The Swedish Society for Clinical Microbiology organizes medical specialists and biologists working within diagnostic microbiology in Sweden. The society has been active in supporting the Swedish clinical microbiology laboratories in implementation of IVDR, in particular compliance with article 5.5 for in-house IVDs. We can conclude that the implementation of the requirements under article 5.5 is very problematic for clinical microbiology laboratories.

1. We welcome the Commission's initiative to revise the EU rules for medical devices and in vitro diagnostics and appreciate the opportunity to participate.
2. Clinical microbiology is diverse and complex, dealing with a wide range of sample types and hundreds of pathogens. A very large number of diagnostic procedures fall within the IVDR definitions for in-house manufacturing.
3. We endorse the urgent call to simplify and contextualize IVDR Article 5.5 for tailored and precision diagnostics as recently addressed in the publication of EFLM Committee on European Regulatory Affairs (EFLM C-ERA): *Cobbaert C, Schweiger C, Buchta C, Streichert T, Vanstapel F, Mullier F, Biaggini L, Capoluongo E, Bossuyt P, Bhattoa HP, Melvin T, Neumaier M; EFLM Committee on European Regulatory Affairs (EFLM C-ERA) and endorsed by the DGKL Board. Urgent call to the European Commission to simplify and contextualize IVDR Article 5.5 for tailored and precision diagnostics. Clin Chem Lab Med. 2025 Aug 20. doi:10.1515/cclm-2025-1033. Epub ahead of print. PMID: 40827911.* https://www.degruyterbrill.com/document/doi/10.1515/cclm-2025-1033/html
4. In addition to this we would like to draw the Commission's attention to the severe conceptual disagreement between IVDR and established laboratory routines for work and quality management (EN-ISO-15189) in clinical microbiology. IVDR regulates products or "devices" and article 5.5 stipulates the requirements for production and use of non-CE-IVD marked products or combinations thereof in diagnostic laboratories. Any use of non-CE-IVD products; or combinations including such products; or product use outside the specifications of the manufacturer, is considered in-house manufacturing. This redefinition of product use to device manufacturing has shown very problematic to interpret, apply, and document in the laboratories. The simple reason is that diagnostic laboratories do not manufacture products and are not organized around producing and selling products, unlike the diagnostics device industry. Laboratories deliver diagnostic services, i.e. analytical procedures. The present quality management system, EN-ISO-15189, is structured around these diagnostic procedures, and assures safe delivery of these services, including control of used products. A parallel system organized around documentation of imaginary manufacturing has proven complicated, confusing, and extremely time-consuming to apply. Consequently, the Society is not aware of any clinical microbiology laboratory that to date has managed to present a working model for demonstrating compliance with article 5.5 of IVDR.
5. Since compliance with the general safety and performance requirements set out in Annex I is also defined at the imaginary "device" level, also this part of article 5.5 is difficult to apply in a diagnostic laboratory.
6. We agree with the expressed view in the above-mentioned publication that accreditation by EN-ISO-15189 is a very efficient quality management system for diagnostic laboratories.
7. As a consequence of the observations above, we strongly recommend that Article 5.5 in its entirety is simplified to:
   "The requirements of this regulation shall not apply to devices manufactured and used

only within health institutions established in the Union, provided that the laboratory of the health institution is compliant with standard EN-ISO-15189."