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.

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.

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

Tear Osmolarity in each Subject

TearLab was able to reproduce the expected distribution of normal patients.

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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

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.

Wescor* Data

TearLab® Data

i-Pen* Data

Measurements were closely grouped, demonstrating a repeatable and accurate measurement for each of the three levels

Each of three levels were clearly differentiated

Generated a large standard deviation within each of the three levels tested, which did not permit clear differentiation among them

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 and accurately 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.

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.

- 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

5. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2213906/

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Distributed by:
IQ Medical Pty Ltd
2/86 Mary Street, Unley SA 5061
Phone (08) 8357 8022
Email sales@iqmedical.com.au
Web www.iqmedical.com.au