

TEARLAB - Quality Control Log – Each Box

The High Osmolarity Control Solution is to be used to quality check the Test Cards whenever a new box of Test Cards is opened. Each box contains two free Test Cards which are to be used for quality control testing. Follow the directions in the TearLab Quick Reference Guide. Contact your distributor or TearLab immediately if the testing results fall outside the expected range and do NOT perform patient testing

| TearLab Osmolarity System Serial Number: | High Control Solution Lot Number/Expiration Date: | Electronic Check Card (ECC) Expected Range: | High Control Solution* Optimal Range: |
|--|---|---|---------------------------------------|
| | | 331-337 mOsm/L | 330-346 mOsm/L |

| Date | Operator ID | Raum Temp. | ECC Pen 1 | ECC Pen 2 | Test Card Code | Test Card Lot. Nr. Exp. Date | High control Pen 1 | High Control Pen 2 |
|------|-------------|------------|---|---|----------------|------------------------------|---|---|
| | | | 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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| | *Variance from Expected High Control Solution | Comment |
|------------------------|---|---|
| TearLab Recommended | +/- 8 mOsm/L of 338 mOsm/L | Optimal Performance |
| FDA/CE Labeling Values | +/- 15 mOsm/L of 338 mOsm/L | FDA/CE acceptable variance - but contact TearLab if variance > 8 mOsm/L |

| | **Controlled Room Temperature |
|------------------------|-------------------------------|
| FDA/CE Labeling Values | 20° - 25°C |
| | |

To qualify for FREE high QC solutions, email a mobile phone photo of this QC Log each quarter to: info@medilas.ch IPORANT: Do not forget to write in your contact details.

Clinic / Doctor Name : _____ City : _____

Email : _____ Date : _____