

SIS PQ Procedure: READ INSTRUCTIONS BEFORE TESTING

This procedure is written for the use of this PQ Standard on the AccuSizer Syringe Injection Sampler. Refer to the documentation/instructions of your system for additional operating instructions.

1. Turn instrument on and allow the instrument to warm up for ½ hour.
2. Start software.
3. Verify that the reported sensor voltage (see the sensor status screen from the View pull down menu) is within 10% of the maximum observed voltage. If not remove sensor and clean.
4. Set the minimum detected size of the instrument to 0.56µm (lower threshold is set by using the up and down cursor keys when the screen is blank and can be observed in right most box of the status bar).
5. Flush the instrument with clean (filtered) water until the cumulative count > 0.56µm is less than 20#/ml.
6. If counts do not decrease to < 20#/ml replace the sip tube with a new one and try again.
7. Verify the volumetric accuracy of the SIS as instructed in the manual.
8. Set analysis parameters as in Figure 1.
9. Prepare the PQ standard for immediate introduction into the instrument.
 - a. mix the bottle by inverting 25 times
 - b. sonicate the sample by placing the bottle in a sonic bath for 30 seconds**NOTE:** if the sample rests for more than 60 seconds before sample extraction prepare the sample again.
10. Sample bottles have a stir bar inside. Set stir speed to 25% and place sip tube such that the stir bar does not hit it nor is it in the vortex.
11. Click on the Start measurement from the tool bar.
12. Ensure the Data file is saved to the computer for analysis.

Analyzing the Data

13. Read one of the data files just created (not the *.cb file).
14. Move to the data display to Population Distribution (128 channels).
15. Press Ctrl+B and choose to display the data in 512 channels.
16. Press M to activate the user defined peak option. A window will appear at the bottom of the screen displaying data on the full range of the distribution.
17. Place the mouse cursor over the graph and click. This produces a cross hair on the graph, use the cursor <left> and <right> keys on the keyboard to move the cross hair to the first Lower Channel Size as defined by the attached Certificate of Analysis and press <Enter>. Position of the cross hair is displayed on the status bar.
18. Then move the cross hair to the Upper Channel Size as defined by the attached Certificate of Analysis and press <Enter>.
19. The software places a vertical black line on each side of the peak indicating the range of the sizes you wish to examine. The window at the bottom of the screen now

contains information about this range. Ensure the range is correct and record the “mean diameter”. Repeat this for each peak in the PQ standard.

20. The software allows 3 User Defined Peaks to be defined and can be printed by choosing “Cumul. Result Table” from the print menu.
21. Compare the mean obtained for each peak with the expected results and range as defined by the Certificate of Analysis.

The mean size reported by your AccuSizer SIS should fall within the ranges defined on the Certificate of Analysis provided that the sample was prepared in accordance with the instructions provided and the instrument has been adjusted properly for sample flow rate and cleanliness. If your results do not fall within the range defined by the Certificate of Analysis please check these parameters and repeat the test.

The nature of sampling is by definition a statistical process. Factors such as stirring speed, sip tube location, and sample volume have an influence on the spatial distribution of the particles within the bottle, which determines the particles that are actually sampled.

Menu Parameters
Figure 1

Experimental Parameters [X]

Volume Injectables

Small Volume

Large Volume

Number of Containers:

Number of Pulls:

Volume of Pull: ml

Volume of Container: ml

Tare Volume: ml

Prime Volume: ml

Include First Pull

Channel/Threshold Setting

CH.	Diam.	Max. #/ml	
1			▲
2			
3			
4			
5			
6			
7			
8			
9			
10			
11			
12			
13			▼

OK Cancel