

August XX, 2019

URGENT FIELD SAFETY NOTICE: BDB-19-1585-1

BD FACSLyric™ Flow Cytometer
(REF: 651164; 651165; 654587; 659180; 663029)

Type of Action: Advisory

Dear Customer,

BD has become aware, through customer feedback, that specific serial numbers of **BD FACSLyric™ Flow Cytometers**, belonging to one or more of the configurations listed in the table below, have the potential to read high absolute counts when using the BD Trucount™ beads. Excessive abort counts affect the ratio of cell population events to bead events, resulting in erroneously high cell count.

Instrument Name	REF
FACSLyric 2L4C Instrument	651164
FACSLyric 2L6C Instrument	651165
FACSLyric 3L8C Instrument	654587
FACSLyric 3L10C Instrument	659180
FACSLyric 3L12C Instrument	663029

As a result, BD is issuing this Field Safety Notice to provide customers with an **Abort Count Quantification Protocol** (Appendix 1) which will enable them to identify if their BD FACSLyric™ Flow Cytometer is underperforming and requires follow-up activity.

BD Multitest™ and BD TriTest™ with BD Trucount™ tubes are intended for use with FACSLyric™ for the immunological assessment of normal individuals, and patients having, or suspected of having, immune deficiency. These reagents determine the percentages and absolute counts of mature human lymphocyte subsets: T, B, and NK cells.

When using the BD Multitest™ and BD TriTest™ reagent with BD Trucount tubes for the determination of CD4 absolute counts in HIV patients, a falsely high CD4 count can be generated as a consequence of an high Trucount abort count. This in turn may cause a delay in the initiation of a prophylactic therapy for Opportunistic Infections (OIs). Current clinical guidelines use a combination of HIV viral load, CD4 absolute counts, and other disease sequelae for the overall evaluation of a patient's disease burden and subsequent clinical decisions.

There is also a potential for falsely high absolute cell counts from samples stained with BD Multitest™ or BD Tritest™ reagent which may result in an erroneous assessment of the immune function for Primary Immune Deficiency (PID) initial screening, or immune suppressive therapy management. For PID and immune suppressed patients (post-organ or stem cell transplantation), the assessment of T-, B- and NK subpopulation as part of the initial screening or ongoing monitoring has the potential to affect decisions regarding care and management.

Excessive abort counts may also affect laboratory developed tests (LDT) or experiments in which the absolute count of cell populations is determined using BD Trucount™ tubes. Falsely high absolute counts may be generated.

The absolute count of stem cells is used to assess the quality of the transplant product for stem cell transplantation. When stem cell enumeration is determined using BD Trucount™ tubes on BD FACSLyric as a LDT, a high abort count may cause a false high absolute counts affecting the specimen engraftment potency.

For leucoreduced blood product testing using BD Trucount™ tubes to identify residual nucleated cells, with propidium iodide as an LDT, a falsely high number of residual cell counts may prevent the use of the leucoreduced blood products for transfusion.

Advice on actions to be taken by the Customer:

1. Share this product notification with all users of the designated **BD FACSLytic™ Flow Cytometer** instruments within your facility to ensure awareness.
2. If you have further distributed the instruments, please identify those users and notify them at once of this product notification.
3. Perform **Abort Count Quantification Protocol** per Appendix 1 provided here below to identify if your BD FACSLytic™ Flow Cytometer performs as per manufacturing specifications or requires follow-up activities.
4. On completion of the Abort Count Quantification Protocol, if the **percentage aborted events are less than 1.0%**, your instrument(s) performs as per manufacturing specifications and no follow-up activities are required for your instrument(s)
 - a. Email the completed Customer Reply Form to techsupport@bd.com providing your device serial number (located on the model plate on the back of the instrument) and percent abort events,
5. Differently, if on completion of the Abort Count Quantification Protocol, the **percentage of aborted events is greater than or equal to 1.0%**, follow-up activities are required for your instrument
 - a. Suspend all clinical testing until your instrument is evaluated by your field service engineer and the abort count issue is resolved
 - b. Email the completed Customer Reply Form to techsupport@bd.com providing your device serial number (located on the model plate on the back of the instrument) and percent abort events, and call <<country hotline number>>
 - c. If your instrument is aborting a percentage of BD Trucount™ beads equal to or higher than 1.0%, it is likely that the absolute counts of your clinical testing may be falsely high. BD recommends that you review both the results obtained when using your process controls (i.e. BD™ Multi-Check and BD™ Multi-Check CD4 Low Controls) and your instrument validation data. The impact to patient data is likely minimal when your process controls fall within your laboratory defined ranges and are reviewed on a daily basis. Additional recommended checks to verify the correctness of the patient data generated until now can include: 1.) Calculations of absolute counts using a dual platform method where absolute counts were determined by a hematology analyzer; and 2.) A review of historical patient data acquired on an alternative platform.

In all cases, it is important that we receive the Customer Reply Form from your facility for reconciliation purposes. The relevant regulatory authorities have been notified of the field safety corrective action.

If you have additional questions, please contact your local BD Biosciences Application Specialist on <<insert telephone details here>> or e-mail <<insert contact email address here>>.

BD is committed to advancing the world of health. Our primary objectives are patient and user safety and providing you with quality products.

We apologise for any inconvenience this issue may have caused you and thank you in advance for helping us to resolve this matter as quickly and effectively as possible. We remain at your disposal for any question you might further have

Yours Sincerely,

William David
Senior Director, EMEA Quality Compliance
BD Switzerland Sarl

Appendix 1 - Abort Count Quantification Protocol

FIELD SAFETY NOTICE: BDB-19-1585-1 Customer Response Form

BD FACSLyric™ Flow Cytometer
 (REF: 651164; 651165; 654587; 659180; 663029)

Please read in conjunction with Field Safety Notice BDB-19-1585-1 and return completed form as soon as possible or **no later than September 27th, 2019.**

- I have read and understood the contents of this Field Safety Notice and performed the Abort Count Quantification Protocol on each of my instruments
- I have noted the Percentage Aborted Events per the Abort Count Quantification Protocol for each of my instruments and the results are listed in the Table below for each instrument serial number

$$\frac{\text{Abort Count}}{\text{Processed Events}} \times 100\%$$

Serial Number	Abort Count (events) (per the Abort Count Quantification Protocol)	÷	Processed Events (per the Abort Count Quantification Protocol)	X 100	% Aborted Events
		÷		X 100	
		÷		X 100	
		÷		X 100	
		÷		X 100	
		÷		X 100	

Email the Customer Reply Form to techsupport@bd.com or telephone <<country hotline number>>.

Name of Hospital / Facility	
Hospital / Facility Address	
Email Address	
Telephone Number	
Name	
Signature	
Date	

Abort Count Quantification Protocol

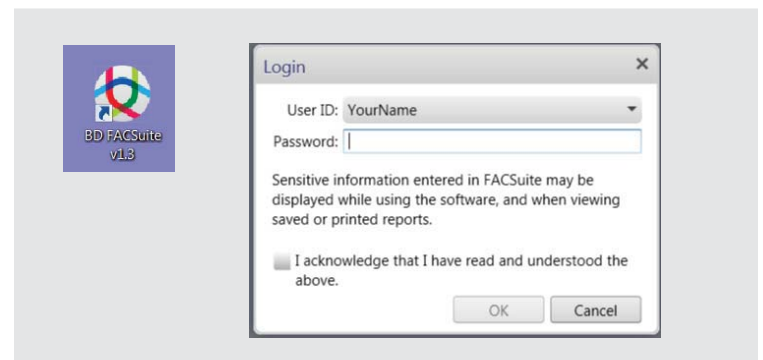
This procedure applies to the BD FACSLyric™ flow cytometer

Materials Needed

- BD Trucount™ Tubes
- BD FACSTow™ Sheath fluid
- BD FACSClean solution or 10% bleach (if necessary)

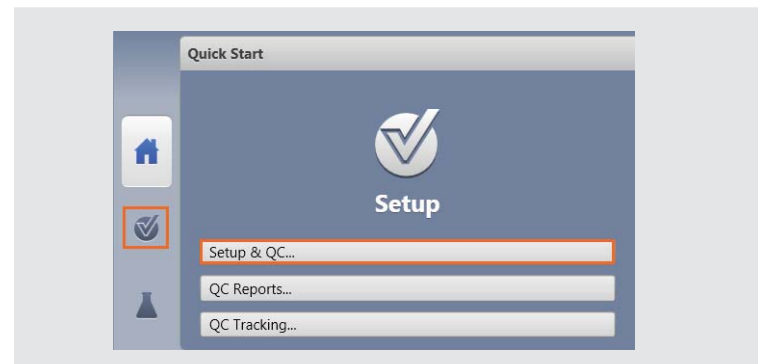
Procedure

Open BD FACSuite software and log in.

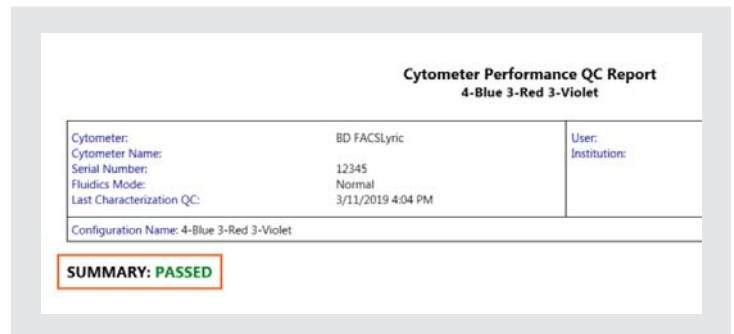
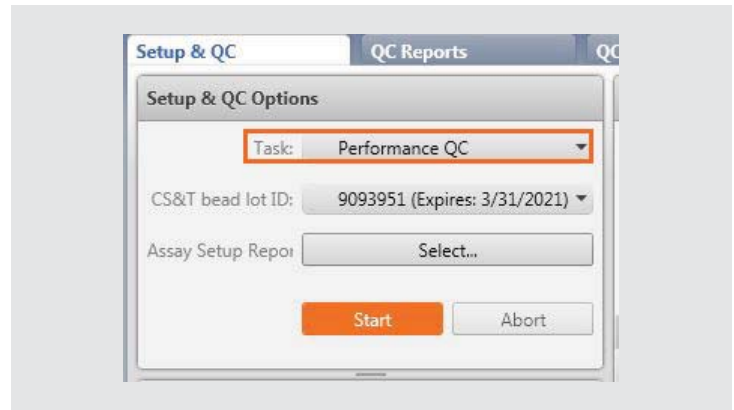


Perform Daily Performance Check

- 1 Prepare a tube of BD CS&T Beads according to the directions in the technical data sheet.
- 2 On the navigation bar, click **Setup & QC**.
 - The **Setup & QC** workspace opens

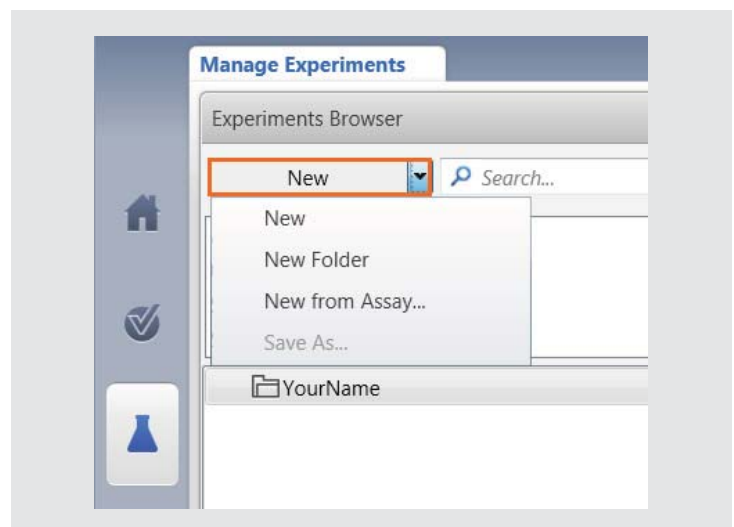


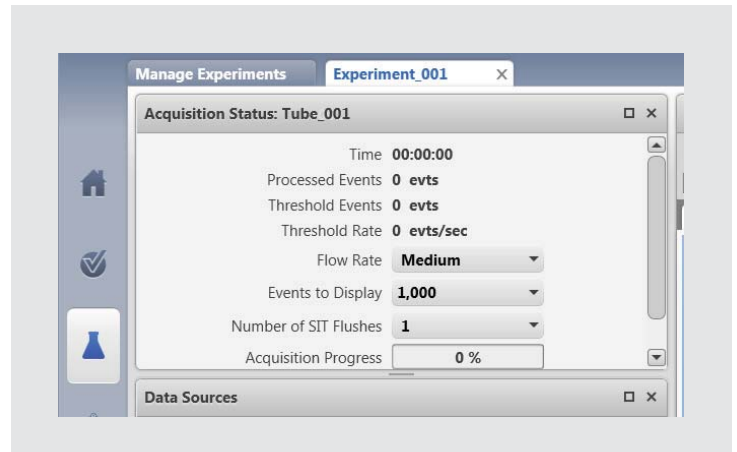
- 3 In the **Setup & QC Options** panel, verify that the **Performance QC** task is selected.
- 4 Verify that the correct CS&T Bead lot ID is selected.
- 5 In the **Setup & QC Options** panel click **Start**.
 - The Load Tube dialog opens.
- 6 Load the tube of BD CS&T Beads onto the manual tube port.
 - The system detects the tube, and the setup tasks begin.
 - When all tasks are complete, a dialog opens and indicates whether the task completed successfully.
- 7 Click **Yes** to view the Performance QC report and verify that the **SUMMARY** reads **PASSED**.
- 8 Unload the tube.



Create an experiment

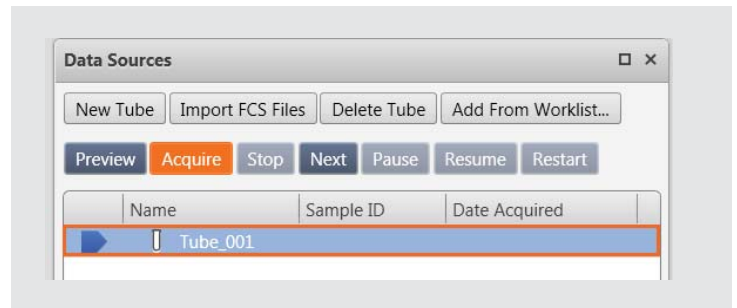
- 1 On the navigation bar, click **Experiments**.
 - The **Manage Experiments** tab opens in the Experiments workspace.
- 2 In the **Experiments Browser** panel, click **New**.
 - A new experiment opens. The new experiment name and creation date are displayed in the **Experiments Browser**, and a new tab opens in the Experiments workspace.
 - (You may consider renaming the Experiment as Instrument Serial Number)



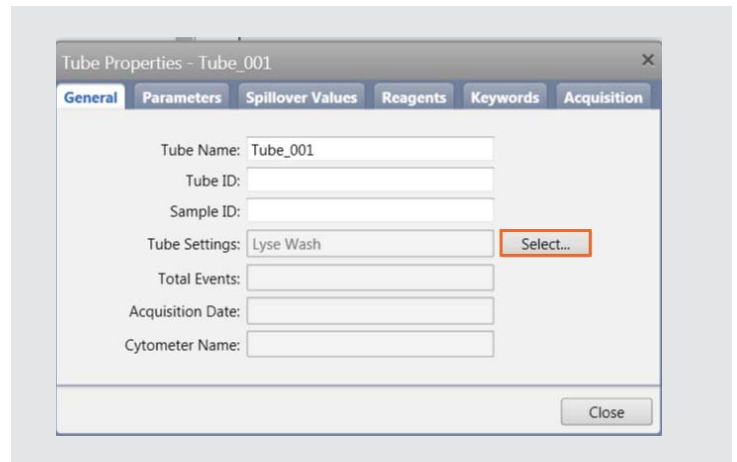


3 In the **Data Sources** panel, double click on **Tube_001**.

- (You may consider renaming the Tube as <TruC_Lot number of the TruC>).



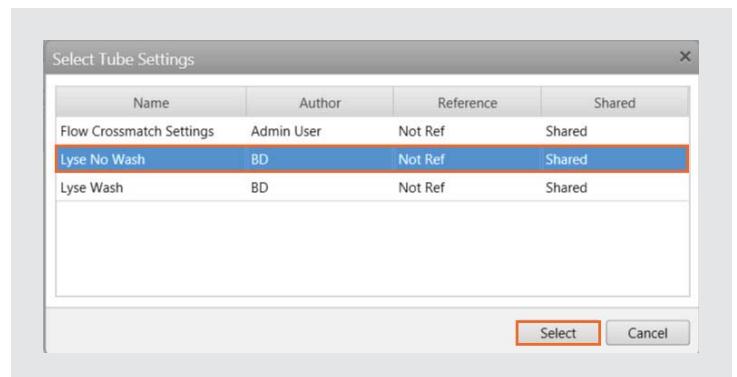
4 The **Tube Properties** dialog box opens.



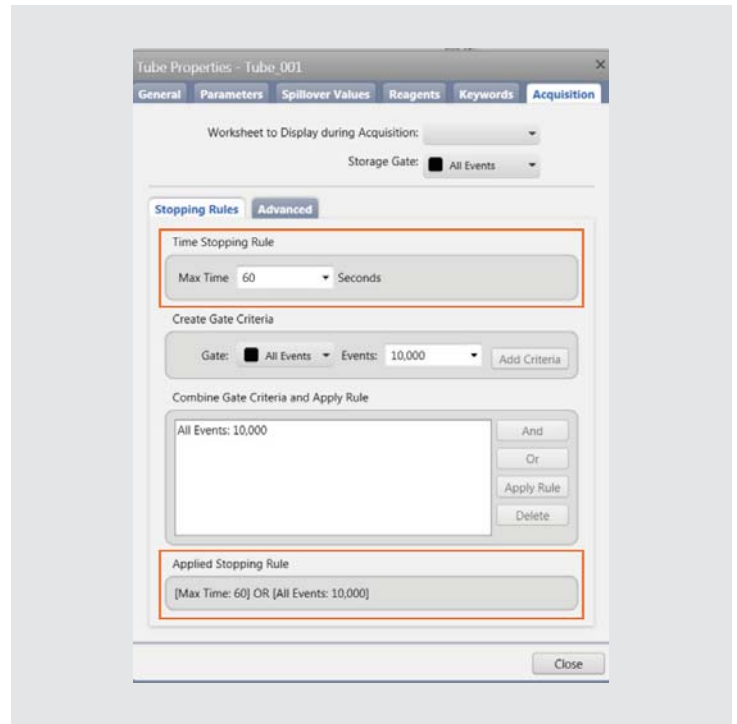
5 On the **General** tab, click on **Select** to the right of the **Tube Settings**.

6 In the **Select Tube Settings** dialog panel, choose **Lyse No Wash**

7 Click on **Select**.



- 8 In the **Tube Properties** Dialog box, click on the **Acquisition** tab.
- 9 Change the **Time Stopping Rule** by entering **60 seconds** as the **Max Time** and press Enter. Verify the **Applied Stopping Rule**.
- 10 Click Close.
- 11 No additional plots or gates need to be created.



Preparing BD TruCount Tubes

Store BD TruCount tubes in their original foil pouch at 2°C–25°C.

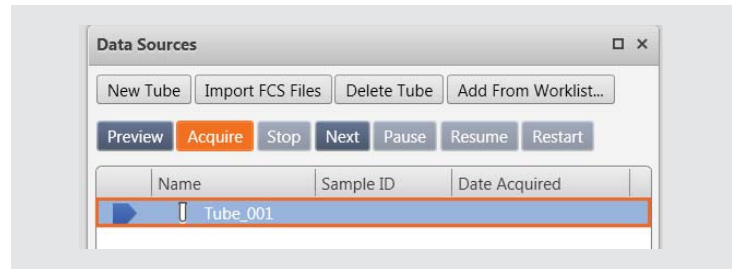
- Open the pouch only after it has reached room temperature, if stored in the refrigerator, and carefully reseal the pouch immediately after removing a tube.
 - Examine the desiccant each time you open the pouch.
 - If the desiccant has turned from blue to lavender, discard the remaining tubes.
 - Use the tube within 1 hour after removal from the pouch.
 - Examine the BD TruCount tube and ensure that the pellet is below the retainer and intact as shown.
- 1 Pipette 500 μL of sheath fluid into the BD TruCount tube.

NOTE: We recommend the use of calibrated pipettes. Do not estimate the volume when adding sheath fluid. The addition of a precise volume is critical to determining an accurate count.
 - 2 Vortex the tube gently to mix.

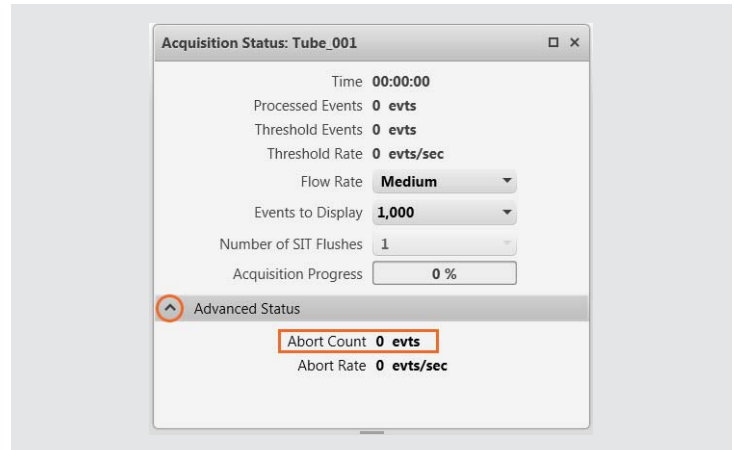


Acquiring the BD Trucount tube

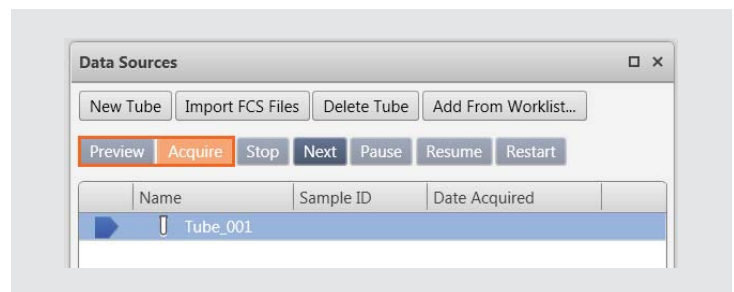
- 1 In the **Data Sources** panel, set the run pointer to Tube_001.
- 2 Install the BD Trucount tube on the manual tube port.



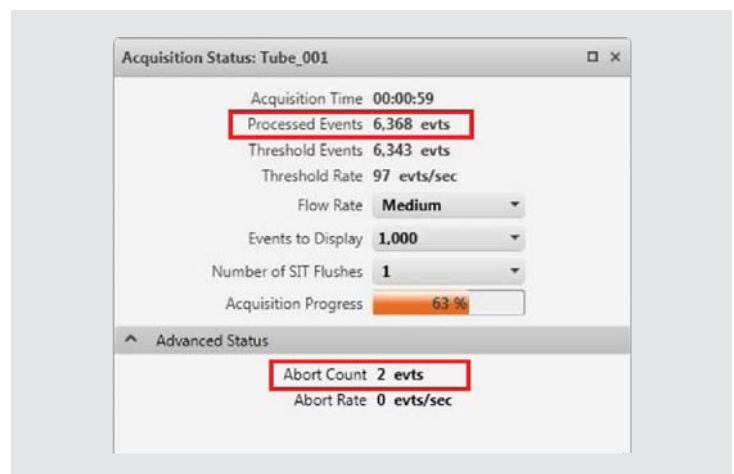
- 3 In the **Acquisition Status** panel, click the arrow to the left of **Advanced Status** to display additional information.



- 4 Click **Preview** in the **Data Sources** panel.
 - Preview for at least **17** seconds before acquiring data. This delay is necessary to ensure a proper count.
- 5 Click **Acquire** and wait for the acquisition to complete.



- 6 Record the Abort Count and Processed Events as shown in the Acquisition Status panel
- 7 Remove Trucount tube from Manual tube port and install a tube of DI.
 - If the percentage of aborted events is less than 1.0%, your instrument is not impacted. Please follow the instructions at the end of this document to report your results.
 - If the percentage of aborted events is greater than or equal to 1.0%, perform troubleshooting as stated below.



- To perform this calculation, divide the Abort Count by the Processed Events then multiply by 100 to determine the percentage of aborted events.

$$\frac{\text{Abort Count}}{\text{Processed Events}} \times 100 =$$

If the value is < 1.0%, you are not impacted
 If the value is ≥ 1.0%, perform troubleshooting procedure

Example: Less than 0% aborted events

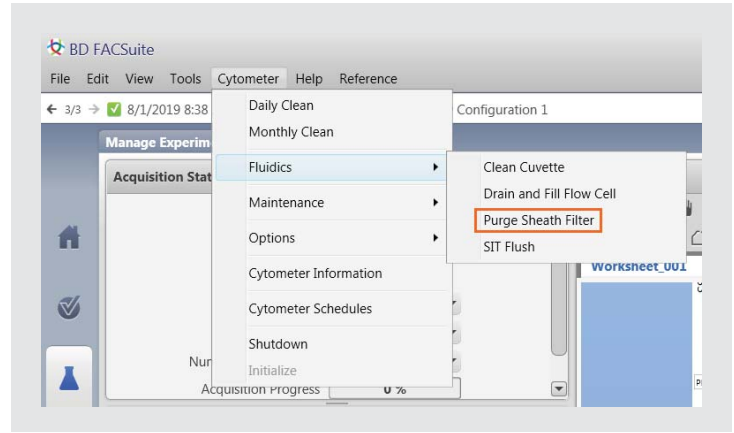
$$\frac{2}{6368} \times 100 = 0.03\%$$

Example: Greater than 4.4% aborted events

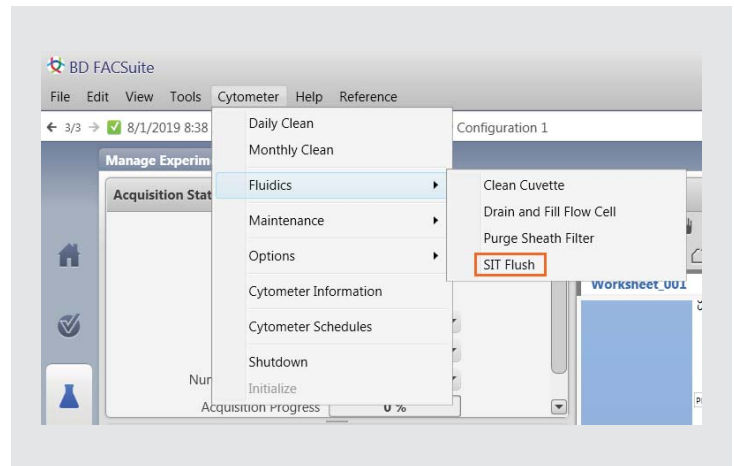
$$\frac{230}{5234} \times 100 = 4.39\%$$

Troubleshooting procedures:

1 Go to **Cytometer > Fluidics > Purge Sheath Filter** to remove air from the sheath filter. Repeat as needed.

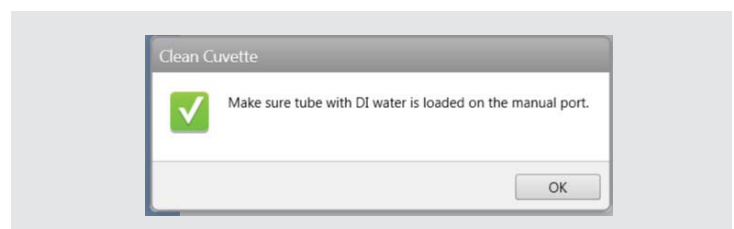
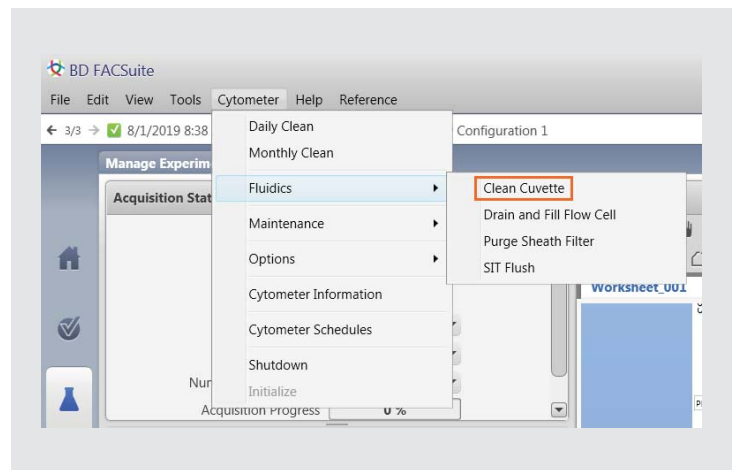


2 Go to **Cytometer > Fluidics > SIT flush** to flush the SIT. Repeat as needed.

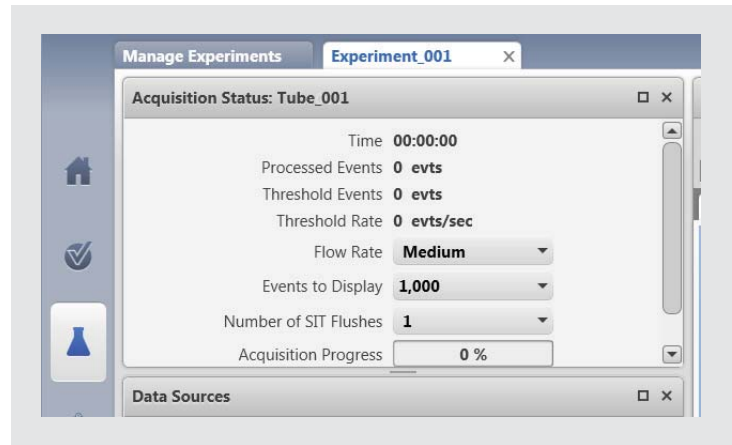


3 Go to **Cytometer > Fluidics > Clean Cuvette** clean the cuvette.

- Install a tube containing 3 mL of 10% FACSClean or 10% bleach on the manual tube port and click **OK**.
- When the process is complete, the dialogue box closes automatically.
- Allow the 10% bleach to remain in cuvette for a several minutes. Remove the tube.
- Go to **Cytometer menu > Fluidics commands > Clean Cuvette**.
- Install a tube containing 3 mL of DI water on the manual tube port and click **OK**.
- When the process is complete, the dialogue box closes automatically.
- Allow the water to remain in cuvette for a several minutes. Remove the tube.

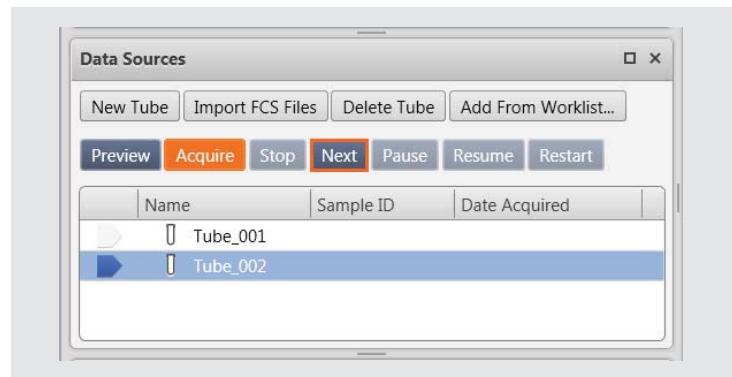


4 Navigate back to the Experiment workspace.



5 Vortex the BD Trucount tube.

6 In the Experiment, click on **Next** to add an additional tube.

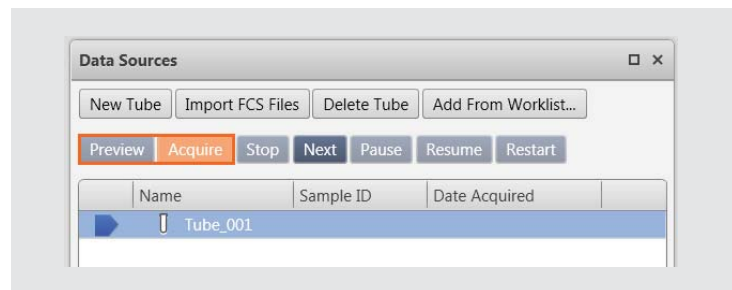


7 Click **Preview** in the **Data Sources** panel.

- Preview for at least 17 seconds before acquiring data. This delay is necessary to ensure a proper count.

8 Click **Acquire** and wait for the acquisition to complete.

- **Capture the Abort Count and Processed Events using a mobile phone or Snipping tool on the computer.**



If the percentage aborted events is less than 1.0%, no follow-up activities are required for your instrument

a. Email the customer reply form to techsupport@bd.com

If the percentage aborted events is greater than or equal to 1.0%, follow-up activities are required for your instrument

b. Email the customer reply form to techsupport@bd.com or telephone 0800 917 8776, select option 1, then 3.

X23-21761-00

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