

Scenario 2

A lab using the ProbeTec instrument suddenly has multiple samples positive for GC and on repeat the same samples were still positive, but not all. This occurred periodically over a 4 month period. See table below. Multiple techs processed and ran the samples. The controls were always the last 2 samples in the 96 well plate.

Set of sample	Initial test	Repeat	Re-collected samples
1	6 of 6 samples GC +, controls were okay	5 of 6 samples GC +, controls okay	3 of 6 samples GC +, controls okay
2, 3, 4	0 samples GC +, controls okay	Not done	Not done
5	5 of 8 samples GC +, controls okay	6 of 8 samples GC +	1 of 8 samples GC +
6	CAP panel 2 GC +	Did not repeat and all passed	
7	Only tested the QC and both CT and GC failed	Both failed again	
8, 9, 10	0 samples GC+, controls okay	Not done	Not done
11	2 of 8 samples GC+, controls okay	4 of 8 samples GC+, controls okay	3 of 8 samples GC+

Focused Questions

What is the likelihood this is a specimen processing error? If yes, what proof?

What is the likelihood this is an instrument malfunction? If yes, what proof?

What is the likelihood this is a reagent problem? If yes, what proof?

What would you do to investigate after seeing these results?

Talking Points

When there were no specimens truly positive for GC the whole run was GC negative. When there was only one specimen truly positive, many other samples were false positive.

Because the controls were always the last samples in the tray, the likelihood of cross contamination was very low but when they ran only controls there was failure.

The CAP panel was a fluke that there was no cross contamination and all were correct even with positive samples in the run.

Interestingly, this did not happen with the CT.

The Probetec pipettor had broken and a substitute one was used. However, no one took this into consideration when trying to troubleshoot because they were given incorrect advice from the company that made the substitute pipettor. The substitute pipettor was causing cross-contamination.

Moral of this story is random errors are some of the most difficult to determine the cause.