PRODUCT TECHNICAL DATA SHEET

ROLLER 20-MC

Rev.1.3 – 2016.06.01

NAME: **Roller20**

REF Code: **SI R20-MC**

INTEDED USE: Automatic analyzer for Erythrocyte Sedimentation Rate (ESR) determination.

DESCRIPTION: Model with manual external withdrawal tip for pediatric test-tubes and for test tubes that can be uncapped.

ANALYSIS PRINCIPLE: Microphotometrical capillary using stopped flow kinetic analysis.

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

SAMPLE REQUIREMENTS:

- the sample must be of whole blood collected in EDTA anti-coagulant.
- the blood sample must be neither coagulated nor haemolysed.
- it would be better to test the sample within 4-6 hours from venipuncture or within 24 hours if kept at +4 / +8 °C, allowing it to warm-up to room temperature before testing.
- the minimum blood volume for the withdrawal (dead volume) is 100 microliters
- the minimum blood working volume required for the analysis is about 30 microliters except for the first sample from which supplementary 50 microliters are approximately withdrawn for priming.
- samples separation inside the capillary by air bubble.
- blood sample must be mixed by external mixer (min. 3 minutes) before starting the withdrawal
- If the sample is from a capillary micro-tube, ensure that during the mixer the blood is moving inside the tube. If not, gently shake the tube in order to start the traveling top-down of blood and then complete the mixing with the external mixer as above described

TUBE REQUIREMENTS: Any kind of test-tubes with maximum height of 75 mm
It is suggested the sample volume should not exceed the 50-60% of the total volume of the test-tube

PEDIATRIC TUBE COMPATIBILITY **For tubes not listed here, please contact you Alifax Distributor**	**Roller20PN2** With mixer, internal and external withdraw 	**Roller20MC** Without mixer, external withdrawn only 	**Roller10PN** With mixer, external withdraw only 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	Internal mixing External withdraw only
 Tapval pediatric tube and SI195590 Tube Adapter	Internal mixing Internal withdraw External withdraw	External mixing External withdraw only	Iternal mixing Extenal withdraw only

 BD Vacutainer pediatric tube and SI195593 Tube Adapter	Internal mixing Internal withdraw External withdraw	External mixing External withdraw only	Internal 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	Internal mixing (use centrifuged 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	Internal mixing (use centrifuged 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	Internal mixing (use centrifuged mixing) External withdraw

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

- Only 30 uL of blood used for analysis, suitable for pediatric samples
- Results available in 18 seconds after starting manual withdrawal
- Thermoplastic cover with lid for protecting withdrawal probe.
- New Smart Card with divisible credit enabled by codes.
- Photometer check after each washing, to ensure continuous control of the instrument.
- New photometer (Mecca) with two detectors for ESR analysis and blood flow management.
- Automatic washing request programmable at the end of each cycle
- 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).**

- 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 (on R20-MC the mixing MUST BE DONE only externally).
    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.

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

Agreement with TEST1: **R = 0.95**

Repeatability: mean CV% < 12% on the whole range 2 - 120 mm/h
Reproducibility: mean CV% < 5% 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 and some others at room temperature, have been analyzed 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 (r=0.980). Those stored at room temperature did not correlate quite as well as those stored at 4 °C, 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, Roller), 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.

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.
Furthermore in presence of this disease 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.

3. Samples mixing of 3 at least minutes before the analysis with the purpose of disaggregating erythrocytes. An inefficient disaggregation or micro-clots presence can affect the result 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.

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ENVIRONMENTAL AND PHYSICAL SPECIFICATIONS

Permissible environment conditions for operation:

Temp.: from 15 to +30°C
Humidity: from 15% to 85% - no dew

Permissible environment conditions for transportation and storage:

Temp.: from -20 to +65°C
Humidity : from 5% to 95% - no dew

Size and weight:

Width: 240 mm
Depth: 380 mm
Height: 450 mm
Weight: 11 Kg

Packaging: Cardboard box

Width: 650 mm
Depth: 340 mm
Height: 500 mm
Gross Weight: 15 Kg
Volume: 0,1105 m^3
Pallet: No

ELECTRICAL SPECIFICATIONS

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Voltage: 115 - 230 Vac
Switch Mode Power Supply (SMPS)

Power consumption: 40 VA

Frequency: 50/60 Hz

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

OTHER OPERATIVE SPECIFICATIONS:

Heat dissipation in the environment: about 136 BTU/hour

Noise:
39,5 dB(A) standby
53.4 dB(A) printing
50.2 dB(A) working/washing

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 (distillate water, chlorine, distillate water) 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 analysers allow the control of the calibration stability of TEST1, MicroTEST1; Roller 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 +0/-1 mm x Max 32 mm external diameter

Smart Card: Conform to ISO 7816-1 specifications – 85.6 x 54 x 0.8 mm
Coded using Alifax proprietary algorithm
Available for:
1000 test (Ord. code **SI 195901**)
4000 test (Ord. code **SI 195904**)
5000 test (Ord. code **SI 195950**) New Smart Card with divisible credit enabled by codes
10000 (Ord. code **SI 195910**)
20000 (Ord. code **SI 195920**)
Universal Card for TEST1 family analysers (TEST1; MicroTEST1; Roller).

Waste Tank: 500 ml plastic waste tank with screw cap.

OPTIONAL AVAILABLE TOOLS

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

REGULATORY INFORMATIONS:

Classification	IVD	
EAN13 Code	805604014340	
CND Code	W02029001	APPARECCHIATURE PER VELOCITA` DI ERITRO-SEDIMENTAZIONE
FDA-CFR Code	Product code: GKB	Regulation Number: 864.5800 Automated sedimentation rate device
EDMA Code	23091001	Other_HHIHC Hardware + accessories + consumables + software
GMDN Code	35488	An automatic or semi-automatic instrument used to measure the sedimentation (sinking) velocity of red blood cells in a sample of whole blood using photometry. This is also called, erythrocyte sedimentation rate (ESR).
RoHS2 2011/65/EU	Compliant	

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.**

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