Appendix 1 Declaration of in-house developed in-vitro diagnostics

Part A Declaration on the use of in-house developed in vitro diagnostics	
Institute / Laboratory	
Name:	Hospital Pharmacy Gelre Hospitals
Department:	Clinical Pharmaceutical and Toxicology Laboratory
Address:	Albert Schweitzerlaan 31 7334 DZ Apeldoorn
Contactperson	
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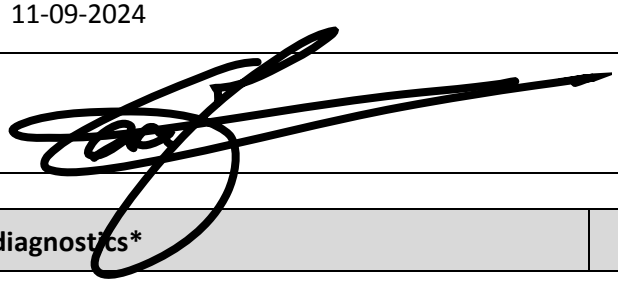
Statement	
For all in vitro diagnostics mentioned in Part B, the above institute declares: i) These diagnostics are manufactured or modified in-house under the existing EN ISO 15189 accreditation. ii) These diagnostics meet the relevant general safety and performance requirement as decribed in Annex I of the European Regulation 2017/746 on in vitro diagnostic medical devices. Deviations are justified and documented in quality documentation. iii) The accountability for the use of in-house developed in-vitro diagnostics is registered in quality documentation by 26 May 2028 at the latest.	
Signature	
Name:	Dr. Lutea A.A. van Gendt - de Jong
Date:	11-09-2024
Signature:	

Part B Description of in-vitro diagnostics*	
Risk class: divided into four classes (A, B, C, D) based on the risk to the patient in case of failure. IVDR classification: I (CE-IVD, low); II (CE-IVD, high); III (LDT, CE-IVD alternative not suitable); IVa (research-use-only); IVb (no CE-IVD).	

* The specific risk class and IVDR classification for each analysis can be found on www.gelre-ilab.nl within the test details.