

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 mOsm/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.

Date	Operator ID	Room Temp	ECC Pen 1 Record Test Result	ECC Pen 2 Record Test Result	Date	Operator ID	Room Temp	ECC Pen 1 Record Test Result	ECC Pen 2 Record Test Result
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*FDA Labeling Values	Room Temperature
Allowed	15°-30°C / 59°-86°F
Transport and Storage	Controlled Room 20°-25°C / 68°-77°F
Transport and Storage	Excursions Permitted To 15°-30°C / 59°-86°F

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:

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

Date	Operator ID	ECC Pen 1	ECC Pen 2	Test Card Lot Number/ Expiration Date	Normal Control	High Control
Example 4-12-2013	RAW	334	335	00000242 3/31/2014	297 mOsm/L	338 mOsm/L
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*FDA Labeling Values	Expected	Value Expected Ranges
Normal	297 mOsm/L	282 – 312 mOsm/L
High	338 mOsm/L	323 – 353 mOsm/L

