



AQUISEL, S.L.

ESPECIFICACIÓN ARTÍCULO (COMERCIAL)

Doc. – Sub

ESP-1750224-02

Rev.

E

Fecha / Date

23/02/2015

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AQUISEL CODE

1750224

DESCRIPTION

GRADUATED PIPETTE AQUISEL A-2 FOR E.S.R.

COMMERCIAL REF.

1750224

Intention use

Single use plastic pipette for Erythrocyte Sedimentation Rate (E.S.R.), following up Westergren Method (method recommended by the International Committee of Standardization in Haematology)

Materials Characteristics

Pipette	Polystyrene (PS)	Scale	Blue ink
Filter	Polythene (PE)		

Measurements Characteristics

Total length of the pipette	230 ± 2 mm		
Nominal length up to "0" position	200 ± 2 mm		
Reading length of scale	170 mm		
Outside Ø	4,55 ± 0,1 mm	Inner Ø	2,55 ± 0,15 mm

Storage and keeping recommendations

Expiry date : 5 years since its production (see carton label)

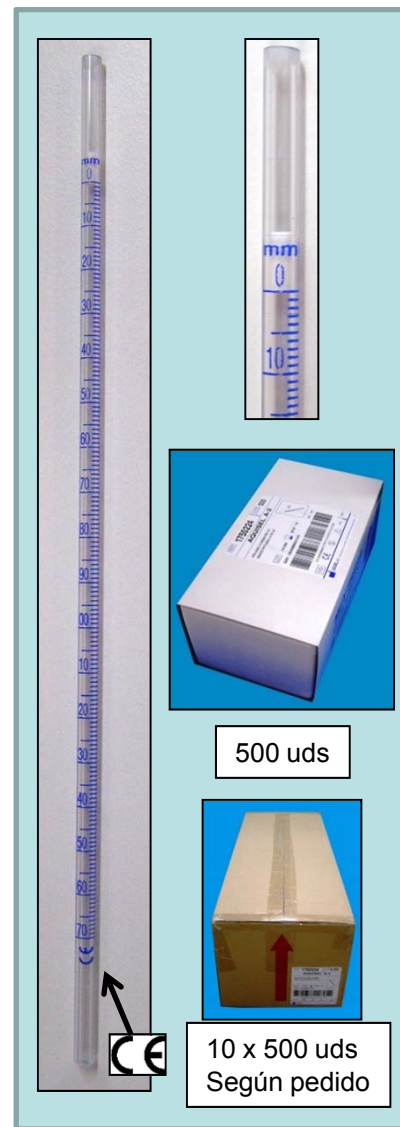
Avoid exposure to direct sunlight and recommended storage between 4° to 35° C

Goods packaging Product presentation

500 pcs. x EPS box
10x500 pcs. carton

EPS box dimensions (500 pcs.)	27,5 x 14,5x10cm (width x length x height)
Carton dimensions (10x500 pcs.)	29 x 76 x 25 cm (width x length x height)

Volume (500 pcs.)	4 L	Weight approximated	1,5 kg
Volume (5000 pcs.)	55 L	Weight approximated	15 Kg



Disposal Recommendations:

Enforce existing legislation on disposing of material with biological risk.

By incineration at 500°C with remains about 2% of its mass (mainly calcium carbonate).

Legislation and Standards as guidelines:

In Vitro Diagnostic Medical Devices (IVD): Dir. 98/79/CE # R.D. 1662/2000

Quality Management System: UNE EN ISO 9001 – 13485

Product: UNE EN ISO 13079 ; Westergren Method ; H02 (CLSI) Procedure.

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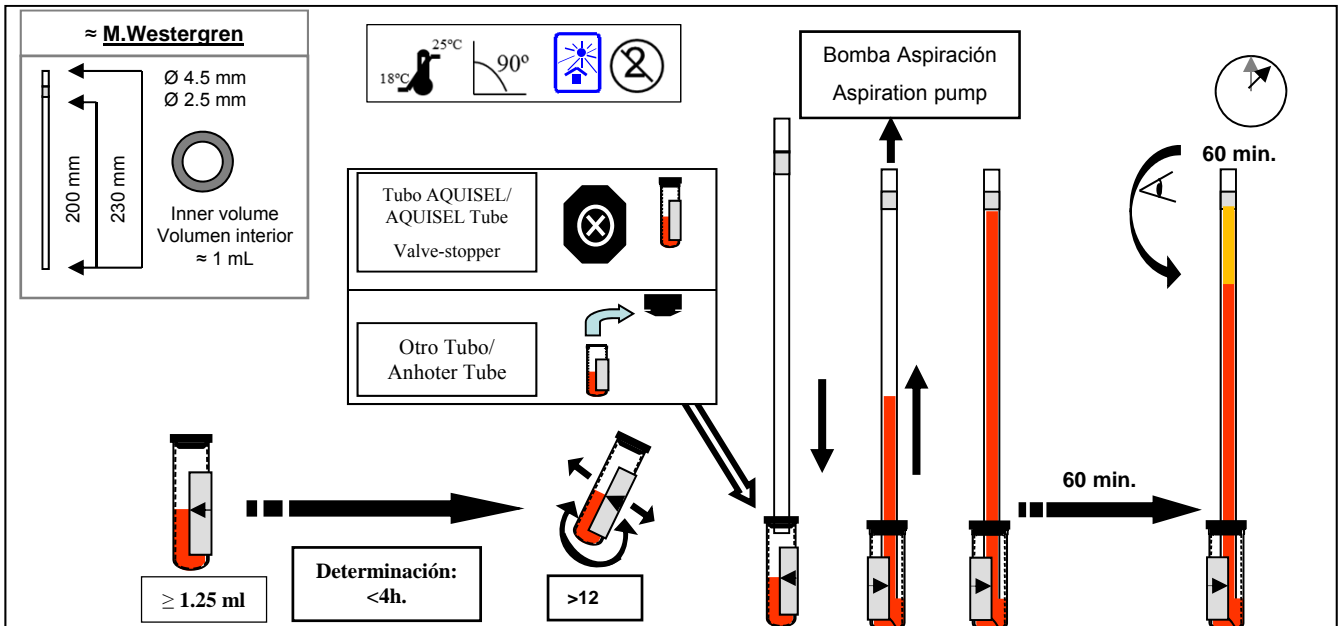
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Recommendations for use:



Recommendations of the method:

- 1.- Any tube with at least 1,25 ml of sample contain can be used.
- 2.- According to the procedure of the laboratory, the blood should mix with EDTA or 3Na Citrate (1:4).
- 3.- The room must be between 18° - 25°C.
- 4.- A well-mixed blood to the anticoagulant after drawing and before filling the pipette must be ensure. There should be a minimum of 12 complete inversions.
- 5.- The test must be set up within 4 hours after the drawing, if it would be later the specimen should be in the refrigerator at 4°C up to 12 hours and the specimen should be return to room temperature and mixing again before using it.
- 6.- Inserting the pipette into the test tube. If the test tube has an AQUISEL valve-stopper is not needed to uncorked.
- 7.- Filling the pipette by aspiration pump or similar up to "0" mark.
- 8.- Once filling the pipette (ensuring the pipette is bubble-free and filling exactly to "0" mark), places in a vertical position (90°) in an area free of vibrations, drafts and direct sunlight.
- 9.- At 60 minutes read the distance (a second reading can be done at 120 minutes, but it is depend on each laboratory procedure).
- 10.- After carrying out the determination disposal the material according to usual procedure of any laboratory as biological material risk.



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IDENTIFICATION AND INFORMATION

E.g. EPS box label 110x120
A-2 pipette (500 pcs)



E.g. Carton label 110x120
A-2 pipette (5000 pcs.)



FIELD	MEANING
REF	1760200
LOT	12: (year of production) 3456 (correlative No. within year of production)
Expiry Date	AAAA-mm (Year – Month)
No.	Correlative carton No. within production
GS1-128 (EAN – 128) BAR CODE	
(01)	Apply identification, EAN code – identify the units with outside function
084	National digit (AECOC – Spain)
29889	Aquisel No. as associate of AECOC
00114	Product code given by Aquisel
4	Control digit (automatic calculus)
(17)	Application identification – Expiry Date
000000	12: Year 34: Month 56: Day
(10)	Application identification – Lot No.
000000	12: Last two numbers of Year 3456: Correlative No. production/Year
Symbols	
IVD	In Vitro Diagnostic
CE	CE marked according to RD 1662/2000 medical device IVD
Single Use	Single Use
Instructions for use available	Instructions for use available
Storage temperature recommended	Storage temperature recommended
Manufacturer	Manufacturer
Software	-----

Other remarks:

Distributed by: J.P. Selecta s.a. – Autovía A-2, Km 585,1 – 08630 – Abrera (Barcelona) Spain

Commercial contact: tender@jpselecta.es

Manufactured by : AQUISEL S.L.U. – Autovía A-2, Km 585,1 - 08630 Abrera (Barcelona) Spain

Technical contact: ecatalan@aquisel.es

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