

ScoutPro™

Osmolarity System

PORTABLE ♦ PRACTICAL ♦ PRECISE

Osmolarity Testing CLIA Log Book



BAUSCH+LOMB

See better. Live better.

CLIA REQUIREMENTS

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 your Bausch + Lomb representative.

QUALITY CONTROL LOG

CLIA Waiver

DAILY

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Osmolarity System

by Bausch + Lomb

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 Medical Quick Reference Guide. Call Bausch + Lomb at (800) 338-2020 if testing fails.

ScoutPro Serial Number	Electronic Check Card (ECC) Expected Range	Optimal Room Temperature for Testing
	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	KAD	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
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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			_____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
		_____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

QUALITY CONTROL LOG

CLIA Waiver

MONTHLY

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Osmolarity System

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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 Bausch + Lomb at (800) 338-2020 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	ECC Record Test Result	Test Card Lot No. & Expiration Date	Normal Solution Control	High Solution Control
3/11/2024	KAD	<u>334</u> mOsm/L <input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	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
		_____ 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

QUALITY CONTROL LOG

CLIA Waiver

TEST CARDS RECEIVED

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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 Bausch + Lomb at (800) 338-2020 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 No.	Test Card Lot No. & Expiration Date	Normal Solution Control	High Solution Control
3/11/2024	KAD		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
				_____ 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

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 Bausch + Lomb at (800) 338-2020.

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				

Practice Name	
Customer Signature	
Customer Printed Name	
Date Submitted	

FOR INTERNAL USE ONLY
Rep Name _____
Rep Signature _____
Date Processed _____