CLINICAL TRIALS OF MEDICAL DEVICE
ANESA Analyzer (AMP)

The producer of ANESA analyzer held clinical trials in Ukraine, Russia, Hungary (EU), Belarus and China. All the clinics and laboratories were assigned by the respective Notified Body. Some of the trials were done after registration of the device; they must be characterized as post-clinical trials.

Year	Approvals	Agency (s)	Assigned institution	Comparative equipment	Quantity of people	Accuracy
2007	State registration Certificate of **Ukraine**, No.5995/2007	State Service of Pharmaceuticals and Medical-Purpose Products/ Ukraine Ministry of Health	National University of Pharmacy Year 2006	Sysmex N-2000 (Japan)	60	95%
			National University of Pharmacy Year 2007	Sysmex N-2000 (Japan) Express + (Bayer Diagnostic, Germany)	16	95%
2007	**EC Certificate** – Production Quality Assurance, No.5-628-500-0911 **Hungary**	Institute of Healthcare Quality Improvement and Hospital Engineering EMKI, ID 1011 (1125 Budapest, Hungary)	Honved Poliklinika KFT Budapest, Hungary	No info	60	87-93%
2008	Registration Certificate of **Russian Federation**, No.ФС3-208/02305	Federal Service of Health Care and Social Development Control	Clinical-diagnostic Department of Moscow Municipal Clinical Hospital No. 20	No info	180	85-95%
2010	SFDA Certificate in **China**, No.20102400855	State Food and Drug Administration of China	Air Force PLA General Hospital Beijing China	No info	126	82-91%
2010	Registration Certificate of **Republic of Belarus**, No.ИФ-7.96780	Republic of Belarus Ministry of Health	9th Municipal Clinical Hospital, Minsk, Belarus	No info	30	93%
2010	Registration Certificate of **Republic of Kazakhstan**, No.РК-МТ-5№007415	Republic of Kazakhstan Ministry of Health	The results of previous tests were taken into account. The Analyzer were registered according to the national laws and rules with submitting of all required documents			
2012	Registration Certificate of **Socialist Republic of Vietnam**, №:786/BYT-TB-CT007415	Socialist Republic of Vietnam	The results of previous tests were taken into account. The Analyzer were registered according to the national laws and rules with submitting of all required documents			
2012	Post-clinical trials **Ukraine**	Ukraine Ministry of Health	Ukrainian Research center for Emergency Medicine and Disaster Medicine	Semi-automatic hematology analyzer BC-2300 (USA) Semi-automatic Biochemical analyzer BA-88A (USA)	80	95%
2012	Post-clinical trials **Ukraine**	LLC "Sitora Grand"	Bogomolets National Medical University Internal Medicine Department No. 3	**Hematology Analyzer MS-4 (France) Biochemical Analyzer Humalyser 2000 (Germany)**	100	62-99%

According to the required tests and procedures, ANESA/AMP device was certified in each country. Notification body of each country made a decision, that received results and documentation were completed and fulfill the registration conditions. Valid certificates approving legal using of the ANESA/AMP in each country are placed on our website:

(http://www.onkocet.eu/en/produkty-detail/17/1/)

Producer together with the experts from relating Notified Bodies have concluded that declared accuracy 85-90% is enough for a screening diagnostic medical device.