Assignment: How would you response to this client?

Letter from a client

. ***,

There are two studies of diagnostic tests that we are in the process of planning.

The first study will be done to evaluate the ability of a new PCR-based test to detect the presence of the toxin of Clostridium difficile in stool samples. The best test at this time has a sensitivity of around 85 to 90%. We'd like to test the hypothesis that the PCR-based test is superior (better sensitivity). About one-fourth to one-third of the stool samples that are sent to the lab are positive by the current test. We were wondering what would be an appropriate sample size for this study.

In another study I plan to evaluate the utility of a flow cytometer to serve as a screening test for urinary tract infections. The current screening test that we use has a sensitivity of 97%. About 10 to 20% of urine samples sent to the lab are positive by the current screening tool. We would like to test the hypothesis that the flow cytometer is not inferior to this. What would be an appropriate sample size?

Thank you,

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Assignment: How would you response to this client?

The material above was a letter send from a client to a statistician.

- Provide sample size suggestions. (Possible studies could be confidence interval estimation of sensitivity, testing hypothesis on sensitivity, …)
- Recommend possible approaches and test procedures for this study.

You can do some research on our Library or Internet to find resources for solving this problem.