

Calibration Certificate

DT : 09/01/2024

To,
Redcliffe Lifetech Pvt Ltd.,
SURAT

Dear Sir,
As desired by you please find enclosed herewith Technical calibration report for your Electrolyte Analyzer EC 90 Serial No. 5257-2-202301

Date of Calibration - 09/01/2024

Next Due Date Before- 08/01/2025

Calibration status

1	24V POWER SUPPLY	Ok
2	SLOP EVALUE OF BIOSCENCER	Ok
3	ELECTRODE VALUE	Ok
4	PUMP CAL VALUE	Ok

Calibration of instrument is ok.

Thanking you and assuring of our prompt attention at all times.

Yours faithfully,



For TRANSASIA BIO-MEDICALS LTD.

TRANSASIA BIO-MEDICALS LTD.

Certificate of Analysis

Product name: **EC 90**

Serial No.: **5257-2-202301**

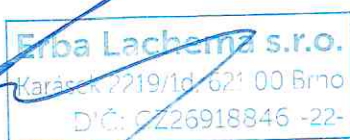
Catalog No.: **INS00079**

Manufacturing Date: **01/2023**

Results of testing

Testing	Limit/criterion	Test results	Remarks
Instrument QC	pass	pass	ok
QC measurements	more than 91,7 % valid	100 %	ok
Conclusive SW check	pass	pass	ok
Completeness	pass	pass	ok

Date: 25.01.2023



Ing. R. Herrmann
Quality Manager

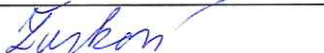
COA_EC 90 _257-2

System QC protocol

EC 90 Analyzer

Serial number of product	5257-2-202301	Manufacturing Date	01/2023
SW version	1.13.3	Test performed by	Žurková
EC cartridge lot	2111140	Test performed at	23.01.2023

No.	Performance content	Limit/Criterion	Sample	Notice	Pass/Fail
1.	Final QC instrument	valid protocol	-	-	✓
Basic QC measurements					
2.	QC measurement performance	less than 8,3% of all values are out of target range	Erba Norm	100 %	✓
3.			Lot:	2203100	
			Erba Path	100 %	✓
Lot:			2203101		
Conclusive system check					
4.	SW check	all tasks could be done per SW, no SW-freeze	-	-	✓
5.	Mechanical check	no mechanical damage detectable	-	-	✓
6.	Put into operation	no additional maintenance for put into operation required	-	-	✓
7.	Closing activities	Cleaning, visual tube check, shutdown	-	-	✓

Disposition	Name	Date	Signature
Pass/Fail	Žurková	23.01.2023	

Serial number:	5257-2-202301
Date:	23.1.2023
Technician	Žurková

Materials	Lot Number
EC cartridge plus iCa	2111140
Elite H Clean	20210906

Kučerka

		QC									
		Na	Result	K	Result	iCa	Result	CI	Result	CI	Result
Erba Norm	1	128,760	OK	4,020	OK	0,799	OK	96,960	OK	96,960	OK
	2	129,430	OK	4,015	OK	0,791	OK	96,500	OK	96,500	OK
	3	127,850	OK	3,962	OK	0,782	OK	97,690	OK	97,690	OK
	4										
	5										
	6										
	7										
	8										
	9										
	Mean	128,760	-	4,015	-	0,791	-	96,960	-	96,960	-

		Na	Result	K	Result	iCa	Result	CI	Result
Erba Path	1	168,230	OK	6,392	OK	1,095	OK	124,310	OK
	2	175,230	OK	6,730	OK	1,127	OK	130,710	OK
	3	177,170	OK	6,778	OK	1,142	OK	130,580	OK
	4								
	5								
	6								
	7								
	8								
	9								
	Mean	175,230	-	6,730	-	1,127	-	130,580	-

Target values									
Control material /lot	Na	range	K	range	iCa	range	CI	range	
Erba Norm/2203100	130	118,0 142	4,04	3,65 4,43	0,82	0,70 0,94	99,4	89,5 109,3	
Erba Path/2203101	174	156 192	6,64	5,98 7,30	1,11	0,93 1,29	130	118 142	

Requirement	8,3% of all QC measurement can be out of the range	
Material	Erba Norm	Erba Path
Values OotR	0	0
Total measur. %	12	12
	0,0	0,0
Result	OK	

Erba[®]
Mannheim

EC 90

QC PROTOCOL

SN: 05257 SW: v1.13.3

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22/02/2024 01:29 PM

TEST#: 000049

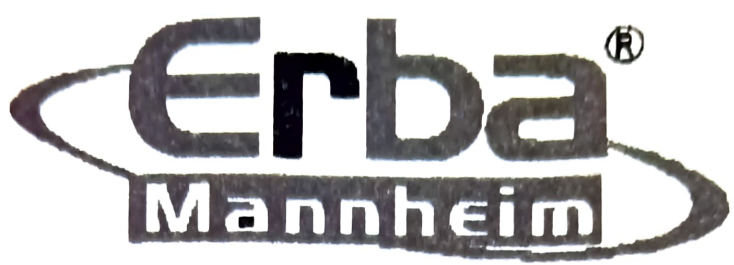
TYPE: Plasma/Serum

LEVEL: 1

LOT: S022358

Na: 138.7 mmol/l OK
[122.0 - 152.0]
K: 4.35 mmol/l OK
[3.75 - 4.59]
Cl: 109.3 mmol/l OK
[92.0 - 110.0]





EC 90

QC PROTOCOL

SN 05257 SW: v1.13.3

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22/02/2024 01:27 PM

TEST#: 000048

TYPE: Plasma/Serum

LEVEL: 2

LOT: S022359

Na: 193.8 mmol/l OK
[162.0 - 198.0]

K: 7.56 mmol/l OK
[6.21 - 7.59]

Cl: 136.6 mmol/l OK
[120.0 - 144.0]