



Certificate

No. Q5 095123 0007 Rev. 03

Holder of Certificate:	Hangzhou AllTest Biotech Co., Ltd. 550#, Yinhai Street Hangzhou Economic and Technological Development Area 310018 Hangzhou PEOPLE'S REPUBLIC OF CHINA
Facility(ies):	Hangzhou AllTest Biotech Co., Ltd. 550#, Yinhai Street, Hangzhou Economic and Technological Development Area, 310018 Hangzhou, PEOPLE'S REPUBLIC OF CHINA
Certification Mark:	
Scope of Certificate:	Design and Development, Production and Distribution of In Vitro Diagnostic Kit for Obstetrics and Gynecology, Infectious Disease, Drug of Abuse, Vitamin, Special Protein, Oncology, Cardiology and Biochemistry, and Digital test for pregnancy and ovulation. Home use, Clinical Laboratory use and Near Patient In-vitro Diagnostic Devices and the related POCT analyzer.
Applied Standard(s):	EN ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016) DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.:	SH20106401
Valid from:	2020-09-25
Valid until:	2023-09-24