

WHITE PAPER

REDx™ FLOQ® Point of Care (POC) Quality Control and testing frequencies

Use of REDx™ FLOQ® SARS-CoV-2 Ag Swab Positive Control and REDx™ FLOQ® Respiratory Swab Negative Control as Quality Control by POC devices in various testing conditions.

1. Scope

The surge in SARS-CoV-2 testing volumes associated with the COVID-19 pandemic has warranted the extensive use of rapid point of care tests (POCT) for proper patient management and infection control. While antigen POCT provide an easy-to-use, and rapid solution for population surveillance and mass screening, they too are subject to pre-analytical, analytical, and post-analytical errors, which can influence test accuracy and precision¹.

The use of external quality controls plays a vital role in minimizing the likelihood of test errors by evaluating workflow integrity and test accuracy. This is especially true in cases of high frequency testing and thus, should be used to monitor SARS-CoV-2 antigen POCT. Unfortunately, very few antigen POCT kits are currently manufactured to include external quality controls, forcing end-users to find suitable alternatives. Included herein are evidence to support the use of external controls with POC devices, and recommendations for selecting adequate antigen controls and their respective frequencies of use.

2. Rationale and Interpretation

Despite the perceptions of POCT infallibility, several publications allude to the common occurrence of pre-analytical errors that can impair POCT results, such as poor sample preparation, improper operator training, and environmental distractions^{2,3}. Implementing proper quality control is critical for eliminating such errors and for compliance with ISO 22870, in conjunction with ISO 151893.

To date, SARS-CoV-2 antigen POCT are authorized for use under emergency conditions, Emergency Use Authorization (EUA) in the United States and Interim Order (IO) in Canada and have yet to undergo comprehensive regulatory review. Thus, the use of external quality controls is advised⁴. Acceptable quality controls are those that mimic the format and storage conditions of the collected patient samples and control for entire test throughput, implying that swab controls are mandatory for swab-based POCT⁵. As per the original equipment manufacturer (OEM) antigen POCT package inserts, one positive and one negative external control are typically included in each test kit to verify that the reagents and assay procedure perform properly^{6,7}. External quality controls should also be used for untrained POCT operators and upon receiving a new shipment of kits⁶. Given that SARS-CoV-2 antigen POCT are EUA/IO and adhere to non-waived regulations, Microbix has proposed an external quality assessment scheme for POCT using OEM recommendations as a reference (outlined in the table below). Ultimately, more frequent use of external controls is warranted in fast pace testing environments, which have confounding variables that can hinder POCT workflow.

Quality Control	REF	Frequency of QC		
		Low complexity device/low frequency testing	High complexity device/low frequency testing	High/low complexity device/high frequency testing
REDx™ FLOQ® SARS-CoV-2 Ag Swab Positive Control	RED-S-19-02	once a new lot	once a day	once a kit box (25 tests)
REDx™ FLOQ® Respiratory Swab Negative Control	RED-S-99-01	once a new lot	once a day	once a kit box (25 tests)

3. Conclusion

In conclusion, external antigen SARS-CoV-2 swab controls should be used for routine monitoring of POCT with various frequency based on the device complexity and the testing intensity.

References

1. Management of point of care testing
2. Arch Pathol Lab Med. 2005 Oct;129(10):1262-7
3. Quality Control of POCT instruments
4. SARS-CoV-2 antigen-detecting rapid diagnostic tests: An implementation guide
5. CAP Point-of-Care-Testing Checklist
6. QuickVue SARS Antigen Package Insert
7. Veritor™ System For Rapid Detection of SARS-CoV-2



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