

## Validation Manual Included

Every RapidTrace SPE Workstation comes with its own Validation Manual. This is a comprehensive document that includes detailed, step-by-step instructions to help you meet GLP, GMP and GOP requirements. Experienced Caliper Life Sciences consultants are available on a contract basis to assist with any validation assignment.

## TurboVap LV Workstation Is the Ideal Productivity Partner

Caliper's TurboVap LV Evaporation Workstation offers "load it and leave it" high throughput, controlled evaporation for up to 50 samples simultaneously. Patented "gas vortex shearing" is 3-10 times faster than conventional nitrogen blow-down techniques.



## We only succeed when you're successful

Caliper's Bioanalytical Group was formed specifically to meet the automation needs of pharmaceutical drug development, forensic and racing commission laboratories and contract research organizations.

The first step on the path to higher productivity starts with a phone call. To find out more about innovative Caliper Life Sciences Workstations for bioanalytical extractions, call (508) 435-9500 today.



Caliper Life Sciences  
Corporate Headquarters  
68 Elm Street  
Hopkinton, MA 01748-1668  
1-508-435-9500  
www.caliperLS.com  
Fax: (508) 435-3439  
Email cust.support@caliperLS.com

### Worldwide Offices

*Benelux*  
Caliper Life Sciences N.V.  
Klapstraat 13  
B-1790 Terafene  
Belgium  
Telephone: +32-53-66-26-70  
Fax: +32-53-66-27-32

*France*  
Caliper Life Sciences S.A.  
ZAC PARIS-NORD II  
13 rue de la Perdrix  
BP 48016 Tremblay en France  
95911 Roissy CDG Cedex  
France  
Telephone: +33-1-48-63-71-35  
Fax: +33-1-48-63-71-53

*Germany*  
Caliper Life Sciences GmbH  
Eisenstrasse 9c  
DE-65428 Rüsselsheim  
Germany  
Telephone: +49 6142 834 93-0  
Fax: +49 6142 162 821

*Japan*  
Caliper Life Sciences Japan  
Saito-Bldg. 2F  
Yushima 2-17-15, Bunkyo-ku  
Tokyo 113-0034  
Japan  
Telephone: +81-3-5840-6551  
Fax: +81-3-5840-6554

*Switzerland*  
Caliper Life Sciences AG  
Nordstrasse 17  
CH-4665 Oftringen  
Switzerland  
Telephone: +41-62-788-7000  
Fax: +41-62-788-7017

*United Kingdom*  
Caliper Life Sciences Ltd.  
1 Wellfield  
Preston Brook  
Runcorn, Cheshire WA7 3AZ  
United Kingdom  
Telephone: +44-1928-711448  
Fax No: +44-1928-791228

Caliper Life Sciences has representative offices worldwide. Please visit [www.caliperLS.com](http://www.caliperLS.com) for locations and contact information.

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PRT/RT-BR-01

# RapidTrace Solid Phase Extraction (SPE) Workstation



*Automated High  
Throughput  
SPE Extraction*



## RapidTrace Workstation

Advanced bioanalytical techniques like LC/MS/MS and GO/MS are meeting the increasing demand for greater speed and specificity in toxicological screening. But conventional sample preparation methods have not kept pace. In particular, solid phase extraction (SPE), an essential step in the analysis of many biomolecules, has become a through-put limiting handicap in many laboratories.

Caliper Life Sciences RapidTrace SPE Workstation eliminates SPE bottlenecks, so that your lab can realize the full benefits of today's powerful -and costly-analytical instruments.

RapidTrace is the perfect complement to high-speed analytical techniques, a powerful high-throughput workstation dedicated specifically to SPE bioextraction. In its full modular configuration, a single workstation can process 40-60, even 100, samples per hour!

Designed especially for the regulated pharmaceutical, clinical and forensic environment, RapidTrace is also a robust automated platform for quickly developing rugged, reliable SPE methods. These procedures can be easily transferred from workstation to workstation from site to site, or from the pharmaceutical to an outside Contract Research Organization.

## SPE

### Automated High Throughput SPE Extraction

#### Increased Throughput for Routine Sample Handling

Your SPE processes can keep up with your analytical capabilities. Plus, the modular design of the RapidTrace workstation lets you add capacity as required; for example, as a compound moves from initial toxicology screening into more formal pre-clinical studies and then into human clinical trials.

#### Accelerated Methods Development and Optimization

Using a friendly, familiar Windows interface, you can easily implement a structured, "rational" strategy for SPE experiments to determine optimum SPE conditions for each of your samples.

#### Readily Transferable Methods

Methods stored in the RapidTrace controller can be instantly recalled, and can be transferred to other RapidTrace workstations with 100% confidence.

#### "Parallel Processing"

##### Assures Maximum Productivity

Each module operates independently. So if one is shut down for operator attention, the others stay on-line.

#### Improved Operator Safety

Caliper's automated approach improves lab safety by minimizing operator contact with hazardous samples and chemicals.

#### Validation Documentation Included with Each Workstation

##### Better Analytical Results

Finally, RapidTrace provides the consistently clean extracts that sophisticated analytical instruments like LC/MS/MS and GO/MS require for optimum performance.

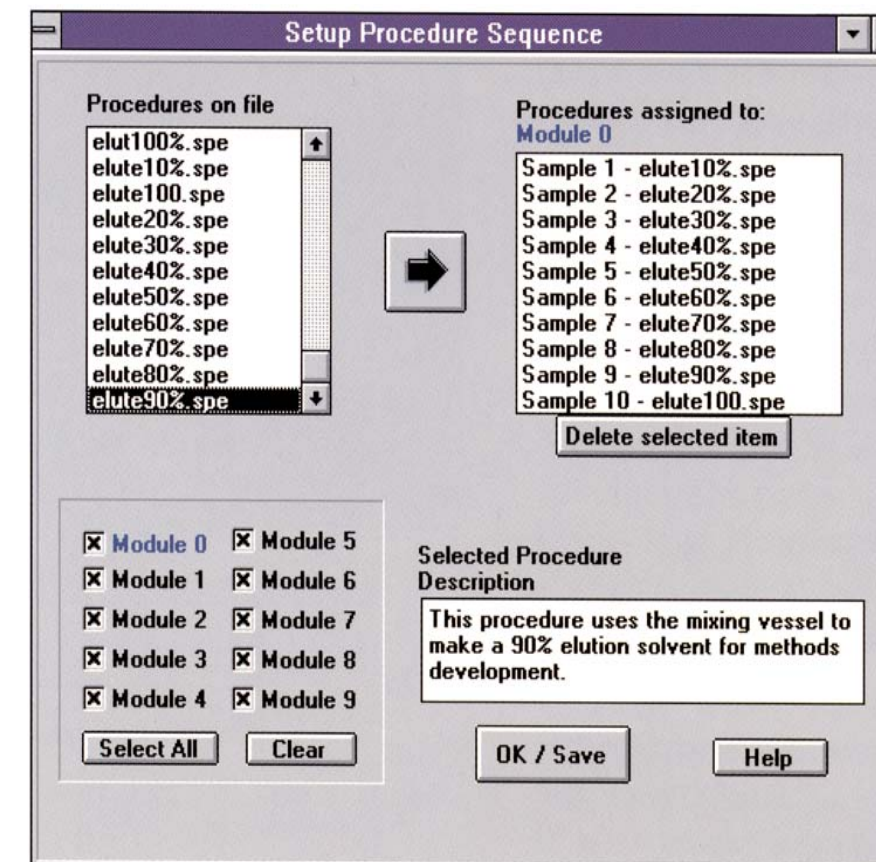
## Rational Methods Development

### OPTIMIZING EXTRACTION STRATEGIES

#### Automated SPE Methods Speed Assay Development

Developing an HPLC assay for an investigational peptide, a high-throughput drug metabolism laboratory used SPE techniques to isolate the peptide and an internal standard from rat plasma. The RapidTrace Workstation allowed them to develop an optimized extraction strategy in a fraction of the time required by conventional bench methods.

By applying stored methods to a series of samples, and selectively varying extraction conditions, the lab was able to achieve analyte recovery of about 85% (compared with the previous 60-65%), with no loss of precision. Based on these results, the RapidTrace methods were later extended to human samples, and showed excellent accuracy and precision over a standard curve range of 2.5-2500 ng/mL.



Recovery Data for RapidTrace SPE Extraction Method of Investigational Peptide in Human Plasma

| Concentration Range of Standard (ng/mL) | Mean Concentration Found (n=5) (ng/mL) | % Recovery |
|---|--|------------|
| 2.5                                     | 2.47                                   | 99%        |
| 5.0                                     | 5.07                                   | 101%       |
| 10.0                                    | 10.2                                   | 102%       |
| 25.0                                    | 25.4                                   | 102%       |
| 50.0                                    | 50.7                                   | 101%       |
| 100.0                                   | 95.3                                   | 95%        |
| 250.0                                   | 248.0                                  | 99%        |
| 500.0                                   | 519.5                                  | 104%       |
| 1000.0                                  | 1042.5                                 | 104%       |
| 1750.0                                  | 1735.7                                 | 99%        |
| 2500.0                                  | 2448.5                                 | 98%        |

# High Sample Throughput Assay

## SCREENING FOR COCAINE METABOLITE (BZE)

### Drug Testing Lab Processes 56 Samples/Hour with High Reliability

A common test for drugs of abuse is screening urine for the presence of Benzoylcegonine (BZE) for confirmation by GO/MS. The SPE cleanup is labor intensive, and, using conventional vacuum manifold methods, is highly susceptible to operator variations.

To bring the process under control, to improve lab throughput and to reduce analysis costs, a contract testing lab automated the procedure using a RapidTrace Workstation. The automatic procedure can be run in just 11 minutes; on the lab's 10-module Workstation, it now takes less than two hours to process 100 samples!

| Step | Source        | Destination                    | Volume (mL)       | Flow (mL/sec) |     |
|------|---------------|--------------------------------|-------------------|---------------|-----|
| 1    | Condition     | MeOH                           | Waste 2           | 3.0           | .30 |
| 2    | Condition     | diH <sub>2</sub> O             | Waste 1           | 3.0           | .30 |
| 3    | Condition     | pH6                            | Waste 1           | 3.0           | .30 |
| 4    | Load          | Sample                         | Waste 1           | 4.0           | .04 |
| 5    | Pause         | —                              | Time = 0.1 minute |               |     |
| 6    | Purge-Cannula | diH <sub>2</sub> O             | Cannula           | 4.0           | .40 |
| 7    | Rinse         | diH <sub>2</sub> O             | Waste 1           | 3.0           | .15 |
| 8    | Rinse         | H <sub>3</sub> PO <sub>4</sub> | Waste 1           | 3.0           | .15 |
| 9    | Rinse         | MeOH                           | Waste 2           | 3.0           | .15 |
| 10   | Rinse         | Vent                           | Waste 1           | 5.0           | .30 |
| 11   | Collect       | Mixed                          | Fraction 1        | 3.0           | .20 |
| 12   | Rinse         | Mixed                          | Waste 2           | 2.5           | .20 |
| 13   | Rinse         | MeOH                           | Waste 2           | 2.5           | .20 |
| 14   | Purge-Cannula | MeOH                           | Cannula           | 3.0           | .40 |
| 15   | Purge-Cannula | diH <sub>2</sub> O             | Cannula           | 3.0           | .40 |

| Within Run                   |     |     |            |     |     |      |          |               |
|------------------------------|-----|-----|------------|-----|-----|------|----------|---------------|
| Control Target Value (ng/mL) | 1   | 2   | Sample # 3 | 4   | 5   | Mean | C.V. (%) | Avg. Recovery |
| 120                          | 113 | 118 | 120        | 119 | 113 | 117  | 2.9      | 97.5%         |
| 180                          | 182 | 176 | 186        | 176 | 174 | 179  | 2.8      | 99.4%         |
| Run-To-Run                   |     |     |            |     |     |      |          |               |
| Control Target Value (ng/mL) | 1   | 2   | Run # 3    | 4   | 5   | Mean | C.V. (%) | Avg. Recovery |
| 113                          | 117 | 117 | 119        | 122 | 124 | 120  | 2.4      | 106.2%        |

**Linearity**  
R<sup>2</sup> = 0.9999 (75-1000 ng/mL)

**Throughput**  
56 samples/hour (10 module RapidTrace Workstation)

# RapidTrace SPE Workstation, UNMATCHED PERFORMANCE AND THROUGHPUT

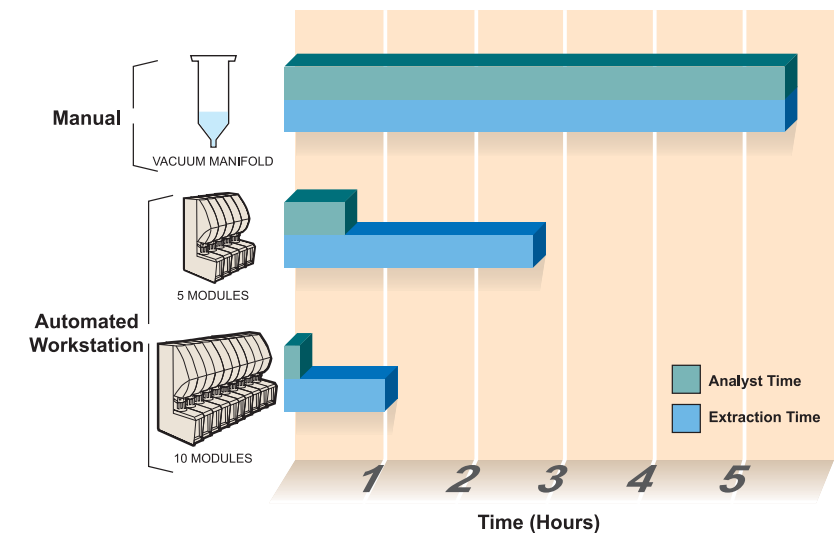
RapidTrace eliminates tedious and time-consuming manual bioextraction methods. Every step of the SPE process is automated and rigorously controlled, to give you a level of reproducibility that simply can't be obtained with conventional techniques.

Capable of handling up to ten samples/module, a 10 module RapidTrace Workstation delivers the throughput a busy lab needs to keep up with 2-5 minute LC/MS/MS cycle times.

- Modular design lets you add throughput capability as required-up to 100 samples per run at up to 100 SPE samples per hour! Modules within a group can run different methods. Or, modules can be separated and even used in different labs.

- All sample and solvent flow rates are individually controlled under positive pressure. You'll improve results by optimizing each step of the SPE process for maximum accuracy and precision (something you can't do with a conventional vacuum manifold).

- You can program individual modules and even individual samples with different conditions to speed development and test methods for ruggedness and reliability.



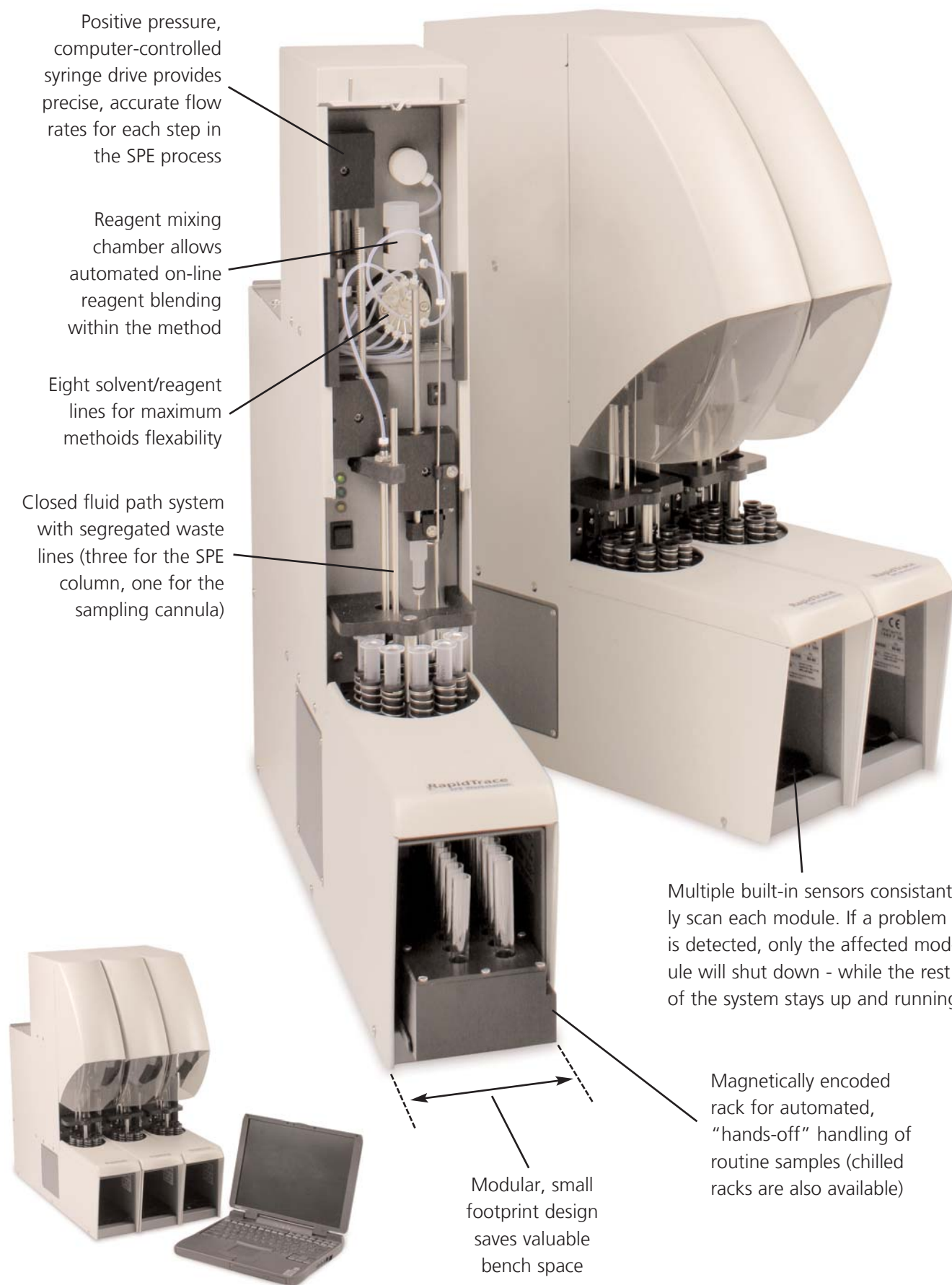
**Improved Throughput and Workflow** - In one lab using a RapidTrace Workstation versus a vacuum manifold to extract 75 samples, there was a 93 % reduction in analyst time and a 72 % reduction in extraction time.

## FAST AND EASY DEVELOPMENT OF "BULLET-PROOF" METHODS

Because you can write methods in minutes (and call them up in seconds), you can optimize your SPE conditions in a fraction of the time required using conventional techniques. Column types, reagents, concentrations and flow rates can be thoroughly explored; for example, you can vary a single parameter (pH, percent solvent, cartridge type, flow rate, etc.) incrementally to see its affect on recovery and precision. This unique "rational SPE design" capability dramatically speeds the development of rugged, reliable methods.

The familiar Windows interface makes methods set up and editing as easy as "point and click." Simply select an operation, then enter the desired reagent, reagent volume and flow rate; each of these parameters can be defined independently for each step. As each operation is selected, RapidTrace automatically adds it to the procedure.

Editing methods is just as easy. You can insert, delete or change steps, or adjust any of the parameters. Methods can be assigned to an individual sample or by module. They can be saved and run together for true "multi-method" SPE, in an unattended run.



Positive pressure, computer-controlled syringe drive provides precise, accurate flow rates for each step in the SPE process

Reagent mixing chamber allows automated on-line reagent blending within the method

Eight solvent/reagent lines for maximum methods flexibility

Closed fluid path system with segregated waste lines (three for the SPE column, one for the sampling cannula)

Multiple built-in sensors consistently scan each module. If a problem is detected, only the affected module will shut down - while the rest of the system stays up and running

Magnetically encoded rack for automated, "hands-off" handling of routine samples (chilled racks are also available)

Modular, small footprint design saves valuable bench space

RapidTrace Controller provides direct PC control with either desktop or laptop PC

Ten 13x100mm sample input tubes in each RapidTrace module allow simultaneous processing of up to 10 SPE samples



Locations for 10 12x75mm fraction collection tubes allowing for collection of up to 10 fraction/samples



Ten position SPE column turret accepts any 3 mL or 1 mL syringe barrel SPE columns (adapters available for SPE disks or soft gel cartridges)

## Improved Productivity

### NEW DRUG CANDIDATE PLASMA STUDIES

#### **Pharmaceutical Lab Improves Productivity and Reduces Assay Costs**

A large pharmaceutical company required analytical data on plasma levels for a new drug candidate in early phase clinical trials. Considered a "routine" analysis, the sample load was outsourced to a contract lab.

In an effort to improve turnaround time and reduce costs, the lab turned to RapidTrace SPE automation. The original method, developed using 3 mL SPE cartridges on a vacuum box, was transferred to the automated unit, further optimized, and quickly validated. Within days, the 10-module RapidTrace workstation was on-line, delivering a faster, more reliable assay and considerable savings in time and labor.

#### Performance/Productivity Comparison

##### Drug in Plasma Extraction

| Item  | RapidTrace (10 Modules) | Vacuum Manifold |
|---|-------------------------|-----------------|
| # of Manual steps to run a sample               | 5                       | 17              |
| Time to run 75 samples                          | 1 Hour                  | 4.5 Hours       |
| % Failures                                      | 0%                      | 15%             |
| # of Runs required for 75 sample batch          | 1 Run                   | 3 Runs          |
| # of Standards and controls for 75 sample batch | 5                       | 15              |
| Operator time                                   | 0.3 Hour                | 4.5 Hours       |