autogen

Advanced Research and Diagnostic Laboratory of University of Minnesota

Case Study

> It's rare to see the kind of support that you receive from AutoGen after the sale. When dealing with larger companies, you just don't get the [same level of] dedication and rapid response.
>
> Jennifer Peters, Operations Manager

Improving the Quality of Processed Samples and Ensuring Efficiency of Utilized Resources

Background

The Advanced Research and Diagnostic Laboratory (ARDL) of the University of Minnesota (UMN) is a fully accredited central biochemistry laboratory, largely funded by the National Institutes of Health (NIH). The laboratory boasts a 16,000 square foot facility recognized worldwide for its innovative, customized design and operational excellence that supports its equally acclaimed services that include:

- Clinical trials and testing
- Collection, processing, testing, and analysis of specimens through high-volume immunoassay testing platforms
- Assay development and validation, sample analysis, and quantitative proteomics through their Mass Spectrometer Center
- Long-term storage of samples through their biorepository

> Labs know that if UMN did the extraction, they're going to get great DNA.
>
> Jennifer Peters, Laboratory Operations Manager

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ARDL possesses an industry reputation of delivering only the highest quality of DNA sample results with its usage of precipitation chemistry. In order to maintain its level of quality, ARDL looked to utilize its resources more efficiently by automating a previously manual process of extracting nucleic acids (DNA and RNA). It obtained its first automation instrument, the Autopure (which utilizes Qiagen's Puregene chemistry), through Gentra, a local Minnesota supplier. However, the discontinuance of the Autopure and quality issues drove ARDL to search for an alternative solution that ultimately led to AutoGen's FlexSTAR+ which utilizes Qiagen's FlexiGene chemistry.

I. Challenges

Manual nucleic acid extraction monopolized laboratory technicians' valuable time

Manually extracting nucleic acids is a time-consuming, labor-intensive process that requires highly focused attention at every step. The execution can be tedious and repetitive. Automating this process through the Gentra-supplied Autopure allowed laboratory technicians at ARDL to turn their attention to providing more skill-based services. However, the Autopure ended up requiring partial manual work due to its insufficient performance.

Processing samples through the Autopure resulted in an unacceptable failure rate, causing quality maintenance concerns

ARDL supports anywhere from 20 to 30 clinical trials on an ongoing basis, in addition to providing other services such as projects from epidemiology studies. It has strict standards for the yield, integrity, and purity of the samples it processes – and the sample failure rate with the Autopure conflicted with these standards. A greater than 2% sample loss rate compromised ARDL's reliability, and reflected poorly on its ability to deliver to its clients.

Quality issues required a manual portion to the extraction process, adding back the strain on laboratory technicians' time

Gentra's solution to reducing the sample failure rate was to change the way the laboratory technicians processed samples: technicians began to perform the cell lysis step manually, which included an overnight lysis. This ensured a cleaner product for the Autopure's white cell pellet step, and ultimately, a cleaner preparation. However, this now elongated, partially manual process negatively impacted the workflow and reduced overall efficiency.

II. Approach

Objectively evaluating the alternative options that utilize precipitation chemistry through robust research

After reintroducing a manual element to their DNA extraction process, ARDL turned to researching automated instrumentation with proven performance within the industry.

The main requirement in the decision-making process was continuing to use precipitation chemistry as the DNA extraction technology. Precipitation chemistry allows the laboratory technicians to focus on fragment size – critical to ARDL's processes because of the demand for stability in long-term storage.

Consulting industry peers for validation on automated nucleic acid extraction instrument choice

In addition to ARDL's individual research, decision-makers also considered the instruments used by other biorepositories in the industry. Of particular interest was the Mayo Clinic, which houses one of the world's largest biobanks and is within close proximity to ARDL. The Mayo Clinic uses 13 of AutoGen's FlexSTAR+ instruments with Qiagen's FlexiGene chemistry.

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Choosing an instrument that enabled them in maintaining quality results and upholding high expectations

It was crucial that ARDL find a DNA extraction instrument that would truly fulfill the purpose of automation: to increase efficiency, but not at the expense of quality. Ideally, the new instrument would produce high-quality sample results while allowing the laboratory technicians to reallocate their time to more demanding responsibilities. This would ensure that ARDL is able to sustain the expectations of its clients as well as its internal standards.

III. Results

Objective and responsive support from the AutoGen team at every step of the decision-making and purchasing process

Once ARDL decided to explore the AutoGen FlexSTAR+, the AutoGen team provided honest insights to help problem-solve and address the laboratory's needs. The level of dedication and accessibility shown by the team's responsiveness and on-site consulting contributed to a smooth, valuable experience when compared to less communicative, larger suppliers. This support continued even after the purchase of the FlexSTAR+, ensuring a seamless transition. AutoGen's specialized expertise in effective automated instruments that use precipitation chemistry proved to be the best fit for ARDL's unique needs.

> "If you're in the biobanking business, quality and reputation are important to your organization, and you perform complex, downstream testing, then you need the highest quality DNA prep. That's what you get from the FlexSTAR+ and FlexiGene chemistry."
>
> Chis Zaun, Technical Lead

Resolution of quality issues and sample failure

Thus far, ARDL has processed more than 20,000 samples with favorable results – laboratory technicians have seen a significant reduction in sample failure. In addition to the decrease in sample loss, ARDL is able to secure backup samples during extraction via the FlexSTAR+'s ability to divide 10 mL samples.

The raw data of 500 extractions processed with the Autopure compared to 500 extractions processed with the FlexSTAR+ is demonstrated in Table 1 below. With an average 8.5 mL sample size of whole blood, the FlexSTAR+ yielded comparable or significantly increased results when compared to the Autopure's performance.

	Whole Blood (mL)	Conc (ng/µL)	260/280	Vol (µL)	Total DNA (µg)	Yield (µg/mL)
Autopure	8.5	404.66	1.85	494.4	202.3	23.57
FlexSTAR+	8.5	450.46	1.83	509.18	229.47	26.99

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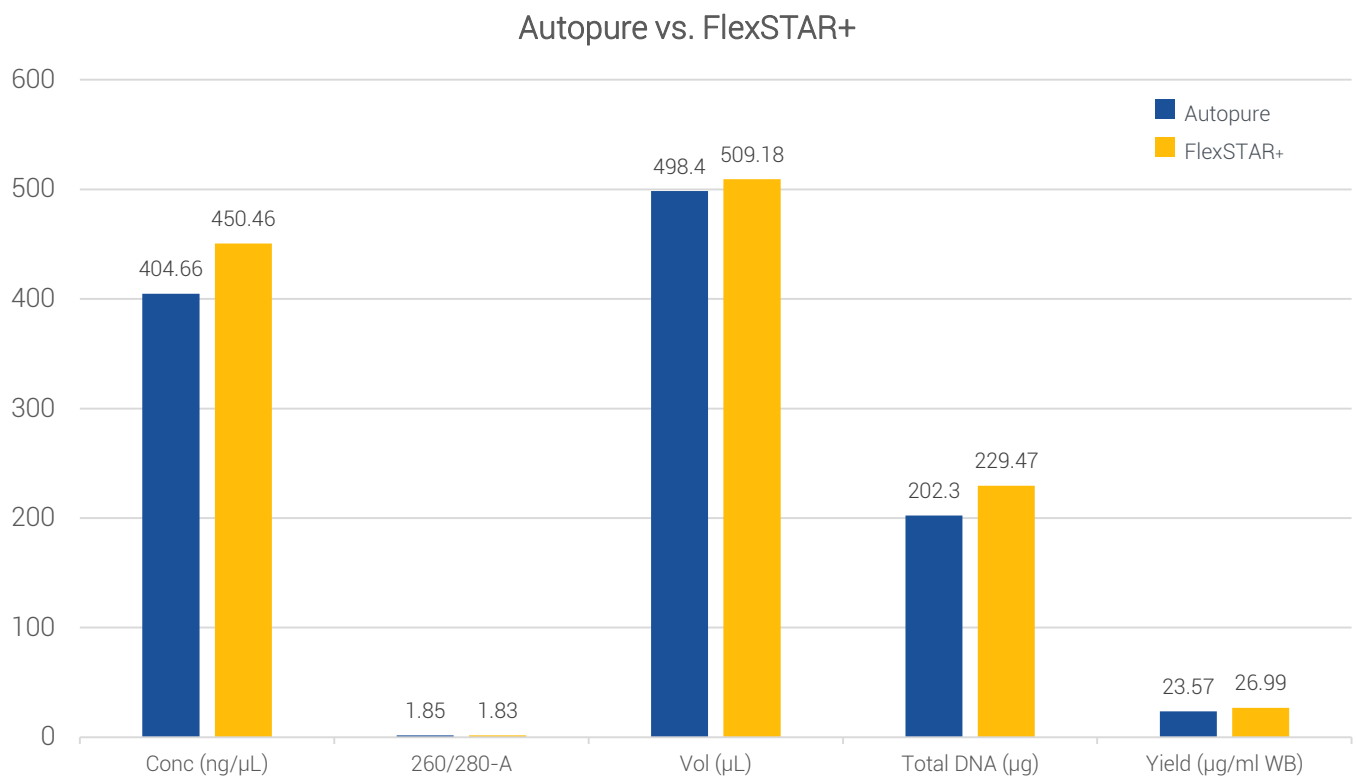

Ability to reallocate valuable resources

Beyond enabling ARDL to maintain its standards of quality, AutoGen's FlexSTAR+ fulfilled the original purpose of automating DNA extraction: to increase efficiency. Now that laboratory technicians no longer need to execute the overnight lysis step (as was needed for the old Autopure) and the eluate transfer is automated by the FlexSTAR+, their attention can be focused on other tasks in the lab. AutoGen's FlexSTAR+ aided ARDL in maintaining its strong reputation and allowed its resources to be more strategically allocated.

About AutoGen

AutoGen is a leading provider of automated nucleic acid extraction workflows that allows lab professionals to produce premier quality and value-added extraction results. Our workflows provide solutions that are the best fit for our customers' laboratory needs and budget, and our customers include biorepositories, contract research organizations, academic research laboratories, pharmaceutical companies, clinical diagnostic laboratories, and government institutions all over the world. We strive to provide quality instrumentation and chemistries, as well as dedicated technical support – all with a level of post-sale service that is truly unmatched. Visit www.AutoGen.com to learn more.

84 October Hill Road, Holliston, MA 01746

Phone number: 774-233-3000

International number: +00+1+774-233-3000

Email: info@autogen.com