

WHITE PAPER



Expected stability of REDx™ FLOQ® SARS-CoV-2 Swab Positive Control and REDx™ FLOQ® SARS-CoV-2 Swab Negative Control in various sample transport media and storage conditions.

1. Scope

The COVID-19 pandemic has created a global supply chain crisis for patient sample collection devices (PSCD) with particular impact on the supply of viral transport medium. Globally, the current needs of clinical laboratories exceed the supply of this product causing many new vendors to enter the market providing various forms of medium.

Microbix’s mandate as an IVD Quality Control manufacturer is to provide shelf-life claims for its products, but this does not cover long term storage of the eluate from single use swabs. This information could be found in the existing literature, with a focus on the storage and stability of patient specimens in different medium formats.

2. Rationale

We have used data from the literature for SARS-CoV-2 stability in different medium types to extrapolate the degradation rate findings in different storage conditions, and try to predict the shelf life of the eluted swab quality control (QC) material. The benefit of swab based samples is that they share the same workflow as patient specimen, including all the stability properties based on the types of medium used in the specimen collection.

3. Interpretation and conclusion

By using the information provided in the following publications Link1 / Link2 / Link3 and based on the fact that the sample degradation is mostly due to non-targeted nucleic acid hydrolysis, we can extrapolate the stability of the eluted swab samples by using the testing data for N, S, E, ORF1ab, ORF8, nsp2 and RP genes provided from the laboratories participating in our validation study. We used the average data from 13 different platforms and estimated shelf-life for the controls in different media based on degradation rate provided in the mentioned publications (Table 1 and 2).

Medium name	Sample (Ct*)		Days storage		
	Range (Ct*)	Average (Ct)*	18 to 26°C	2 to 8°C	-10 to -30°C
UTM®	26-34	29	7	14	14
UTM-RT™			7	14	14
ESwab®			7	14	14
Saline			7	14	14
BAL fluid			7	14	14
Sputum			7	14	14

Table 1. Estimated shelf-life for the controls in different media based on published SARS-CoV-2 degradation rate for certain temperature ranges.

Medium name	Sample (Ct*)		Days storage		
	Range (Ct*)	Average (Ct)*	35°C	22 to 25°C	4°C
eNAT®	26-34	29	14	14	14

Table 2. Estimated shelf-life for the controls in eNAT® based on published SARS-CoV-2 degradation rate for certain temperature ranges.

*Information provided on Table 1 and 2. should be used only as guidance for establishing stability of the eluate.

*Ct - average and range values are reported from the 'end-users' upon use of REDx™ FLOQ® SARS-CoV-2 Swab Positive Control and REDx™ FLOQ® SARS-CoV-2 Swab Negative Control with 13 commercial platforms detecting N, S, E, ORF 1ab, ORF8, nsp2 (SARS-CoV-2) and RP (Human) genes. REDx™ FLOQ® SARS-CoV-2 Swab Positive Control and REDx™ FLOQ® SARS-CoV-2 Swab Negative Control are unassayed controls, information about sample concentration is not provided on the Certificate of Analysis.



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UTM®, UTM-RT™, is a trademark of Copan Italia SPA

*Link1:<http://dx.doi.org/10.1128/JCM.06551-11>
*Link2:<https://doi.org/10.1128/JCM.00708-20>
*Link3:<http://doi.org/10.1128/JCM.00110-21>



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RD-WP2-v4(12Dec20)