

The Idylla™ SARS-CoV-2 test is an automated rRT-PCR in vitro diagnostic test, performed on the Idylla™ system intended for the qualitative detection of SARS-CoV-2 viral RNA in nasopharyngeal swabs. The cartridge is the core part of the Idylla system. Each cartridge is loaded with one clinical sample. The calling result of the cartridge is either 'Detected' or 'Not Detected', indicating that whether SARS-CoV-2 is present in the tested sample or not. The limit of detection of the Idylla™ SARS-CoV-2 assay was determined using a sample dilution series of positive clinical samples collected at 4000, 2000, 1000, 750, 500, 250, 125 input levels (copies/ml) and 24 cartridges at each input level.

Data files

Idylla File: "Results_LODest_COVID19.csv"

- CartridgeSerialNumber: cartridge identifier
- Name: result name. The result reports the calling result of 'SARS-CoV-2' and the quality of the input clinical sample (In this exercise, we do not need to consider the quality status).
- Value: values of column 'Name'. This column tells the cartridge calling result of 'SARS-CoV-2', 'detected' or 'not detected'.

Disc File: "DiscInspectionTemplate_AIO_5561_02_biostat.xlsx"

- Run time: run time of the assay
- Operator: operator name
- Cartridge ID: cartridge identifier
- Sample ID: clinical sample identifier, it indicates the input levels (copies/ml).

Try to resolve the following questions by using R-code and present the results during the interview by means of a powerpoint:

1. Make a table of cartridge detection rates ('positive call rates') at each input level.
2. Make a figure to visualize the relationship between the positive call rates and the input levels.
3. Use a statistical model to estimate the lowest input level (cps/ml) that gives 95% positive call rates and the corresponding two-sided 95% Wilson confidence interval of the input level.

Make sure to send over your results and R-code 4 hours before the interview.