

Health and environment division
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Decision on changed accreditation (2 appendices)

Decision

The Swedish Board for Accreditation and Conformity Assessment (Swedac) decides to change the accreditation of Landspítali - National University Hospital in accordance with the application/notification dated 2021-11-01 and 2021-12-10, case file 2020/2830. The issued accreditation is of the scope detailed in Appendix 1. This decision replaces previous decisions dated 2020-11-27, case file 2019/1842.

The accreditation is valid until further notice.

Basis for decision

Landspítali - National University Hospital has applied for changed accreditation as a testing laboratory.

Based on the performed assessment of Landspítali - National University Hospital it is Swedac's judgment that Landspítali - National University Hospital fulfils the accreditation requirements for the scope of accreditation detailed in Appendix 1.

The amendment refers to addition of Cobas 801, methods for SARS-CoV and removal of two methods from the scope.

Information concerning requirements for accreditation

An accredited body is obliged continuously to fulfil the requirements for accreditation. Failing this, Swedac may decide to withdraw the accreditation. The applicable requirements for your accreditation are detailed at www.swedac.se (<https://search.swedac.se/en/accreditations>).

Swedac performs surveillance of the accredited activities in accordance with its regulations for accreditation. The cost of the surveillance activities are borne by the accredited bodies through the payment of an annual accreditation fee. The fee regulations currently applicable are found at www.swedac.se.

Applications for extension or reduction of the scope of accreditation shall be submitted to Swedac. The application forms currently applicable are found at www.swedac.se.

This decision has been taken by the acting division manager Bente Zettergren after a hearing, detailing the pertinent particular circumstances, with case officer Tomas Persson.

Bente Zettergren

Appendices

1. Scope of Accreditation
Accreditation Certificate

ACKREDITERINGSCERTIFIKAT/ACCREDITATION CERTIFICATE



Ackred. nr 10446

Testing

ISO 15189

Landspítali - National University Hospital

Department of Clinical Microbiology

Registration number

är ackrediterat som provningslaboratorium för uppgifter enligt bilaga 1 i beslut daterat 2022-06-29/is accredited as a testing laboratory for the scope specified in appendix 1 to decision dated 2022-06-29.

Laboratoriet är ackrediterat enligt den internationella standarden ISO 15189:2012. Ackrediteringen innebär att det ackrediterade laboratoriet har bedömts ha erforderlig kompetens och att opartiskt och konsekvent utföra ackrediterade tjänster inom de områden som definieras i bilaga 1 enligt ovan. Det ackrediterade laboratoriet ansvarar för resultat av utförd provning./*This laboratory is accredited to the International Standard ISO 15189:2012. The accreditation is a recognition of the competence for and consistent performance and impartiality in the provision of the services defined in appendix 1. The accredited laboratory is responsible for the outcome of performed testing.*

Ackrediteringen gäller tills vidare. Styrelsen för ackreditering och teknisk kontroll (Swedac) genomför regelbundet tillsyn, och vart fjärde år en förnyad bedömning, för att bekräfta att gällande krav för ackrediteringen kontinuerligt uppfylls./*The accreditation is valid until further notice. The Swedish Board for Accreditation and Conformity Assessment (Swedac) regularly carries out surveillance, and a full reassessment every fourth year, in order to verify that the applicable requirements for accreditation continuously are fulfilled.*

Detta ackrediteringscertifikat utfärdades 2022-06-29/*This accreditation certificate was issued 2022-06-29*

Bente Zettergren,

Tf. Enhetschef enheten för miljö och hälsa/*Acting Division Manager of the Health and Environment Division*

Beslutet om ackreditering utfärdades med stöd av artikel 5.1 i Europaparlamentets och rådets förordning (EG) nr 765/2008 om krav för ackreditering och marknads kontroll m.m. och lagen (2011:791) om ackreditering och teknisk kontroll. Swedac är nationellt ackrediteringsorgan ansvarigt för bedömning av certifieringsorgan, kontrollorgan, laboratorier, miljökontrollanter, verifierings-/valideringsorgan och arrangörer av program för kompetensprövning som ansöker om ackreditering. Den här ackrediteringen har utfärdats under EA:s MLA-avtal och kan därmed betraktas som likvärdig andra ackrediteringar under EA:s MLA-avtal med samma ackrediteringsomfattning./*Accreditation was granted in accordance with Article 5 (1) of Regulation (EC) No 765/2008 regarding accreditation and market surveillance etc. and the Act (SFS 2011:791) concerning Accreditation and Conformity Assessment. Swedac is the Swedish national accreditation body responsible for the assessment of certification bodies, inspection bodies, laboratories, environmental verifiers, validation and verification bodies and bodies for providing programme for proficiency testing applying for accreditation. This accreditation has been issued under the EA MLA and is therefore recognised as equivalent to other accreditations with the same scope of accreditation issued under the EA MLA.*