

# EFLM Publications

## Section 1: Education, Training and Professional Registration

Laboratory Medicine in the European Union.

*Oosterhuis WP, Zerah S.*

Clin Chem Lab Med 2015;53:5-14

[Click here to download the paper](#)

**Keywords:** harmonization; training; Union Européenne de Médecins Spécialistes (UEMS)

The EC4 European syllabus for post-graduate training in clinical chemistry and laboratory medicine: Version 4 - 2012.

*Wieringa G, Zerah S, Jansen R, Simundic AM, Queralto J, Solnica B, Gruson D, Tomberg K, Riittinen L, Baum H, Brochet JP, Buhagiar G, Charilaou C, Grigore C, Johnsen AH, Kappelmayer J, Majkic-Singh N, Nubile G, O'Mullane J, Opp M, Pupure S, Racek J, Reguengo H, Rizos D, Rogic D, Spanar J, Strakl G, Szekeres T, Tzatchev K, Vitkus D, Wallemacq P, Wallinder H.*

Clin Chem Lab Med 2012;50:1317-28

[Click here to download the paper](#)

**Keywords:** competence to practice; continuous professional development; specialist in laboratory medicine

Our profession now has a European name: Specialist in Laboratory Medicine.

*Zerah S, McMurray J, Horvath AR.*

Biochem Med (Zagreb). 2012;22:272-3

[Click here to download the paper](#)

**Keywords:** laboratory medicine; medical specialty; profession name

The European Register of Specialists in Clinical Chemistry and Laboratory Medicine: Code of Conduct, Version 2 – 2008.

*McMurray J, Zerah S, Hallworth M, Koeller U, Blaton V, Tzatchev K, Charilaou C, Racek J, Johnsen A, Tomberg K, Harmoinen A, Baum H, Rizos D, Kappelmayer J, O'Mullane J, Nubile G, Pupure S, Kucinskiene Z, Opp M, Huisman W, Solnica B, Reguengo H, Grigore C, Spanar J, Strakl G, Queralto J, Wallinder H, Schuff-Werner P.*

Clin Chem Lab Med 2009;47: 372-5

[Click here to download the paper](#)

**Keywords:** European Register (EC4); European Union (EU); registration

The EC4 European Register of Specialists in Clinical Chemistry and Laboratory Medicine.

*Pazzagli M, McMurray J, Zerah S.*

Clin Chim Acta 2008;393:27-30

[Click here to download the paper](#)

**Keywords:** European Register (EC4); professional standards; professional qualifications

The European Register for Specialists in Clinical Chemistry and Laboratory Medicine: Code of Conduct.

*Sanders G, Opp M, McMurray J, Koeller U, Blaton V, Lund E, Harmoinen A, Zerah S, Baum H, Rizos D, Kenny D, Pazzagli M, Hoffman H, Reguengo H, Queralto JM, Wallinder H, Hallworth M, Schuff-Werner P.*

Clin Chem Lab Med 2004;42:563-5

[Click here to download the paper](#)

**Keywords:** code of conduct; European Register (EC4); registration

## Section 2: Guidelines & Recommendations

Fasting is not routinely required for determination of a lipid profile: clinical and laboratory implications including flagging at desirable concentration cut-points—a joint consensus statement from the European Atherosclerosis Society and European Federation of Clinical Chemistry and Laboratory Medicine.

*Nordestgaard BG, Langsted A, Mora S, Kolovou G, Baum H, Bruckert E, Watts GF, Sypniewska G, Wiklund O, Bore J, Chapman MJ, Cobbaert C, Descamps OS, von Eckardstein A, Kamstrup PR, Pulkki K, Kronenberg F, Remaley AT, Rifai N, Ros E, Langlois M*

Clin Chem 2016;62:930–46

[Click here to see the paper summary](#) (posted on September 8, 2016)

**Keywords:** lipids, reference values, cardiovascular disease

Fasting is not routinely required for determination of a lipid profile: clinical and laboratory implications including flagging at desirable concentration cut-points—a joint consensus statement from the European Atherosclerosis Society and European Federation of Clinical Chemistry and Laboratory Medicine.

*Nordestgaard BG, Langsted A, Mora S, Kolovou G, Baum H, Bruckert E, Watts GF, Sypniewska G, Wiklund O, Bore J, Chapman MJ, Cobbaert C, Descamps OS, von Eckardstein A, Kamstrup PR, Pulkki K, Kronenberg F, Remaley AT, Rifai N, Ros E, Langlois M.*

European Heart Journal DOI:10.1093/eurheartj/ehw152

[Click here to download the paper](#) (posted on April 29, 2016)

**Keywords:** lipids, reference values, cardiovascular disease

Are guidelines guiding us on how to utilize laboratory tests?

*Horvath AR.*

eJIFCC 2015;26:146:57

[Click here to download the paper](#) (posted on August 28, 2015)

**Keywords:** evidence-based laboratory medicine; outcome; test utilization

How useful are laboratory practice guidelines?

*Misra S, Moberg-Aakre K, Langlois M, Watine J, Twomey PJ, Oosterhuis WP, Barth JH on behalf of the joint EFLM-UEMS Working Group on Guidelines*

eJIFCC 2015;26:190-6

[Click here to download the paper](#) (posted on August 28, 2015)

**Keywords:** patient care; laboratory practice guideline; clinical decision making

How good is the evidence base for test selection in clinical guidelines?

*Misra S, Barth JH.*

Clin Chim Acta 2014;432:27-32

[Click here to download the paper](#)

**Keywords:** evidence based medicine; clinical audit; clinical decision making

Do laboratories follow heart failure recommendations and guidelines and did we improve? The CARdiac MARKer Guideline Uptake in Europe (CARMAGUE).

*Hammerer-Lercher A, Collinson PO, Dieijen-Visser MP, Pulkki K, Suvisaari J, Ravkilde J, Stavljenic-Rukavina A, Baum H, Laitinen P.*

Clin Chem Lab Med 2013;51:1301-6

[Click here to download the paper](#)

**Keywords:** B-type natriuretic peptide; guideline implementation; N-terminal B-type natriuretic peptide (NT-proBNP)

Evidence-Based Laboratory Medicine: How Well Do Laboratories Follow Recommendations and Guidelines? The Cardiac Marker Guideline Uptake in Europe (CARMAGUE) Study.

*Collinson PO, Dieijen-Visser MP, Pulkki K, Hammerer-Lercher A, Suvisaari J, Ravkilde J, Stavljenic-Rukavina*

A, Baum H, Laitinen P.

Clin Chem 2012;58:305-6

[Click here to download the paper](#)

**Keywords:** guideline; myocardial infarction; troponin

Self-monitoring of blood glucose in patients with diabetes who do not use insulin--are guidelines evidence-based?

Aakre KM, Watine J, Bunting PS, Sandberg S, Oosterhuis WP.

Diabet Med 2012;29:1226-36

[Click here to download the paper](#)

**Keywords:** blood glucose; diabetes mellitus; insulin

How well do laboratories follow guidelines on cardiac markers? The cardiac marker guideline uptake in Europe study.

Collinson P, Pulkki K, Suvisaari J, Ravkilde J, Stavljenic-Rukavina A, Hammerer-Lercher A, Baum H, van Diejen-Visser MP, Laitinen P.

Clin Chem 2008;54:448-9

[Click here to download the paper](#)

**Keywords:** emergency service; acute coronary syndrome; guideline

## Section 3: Positions & Opinion Papers

Could accreditation bodies facilitate the implementation of medical guidelines in laboratories?

Aakre KM, Oosterhuis WP, Misra S, Langlois MR, Watine J, Twomey PJ, Barth J from the EFLM WG on Guidelines

Clin Chem Lab 2016 DOI 10.1515/cclm-2016-0577

[Click here to download the paper](#) (posted on January 27, 2017)

**Keywords:** accreditation, ISO standards, clinical practice

Order of blood draw: Opinion Paper by the European Federation for Clinical Chemistry and Laboratory Medicine (EFLM) Working Group for the Preanalytical Phase (WG-PRE).

Cornes M, van Dongen-Lases E, Grankvist K, Ibarz M, Kristensen G, Lippi G, Nybo M, Simundic A-M

Clin Chem Lab Med 2016 DOI 10.1515/cclm-2016-0426

[Click here to download the paper](#) (posted on November 14, 2016)

**Keywords:** patient safety; phlebotomy; preanalytical quality

Why are clinical practice guidelines not followed?

Barth JH, Misra S, Aakre KM, Langlois MR, Watine J, Twomey PJ, Oosterhuis WP on behalf of the EFLM-UEMS joint WG on Guidelines

Clin Chem Lab Med 2016 DOI 10.1515/cclm-2015-0871

[Click here to download the paper](#) (posted on September 8, 2016)

**Keywords:** guidelines; quality assurance; quality indicator

Criteria for assigning laboratory measurands to models for analytical performance specifications defined in the 1st EFLM Strategic Conference.

Cerioti F, Fernandez-Calle P, Klee GG, Nordin G, Sandberg S, Streichert T, Vives-Corrans JL, Panteghini M on behalf of the EFLM Task and Finish Group on allocation of laboratory tests to different models for performance specifications (TFG-DM)

Clin Chem Lab Med 2016 DOI 10.1515/cclm-2016-0091

[Click here to download the paper](#) (posted on August 29, 2016)

**Keywords:** analytical performance specifications; analytical quality; biological variation

Patient identification and tube labelling – a call for harmonisation.

*van Dongen-Lases E, Cornes MP, Grankvist K, Mercedes Ibarz M, Kristensen GBB, Lippi G, Nybo M, Simundic AM on behalf of the Working Group for Preanalytical Phase (WG-PRE), European Federation of Clinical Chemistry and Laboratory Medicine (EFLM)*

Clin Chem Lab Med 2016;54:1141-5

[Click here to download the paper](#) (posted on May 6, 2016)

**Keywords:** harmonisation; patient safety; preanalytical phase

EFLM WG-Preanalytical phase opinion paper: local validation of blood collection tubes in clinical laboratories.

*Lippi G, Cornes MP, Grankvist K, Nybo M, Simundic AM*

Clin Chem Lab Med 2016;54:755-60

[Click here to download the paper](#) (posted on March 4, 2016)

**Keywords:** errors; preanalytical variability; venipuncture

Laboratory medicine in the new healthcare environment.

*Ferraro S, Braga F, Panteghini M.*

Clin Chem Med Lab 2016;54:523-33

[Click here to download the paper](#) (posted on October 19, 2015)

**Keywords:** laboratory-clinic interface, laboratory medicine; patient outcomes

How to assess the quality of your analytical method?

*Topic E, Nikolac N, Panteghini M, Theodorsson E, Salvagno GL, Miler M, Simundic AM, Infusino I, Nordin G, Westgard S.*

Clin Chem Lab Med 2015;53:1707-18

[Click here to download the paper](#) (posted on September 30, 2015)

**Keywords:** measurement uncertainty; method validation; method comparability

European views on patients directly obtaining their laboratory test results.

*Watson ID, Siodmiak J, Oosterhuis WP, Corberand J, Jorgensen PE, Gunnur Dikman Z, Jovicic S, Theodorsson E for the EFLM Working Group on Patient Focused Laboratory Medicine (WG-PFLM)*

Clin Chem Lab Med 2015;53:1961-6

[Click here to download the paper](#) (posted on June 5, 2015)

**Keywords:** laboratory results; interpretation; patient focused

Setting analytical performance specifications based on outcome studies – is it possible?

*Horvath AR, Bossuyt PMM, Sandberg S, StJohn A, Monaghan PJ, Verhagen-Kamerbeek WDJ, Lennartz L, Cobbaert CM, Ebert C, Lord SJ on behalf of the joint EFLM Working Group on Test Evaluation (WG-TE)*

Clin Chem Lab Med 2015;53:841-8

[Click here to download the paper](#) (posted on May 11, 2015)

**Keywords:** analytical performance; clinical effectiveness; outcome

Making test results more easily understood by patients

*Watson I on behalf of the EFLM Working Group on Patient Focused Laboratory Medicine (WG-PFLM)*

BMJ 2015;350:h1942

[Click here to download the paper](#) (posted on Apr 17, 2015)

**Keywords:** laboratory medicine; data collection; patient-focused

Defining analytical performance specifications: Consensus Statement from the 1st Strategic Conference of the European Federation of Clinical Chemistry and Laboratory Medicine.

*Sandberg S, Fraser CG, Horvath AR, Jansen R, Jones G, Oosterhuis W, Hyltoft Petersen P, Schimmel H, Sikaris K, Panteghini M.*

DOI 10.1515/cclm-2015-0067

[Click here to download the paper](#) (posted on Feb 20, 2015)

**Keywords:** analytical performance; consensus statement; outcome studies

Implementation of a companion diagnostic in the clinical laboratory: The BRAF example in melanoma.  
*Mancini I, Pinzani P, Simi L, Brandslund I, Vermeersch P, Di Resta C, Schwab M, Marc J, van Schaik R, Pazzagli M.*

Clin Chim Acta 2015;439:128-36

[Click here to download the paper](#) (posted on Jan 20, 2015)

**Keywords:** companion diagnostics; BRAF; melanoma

From biomarkers to medical tests: The changing landscape of test evaluation

*Horvath AR, Lord SJ, StJohn A, Sandberg S, Cobbaert CM, Lorenz S, Monaghan PJ, Verhagen-Kamerbeek WDJ, Ebert C, Bossuyt PMM for the Test Evaluation Working Group of the European Federation of Clinical Chemistry Laboratory Medicine*

Clin Chim Acta 2014;427:49–57

[Click here to download the paper](#)

**Keywords:** clinical effectiveness; evidence-based laboratory medicine; medical test

A position paper of the EFLM Committee on Education and Training and Working Group on Distance Education Programmes/E-Learning: developing an e-learning platform for the education of stakeholders in laboratory medicine.

*Gruson D, Faure G, Gouget B, Haliassos A, Kisikuchin D, Reguengo H, Topic E, Blaton V.*

Clin Chem Lab Med 2013;51:775-80

[Click here to download the paper](#)

**Keywords:** distance learning; e-learning; distance education

Position paper of EPMA and EFLM: a global vision of the consolidated promotion of an integrative medical approach to advance healthcare.

*Golubnitskaja O, Watson I, Topic E, Sandberg S, Ferrari M, Castigliola V.*

EPMA J. 2013;4:12

[Click here to download the paper](#)

**Keywords:** integrative medical record, patient in focus, bioinformatics

## Section 4: Reviews & Surveys

The use of extra-analytical phase quality indicators by clinical laboratories: the results of an international survey.

*Plebani M, O'Kane M, Vermeersch P, Cadamuro J, Oosterhuis W, Sciacovelli L on behalf of the EFLM Task Force on "Performance specifications for the extra-analytical phases" (TFG-PSEP)*

Clin Chem Lab Med 2016 DOI 10.1515/cclm-2016-0770

[Click here to download the paper](#) (posted on October 11, 2016)

**Keywords:** extra-analytical phases; quality indicators; quality specifications

Harmonisation of the laboratory testing process: need for a coordinated approach.

*Cerioti F, Gligorovic Barhanovic N, Kostovska I, Karel Kotaska K, Perich Alsina MC on behalf of the EFLM Working Group on Harmonisation of Total Testing Process*

Clin Chem Lab Med 2016 DOI 10.1515/cclm-2016-0244

[Click here to download the paper](#) (posted on September 8, 2016)

**Keywords:** harmonisation; total testing process; units of measurement

How well do laboratories adhere to recommended clinical guidelines for the management of myocardial infarction: the CARdiac MArker Guidelines uptake in Europe study (CARMAGUE)

*Collinson P, Hammerer-Lercher A, Suvisaari J, Apple FS, Christenson RH, Pulkki K, van Dieijen-Visser MP, Duff CJ, Baum H, Stavljenic-Rukavina A, Aakre KM, Langlois MR, Stankovic S, Laitinen P on behalf of the EFLM Working Group for Cardiac Markers*

Clin Chem 2016; 62:1264-71

[Click here to see the paper summary](#) (posted on August 30, 2016)

**Keywords:** B-type natriuretic peptide; guideline implementation; N-terminal B-type natriuretic peptide (NT-proBNP)

Is D-dimer used according to clinical algorithms in the diagnostic work-up of patients with suspicion of venous thromboembolism? A study in six European countries.

*Kristoffersen AH, Ajzner E, Rogic D, Sozmen EY, Carraro P, Faria AP, Watine J, Meijer P, Sandberg S for the joint EFLM-EQALM Working Group on Postanalytical Phase (WG-POST)*

Thromb Res 2016;142:1-7

[Click here to see the paper summary](#) (posted on August 29, 2016)

**Keywords:** clinical decisions rules; pre-test probability; venous thromboembolism

Biomarker development targeting unmet clinical needs.

*Monaghan P, Lord SJ, St John A, Sandberg S, Cobbaert CM, Lennartz L, Verhagen-Kamerbeek WDJ, Ebert C, Bossuyt PMM, Horvath AR for the EFLM Working Group on Test Evaluation*

Clin Chim Acta 2016;460:211-9

[Click here to download the paper](#) (posted on July 26, 2016)

**Keywords:** medical tests, clinical pathway, checklist

The role of European Federation of Clinical Chemistry and Laboratory Medicine Working Group for Preanalytical Phase in standardization and harmonization of the preanalytical phase in Europe.

*Cornes MP, Church S, van Dongen-Lases E, Grankvist K, Guimaraes JT, Ibarz M, Kovalevskaya S, Kristensen GBB, Lippi G, Nybo M, Sprongl L, Sumarac Z, Simundic AM*

Ann Clin Biochem 2016;53:539-47

[Click here to download the paper](#) (posted on May 6, 2016)

**Keywords:** preanalytical phase, standardization, harmonization

Is laboratory medicine ready for the era of personalized medicine ? A survey addressed to laboratory directors of hospitals/academic schools of medicine in Europe.

*Malentacchi F, Mancini I, Brandslund I, Vermeersch P, Schwab M, Marc J, van Schaik RHN, Siest G, Theodorsson E, Pazzagli M, Di Resta C on behalf of the joint EFLM-ESPT Working Group on Personalized Laboratory Medicine (WG-PLM)*

Clin Chem Lab Med 2015;53:981-8

[Click here to download the paper](#) (posted on Apr 20, 2015)

**Keywords:** "-omics" technologies; personalized medicine; laboratory medicine

An international study of how laboratories handle and evaluate patient samples after detecting an unexpected APTT prolongation.

*Ajzner E, Rogic D, Meijer P, Kristoffersen AH, Carraro P, Sozmen E, Faria AP, Sandberg S on behalf of the joint EFLM-EQALM Working Group on Postanalytical Phase (WG-POST)*

Clin Chem Lab Med 2015;53:1593-603

[Click here to download the paper](#) (posted on Feb 25, 2015)

**Keywords:** activated partial thromboplastin time (APTT); clinical interpretation; postanalytical phase

Compliance of blood sampling procedures with the CLSI H3-A6 guidelines: An observational study by the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) working group for the preanalytical phase (WG-PRE).

*Simundic AM, Church S, Cornes MP, Grankvist K, Lippi G, Nybo M, Nikolac N, van Dongen-Lases E, Eker P,*

*Kovalevskaya S, Kristensen GBB, Sprongl L, Sumarac Z.*  
Clin Chem Lab Med 2015;53:1321-31

[Click here to download the paper](#) (posted on Jan 20, 2015)

**Keywords:** observational study; phlebotomy; preanalytical phase

Clinical impact of direct HDLc and LDLc method bias in hypertriglyceridemia. A simulation study of the EAS-EFLM Collaborative Project Group.

*Langlois MR, Descamps OS, van der Laarse A, Weykamp C, Baum H, Pulkki K, von Eckardstein A, De Bacquer D, Borén J, Wiklund O, Laitinen P, Oosterhuis WP, Cobbaert C.*

Atherosclerosis 2014;233:83-90

[Click here to download the paper](#)

**Keywords:** HDL-cholesterol; LDL-cholesterol; risk classification

Survey of national guidelines, education and training on phlebotomy in 28 European countries: an original report by the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) working group for the preanalytical phase (WG-PA).

*Simundic AM, Cornes M, Grankvist K, Lippi G, Nybo M, Kovalevskaya S, Sprongl L, Sumarac Z, Church S.*

Clin Chem Lab Med 2013;51:1585-93

[Click here to download the paper](#)

**Keywords:** healthcare education; phlebotomy; preanalytical phase

Critical review of laboratory investigations in clinical practice guidelines: proposals for the description of investigation.

*Aakre KM, Langlois MR, Watine J, Barth JH, Baum H, Collinson P, Laitinen P, Oosterhuis WP.*

Clin Chem Lab Med. 2013;51:1217-26

[Click here to download the paper](#)

**Keywords:** clinical chemistry tests; laboratory personnel; quality improvement

A pilot survey of the use and implementation of cardiac markers in acute coronary syndrome and heart failure across Europe. The CARdiac MARker Guideline Uptake in Europe (CARMAGUE) study.

*Pulkki K, Suvisaari J, Collinson P, Ravkilde J, Stavljenic-Rukavina A, Hammerer-Lercher A, Baum H, van Dieijen-Visser MP, Laitinen P.*

Clin Chem Lab Med. 2009;47:227-34

[Click here to download the paper](#)

**Keywords:** cardiac markers; implementation of guidelines; diagnostic biomarker

## Section 5: Laboratory Management, Staffing and Professional Practice

Continuing professional development crediting system for specialists in Laboratory Medicine within 28 EFLM National Societies.

*Topic E, Beletic A, Zima T.*

Biochem Med (Zagreb) 2013;23:332-41

[Click here to download the paper](#)

**Keywords:** continuing medical education; professional education

A guide to defining the competence required of a consultant in clinical chemistry and laboratory medicine.

*Beastall G, Kenny D, Laitinen P, ten Kate J.*

Clin Chem Lab Med 2005;43:654-9

[Click here to download the paper](#)

**Keywords:** assessment of competence; European Union (EU); model job description

The number of consultant clinical chemists in the 15-nation European Union.

*Smit E, Beastall G, Bjorses U-M, Candito M, Fiorentini P.*

Clin Chem Lab Med 2005;43:335-41

[Click here to download the paper](#)

**Keywords:** European Union (EU); population demographics; staffing model

## Section 6: Quality Management and Laboratory Accreditation

Accreditation process in European countries - an EFLM survey.

*Boursier G, Vukasovic I, Mesko Brguljan P, Lohmander M, Ghita I, Bernabeu Andreu FA, Barrett E, Brugnioni D, Kroupis C, Sprongl L, Thelen MHM, Vanstapel F, Vodnik T, Huisman W, Vaubourdolle M on behalf of the Working Group Accreditation and ISO/CEN standards (WG-A/ISO) of the EFLM*

Clin Chem Lab Med 2016;54:545-51

[Click here to download the paper](#) (posted on Feb 19, 2016)

**Keywords:** accreditation; ISO 15189; national accreditation body

Once upon a time: a tale of ISO 15189 accreditation.

*Plebani M, Sciacovelli L, Chiozza ML and Panteghini M.*

Clin Chem Lab Med 2015;53:1127-9

[Click here to download the paper](#) (posted on Sep 3, 2015)

**Keywords:** ISO 15189, laboratory accreditation, quality management system

Flexible scope for ISO 15189 accreditation: a guidance prepared by the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) Working Group Accreditation and ISO/CEN standards (WG-A/ISO).

*Thelen MHM, Vanstapel FJLA, Kroupis C, Vukasovic I, Boursier G, Barrett E, Bernabeu Andreu F, Meško Brguljan P, Brugnioni D, Lohmander M, Sprongl L, Vodnik T, Ghita I, Vaubourdolle M, Huisman W.*

Clin Chem Lab Med 2015;53:1173-80

[Click here to download the paper](#) (posted on Sep 3, 2015)

**Keywords:** ISO 15189, laboratory accreditation, quality management system

Influence of pre-analytical procedures on genomic DNA integrity in blood samples: The SPIDIA experience.  
*Malentacchi F, Ciniselli CM, Pazzagli M, Verderio P, Barraud L, Hartmann CC, Pizzamiglio S, Weisbuch S, Wyrich R, Gelmini S.*

Clin Chim Acta 2015;440:205-10

[Click here to download the paper](#) (posted on Mar 24, 2015)

**Keywords:** pre-analytical phase; high molecular weight gDNA; external quality assessment

Preanalytical quality improvement. In pursuit of harmony, on behalf of European Federation for Clinical Chemistry and Laboratory Medicine (EFLM) Working group for Preanalytical Phase (WG-PRE).

*Lippi G, Banfi G, Church S, Cornes M, De Carli G, Grankvist K, Kristensen GB, Ibarz M, Panteghini M, Plebani M, Nybo M, Smellie S, Zaninotto M, Simundic AM.*

Clin Chem Lab Med 2015;53:357-70

[Click here to download the paper](#) (posted on Jan 20, 2015)

**Keywords:** harmonization; laboratory errors; preanalytical variability

SPIDIA-RNA: first external quality assessment for the pre-analytical phase of blood samples used for RNA based analyses.

*Pazzagli M, Malentacchi F, Simi L, Orlando C, Wyrich R, Gunther K, Hartmann CC, Verderio P, Pizzamiglio S, Ciniselli CM, Tichopad A, Kubista M, Gelmini S.*

Methods 2013;59:20-31

[Click here to download the paper](#)

**Keywords:** pre-analytical phase; RNA quality; external quality assessment,

Preanalytical quality improvement: in quality we trust.

*Lippi G, Becan-McBride K, Behúlová D, Bowen RA, Church S, Delanghe J, Grankvist K, Kitchen S, Nybo M, Nauck M, Nikolac N, Palicka V, Plebani M, Sandberg S, Simundic AM.*

Clin Chem Lab Med 2013;51:229-41

[Click here to download the paper](#)

**Keywords:** laboratory errors; preanalytical phase; standardization

European medical laboratory accreditation. Present situation and steps to harmonization. Review.

*Huisman W.*

Clin Chem Lab Med 2012;50:1147-52

[Click here to download the paper](#)

**Keywords:** accreditation; assessor; ISO15189

Preanalytical quality improvement: from dream to reality.

*Lippi G, Chance JJ, Church S, Dazzi P, Fontana R, Giavarina D, Grankvist K, Huisman W, Kouri T, Palicka V, Plebani M, Puro V, Salvagno GL, Sandberg S, Sikaris K, Watson I, Stankovic AK, Simundic AM.*

Clin Chem Lab Med 2011;49:1113-26

[Click here to download the paper](#)

**Keywords:** laboratory errors; patient safety; preanalytical phase

Accreditation of medical laboratories in the European Union.

*Huisman W, Horvath AR, Burnett D, Blaton V, Czikkely R, Jansen RT, Kallner A, Kenny D, Mesko P, Plebani M, Queralto J, Schumann G, Sprongl L, Vitkus D, Wallinder H, Zerah S.*

Clin Chem Lab Med 2007;45:268-75

[Click here to download the paper](#)

**Keywords:** accreditation; ISO standards; European Union (EU)

EQUAL-qual: A European Program for External Quality Assessment of Genomic DNA Extraction and PCR Amplification.

*Orlando C, Verderio P, Maatman R, Dannberg J, Ramsden S, Neumaier M, Taruscio D, Falbo V, Jansen R, Casini-Raggi C, Malentacchi F, Marubini E, Pizzamiglio S, Vernelen K, Libeer JC, Palicka V, Pazzagli M.*

Clin Chem 2007;53:1349-57

[Click here to download the paper](#)

**Keywords:** DNA; external quality assessment; polymerase chain reaction

## Section 7: Standardisation & Harmonisation in Clinical Laboratories

Harmonization initiatives in Europe.

*Cerioti F.*

eJIFCC 2016;27:23-9

[Click here to download the paper](#) (posted on Feb 9, 2016)

**Keywords:** harmonisation; total testing process; laboratory best practice

A checklist for critical appraisal of studies of biological variation.

*Bartlett WA, Braga F, Carobene A, Coskun A, Prusa R, Fernandez-Calle P, Roraas T, Jonker N, Sandberg S on behalf of the Biological Variation Working Group, European Federation of Clinical Chemistry and Laboratory Medicine (EFLM)*

Clin Chem Lab Med 2015;53:879-85

[Click here to download the paper](#) (posted on Feb 19, 2016)

**Keywords:** checklist; critical appraisal; reference values

Colour coding for blood collection tube closures – a call for harmonisation.

*Simundic AM, Cornes MP, Grankvist K, Lippi G, Nybo M, Ceriotti F, Theodorsson T, Panteghini M on behalf of the European Federation for Clinical Chemistry and Laboratory Medicine (EFLM)*

Clin Chem Lab Med 2015;53:371-6

[Click here to download the paper](#)

**Keywords:** blood specimen collection; harmonization; venipuncture

Harmonization of critical result management in laboratory medicine.

*Campbell CA, Horvath AR.*

Clin Chim Acta 2014;432:135-47

[Click here to download the paper](#)

**Keywords:** alert result; critical result; patient safety

Standardization of collection requirements for fasting samples: for the Working Group on Preanalytical Phase (WG-PA) of the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM).

*Simundic AM, Cornes M, Grankvist K, Lippi G, Nybo M.*

Clin Chim Acta 2014;432:33-7

[Click here to download the paper](#)

**Keywords:** fasting; specimen collection; preanalytical phase

Trueness verification of actual creatinine assays in the European market demonstrates a disappointing variability that needs substantial improvement. An international study in the framework of the EC4 creatinine standardization working group.

*Delanghe JR, Cobbaert C, Galteau MM, Harmoinen A, Jansen R, Kruse R, Laitinen P, Thienpont LM, Wuyts B, Weykamp C, Panteghini M.*

Clin Chem Lab Med 2008;46:1319-25

[Click here to download the paper](#)

**Keywords:** analytical error; bias; creatinine

Trueness verification and traceability assessment of results from commercial systems for measurement of six enzyme activities in serum: an international study in the EC4 framework of the Calibration 2000 project.

*Jansen R, Schumann G, Baadenhuijsen H, Franck P, Franzini C, Kruse R, Kuypers A, Weykamp C, Panteghini M.*

Clin Chim Acta 2006;368:160-7

[Click here to download the paper](#)

**Keywords:** enzymes; reference methods; analytical error