

# 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.



*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. It is mandatory that each employee check their body temperature at the start of the day when arriving onsite using the temperature kiosk station or hand-held thermometer provided. In case of a fever 99.5° F [37.5° C] or greater (the temperature kiosk will provide audible and visual “red” notification of a high temperature) they must promptly notify their supervisor and refrain from entering the workplace. In addition to taking their temperature prior to site entry at the start of the workday, employees entering **GMP access points** must also take their temperature daily the first time entering the GMP space and use the logbook provided to fill in time, date, employee initials, and yes/no if entry is allowed.
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. If an employee is tested for COVID-19 due to symptoms and the test is negative, they may return to work once their symptoms are gone without having to wait an additional 48 hours.
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 due to symptoms or having 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. Notification of tests taken as a precaution as required for travel purposes, medical procedures or to access public venues local authority requirements is not required unless there is a positive test result. In all cases a positive test result must be reported.
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 notifications and quarantine measures are implemented.
13. Unless otherwise specified by local public health authority requirements, the length of quarantine for close contact persons will be:
  - 10 days without testing and the person is free of symptoms

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- 7 days with a negative test result (taken within 48 hours of the end of quarantine) and the person is free of symptoms.

### 14. 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 2 days before illness onset (or, for asymptomatic patients, 2 days prior to test specimen collection) until the time the patient is isolated.

### 15. Instances where a person has had COVID-19 and recovered, and later is in close contact with someone who has tested positive for COVID-19

Personnel who have tested positive for COVID-19 do not need to quarantine or get tested again for up to 8 months unless additional restrictions from home country or region (e.g. U.S. requirement is 3 months) as long as they do not develop symptoms. People who develop symptoms again will need to be tested if there is no other cause identified for their symptoms.

### 16. Instances where a person has been vaccinated for COVID-19 and later is in close contact with someone who has tested positive for COVID-19

Unless required otherwise by local requirements, personnel who have been fully vaccinated for COVID-19 do not need to quarantine provided the following criteria are met:

- Must be fully vaccinated ( $\geq 2$  weeks following final dose in the series)
- Have remained asymptomatic since the current COVID-19 exposure.
- Must get tested 3-5 days after exposure even if no symptoms

### 17. 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.

### 18. 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.

### 19. 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).

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- 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 ≥ 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 ≥ 24 hours apart.
20. 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. With the exception of single offices and workstations provided with protective shielding, masks must be worn by all personnel in indoor areas. Follow prescribed department requirements for type of mask and usage within GMP workspaces. Approval for an exemption from facemasks to use a full face shield must be obtained through the site EHS manager based on a doctor's recommendation. Consideration should also be given to working remotely in these situations, if possible.
21. Mask and social distancing requirements will be maintained at each location until both of the following thresholds are reached:
- a. Site has a fully vaccinated rate of 80% (or 80% country/region rate where site data is not available)
  - b. Mask and social distancing requirements have been removed by local health authorities based on improved community infection and vaccination data
22. Established an increased awareness and ongoing guidance through various means of communication including email, postings and a dedicated website, Coronavirus (COVID-19) Advisory page:  
<http://www.agcbio.com/covid-19>
23. 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.
24. 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.
25. 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 when the purpose has been determined by site management to be essential and the site has the capability to host the activity given local restrictions. This applies to contractors engaged in essential work as well as customer/client related
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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 temperature kiosk station or hand-held 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 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 a distance of 6 feet or 2 meters from others within the workplace unless indicated otherwise by local health authority requirements.
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 the number of participants where the required social distance can be maintained for the meeting space. Reduce meeting times as much as possible to minimize contact. For face-to-face meetings involving more than 2 people, facemasks must be worn at all times and are always mandatory whenever social distancing cannot be maintained.
6. Company gatherings, events and dinners are permitted but must be in accordance with applicable local government guidelines and restrictions.
7. Avoid carpooling when commuting to work. AGC will work with employees to explore alternative commuting options.
8. If public transportation must be used, please practice social distancing guidelines above and if possible travel at times when public transportation is less crowded.
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. If stairs are not an option for moving between floors, use of elevators should be limited to the maximum number of persons that can maintain social distance requirements.

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.

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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	EHS, HR & your Manager – Mandated – at time of testing and when results received  In the interests of privacy and calm please do not inform your colleagues  EHS CONTACTS BELOW:  Global EHS / Seattle David Steinbacher <a href="mailto:dsteinbacher@agcbio.com">dsteinbacher@agcbio.com</a> 206-375-0427  Boulder/Longmont EHS Jen Wingard <a href="mailto:jwingard@agcbo.com">jwingard@agcbo.com</a> 303-886-6410  EU EHS Shahida Hamid <a href="mailto:shamid@agcbio.com">shamid@agcbio.com</a> 22656902  EHS, HR & your Manager – Discretionary  No action required.	(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 required until test results are known and proceed according to correct category.		After testing negative for COVID-19 and symptoms are gone
3	You are someone who is symptom free, fully vaccinated and have had Close Contact with a person diagnosed with COVID-19	Quarantine is not required. Get a COVID test 3-5 days after close contact as precaution. Follow more restrictive government requirements as applicable.		Quarantine not required. If test positive, isolation required per category 1.
4	You are someone who is symptom free, not fully vaccinated and have had Close Contact with a person diagnosed with COVID-19	Quarantine for 10 days without test or 7 days with a negative test result (taken within 48 hours of end of quarantine). Follow more restrictive government requirements as appropriate.		After quarantine per guidelines or where applicable per government regulations.
5	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.	Observe quarantine and covid testing per requirements of home country upon return		After quarantine period as applicable for home country.
6	You are someone who is symptom free, not fully vaccinated and have had Close Contact with someone being tested for COVID19	Quarantine required until test results are known and proceed according to correct category. Fully vaccinated persons do not need to quarantine.		Proceed according to correct category depending on the test results for the Close Contact
7	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.
8	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.
9	You are someone who is symptom free who is being tested as a precaution due to travel requirements, medical procedure or access to public venues, etc.	Exercise Caution		N/A
10	You are someone who is symptom free but has had Close Contact with someone at Category 3 – 6			
11	You are symptom free and have not had Close Contact with any of the levels above			

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## 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**