# improved efficiency and lower costs using simultaneous testing for TOC and conductivity

## challenge

Total Organic Carbon (TOC) and conductivity measurements are required for compendial water quality. Manual testing of both parameters can take hours of analyst time. This time-consuming process includes collecting samples, testing samples, recording data, and waiting on review and approval of the recorded data either on paper or in an electronic Laboratory Informatics Management System (LIMS). A Global Biotechnology Company, located in the US, was motivated to find a testing platform for both TOC and conductivity that would gain efficiency, lean out processes, and enable results to be exported to the LIMS.

## solution

To improve efficiency and lower costs, the company chose to evaluate the Sievers* M9 Laboratory TOC Analyzer. This instrument simultaneously measures TOC and USP Stage 1 Conductivity from a single container, the Dual Use Conductivity and TOC (DUCT) vial. The M9 Lab Analyzer also features a shorter sample analysis time, uses less sample volume, and has the ability to integrate with a LIMS.

The method verification approach followed by this Global Biotechnology Company was an interpretation of USP <1225>, "Validation of Compendial Procedures". The company evaluated three areas of testing. The first two areas were verification of the suitability of the TOC and USP Stage 1 Conductivity test methods. This is a direct requirement per USP <1225>. The third area of testing performed was to verify suitability of the new DUCT sampling containers and evaluate sample hold time in those containers to support internal operating procedures.

This testing will not be discussed here, as the company performed independent testing supporting a five-day hold time for TOC and conductivity samples in DUCT vials.

The company performed a method transfer for conductivity with the M9 Lab Analyzer and clearly demonstrated that the method is accurate, precise, and linear. These data are presented in **Table 1**.

**Table 1: Summary of Conductivity Method Transfer Results**

| Analytical Performance Characteristic | Results | | |
|---|---|---|---|
| | Run 1 | Run 2 | Run 3 |
| **Accuracy (%)** | 95 | 95 | 91 |
| **Precision (% RSD)** | 1 | 1 | 5 |
| **Linearity (r2)** | 0.9999 | 0.9999 | 0.9995 |

The method for TOC analysis had been validated on the current TOC analyzer, which used comparable technology. Therefore, this company chose to run system suitability kits from the same lot on both the new M9 Lab Analyzer and the existing TOC analyzer to serve as a bridging study. Due to the change in vial type, a system suitability kit made in DUCT vials was also run to demonstrate comparability of the container.

All three system suitability kits passed the acceptance criterion of 85-115% using the Sievers M9 Lab. This response efficiency demonstrated suitability and acceptability for use of both the M9 Lab Analyzer and the DUCT vials. These data are presented graphically in **Figure 1**.

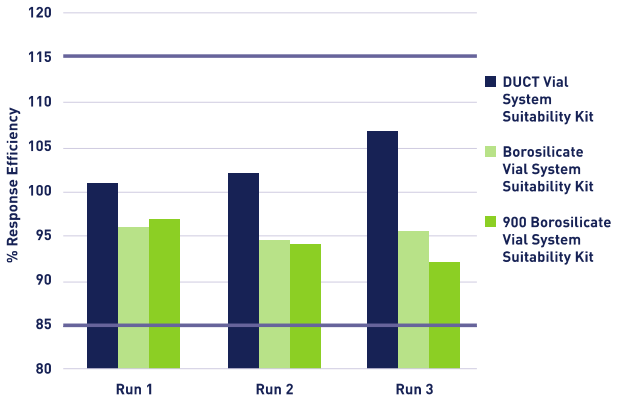


**Figure 1: TOC Method Transfer Results**

In addition to superior analytical performance, the M9 Lab Analyzer demonstrated compatibility with the laboratory data management system for both TOC and conductivity analyses. This ability to export both TOC and USP Stage 1 Conductivity results electronically eliminated human transcription errors and saved analyst time. In this specific case, the company was able to configure the system to auto-populate results for multiple samples. If the results are passing, the LIMS makes them available for review and approval. This enabled the workflow from sampling to result review to be entirely paperless. The company estimated a time savings of approximately four hours per day.

## results

The calculated ROI, payback period, and net present value realized by the company were 400%, seven months, and approximately $400,000, respectively. The most striking aspect of the ROI is, despite the higher costs of DUCT vials (**Table 2**), the reduction in number of samples resulted in significant overall savings to the company (**Table 3**).

**Table 2: Summary of Sample Cost**

| Cost Type (per sample) | Current | Future |
|---|---|---|
| **Conductivity Consumables** | $ 2.58 | $ 15.70 |
| **TOC Consumables** | $ 4.83 | N/A |
| **Total Consumable Cost** | $ 7.41 | $ 15.70 |
| **Labor Cost** (5 min. reduction) | $ 8.17 | $ 2.33 |
| **Maintenance**[1] | $ 0.44 | $0.88 |
| **Overall Total Cost** | **$ 16.01** | **$18.91** |

1. Note that the combination of TOC and USP Stage 1 Conductivity testing doubles this number.

**Table 3: Summary of Year 1 Data**

| Cost Factors | Current | Future |
|---|---|---|
| **Capital Costs** | N/A | $ (99,710) |
| **Variable Costs**[1] | $ (271,454) | $ (163,234) |
| **Projected Labor Savings** | N/A | $ 72,800 |
| **Total Cost** | **$ (271,454)** | **$ (190,144)** |
| **Overall Cost Savings** | **$ 81,310** | |
| **Payback Period** | **7 months** | |

1. This reflects labor, maintenance, and material costs.

The demonstrated ROI accounts for the integration of the analyzer with the LIMS. If a manual process continues to be used in lieu of the LIMS, the payback period increases to 11 months but still under a year. This is an excellent example of how implementation of combined TOC and USP Stage 1 Conductivity testing using the M9 Lab Analyzer can save companies time and money. This approach reduced the total number of samples being testing in the laboratory, resulted in a large cost savings, and allowed the organization to redirect resources to focus on other operational excellence and lean initiatives.

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