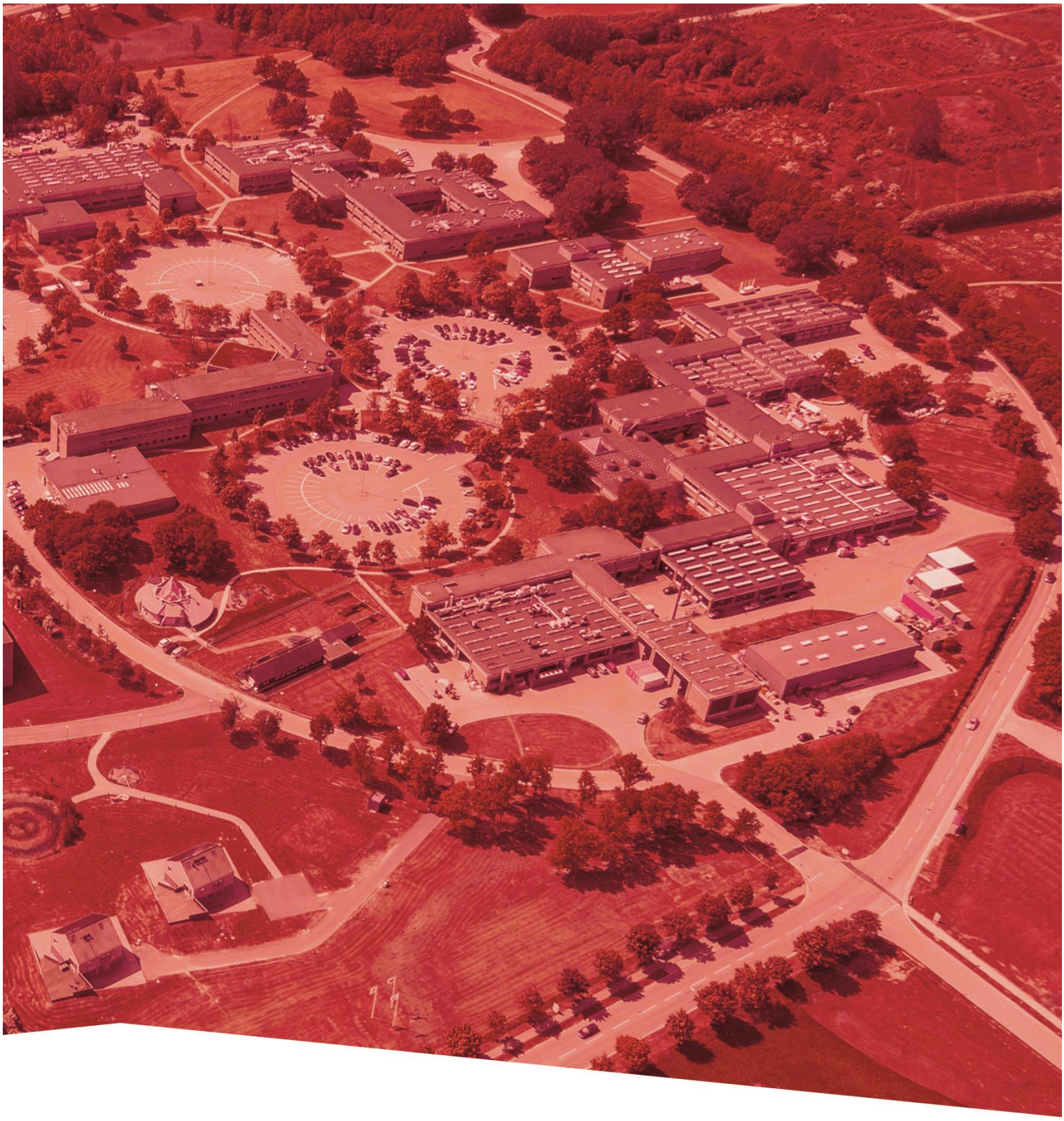

Review of Test Report from GC Healthcare A/S

Review of 'Efficacy of Airgle AG900 againstSARS-CoV-2 USA-CA-1/2020 Pathogen'

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Review of 'Efficacy of Airgle AG900 against SARS-CoV-2 USA-CA-1/2020 Pathogen'

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1. Purpose

This report is a review of the report: 'Efficacy of Airgle AG900 against SARS-CoV-2 USA-CA-1/2020 pathogen from Innovative Bioanalysis Inc. received by GC Healthcare A/S'.

This report will contain comments on the credibility of the mentioned report. It will be examined if the report can be used as evidence of an effect on covid-19 in Denmark and in the European Union.

2. Credibility of the test report

The report is considered credible.

2.1. Test procedure

The report is performed according to GLP (Good Laboratory Practice), which means that the entire test procedure and all controls included are thoroughly described.

The identity of the used test organism, SARS-CoV-2-USA-CA1/2020, was confirmed using NGS (Next-generation Sequencing) showing a similarity of 99.9% with the database. The controls made guarantee the credibility of the used cells and reagents.

During the test, the natural decay in the room was tested. The control samples showed a very low natural decay of virus in the air during the 60 min. of sampling, showing that the test set-up was suitable for demonstrating the virucidal efficacy of Airgle AG900.

An effort was made by the laboratory to simulate a real-life environment. The laboratory has given much thought to how this can be realized when it is considered that it is a simulated real-life environment. The report also contains a very good description of how the set-up in the laboratory differs from real-life as well as considerations on the different parameters that will influence the results. These parameters must be defined by the laboratory.

2.2. Result

According to the test report results, Airgle AG900 can reduce the airborne virus with 99.998% within 60 minutes. Therefore, Airgle AG900 shows the ability to reduce collectable virus in the air faster than the natural decay. According to the test report there is no reason to question the results in the test report.

2.3. The laboratory

According to the test report, the laboratory is not certified or licensed by US EPA but it works according to GLP (Good Laboratory Practice). According to the thorough documentation there is no reason to question the work of the laboratory.

3. Use of the test report in Denmark and in the EU

It is assessed that this test report can be accepted in Denmark and the European Union.

The requirements in Denmark and the rest of the European Union are the same.

3.1. Requirements for air disinfection

In EU there are no requirements for air purification of air disinfection. However, for surface disinfection using Airborne Room Disinfection by Automated Processes requirements have been determined, and these requirements can be used as an indicator.

The European requirements for virucidal efficacy of surface disinfection using airborne processes are stated in the European Norm, EN 17272:2020.

According to EN 17272:2020 the requirement for virucidal efficacy is ≥log 4 reduction which equals ≥99.99%, when an airborne process for surface disinfection is used.

The requirements are set as an assessment of when the concentration of virus or other microorganisms does not possess any health risk.

3.2. Evaluation of result according to requirements

The natural decay of virus in the air was <0.5 log reduction within 60 min.
The start concentration of virus in the air was log 6.8 and a limit of quantification (LOQ) at log 2.1.
Therefore, it was possible to determine >log 4 reduction or >99.99% reduction using this test set-up.

To examine if the proposed European requirements are met, the log reduction has been calculated according to the numbers from the results in the test report.

The log reductions achieved with and without consideration for the natural decay have been calculated. See Table 1.

Table 1: The results of the test report have been re-calculated to a log-reduction. The log reductions achieved with and without consideration for the natural decay have been calculated. Results of reduction in percentage (%-reduction) are taken from the test report.

	Log reduction [natural decay only] "AVG Control"	Total log reduction [air purifier + natural decay] "AVG Experiment"	Log reduction [air purifier only]	%-reduction
Reduction: 15 min	<1	<1	<1	76.846%
Reduction: 30 min	0.21	1.31	1.10	95.116%
Reduction: 45 min	0.31	3.96	3.64	99.989%
Reduction: 60 min	0.48	4.72	4.25	99.998%

According to Table 1, ≥log 4 reduction was achieved after 60 minutes.
Because there are no requirements for disinfection of the air ≥log 4 is not a set requirement that must be achieved.

However, the airborne virus will settle on the surfaces over time. By reducing the virus in the air with ≥log 4 this also reduces the contamination of the surfaces to an extent that is so low that it does not possess any health risk.

An alternative method for assessing the efficacy of air purifiers to reduce airborne microorganisms is described in ISO16000-36:2018 *"Standard Method for assessing the reduction rate of culturable airborne bacteria by air purifiers using a test chamber".*

Using this method, the calculated Reduction Rate for the Airgle AG900 air purifier is 99.994% in 60 minutes. No minimum requirements are defined in ISO16000-36:2018 regarding Reduction Rate.

3.3. Comparison between product claims and test report

The Airgle AG900 is tested in a 36.2 m^3 (1280 cubic feet) test chamber with a floor area of 14.6 m^2 (160 square feet). The experimental results from the test report must only be used to make claims on %-removal rate for a room of similar size.

Furthermore, it should be noted that this review has not assessed the product claims made by GC Healthcare A/S or Airgle in the marketing material (website etc.) and should not be used as support for any product claims on the overall efficacy of the Airgle AG900 air purifier.

4. Conclusion

Because the reduction of Airborne virus equals the requirements for reduction of virus on the surfaces it is assessed that the results can be accepted in Denmark as well as the European Union.

Due to the assessed credibility of this report it is also assessed that this report can be used as documentation in Denmark and the EU.

5. References

1. Efficacy of Airgle AG900 against SARS-CoV-2 USA-CA-1/2020 Pathogen from The Innovative Bioanalysis, Inc. 2021.06.14. Laboratory project number: 1042.

2. EN 17272:2020. Quantitative Carrier test for Airborne Room Disinfection by Automated Processes - Determination of Bactericidal, Fungicidal, Yeasticidal, Sporicidal, Tuberculocidal, Mycobactericidal, Virucidal and Phagocidal Activities in the Medical Area, Veterinary Area and Food, Industrial, Domestic and Institutional Areas - Test Methods and Requirements Phase 2, Step2)"

3. ISO16000-36:2018 "Standard Method for assessing the reduction rate of culturable airborne bacteria by air purifiers using a test chamber".

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