

**Tento dokument projednal a odsouhlasil výbor ČHS ČLS JEP**

Zpracovaly: Ludmila Bourková, Ingrid Hrachovinová, Miloslava Matýšková, Dana Mikulenková

**Poznámka: Takto jsou pro přehlednost označeny změny.**

Základní informace o procesu certifikace v systému EHK a rovněž seznam použitých zkratk naleznete v dokumentu Certifikace 2023 – obecný úvod.

**Certifikované zkoušky****Program EHK: HKG - Hemokoagulace**

Zkouška	Referenční metoda	Certifikovaný referenční materiál	D <sub>max</sub> pro EHK	Teoretický D <sub>max</sub>	Typ AV
Antitrombin	-	3 <sup>rd</sup> international standard WHO, code: 08/258	25 % (pro AT ≤ 50 %) 18 % (pro AT > 50 %)	8,3 %	CVP
APTT - poměr	-	-	20 %	4,5 %	CVPG
Fibrinogen	Metoda podle Clausse	3 <sup>rd</sup> international standard WHO, code: 09/264	25 %	14 %	CVP
Protrombinový test (INR i ratio)	-	5 <sup>th</sup> international standard WHO, code: rTF/16 5 <sup>th</sup> international standard WHO, code: RBT/16	20 %	5,3 %	CVP

**Program EHK: KO – Krevní obraz**

Zkouška	Referenční metoda	Certifikovaný referenční materiál	D <sub>max</sub> pro EHK	Teoretický D <sub>max</sub>	Typ AV
Leukocyty	Elektronické počítání v jednobanální impedanční apertuře	-	15 % (počet > 4 · 10 <sup>9</sup> /L) 18 % (počet ≤ 4 · 10 <sup>9</sup> /L)	15 %	CVP
Erytrocyty	Elektronické počítání v jednobanální impedanční apertuře	-	7 %	4,4 %	CVP
Hemoglobin	Fotometrická hemoglobinkyanidová	WHO International Standard, NIBSC code 98/708, JCCRM 912	6 %	4,2 %	CVP
Hematokrit	Mikrohematokritová	-	10 %	4 %	CVP
MCV	-	-	10 %	2,4 %	CVP
Trombocyty	Elektronické počítání v jednobanální impedanční apertuře	-	18 %	13 %	CVP

**Program EHK: RC - Retikulocyty na analyzátoru**

Zkouška	Referenční metoda	Certifikovaný referenční materiál	D <sub>max</sub> pro EHK	Teoretický D <sub>max</sub>	Typ AV
Retikulocyty (počet)	Průtoková cytometrie	-	40 %	17 %	CVP

**Literatura****K programu HKG**

- Campbell PJ. International biological standards and reference preparations. 1. Preparations and presentation of materials to serve as standards and reference preparations. J Biol Standardisation 2, 249-258 (1974).
- Tripodi A, Poller L, van den Besselaar AMHP, Mannucci PM. A proposed scheme for calibration of international reference preparations of thromboplastin for the prothrombin time. Thromb Haemost 1995; 74: 1368-9.
- Poller L, Keown M, Chauhan N, van den Besselaar AMHP, Tripodi A, Shiach C, Jespersen J. A multicentre calibration of WHO international rabbit (RBT/90) and human (rTF/95) thromboplastin reference preparations. J Clin Pathol 2005; 58: 667-9.
- ICSH panel: International Council for Standardization in Haematology Recommendations for Hemostasis Critical Values, Tests, and Reporting. Sem Thromb Hemostas 2019, dostupné na: DOI <https://doi.org/10.1055/s-0039-1697677>.
- Kolektiv autorů: Pre-analytical practices for routine coagulation tests in European laboratories. A collaborative study from the European Organisation for External Quality Assurance Providers in Laboratory Medicine (EQALM). Clin Chem Lab Med 2019, 57/10:1511-1521.
- Favaloro EJ. a spol.: Towards harmonization of external quality assessment/proficiency testing in hemostasis. Clin Chem Lab Med 2019, 57/1:115-126.
- Favaloro EJ. a spol.: Recent initiatives in harmonization of hemostasis practice. Clin Chem Lab Med 2018, 56/10:1608-1619.
- Kitchen S, Adcock DM, Dauer R. a spol.: ICSH recommendations for collection of blood samples for coagulation testing. Int J Lab Hematol 2021, 43:907-916.

9. Gardiner C, Coleman R, de MaatMPM. a spol.: ICSH laboratory guidance for the verification of haemostasis analyser-reagent test systems. Part 2: Specialist tests and calibrated assays. *Int J Lab Hematol* 2021; 43:571-580.
10. Yuang H, Gao Z, Zhang J. a spol.: Homogeneity and Stability Evaluation of External Quality Assessment Control Materials for Four Coagulation Tests. *Clin Lab* 2021, 67/5. Dostupné na: DOI: 10.7754/Clin.Lab.2020.200911.
11. Van den Besselaar AMHP, Cobbaert HM.: Effect of the reaction temperature on the prothrombin time and the apparent International Normalized Ratio determined with International Standards for thromboplastins. *Int J Lab Hematol* 2022; 44:379-384.
12. Dorgalaleh A, Favoloro EJ, Bahraini M. a spol.: Standardization of Prothrombin Time/International Normalized Ratio (PT/INR). *Int. J. Lab Hematol* 2021, 43:21–28.

### **K programu KO**

1. The expert panel on cytometry of the ICSH: Reference method for the enumeration of erythrocytes and leucocytes. *Clin. Lab. Haemat.* 16: 131-138, 1994.
2. The expert panel on cytometry of the ICSH: Proposed reference method for reticulocyte counting based on the determination of the reticulocyte to red cell ratio. *Clin. Lab. Haemat.* 20: 77 - 79, 1998.
3. Reference and Selected Procedures for the Quantitative Determination of Haemoglobin in Blood – 3rd Edition, Approved Standard; NCCLS document H15-A3, NCCLS, 940 West Halley Rd., Suite 1400, Wayne, PA 19087-1898, 2000.
4. Procedures for Determining Packed Cell Volume by the Microhematocrit Method – 3rd Edition, Approved Standard; NCCLS document H7-A3, NCCLS, 940 West Halley Rd., Suite 1400, Wayne, PA 19087-1898, 2000.
5. International Council for Standardization in Haematology (ICSH) recommendations for "surrogate reference" method for the packed cell volume. *Bull BS*, Fujimoto K, Houwen B et al – ICSH Expert Panel on Cytometry. *Lab Hematol.* 2003;9(1):1-9.
6. An Interlaboratory Study of a Candidate Reference Method for Platelet Counting. Harrison, P, Ault, KA, Chapman, S. et al. *Am J Clin Pathol* 2001;115:448-459.
7. Kummrow A.: Overview of reference measurement system approach of blood cell counting. PTB Berlin Braunschweig. BIPM-JCTLM-12-2019.
8. Grote-Koska D. a spol.: Total haemoglobin – a reference measuring system for improvement of standardization. *Clin Chem Lab Med* 2020, 58/8:1314-1321.
9. Vidali M, Carobene A, Esposito SA. a spol.: Standardization and harmonization in hematology: Instrument alignment, quality control materials, and commutability issue. *Int J Lab Hematol* 2021, 43/3:364-371.
10. Favoloro EJ, Pasalic L, Lippi G.: Towards 50 years of platelet function analyser (PFA) testing. *Clin Chem Lab Med* 2022. Dostupné: <https://doi.org/10.1515/cclm-2022-0666>.
11. Herroelen PH, Demeester S, Damiaens S. a spol.: Performance of Abbott Alinity hq hematology analyzer for automated cell counting of body fluids. *Int J Lab Hematol* 2022, 44:96– 103.

### **K programu RC**

1. CLSI/NCCLS. Methods for reticulocyte Counting (Automated Blood Cell Counters, Flow Cytometry, and Supravital Dyes), approved guideline-second edition, CLSI/NCCLS document H44-A2, Wayne, PA:NCCLS; 2004.
2. ICSH guidelines for the evaluation of blood cell analysers including those used for differential leucocyte and reticulocyte counting, International Council for Standardization in Haematology, Writing Group: Briggs C, Culp N, Davis B, d'Onofrio G, Zini G, Machin SJ, on behalf of The International Council for Standardization of Haematology, 2014 John Wiley & Sons Ltd, *Int. Jnl. Lab. Hem.* 2014, 36, 613–627.