Physician Office Laboratory CLIA Manual (Waived)

PLEASE READ AND KEEP THIS IMPORTANT MANUAL





Congratulations.

Your TearLab® Osmolarity System is almost ready to be used. The TearLab 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 Forms to log your information. Please make copies of the Daily QC, Monthly QC and Received Test Cards QC logs and follow the below instructions.

The Blue Electronic Check Card should be used to test each pen before each day of patient testing. The Blue Electronic Check Cards is used to confirm the function and calibration of the TearLab Osmolarity System. The Electronic Check Cards can be used simultaneously for quality control testing, one with each pen. Record all results on the Daily Quality Control Log.

Good laboratory practice suggests the use of Normal and High Osmolarity Control Solutions to ensure that the TearLab Test Cards are functioning properly. Normal and High Osmolarity Control Solutions should be tested once per month or 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 results of testing either on the Monthly Quality Control Log or the Received Test Cards Quality Control Log.

If you have any questions regarding this binder, please contact Tearlab Corporation.

Tel: 855 TearLab (855-832-7522) or 858-455-6006 9980 Huennekens St., Suite 100 San Diego, CA 92121



DAILY - TearLab Quality Control Log - CLIA Waiver

TearLab Osmolarity System Serial Number:	Electronic Check Card (ECC) Range to Pass	Optimal Room Temperature*	
	331 – 337 mOsms/L	20-25C/68-77F	

Use the blue Electronic Check Cards (ECC) each day of patient testing to test the TearLab Osmolarity System. Record the test results and daily room temperature in the table below. Follow instructions in the TearLab Quick Reference Guide. Call TearLab at (858) 455-6006 if testing falls outside of range.

	Operator		ECC Pen 1	ECC Pen 2		Oneveter		ECC Pen 1	ECC Pen 2
Date	ID	Room Temp	Record Test Result	Record Test Result	Date	Operator ID	Room Temp	Record Test Result	Record Test Result
Example	RAW	72°	334	335					
4-12-2013	ZHW	12	☐ Pass ☐ Fail	☐ Pass ☐ Fail				☐ Pass ☐ Fail	☐ Pass ☐ Fail
			☐ Pass ☐ Fail	☐ Pass ☐ Fail				☐ Pass ☐ Fail	☐ Pass ☐ Fail
			Pass Fail	☐ Pass ☐ Fail				☐ Pass ☐ Fail	☐ Pass ☐ Fail
			Pass Fail	☐ Pass ☐ Fail				Pass Fail	☐ Pass ☐ Fail
			Pass Fail	☐ Pass ☐ Fail				Pass Fail	Pass Fail
			Pass Fail	Pass Fail				Pass Fail	Pass Fail
			Pass Fail	Pass Fail				Pass Fail	Pass Fail
			□ p □ □ = ::	□ p □ □ -:				□ p □ □ -::	□ p □ r-:
			Pass Fail	Pass Fail				Pass Fail	Pass Fail
			☐ Pass ☐ Fail	☐ Pass ☐ Fail				☐ Pass ☐ Fail	☐ Pass ☐ Fail
			L Fass L Fall	rassran				L Fass L Fall	L rass Liaii
			Pass Fail	Pass Fail				☐ Pass ☐ Fail	☐ Pass ☐ Fail
			☐ Pass ☐ Fail	☐ Pass ☐ Fail				☐ Pass ☐ Fail	☐ Pass ☐ Fail
			☐ Pass ☐ Fail	☐ Pass ☐ Fail				☐ Pass ☐ Fail	☐ Pass ☐ Fail
			☐ Pass ☐ Fail	☐ Pass ☐ Fail				☐ Pass ☐ Fail	☐ Pass ☐ Fail
			☐ Pass ☐ Fail	☐ Pass ☐ Fail				☐ Pass ☐ Fail	☐ Pass ☐ Fail
*FDA Lab	eling Values		Room Tempera	ature]				
	Allowed		15°-30°C / 59°-						
Transpor	rt and Storage	Cor	ntrolled Room 20°-25						
	rt and Storage		ions Permitted To 15	-					

MONTHLY - TearLab Quality Control Log - CLIA Waiver

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

TearLab Osmolarity System Serial Number:		Normal Control Solution Lot # / Expiration Date:		High Control Solution Lot # / Expiration Date:		
	onic Check Ca Expected Ran		Normal Contro Optimal R		High Control Optimal	
3	31–337 mOsr	ns/L	289-305 m(Osms/L	330-346 mOsms/L	
Date	Operator ID	ECC Pen 1	ECC Pen 2	Test Card Lot Number/ Expiration Date	Normal Control	High Control
Example	D.Mu	334	335	00000242	297 mOsms/L	338 mOsms/L
4-12-2013	RAW	Pass Fail	Pass Fail	3 31 2014	Pass Fail	Pass Fail
					mOsms/L	mOsms/L
		Pass Fail	Pass Fail		Pass Fail	Pass Fail
					mOsms/L	mOsms/L
		Pass Fail	Pass Fail		Pass Fail	Pass Fail
					mOsms/L	mOsms/L
		Pass Fail	Pass Fail		Pass Fail	Pass Fail
					mOsms/L	mOsms/L
		Pass Fail	Pass Fail		Pass Fail	Pass Fail
					mOsms/L	mOsms/L
		Pass Fail	Pass Fail		Pass Fail	Pass Fail
					mOsms/L	mOsms/L
		Pass Fail	Pass Fail		Pass Fail	Pass Fail
					mOsms/L	mOsms/L
		Pass Fail	Pass Fail		Pass Fail	Pass Fail
					mOsms/L	mOsms/L
		Pass Fail	Pass Fail		Pass Fail	Pass Fail
					mOsms/L	mOsms/L
		Pass Fail	Pass Fail		Pass Fail	Pass Fail
					mOsms/L	mOsms/L
		Pass Fail	Pass Fail		Pass Fail	Pass Fail
					mOsms/L	mOsms/L
		Pass Fail	Pass Fail		Pass Fail	Pass Fail
					•	
*FDA Lab	eling Values	Expected	Value Expected Rang	ges		
	Normal	297 mOsms/L	282 — 312 mOsms/L			
1	High	338 mOsms/L	323 — 353 mOsms/L			



RECEIVED TEST CARD'S Q.C.

TearLab Quality Control Log – CLIA Waiver

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 of the same lot number as that of Test Cards received previously. Record test results below. Follow instructions in the TearLab Quick Reference Guide. Call TearLab at (858) 455-6006 if testing falls outside of range.

Electronic Check Card (ECC)	Normal Control Solution*	High Control Solution*
Expected Range:	Optimal Range:	Optimal Range:
331–337 mOsms/L	289-305 mOsms/L	330-346 mOsms/L

Date	Operator ID	TearLab Osmolarity System Serial Number	Test Card Lot Number/ Expiration Date	Test Card Code	Normal Control	High Control
Example	RAW	0110060001238	00000238	5	300 mOsms/L	<i>34</i> 1 mOsms/L
4-12-2013	2700	0110000001258	2 28 2014		Pass Fail	Pass Fail
					mOsms/L	mOsms/L
					Pass Fail	Pass Fail
					mOsms/L	mOsms/L
					Pass Fail	Pass Fail
					mOsms/L	mOsms/L
					Pass Fail	Pass Fail
					mOsms/L	mOsms/L
					Pass Fail	Pass Fail
					mOsms/L	mOsms/L
					Pass Fail	Pass Fail
					mOsms/L	mOsms/L
					Pass Fail	Pass Fail
					mOsms/L	mOsms/L
					Pass Fail	Pass Fail
					mOsms/L	mOsms/L
					Pass Fail	Pass Fail
					mOsms/L	mOsms/L
					Pass Fail	Pass Fail
					mOsms/L	mOsms/L
					Pass Fail	Pass Fail
					mOsms/L	mOsms/L
					Pass Fail	Pass Fail
					mOsms/L	mOsms/L
					Pass Fail	Pass Fail
					mOsms/L	mOsms/L
					Pass Fail	Pass Fail

*FDA Labeling Values	Expected	Value Expected Ranges
Normal	297 mOsms/L	282 — 312 mOsms/L
High	338 mOsms/L	323 — 353 mOsms/L



OPERATOR TRAINING LOG – CLIA Waiver

TRAINEE NAME	TRAINER NAME	DATE

TearLab operators are to be competent in all of the following:

Set Up:

Reader plugged-in and left on 24/7 Pens docked in cradles and battery icon displayed Set to local time and language

Quality Control - Electronic Check Card:

ECC Testing Daily QC Log

Quality Control - Control Solutions

Control Solution Testing
Completion of Monthly and New Shipment QC Log

Tear Collection

Proper insertion of Test Card onto Pen Proper removal of Test Card cover Successful collection of tear sample Input numeric Test Card code into Reader Obtained test result

