

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) Expected Range:	Normal Control Solution* Optimal Range:	High Control Solution* 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 4-12-2013	RAW	0110060001238	00000238 2/28/2014	5	300 mOsms/L	341 mOsms/L
					<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
					mOsms/L	mOsms/L
					<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
					mOsms/L	mOsms/L
					<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
					mOsms/L	mOsms/L
					<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
					mOsms/L	mOsms/L
					<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
					mOsms/L	mOsms/L
					<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
					mOsms/L	mOsms/L
					<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
					mOsms/L	mOsms/L
					<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
					mOsms/L	mOsms/L
					<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
					mOsms/L	mOsms/L
					<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
					mOsms/L	mOsms/L
					<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
					mOsms/L	mOsms/L
					<input type="checkbox"/> Pass <input type="checkbox"/> Fail	<input type="checkbox"/> Pass <input type="checkbox"/> Fail

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