

20 March 2020

Re: PPD® Laboratories Central Lab | COVID-19 Advisory

Dear Site Staff,

PPD Laboratories' senior leadership is closely monitoring progression of the novel coronavirus (COVID-19). Patient safety is at the forefront of our continuity plans, and we appreciate your partnership to maintain clinical trial activities. Our central lab locations are currently operating at full capacity with no disruption to laboratory services. We will assess the current situation and adjust plans as necessary based on quickly changing local and regional government guidelines.

We do expect additional government and health authority restrictions to increase in the coming weeks and continue to adjust our plans daily. Please be advised that if local government or health authority guidelines impact the transportation of samples you may need to perform testing within your on-site laboratory and/or engage a local (accredited) lab for urgent testing or specimen storage.

If PPD Laboratories central lab is made aware of any major disruption, we will contact you and make every effort to facilitate and advise on alternate testing or courier solutions to help you maintain the continuity of your trial. If such a disruption should occur, please follow the general guidelines listed below for specific sample types in your study.

Sample Guidelines (complete *ONLY* in case of major disruption and after contacting your sponsor study team for specific directions):

- Chemistry samples:
 - Freeze and store at -20C if NOT required for immediate patient assessment
 - If samples are used to assess patient safety, test on-site or submit to a local lab for testing
- Hematology:
 - Test on-site or submit to local lab for testing to maintain patient safety
- Urinalysis:
 - o Test on-site submit to local lab for testing to maintain patient safety
- HbA1c:
- Freeze and store at -20C if NOT required for immediate patient assessment
- If samples are used to assess patient safety, test on-site or submit to a local lab for testing
- Coagulation:
 - Freeze or submit to local lab for testing if needed for patient safety

- All samples that would normally require frozen shipment:
 - Freeze and store at -20C
 - If samples are used to assess patient safety, test on-site or submit to a local lab for testing
- Flow, PBMC, histology (fresh tissue) and microbiology samples that cannot be stabilized or stored prior to processing or testing, contact trial sponsor study team for guidance
- DNA or RNA should be stored at -70C if available. -20C if -70C is not available.
- Anatomic pathology, if samples are fixed (in paraffin blocks or sections from paraffin blocks) store for future shipment or, under guidance from the trial sponsor, submit for testing to an accredited laboratory local to your site

Please use the Preclarus® investigator site portal to view continuous updates and log all sample collections to assist in sample chain of custody tracking.

If you have not activated your Preclarus investigator site portal account, please contact your local global sites services at the number or email below.

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Warm Regards,

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