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# Unlock Your FFPE Samples. Unleash Your Comprehensive Genomic Profiling Workflow.

## How Covaris' Automated Coextraction Reduces Costs and Improves Success Rates

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### The Challenge

Comprehensive Genomic Profiling (CGP) is a powerful tool to identify somatic mutations and/or other genetic changes in tissue samples through the analysis of hundreds of genes. CGP testing activities are rapidly growing as they fuel advances in oncology research, clinical studies, and medical care. However, the effectiveness of genomic characterization is often limited by the critical upstream step of nucleic acid extraction, particularly from Formalin-Fixed Paraffin-Embedded (FFPE) tissues. These samples are challenging to process due to variability in quality caused by tissue size, fixation conditions, block age, tumor heterogeneity, and position within the block, often resulting in low-quality or insufficient genetic material (Quantity Not Sufficient, or QNS) [1–4]. This can lead to high sample failure rates, costly rework, and critical delays in testing. Some CGP tests have shown assay failure rates as high as 17% [5].

**The Solution:** To address these challenges, Covaris, in collaboration with Hamilton®, has developed the ***truXTRAC® FFPE SMART Solution*** [6], a fully automated workflow for the extraction, isolation, and purification of nucleic acids from FFPE samples [7].

**The Proof:** This white paper details the superior performance of the Covaris solution as described in a peer-reviewed study published in SLAS Technology [7]. The data demonstrates that the truXTRAC workflow delivers higher nucleic acid yield and purity, leading to a significant increase in successful downstream sequencing results. This improvement in technical performance translates directly to substantial operational cost savings, estimated at ***~$1.3 million annually*** for a representative high-throughput workflow [9].

## The Critical Upstream Bottleneck in FFPE-Based NGS Workflows

FFPE tissue is the gold standard for preserving tumor biopsies, but the fixation process presents significant sample preparation challenges. The extraction of high-quality DNA and RNA from FFPE tissues is frequently hampered by factors such as varying tissue masses, fixation conditions, and the inherent difficulty of the tissue type, which can compromise nucleic acid quality and quantity. This is a critical issue, as the downstream success of powerful Next-Generation Sequencing (NGS) assays depends on high-quality starting material [7,8].

Advanced CGP tools like the ***Illumina® TruSight™ Oncology 500 (TSO500) product portfolio*** provide invaluable genomic information but have specific input requirements to ensure reliable performance. The TSO500 assay protocol requires a starting input of ***40 ng of DNA and/or 40 ng of RNA*** extracted from the FFPE tissue [5].

Failure to meet these yield and quality thresholds during the upstream extraction phase is a primary driver of overall workflow failure. When an extraction yields insufficient material, the sample cannot proceed to library preparation and sequencing, necessitating a costly and time-consuming re-extraction that depletes the precious, often irreplaceable, tissue biopsy. Optimizing the extraction workflow is therefore the most critical step in ensuring operational efficiency and maximizing the likelihood of successful NGS testing [7].

## A Fully Automated Solution: The Covaris truXTRAC FFPE SMART Workflow

The Covaris truXTRAC FFPE SMART Solution, powered by the Hamilton Sonication STAR™ Assay Ready Workstation (ARW) (***Figure 1A***), is a comprehensive, walkaway system designed to standardize and improve the quality of nucleic acid extraction. This unique solution removes the critical, time-consuming bottlenecks of manual processing, establishing a new standard for consistent, scalable, and reliable data for genomic profiling [5].

Engineered for exceptional repeatability batch after batch, the system is capable of processing ***8–96 FFPE samples per day*** within a single shift, with minimal user interventions [5,8].

At the core of the workflow is Covaris' proprietary ***Adaptive Focused Acoustics® (AFA®)*** technology (***Figure 1B***) [5]. This non-contact energy transfer method enables efficient and fine-tuned deparaffinization and tissue homogenization. The result is an automated platform that ensures consistent results across different batches, operators, and lab settings, minimizing the variability that plagues manual and semi-automated extraction methods [5,8].

A.

B.

**Figure 1.** The Fully Automated Covaris truXTRAC FFPE SMART Solution. (*A*) The complete Sonication STAR Assay Ready Workstation (ARW), built on a Hamilton Microlab® STAR liquid handler, designed for automated extraction, isolation, and purification of nucleic acids from FFPE samples. (*B*) An inset showing the integrated Covaris R230 Focused-ultrasonicator, which utilizes Adaptive Focused Acoustics (AFA) for active deparaffinization and tissue homogenization of FFPE samples.

## Head-to-Head Performance Validation

The performance of the Covaris truXTRAC FFPE SMART Solution integrated with the ARW was implemented and performance tested by Labcorp with support from Covaris and Hamilton, with results published in the SLAS Technology Journal [7]. The study directly compared the Covaris AFA-based workflow against an automated filter-based Automated Silica Membrane (ASM) method for extracting nucleic acids from FFPE tissue sections. The extracted DNA and RNA were subsequently analyzed using the Illumina TSO500 assay.

The results demonstrate a dramatic improvement in all key performance metrics:

- **Superior Nucleic Acid Yield:** Higher yields are critical for meeting the input requirements of downstream assays and avoiding QNS-related failures.
  - For RNA, ***98.1%*** of samples processed with the ARW had greater yields than those processed with the alternative method. Overall, the median RNA yield was ***6.5-fold higher*** with the truXTRAC FFPE SMART Solution.
  - For DNA, ***88.9%*** of ARW samples had a greater yield than the alternative method.
- **Improved Purity:** Sample purity is essential for enzymatic reactions in library preparation and sequencing. The ARW workflow delivered substantially purer nucleic acids.
  - The median DNA purity (A260/230 ratio) was ***2.14*** with the ARW, compared to just 0.16 with the ASM system.
  - The median RNA purity (A260/230 ratio) was ***1.29*** with the ARW, versus 0.03 with the ASM system.
- **Enhanced Downstream Sequencing Success:** The higher yield and purity from the Covaris workflow directly translated to a higher success rate in the subsequent TSO500 NGS assay.
  - This improved performance resulted in a ***16% increase in the testing success rate***.
  - A remarkable ***100% of the RNA samples*** extracted with the ARW passed all downstream sequencing QC metrics.
  - In contrast to the ARW, the RNA samples extracted using the alternative method had a final pass rate of only 76.7%.

The performance of the Covaris truXTRAC FFPE SMART Solution evaluated by Labcorp demonstrates a robust and reliable method for preparing FFPE samples, ensuring that more samples succeed and yield high-quality data for CGP testing.

## The Economic Impact: Translating Performance into Cost Savings

The technical superiority of the Covaris truXTRAC FFPE SMART Solution, as documented in the *SLAS Technology* Journal, translates directly into significant and quantifiable economic advantages. By minimizing sample failures at the crucial extraction stage, the Covaris workflow dramatically reduces the need for costly and labor-intensive rework, including re-extraction, re-prepping libraries, and re-sequencing.

To quantify this impact, a cost-savings model was developed to compare the total annual wet-lab cost of the automated Covaris workflow against a standard, semi-automated workflow (based on Qiagen® chemistry). The cost model is based on a high-throughput lab processing 10,000 FFPE samples annually for analysis with the Illumina TSO500 assay, using an S2 flow cell on a NovaSeq® 6000 instrument.

The primary driver of the cost difference is the sample failure rate at each stage of the process. The model incorporates the following failure rates:

- **Baseline Workflow:** The cost model's baseline assumes a standard workflow using conventional extraction methods. This workflow incorporates an extraction failure rate of 3%, a sequencing failure rate of 5%, and a library preparation failure rate of 17%. The 17% library prep failure rate is consistent with performance data from the Illumina TSO500 package insert; specifically, the accuracy of NTRK1/2/3 fusion detection was 87% [5].
- **Optimized SLAS Technology Workflow with Covaris:** The CGP workflow utilizing the Covaris truXTRAC FFPE SMART Solution employs significantly lower failure rates in the cost model: 2% for extraction, 2% for library prep, and 1% for sequencing. These lower rates are justified by the superior upstream sample preparation results documented in the *SLAS Technology* article [7]. The study demonstrated that the Covaris workflow delivers significantly higher nucleic acid yield and purity, leading to improved success for downstream applications like TSO500 for CGP and Thermo Fisher's Oncomine™ Immune Response Research Assay (OIRRA) for gene expression profiling.

This reduction in failure rates results in substantial annual savings:

- **20% Reduction in Extraction Costs:** By getting the extraction right the first time, the total annual cost is reduced from $0.3M–$0.2M.
- **19% Reduction in Library Prep Costs:** Fewer failed samples proceeding to this expensive stage results in an annual cost reduction from $6.3M–$5.2M.
- **4% Reduction in Sequencing Costs:** Higher quality libraries and more efficient batching lead to a reduction in sequencing costs from $1.5M–$1.4M.

The cumulative effect for a lab processing 10,000 samples per year is a total annual operational savings of ***approximately $1.3 Million*** as shown in ***Figure 2*** [9].

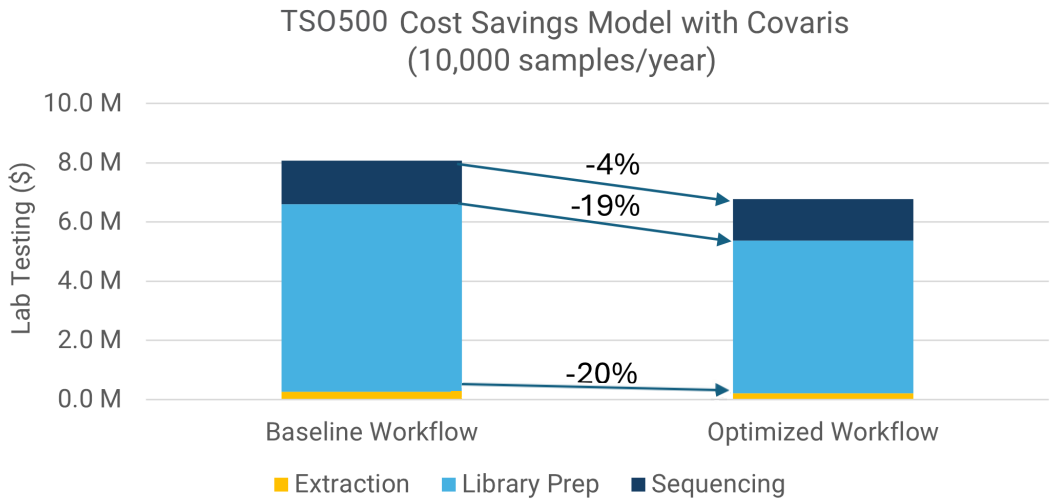


**Figure 2:** Economic Model of TSO500 Annual Lab Testing Costs. The chart illustrates a cost-savings model comparing a referenced Baseline Workflow [5] to the Optimized Workflow described in [6]. The model is based on a laboratory throughput of 10,000 FFPE samples per year for the TSO500 CGP assay, using a NovaSeq 6000 on an S2 flow cell. Costs are broken down by workflow stage: Extraction (yellow), Library Prep (blue), and Sequencing (dark blue). The implementation of the Optimized Workflow demonstrates significant cost reductions of 20% in extraction, 19% in library preparation, and 4% in sequencing.

## Conclusion

The successful implementation of Comprehensive Genomic Profiling hinges on the quality of the upstream sample preparation workflow. As demonstrated in peer-reviewed data [5], the Covaris truXTRAC FFPE SMART Solution directly addresses the most significant challenges associated with FFPE tissue.

By implementing this fully automated, AFA-powered workflow, laboratories can:

- **Achieve Higher Yield and Purity:** Obtain superior quality and quantity of nucleic acids from precious FFPE samples.
- **Increase Downstream Success:** Dramatically reduce QNS-related failures, leading to a 16% increase in fully reported patient results and a nearly 25% improvement in RNA sequencing QC pass rates compared to conventional methods.
- **Reduce Operational Costs:** Realize substantial annual savings by minimizing the need for costly re-analysis and rework.
- **Improve Workflow Efficiency:** Automate a critical bottleneck, increase throughput, and ensure reliable, reproducible results across operators and batches.

The Covaris truXTRAC FFPE SMART Solution is a scientifically and economically proven workflow that empowers laboratories to achieve more reliable, consistent, and cost-effective results, advancing oncology research and testing.

Contact our team today for a personalized cost-savings workflow analysis. We will partner with you to build a more efficient, cost-effective, and high-performance FFPE workflow.

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