

CERTIFICATE OF ANALYSIS	STEL 3-Lyser 0.5 L
--------------------------------	---------------------------

REF	3802010	0.5 L	X
------------	---------	-------	---

Cont	DIL	X	LOT	38034		2020/04	IVD
-------------	------------	----------	------------	-------	---	---------	------------

PHYSICAL AND CHEMICAL CHARACTERISTICS

TEST		SPECIFICATIONS	RESULT	
Appearance	DIL	Transparent liquid; No precipitation, particles, or floccule	ACCEPTED	X
pH	DIL	6.4 ± 0.2	ACCEPTED	X

(ACCEPTED / N/A)

FUNCTIONALITY

INSTRUMENT	STEL 3
-------------------	---------------

TEST	SPECIFICATIONS	RESULTS
Blank counting	Result of a measurement using Hematology Analyzer, test value should be: White blood cell count(WBC) ≤ 0.3*10 ⁹ /L, Red blood cell count(RBC) ≤ 0.05*10 ¹² /L, Platelet count (PLT) ≤ 10*10 ⁹ /L, Hemoglobinometry (HGB) ≤ 2g/L.	WBC:0 0 0 RBC:0 0 0 PLT:0 0 0 HGB:0 0 0
Wavelength of absorption peak	Wavelength of absorption peak of haemoglobin ramification after erythrolysis by Lyse should not exceed ±10nm of nominal value	537.6
Absorbance Value	At wavelength of 750nm, absorbance value of fresh blood after erythrolysis should not exceed 0.012.	0.010
WBC Histogram	Analyze normal person's fresh blood using hematology analyzer. The WBC histogram should meet the following requirements: 1. Include two group peaks of small and large cells. 2. Should be in accordance with the shape of peak and range of peak position of WBC partition histogram of related hematology analyzer. 3. There should not be interference peak within 35fl	pass

(ACCEPTED / N/A)

This lot was assayed by the test method described in the manufacturer's package insert. These results are applicable to this lot and subsequent sublots, for which a capital letter has been assigned after the lot number.

This Certificate of Analysis is a computer printout and has therefore not been signed by hand.

This lot meets our specifications and is released for sale	APPROVED	Signed Date of Manufacture Mercè Oriol Quality Control Dept. 02 May 2017
---	----------	--

