

Business Continuity Plan for an outbreak of infectious diseases

LKF is working on a variety of measures to be prepared in case of the spread of COVID-19 in Europe and especially Germany. According to German law, health authorities will decide on all further steps, such as a virus testing of employees or a lock of the LKF facilities.

Regarding to the status as a medical laboratory a lock and closure of LKF seems to be very unlikely. Nevertheless, LKF has taken several actions to mitigate the risk of such a situation starting in early February 2020.

Preventive actions already taken:

1. The amounts of reagents for analytical measurements in stock have been increased to be prepared for any delay in the supply chain. Suppliers of reagents and shipment material have been asked about the likelihood of such a delay. Although such case is not expected, the stock of kit material (tubes etc.) in the storage facility has been increased as well.
2. For prevention of our employees the stock of disinfectants for skin and surfaces has been increased. In addition, dispensers with disinfectant have been installed at all LKF entrances. LKF has an adequate amount of gloves and face masks to protect all employees.
3. Access to the laboratory for external staff members (e.g. cleaning company, couriers) is prohibited. If the access is inevitable (e.g. for technical support) a questionnaire focusing on the risk of infection needs to be answered and signed in advance.
4. Staff members have been informed not to shake hands and to follow strictly the posted hygiene measures for infection prevention.
5. Additional laptops have been bought and distributed to key personal supporting the work from home offices.
6. Critical points in the analytical processes have been identified under consideration of sample stability and clinical relevance assuring the measurement even with heavily reduced staff.
7. Daily updates regarding all relevant information (e.g. delays in delivery, closed borders) have been implemented on our website.

Currently LKF is working with full staff in all relevant departments. Staff attending at LKF has been reduced to minimize the potential risk of spreading COVID-19.

Actions in case of partial closure of LKF:

1. Information of staff by the LKF crisis management team consisting of CEOs, General Manager, Technical Manager, Occupational Safety Officer and Works Council. There is remote access to all relevant systems like e-mail, LIMS, ERP and CRM system.
2. Different departments are able to work from home. Besides the CEOs this is project management, data management, finance, QA and partly IT.
3. Forwarding internal telephone numbers to the respective mobile phones of staff working from home. LKF will be reachable for sponsors using the known company numbers. In addition, current information is given via our website: <https://www.lkf-kiel.de>

4. Information for sponsors, sites and third parties will be sent by the responsible project manager or its substitute. Ad-hoc consultation of specialists is possible during core work time.
5. Incoming samples will be handled as shown in Appendix A.
6. Kits and study material will be sent out to the sites as possible. Due to unforeseen circumstances regarding couriers and legal restrictions in different countries no definitive statement can be given on this topic.

There is a strong overall level of preparedness in place to provide respective actions for the case of an outbreak of infectious disease. All actions taken will be evaluated and adjusted ongoing to the current situation

Your LKF-Team

Appendix A

Handling of specimens and laboratory measurements

Escalation and de-escalation according to the different levels mentioned below will be decided by the LKF crisis management team.

Level 1: Business as usual, only minor limitations, fully staffed

1. All incoming samples will be handled as usual on a daily basis.
2. Measurement of planned batched samples can be performed.
3. All Biopsies and other samples that need to be sent to third parties will be sent

Level 2: Limited operation, limited staff (> 6 technicians available)

1. If the amount of incoming samples is low, all analyses will be performed. Haematology will be measured on the same day, all other samples may be postponed to the following day if needed). All Biopsies and samples for special analytics will be sent to the respective third parties.
2. If LKF is not capable to perform all analyses due to operating in Level 2, sponsors/CROs and CRAs will be informed by the responsible project manager.

Level 3: Minimal operation, minimal staff (< 6 technicians available)

1. All incoming shipments will be accessioned.
2. Haematology samples will be analysed and blood smears will be prepared and stored for microscopic differential blood count.
3. Sample shipping to third parties will be performed (maybe with lower frequency).
4. All serum, plasma und urine samples delivered under ambient conditions will be stored frozen -20°C. All missing analyses will be performed after de-escalation as soon as possible.
5. All results will be sent out on a daily basis. An authorized signatory for lab results is always available during core working hours.