

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
		<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail		<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
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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