· 专家共识 ·

溶血指数质量指标建立与标本管理专家共识

中国医师协会检验医师分会中医检验专业委员会 北京中医药学会中医检验专业委员会
执笔人：韩冉 段学光 寿好长 张慧芸 杨琦 田丽春 马子坤 林博 刘清林 张省委

作者单位：100078 北京，北京中医药大学东方医院检验科
通信作者：寿好长，Email：dflabs@163.com
DOI：10.3969/j.issn.1674-7151.2019.02.001

【摘要】 溶血是临床实验室标本不合格的主要原因，标本溶血可能干扰检测，导致错误结果。为了提高溶血标本管理应用水平，中国医师协会检验医师分会中医检验专业委员会、北京中医药学会中医检验专业委员会共同制定了《溶血指数质量指标建立与标本管理专家共识》。本专家共识总结了迄今为止国内外已发表的关于溶血指数质量指标建立与标本管理的科学证据，并基于中国国情提出了相应的临床应用推荐建议。本专家共识融入了中外学者对溶血标本管理的智慧与理念，可有效降低临床标本拒收率。

【关键词】 专家共识； 溶血指数； 质量指标； 标本管理

Expert consensus on establishment of hemolysis index quality indicator and specimens management

China Association of Chinese Medicine of Laboratory Medicine, Chinese Medical Doctor Association of Laboratory Medicine of Traditional Chinese Medicine, Beijing Association of Chinese Medicine of Laboratory Medicine; Han Ran, Duan Xueguang, Shou Haochang, Zhang Huiyun, Yang Qi, Tian Lichun, Ma Zikun, Lin Bo, Liu Qinglin, Zhang Shengwei. Department of Laboratory, Dongfang Hospital Affiliated to Beijing University of Chinese Medicine, Beijing 100078, China

Corresponding author: Shou Haochang, Email: dflabs@163.com

【Abstract】 Hemolysis is the leading cause of unsuitable specimens in clinical laboratories, and hemolytic samples can cause interference in testing, resulting in erroneous results. In order to improve the level of hemolytic specimens management and the clinical application of samples, Chinese Medical Doctors Association Laboratory Physicians Branch of Traditional Chinese Medicine Laboratory Professional committee, and Traditional Chinese Medicine Laboratory Professional committee of Beijing Association of Traditional Chinese Medicine jointly established "Expert Consensus on Establishment of Hemolysis Index Quality Indicator and Specimens Management". This expert consensus has summarized the scientific evidences in the already published domestic and foreign reports related to the establishment of hemolysis index quality indicator and specimens management so far, and based on China's national situation, the consensus puts forward the corresponding clinical application and suggestions. This consensus incorporates the wisdom and ideas of Chinese and foreign scholars skillful at the management of hemolytic specimens, that may help effectively reduce the rejection rate of clinical specimens.

【Key words】 Expert consensus; Hemolysis index; Quality indicator; Specimen management

标本溶血是临床实验室（简称实验室）最常见的误差来源，是标本拒收的主要原因，因标本溶血发出错误结果报告可能造成误诊误治，重新抽血给患者增加痛苦、延长报告周期，复测造成人力、物力、经济损失，实验室应开展标本溶血质量指标监测，以降低标本溶血缺陷[1-3]。由于定义、数据采集方法不同等原因，文献报告的标本溶血缺陷结果变异性大，不利于实验室内部纵向和外部横向监测比较、合理评估及采取针对措施预防溶血缺陷[2,4-8]。

为促进实验室充分利用客观、量化、简便、高效的溶血指数质量指标监控标本质量，从源头控制血液标本溶血质量缺陷，降低标本溶血率，在《标本溶血检测与检验结果报告专家共识》发表基础上[9]，中华中医药学会检验医学分会协调中国医师协会检

验医师分会中医检验医学专业委员会、北京中医药学会中医检验专业委员会，组织专家根据国内外相关文献并结合国内实际情况，编写《溶血指数质量指标建立与标本管理专家共识》，旨在提出建立溶血指数质量指标及用于标本质量管理的技术要求，促进医疗机构应用溶血指数质量指标监控分析标本溶血率缺陷，采取有效改进措施，保证标本质量。随着技术发展、认识深化，《溶血指数质量指标建立与标本管理专家共识》将适时修订，以适应检验医学发展和临床应用的需要。

1 溶血指数检测方法建立与质量控制

1.1 开展仪器法检测标本溶血指数，通过自动化生化仪测定标本血清或血浆血红蛋白特定波长吸光度值，报告血清或血浆中的血红蛋白浓度，常以溶血指数表示，检测结果较目测法准确、快速[6, 10]。

1.2 实验室应开展溶血指数检测的性能验证、校准、室内质控、内部比对，参加室间质评计划或进行实验室间比对[11-14]。

2 溶血指数质量指标设置与选用

2.1 建立客观、量化、易实施的溶血指数质量指标，可用于有效监控血液标本采集、送检、标本处理等工作部门、岗位个人工作质量[15-17]。

2.2 实验室应动态监控溶血指数溶血率。参考国内外文献[8, 15-25]，结合国内实验室实际情况，推荐选择仪器法检测溶血指数≥50（相当于血清 / 血浆血红蛋白≥0.5 g/L）、≥25（相当于血清 / 血浆血红蛋白≥0.25 g/L）、≥15（相当于血清 / 血浆血红蛋白≥0.15 g/L）的溶血指数质量指标及限值。见表 1。

2.3 实验室应该优先选择应用溶血指数≥50 标本溶血率质量指标[26]。溶血指数≥25 和溶血指数≥15 标本溶血率指标更为敏感，可选择用于检验前过程各环节、部门、岗位的标本溶血潜在缺陷的监控[17-22]。

2.4 应准确采集、统计数据，纳入全部符合溶血指数血标本，包括让步检验、拒收的溶血标本，排除质控、复测等不适用标本。

2.5 质量指标初建期间，监控反馈周期宜短，比如每月 1 次，随着监控结果稳定，可适当延长。

2.6 推荐的限值量化标准主要参考相关研究文献及国内实验室实际情况，可用于目前监控检验工作质量参考，随着工作进展应适时调整，不属于硬性规定。实验室应用前应确认检测方法性能、检验前工作过程的适用性。尚未达到限值要求的实验室，应结合自身实际分析发生标本溶血的原因，通过优化服务流程、操作规程，消除质量缺陷，达到要求。

3 通过监控溶血指数质量指标改进标本质量缺陷

3.1 标本溶血主要发生在标本采集过程，也可发生在转运、实验室离心处理过程[4, 17]。实验室应开展溶血指数质量指标监测，参加溶血指数质量指标室间质评、实验室间比对，及时与相关部门与临床科室沟通、评估，主动分析查找检验前过程各环节存在的溶血缺陷原因，制定实施改进计划[14, 27-29]。

3.2 静脉血标本溶血常见缺陷类型分析

3.2.1 标本采集[30-35] 采血损伤，如反复进针、血肿部位采血；从静脉留置针、输液管、中心静脉导管等血管通路装置采血；注射器采血；未首选肘前正中静脉、头静脉及贵要静脉；使用细针头；消毒剂未干；止血带使用超过 1 min；未及时混匀、剧烈震荡混匀；采血量不足，未达采血管真空度量刻度；真空采血管分离胶质量差；使用大容量真空采血管等。

3.2.2 标本转运[30-31, 36] 气动传输过程中剧烈震荡；转运时间长；转运车温度过高、剧烈震荡等。

3.2.3 实验室标本处理[30-31, 37] 标本保存时间过长；标本保存温度过高；未及时离心；离心前血液未完全凝固；离心温度过高、速度过快；再次离心等。

3.2.4 体内溶血[38-40] 自身免疫性溶血性，如血型不合输血；遗传、代谢病，如地中海贫血、肝豆状核

表 1 仪器法检测溶血指数质量指标及限值建议

质量指标	指标定义	限值（%）		
		最佳	适当	最低
门诊溶血指数≥ 50 标本溶血率	门诊溶血指数≥ 50 标本数 / 标本总数 ×100%	＜ 0.2	0.2 ~ 0.4	＜ 0.4
门诊溶血指数≥ 25 标本溶血率	门诊溶血指数≥ 25 标本数 / 标本总数 ×100%	＜ 0.5	0.5 ~ 1.2	＜ 2.0
门诊溶血指数≥ 15 标本溶血率	门诊溶血指数≥ 15 标本数 / 标本总数 ×100%	＜ 3.0	3.0 ~ 5.0	＜ 7.0
住院溶血指数≥ 50 标本溶血率	住院溶血指数≥ 50 标本数 / 标本总数 ×100%	＜ 0.4	0.4 ~ 0.8	＜ 1.5
住院溶血指数≥ 25 标本溶血率	住院溶血指数≥ 25 标本数 / 标本总数 ×100%	＜ 1.5	1.5 ~ 3.0	＜ 4.0
住院溶血指数≥ 15 标本溶血率	住院溶血指数≥ 15 标本数 / 标本总数 ×100%	＜ 5.0	5.0 ~ 7.0	＜ 10

变性；用药后药物溶血反应，如静脉注射头孢曲松钠致急性溶血反应；重度感染；弥散性血管内凝血；心脏支架、人工心脏心瓣膜、体外膜肺氧合治疗等。体内溶血造成的标本溶血实验室不应拒收，医师应在申请单上标注说明。

参考文献

1 Lippi G, Cadamuro J, von Meyer A, et al. Practical recommendations for managing hemolyzed samples in clinical chemistry testing [J]. Clin Chem Lab Med, 2018, 56(5): 718-727. DOI: 10.1515/cclm-2017-1104.2.

2 叶圆圆，王薇，赵海建，等. 我国 2017 年常规生化检验血液标本可接受性的现状调查[J]. 临床检验杂志, 2018, 36(6): 467-471. DOI: 10.13602/j.cnki.jcls.2018.06.18.

3 Green SF. The cost of poor blood specimen quality and errors in preanalytical processes [J]. Clin Biochem, 2013, 46(13-14): 1175-1179. DOI: 10.1016/j.clinbiochem.2013.06.001.

4 McCaughey EJ, Vecellio E, Lake R, et al. Current methods of haemolysis detection and reporting as a source of risk to patient safety: a narrative review [J]. Clin Biochem Rev, 2016, 37(4): 143-151.

5 Howanitz PJ, Lehman CM, Jones BA, et al. Practices for identifying and rejecting hemolyzed specimens are highly variable in clinical laboratories [J]. Arch Pathol Lab Med, 2015, 139(8): 1014-1019. DOI: 10.5858/arpa.2014-0161-CP.

6 Dolci A, Panteghini M. Harmonization of automated hemolysis index assessment and use: is it possible? [J]. Clin Chim Acta, 2014, 432: 38-43. DOI: 10.1016/j.cca.2013.10.012.

7 段敏，王薇，赵海建，等. 2018 年全国临床检验质量指标室间质量评价结果分析及初步质量规范的制定[J]. 临床检验杂志, 2018, 36(12): 931-936. DOI: 10.13602/j.cnki.jcls.2018.12.13.

8 Petinos P, Gay S, Badrick T. Variation in laboratory reporting of haemolysis-a need for harmonisation [J].Clin Biochem Rev, 2015, 36(4): 133-137.

9 韩冉，段学光，寿好长，等. 临床标本溶血检测与检验结果报告专家共识[J]. 实用检验医师杂志, 2019, 11(1): 1-3.

10 Šimundić AM, Topić, E, Nikolac N, et al. Hemolysis detection and management of hemolyzed specimens [J].Biochem Med, 2010, 20(2): 154-159. DOI: 10.1258/acb.2009.009187.

11 Clinical Laboratory and Standards Institute. CLSI 56-A-2012 Hemolysis, icterus, and lipemia/turbidity indices as indicators of interference in clinical laboratory analysis [S].Wayne, PA: 2012.

12 Nikolac Gabaj N, Miler M, Vrtarić A, et al. Precision, accuracy, cross reactivity and comparability of serum indices measurement on Abbott Architect c8000, Beckman Coulter AU5800 and Roche Cobas 6000 c501 clinical chemistry analyzers [J]. Clin Chem Lab Med, 2018, 56(5): 776-788. DOI: 10.1515/cclm-2017-0889.

13 Lippi G, Cadamuro J, von Meyer A, et al. Local quality assurance of serum or plasma (HIL) indices [J]. Clin Biochem, 2018, 54: 112-118. DOI: 10.1016/j.clinbiochem.2018.02.018.

14 Li L, Vecellio E, Gay S, et al. Making sense of a haemolysis monitoring and reporting system: a nationwide longitudinal multimethod study of 68 Australian laboratory participant organisations [J]. Clin Chem Lab Med, 2018, 56(4): 565-573. DOI: 10.1515/cclm-2017-0056.

15 Alpdemir M, Alpdemir MF, Akil Z. The effect of education and 4-year experience in the evaluation of preanalytical process in a clinical

chemistry laboratory [J]. Med Science, 2018, 7(4): 905-909. DOI: 10.5455/medscience.2018.07.8881.

16 Cadamuro J, von Meyer A, Wiedemann H, et al. Hemolysis rates in blood samples: differences between blood collected by clinicians and nurses and the effect of phlebotomy training [J]. Clin Chem Lab Med, 2016, 54(12): 1987-1992. DOI: 10.1515/cclm-2016-0175.

17 Damato C, Rickard D. Using Lean-Six Sigma to reduce hemolysis in the emergency care center in a collaborative quality improvement project with the hospital laboratory [J]. Jt Comm J Qual Patient Saf, 2015, 41(3): 99-107.

18 Söderberg J, Jonsson PA, Wallin O, et al. Haemolysis index--an estimate of preanalytical quality in primary health care [J]. Clin Chem Lab Med, 2009, 47(8): 940-944. DOI: 10.1515/cclm-2009-227.

19 Bölenius K, Söderberg J, Hultdin J, et al. Minor improvement of venous blood specimen collection practices in primary health care after a large-scale educational intervention [J]. Clin Chem Lab Med, 2013, 51(2): 303-310. DOI: 10.1515/cclm-2012-0159.

20 Plebani M, Lippi G. Hemolysis index: quality indicator or criterion for sample rejection? [J]. Clin Chem Lab Med, 2009, 47(8): 899-902. DOI: 10.1515/CCLM.2009.229.

21 杨琦,张兰,田丽春,等. 生化免疫分析仪检测溶血指数的临床应用[J]. 实用检验医师杂志, 2018, 10(3): 141-142. DOI: 10.3969/j.issn.1674-7151.2018.03.005.

22 Lippi G, Giavarina D, Gelati M, et al. Reference range of hemolysis index in serum and lithium-heparin plasma measured with two analytical platforms in a population of unselected outpatients [J]. Clin Chim Acta, 2014, 429: 143-146. DOI: 10.1016/j.cca.2013.12.010.

23 Plebani M, Sciacovelli L, Aita A, et al. Performance criteria and quality indicators for the pre-analytical phase [J]. Clin Chem Lab Med, 2015, 53(6): 943-948. DOI: 10.1515/cclm-2014-1124. DOI: 10.1515/cclm-2014-1124.

24 Sciacovelli L, Lippi G, Sumarac Z, et al. Quality indicators in laboratory medicine: the status of the progress of IFCC Working Group "Laboratory Errors and Patient Safety" project [J]. Clin Chem Lab Med, 2017, 55(3): 348-357. DOI: 10.1515/cclm-2016-0929.

25 田丽春,杨琦,张兰,等. 干化学分析仪监测血液标本溶血指数的临床应用[J]. 国际检验医学杂志, 2019, 40(9): 1121-1124.

26 Plebani M, Astion ML, Barth JH, et al. Harmonization of quality indicators in laboratory medicine. A preliminary consensus [J]. Clin Chem Lab Med, 2014, 52(7): 951-958. DOI: 10.1515/cclm-2014-0142.

27 Badrick T, Barden H, Callen S, et al. Consensus statement for the management and reporting of haemolysed specimens [J]. Clin Biochem Rev, 2016, 37(4): 140-142.

28 Howanitz PJ, Lehman CM, Jones BA, et al. Clinical laboratory quality practices when hemolysis occurs [J]. Arch Pathol Lab Med, 2015, 139(7): 901-906. DOI: 10.5858/arpa.2014-0252-CP.

29 International Organization for Standardization. ISO 15189 Medical laboratories-requirements for quality and competence [S]. Geneva: ISO, 2012.

30 Heireman L, Van Geel P, Musger L, et al. Causes, consequences and management of sample hemolysis in the clinical laboratory [J]. Clin Biochem, 2017, 50(18): 1317-1322. DOI: 10.1016/j.clinbiochem.2017.09.013.

31 Fernandez P, Llopis MA, Perich C, et al. Harmonization in hemolysis detection and prevention. A working group of the Catalonian Health Institute (ICS) experience. [J]. Clin Chem Lab Med, 2014, 52(11): 1557-1568. DOI: 10.1515/cclm-2013-0935.

32 Heyer NJ, Derzon JH, Winges L, et al. Effectiveness of practices to reduce blood sample hemolysis in EDs: a laboratory medicine best practices systematic review and meta-analysis [J]. Clin Biochem, 2012, 45(13-14): 1012-1032. DOI: 10.1016/j.clinbiochem.2012.08.002.

33 Milutinović D, Andrijević I, Ličina M, et al. Confidence level in venipuncture and knowledge on causes of in vitro hemolysis among healthcare professionals [J]. Biochem Med (Zagreb), 2015, 25(3): 401-409. DOI: 10.11613/BM.2015.040.

34 Phelan MP, Reineks EZ, Schold JD, et al. Preanalytic factors associated with hemolysis in emergency department blood samples[J]. Arch Pathol Lab Med, 2018, 142(2): 229-235. DOI: 10.5858/arpa.2016-0400-OA.

35 McCaughey EJ, Vecellio E, Lake R, et al. Key factors influencing the incidence of hemolysis: a critical appraisal of current evidence [J] Crit Rev Clin Lab Sci, 2017, 54(1): 59-72. DOI: 10.1080/10408363.2016.1250247.

36 Streichert T, Otto B, Schnabel C, et al. Determination of hemolysis thresholds by the use of data loggers in pneumatic tube systems [J]. Clin Chem, 2011, 57(10): 1390-1397. DOI: 10.1373/clinchem.2011.167932.

37 Ko DH, Won D, Jeong TD, et al. Comparison of red blood cell hemolysis using plasma and serum separation tubes for outpatient specimens [J]. Ann Lab Med, 2015, 35(2): 194-197. DOI: 10.3343/alm.2015.35.2.194.

38 Lippi G, Favaloro EJ, Franchini M, et al. Haemolysis index for the screening of intravascular haemolysis: a novel diagnostic opportunity? [J]. Blood Transfus, 2018, 16(5): 433-437. DOI: 10.2450/2018.0045-18.

39 Lippi G, Mattiuzzi C, Cadamuro J. Is the hemolysis index always suitable for monitoring phlebotomy performance? [J]. J Lab Med, 2018, 42(3): 67-72. DOI: 10.1515/labmed-2018-0028.

40 Bosma M, Waanders F, Van Schaik HP, et al. Automated and cost-efficient early detection of hemolysis in patients with extracorporeal life support: Use of the hemolysis-index of routine clinical chemistry platforms [J]. J Crit Care, 2019, 51: 29-33. DOI: 10.1016/j.jcrc.2019.01.028.

（收稿日期：2019-06-17）

（本文编辑：张耘菲）