

DRAFT OF CERTIFICATE OF ANALYSIS

Product: ANY SET CPD / SAGM

LOT

Lot number: ...



Expiry date: ...

REF

	Tests	Requirements according to manufacturer's Specifications*	Test result
1.	Sterility	no living microbes present	Conforms with Specification
2.	Content of bacterial endotoxines	less than 5.56 EU/mL	Conforms with Specification
3.	Anticoagulant CPD solution		
	3.1. Colour	colourless	Conforms with Specification
	3.2. Solution volume fluctuation	63 mL ± 10%	Conforms with Specification
	3.3. Reaction	pH = 5.0 ÷ 6.0	Conforms with Specification
	3.4. Chlorides	not more than 0.0035 %	Conforms with Specification
	3.5. Total citrate expressed as citric acid, anhydrous (C ₆ H ₈ O ₇)	1.916 ÷ 2.118 g/100 mL	Conforms with Specification
	3.6. Monobasic sodium phosphate (monohydrate; NaH ₂ PO ₄ ·H ₂ O) content	0.211 ÷ 0.233 g/100 mL	Conforms with Specification
	3.7. Sodium (Na) content	0.621 ÷ 0.686 g/100 mL	Conforms with Specification
	3.8. Dextrose (anhydrous; C ₆ H ₁₂ O ₆) content	2.204 ÷ 2.436 g/100 mL	Conforms with Specification
4.	SAGM solution		
	4.1. Colour	colourless	Conforms with Specification
	4.2. Solution volume fluctuation	100 mL ± 10%	Conforms with Specification

4.3.	Reaction	pH = 5.0 ÷ 6.5	Conforms with Specification
4.4.	Sodium chloride (NaCl) content	0.833 ÷ 0.921 g/100 mL	Conforms with Specification
4.5.	Adenine content	15.21 ÷ 18.59 mg/100 mL	Conforms with Specification

*SB/01, SB/02, SB/12, SB/16

SUMMARY:

Blood collection bags with anticoagulant CPD/SAGM conform with specifications



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Quality Control Manager

WARRANTY CONDITIONS:

The warranty covers all flaws of the product caused by faulty parts and/or production defects
Warranty covers only exchange of the product for the one free from flaws in the period of validity specified by "Expiry date". Warranty does not cover:

- damages made during transportation and reloading
 - damages made by storage not according to the Instruction of Use
 - malfunction or damages caused by inappropriate use or use not according to the Instruction of Use
- malfunction or damages caused by act of God