MFI System Suitability Tests

INTRODUCTION

The Lumetics LINK™ software platform scans network locations for new measurement data files, copies data directly to a centralized database, and provides a powerful user interface for rapid multi-measurement multi-technique data aggregation, visualization, analysis, and reporting. LINK employs a client/server-based architecture where the LINK server hardware is provided by the end user and resides on the end user's network. The LINK client is a portable web-based application that may be placed on any computer with network connectivity to the LINK server. For successful import, the LINK webserver requires read access to the folders where user data resides.

System Suitability Tests (SST) are used to verify that the MFI system performs in accordance with the criteria set forth in the User Manual. The LINK software platform may be utilized to easily determine instrument performance/readiness and produce long-term trends for detecting instrument performance drift.

SST Elements and Specifications (MFI 5100/5200 Flow Microscope, Users Manual D-0000120-00_01)

- 5 µm size standard: ECD average 3.5-6.5 µm +/- 5% of the nominal size of 5 µm
- 10 µm size standard: ECD average 8-12 µm +/- 5% of the nominal size of 10 µm
- 5 µm count cal standard: particle concentration 3.5-6.5 µm +/- 10% of 3000/ml
- 10 µm count cal standard: particle concentration 8-12 µm +/- 10% of 3000/ml
- Blank for 5 µm count cal: particle concentration 3.5-6.5 µm < 2% of 3000/ml
- Blank for 10 µm count cal: particle concentration 8-12 µm < 2% of 3000/ml

DESCRIPTION

LINK dashboards have been generated for the purpose of producing trend charts and measurement summary table summaries that allow one to view each SST result as a function of analysis date. Limit lines representing upper and lower spec limits have been applied to the trend chart. Similarly, conditional cell formatting has been applied to the measurement summary tables.

To import the LINK dashboards to your LINK platform, follow the steps below (upon dashboard import, all requisite measurement summary tables and LINKdb fields shall be created automatically):

1. Click the link to download MFI system suitability dashboards: http://lumetics.com/dashboards/MFI_SST/MFI_SST.zip
2. Open any existing project and analysis template (or New Template)
3. Right-click on any existing dashboard in the template and select 'Import Dashboard',
4. Select one of the SST dashboards that has been downloaded, and follow the software prompts
5. Repeat this process for each of the SST dashboards provided
6. Save the analysis template

To apply the LINK dashboards to a project containing system suitability measurement results, follow these steps:

1. Open any project containing SST data, and the analysis template containing your new SST dashboards
2. Using Add/Edit LINKdb Fields (under the Edit menu), add the SST_MFI_Measurement Type field to the table
3. Assign one of the following to each of the measurements:
    a. 5 µm Count Cal
    b. 10 µm Count Cal
    c. 5 µm Size Std.
    d. 10 µm Size Std.
    e. Blanks Long Term Trend
    f. Blanks as Percentage of Count Cal (3.5

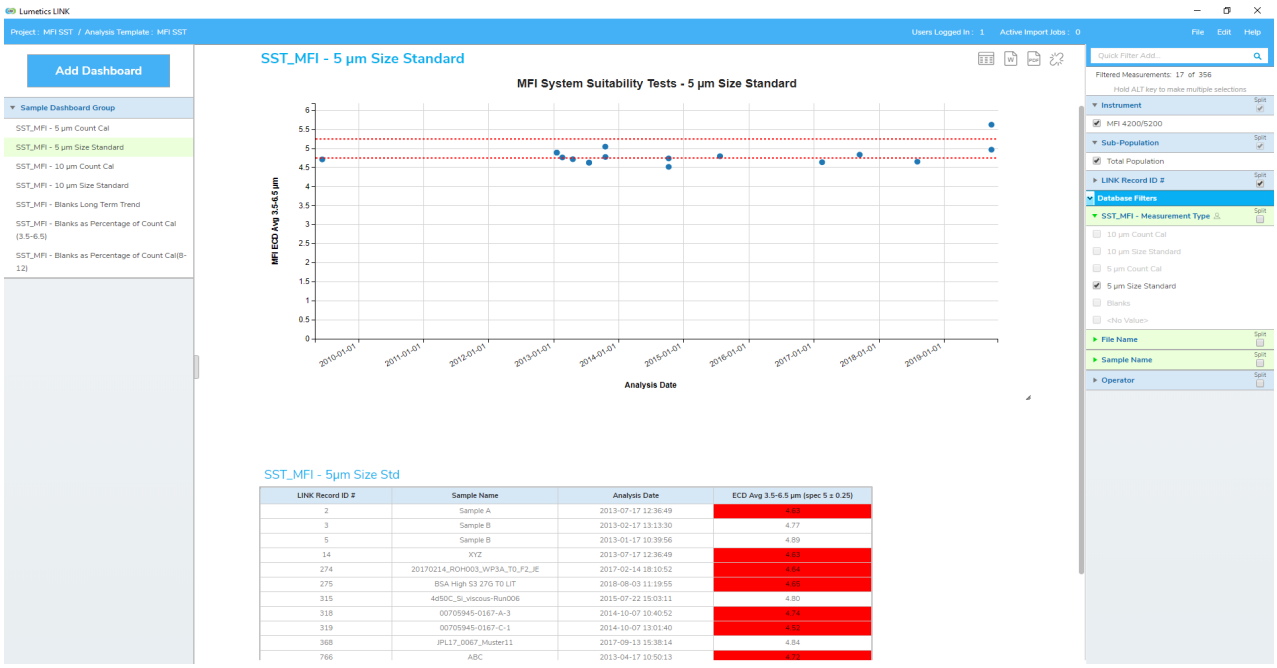
4. Using each dashboard's filter panel, ensure that only appropriate SST_MFI_Measurement Type values are selected.

Your dashboards are now ready to report your SST results!

EXAMPLES

Example 1: 5 µm Size Standard

Where the x-axis is the analysis date and the y-axis is the ECD average between 3.5-6.5 µm.



LINK Record ID #	Sample Name	Analysis Date	ECD Avg 3.5-6.5 µm (spec 5 ± 0.25)
2	Sample A	2013-07-17 12:36:49	4.63
3	Sample B	2013-02-17 13:13:30	4.77
5	Sample B	2013-01-17 10:39:56	4.89
14	XYZ	2013-07-17 12:36:49	4.63
274	20170214_ROH003_WP3A_T0_F2_JE	2017-02-14 18:10:52	4.64
275	BSA High S3 27G T0 LIT	2018-08-03 11:19:55	4.65
315	4d50C_Si_viscous-Run006	2015-07-22 15:03:11	4.80
318	00705945-0167-A-3	2014-10-07 10:40:52	4.74
319	00705945-0167-C-1	2014-10-07 13:01:40	4.52
368	JPL17_0067_Muster11	2017-09-13 15:38:14	4.84
766	ABC	2013-04-17 10:50:13	4.22

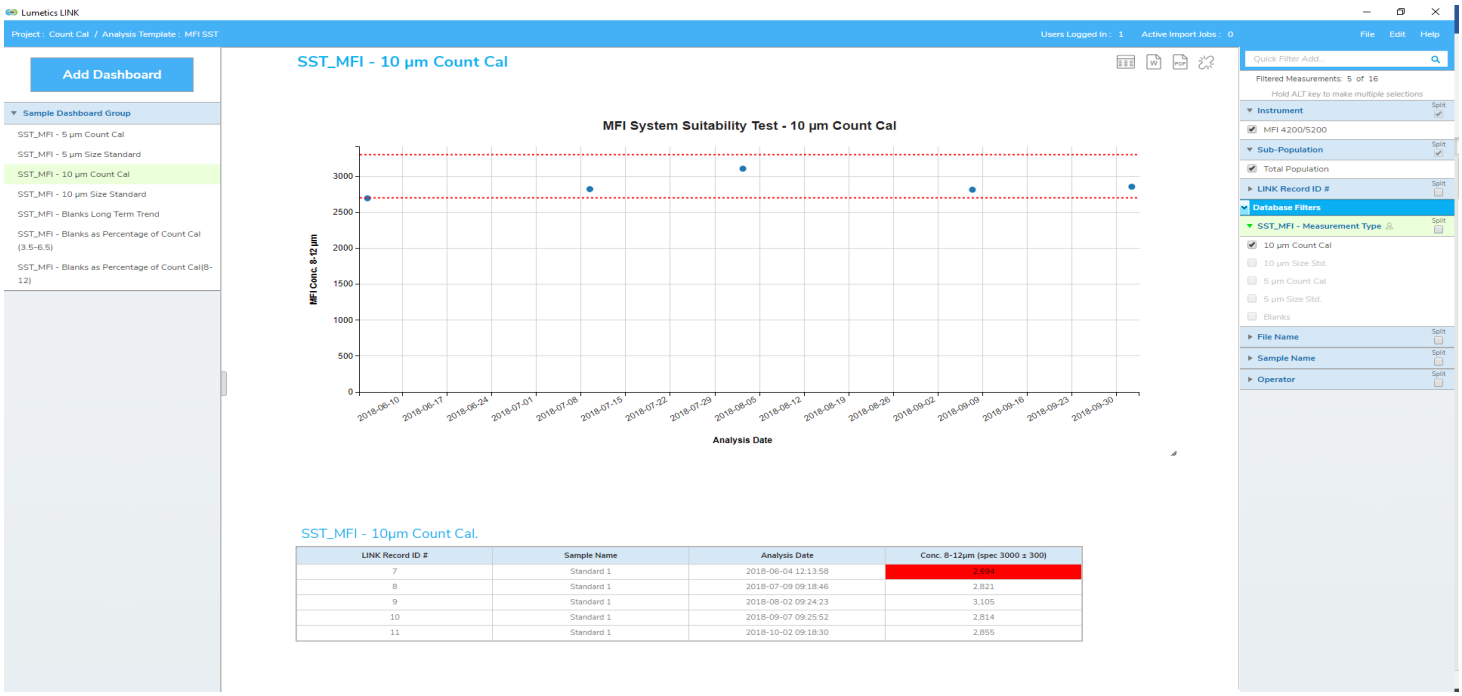
Example 2: 10 µm Size Standard

Where the x-axis is the analysis date and the y-axis is the ECD average between 8-12 µm.

LINK Record ID #	Sample Name	Analysis Date	ECD Avg 8-12µm (spec 10 ± 0.5)
1	Sample A	2013-02-17 13:44:37	9.38
4	Sample C	2013-01-17 13:19:18	9.78
6	Sample C	2013-02-17 11:42:15	9.68
276	20140324_AlN457 Form Screen-Run026	2014-03-24 19:44:39	9.45
278	Sample_W	2011-05-17 09:16:03	9.49
303	s31631	2018-05-16 10:04:47	8.76
306	s31632	2018-05-16 10:12:45	9.87
312	2w50C_Si_viscous-Run003	2015-08-03 17:34:07	10.04
313	4d50C_Si_platform_buf-Run005	2015-07-22 14:48:02	9.43
314	4d50C_Si_hist-Run004	2015-07-22 14:32:49	9.79
337	Lyo7 post dil 4ml-Run002	2016-03-11 19:52:02	9.60

Example 3: 10 µm Count Cal

Where the x-axis is the analysis date and the y-axis is the particle concentration between 8-12 µm

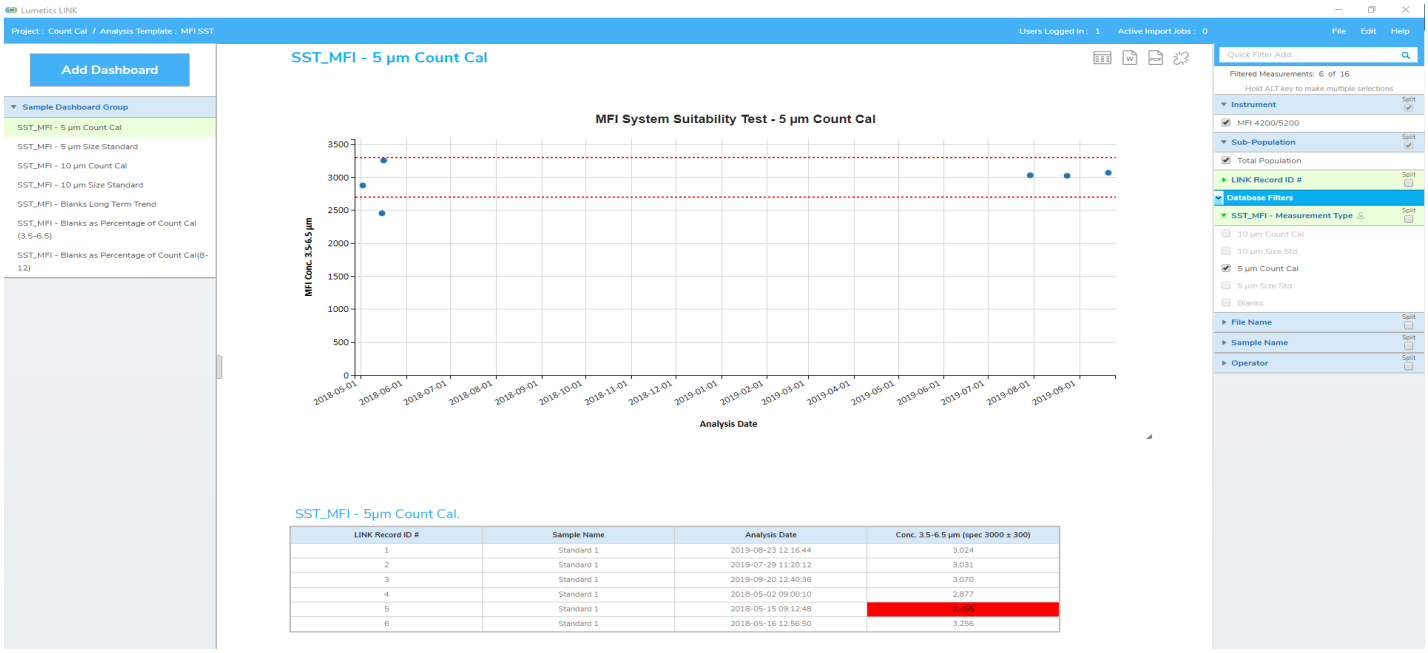


SST_MFI - 10µm Count Cal.

LINK Record ID #	Sample Name	Analysis Date	Conc. 8-12µm (spec 3000 ± 300)
7	Standard 1	2018-06-04 12:13:58	2,694
8	Standard 1	2018-07-09 09:18:46	2,821
9	Standard 1	2018-08-02 09:24:23	3,105
10	Standard 1	2018-09-07 09:25:52	2,814
11	Standard 1	2018-10-02 09:18:30	2,855

Example 4: 5 µm Count Cal

Where the x-axis is the analysis date and the y-axis is the particle concentration between 3.5-6.5 µm

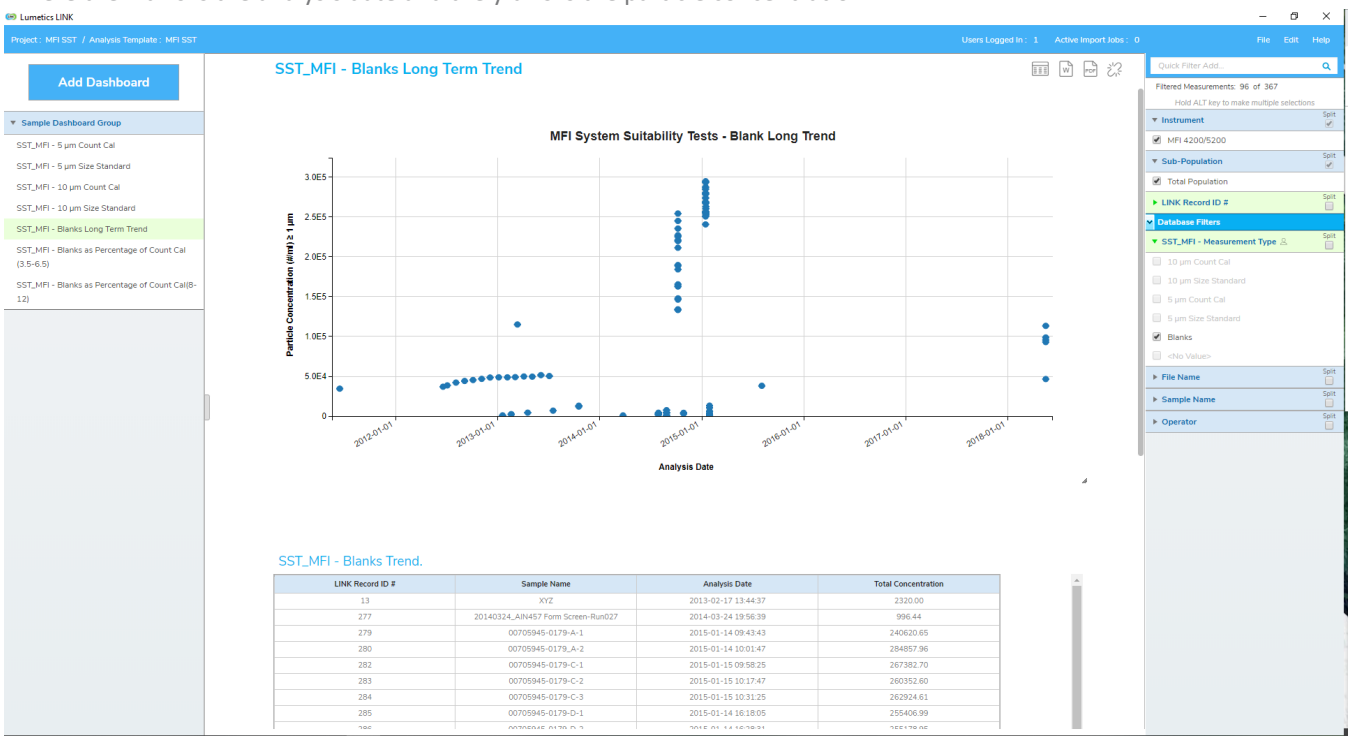


SST_MFI - 5µm Count Cal.

LINK Record ID #	Sample Name	Analysis Date	Conc. 3.5-6.5 µm (spec 3000 ± 300)
1	Standard 1	2019-08-23 12:16:44	3,024
2	Standard 1	2019-07-29 11:20:12	3,031
3	Standard 1	2019-09-20 12:40:36	3,070
4	Standard 1	2018-05-02 09:00:10	2,877
5	Standard 1	2018-05-15 09:12:48	2,455
6	Standard 1	2018-05-16 12:56:50	3,256

Example 5: Blanks – System Cleanliness

Where the x-axis is the analysis date and the y-axis is the particle concentration.



CONTACT LUMETICS

For direct assistance, please contact Lumetics LINK™ Support:

E-mail: support@lumetics.com
Phone: 1.613.417.1839
Website: http://lumetics.com/