



East Anglian Medical Genetics Service

Case Study “

The FlexSTAR system and accompanying FlexiGene chemistry produce top-notch quality DNA, immediately ready for downstream assays or long-term storage. ”

Howard Martin, Principle Clinical Scientist

Constantly Optimizing the Efficiency and Quality of the Nucleic Acid Extraction Process

Background

The East Anglian Medical Genetics Service is the Molecular Genetics Laboratories housed at the internationally acclaimed Addenbrooke's Hospital, located in the UK. Addenbrooke's Hospital is affiliated with Cambridge University and renowned as a teaching hospital. All cytogenetic (involving chromosomes) and molecular genetic (involving DNA) analyses are helmed by the East Anglian Medical Genetics Service. Established in 2007, its 40+ dedicated health care professionals and staff offer crucial testing services for both clinical and research purposes.

The East Anglian Medical Genetics Service has the following primary responsibilities:

- Diagnosing genetic disorders at the clinic through the results of lab tests
- Counseling and advising patients and their families regarding potentially inherited genetic disorders (e.g. familial cancer syndrome)
- Researching the cause of birth defects and genetic diseases
- Educating health care professionals on genetics

In order to meet high demand, the East Anglian Medical Genetics Service turned from manual methods to automation of its nucleic acid extraction with Qiagen's extraction system, the Autopure, which utilizes Qiagen's Puregene chemistry. However, the insufficient performance of the Autopure led the laboratory to investigate other extraction instruments that could further optimize its efficiency and quality results. The lab's search led to AutoGen's FlexSTAR, which utilizes Qiagen's FlexiGene chemistry.

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I. Challenges

Manual extraction methods caused inconsistencies in output quality and throughput, emphasizing the need for more precise and efficient automation

The nucleic acid extraction process calls for careful and accurate handling. Manual methods leave too much room for error, resulting in a severe lack of consistency in the output quality. The number of samples that can be processed through manual extraction methods also varied greatly, compromising reliability. It was obvious that the East Anglian Medical Genetics Service needed to invest in an automated extraction instrument to ensure consistently high quality in output and throughput.

Failure of the initial automation instrument to meet all of East Anglian Medical Genetics Service's needs

The first automated extraction system the East Anglian Medical Genetics Service chose was Qiagen's Autopure, which utilized Puregene chemistry (precipitation technology). Although this automation was an improvement from their manual process, the instrument's technology did not include a necessary functionality the lab required. The Autopure satisfactorily extracted total nucleic acid (both DNA and RNA) but was unable to isolate only DNA – a critical capability. The lab needed to continue its search for a fully automated extraction instrument that satisfied all essential needs.

Deciding which chemistry to select: precipitation or magnetic bead technology?

There are two distinct extraction technologies available – precipitation chemistry and magnetic bead chemistry. The East Anglian Medical Genetics Service needed to decide whether to continue with precipitation technology (Autopure's Puregene chemistry) or opt for an instrument that utilized magnetic bead technology. This added another dimension to the already complex decision of purchasing a new automation instrument.

“We routinely run the AutoGen FlexSTAR instrument at capacity, and couldn't be more pleased with the rock-solid performance. The flexibility and throughput of the FlexSTAR platform allow for us to meet each day's needs, and we are no longer constrained by the limitations of the Autopure's long extraction times and rigid operation.”

Howard Martin, PhD, Principal Clinical Scientist

II. Approach

Objectively validating the decision to adhere to precipitation chemistry

Precipitation chemistry had been the standard extraction method for the lab, and after assessing the extraction outputs' uses, precipitation chemistry still proved to be the best fit. Compared to other extraction technologies, precipitation chemistry allows for the extracted material to be utilized in downstream assays without requiring further clean-up or sample manipulation (which would result in additional technician time and effort, defeating the purpose of the efficiency of automation).

Studies have also proven that extraction via precipitation chemistry produces ideal material for long-term storage. Studies demonstrate no degradation in sample integrity even after more than 15 years of storage in 2-8°C and -20°C. Maintaining the use of precipitation chemistry will also minimize the transition efforts of the purchase of a new instrument, ensuring consistent capacity. This strengthened the case for purchasing AutoGen's automation instrument that utilized precipitation technology: the FlexSTAR which boasts the FlexiGene chemistry.

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Coordinating a test run of AutoGen's FlexSTAR in order to compare the performance of the old and new instruments by assessing the quantitative results

To ensure that the FlexSTAR possessed the full capabilities that East Anglian Medical Genetics Service required for nucleic acid extraction, AutoGen coordinated with the lab to compare the performance of the Autopure and FlexSTAR instruments. A rigorous and carefully constructed study was run on the two instruments and evaluated thoroughly. This enabled the lab to make a fully informed purchase decision, supported by sound, quantitative data.

Drawing on years of experience, expertise, and knowledge to help navigate the complex process of purchasing a new automated instrument

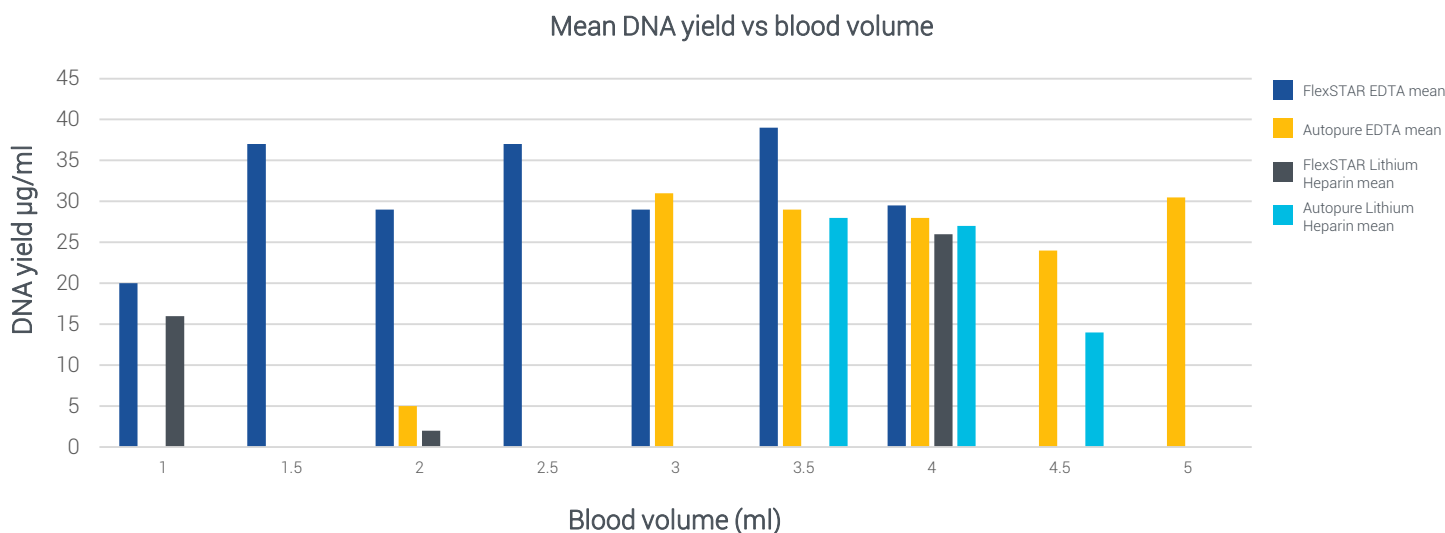
AutoGen's reputation in the field as nucleic acid extraction specialists instilled trust in the decision makers at East Anglian Medical Genetics Service. From initial inquiry to installation of the new extraction instrument, AutoGen's team provided objective and insightful knowledge to aid in the decision-making process. This didn't stop once the purchase was completed; AutoGen provided a robust post-purchase support system that included 3-4 days of installation training and validating the client's unique standards. It was obvious from the accommodation and responsiveness of the specialists that AutoGen's mission is to help and assist in selecting the best solution for each organization's unique challenges. Its sole focus of providing nucleic acid extraction instruments utilizing precipitation chemistry enables AutoGen to be the streamlined expert in this niche.

III. Results

Quantifiable improvement in quality and operational throughput

Results of the tested samples demonstrated the higher quality and more precise DNA isolation of AutoGen's FlexSTAR in comparison to the old Autopure (see below for quantitative data). This validated the East Anglian Medical Genetics Service's high expectations of the new instrument and assured their initial concerns of consistency in quality and throughput. The FlexSTAR and its FlexiGene chemistry performed better than the original manual process, Autopure's Puregene chemistry, and several other solutions that the lab assessed in order to make an informed decision.

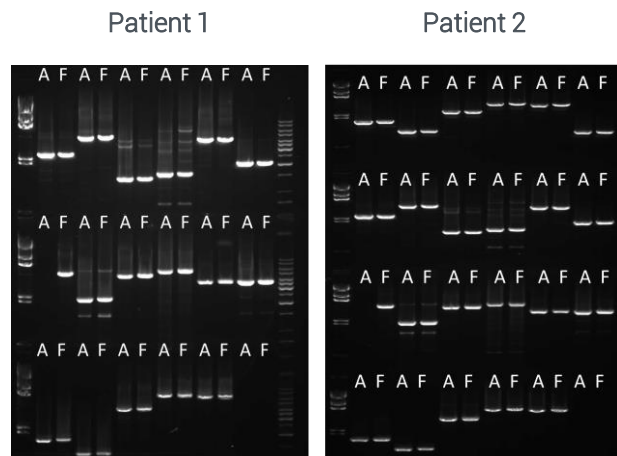
The table below is a comparison of DNA yield from different starting samples run through the Autopure and the FlexSTAR. Whole blood was taken in either Lithium Heparin or EDTA-coated sample tubes.



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A performance evaluation to assess DNA integrity (presence of high molecular weight DNA fragments) was run to determine suitability for long-range PCR applications. Downstream diagnostic use of genomic DNA extracted typically includes long-range PCR amplification. Therefore, recovering high molecular weight DNA from whole blood is very important.

The images to the right showcase a comparison of long range PCR amplification products performed on genomic DNA extracted through both the FlexSTAR (F) and the Autopure (A), on Patient 1 (products BRCA1 and BRCA2, 17 amplicons in addition to water controls) and 2 (products BRCA1 and BRCA2, 23 amplicons in addition to water controls). Data shows comparable amplification performance between Autopure and FlexSTAR extractions across a range of large amplification products up to 10kb. Product specificity is comparable between the two platforms.



Seamless, painless transition from the old instrument to the new

The consistency in extraction chemistry utilized (precipitation technology) and the efforts of the AutoGen team ensured that the lab's staff didn't have to expend time training to use an entirely different chemistry and process. The transition overall had minimal disruptive impact on the East Anglian Medical Genetics Service's workflow and operational processes.

More efficient and optimized nucleic acid extraction process that produces quality results and upholds valued standards

With AutoGen's FlexSTAR and its FlexiGene chemistry, the East Anglian Medical Genetics Service was finally able to fully automate its extraction workflow. The lab can now function at its optimal capacity and consistently produce the quality results that will enable the accurate and timely analyses the lab's patients and clients need.

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.



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