

Calculating Savings in a Laboratory Using ASCENT™

Overview

In its report, *Lab Automation Markets, 2nd Edition (Systems, Key Companies, Forecasts and Trends)*, healthcare market research publisher Kalorama Information discusses a number of issues that are challenging the ability of clinical laboratories to remain competitive:

- the reduction of government reimbursement rates for lab tests;
- cost-restraint measures established by the managed care industry;
- increased government regulations;
- growing demand for testing as the population ages;
- a diminishing labor pool; and
- increasingly sophisticated tests that produce greater amounts of data.

“In order to survive in the future”, the report continues, “labs will need to run more tests, test in fewer sites, operate with less equipment, maintain lower operating costs, and hire less skilled labor.” For clinical laboratories, automation is now a “must-have”, explains Bruce Carlson, publisher of Kalorama Information.

For years now the combination of liquid chromatography or gas chromatography with mass spectrometry has been globally accepted as the most powerful technique for analyzing complex chemicals. Initially used solely by academia, pharmaceutical and the biotechnology industries, this technique is becoming widely used in clinical diagnostics to obtain faster, more accurate results. Mass spectrometry is seen by the industry as an answer to the movement to run more tests with less equipment. Mass spectrometry has the capability of multiplexing several tests in one single run.

However the promise of mass spectrometry, and its adoption have been slowed by the requirement to have highly skilled people performing very time consuming data analysis and review.

Typical Current Process

Typically, the data analysis and review process involves many manual steps including:

- Setting of parameters for data analysis techniques
- Calibration
- Baseline selection
- Peak picking
- Quantitation
- Application of assay QC rules
- Transfer to LIMS

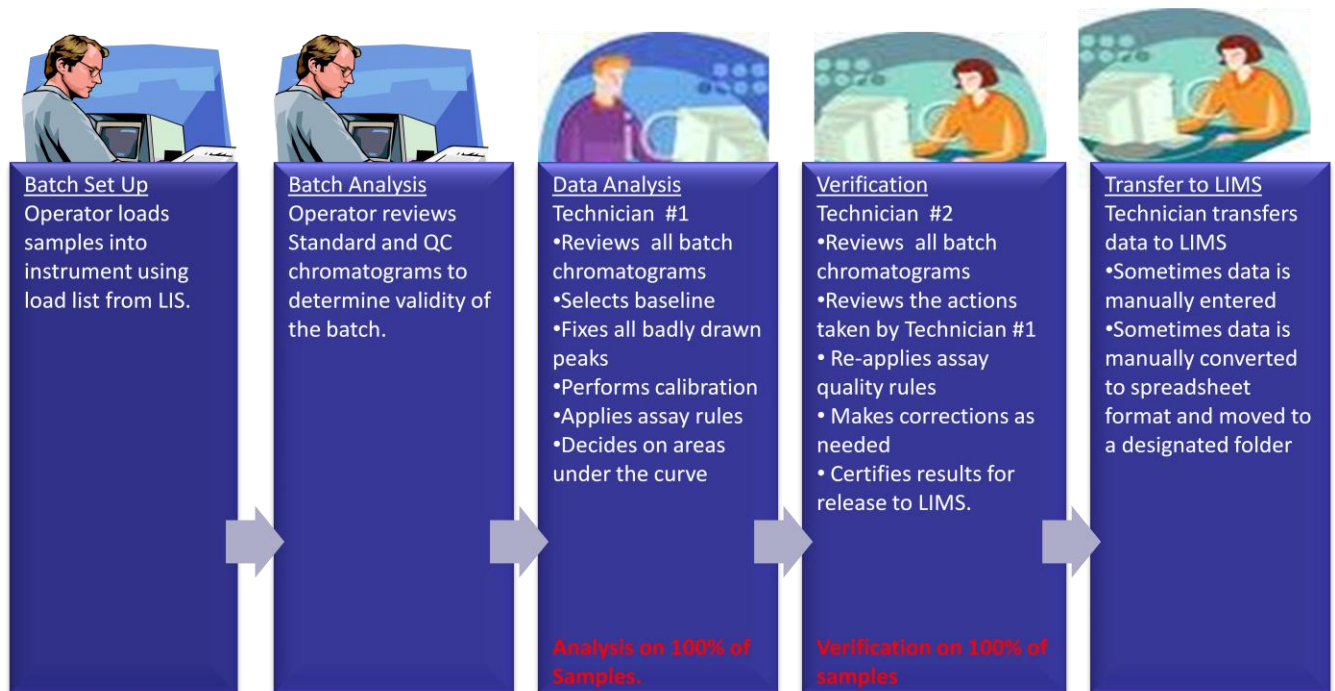
These steps are conducted using a combination of tools that usually include:

- Instrument chromatographic data system or data analysis software

- Handwritten documents
- Excel Spreadsheets
- PDF files
- LIMS screens

Often more than one of these is used at the same time with multiple screens. At times the sequence of the analytes under review differs from one display to the other.

It is not uncommon to find one or two individuals that are well versed at these reviews and can do it in a reasonable amount of time. However, it is more common to find that the majority of technicians struggle with this repetitive task. Usually during extended periods of data review, concentration lapses lead to mistakes. To alleviate this error occurrence, most laboratories have a second reviewer and a certifier checking and correcting the work done by the first reviewer. The typical process is shown in the figure below



ASCENT™ Process

ASCENT™ was designed to automate the complete process comprising data analysis and review of chromatographic assays as well as transfer of data and or results into the LIS/LIMS. This process is highly automated and provides significant benefits including enhanced quality, greater productivity and laboratory efficiency, reduced turn-around-time, reduction in personnel, and increased instrument utilization.

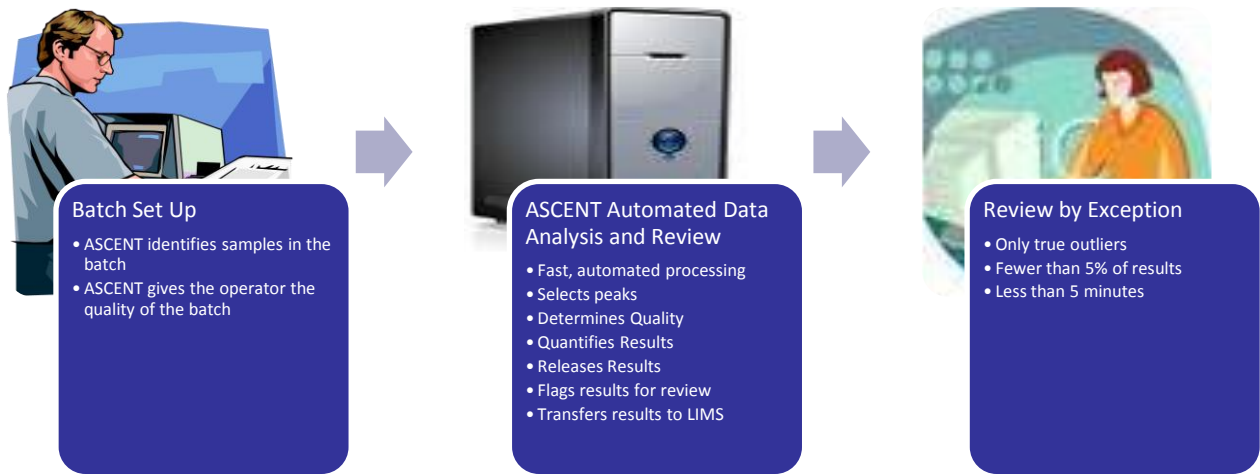
ASCENT™ works with any vendor mass spectrometer software platform and applies to any chromatographic technique and any assay.

ASCENT™ has been used for a variety of assays: pain management panels (e.g., opiates), endocrinology assays (e.g., Vitamin D), genetic assays (e.g., Newborn Screening), and many others.

ASCENT™ has been developed to scale to very high volume tests some as high as tens of thousands per day producing calculated results within minutes.

ASCENT™ replaces the technician manual steps with automated functions that

- Retrieve the results from the instrument computer
- Establish baselines
- Select peaks
- Quantify results
- Calculate calibrations
- Apply all assay QC rules
- Flag results for review
- Transfer results to LIMS



In the ASCENT™ process, the technician is required to review only those results that are flagged, significantly reducing the time spent on data analysis and review:

- No need to manually transfer results from instrument computer to the area where the analyst will perform analysis and review
- No need to review all peaks
- No need to manually select baselines
- No need to manually optimize and calculate calibration curve

- No need to look at multiple screens or pieces of paper to make decisions
- No need to remember to apply all QC rules established for an assay
- No need to invoke Excel or other programs to execute additional calculations or data conversions
- No need to manually transfer the results to the LIMS, LIS or database

Estimating the Savings

Estimating the savings is a critical step in the decision to acquire ASCENT™. Answers to the following questions are needed to estimate the savings about current process. For each, describe the steps and estimate the time required per batch or sample as applicable.

1. Describe how the batch load (sequence) list is generated, obtained and matched to samples.
2. Describe the steps for initially ensuring the batch quality prior to release for review by analysts
3. Describe how the results are transferred from the instrument acquiring computer to the computer/server used by reviewers.
 - a. If a batch finishes in the middle of the night or in between shifts, how long does it sit before the next person takes over the process?
4. Describe the review process
 - a. What software is used for review?
 - b. Are results reviewed by 2 or more individuals (analyst, reviewer, certifier)?
 - c. Describe the displays/paper reports used to review the results?
 - d. How are changes made to the chromatograms?
 - e. How is calibration performed?
 - f. How are assay QC rules applied?
 - g. How do you know the QC rules have been applied?
 - h. How are reworks/reruns determined, communicated to operator and set up for execution?
 - i. How are changes to results made?
 - j. How are results signed off?
5. Describe the process of transferring results to the LIMS/LIS
 - a. Is the transfer automated or does it require a manual process?
 - b. Do the results need to be reviewed once they have been transferred into the LIMS?
 - c. Are there changes to results that must be made in the LIMS (e.g., changing to "<" or ">", + or - signs or zeroing out)?
6. Other important information
 - a. Average hourly cost of FTE (fully loaded)
 - b. Number of shifts
 - c. Hours per shift

Once the process gets mapped out and the time required to complete a full batch estimated, the savings can be calculated using the ASCENT™ Savings Calculator. The figure below shows a sample of an estimated savings. The cells highlighted in yellow represent numbers entered by the lab. The cells

highlighted in blue are assumptions based on tests conducted with common assays in several laboratories. The % of determinations flagged may vary from 10% to less than 5% depending on the flag limits selected. The average review time of 20 seconds per review flag is fairly consistent.

ESTIMATED SAVINGS FROM ASCENT™			
COMPANY:	Company		
ASSAY:	Assay		
<i>Sample and Batch Workload</i>		<i>Work Schedule and Labor Costs</i>	
Patient Samples/day:	1,000	Lab Work Days/Week:	7
Patient Samples/Year:	364,000	Analyst Annual Salary:	\$ 50,000
Patient Samples/Batch:	60	Benefit Allocation:	30%
Batches/day:	17	Fully Loaded Annual Cost:	\$ 65,000
Determinations/Patient Sample:	7	Cost per FTE per Hour:	\$ 31.25
Determinations/Batch:	420	Costs per FTE per Day:	\$ 250.00
Determinations/Day:	7,000	Effective Work Hrs/Day/FTE:	7
<i>Labor Costs Current</i>		<i>Labor Costs with Indigo</i>	
% of Determination Reviewed by Analyst:	200%	% of Determinations Reviewed by Analyst:	10%
Analyst Time/Batch (min)	150	Analyst Time/Batch (min):	14
Analyst Time/Batch (hrs):	2.5	Analyst Time/Batch (hrs):	0.23
# of Determinations reviewed by Analyst/batch:	840	# of Determinations reviewed by Analyst/batch:	42
Analyst Time/Determination (sec):	21	Analyst Time/determination (sec):	20
Total Analyst Time/Day (hrs):	42	Total Analyst Time/Day (hrs):	4
Analyst FTEs/Day:	6.0	Analyst FTEs/Day:	0.6
Total Analyst FTE Cost/Day:	\$ 1,488	Total Analyst FTE Cost/Day:	\$ 139
FTE Cost per Batch:	\$ 78.13	FTE Cost per Batch:	\$ 8.33
FTE Cost per sample:	\$ 1.49	FTE Cost per sample:	\$ 0.14
FTE SAVINGS			
Savings Per Sample (Min):	2.27	Savings per Batch (Min):	136.00
Savings Per Sample:	\$ 1.35	Savings per Batch:	\$ 69.79
Annual FTE Cost Savings			\$ 491,111