Analysis and Optimization of a Drug Testing Process (Under NDA)

Natalie Coaster, Scott Lyon, & Courteney Roberts
Client: Trident Biometrics, Faculty Advisor: Dr. Jade Mitchell

Background

Trident Biometrics (Trident) is a drug testing company in Holland, Michigan, which receives hundreds of urine and oral fluid samples daily. Forty clients send samples, including hospitals and doctors. Trident performs a confirmation test on these samples and the first phase of the test is to undergo solid phase extraction (SPE). The analytes extracted from SPE are analyzed using liquid-chromatography mass spectroscopy (LCMS). This test detects if a certain analyte is present in the sample and then quantifies the concentration. Trident currently has six urine LC methods and three SPE methods.

Trident receives client samples from United Parcel Service (UPS) each day at 10:15 A.M. Each sample is scanned and aliquoted before SPE. Once SPE is performed on the samples that need it, the samples are loaded on the LCMS machines. For an Agilent machine to run all 130 samples, multiple machines are used in sequence. Each machine runs for 16 hours and produces 130 urine samples. The machines have to be cleaned after running for 16 hours, resulting in a total of 4 hours per day. If one of the machines is not being used, the machine is run for 17 hours. All machines were dedicated for PFAS and oral samples. The last machine was not in use. For an Agilent machine to run urine samples it must go through a two-month validation process. Trident has three HPLC Agilent machines. Two of them were designated for PFAS and oral samples. The last machine was not in use. For an Agilent machine to run urine samples it must go through a two-month validation process. If clients input patient data and tests into a computer software used by laboratories to keep track of data and results Currently, 3 hours are spent scanning and aliquoting before SPE. Once SPE is finished, the sample is run on the LC method machine. The team observed a bottleneck from the scanning step to the aliquoting step. The new sample volume would also put the Sample Intake scanning step at risk. Hiring a full-time aliquoter and part-time scanner would reduce bottleneck risk.

Methods

Technical Analysis

- Using Microsoft Project's WBS, the team performed a time study of all the steps from 'Sample Intake' to 'Report Results' for a typical day of 130 urine samples and 30 oral samples
- Assigned employees to each step
- Assigned predecessors to reflect daily workflow
- Calculated a critical path via Microsoft Project's algorithm (Figure 2)
- Formulated design recommendations that aimed to shorten critical tasks' durations to ensure samples finish on time
- Justified with Gantt Chart (Figure 4)

Design Alternatives

- #1: Move Sample Ordering to LIMS
  - Trident received client samples from United Parcel Service (UPS) each day at 10:15 A.M. Each sample is scanned and aliquoted before SPE. Once SPE is performed on the samples that need it, the samples are loaded on the LCMS machines (Figure 1). LC data is reviewed the next day by trained lab personnel. Once the data passes the quality control checks, the report gets sent out to clients via email. For 130 samples, the entire process is completed within 48 hours.

- #2: Hire a Full-Time Aliquoter and Part-Time Scanner
  - The aliquoting process takes up to 3 hours to complete and is a part of the Sample Intake process. Hiring a full-time aliquoter and part-time scanner would reduce bottleneck risk.

- #3: Rearrange Methods on LC Machines
  - The team needed to find the combination of methods that resulted in the earliest finish times possible for each method using the projected process time per sample for each method once sample volume doubled (Table 1).

- #4: Validate Agilent Machine for LC-10
  - Trident has three HPLC Agilent machines. Two of them were designated for PFAS and oral samples. The last machine was not in use. For an Agilent machine to run urine samples it must go through a two-month validation process. A sample manager must also be installed for the machine to automatically test each sample.

Selected Design

The design recommendation was formulated by optimizing the five critical tasks from the work breakdown structure (Sample Intake, SPE, and LC Method-7). The methods design recommendation was a three-pronged approach to:

- Rearrange methods on the LCMS machines
- Combine LC methods 11 and 12 into method 10
- Hire full-time aliquoter/data analyzer and part-time Sample Intake scanner

Economic Analysis

The team provided Trident with a payback period for purchasing a new LCMS machine. Since LC method-7 was a critical task, it was determined that purchasing a new machine was the only design recommendation that would guarantee all samples would be processed without impacting project completion.

For this analysis, the team gathered information from Trident regarding total labor costs, consumable costs, and shipping costs. The team also obtained an average profit and cost that Trident has per sample via their largest client, who was responsible for 94.5% of their sample volume. Trident received a profit of $89.60/sample and a total cost of $21.53 per sample. This yielded a net profit of $68.07/sample. To calculate the total payback period, the team took the average profit and cost per sample and used the lowest number of samples Trident received in one day over the course of a two-week period, which was 105 samples.

The team calculated a payback period using the total net profit of $5,340/day. The payback period for purchasing a typical $60,000 machine was less than a month. The actual payback period would be longer (about a year). This is because fringe benefits, insurance, non-laboratory staff costs, and other building costs weren’t accounted for in the calculation.

References
