

Transforming fertility treatment through streamlined processes at Examen

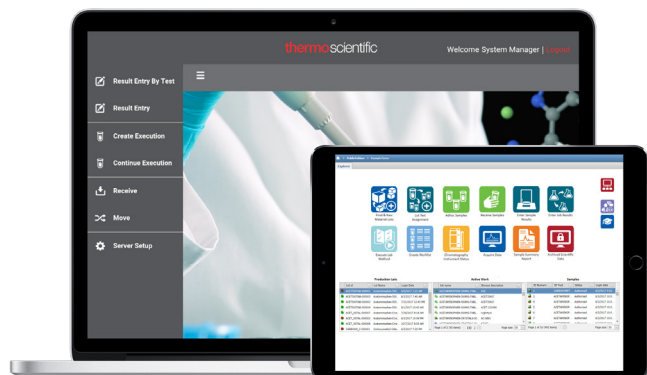
For people struggling with fertility issues, timing can mean everything. From the age at which an individual seeks intervention to the days on which treatment occurs, timing is one of the most crucial factors in fertility treatment. Fertility specialists encourage patients to follow meticulously planned timelines to optimize the chances of success. As a result, fertility specialists must rely on their suppliers and business partners to deliver their products and services on time.

As a company trying to improve the odds for fertility patients, Examen understands the importance of promptness. Examen is a growing diagnostics company focused on transforming the diagnosis and treatment of male reproductive issues. Based in Belfast, Northern Ireland, Examen was founded by Professor Sheena Lewis, PhD, FRSB. The company started as a spin out from Queens University in Belfast. Examen was set up in response to public demand for its sperm DNA fragmentation test, the SpermComet®.

SpermComet was developed following more than twenty years of research into better tests for male infertility and treatment. The test measures DNA damage in sperm, which can affect a couple's ability to have a healthy baby. Examen believes the test, coupled with a semen analysis, gives a complete picture of sperm health and a better prediction of fertility treatment success. The data helps couples make informed decisions about in vitro fertilization (IVF).

Like many growing laboratories, Examen encountered difficulty scaling its processes to meet growing demand. Alastair Sloan, Laboratory Technician at Examen, recalled the struggle to handle increasing sample volume. "When I started at Examen, there were only two other technicians in the lab," Alastair said. "Our sample receipt and report generation processes were very manual. There was a lot of manual paperwork, but we could cope with it. We had to make each report individually and send it out to the customer."

Within the last year, Alastair and his colleagues noticed a change in their laboratory workload. "Things have just exploded! We've had more samples coming through the door, and with everything being manual, it was impossible to get any work done," Alastair admitted. The tipping point for Examen was when the laboratory experienced a 27 percent spike in sample volume. Between the sample volume increase and the manual processes, Examen knew it was time for a change.



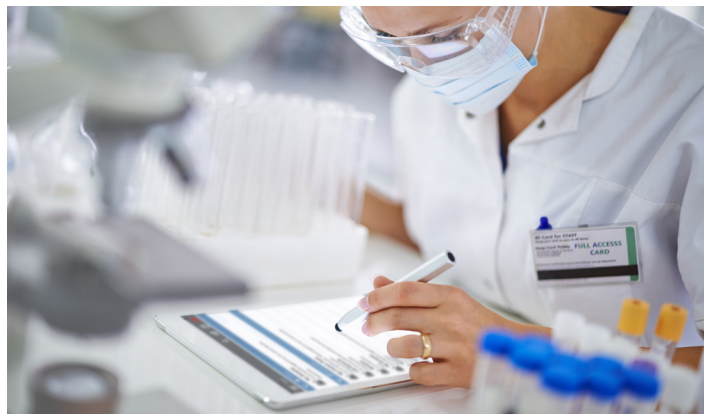
Choosing a LIMS

Examen knew a Laboratory Information Management System (LIMS) would improve their operational efficiency. The company needed a partner to help guide the implementation process, highlighting all the potential benefits of a LIMS. The company chose to partner with Thermo Fisher Scientific.

As part of Examen's LIMS search, the laboratory took a closer look at its operations and established some benchmarks. It found that laboratory technicians were spending 60 to 90 minutes each day on sample receipt. Data for each sample processed in the laboratory was stored in 3 to 4 different places, often copied and pasted from one Microsoft® Excel® spreadsheet to another. Once the testing was complete, the technicians spent 2 additional hours generating reports for customers. In total, Alastair estimated the laboratory spent 3 to 3.5 hours a day doing paperwork. "It felt like we were wasting time that we could have been using to make our test better."

Examen feared that increased demand and inefficient processes could impact turnaround time. Physicians ordering the tests expect to have the results promptly and patients need their results in time for scheduled consultations. Any delays in finishing the reports could adversely affect the patient's experience and the doctor's reputation. In addition to the manual processes, the laboratory testing is a complex and lengthy process making rapid turnaround even more difficult. The SpermComet test takes 7 hours to complete - after 60 to 90 minutes of sample registration and 7 hours of testing, the technicians would often run out of time to complete the reports on the same day as the tests. In these cases, the reports would wait until the following day and during busy weeks, reports might wait until Friday for completion. Delays in reporting not only risk customer satisfaction, but also data integrity. If the technician made observations during the testing process, those observations could be lost by the end of the week.

Aside from the time required, Examen also considered the risk associated with the manual processes. Manually entering results data into reports introduces the possibility of human error. Manually copying and pasting data between spreadsheets can also be error-prone, especially on days of high volume. As the company pursued ISO 9001 certification, it knew data integrity had to be improved.



Implementing Thermo Scientific SampleManager LIMS software

After selecting Thermo Scientific™ SampleManager LIMS™ software, Examen worked with the Thermo Fisher LIMS services team to define the scope of the project. A critical step to ensure the success of any LIMS deployment is to establish an internal product owner. Being a start-up company with a fast-paced laboratory, it was difficult to find resources to dedicate to a LIMS project, but Examen understood the importance of the role and chose Alastair. The product owner is responsible for the design and implementation of the system and works closely with the Thermo Fisher technical lead throughout the design workshops.

Having limited IT support or expertise in-house, Examen opted for an Infrastructure as a Service (IaaS) approach, hosting the system on the cloud with Amazon Web Services (AWS). The cloud deployment helped Examen avoid a large expenditure on hardware and the challenges associated with managing the system themselves. The Thermo Fisher LIMS services team provided support in requesting the server set up with AWS and recommended architecture, including a solid disaster recovery plan to meet Examen's needs.

With the architecture decisions made, the team shifted its focus to system design. The team streamlined and automated laboratory processes. Looking to maximize efficiency, Examen took a very pragmatic approach to their LIMS implementation, adapting their processes to optimize the results. The sample transport and registration and results reporting processes were revamped. Instruments were connected to the LIMS, expediting result reporting and reducing human error. Management of stocks and standards for gel processing was configured into the system, and data archival was established using the SDMS integrated within SampleManager LIMS software. Finally, reports were created to track KPIs and operational efficiencies, to provide Examen with a complete picture of their lab workflow.

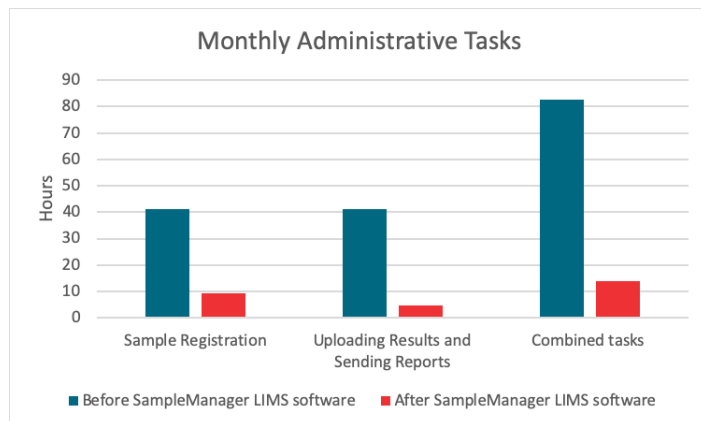
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– Alastair Sloan, Laboratory Technician at Examen

“Working with the Thermo Fisher LIMS services team on our project was a pleasure and was a key part of our project’s success,” Alastair said. “The technical lead was attentive, experienced, knowledgeable, and always had workarounds for any issues or sticking points that arose. His focus was always on our requirements and he made sure each was met to a standard that we could accept for go live. His knowledge on AWS was also vital in the successful launch of our system.”

Better business and better science

Just one month after go-live, Examen already noticed significant time savings and increases in productivity. The biggest savings were realized in the sample registration and results reporting processes. SampleManager LIMS software helped Examen reduce their administrative effort on these processes from 82.5 hours/month to 13.75 hours/month. The results reporting process was cut from 41.25 hours/month to 4.5 hours/month.



The time savings on these tasks enable Examen to complete their reports on the same day as testing. The result is improved report turnaround time, reduced risk of missed data, and improved referring physician satisfaction.

The process of verifying whether tests were completed correctly was also automated. Prior to the LIMS implementation, Examen used spreadsheets to calculate variation between replicates of a sample.

The technician prepared each sample on two microscope slides and would score 50 cells on each slide. The results were entered for comparison, and if they were outside of 5 percent difference the analysis would need to be repeated. With SampleManager LIMS software, the measurements are automatically read directly from the microscope and compared against the limits and criteria defined in the LIMS. Out of specification results are highlighted and re-tests are automatically ordered, avoiding any delays.

In the near term, Examen is using the efficiency gains to focus more on its science. Instead of registering samples and creating reports, the company can continue improving its tests and building the business. “We’re constantly doing research to validate and improve the test and to grow our business. Saving 4 to 7 working days a month has a big impact for a small lab.”

Improved container management

The SampleManager LIMS software implementation helped Examen better manage its liquid nitrogen containers. These containers are a critical component of the Examen testing process, keeping the samples cold during their transfer to the lab. “Any delays in getting the samples back to the lab or issues with the temperature will make the samples unusable,” Alastair said. The canisters require calibration by Examen every two days. Previously, Examen relied on pen-and-paper logs to track the calibration. While the manual process worked, Examen sought a more automated process to handle its increasing sample volume and reduce the risk of error.

Now, Examen digitally manages canister calibration and maintenance using the built-in Instrument Calibration and Maintenance System (ICMS) in SampleManager LIMS software. The laboratory’s manual canister management process is now obsolete, with SampleManager LIMS software providing improved management of this crucial element of the testing process.

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– Alastair Sloan, Laboratory Technician at Examen

Integration and data integrity

SampleManager LIMS software also helps Examen operate under an ISO 9001 quality management system, ensuring data integrity. The LIMS connects to Examen’s microscopes, collecting raw data directly from the instruments. The data is parsed into the report within seconds, and the original raw data is maintained for audit purposes. The integration not only saves time, but also eliminates potential transcription errors. Examen can now approach quality audits with confidence. “Everything that happens from the time a sample comes in until the report goes out is tracked and captured in one system, making it a lot more streamlined and easy to locate data for audit purposes.”

Looking ahead

After the successful introduction to SampleManager LIMS software, Examen is already looking to the future. The company is planning a second phase to the project, which may include sample barcoding. Barcoding will afford additional time savings and an increase in sample traceability.

Phase 2 may also include adopting the built-in laboratory execution system (LES) within SampleManager LIMS software to digitize its standard operating procedures (SOPs) and enable technicians to work through procedures on tablets in the lab. Examen’s SOPs are currently paper-based, with technicians printing the procedures each morning. Using the LES would improve efficiency, and help improve data quality, capturing additional environmental data such as humidity and temperature during the tests.

To streamline the results delivery process, Examen is also considering a new customer portal. Whenever a report is authorized in SampleManager LIMS software, it could be uploaded to the new customer portal with a notification automatically sent to the customer.

Examen believes its LIMS investment will continue to enhance its position as a market leader in male infertility treatment. The improvements in productivity and efficiency, along with the AWS deployment model will enable Examen to scale as demand increases. Examen’s customers appreciate the fast, consistent service, which could lead to increased global demand.

Find out more at thermofisher.com/digitalscience