

# Confirming CTech™ SoloVPE® System Readiness with NIST Traceable ConfiRM® Slope Reference Materials

Standard Operating Procedure



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## Abstract

This procedure has been prepared to provide CTech™ SoloVPE® System users with clear guidance on the proper use of the NIST-traceable, certified CTech™ ConfiRM® slope reference materials from Repligen. Designed specifically for variable pathlength systems, ConfiRM slope reference materials is the ideal material to use for system suitability, daily health, and quality control checks of the SoloVPE System.

## Applicability

This procedure explains the steps for using ConfiRM slope reference materials with the SoloVPE System. If unexpected results are observed, contact Repligen at US +1 908-707-1201. Please have the SoloVPE serial number and ConfiRM lot number available.

## Materials Required

- Part Numbers (**ConfiRM**® MRM-01 Standard): **MRM-01-P10** (10-Ampule Pack), **MRM-01-P1** (Single Ampule)
- Pipette with disposable tips (100µl Dispensing Range)
- New small plastic vessels (Part Number: OC0009-1-P50)
- New Fibrette® Optical Components (Part Number: OF0002-P50)
- Ampule opener (Optional/Recommended)

## General Information and Safety Precautions for ConfiRM Usage

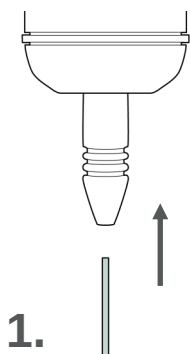
- The **ConfiRM safety data sheet (SDS)** can be found at [ctech.repligen.com](http://ctech.repligen.com)
- Follow all site policies and guidance on personal protective equipment and laboratory safety best practices.
- **ConfiRM slope reference materials** are provided with a certificate that includes the NIST-traceable, certified slope value and uncertainty required by this procedure.
- The **ConfiRM** expiration date is provided with the product and should be checked prior to use.
- All surfaces should be thoroughly cleaned before beginning the procedure.
- Dispose of chemicals and sharps according to site policies and procedures.
- Additional prompts may be observed when this procedure is performed on SoloVPE Systems implemented in GxP environments (e.g. Autosave Prompts, E-Signature Prompts, etc.).

## Standard Operating Procedure

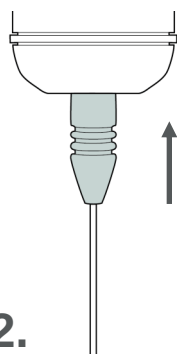
- 1.0 Open the Quick Slope utility by clicking the Quick Slope button on the SoloVPE sidebar. The Quick Slope application window will appear.
- 1.1 A Quick Slope run cannot be started without certain required information being provided. After method information is entered, the user must click **Set Method** to start the measurement.
- 1.2 The user must provide the following information:
  - Sample Name: Specify in an existing field
  - Additional user-defined fields for product name, lot number, etc. are available by clicking the ellipsis (...) button.
  - Slope Mode: Quick-M
  - Sample Vessel: PV-OC0009-1
  - Wavelength(nm): 272 nm
  - Quick Slope Results: Concentration
  - Extinction Coefficient: Unknown
  - Baseline Correction: Off
  - Scatter Correction: Off
  - Rep Mode: Repeat
  - Rep Count: 3

1.3 Click **Set Method** to confirm and commit the method parameters in the Quick Slope application.

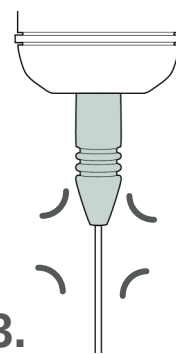
1.4 **Quick Set Fibrette Loading:** To load the Fibrette Optical Component, follow the instructions below. Afterwards, the Fibrette Optical Component is now properly positioned for data acquisition.



1. Gently insert Fibrette® Optical Component until it stops against the surface of the Delivery Fiber.



2. Push up on the silver Quick Set Coupler Insert and push upward until it stops.



3. Release Quick Set Coupler for an audible click, allowing it to automatically drop down.

#### TBA Fibrette Coupler Loading:

Gently insert Fibrette® Optical Component until it stops against the surface of the Delivery Fiber.

Manually pull the Fibrette Optical Component down anywhere between 2 mm and 10 mm to prepare the Fibrette for data acquisition.



1.5 The ConfiRM slope reference materials must be properly mixed in the ampule before use. Five cycles of ampule inversion is recommended. After mixing, if necessary, tap the ampule gently to ensure that no solution remains in the neck of the ampule.

1.6 Use an ampule opener if available, to open the ConfiRM ampule. Prepare the sample for measurement by pipetting 100  $\mu$ l of ConfiRM slope reference materials into the sample vessel.

1.7 Place the sample vessel into the **small vessel holder** and position the small vessel holder in the SoloVPE sample platform in the opening above the Detector.



**1.8** Slide the SoloVPE cover down.

**1.9** Click **Start Collect** to initiate data acquisition. The software will prompt the user to prepare for Quick Slope collection with reminders about preparing the sample and loading a clean Fibrette Optical Component. After system readiness is confirmed, click OK to continue. After the data acquisition cycle is complete, the results of the Quick Slope measurement will be displayed in the Report window.

**1.10** Click **Done** to close the Quick Slope window and to view the reported results. The SoloVPE software may prompt the user to return the Fibrette Optical Component to the Home Position. Click Yes if no additional data will be collected with the installed Fibrette Optical Component. Click No to have the Fibrette Optical Component remain at the Zero Pathlength Position, which allows for data acquisition with the same Fibrette Optical Component.

**1.11** Compare the Quick Slope results with the slope value and uncertainty range from the ConfiRM certificate (see example certificate on last page).

- Verify that the average slope value lies within the range certified on the ConfiRM certificate.
- Verify that the  $R^2$  values are greater than or equal to 0.999.
- Verify that the %RSD should be <2%.

Average-M	Sidev-M	Max-M	Min-M	Range-M	%ReDiff	%RSD	Pnt-Uti
23.17133	0.02784	23.20134	23.14635	0.05499	0.237322	0.120142	1.000000

#### TS180424020 Detailed Data:

RepID	Section Name	Slope (AU/mm)	R-Sqr	Delta Mean (AU/mm)	Delta%
1	PLXQ{TS180424020}[1]@272.00nm	23.20134	23.14635	0.05499	0.129513
2	PLXQ{TS180424020}[2]@272.00nm	23.16630	0.999617	-0.00503	-0.021718
3	PLXQ{TS180424020}[3]@272.00nm	23.14635	0.999588	-0.02498	-0.107809

**1.12** Save the data in the desired location as a Batch (.BVP) by clicking File > Save As from the menu bar or by using one of the Save buttons provided in the SoloVPE software.

## Troubleshooting and Assistance

If the testing results of the ConfiRM slope reference materials do not meet the acceptance criteria, please follow the guidelines provided in the DOC0153 CTech SoloVPE Best Practices.

If unexpected results continue to be observed, contact SoloVPE Service & Support for assistance:

#### Customer Support

[analytics-support@repligen.com](mailto:analytics-support@repligen.com)

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