

Laboratory Documentation Exercise

Please review the following and note possible documentation errors.

1. System suitability was run and everything was fine.

~~120~~ 130 BK 5/10/99
~~100~~ ml of sample was tested.

3. Weigh three samples and record their weights.

Sample A: 8.0 grams

Sample B: 8.0 grams

Sample C: 8.0 grams

Average: 8.0 grams

4. Assay performed by: MARK Date: 3/7/99 Results checked by: BKM Date: 9/7/99

5. Assay was performed using appropriate SOP.

6. Comments:

The instrument system crashed during the run. Tom was in the lab. Since we had already started, we just finished the run. We used the June samples. Everything tested OK.

- 7.

<u>Column A</u>	<u>Column B</u>	<u>Sum (Column A + Column B)</u>
2.0 ml	6.0 ml	8.0 ml
4.5 ml	8.0 ml	10.5 ml
3.2 ml	7.0 ml	9.2 ml

8. **RESULTS:** () No growth observed in sample bottle OR negative controls after 7 days; SAMPLE PASSES STERILITY TEST

Growth observed in sample bottles; DOES NOT PASS

Growth observed in negative controls: TEST INVALID

Technician: A. Davies

Date: 1/25/00

Verification: H. Marchado
1/25/00