

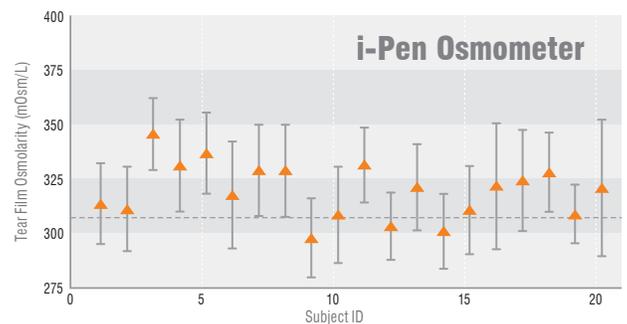
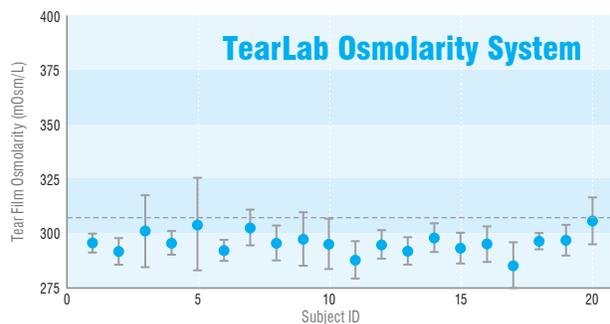
# Why TearLab®

## Proven Accuracy and Precision<sup>1</sup>

- In a recently published peer-reviewed article, 20 healthy adults with healthy ocular surfaces were evaluated (low OSDI score (<5), normal TBUT (TBUT>10 OU) and no evidence of fluorescein staining in either eye.)
- Five consecutive, bilateral measurements were taken from each subject according to the manufacturers' instructions for use, i.e. *in vivo* for the i-Pen, for a total of 200 measurements per device.

|  | <b>TearLab®</b>  | <b>i-Pen*</b>     |
|--|------------------|-------------------|
| Average osmolarity   | 295.4±8.6 mOsm/L | 319.4±20.3 mOsm/L |
| % of measurements in normal range (≤308 mOsm/L)<br><i>(200 individual measurements per device)</i> | 90.9%            | 37.5%             |
| % of subjects in normal range (≤308 mOsm/L)<br><i>(When measurements grouped by patient)</i>       | 100%             | 15%               |

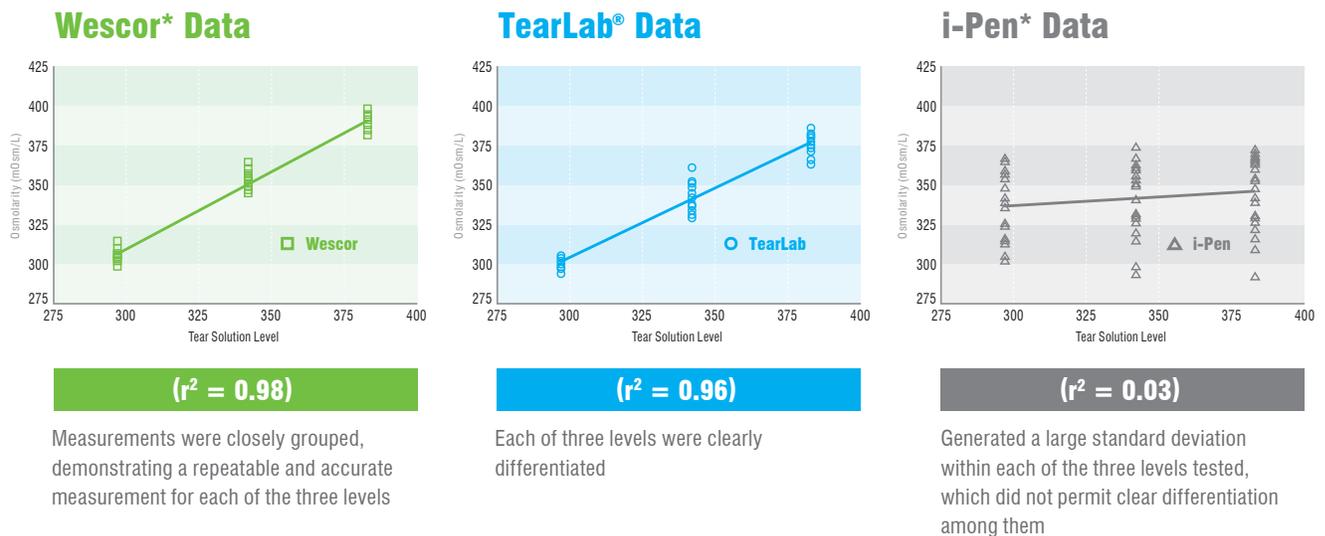
### Tear Osmolarity in each Subject<sup>1</sup>



- TearLab was able to reproduce the expected distribution of normal patients.
- i-Pen was unable to differentiate the cohort of normal subjects from data frequently observed in moderate to severe dry eye patients.
- i-Pen produced random values across the physiological range of tear osmolarity, and lacked sufficient performance to delineate subjects with and without dry eye disease in the clinical setting.

# Osmometer Performance Comparison<sup>2</sup>

- Randomized, masked study compared varying levels of contrived tear solution (297 mOsm/L, 342 mOsm/L, 383 mOsm/L) representing the physiologic range across three osmometers, including a Wescor vapor pressure reference laboratory osmometer.
- Manufacturers' recommended procedures, including sample collection and calibration, were followed for each device.



- TearLab and Wescor performed similarly in their ability to accurately and precisely delineate the osmolarity of contrived tear solutions of known target values
- i-Pen demonstrated insufficient performance to precisely identify and delineate different osmolarity levels within the physiological range

## Proven Point-of-Care Technology

- ISO 13485 and Good Clinical Laboratory Practice (GCLP) standards require that a quality control program must be in place when utilizing a diagnostic medical device or laboratory testing. They assure the accuracy and reliability of test results, particularly if the data are used for patient management or product advancement decisions.<sup>3-6</sup>
- TearLab utilizes a temperature-corrected impedance measurement to accurately assess osmolarity. Temperature compensation is important since measurements are strongly affected by the temperature of the sample.<sup>7-8</sup>
  - Temperature variations in the conjunctiva can be from 31° C to 37° C. For every degree temperature change, the measurement of impedance changes ~2%.

### REFERENCES

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