

# ScoutPro

Osmolarity System

## Osmolarity Testing CLIA Log Book



**Trukera**<sup>™</sup>  
MEDICAL

## Congratulations.

Your ScoutPro Osmolarity System is almost ready to be used. The ScoutPro Osmolarity System, categorized under the Clinical Laboratory Improvement Amendments (CLIA) as waived, is fully automated and not operator dependent. However, there are certain requirements to ensure that your device continues to operate at peak efficiency.

This binder will provide instructions and the data sheets necessary to log your quality test results, in accordance with CLIA requirements. Use these sheets as the Master to log your information. Please make copies of the Daily QC, Monthly QC and Received Test Cards QC logs and follow the instructions below.

The Blue Electronic Check Card should be used to test the ScoutPro Pen before each day of patient testing. The Blue Electronic Check Card is used to confirm the function and calibration of the ScoutPro Osmolarity System. Record all results on the Daily Quality Control Log.

Good laboratory practice requires the use of Normal and High Osmolarity Control Solutions to ensure that the Test Cards are functioning properly. Normal and High Osmolarity Control Solutions should be tested once per month, with each lot number of Test Cards, or when a new shipment is received, even if it is of the same lot number as that of Test Cards received previously. Record all test results on either the Monthly Quality Control Log or the Received Test Cards Quality Control Log.

If you have any questions regarding this binder, please contact Trukera Medical.

Tel: (855) 832-7522 or (858) 455-6006  
42309 Winchester Road, Suite I  
Temecula, CA 92590

Clinic Name: \_\_\_\_\_

Trainee Name	Trainer Name	Completed Training Date

### ScoutPro operators are to be competent in all of the following:

#### Set Up

- AAA rechargeable batteries installed in ScoutPro Pen
- Charger Base plugged into electrical outlet
- ScoutPro Pen docked in Charger Base and battery icon displayed

#### Tear Collection

- Proper insertion of Test Card onto Pen
- Proper removal of Test Card cover
- Input of numeric Test Card code into Pen
- Successful collection of tear sample
- Obtain test results and previous test results in memory
- Removal of Test Card from Pen and disposal

#### Quality Control - Electronic Check Card

- ECC Testing
- Daily QC Log

#### Quality Control - Control Solutions

- Control Solution Testing - Normal and High Control Solutions
- Completion of Monthly and Received Test Card Shipment QC Logs

# QUALITY CONTROL LOG

CLIA WAIVER

DAILY

# ScoutPro

Osmolarity System

Use the blue Electronic Check Cards (ECC) each day of patient testing to test the ScoutPro Osmolarity System. Record the results in the table below. Follow instructions in the Trukera Medical Quick Reference Guide. Call Trukera at (858) 455-6006 if testing fails.

ScoutPro Serial Number	Electronic Check Card (ECC) Expected Range	Optimal Room Temperature*
	331 - 337 mOsm/L	20 - 25 C 68 - 77 F

Date	Operator ID	ECC Record Test Result	Date	Operator ID	ECC Record Test Result
3/11/2024	KAP	334 mOsm/L <input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail			_____ mOsm/L <input type="checkbox"/> Pass <input type="checkbox"/> Fail
		_____ mOsm/L <input type="checkbox"/> Pass <input type="checkbox"/> Fail			_____ mOsm/L <input type="checkbox"/> Pass <input type="checkbox"/> Fail
		_____ mOsm/L <input type="checkbox"/> Pass <input type="checkbox"/> Fail			_____ mOsm/L <input type="checkbox"/> Pass <input type="checkbox"/> Fail
		_____ mOsm/L <input type="checkbox"/> Pass <input type="checkbox"/> Fail			_____ mOsm/L <input type="checkbox"/> Pass <input type="checkbox"/> Fail
		_____ mOsm/L <input type="checkbox"/> Pass <input type="checkbox"/> Fail			_____ mOsm/L <input type="checkbox"/> Pass <input type="checkbox"/> Fail
		_____ mOsm/L <input type="checkbox"/> Pass <input type="checkbox"/> Fail			_____ mOsm/L <input type="checkbox"/> Pass <input type="checkbox"/> Fail
		_____ mOsm/L <input type="checkbox"/> Pass <input type="checkbox"/> Fail			_____ mOsm/L <input type="checkbox"/> Pass <input type="checkbox"/> Fail
		_____ mOsm/L <input type="checkbox"/> Pass <input type="checkbox"/> Fail			_____ mOsm/L <input type="checkbox"/> Pass <input type="checkbox"/> Fail
		_____ mOsm/L <input type="checkbox"/> Pass <input type="checkbox"/> Fail			_____ mOsm/L <input type="checkbox"/> Pass <input type="checkbox"/> Fail
		_____ mOsm/L <input type="checkbox"/> Pass <input type="checkbox"/> Fail			_____ mOsm/L <input type="checkbox"/> Pass <input type="checkbox"/> Fail

<b>*FDA Labeling</b>	Room Temperature
<b>Allowed</b>	15 - 30°C, 59 - 86°F
<b>Transport and Storage</b>	Controlled Room 20 - 25°C, 68 - 77°F
	Excursions Permitted to 15 - 30°C, 59 - 86°F

# QUALITY CONTROL LOG

CLIA WAIVER  
MONTHLY

# ScoutPro

Osmolarity System

Normal and High Osmolarity Control Solutions are to be tested on each ScoutPro Osmolarity System once per month. Record test results below. Follow instructions in the ScoutPro Quick Reference Guide. Call Trukera Medical at (858) 455-6006 if testing falls outside of range.

ScoutPro Serial Number	Normal Control Solution Lot # and Expiration Date	High Control Solution Lot # and Expiration Date

Electronic Check Card (ECC) Expected Range	Normal Control Solution* Optimal Range	High Control Solution* Optimal Range
331 - 337 mOsm/L	288 - 305 mOsm/L	330 - 346 mOsm/L

Date	Operator ID	Electronic Check Card	Test Card Lot No. & Expiration Date	Normal Control Solution	High Control Solution
3/11/2024	KAP	334 mOsm/L <input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	00001630 Sep 2026	300 mOsm/L <input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	341 mOsm/L <input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
		_____ mOsm/L <input type="checkbox"/> Pass <input type="checkbox"/> Fail		_____ mOsm/L <input type="checkbox"/> Pass <input type="checkbox"/> Fail	_____ mOsm/L <input type="checkbox"/> Pass <input type="checkbox"/> Fail
		_____ mOsm/L <input type="checkbox"/> Pass <input type="checkbox"/> Fail		_____ mOsm/L <input type="checkbox"/> Pass <input type="checkbox"/> Fail	_____ mOsm/L <input type="checkbox"/> Pass <input type="checkbox"/> Fail
		_____ mOsm/L <input type="checkbox"/> Pass <input type="checkbox"/> Fail		_____ mOsm/L <input type="checkbox"/> Pass <input type="checkbox"/> Fail	_____ mOsm/L <input type="checkbox"/> Pass <input type="checkbox"/> Fail
		_____ mOsm/L <input type="checkbox"/> Pass <input type="checkbox"/> Fail		_____ mOsm/L <input type="checkbox"/> Pass <input type="checkbox"/> Fail	_____ mOsm/L <input type="checkbox"/> Pass <input type="checkbox"/> Fail
		_____ mOsm/L <input type="checkbox"/> Pass <input type="checkbox"/> Fail		_____ mOsm/L <input type="checkbox"/> Pass <input type="checkbox"/> Fail	_____ mOsm/L <input type="checkbox"/> Pass <input type="checkbox"/> Fail
		_____ mOsm/L <input type="checkbox"/> Pass <input type="checkbox"/> Fail		_____ mOsm/L <input type="checkbox"/> Pass <input type="checkbox"/> Fail	_____ mOsm/L <input type="checkbox"/> Pass <input type="checkbox"/> Fail
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		_____ mOsm/L <input type="checkbox"/> Pass <input type="checkbox"/> Fail		_____ mOsm/L <input type="checkbox"/> Pass <input type="checkbox"/> Fail	_____ mOsm/L <input type="checkbox"/> Pass <input type="checkbox"/> Fail

*FDA Labeling	Expected	Ranges
Normal Control Solution	297 mOsm/L	282 - 312 mOsm/L
High Control Solution	338 mOsm/L	323 - 353 mOsm/L

# QUALITY CONTROL LOG

CLIA WAIVER

**TEST CARDS RECEIVED**

# ScoutPro

Osmolarity System

Normal and High Osmolarity Control Solutions are to be tested with each new lot number of Test Cards or when a new shipment of Test Cards is received, even if it is the same lot number as Test Cards received previously. Follow instructions in the ScoutPro Quick Reference Guide. Call Trukera Medical at (858) 455-6006 if testing falls outside of range.

Electronic Check Card (ECC) Expected Range	Normal Control Solution* Optimal Range	High Control Solution* Optimal Range
331 - 337 mOsm/L	288 - 305 mOsm/L	330 - 346 mOsm/L

Date	Operator ID	ScoutPro Serial Number	Test Card Lot No. & Expiration Date	Normal Control Solution	High Control Solution
3/11/2024	KAP	0110060001238	00001630 Sep 2026	<u>300</u> mOsm/L <input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	<u>341</u> mOsm/L <input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
				_____ mOsm/L <input type="checkbox"/> Pass <input type="checkbox"/> Fail	_____ mOsm/L <input type="checkbox"/> Pass <input type="checkbox"/> Fail
				_____ mOsm/L <input type="checkbox"/> Pass <input type="checkbox"/> Fail	_____ mOsm/L <input type="checkbox"/> Pass <input type="checkbox"/> Fail
				_____ mOsm/L <input type="checkbox"/> Pass <input type="checkbox"/> Fail	_____ mOsm/L <input type="checkbox"/> Pass <input type="checkbox"/> Fail
				_____ mOsm/L <input type="checkbox"/> Pass <input type="checkbox"/> Fail	_____ mOsm/L <input type="checkbox"/> Pass <input type="checkbox"/> Fail
				_____ mOsm/L <input type="checkbox"/> Pass <input type="checkbox"/> Fail	_____ mOsm/L <input type="checkbox"/> Pass <input type="checkbox"/> Fail
				_____ mOsm/L <input type="checkbox"/> Pass <input type="checkbox"/> Fail	_____ mOsm/L <input type="checkbox"/> Pass <input type="checkbox"/> Fail
				_____ mOsm/L <input type="checkbox"/> Pass <input type="checkbox"/> Fail	_____ mOsm/L <input type="checkbox"/> Pass <input type="checkbox"/> Fail
				_____ mOsm/L <input type="checkbox"/> Pass <input type="checkbox"/> Fail	_____ mOsm/L <input type="checkbox"/> Pass <input type="checkbox"/> Fail
				_____ mOsm/L <input type="checkbox"/> Pass <input type="checkbox"/> Fail	_____ mOsm/L <input type="checkbox"/> Pass <input type="checkbox"/> Fail

*FDA Labeling	Expected	Ranges
Normal Control Solution	297 mOsm/L	282 - 312 mOsm/L
High Control Solution	338 mOsm/L	323 - 353 mOsm/L

# ERROR LOG

## CLIA WAIVER

Please record any error code (ER or BR) displayed by the ScoutPro when performing a patient or quality control test. Repeat the test with a new Test Card, and if the error persists, contact Trukera Medical Technical Support at (855) 832-7522 x1 or technicalsupport@trukera.com.

Test cards recorded on the Error Log will be replaced free of charge 40 at a time.

No.	Date	Error Code	Pen Serial No. (last 4 digits)	Operator ID	No.	Date	Error Code	Pen Serial No. (last 4 digits)	Operator ID
1					21				
2					22				
3					23				
4					24				
5					25				
6					26				
7					27				
8					28				
9					29				
10					30				
11					31				
12					32				
13					33				
14					34				
15					35				
16					36				
17					37				
18					38				
19					39				
20					40				

<b>Practice Name</b>	
<b>Customer Signature</b>	
<b>Customer Printed Name</b>	
<b>Date Submitted</b>	

<b>FOR INTERNAL USE ONLY</b>	
Rep Name	_____
Rep Signature	_____
Date Processed	_____