

Dimopoulou HA<sup>1</sup>, Theodoridis T<sup>2</sup>, Galea V<sup>2</sup>, Christopoulou-Cokkinou V<sup>2</sup>, Spyridaki MH<sup>1</sup>, Georgakopoulos CG<sup>1</sup>

## **ISO/IEC 17025 Sysmex R-500 Hematology Reticulocyte Analyzer Validation**

1. Doping Control Laboratory of Athens, Olympic Athletic Center of Athens, Kifissias 37, 15123 Maroussi, Greece, oaka@ath.forthnet.gr
2. Hematology Laboratory, 'Evangelismos' Hospital, Athens, Greece

The Sysmex R-500 (R-500) Hematology Analyzer is a bench-top system appropriate for the analysis of limited batches of blood samples. The R-500 provides percentage proportional (RET%), absolute reticulocyte (RET#), and absolute red blood cell (RBC#) counts. The system was validated at the Doping Control Laboratory of Athens, according to the International Committee for Standardization in Hematology, International Standards Organization (ISO/IEC) 17025, and World Antidoping Agency (WADA) specifications [1]. The instrument calibration was performed according to the manufacturer and validation parameters comprised linearity, precision, uncertainty (intermediate and long-term precision), comparability, effect of drift, carryover, stability, and accuracy. The linearity and the comparability studies for RET#, RET%, and RBC# were expressed in regression factors (R<sup>2</sup>) and coefficients of correlation [r(x, y)], respectively. For the precision studies, the coefficients of variation for RET#, RET%, and RBC# were 9.49%, 9.83%, and <1.5%, respectively. For the intermediate precision studies, the coefficients of variation for RET#, RET%, and RBC# were 3.1%, 3.6%, and 0.6%, respectively. Carryover was found to be negligible. Sample stability was demonstrated at both room temperature and at 4 degrees C over a 24-hour period. Comparability studies for the R-500 were performed using a Sysmex SE-9500. The total evaluation led to the conclusion that the R-500 is an accurate and precise analyzer and because of its relatively limited size, it can be considered a portable instrument, capable to be used in sports competition and training sites, where doping control and health tests are conducted. The analytical methodology of RET% measurement by the R-500 has been

incorporated into the Doping Control Laboratory of Athens' Scope of Accreditation according to the ISO/IEC 17025 and WADA specifications.

1. Dimopoulou, H.A., Theodoridis, T., Galea, V., Christopoulou-Cokkinou, V., Spyridaki, M.H., Georgakopoulos, C.G. (2007) ISO/IEC 17025 Sysmex R-500 Hematology Reticulocyte Analyzer Validation. *Laboratory Hematology* **13**, 43-48.