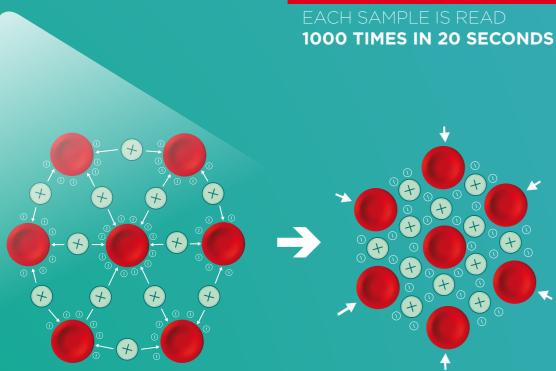
NEW ESR SYSTEM GENERATION

TEST1 is the only analyzer capable to give ESR results in 20 seconds by measuring the kinetic of red cells aggregation.

Alifax technology is classified by CLSI guidelines as an alternative method for ESR and included in the most prestigious External Quality Assurance and Proficiency Testing programs.



TEST1 CAPILLARY PHOTOMETRY TECHNOLOGY overcomes the majority of the variables and limitations of the sedimentation method also listed in the ICSH document*. (1).

LIMITS

SEDIMENTATION ESR

Temperature variability

Hematocrit influence

Dilution problems using Sodium Citrate

Inadequate materials and pipettes variability

Vibrations and pipettes verticality

Not standardized sample mixing

Controls and Calibrators lack

Poor reproducibility

ADVANTAGE

CAPILLARY PHOTOMETRY

ESR BY RED CELLS

AGGREGATION

IN 20 SECONDS

Temperature control 37°C

Independent from Hematocrit value

No dilution, use of EDTA tube

Use of the same capillary for all samples

No influence of vibration or other external factors

Automated mixing step

Latex Controls and Calibrators available

High reproducibility

Several studies show a high correlation with the sedimentation method in heterogeneous subjects concering clinical laboratory (7, 11, 21, 26, 30) however "ESR measurements by TEST1 reflect inflammation better than do those by the Westergren method in patients with malignancy, autoimmune disease, or infection. "(4).

PUBLICATIONS

1.Kratz A, Plebani M, Peng M, Lee YK, McCafferty R, Machin SJ International Council for Standardization in Haematology (ICSH) recommendations for modified and alternate methods measuring the erythrocyte sedimentation rate Int J Lab Hematol. 2017 Oct; 39(5):448-457.

2.Cha CH1, Cha YJ, Park CJ, Kim HK, Cha EJ, Kim DH, Honghoon, Jung JS, Kim MJ, Jang S, Chi HS, Lee DS (Departments of Laboratory Medicine, Chung-Ang University College of Medicine, Seoul, University of Ulsan College of Medicine and Asan Medical Center, Seoul, Seoul National University College of Medicine, Seoul; Department of Biomedical Engineering, School of Medicine, Chungbuk National University, Cheongju, Korea) "Evaluation of the TEST 1 erythrocyte sedimentation rate system and intra- and inter-laboratory quality control using new latex control materials" Clin Chem Lab Med 2010;48(7):1043–1048

3.Scott G, Nguyen T, Leunda Ostolaza S, Galiano C, Nalbandian G and Miller B (Iris Diagnostics, Chatsworth, CA) "Roller 20PN and Westergren Correlation" White Paper 2012 Chatsworth, CA

4.Cha CH, Park CJ, Cha YJ, Kim HK, Kim DH, Honghoon, Bae JH, Jung JS, Jang S, Chi HS, Lee DS, Cho HI (Department of Laboratory Medicine, University of Ulsan College of Medicine and Gangneung Asan Hospital, Gangneung, Korea) "Erythrocyte Sedimentation Rate Measurements by TEST 1 Better Reflect Inflammation Than Do Those by the Westergren Method in Patients With Malignancy, Autoimmune Disease, or Infection" Am J Clin Pathol. 2009 Feb:131(2):189-94

5.Frollano B, Cigliana G, Vitelli G, Fontinovo R, Giommi S, Cordone I (Clinical Pathology, Regina Elena Cancer Institute, IFO, Rome – Italy) "Capillary Erythrocyte Sedimentation Rate (ESR) in oncological patients: low haematocrit pitfalls and sample collection optimization in a certified quality system laboratory" SIBioC National Congress 28-31 October 2008. Rimini. Italy.

6. Pajola R, Piva E, Robecchi B, Tosato F, Plebani M (Dep. of Laboratory Medicine, Padua University School of Medicine, Padua, Italy) "The Erythrocyte Sedimentation Rate (ESR): an old test with new contents" SIBioC National Congress 28-31 October 2008, Rimini, Italy.

7.Reis J, Diamantino J, Cunha N, Valido F (Clinical Pathology Department, IPO Coimbra; Francisco Gentil, EPE, Portugal), "Erythrocyte sedimentation rate in blood a comparison of theTest 1 ESR system with the ICSH reference method" Clinical Chemistry and Laboratory Medicine 2007 June; 45, Special Supplement, p.S118, M077.

8.Piva E, Pajola R, Temporin V, Plebani M (Dept. of Laboratory Medicine, University-Hospital, Padova, Italy) "A new turbidimetric standard to improve the quality assurance of the erythrocyte sedimentation rate measurement" Clinical Biochemistry 2007 Apr; 40(7):491-5. Epub 2007 Jan 8.

9.Arikan S, Akalin N. (Biochemistry Department, Baskent University, Ankara, Turkey) "Comparison of the erythrocyte sedimentation rate measured by the Micro Test 1 sedimentation analyzer and the conventional Westergren method" Ann Saudi Med 2007; 27(5): 362-365.

10.Li LY, Chen WB, Feng G, Shen SF (Dep of Clinical Laboratory, Sixth People's Hospital Affiliated to Shangai Jiaotong University, Shangai 200233, China) "Evaluation of the Microtest 1 ESR analyzer and investigation of the reference value" Chin J Lab Med, March 2007. Vol 30. N 3 (article in Chinese)

11.Ozdem S, Akbas HS, Donmez L, Gultekin M (Clinical Biochemistry Unit, Medical Faculty, Central Laboratory, Akdeniz University, Antalya, Turkey) Comparison of TEST 1 with SRS 100 and ICSH reference method for the measurement of the length of sedimentation reaction in blood. Clin Chem Lab Med. 2006;44(4):407-12

12.Ajubi NE, Bakker AJ, van den Berg GA (Stichting KCL, Dept. of Clinical Chemistry, Leeuwarden, The Netherlands), "Determination of the length of sedimentation reaction in blood using the Test 1 system: comparison with the Sedimatic 100 method, turbidimetric fibrinogen levels and the influence of M proteins" Clin Chem Lab Med 2006, 44 (7): 904-906

13.Kagawa Y, Ikeda N, Ito S, Makino S, Miyake N (Clinical Test Section of Eiju Hospital, Finggal Link Co. and Dept. of Clinical Pathology of Juntendo University), "Evaluation for ESR automated measuring instrument with EDTA", 36th Japan Society for Clinical Laboratory Automation, 30 September 2004, Japan.

14.Rosas B, Díaz P, Musa C, Aldunate J (Servicio Laboratorio Clínico, Hospital Universidad de Chile), "Estudio Comparativo de 2 equipos que realizan VHS, Test1 y Vesmatic", XII Congreso Chileno de Tecnologia Medica, 20–22 October 2004, Santiago, Chile (article in Spanish).

15.Plebani M, D'Altoé P, Temporin V, Piva E, Buttarello M, Sanzari M (Dept. of Laboratory Medicine, University-Hospital, Padova, Italy), "Variabilità Biologica Intra ed Interindividuale della Velocità di Eritrosedimentazione", 36th SIBioC, 8-11 June 2004, Padova, Italy (article in Italian).

16.Melkic E, Piskar M, Lenart P (Klinicni center Ljubljana, Klinicni intitut za klinicno kemijo in biokemijo) "Nov način merjenja hitrosti sedimentacije eritrocitov z analizatorjem Test1 Alifax", 2 Kongres Hematologov in Transfuziologov Slovenije z Mednarodno Ubelelbo, 23–24 April 2004, Portoroz, Slovenia (article in Slovenian).

17. Olivera Alonso B, Sirvent Monerris M, Rotella Belda MT, Ballenilla Antón V, Vidal G (M Laboratorio Hospital San Vicente y Area Sanitaria 18. Alicante, Spain), "Cambio De Método Para La Determinación De V.S.G.: Repercusiones Sobre La Fase Preanalítica", Generalitat Valenciana - Conselleria De Sanitat (for Valencia Government – MOH), Spain 2004 (poster in Spanish).

18. Galiano P, "Quality and Automation in the Determination of the Erythrocyte Sedimentation Rate", Symposium 046, 22nd World Congress of Pathology & Laboratory Medicine, 30 August- 1 September 2003, Busan, Korea.

19.Nicoli M, Lanzoni E, Massocco A (Laboratory of Clinical Chemistry and Haematological Analysis, Ospedale Civile Maggiore, Verona, Italy) "Integrated Haematology and Coagulation Laboratory", Poster, Euromedlab Congress, 1-5 June 2003. Barcelona. Spain.

20.Plebani M (Dept. of Laboratory Medicine, University-Hospital, Padova, Italy), "Erythrocyte Sedimentation Rate: Innovative Techniques for an Obsolete Test?", Clinical Chemistry and Laboratory Medicine, 2003, 41 (2): 115-116.

21.Romero A, Muñoz M, Ramirez G (Dept. of Haematology, H.C.U. "Virgen de la Victoria", Málaga & *GIEMSA, School of Medicine, University of Málaga, Spain), "Determination of the Length of Sedimentation Reaction in Blood: a Comparison of the Test1 ESR System with the ICSH Reference Method and the Sedisystem", Clinical Chemistry and Laboratory Medicine 2003, 41 (2).

22. Giavarina D, Capuzzo S, Cauduro F, Carta M, Soffiati G (Clin. Chem. & Hematol. Lab., San Bortolo Hospital, Vicenza, Italy), "Internal Quality Control for Erythrocyte Sedimentation Rate Measured Test 1 Analyzer" Clinical Laboratory 2002, 48:459-462.

23.Heverin E (Galway-Mayo Institute of Technology, Ireland), "Comparison of the Westergren method versus the TEST1 technique for determining the Erythrocyte Sedimentation Rate" May 2002, private communication.

24.Lee BH, Choi J, Gee MS, Lee KK, Park H (Dept. of Laboratory Medicine, Kangbuk Samsung Hospital, Sungkyunkwan University School of Medicine, Seoul, Korea), "Basic Evaluation and Reference Range Assessment of TEST1 for the Automated Erythrocyte Sedimentatioon Rate" Journal of Clinical Pathology and Quality Control, Vol. 24, No. 1, 2002 (article in Korean).

25.Piva E, Fassina P, Plebani M (Dept. of Laboratory Medicine, University-Hospital, Padova, Italy), "Determination of the length of sedimentation reaction (erythrocyte sedimentation rate) in non-anticoagulated blood with the Microtest 1" Clin Chem Lab Med. 2002 Jul;40(7):713-7.

26.Plebani M, Piva E (Dept. of Laboratory Medicine, University-Hospital, Padova, Italy), "Erythrocyte Sedimentation Rate. Use of Fresh Blood for Quality Control", American Journal of Clinical Pathology, 2002, 117:621-626.

27. Smith D, Spedding D, (Dade Behring Diagnostics, New Zealand), "Evaluation of Agreement between the TEST1 and Starrsed Automated ESR Analysers", November 2001, private communication.

28. Giavarina D, Capuzzo S, Carta M, Cauduro F, Soffiati G (Clin. Chem. & Hematol.

Lab., San Bortolo Hospital, Vicenza, Italy), "Internal Quality Control for Erythrocyte Sedimentation Rate (ESR) measured by TEST-1 Analyzer", Clinical Chemistry, June 2001, 47: 162.

29.Piva E, Sanzari MC, Servidio G, Plebani M (Dept. of Laboratory Medicine, University-Hospital, Padova, Italy), "Length of Sedimentation Reaction in Undiluted Blood (Erythrocyte Sedimentation Rate): Variations with Sex and Age and Reference Limits", Clinical Chemistry and Laboratory Medicine, May 2001, 39: 451-454.

30.de Jonge N, Sewkaransing I, Slinger J, Rijsdijk JJM (Dept. Clinical Chemistry, Leyenburg Hospital, The Netherlands) Erythrocyte Sedimentation Rate by Test-1 Analyzer Clinical Chemistry, June 2000, 46: 881-882.

31.Plebani M, De Toni S, Sanzari MC, Bernardi D, Stockreiter E (Department of Laboratory Medicine, University-Hospital of Padua, Italy) The TEST 1 automated system: a new method for measuring the erythrocyte sedimentation rate. Am J Clin Pathol. 1998 Sep;110(3):334-40.

32. Soffiati G (Clinical Chemistry and Hematology Laboratory, San Bortolo Hospital, Vicenza, Italy), "Nuovo Metodo per la Determinazione della Velocità di Eritrosedimentazione (VES)", August 1998, private communication.

33. Cirilli N, Abu Asy Z, Giacchè N, Bordicchia F, Paolucci S, Tocchini M (Dept. of Laboratory Medicine, G. Salesi Hospital, Ancona, Italy), "TEST1: Un Nuovo Metodo per la Determinazione della VES", Biochimica Clinica, Vol. 22, N. 5-6, 1998, p. 339.

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Fully automated analyzers

for the determination of the erythrocyte sedimentation rate





ROLLER 20











Test1 THL SI 195.210/THL

175 µl EDTA blood sample per test Only 800 µl sample requested in the tube Capacity up to 60 samples Direct loading of CBC racks Throughput up to 150 samples/hour Internal bar code reader Bidirectional connection to LIS Latex controls



Direct loading from original cell blood counter rack

Test1 BCL

SI 195.220/BCL



Up to 60 samples per session with ALIFAX green plastic racks. Up to 48 samples per session with Beckman Coulter Series LH 700 CBC racks

Positions

Sampling

Throughput

Min Volume

Testing volume

Internal mixing

Thermostatation 37°C

TTFR

TTR

COMPARATIVE CHART





Up to 40 samples per session with ALIFAX vellow plastic racks. Up to 40 samples per session with Sysmex Series SF. SÉ. XE. XN. XT. XS CBC racks.

TEST1

Up to 60

Up to 150/h

20"

800 µl

175 µl

Automatic 4 racks

direct loading of CBC and Manual

Test1 YDL

SI 195.240/YDL



Up to 40 samples per session with ALIFAX blue plastic racks. Up to 40 samples per session with Siemens Series ADVIA CBC racks.

20

Automatic

Up to 120/h

800 µl (auto)

175 µI (auto)

100 µl (manual)

30"



18

Automatic

Up to 100/h

20"

800 μΙ

175 µl

Test1 MDL

SI 195.250/MDL



Up to 40 samples per session with Beckman Coulter Series LH 500 CBC

ROLLER 20 PN ROLLER 20 LC ROLLER 10 PN ROLLER 20 MC

10 - for mix

Manual

4'

18"

100 μΙ

30 ul

SI 195.260/XDL

Test1 XDL



Up to 40 samples per session with Beckman Coulter Series DxH CBC

Manual

18"

100 µl

30 µl

Roller 20PN



Double circuit for automatic and manual sampling from uncapped tubes 100 µl EDTA blood sample manual withdrawal

175 µl EDTA blood sample automated withdrawal per test Only 100 µl sample requested in the tube for manual withdrawal LCD touch screen User-friendly software Automatic washing system









175 µl EDTA blood sample per Only 800 µl sample requested in the tube 18 samples Simplified needle replacement Thermal printer Automated washing Latex controls



SI R10-PN



New generation CPS Only 30 µl EDTA blood sample Internal rotor with 10 positions for standardized mixing procedure LCD touch screen User-friendly software External barcode reader Latex controls

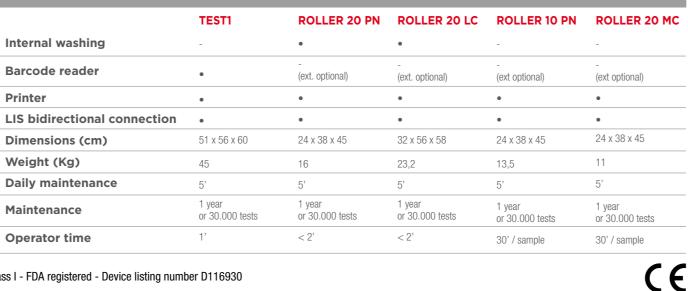


SI R20-PN

SI R20-MC



Latex controls



JO PLUS





SI 804.100

Jo Plus is conceived for mega laboratories with high routine volumes equipped with Laboratory Automation System (LAS).

Jo Plus is based on the same Test1 family technology.

120 samples processed in about 1 hour

Jo Plus is based on the same Test1 family technology 175 µl EDTA blood sample per test

Results available in 30 seconds

On line ESR system for total laboratory

automation Power supply: 115-230 VAC (SMPS), 50/60 Hz | Power consumption: 66VA | Temperature: from +10 to +30°C Size: 300x340x200 mm | Weight: 11 Kg | In/out specifications: Two RS232 serial ports

Smart Card



	1000 tests	4000 tests	10000 tests	2000C tests
TEST1 ROLLER	code SI 195.901	code SI 195.904	code SI 195.910	code SI 195.920
JO PLUS	-	-	code SI 804.910	code SI 804.920

Environmentally friendly cards save storage and transport costs. Only pay for a test when needed.

Latex controls

Three levels to guarantee: precision, accuracy, repeatability

LATEX CONTROLS 6 TESTS



SI 305.100-A (Greiner tubes)

SI 305.102-A (Sarstedt tubes)



LATEX CONTROLS

30 TESTS

SI 305.300-A (Greiner tubes) SI 305.302-A (Sarstedt tubes)

SHELF LIFE: From production: 6 months. From the 1st piercing: 6 weeks STORAGE CONDITIONS: From production: +4÷25°C. From the 1st piercing: +4÷8°C

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