

ASP AERO-OPA™ Solution Efficacy Against Human Coronavirus

Background

Coronaviruses are a family of enveloped positive-sense single-stranded RNA viruses, capable of rapid mutation and recombination. Coronaviruses are a common cause of mild upper respiratory infections, but they also include more serious illness like SARS and MERS, which can lead to severe disease. Coronaviruses are common in many mammals and, although rare, animal coronaviruses can infect humans and then spread between people¹.

The 2019 novel coronavirus, designated as SARS-CoV-2, is a new virus responsible for causing Coronavirus disease 2019 (COVID-19). It was first identified during an outbreak in Wuhan, Hubei Province, China in late 2019² and has since spread globally. COVID-19 has confirmed human-to-human transmission as well as demonstrated community transmission in the United States³. Although most patients with coronavirus have mild symptoms, the SARS-CoV-2 has demonstrated that it can escalate to a more severe form of the disease, which can include escalating to pneumonia. The outbreak was declared a Public Health Emergency of International Concern by the World Health Organization (WHO) on 30 January 2020⁴.

SARS-CoV-2 is spread primarily from person-to-person between people who are in close contact with one another (under 6 feet) and via respiratory droplets produced when an infected person coughs or sneezes¹. Spread and viral shedding has been shown to be possible prior to the onset of symptoms³. Lastly, it may be possible that COVID-19 can be spread by touching a surface of object that has the virus on it and then touching susceptible areas of the face, such as eyes, mouth and nose³. A recent study reported evidence that indicate the virus can survive on hard surfaces such as plastic and stainless steel for up to 72 hours and on cardboard for up to 24 hours⁵. SARS and MERS viruses can also survive on hard surfaces for greater than 48 hours⁶.

Efficacy against Coronavirus

Although ASP has not specifically conducted testing of ASP AERO-OPA Solution against SARS-CoV-2, Cidex® OPA Solution, which is an equivalent formulation to ASP AER-OPA Solution, has been tested for efficacy against human coronavirus. Product development testing was performed using the United States Environmental Protection Agency (EPA) Virucide Assay Method⁷. In this development testing, preparations of viral samples of human coronavirus were inactivated by Cidex® OPA Solution after a 5-minute† exposure time at 20°C; and achieved the required $\geq 3\text{-log}_{10}$ reduction in virus titer. Testing was also completed using a diluted strength Cidex® OPA Solution formulation to present adequate challenge to the Solution. The results show that even at a diluted concentration, Cidex® OPA, and therefore ASP AERO-OPA Solution, inactivate Human Coronavirus. These test results satisfy EPA requirements.

Based on this testing data regarding the efficacy of Cidex OPA Solution against coronaviruses, SARS-CoV-2 should be susceptible to ASP AERO-OPA Solution.

Additionally, coronaviruses such as SARS-CoV-2 are lipid viruses (enveloped viruses). Lipid viruses are typically susceptible to various low and medium disinfection modalities according to the guide of the hierarchy of biocide resistance published by the Centers for Disease Control and Prevention (CDC)⁸. ASP AERO-OPA Solution is a High-Level-Disinfectant and has been shown to be effective against microorganisms such as mycobacteria and polio virus, which are microorganisms that typically exhibit greater resistance to disinfection modalities than lipid viruses like the coronavirus. Based on what is currently known about microorganism resistance to disinfection, ASP AERO-OPA Solution would be efficacious against lipid viruses such as coronavirus.

Please note that the ASP AERO-OPA Solution is intended for use only with the ASP AEROFLEX™ Automated Endoscope Reprocessor (AER) with AUTOSURE™ MRC Monitor. Per the ASP AERO-OPA Solution Instructions For Use (IFU), during normal usage, the ASP AEROFLEX AER maintains a minimum temperature and contact time based on pre-programmed cycles. It is important to properly follow the ASP AERO-OPA Solution IFU for detailed directions when processing any instrument using

ASP AERO-OPA Solution, especially the pre-cleaning of all instruments as well as rinsing procedures within the IFU to ensure complete high-level disinfection. HLD guidelines in your facilities as well as the HLD instructions of manufacturers should also be followed.

Please keep in mind to follow the safety precautions of the local health authorities of your country as well as health care facility when dealing with infected patients.

For any additional questions regarding SARS-CoV-2 or Coronaviruses in relation to our products, please submit a Medical Information Request by visiting www.asp.com.

† Note that this parameter was used during development testing with Cidex OPA Solution, when performing actual reprocessing of medical devices or equipment with ASP AERO-OPA, the ASP AEROFLEX AER maintains a minimum temperature and contact time based on pre-programmed cycles.

Sincerely,

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DISCLAIMER

Important information: Prior to use, refer to the instructions for use supplied with this device for indications, contraindications, warnings and precautions.

ADVERSE EVENT REPORTING

Remember to contact our local representative in case any adverse event or product quality complaint occur while using our product and comply with your local regulations in terms of notification.