

EN • CREATININE***In vitro* diagnostic medical device – CE Mark - In compliance with EC Directive 98/79**

Cod. CRS-102: 1 box containing n. 25 test strips; n.1 code chip; n. 30 35 µL capillaries; leaflet.

Manufacturer

Hangzhou Lysun Biotechnology Co., Ltd.

Distributor

Callegari S.r.l.

Intended Use

The CRS-102 test strips allow the quantitative analysis of creatinine in whole blood, plasma, and serum samples. CRS-102 strips are to be used with the Renal Function Analysis Meter RFM-202. CRS-102 strips are intended for professional use.

Test Strip Composition

Creatininase >1.5 U; Creatinase >2 U; Sarcosine Oxidase >0.9 U; Peroxidase >1 U; Ascorbate Oxidase >1.5 U; 4-aminoantipyrine >0.006 mg

Test Strip Preparation and Stability

The test strips are ready to use. When stored at room temperature or in a refrigerator (2-30 °C) in an intact sealed blister, the test strips are stable until the expiry date shown on the pack.

Performance CharacteristicsMeasurement range:

0.044 - 1.320 mmol/L

0.5-14.93 mg/dL

Linearity

Linearity results are presented below.

Lot of test strips	Linear equation	R
Lot 1	$y = 1.0034x - 0.0126$	0.995
Lot 2	$y = 0.9707x + 0.0013$	0.996
Lot 3	$y = 0.9990x + 0.0068$	0.994

Precision

Within-run precision using whole blood specimens statistical analysis gives the mean, standard deviations (SD), and coefficients of variation (CV%) listed below:

Precision	Level 1 (n=20)			Level 2 (n=20)			Level 3 (n=20)		
Lot Number	Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3
Mean (mmol/L)	0.077	0.079	0.076	0.179	0.183	0.181	0.628	0.621	0.636
SD (mmol/L) or %CV	0.005	0.006	0.003	4.47%	5.46%	4.42%	4.14%	4.35%	3.30%

Total precision is listed below:

Total Precision	Level 1 (n=60)	Level 2 (n=60)	Level 3 (n=60)
Lot	Lot 1	Lot 2	Lot 3
Mean (mmol/L)	0.077	0.181	0.628
SD (mmol/L) or %CV	0.005	4.97%	3.98%

Accuracy

The results are compared below:

Specimen	Slope	Intercept	R	N
Venous whole blood	0.9806	0.0053	0.993	100