Exemplar LIMS for NGS Labs

Introduction

Few can argue that Next Generation Sequencing is having a major impact on genomics research. The progress in this field exceeds even that of computational growth according to Moore's Law, and this rapid progression will be continuing for several more years. The net result is that more labs will be able to afford NGS instruments and to perform high volume sequencing for research and clinical applications. The adoption of NGS sequencers presents new challenges in handling requests for services, preparing samples and tracking results. Exemplar LIMS addresses each of these areas and improves NGS laboratory operations through increased efficiencies, quality of operations and overall throughput.

NGS Workflows and the Laboratory

So what is a workflow? According to Wikipedia a workflow: *consists of a sequence of connected steps. It is a depiction of a sequence of operations, declared as work of a person, a group of persons, an organization of staff, or one or more simple or complex mechanisms*.

A laboratory's overall daily workflow is an overarching construct that may itself be comprised of several sub-processes. Each of the sub-processes can be further defined as a sequence of steps that a person or group follow to achieve some end result.

For NGS labs, there are common sub-processes that comprise the overall workflow, these include:

- Request for Services
- Sample Receiving
- DNA/ RNA Extraction
- Library Construction
- Sequencing
- Post Sequencing Processes such as Primary and Secondary Analysis

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Exemplar LIMS has built workflow solutions for each of these NGS areas that allow us to easily adapt Exemplar to each client's specific needs. Workflows in Exemplar walk the user through each step of the process so there is very little or no training required for lab technicians to immediately begin using the system. Workflows can even be connected together so that one workflow can initiate another workflow, further streamlining the process.

An overarching workflow process implemented in Exemplar LIMS in an NGS lab may look as below. This overall workflow is comprised of several workflow sub-processes:

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Consumables Tracking

A key aspect of NGS process tracking is tracking consumables. Exemplar LIMS Materials Management Module enables detailed tracking and usage of reagent lots in NGS and other workflows. This module has several key features that make lab operations more efficient and traceable:

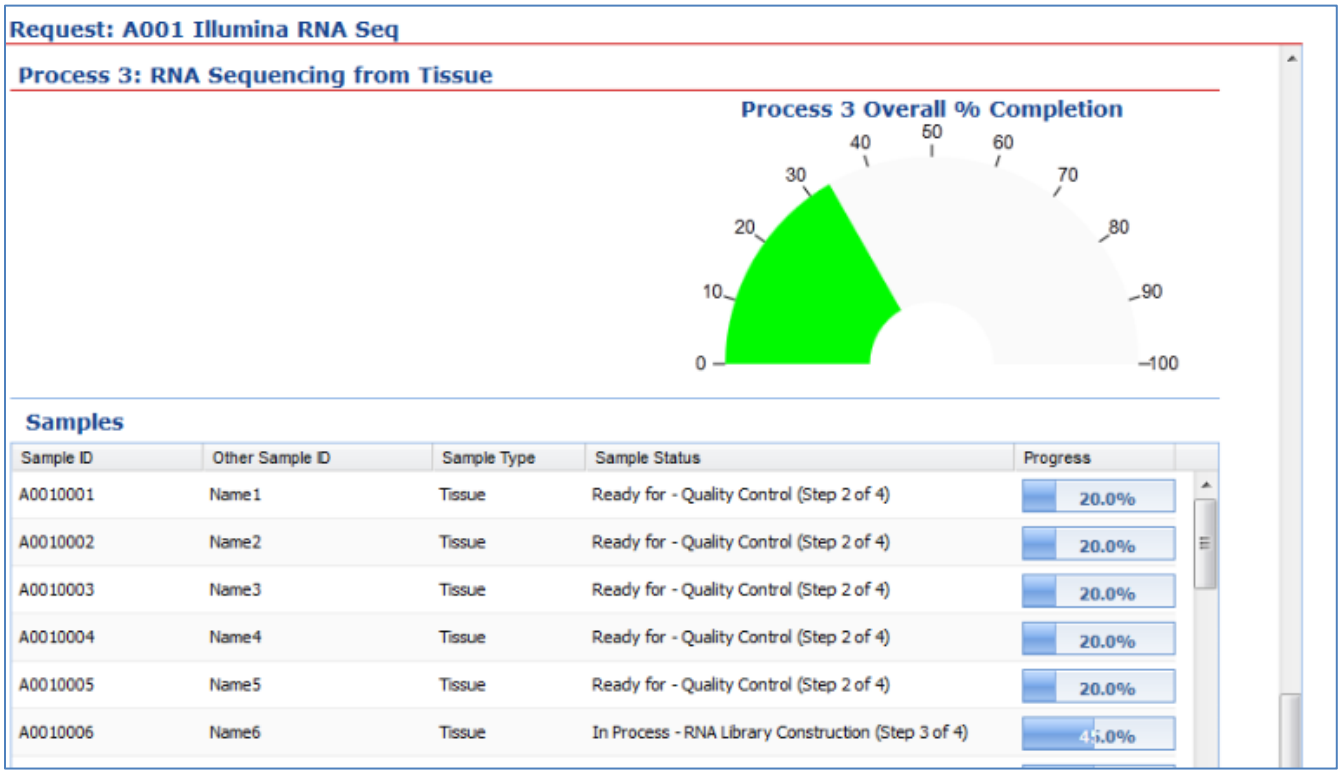
- Reagent inventory tracking
- Flexible implementation to changes in NGS process chemistry can easily be added via configuration
- Master Mix automatic computations for constituent reagents
- Reagent volume on hand tracking with preset order levels and email alerts
- Reagent validation
- Optional "default-to-oldest" value insertion to ensure consumption of oldest reagents first, and to limit data entry needs by lab techs
- Reagent storage location tracking
- Integration with back end financial systems for purchasing and receiving

Process Tracking

Many NGS labs want to enable electronic ordering of services via the internet. Exemplar LIMS Request Portal enables client order entry over the internet via a secure connection. When NGS services are requested, there can be multiple NGS services for each sample (e.g. "PacBio and Illumina HiSeq DNA Sequencing for Sample A") along with other NGS instrument-specific request items. Exemplar LIMS Request Portal enables these complex order types via configuration in Exemplar, allowing for very flexible portal configuration and rapid deployment.

The Request Portal enables sample pre-registration, which streamlines the request approval and sample-receiving processes as the samples already exist in the LIMS when they arrive. Once received, samples are marked as being ready for the assigned workflows per their requested NGS service(s), and Exemplar notifies the requestor that the samples are now at the lab.

Importantly, the Exemplar Process Tracking enables the requestor to get a dashboard view showing where each sample is in the processing (see next page). This reduces calls to the lab as the requestor is never in doubt as to where their samples are at in the process.



Compliance

In recent years, NGS has largely been a research and development technology, and it will continue to experience high growth in this area as the cost and quality if NGS improves. There have been some prominent stories of NGS saving lives when all other attempts to understand a person's conditions had failed, indicating the potential of NGS in clinical applications.

Presently a few CLIA compliant NGS labs service the clinical market. In the future, this will be a very large growth area as more specific NGS clinical applications are discovered and validated. Leading edge, CLIA certified NGS labs are already using Exemplar LIMS for their compliant process tracking demonstrating the high quality of Exemplar LIMS software and process tracking. Sapio expects to stay at the forefront of the clinical NGS market with its strong experience in this area.

Exemplar LIMS for NGS – Summary

Exemplar has pre-built, NGS related capabilities:

- Templatized workflows for rapid implementation of custom NGS library preparations and sequencing workflows
- Overarching process tracking that connects workflows together

- Reagent Materials Management Module with flexible implementation so that changes to reagents in processes can be easily accommodated with no programming required
- Intuitive, step by step workflows that guide lab techs through a defined process
- Workflow step level help to provide detailed descriptions to end users as needed
- Graphical request level dashboard to show progress of each sample through its process
- Instrument status and maintenance monitoring

The combination of these features separates Exemplar LIMS from other solutions. We invite you to view a detailed NGS presentation of Exemplar LIMS. To schedule a detailed technical demonstration, please contact Sapio at sales@sapiosciences.com.