X-Prize Protocol

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[1]ArcDia

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1 Works for me This document is published without a DOI.

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Testing Protocol:

Please see user manual for more detailed protocols for use.

a. Amount: Nasopharyngeal flocked swab, 1.5mL of RTI sample buffer.

b. Concentration: 2 ng/ml recombinant antigen

c. Temperature: Ambient temperature. 8-30 C

d. Duration: Pretreatment of the samples take one minute. After the pretreatment20 minutes in analyzer for initial result (80% of positives return positive in this time) and 95 minutes for complete run. mariPOC is a continuous feed automated analyzer. Maximum six samples can be inserted at once. Capacity of the analyzer is 308 tests in 24 hours.

e. Equipment: Analyzer, laptop, vortex, label printer. See charts below for full list.

f. Reagent: RTI sample buffer (1.5mL placed in sample tube), mariPOC wash solution (in analyzer), mariPOC system solution (in analyzer)

Principles

mariPOC SARS CoV2 is an immunofluorometric assay method for detection SARS CoV-2 viral antigens from nasopharyngeal swabs and aspirates. The test method is based on ArcDia TPX technology (references). ArcDia TPX allows separation-free detection in bioaffinity binding reactions, such as immunometric sandwich assays.

The TPX technique employs polymer microparticles as solidphase carriers for bioaffinity binding reactions. The microparticles have been coated with a primary antibody, which recognizes the antigen. Fluorescently labeled secondary antibody is the other reagent component. Upon addition of a sample, which contains the antigen(SARS-CoV-2), three component immunocomplexes (sandwich) are formed on the microparticles according to the immunometric binding principle (sandwich assay).

The microbeads become fluorescent as the immunocomplexes binds to it. The fluorescence from individual microbeads are recorded as they pass the focal point of the microfluorometer (mariPOC analyzers AD-070). mariPOC analyzer generates fluorescence by means of two-photon excitation [110]. Two-photon excitation is charaterized with high spatial resolution, which allows differentiation of the specific bioaffinity fluorescence (from the microbeads) and from the background fluorescence of the continuous phase

Control and Calibration

mariPOC test system is automated. The test system interprets the results of the control samples automatically on behalf of the end-user. The test system notifies the end-user whether the control sample returned an acceptable or failed result. In case the analyzer returns a failed result, the operator shall contact the technical support of the supplier, who shall sort out the root cause of the failure. The mariPOC software monitors the data of control samples throughout the history of the analyzer and stores the last 60 days of controls on the machine. This history data provides valuable information of the health of the mariPOC analyzer. The software algorithm and the acceptance criterion of control samples are confidential information of the manufacturer and are disclosed to the FDA only upon request.

The function of the mariPOC test system is monitored by a weekly analysis of the multianalyte control samples (positive control and negative control). Controls are provided by the manufacturer with the test kit. One positive control sample includes control material for all analytes of a particular test application. Control samples are not used to calibrate the system. The test system is calibration free.

The mariPOC software gives an automated pop-up reminder when one week has passed since the last run of control samples for the corresponding test plate type. The reminder includes instructions on handling a control sample (see user manual Figure 37). If the reminder window is closed without analyzing the control samples, a new reminder will appear until both positive and negative controls have been run.

Control samples are stored in foil bags at 2-8 C. One bag contains a positive control sample tube and a negative control sample tube. Control sample tubes are bar coded thus recognized by the analyzer. The concentration of positive control material represents the analyte concentration of low-positive samples.

Stability

Shelf life stability test are ongoing for mariPOC SARS CoV2. According to the plan, the shelf life stability will be verified by following the same procedure as for the other test application of the mariPOC family. The other products' shelf life is over 15 months.

Shelf life stability verification plan:

Shelf life stability study will be carried out for mariPOC® mariPOC SARS CoV2 (1204S, 1184M) test plates in their original package and in the claimed storage conditions +2 to +8 °C. The verification is real time stability study performed in either three months intervals and planned to extend until 15 months. The real time shelf life verification isdone by using three different test plate lots manufactured under routine production conditions. Verification covered shelf life stability of the following analyte-specific methods: SARS CoV2. The shelf life stability test is performed utilizing the QC release test and acceptance criteria.

mariPOC® control samples

The shelf life stability is verified for mariPOC® control sample products in their primary package and in the claimed storage

conditions +2 to +8 °C. The verification is real time study performed in three months intervals and planned to extend until 15 months. Shelf life verification is done by using three different control lots manufactured under routine production conditions. Verification covered shelf-life stability of the following analytes: SARS CoV2.
The shelf life stability test is performed utilizing the QC release test and acceptance criteria.
“In use” stability
The “in use” stability for mariPOC SARS CoV2 test plate product in mariPOC® analyzer was determined by real time study of five weeks with measuring intervals of one week. The study covered in use stability of the following analytes: SARS CoV2. In use stability of 30 days will be claimed.
Shipping stability
mariPOC® test plates are shipped in insulated box with frozen gel ice packs to slow down temperature rise during shipping [154] (document in Finnish). The transport simulation will be performed to determine the shipping stability of the mariPOC® SARS CoV2 test plate products in their primary package using one test plate lot. The test plates will be stored for 5 days at +18 to +25 °C and then transferred to +2 to +8 °C and stored there until tested. The shipping stability test will be performed utilizing the QC release test and acceptance criteria. The shipping stability verification results shall show that all SARS CoV2 fulfills the acceptance criteria after transport simulation. mariPOC® test plates shall be stable for 5 days at shipping temperature of +18 to +25 °C.
mariPOC® control samples
mariPOC® control samples are shipped in insulated box with frozen gel ice packs to slow down temperature rise during shipping [154] (document in Finnish). Transport simulation will be performed to determine the shipping stability of the mariPOC® control samples in their primary package using one control lot. The control samples were stored for 5 days at +18 to +25 °C and then transferred to +2 to +8 °C and stored there until tested. The shipping stability test will be performed utilizing the QC release test and acceptance criteria. The shipping stability verification results shall show that all control samples fulfill the acceptance criteria after transport simulation. mariPOC® control samples shall be stable for 5 days at shipping temperature of +18 to +25 °C.

Clinical Cut Off

The method used for determining the SARS-CoV test clinical cut offs followed the same principles as other mariPOC® RTI tests [13]. The clinical cut offs were specified based on internal performance evaluation data. Measuring range of the SARS coronavirus test was determined with a dilution series of recombinant SARS-CoV-2 nucleocapsid protein (Figure 2). The measuring range was estimated to be 6 logs in two hour measurement point when clinical cut off was used, and clinical sensitivity and over hook positive response area were extrapolated from the dose response plot be to 1 and 106 ng/mL, respectively.

Cross Reactivity