PRODUCT TECHNICAL DATASHEET
ROLLER20-PN

Rev.3.2 – Valid from 2023-10 31

NAME: **ROLLER 20**

REF Code: **SI R20 PN**

INTENDED USE: ROLLER 20 is an automated in vitro diagnostic analyzer for the quantitative determination of erythrocyte sedimentation rate (ESR) in human blood samples with EDTA from adult and pediatric patients with suspected inflammation.
ROLLER 20 provides results to inform clinical management of serious and non-serious conditions requiring further diagnostic investigation and assessment of clinical status.
The physician performs the assessment based on the information provided by the device using his or her professional knowledge, skills and abilities as required by local law.

DESCRIPTION: Model with 2 rotors for 20 samples total equipped with an automatic washing system and manual external withdrawal tip for pediatric test-tubes and for test tubes that can be uncapped.

ANALYSIS PRINCIPLE: Quantitative Capillary Photometry for the Erythrocyte-Sedimentation Rate (ESR)

- At the first daily switch ON wait 3 minutes before starting an analysis cycle to allow the thermal stabilization.
- Instrument uses a technology that allows the measurement of the ESR at a stabilized temperature of 37±0.5°C (98.6±0.9°F)

RESULTS: Given in mm/h in the range from 2 to 120 mm/h.

SAMPLE REQUIREMENTS: In case of use of sample coming from patients affected by an oncological pathology, we remark that ESR result of those samples could be eventually NOT reliable as explained in section “method limitations” paragraph 2.

- the sample must be of whole blood collected in EDTA anti-coagulant.
- the blood sample must be neither coagulated nor hemolyzed.
- Samples mixing is done at the beginning of the analysis with the purpose of disaggregating erythrocytes. A possible ineffective disaggregation could affect the results given by the instrument which measures system is based on the detection of the kinetics of aggregation of the red cells.
- The use of sample tubes with different volumes could affect the performance of the instrument

Automatic withdrawal:

- the minimum blood volume for the withdrawal is 800 microliters
- In the event paediatrics samples with **internal withdrawl** method the minimum volume suggested is 500 uL,
- the minimum blood working volume required for the analysis is about 175 microliters except for the first two samples from which supplementary 116 microliters are approximately withdrawn for priming. In total from the first two samples around 232 microliters are withdrawn. In case there is only one sample, the amount withdrawn for priming is around 232 microliters.
- samples separation inside the capillary by air bubble.

Manual withdrawal:

- the minimum blood working volume required for the analysis is about 100 microliters, except for the first sample from which supplementary 100 microliters are approximately withdrawn for priming.
- samples separation inside the capillary by air bubble.

TUBE REQUIREMENTS: Test-tubes 13x75 mm (0,512 x 2,953 inches) like BD Vacutainer® or BD Microtainer® or Greiner Bio-one or with 13 mm (0,512 inches)diameter and from 75 to 83 mm (2,953 – 0,3268 inches) high, cap included like, for example, the Sarstedt tubes that measure 11,5x66 mm (0,4528x0,2598 inches) without cap.
Compatible also with test tubes Terumo Venoject II® models VP-DK052K, VP-DK052K05 and VJ-DK052E004

- It is possible to use “BD Microtainer MAP®” tubes directly (also in conjunction with other 13x75, 0,512 x 2,953 inches tubes) but could be necessary to verify the needle offset adjusting its excursion in case of volumes lower than 500 uL

- It is possible to use “Sarstedt S-Monovette EDTA®”, “Tapval® pediatric tube”, “BD Vacutainer® pediatric tube” tubes; for these models of test tubes it is required the use of specific test tube adapters as well as it could be necessary to verify the needle offset adjusting its excursion in case of volumes lower than 500 uL
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PEDIATRIC TUBE COMPATIBILITY **For tubes not listed here, please contact you Alifax Distributor**	**Roller20-PN** With mixer, internal and external withdraw 	**Roller20-MC** Without mixer, external withdrawn only 
 Sarstedt S-Monovette EDTA 1.2 ml pediatric tube and SI195595 Tube Adapter	Internal mixing Internal withdraw External withdraw also	External mixing External withdraw only
 Tapval pediatric tube and SI195590 Tube Adapter	Internal mixing Internal withdraw External withdraw	External mixing External withdraw only
 BD Vacutainer pediatric tube and SI195593 Tube Adapter	Internal mixing Internal withdraw External withdraw	External mixing External withdraw only
 BD Microtainer MAP from 250 to 500 uL pediatric cuvette into 13x75mm tube with pierceable cap No tube adapter required	Can be used together with other 13x75mm test-tubes if the blood volume is at least 250uL and the following shrewdness: turn upside down each tube and give a flip to the cap for bring down the blood towards the cap just before loading the tube into the rotor	External mixing External withdraw only

	Sarstedt Microvette 500 K3E Code 20.1341.100 Capillary pediatric test tube for 500uL and SI205052 Tube Adapter	Internal mixing (use centrifuged mixing) **Internal withdraw (minimum 300uL)** External withdraw (less than 300 uL)	External mixing External withdraw only
	Sarstedt Microvette 200 K3E Code 20.1288.100 Capillary pediatric Test tube for 200uL and SI205052 Tube Adapter	Internal mixing (use centrifuged mixing) **No internal withdraw (too few blood 200uL)** External withdraw (200 uL is enough)	External mixing External withdraw only

Please notice all above tubes, have been tested mechanically to check compatibility with the instrument rotor and piercing system. There is not available any specific comparative performance information about them.

OPERATIVE PERFORMANCES

Operative performances:

- New design with thermoplastic cover, front door for easy access to waste and washing tanks and needle.
- Simplified and safe needle replacing procedure.
- Simplified Smart Card downloading.
- Photometer check after each washing, to ensure continuous control of the instrument.
- New photometer (CPS) with three detectors for ESR analysis and blood flow management.
- New automatic washing programmable at the end of each cycle.
- New withdrawal tip for pediatric test-tubes and for test tubes that can be uncapped.
- To compare the ESR testing between manual and automatic procedure performed with Roller 20 PN it is mandatory to open the cap of the tube both for automatic - manual procedure and vice versa
- Management of Latex Controls kits for TEST1 family analyzers **(Ord. code SI 305.100-A/SI 305.102-A and SI 305.300-A/ SI 305.302-A).**

Automatic withdrawal:

- Start the analysis within 2-4 hours from vein-puncture, otherwise keep the samples in refrigerator at +4÷8 °C (39.2÷46.4°F) for a maximum of 24 hours. If the samples have been conserved in refrigerator at +4÷8 °C (39.2÷46.4°F), it is necessary to leave them at room temperature at least for 30 minutes before their analysis, even if it is in any case suggested to let the samples remain at room temperature preferably for about 60 minutes, after that, test should be executed within 4 hours
- In the event paediatrics samples with **internal withdrawal** method the minimum volume suggested is 500 uL,
- Instrument offers three mixing speeds (60 rpm, 32 rpm, 24 rpm); it is recommended to configure a speed of 32 rpm and 140 cycles for an adequate homogenization of the samples.
- Minimum volume required is 800 uL
- First result available after 4,4 minutes (mixing) and 30 seconds (analysis), the other results are given every 30 seconds each; 20 samples processed in about 10 minutes (120 samples per hour) without considering the time taken for loading and unloading of test-tubes from the instrument.
- The above throughput could be delayed in case of connection to the Host Computer with reply output time more than 1 second.
- verify that the sample volume should in any case not exceed the 50-60% of the total volume of the test-tube in order to optimise the blood homogenization.

- It is suggested the sample volume should not exceed the 50-60% of the total volume of the test-tube.

- In the event customer uses collecting tubes with 4ml capacity, it is possible to obtain good correlation with the method used into the laboratory with the following suggestions:
  1. Using the gain of the instrument during correlation with lab reference method
  2. Increasing the mixing time (this can be obtained using an external mixer before the ESR analysis or/and increasing the mixing time of the ESR analyzer).
  3. If the CBC has the venting function, possibly execute first the CBC analysis and then the ESR analysis.

Manual withdrawal:

- Start the analysis within 2-4 hours from vein-puncture, otherwise keep the samples in refrigerator at +4÷8 °C (39.2÷46.4°F) for a maximum of 24 hours. If the samples have been conserved in refrigerator at +4÷8 °C (39.2÷46.4°F), it is necessary to leave them at room temperature at least for 30 minutes before their analysis, even if it is in any case suggested to let the samples remain at room temperature preferably for about 60 minutes, after that, test should be executed within 4 hours.

- Minimun volume required is 100 uL except for the first sample from which supplementary 100 microliters are approximately withdrawn for priming.
- verify that the sample volume should in any case not exceed the 50-60% of the total volume of the test-tube in order to optimise the blood homogenization.
- In case of external mixing of the samples, use a rotating wheel or a tilting bed set at speed of 32 rpms and 140 cycles of mixing to allow a suitable homogenization of the samples.
- In the event customer uses collecting tubes with 4ml capacity, it is possible to obtain good correlation with the method used into the laboratory with the following tips:
  1. Using the gain of the instrument during correlation with lab reference method
  2. Increasing the mixing time (this can be obtained using an external mixer before the ESR analysis or/and increasing the mixing time of the ESR analyzer).
  3. If the CBC has the venting function, possibly execute first the CBC analysis and then the ESR analysis.

Error notice:
The instrument in case of error or malfunction, reports this situation with a specific message on the screen plus with an acoustic intermittent signal of 62,5 dBA.

CAPACITY: max 20 samples/session

ANALYTICAL PERFORMANCES (obtained with 3 ml test-tubes):

Agreement with TEST1: **$R^2 = 0.91$**

Repeatability: mean CV% = 5.7% on the whole range 2 - 120 mm/h
Reproducibility: mean CV% = 5.1% on the whole range 2 - 120 mm/h

Stability of samples stored for 24 h at room temperature:
In order to view the effects of different methods of storage on the ESR value, 272 K_3EDTA-anticoagulated whole blood samples, some of which have been stored at 4 °C (39.2°F) and some others at room temperature, have been analysed after 4 hrs and after 24 hrs on TEST1 device. Good correlation was found between the results taken at 4 hrs and those taken at 24 hrs on the samples stored at 4 °C (39.2°F) (r=0.980). Those stored at room temperature did not correlate quite as well as those stored at 4 °C (39.2°F), but still had very good correlation (r=0.917)[1].

METHOD LIMITATIONS:

1. The erythrocyte sedimentation rate is a phenomenon confined to fresh blood and transient[2], not a hematic matrix component (at corpuscular / molecular level). The procedures used to determine the ESR cannot be calibrated as they are susceptible to a variety of errors (temperature, hematocrit, erythrocyte mean corpuscular volume, plasma viscosity, etc.)[2]**.** Based on the acquired experience,TEST1 family instruments (TEST1, MicroTEST1, Roller20LC, Roller20PN, Roller20MC, Roller10PN and JO-PLUS), are limitedly affected by these variables. For this reason it is possible to observe instrument performances deviations compared to other procedures if the above variables are not taken into account.

2. Erythrocyte sedimentation remains an only partly understood phenomenon….is a nonspecific reaction (from a clinical point of view)[2] that is affected by several technical aspects [3]. The ESR is often normal in patients with cancer[3]**.**

International guidelines for diagnosis and management of multiple myeloma do not mention the Erythrocyte Sedimentation Rate [4]. It is then necessary to point out that even though TEST1 analytical performances have been confirmed in patients affected by multiple myeloma [5,6]**,** there have been some cases of patients affected by multiple myeloma in which TEST1 has reported clinically negative ESR values in comparison to other methods. Based on this experience there could be cases in which Roller gives low ESR results likewise TEST1 in presence of Multiple Myeloma.

Furthermore in presence of this disease and/or other oncological pathologies it is possible to observe deviations form other methods since other phenomena in addition to the rouleaux formation can contribute to the sedimentation like for example amorphous aggregates formation (crystallization of paraproteins or mineral materials like calcium) resulting from bone tissue alteration.

It is then highly recommended to perform other tests together with the ESR in the diagnosis of cancer since a normal ESR value is not enough to exclude that the patient is not affected by this pathology.

3. Samples mixing is programmed at the beginning of the analysis with the purpose of disaggregating erythrocytes. An inefficient disaggregation could affect the results given by the instrument that in fact measures erythrocytes aggregation kinetics.

4. The above instrument performances have been obtained using test tubes with a capacity of 3 ml and 13x75 mm size with K_3EDTA anticoagulant. The use of such tubes optimizes the mixing phase and consequently the results reproducibility.

ENVIRONMENTAL AND PHYSICAL SPECIFICATIONS

Permissible environment conditions for operation:

Temp.: from +10÷30°C (50÷86°F)
Humidity: from 15% to 85% - no dew

Permissible environment conditions for transportation and storage:

Temp.: from -20÷65°C (-4÷149°F)
Humidity : from 5% to 95% - no dew

Size and weight:

[L] Length: 24 cm (9.4488 inches)
[W] Width: 39 cm (15.354 inches)
[H] Height: 46 cm (18.11 Inches)
Weight: 16 Kg (35.274 Lb)

Packaging: Cardboard box

[L] Length: 65 cm (25.591 inch)
[W] Width: 34 cm (13.386 inch)
[H] Height: 50 cm (19.685 inch)
Gross Weight: 20 Kg (44.092 Lb)
Volume: 0,1105)m^3 (3,902 F^3)
Pallet: No

ELECTRICAL SPECIFICATIONS

Voltage: 115 / 230 Vac ± 10% (For USA and Canada 115 VAC only)

Power consumption: 115/150 VA
Switch on cons: 132 W

Frequency: 50/60 Hz

Classification: Class I (EN61010-1 – IEC 1010-1 – CEI 66-5)

OTHER OPERATIVE SPECIFICATIONS:

Heat dissipation in the environment: about 230 BTU/hour

Noise: ≤ 62,5 dB(A)

Maximum rated altitude: 3000 mt asl

Communication: 2 serial RS232 ports located on the rear side of the instrument:
Port 1 (DB25) is dedicated to connect an external scanner
Port 2 (DB) is dedicated to connect the instrument to an Host Computer
1 USB serial ports (for future applications)

Functioning: The instrument is designed to remain switched ON 24 hours a day, it is however suggested to switch it off at the end of the working day, applying previously a washing procedure using 3 washing tube to ensure a long capillary's and sensors' life.

Restrictions: Indoor user appliance

Rated pollution degree: Grade 2

Working life of the instrument: 10 years (if maintenance is done correctly)

INTERNAL QUALITY CONTROL

Latex Controls: With the purpose of guarantee an always optimum performance of the instrument, the daily use of the latex control kit is recommended.

Latex Controls for TEST1 family analyzers allow the control of the calibration stability of TEST1, MicroTEST1; Roller10, Roller20LC, Roller20PN, Roller20MC, Roller10PN and JO-PLUS.

They are available in two kinds of test tubes:

- ♦ 13x75 mm Greiner: **Latex Controls (6 tests) - code SI 305.100-A;** **Latex Controls (30 tests) – code SI 305.300-A**
- ♦ 11,5x66 mm Sarstedt: **Latex Controls (6 tests) - code SI 305.102-A;** **Latex Controls (30 tests) - code SI 305.302-A**

CONSUMABLES

Printer Paper: Thermal roller paper 58 ±1/mm (0.2283 inch ± 0.004inch) x Max 32 mm(0.126 inch)

Smart Card: Coded using Alifax proprietary algorithm. Use only original card manufactured by Alifax: for 1,000 (Ord. code SI 195.901) - 4,000 (Ord. code SI 195.904) - 10,000 (Ord. code SI 195.910) - 20,000 (Ord. code SI 195.920) tests / Universal Card.

Waste Tank: 500 ml plastic tank with screw cap to collect blood and washing effluents. **SI205801**

Wash Tank: 500 ml plastic tank with screw cap for the water used to wash the instrument. (Available only on SI R20 PN Model) **SI195145**

OPTIONAL AVAILABLE TOOLS

Patient identification: External CCD bar-code reader (**SI195820**)

REGULATORY INFORMATIONS:

Classification	IVD	
UDI-DI (GTIN13)	8056040140345	
CND Code	W02029001	APPARECCHIATURE PER VELOCITA` DI ERITRO-SEDIMENTAZIONE
FDA-CFR Code	Product code: GKB	Regulation Number: 864.5800 Automated sedimentation rate device
GIVD Code	23.09.10.01	Other_HHIHC Hardware + accessories + consumables + software

GMDN Code	56691	An electrically-powered automated or semi-automated laboratory instrument intended to be used to determine the erythrocyte sedimentation rate (ESR) of red blood cells in an anticoagulated whole blood specimen.

REFERENCES:

1. E. Heverin (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
2. NCCLS “Reference and Selected procedure for the Erythrocyte Sedimentation rate (ESR) Test; Approved Standard-Fourth Edition”, Vol. 20 No. 27
3. Sox HC, Liang MH: “The Erythrocyte Sedimentation Rate”, Annals of Internal Medicine 1986; 105:515-523.
4. NCCN (National Comprehensive Cancer Network) Clinical Practice Guidelines in Oncology “Multiple Myeloma” (V.I.2007)
5. Ajubi et al.: “Determination of the lenght of sedimentation reaction in blood using the TEST1 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
6. Mercurio S. et al.: “Comparison between two methods for ESR measure in patients affected by myeloma”, 37° SIBioC National Congress, 11-14 October 2005 Rome.
7. H02-A5 vol 31 No.11 PROCEDURES FOR THE ERYTHROCYTE SEDIMENTATION RATE TEST; APPROVED STANDARD – FIFTH EDITION
8. Automated measurement of the erythrocyte sedimentation rate: method validation and comparison Ivana Lapić*, Elisa Piva, Federica Spolaore, Francesca Tosato, Michela Pelloso and Mario Plebani Clin Chem Lab Med 2019

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