

AGC Biologics Requirements and Guidance

Response to Worldwide COVID-19 Pandemic

The following requirements and guidelines are issued to all locations of AGC Biologics in alignment with AGC Pandemic Response Level IV. These are provided taking into account current AGC Inc. coronavirus task force requirements and guidelines, World Health Organization (WHO) guidelines as well as the requirements of country-specific public health ministries. This is a worldwide pandemic crisis that is being monitored closely by the AGC, Inc. global coronavirus task force with guidance updated on a daily basis.

COVID-19 Symptoms may develop within 14 days of exposure and range from mild to very serious or death.

Common symptoms may include:

- Fever
- Cough
- Shortness of breath, which in serious cases can lead to pneumonia.



Cough



Fever



Shortness of breath

Other symptoms may include:

- Aches and pains
- Sore throat
- Nausea and gastrointestinal symptoms have been observed in some cases
- Loss of sense of taste and smell are unusual symptoms, but it has been observed that in some cases these are the only symptoms they have at all

Coronavirus Transmission: The virus may spread from:

- Close person-to-person contact through respiratory droplets from coughing and sneezing
- Airborne transmission when tiny droplets remain in the air even after the person with the virus leaves the area
- Contaminated surfaces then touching the eyes, nose, or mouth

At the current level of virus prevalence, the following guidance is provided for all AGC Biologics employees, temporary employees, contractors and visitors:

1. Monitor local health agencies on appropriate response measures recognizing that the intensity of the outbreak and guidance from local officials may differ according to geographic location and community needs.
2. All employees are reminded that they are required to adhere to their site's SOPs and Policies regarding personal health and their ability to engage in activities that could impact product quality.
3. Observe good hygiene practices for flu prevention:
 - Frequently wash your hands with soap and water for at least 20 seconds. When soap and running water are unavailable, use an alcohol-based hand rub with at least 60% alcohol. Always wash hands that are visibly soiled.
 - Avoid touching your eyes, nose, or mouth with unwashed hands.
 - Avoid close contact with people who are sick.

Reference: *WHO webpage* at: <https://www.who.int/emergencies/diseases/novel-coronavirus-2019>
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4. Before going to work, each employee must take their body temperature. In case of a fever 99.5° F [37.5° C] or greater, they must promptly notify their supervisor, refrain from going to the workplace, and seek medical advice. Specifically for entering **GMP access points** use the logbook provided and fill in time, date, your initials, and yes/no if entry is allowed. Temperature must be taken daily on site –the first time you enter the GMP space each day.
5. General cleaning of office areas is to be scheduled more frequently and in-depth at touch point and high traffic areas including door knobs, hand rails, workstations, countertops meeting rooms, bathrooms and food areas.
6. Cleaning and disinfecting procedures are established for offices and work areas of persons currently being tested or test positive for COVID-19.
7. Ensure hand sanitizers and cleaning supplies are readily available to aid in personal hygiene.
8. Discontinue food buffets or the placement of shared food, candy bowls, etc. in common areas.
9. Employees who have symptoms of acute respiratory illness are to stay home and not come to work until they are free of fever (99.5° F [37.5° C], signs of a fever, and any other symptoms for at least 48 hours, without the use of fever-reducing or other symptom-altering medicines (e.g. cough suppressants). Employees must notify their supervisor and stay home if they are sick.
10. Employees who arrive at work or become sick during the day and who appear to have acute respiratory illness symptoms (i.e. cough, shortness of breath) will need to go home immediately. Sick employees should cover their noses and mouths with a tissue when coughing or sneezing (or an elbow or shoulder if no tissue is available).

11. Notification of COVID-19 Testing

In the event that an employee is tested for COVID-19 (including those that are symptom free and only tested for data purposes), receives test results for COVID-19, or has been in close contact with a person currently being tested or has tested positive for COVID-19, they must immediately report this to their Manager and Site EHS Department.

12. Identification and Quarantine of Close Contact Persons

In the event that an AGC Biologics employee is tested for COVID-19 due to symptoms, diagnosed based on symptoms alone or receives a positive test result, steps will be taken to identify any co-workers found to be in close contact so that appropriate quarantine measures are implemented.

13. Close Contact Person

A person is defined as being in “close contact” if they have had:

- a. Direct contact (handshake, etc.) or indirect contact (within 2m / 6ft or less for 15 minutes or longer without a protective mask) and,
 - b. The close contact occurred starting from 6 days prior to a positive diagnosis.
14. The need to self-isolate, quarantine or exercise additional caution is dependent on the specific situation. The requirements outlined in the **COVID-19 Health Decision Matrix** of these guidelines must be followed to ensure appropriate infection mitigation and preventive measures are taken to prevent the spread of the virus.

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15. In the event that an employee is diagnosed or tests positive for COVID-19, the work area (including desk, chair, locker and common areas) used by the impacted employee must be thoroughly disinfected. Should it be necessary to retrieve items from the site in order to work remotely from home, do not come back on site. Make alternate arrangements (e.g., someone that is not in quarantine or isolation to pick up items) if they are needed to work remotely.
16. Positive COVID Test – Isolation and Return to Work

Should an employee test positive for COVID-19, they must self-isolate at home and not come to work until they are fully recovered and no longer infectious. This requires one of the following:

 - a. The individual must be free of fever (99.5° F [37.5° C] or greater, signs of a fever, or any other symptoms for at least 72 hours, without the use of fever-reducing or other symptom-altering medicines (e.g. cough suppressants), it has been at least 10 days since symptoms first appeared, and they have been cleared by a medical professional to return to work (a written release should be requested from the physician).
 - b. The individual must be free of fever (99.5° F [37.5° C] or greater, signs of a fever, or any other symptoms without the use of fever-reducing or other symptom-altering medicines (e.g. cough suppressants) and negative results of an authorized COVID-19 molecular assay for detection of SARS-CoV-2 RNA from at least two consecutive respiratory specimens collected \geq 24 hours apart (total of two negative specimens). The person must also be cleared by a medical professional to return to work (a written release should be requested).
 - c. Individuals that are asymptomatic and test positive for COVID-19, must self-isolate at home for 10 days from the date of the test, or have two consecutive negative tests \geq 24 hours apart.
17. Surgical masks, face coverings or N-95 face masks will be made available to AGC Biologics employees for use in office and common areas to prevent the spread of illness to others. The masks are to be worn by any two or more employees working together closer than 6 feet or 2 meters. Follow prescribed department requirements for type of mask and usage within GMP workspaces.
18. Established an increased awareness and guidance on this situation through various means of communication including email, postings and a dedicated website, Coronavirus (COVID-19) Advisory page:
<http://www.agcbio.com/covid-19>
19. Working from Home – Various situations may result in employees needing or opting (after discussion with employee’s manager) to work from home. These may include school closures impacting families, “close contact” employees required to self-quarantine as a precaution, and individuals in a high risk category from local health ministries (e.g. over 65 years of age; have underlying health conditions such as heart disease, lung disease, or diabetes; have a weakened immune system; are pregnant). Each situation will be evaluated on a case by case basis.
20. There are currently no special requirements for handling of packages, mail and other goods in shipping and receiving areas. Public health information indicates poor survivability of coronaviruses on surfaces; therefore there is likely very low risk of spread from products or packaging that are shipped over a period of days or weeks at ambient temperatures. Existing site SOPs for handling inbound materials for GMP operations must be followed.

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21. Visitors to AGC Biologics Facilities

Due to the varying rates of COVID-19 infections and government requirements and guidelines in the countries that AGC Biologics operates, visitors to AGC Biologics facilities will only be permitted in rare circumstances when the purpose has been determined by site management to be urgent/essential and the site has the capability to host the activity given local restrictions. This applies to contractors engaged in urgent/essential work as well as customer/client related activities. The health of employees and the protection of AGC Biologics operations are paramount and will be the basis for making this determination. In these situations, all COVID-19 Guidelines and Coronavirus Travel Policy requirements must be strictly observed at all times. All visitors will be required to take their body temperature using a thermometer provided at the entrance of the facility, sanitize their hands using available hand sanitizer, and provide satisfactory responses to the visitor screening checklist provided in order to gain entry to the facility. If their temperature is 99.5° F [37.5° C] or greater, entry will be prohibited. The extent of site access will be restricted to non-GMP areas for customer-related business as determined by site management to minimize risk.

Social Distancing

Extensive social distancing measures are being adopted in many countries to address the widespread person to person transmission of the coronavirus. Each location is required to implement social distancing to prevent the spread of the virus within the workplace. This includes:

1. Identify and implement options for working remotely from home.
2. Maintain 6 feet or 2 meters distance from others within the workplace.
3. Refrain from shaking hands or other direct contact.
4. Limit face-to-face meetings and discussions. Use teleconferencing (Zoom, Skype, etc.) or communicate by email wherever possible to minimize close personal contact.
5. If a face-to-face meeting is required, limit the group size to 10 participants or less. The use of facemasks is strongly encouraged at all times and is mandatory if the social distance of 2 meters cannot be maintained at all times.
6. Large company gatherings and meetings are to be postponed and remote technology employed where possible.
7. Avoid carpooling when commuting to work. AGC will work with employees to explore alternative commuting options.
8. If public transportation must be used as a last resort, please practice social distancing guidelines above and if possible travel at times when public transportation is less crowded. Your management will work with you if this means an adjustment to your work schedule.
9. Limit the extent of visitor access to facilities and contact with AGC Biologics employees.
10. Avoid eating together if you can (sit at a desk, car, outside or bring your own lunch in) – be especially mindful when getting coffee, water or snacks in common spaces.
11. Keep note of which people you have had close contact with and which rooms/spaces you have utilized.
12. Use of elevators should be limited to 1 person at a time if stairs are not an option for moving between floors.

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Local health authority requirements must also be addressed as they are communicated by public health departments during this health crisis. Therefore, each location may be taking additional measures based on local guidance and government requirements.

COVID-19 – Health Decision Matrix

Cat.	Your Condition	What should I do?	Who Should I inform?	When can I come back to work?
1	You are someone diagnosed with COVID-19, (based on symptoms alone or positive test result)	Isolate		(A) >72 hours after being symptom free without medication and at least 10 days since symptoms first appeared (B) Cleared by a medical professional, or (C) Symptom free and at least 2 negative tests in a row, 24 hours apart and cleared by a medical professional <u>If asymptomatic:</u> (A) 10 days from the date of the test, or (B) have two consecutive negative tests ≥ 24 hours apart.
2	You are someone being tested for COVID-19 because you are showing symptoms	Quarantine until test results are known and proceed according to correct category.	EHS, HR & your Manager – Mandated – at time of testing and when results received	After testing negative for COVID-19 and >48 hours after being symptom free without medication
3	You are someone who is symptom free but has had Close Contact with a person diagnosed with COVID-19	14 Day Quarantine or where applicable per government regulations: Two (2) consecutive negative results (1 st test 4 days after last day of known risk, 2 nd test 6 days after known risk)	In the interests of privacy and calm please do not inform your colleagues	After 14 Day Quarantine or where applicable per government regulations: Two (2) consecutive negative results (1 st test 4 days after last day of known risk, 2 nd test 6 days after known risk)
4	You are someone who is symptom free who has returned from an international flight. This does not apply to domestic and travel to and from approved zones governed by the site's home country.	14 Day Quarantine or where applicable per government regulations: Two (2) consecutive negative results (1 st test 4 days after last day of known risk, 2 nd test 6 days after known risk)	EHS CONTACTS BELOW: Global EHS David Steinbacher dsteinbacher@agcbio.com 206-375-0427 US EHS Shyam Mahanti smahanti@agcbio.com 425-205-7355	
5	You are someone who is symptom free but has had Close Contact with someone being tested for COVID19	Quarantine until test results are known and proceed according to correct category.	EU EHS Shahida Hamid shamid@agcbio.com 22656902	Proceed according to correct category depending on the test results for the Close Contact
6	You are someone who is symptom free, though are an At Risk Person due to age, pregnancy or an existing health condition (heart, respiratory, diabetes, immuno-suppressed)	You have the option to Quarantine		On consultation with EHS, HR and your manager.
7	You are not in Cat. 1 & 2 and are feeling sick (all conditions)	Go home immediately & consult a medical professional		If you are symptom free you can return >48 hours after being symptom free without medication.
8	You are someone who is symptom free who has been asked to take part in or volunteer for any COVID testing for informational purposes or being tested as a precaution.	Exercise Caution		N/A
9	You are someone who is symptom free though has taken a domestic US flight within the last 14 days (Note: quarantine may be required based on requirements of the State or Territory visited)			
10	You are someone who is symptom free but has had Close Contact with someone at Category 3 – 6		EHS, HR & your Manager – Discretionary	
11	You are symptom free and have not had Close Contact with any of the levels above		No action required.	

Assessing Risk Level

- How many layers removed from a potential COVID-19 case do we require quarantine/isolation? The situation obviously resolves itself with a negative diagnosis but we need to align on the period between testing and diagnosis as well as once a positive diagnosis is received.
 - a. **1st Level Risk** - Individual diagnosed (isolation) or awaiting diagnosis is an obvious **YES, you self-isolate**.
 - b. **2nd Level Risk** - Spouse or other household member diagnosed or awaiting diagnosis is an obvious **YES, you self-isolate**.
 - c. **3rd Level Risk** - What about those AGC employees in direct contact with the AGC employee who has someone in their household? – **Quarantine not required**
 - d. **4th Level Risk** - What about those in direct contact with the 3rd level group? – **Quarantine not required**