AKADEMISKA SJUKHUSET

Uppsala
February 12th 2025

Regarding revocation of Akademiska Laboratoriet's accreditation for the areas of clinical chemistry and clinical pharmacology

As of January 13, 2025, Akademiska Laboratoriet at Uppsala University Hospital has been informed by the accrediting authority, Swedac, about revocation of the accreditation in the areas of clinical chemistry and clinical pharmacology. This decision arises from some serious deviations identified in our adherence to the ISO 15189 standard, specifically concerning insufficient compliance with certain routines, delays in addressing reported deviations, and the absence of necessary signatures on certain work processes. We would like to emphasize that our accreditations in Clinical Genetics, Immunology, Microbiology, Transfusion Medicine, and Pathology remain unaffected by this decision.

We maintain a strong conviction that no erroneous test results have been delivered as a consequence of the aforementioned deviations, thereby ensuring that patient safety has remained uncompromised. Our commitment to other stringent quality control measures has been unwavering, and further details regarding these quality assurance systems and routines can be made available through our **Quality Statement** document upon request to avackreditering.kkf@akademiska.se.

While we recognize the significance of ISO 15189 accreditation, it is essential to note that the Good Clinical Practice (ICH GCP E6(R3)) standard does not require such accreditation. However, acknowledging the necessity for some clinical trial samples to undergo analysis in ISO 15189 accredited laboratories, we are actively developing a logistical framework to meet this requirement.

It is the sponsor's responsibility to assess the risks of the resulting situation for the clinical trial concerned. Risks must be assessed in relation to the importance for patient safety and its scientific position in the trial. To facilitate such assessment, we have compiled a detailed report on the measurement quality for selected methods, **Clinical Chemistry quality report 2024**, as well as a risk analysis "**Risk Assessment Summery**" on the potential disadvantages with having samples sent to another laboratory. These documents were completed Feb 11, 2025, and are available on request to the mailbox: avackreditering.kkf@akademiska.se. Sponsors need to assess whether such documentation is sufficient to continue using the Academic Laboratory for analysis within the current trial.

As part of our strategic plan, we will be applying for reaccreditation by the fall of 2025, with the expectation of regaining full accreditation by that time.

We appreciate your understanding and support as we navigate this process.

AKADEMISKA SJUKHUSET

Sincerely,

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Medical Director
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Frequently Asked Questions

When will a solution for sending samples to an accredited lab be available?

We are in the final phase of negotiations with an accredited laboratory for use a subcontractor and establishing logistic solutions for sending samples. Details such as finding feasible solutions for shipment during outside office hours, electronic requests and results reports, sample tube labelling are under way, but we estimate that these issues will take another two weeks before they could be launched. Issues related to disadvantages with sending samples to another accredited laboratory is now addressed in the risk analysis "**Risk Assessment Summary**". This document is available on request to the mailbox: avackreditering.kkf@akademiska.se

Does hematology belong to the processes that was revoked?

Yes, most samples analysed in clinical trials will be affected. Clinical Chemistry and Pharmacology perform the routine analysis of peripheral blood, e.g. blood counts such as concentration of B-Hemoglobin, B-Leukocytes, B-Neutrophil granulocytes or B-Platelets. However, Clinical Pathology is still accredited, and their methods are not affected, e.g. bone marrow diagnostics. If questions arise on specific methods relating to hematology, please use the avackreditering.kkf@akademiska.se mailbox, and we will answer specific issues.

Will results from patient samples released from the lab during 2024 have to be rechecked?

No, that is not our opinion. The abovementioned short **Quality Statement** will be followed by a detailed compilation of the laboratory´s performance during 2024, e.g. with data from the external quality programs/proficiency testing.

Could there be disadvantages with having samples sent to other accredited laboratories?

Yes. Delays from time of blood sampling to analysis does affect some analytes, e.g., CBC (complete blood count). Some analytes are more affected, some are not affected at all. Other accredited laboratories might have other methods than Akademiska Laboratoriet, and thus results might not be fully compatible. For some analytes such differences are neglectable, for others they are clinically relevant. Thus, for each study investigators, sponsors and others involved have to decide what is most appropriate, depending on the details of every specific study. These issues are now addressed in the risk analysis "**Risk Assessment Summary**". This document is available on request to the mailbox: avackreditering.kkf@akademiska.se

Does the withdrawn accreditation affect the possibility to publish academic studies not dealing with drugs?

In general, no. Many scientific journals do not require that blood samples should have been analysed at an accredited laboratory. If the questions is raised in a particular study, all samples analysed before Jan 13, 2025 were analysed by an accredited lab. If information on date of analysis for particular samples are needed, such data could be requested from the laboratory, using the mailbox avackreditering.kkf@akademiska.se.

What person should we contact if we have questions about specific analytes?

Mail your questions to avackreditering.kkf@akademiska.se and the lab will forward to the questions to the appropriate person, e.g. the physician responsible for that particular analyte.