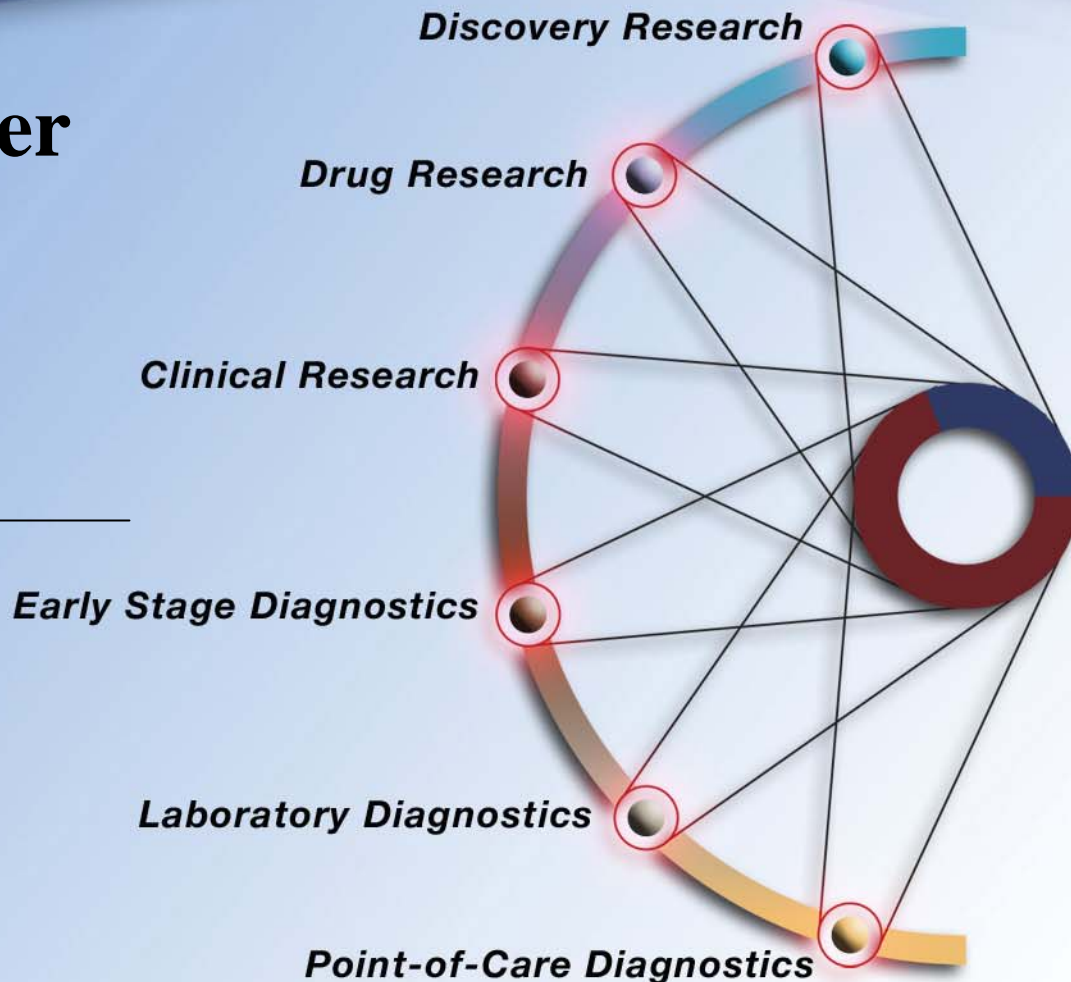


*Why a Diagnostic and Life Sciences Company  
is Interested in Middleware*

# Beckman Coulter Spans the Biomedical Testing Continuum



## What is Middleware?

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- Software interface between analytical instruments/software and LIS/HIS
- Enables technologists to control multiple lab processes
- Enables clinical labs to consolidate test info
- Allows samples to be followed in real time as they move through the lab
- Alerts technologists to important sample info
- Organizes exceptions and pending results for quick review
- Allows more global view of patient by accessing data from multiple instruments (e.g. chemistry, hematology, and coagulation)



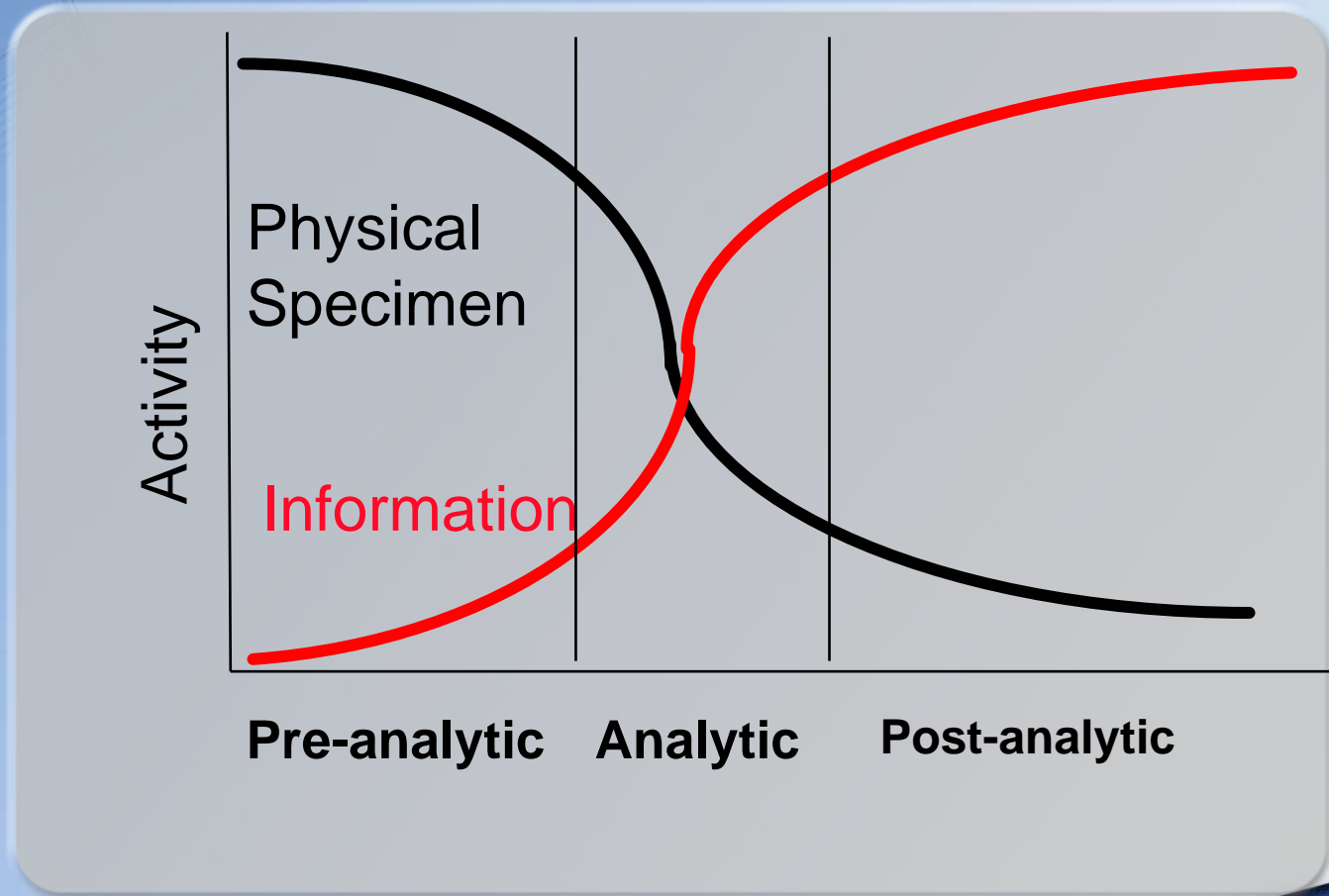
## Beckman Coulter Middleware Solutions

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- DL2000 Data Manager (North America)
- Remisol 2000 Data Manager (outside North America, from Normand Informatique)
- DM Family of Solutions by TC Soft (Asia)



# The Testing Process by Activity Level



## Economic Factors Driving the Need for Automation/Middleware

- Competitive pressures
- Demands to reduce costs while increasing test volume
- Growing populations of uninsured patients
- Inadequate reimbursement for services
- Persistent shortage of laboratory techs (thus, the need to do more with fewer people)

*Automation and middleware*

*reduce costs, reduce labor needs, increase revenues, and streamline operations*

## JCAHO and Patient Safety

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- JCAHO doesn't endorse specific technologies

***BUT...***

- Its patient safety goals are much easier to achieve when automation/middleware are implemented
- JACHO does want institutions to optimize patient safety. Optimal patient safety can only be achieved with automation/middleware

## **For Example:**

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### ***JCAHO 2006 Laboratory Services National Patient Safety Goals for Critical Values***

#### ***Reporting:***

- 2C — “Measure, assess and, if appropriate, take action to improve the timeliness of reporting, and the timeliness of receipt by the responsible licensed caregiver, of critical test results and values.”

## JCAHO Goals

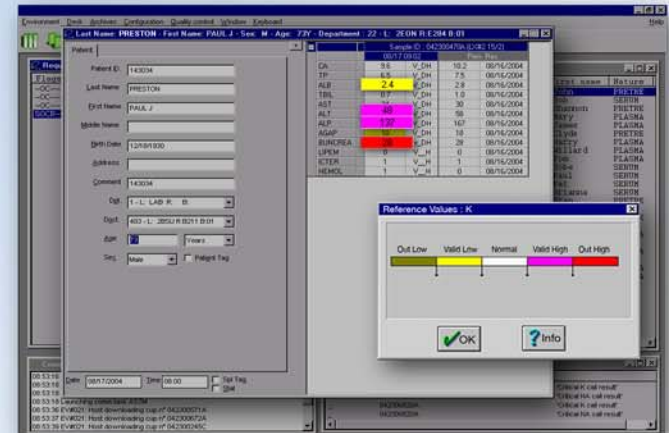
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- 2D – “All values defined as critical by the laboratory are reported to a responsible licensed caregiver within time frames established by the laboratory. ... When the patient's responsible licensed caregiver is not available within the time frames, there is a mechanism to report the critical information to an alternative responsible caregiver.”
- 2E – “Implement a standardized approach to ‘hand off’ communications, including an opportunity to ask and respond to questions.”

## *This is How Beckman Coulter Middleware Meets JCAHO Goals:*

### *DL2000/Remisol 2000/DM Family:*

- Notifies users of critical results – according to user-defined rules – with pop-up screens and brightly colored charts so no critical results are overlooked
- Informs tech of proper, user-defined protocol to follow when a critical value occurs
- Provides contact info so proper clinician can be notified
- Provides space to log time message was delivered and name of recipients



*Non-computerized, human-based alert and reporting systems increase likelihood alert systems will fail*

***“Data from the risk management literature suggest that failure to follow up on abnormal test results is a common problem and a frequent cause of medical malpractice lawsuits [emphasis added].”***

- 25% of providers have no reliable method for making sure that they received the results of all tests they had ordered.
- 36% did not always notify patients of abnormal test results

*Studies by Pinckney et al. and Schiff et al:*

***“Patients with abnormal mammograms, elevated thyroid stimulating hormone levels, and abnormal serum potassium levels failed to receive the appropriate follow-up, which leads to potentially life-threatening outcomes [emphasis added].”***

*Peter Cram, M.D., MBA et al, Joint Commission Journal on Quality and Patient Safety. Feb. 2005.*

## **Another Driver for Middleware: Reducing Medical Errors**

*Reducing medical errors is about patient safety and efficiency.*

*Findings of a survey of sicker adults in six industrialized countries:*

- One-third of US patients reported medical, medication, or lab errors
- Lab errors significantly higher in US than the other five countries
- One-third of US patients reported that test results were not available at MD appointments or MD-ordered duplicate tests
- US often stood out for higher medical error rates and less efficient care

*Schoen, Osborn, et al; "Taking The Pulse Of Health Care Systems: Experiences Of Patients With Health Problems In Six Countries"; Health Affairs Web Exclusive; 11/05*

## The Cost of Medical Errors in the Lab

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- 25% of lab errors harm patients
- 25% of errors lead to higher costs (inappropriate investigations or inappropriate care)

*"Mistakes in a Stat Laboratory: Types and Frequency," Clinical Chemistry, 1997*

# Patient Safety and Error Reduction Benefits of DL2000 et al

## *Patient misidentification alerts*

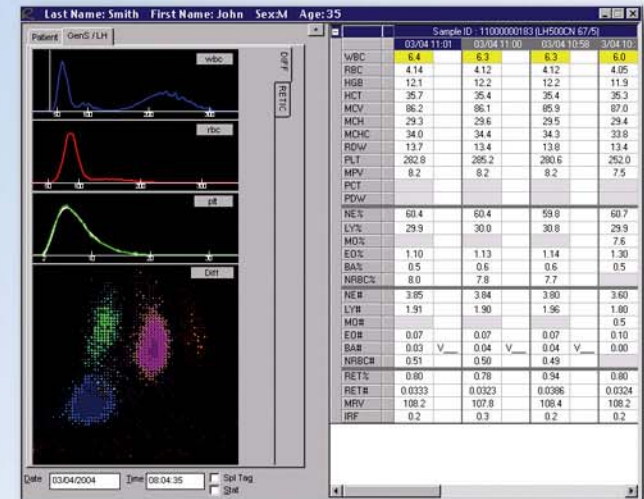
**Function:** Alerts tech when patient ID number has been used on another patient

**Impact:** Eliminates patient ID errors

## *Delta checking*

**Function:** Compares current result to past results, alerts tech to significant changes in results

**Impact:** Helps identify erroneous results.  
Helps techs make better decisions about the disposition of results



## **DL2000 Safety Benefits**

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### *Autovalidation*

**Function:** In tandem with LIS, handles automatic validation and reporting of normal results, according to user-defined rules

**Impact:**

- Shifts massive workload from techs to automation system
- Enables staff to do higher-quality work on manual tests
- Minimizes errors on validation and reporting of normal results
- Improves lab's TAT for results
- Speeds diagnosis and treatment by physicians

## DL2000 Safety Benefits

### *Exceptional data event alerts*

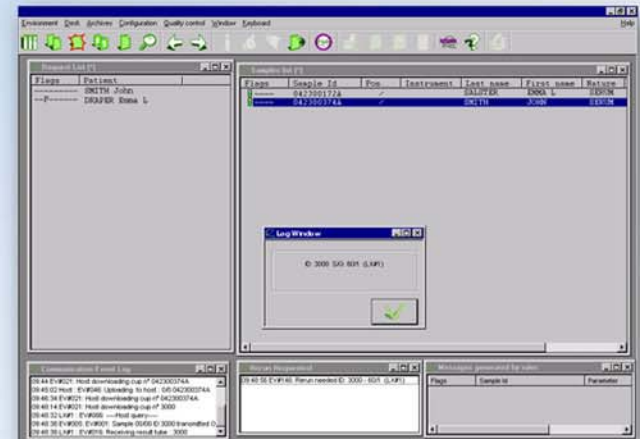
**Function.** Software “decides” if a data event requires human review or intervention.  
Also instructs tech on protocol

**Impact:** Helps staff better manage manual review process and minimize related errors

### *Add-on testing*

**Function:** Integrated with automation system, DL2000 sees a new test request, finds sample, directs sample to be placed back on the track and tested, and autovalidates and reports the result, usually without tech intervention

**Impact:** Allows MD to receive add-on tests from already collected specimens ASAP



## **DL2000 Benefit Summary**

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- Takes over tasks from error-prone humans
- Reduces stress on lab staff, which improves their focus and quality of their work
- Provides sophisticated, reliable tools to manage and respond to lab data



***“It’s a fact of life that no human being is going to do the same task the same way and at the same speed every single time. The speed, accuracy, and consistency of middleware like DL2000 make a world of difference to patient safety.”***

*Kenneth E. Blick, Ph.D., ABCC, NACB, Director of Clinical Chemistry, Oklahoma University Medical Center*

## **Keeping Up with the Healthcare IT Trend**

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*Info technology and robotics are remaking the way healthcare is delivered worldwide*

### **Current systems:**

- Improve institution's capacity and staff productivity
- Speed exchange of crucial info among caregivers
- Dramatically reduce human errors
- Facilitate nationwide sharing of patient-specific info, in line with US policy to create a national healthcare IT network

*“Hospitals need to move from focusing on just what’s going on within the four walls of the lab and more on how lab-based diagnostic testing improves patient flow throughout the whole organization.”*

Leslie Wainwright, VP, Sg2., a leading healthcare consulting company.

## Emergency Department

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- EDs help hospitals increase volume of paying patients. Many compete on basis of faster ED service
- Logjams tie up resources, interfere with normal operations, cause diversions to other hospitals, and harm reputation with patients and physicians



## Emergency Department cont.

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**Fact:** For each percent of lab results that miss a TAT target, length-of-stay in the ED increases 3-7 minutes. Without automation/middleware, significant % of outlier results (e.g. > average TAT) is inevitable

**Fact:** To create space for new patients with serious conditions, you have to free up beds. But you can't do that without lab data confirming that it's safe to send a patient home

### *For hospital to compete:*

- *Minimize outlier test results*
- *Optimize critical values reporting and overall TAT*
- *Only possible with automation and sophisticated middleware*

## Information Onslaught–

# *The Future is Now for Molecular Diagnostics*

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- Researchers have fully sequenced 120 bacterial and viral genomes, working now on dozens more
- Vast amount of data is being utilized for diagnostic tools, creating the new discipline of molecular diagnostics
- The Joint Genome Institute's Production Genome Facility (US Dept. of Energy) *alone* generates about 2,000 gb of data per month

*The Future is Now for Molecular Diagnostics cont.*

## **The Molecular Diagnostics market**

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- Sg2 predicts that all hospitals will need to perform molecular testing *within two years*
- Molecular diagnostics market – about \$6.5 billion today – expected to expand to \$12 billion by 2010 and \$35 billion by 2015

*How will labs efficiently manage all this new info?*

*Middleware has to be part of the solution*

# The Biomedical Testing Market = \$40 billion

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## *Biomedical Research*

Laboratory automation  
Genomics  
Proteomics  
Cell research  
Centrifuges  
Analytical instruments  
Flow cytometry  
Molecular diagnostics  
Biopharma solutions  
+ Industrial solutions  
**\$14 billion**

## *Clinical Diagnostics*

Automation and information systems  
Clinical cellular analysis  
General chemistry  
Hematology  
Immunodiagnostics and proteins  
+ Primary care  
**\$26 billion**

## **Where is the lab's role in all this? Almost everywhere.**

### **The clinical lab:**

- Equals 5% of a health system's costs *BUT* affects 95% of the remaining costs
- Contributes more than 80 percent of objective data to the clinical record
- Influences 60-70 percent of critical decision-making about patients

Rodney Forsman, *Clinical Laboratory News*, July 2004

## Conclusion

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There is an onslaught of data being generated

- Used for patient-care decisions
- Recordkeeping and reporting requirements

All this data must be put into a usable format:

- For efficient, accurate payment
- For regulatory reporting

And for the PRIME reason –

- For the PATIENT
- In the form of a final, clinically useful, diagnostic answer

*You'll need middleware in the middle*

*Thank you for your kind attention*