Trouble Shooting, Flow cytometry.

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Presentation Objectives:

- To introduce the problem.
- Identify the root cause.
- Corrective Action taken.
- Measures to avoid reoccurrence.

Introduction

- MU-JHU is a CAP Accredited lab
- 2nd Runner-up of 2008 MLO award
- We support over 60 Research studies
- On average it performs 16,000 test a month making it one of the busiest research Labs in Uganda.

What went wrong

- The Lab received samples for CD4/CD8 Count from IDC Clinic .
- Samples were tested and Results released a day after, within expected TAT.
- For one of the results, based on the patient's clinical presentation, CBC results, and track of previous lab results, the clinician wasn't comfortable.

Cont,

- Clinician called back the patient.
- A new sample was drawn and sent to the Lab.
- Lab performed the test, released results.
- The two CD4 test results differed greatly.
- He then submitted a customers service concern asking the Lab for clarification

Lab's Reaction to the query

- A number of investigations were carried out in the following areas:
  - Sample collection and transportation
  - Instrument calibration
  - Whether Control runs passed
  - Pipettes used were calibrated
  - Reagent not expired, e.t.c
- All the above were fine.

What was the problem then?

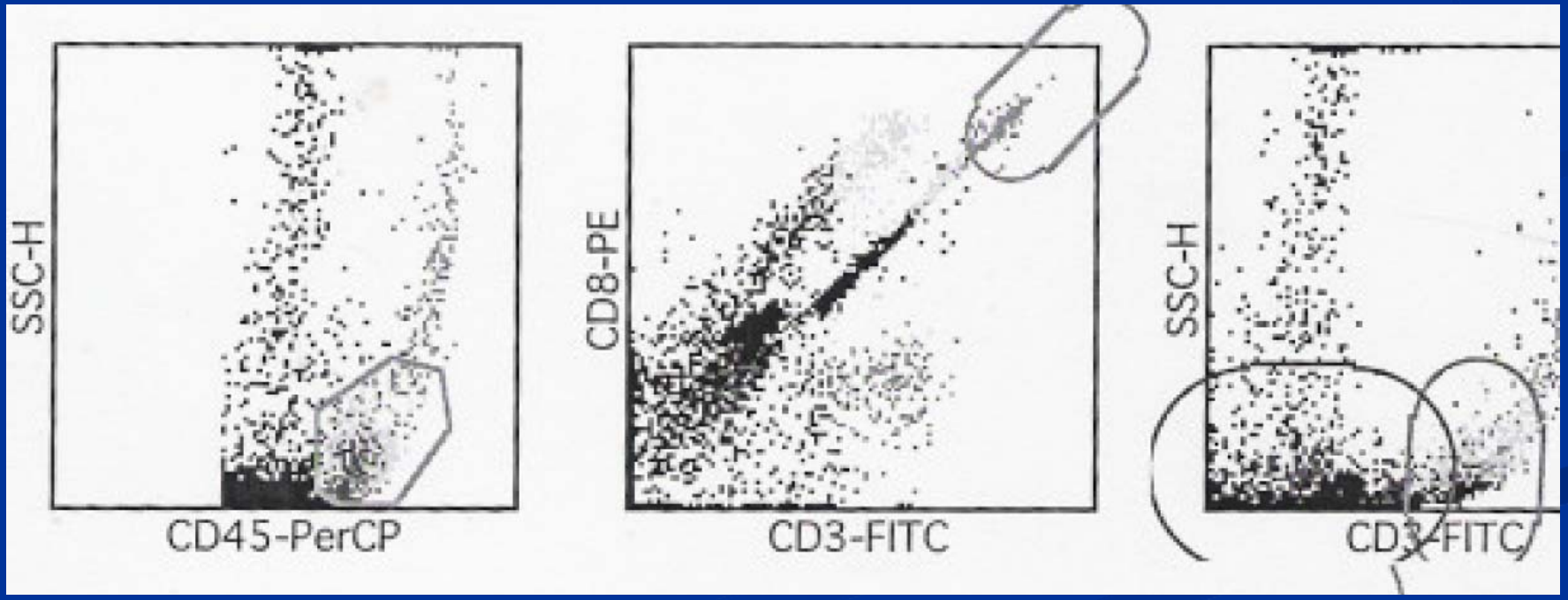
- Lab techs brainstormed over the issue
- Lab supervisor then asked for the instrument print outs for the two results.
- The instrument printouts were retrieved and reviewed. Error codes and a bad scatter plot display noted on first result.
- All result print outs run on day of first result were retrieved for thorough review.

Print outs review

- First result print out showed poor scatter/separation of the cell populations probably as a result of;
- Poor pipetting techniques
- Poor sample staining
- Use of D.H2O for lysis
- Improper instrument settings
- Improper mixing
- Lysing time not adequate
- Poor (aged) sample
- Incompetent staff

Which result may look like…

- Below is a print out of a bad/wrong scatter plot.



Cont,

- Result 2, displayed good scatter plot characterized by:-
  - Excellent separation of different distinct cell populations.
  - Indicator of control beads present.
  - Cells well within attractors

Result 2

- A good result printout scatter plot may look like this:

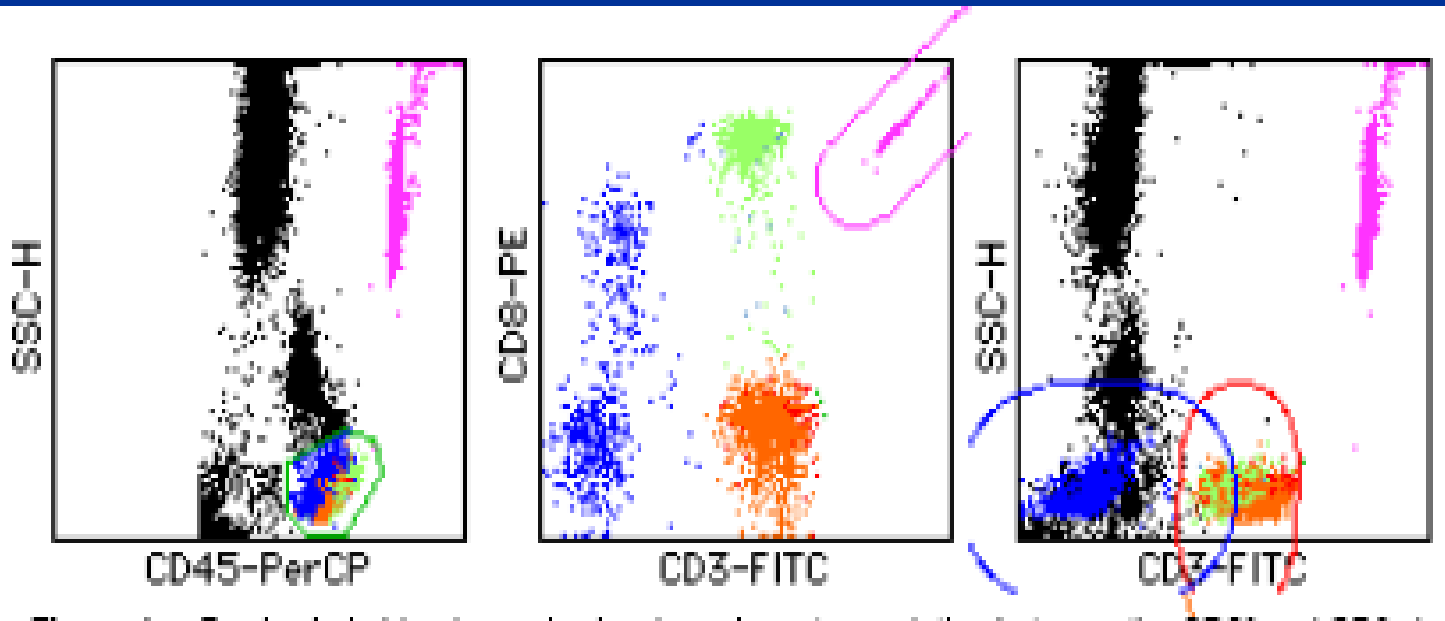


Figure 1a Fresh whole blood sample showing adequate resolution between the CD3+ and CD3- lymphocytes

Clarification of results.

- After review of the two results print outs, result two was found to be acceptable.
- An amended report was made based on this and sent to the clinic.
- Lab apologized to the clinic

Lesson learnt

- It is important to establish and maintain communication channels between the Lab and clinicians/ end users.
- Erroneous Lab results may arise from either pre-analytic, analytic or post analytic stages.
- Some Lab techs needed re-training on flow cytometry.
- It's important that techs are regularly evaluated for competency .

Corrective action

- The lab bore the costs of trouble shooting and re-testing to assure customer satisfaction.
- All the Lab techs were re-trained on;
- principle of flow cytometry.
- Correct sample preparation and staining
- interpretation of scatter plots.

Measures to avoid re-occurrence

- Process Improvement Report (PIR) was made to document cause of incidence and the appropriate corrective action that was taken.
- Samples are run by only trained staff whose competency re-evaluations are up-to-date.
- Two different techs review results before they are finally released.

DISCUSSION

QUESTIONS/COMMENTS?