

CUSTOMER SUCCESS STORY

Autoverification for Hematology

For Santa Clara Valley Medical Center's Laboratory Hematology Department, an investment in new hematology analyzers and a laboratory information system was just the beginning. After adding autoverification with Data Innovations[®] Instrument Manager[™], the laboratory increased value to its patients by automating a manual, time-consuming, and resource-intensive process.

> "Autoverification is the best thing that has ever happened to us - especially for routine tests," - Helen Ferrer, Hematology Supervisor



Facts at a Glance

Santa Clara Valley Medical Center

- Public health hospital with nearly 500 beds
- Serving Santa Clara County, California, for more than 140 years
- Trauma Center, Burn Center, Hematology-Oncology Clinic
- Children's Health, Women's Health, Diabetes Care, Rehabilitation Services
- 600-bed acute care facility

Santa Clara Valley Medical Center Laboratory Hematology Department

- Performs 88,000 monthly tests including 18,000 in hematology
- Epic Beaker Laboratory
 Information System
- Sysmex XN-3000 hematology analyzer, SP-10 automated slide maker / stainer, and CellaVision DM1200 image analysis
- Data Innovations Instrument Manager middleware for hematology autoverification

About Santa Clara Valley Medical Center & Laboratory Hematology Department

Santa Clara Valley Medical Center (SCVMC), located in San Jose, California, has served Santa Clara County patients for more than 140 years. With nearly 500 inpatient beds, SCVMC includes trauma and burn centers as well as a comprehensive hematology-oncology clinic. The centers of excellence also offer specialized care for children, women, diabetes and patient rehabilitation.

SCVMC Clinical and Anatomic Pathology Laboratory performs more than one million tests annually. In addition to inpatient diagnostic services, it is also a key reference laboratory for outpatient clinics and community hospitals throughout northern California.

The SCVMC Laboratory Hematology Department, staffed by 30 employees, performs more than 18,000 CBCs with hemogram tests monthly on Sysmex[®] XN-3000[™], Sysmex SP-10[™] automated slide maker/stainer and CellaVision[®] DM1200 digital morphology analyzers. Analyzers connect with Epic Beaker[™] laboratory information system using Data Innovations'[®] Instrument Manager[™] system.

Key Challenges: Manual Processes, Resource Limitations, Test Turn-around Time

Following the purchase of hematology analyzers and the implementation of Beaker, the timing was appropriate to turbocharge workflow productivity through the introduction of autoverification. Autoverification augments medical technologist efficiency by using user-defined, rules-based logic to verify laboratory test results with precision, accuracy, and consistency.

Challenges were:

<u>Manual Processes</u>: Before autoverification, medical technologists used instrument result printouts to confirm information in the LIS. This required manual analysis and approval of hundreds-of-thousands of results every year as well as a dependency on paper.

"One-by-one, 100% of our hematology tests were manually verified and what we wanted to do was focus on the positives. Those are the ones that needed attention," said Helen Ferrer, Hematology Supervisor.

<u>Staff Coverage Limitations</u>: Like organizations worldwide in the clinical laboratory industry, the SCVMC Laboratory Hematology Department has felt the impact of a staffing shortage particularly during heavy workload periods, lunch hours, and off-shifts.

<u>Routine Specimen Turnaround Time (Routine TAT)</u>: Manual analysis and verification consumed disproportionate amounts of key staff time, causing a delay in routine diagnosis and potentially lengthier hospital stays. TAT was not meeting standards even with department leadership working the bench during peak volumes and taking time away from their administrative responsibilities.

Something had to change ...and it did.

Solution: Autoverification with Data Innovations' Instrument Manager

As part of a research effort, the Hematology Department turned to case studies and peer-reviewed papers to better understand the process towards autoverification and potential outcomes.

During this vetting process, several alternatives were explored including solutions provided by the hematology analyzer vendors. The Hematology Department ultimately selected Instrument Manager (IM) for these primary reasons:

• Robust autoverification functionality (compared to others considered);

• The possibility of adapting rules to the laboratory's unique workflow and not the other way around.

Instrument Manager, for more than 25 years, has been empowering laboratories worldwide to adapt to major forces impacting healthcare.

When asked about what makes IM different, DI customers often comment about its robust and flexible rules engine, which is used to overcome the most challenging workflows in thousands of laboratories worldwide. The rules engine provides hundreds of patient, specimen, and test data elements and actions that can be used in various permutations to handle the most complex decisions for autoverification. The system is designed so you can develop and deploy rules for today's challenges and evolve as your laboratory needs change.

On the connectivity side, DI partners with instrument suppliers and LIS software companies, including Epic, to develop drivers with intelligent and dynamic integration that help laboratories adapt to and mitigate the impact of change, such as instrument and LIS replacements, laboratory expansions, consolidation, and standardization initiatives.

But what did all this mean for the Hematology Department?

Implementation: Getting Started with Autoverification at SCVMC

An interactive process involving DI experts and the laboratory team commenced. First, a DI laboratory solution consultant (DI consultant) visited the laboratory three times. The purpose was to observe the lab's workflow and to discuss desired outcomes and requirements to achieve hematology autoverification.

SCVMC Laboratory Hematology Department staff and the DI consultant reviewed instrument capability, processes, LIS requirements, and more. They noted STAT and routine test workflow; smear review and reflex testing criteria, and handling of digital instrument images, among other areas.

Utilizing Santa Clara's requirements and extensive experience, a DI consultant designed customized rule sets and tailored user screens for their specific workflow requirements and industry best practices. The rule sets included automated hold and release criteria for technologists' evaluation of blood smears with slide images. Based on the laboratory's standard operating procedures (SOPs), specific workflow instructions on handling each of many abnormal scenarios were also created and displayed to the technologist at the time of review to standardize outcomes and efficiency.

"Our workflow is very, very special. DI recognized that and identified our needs and customized the rules for our laboratory."

- Helen Ferrer, Hematology Supervisor

Simulated technologist review workstations were setup about one month before go-live which gave the technologists a chance to practice the new workflow before handling live patient results.

Also, SCVMC super users attended classes at the training center in South Burlington, Vermont. Learning content included basic operations, instrument identification mapping, system troubleshooting, design, creation and validation of rules, among other topics.

"We wanted them to feel comfortable in this new environment because it is completely different from what they were used to."

- Linda Nguyen, Assistant Hematology Supervisor

The team set the following goals for hematology autoverification:

- Customize autoverification rules based on the DI analysis of the Hematology Department workflow;
- Standardize work processes for technologists to follow;
- Standardization of results (information) production across organization regardless of instrument or LIS vendor;
- Obtain laboratory management approval on flagging limits on the XN-3000;
- Establish a process to rapidly disable autoverification, if necessary.

Soon after go-live, the benefits of IM hematology autoverification became clear.

Results: Customized Rules, Accurate Autoverification, 83% Tests Autoverified, Laboratory Efficiency

Instrument Manager operating in conjunction with Sysmex and CellaVision instruments and Epic Beaker LIS, made possible these outcomes for the Hematology Department:

Custom rule set: It's a new world for test verification due to these robust rules, created by DI especially for SCVMC Laboratory Hematology Department:

Results flagging and smear: In this impactful rule, IM criteria recognizes that a blood smear review is necessary based on specific results and/or flags. Then, a slide is made on the SP-10 automated slide maker for examination by technologists.

Platelet count fluorescent (PLT-F) reflex and resulting: The rule set leverages the laboratory's new technology using PLT-F technology.

Delta checking: The comparison of previous values within a specific time horizon becomes especially important to various

combinations of platelet results.



www.datainnovations.com Doc ID: DATAINN-728876664-798 I Version 4.0 *Nucleated red blood cells (NRBCs) calculation:* The laboratory's proficiency in performing >100 cell differential is enabled by IM.

Pathology review: Implement specific and automatic secondary review by a pathologist with a date and time stamp.

Accurate autoverification: IM draws attention to abnormal results requiring technologists' review and enables normal results, which staff previously and tediously reviewed using paper, to be made immediately available to providers.

"Our technologists can focus on the true abnormals and other non-automated tests."

Custom screens and standards guide the laboratory team: Now, computer screens guide technologists in abnormal result decisions. DI's user-friendly technology makes it possible for them to view custom screens displaying SCVMC-specific color coding (for example, red stands for critical results, and green for results already reviewed and released, to name just a couple of examples). Specific work SOP-driven instructions are included with all abnormal results. This gives even the least experienced technologists confidence that abnormal results are being appropriately handled. Prior to launch of IM, steps taken on abnormal results may have differed by individuals and shifts.

"Now, they have instructions about what they definitely need to do and everyone is doing the same thing," Helen said.

Achieved 83% autoverification rate: We now autoverify 83% (or about 15,000) of hematology tests each month. About 3,000 monthly tests (i.e. "abnormals") are manually verified. Prior to implementing IM, 100% of hematology tests were manually verified by several technologists. As time goes on, the rules can be enhanced by the designated user(s) to continue to increase that level of autoverification.

"Results are readily available for physicians; especially inpatient test results. This is important to a timely discharge and we are getting less calls to the labs and less pressure."

Reduced TAT for negative test results: Normal test results, not held for review, can be reported faster to physicians. Turn-around time (TAT) for 83% of the patients is mere seconds where before TAT may have been 15 minutes to one hour—depending on availability of the technologists. Before the launch of autoverification, TAT for normal CBCs was 52 minutes, which included manual reviews. With autoverification, TAT for normal CBCs fell to 28 minutes; an incredible 46% improvement! *Resources are in harmony with workload:* Now, staffing per shift is adequate since the Hematology team is empowered with autoverification. This has significantly reduced overtime.

Paperless workplace emerges: Through elimination of the manual processes, IM middleware made possible a new paperless hematology workflow. Now, there are minimal, if any, printouts and fewer results to manually release.

Staff satisfaction increases as stress is reduced: The new automated workflow has alleviated workplace pressure and made way for new assignments. After technologists load specimens on the analyzer, other challenging duties are pursued. They pick up positive results, held by IM, addressing STATs and critical results immediately.

"Our technologists are less stressed. They don't feel intimidated when they come in the laboratory and see racks of specimens - especially on the PM shift or after the morning (patient) draws. They know most of them are going to be autoverified."

Leadership focused on quality: Leaders concentrate on strategic responsibilities such as quality assurance, technology evaluation, and new business opportunities. They no longer need to backfill bench workflow.

The results compelled the Hematology Department to do even more with IM.

Empowered SCVMC Laboratory Team Takes Next Steps, Plans for More Autoverification with DI

Through its implementation philosophy and continuing education (webinars, regional and onsite training) and 24-7-365 critical support, DI empowers customers to independently maintain and expand autoverification.

Since the hematology autoverification project went live, Hematology super users autonomously changed Delta ranges; added rules to accommodate retic add-ons calculation and smear order for newborns (under oneyear old); and edited rules to accommodate unexpected scenarios.

As for their current plans, the SCVMC Laboratory is engaging DI again for autoverification - this time for



Left to right: Yanu Yang, Marizza Nobida, Joanna Santos, Mark Payne (LIS), Tina Garcia (LIS), Dat Bui, Linda Nguyen, Helen Ferrer, Kristina Garma (LIS)

D Data Innovations

www.datainnovations.com Doc ID: DATAINN-728876664-798 1 Version 4.0 its Roche Diagnostics chemistry analyzers and for coagulation instruments.

Santa Clara leaders, enthused about their work with DI, are quick to advise their hospital colleagues, contemplating autoverification, to:

- Visit a laboratory and observe its autoverification technology;
- Have a firm grasp on the laboratory's day-to-day workflow as well as the unique and specific scenarios that need to be sufficiently accommodated by the rule set;

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"Test, test, test. Give your staff adequate time for training. Have them run through and practice using the system. Autoverification is the best thing that has ever happened to us - especially for routine tests."

- Kristina Garma, CLS, LIS

About Data Innovations

Founded in 1989, Data Innovations[®] (DI) is the world's largest and most successful clinical and blood laboratory middleware company. With a focus solely on laboratory data management, DI offers the most complete middleware system in the market to manage laboratory operations—including pre-analytical, analytical, and post-analytical sample processing, and on-clinical tasks such as equipment maintenance and specimen archiving.

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