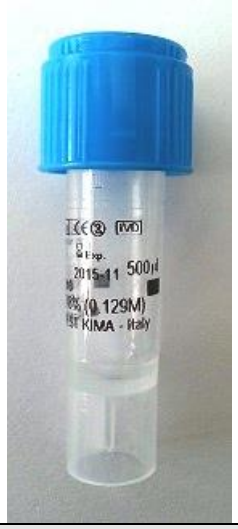
Vacutest Kima S.r.l. Via dell'Industria,12 35020 Arzergrande (PD) ***Technical data sheet***		REF. 814074	PAGE 1
		REVISION 2	DATE 01/02/2019

CODE CND: W050101010201

CODE	***Description***	
814074	**Kima µtest** **Micro tubes sterile in PP** **14x45 Containing** **Na Citrate Vol. 500 µl**	

Size and specification :

Tubes in polypropylene transparent, shockproof.
The test tube is adapted with collector and safety closure.

Material:	polypropylene
Diameter:	14 mm external tube
Height:	45 mm
Cap	polyethylene Ø14 mm

Color of the safety cap to identify tube:
LIGHT BLUE

Shelf life: *24 (twenty four) month from the manufacturing date.*

Additive

50 µl Na Citrate solution 3,2% (0,109 molarity)

Destination of use:

They are used for the collection of samples of blood for the following coagulation test.
Ratio anticoagulant/blood = 1:9
Line of filling at 500 µl
This product has to be used by professionally qualified personnel

Recommended use :

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Indication of mixing : right after the collection re close the tube and gently mix 4-5 times**.**
Minimum time before the centrifugation : none
Maximum time before centrifugation : 2-4 hours after the collection, according to the test to be performed.
Speed of centrifugation : 2000-2500 d for 15-20 min at 20-25 °C. Use time and speed of centrifugation in order to guarantee a plasma with low level of platelet.

Preservation of the sample (plasma separated from the corpuscular part) : The time and the temperature of conservation may change according to the test that has to be performed.

Storage and preservation:

Storage and preservation of the tubes for long periods have to be at a temperature between +5 and +25°C, in dry place. Tubes have to be stored in vertical position with cap on upper side as indicated on each case.

Labels on tubes :

Transparent label in PP, for specific medical usage, printed in black. Reported data : code (REF), additive, lot and expiring date, various symbols (Sterile R,IVD,CE and disposable), drawing level, volume, producer name and country of production.

Packaging :

Rack	Inner box	Shipping case
Rack in plastic of 50 pcs	**50 pcs (1 rack of 50 pcs)** In the packaging are reported the following data : commercial name, name of manufacturer and address, CE mark, IVD, Symbols of sterility, and preservation and use, number of pcs contained. Each box is labeled with: Sealing label, CE marking, manufacturer name and address, code, content description, date of manufacture (year and month), exp date (year and month), lot, quantity and color of identification of the tube, symbol of sterility, storage and use, bar code of the product. Each box contain an graphical instruction with the method for the use of the tube.	**1000 pcs (20 boxes of 50 pcs.)** Each box is printed with: Company name, address, size of tubes, Ce marking, IVD, sterilization, storage and user's directions. Each box is labeled with: Sealing label, CE marking, manufacturer name and address, code, content description, date of manufacture (year and month), exp date (year and month), lot, quantity and color of identification of the tube, symbol of sterility, storage and use, bar code of the product. Each box contain an graphical instruction with the method for the use of the tube.

Size and packaging of the shipment:

Weight : 3,5 Kg – Volume 0.017 m³

Sterilization :

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By irradiation, according to the rules :
UNI EN 556-1 Requirements for the medical devices that reported the indication Sterile
UNI EN ISO 11737-2 Microbiological Method – Test of Sterility made during the validation of the process of sterilization.
UNI EN ISO 11137-1 Sterilization of the health product – Irradiation – Part 1

Compatibility with the analytical instruments :

No incompatibility with instruments present in the market have been reported. The user must verify the compatibility of the external size of the tubes with the dimension requested from the instrument in the lab.

Disposal method :

Before the use the products have to be consider not hazardous material to be disposal according to D.Lgs. 156/06 e s.m.i.
After the use become waste potentially infected that have to collect and disposed applying all particular precautions to avoid infections: CER 18 01 03

Raw material certification :

All raw materials used are no toxic, food and medical certified, as per European and FDA (USA) directives.

System applied during manufacturing and reference standards:

UNI EN ISO 9001:2015, ICIM certificate no. 4264/4 issued by ICIM S.p.a. current issue;
UNI EN ISO 13485:2016, ICIM certificate no. 4265/4 issued by ICIM S.p.a. current issue;

CE: quality guarantee system through issue of Declaration of Conformity CE after preparation of technical files as per Directive CEE 98/79/CE (D.L. 08/09/2000 N.332) available to the competent authorities.

EN 375 In Vitro Diagnostic Devices – Labels and information relative to reagents required on the product for In Vitro Diagnostic Devices destined to professional use.

UNI CEI EN ISO 15223-1 Symbols used in the labels of the medical device, in the labelled and in the information that must be provided (former UNI CEI EN 980:2009).

UNI EN 1041 Information supplier with medical device.

UNI EN 14971 Application of the management of the risk to the medical device.

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NOMOGRAPH

