Effect of reducing the cut-off concentration for opioids in oral fluid screening

Margaux Garnier*, Cynthia Coulter, Christine Moore
Immunalysis Corporation, Pomona, CA, U.S.A.

Introduction

• Opiate and oxycodone ELISA screening data from oral fluid samples received into our laboratory were reexamined.
• Samples that fell between the cut-off concentration (40µg/L) and the low positive control (20µg/L) were extracted and analyzed for codeine (COD), morphine (MOR), hydrocodone (HYC), hydromorphone (HYM), oxycodone (OXYC), oxymorphone (OXYM), 6-acetylcodine (6-AC), and 6-acetylmorphine (6-AM) using LC-MS/MS.

Methods

• Data from opiate and oxycodone ELISA screens from oral fluid samples were retrospectively analyzed.
• Specimens that screened between the cut-off concentration and the low positive control (LPC) were noted and were analyzed using LC-MS/MS.
• Specimens which confirmed > 4µg/L were considered positive.

Results

• Of all the opioids analyzed, morphine had the highest percentage increase in positive results of 50%.
• Four more samples confirmed for codeine, ranging between 11.9 and 33.0µg/L, increasing its positivity rate to 36.3%.
• Twenty samples were positive for hydrocodone which displayed a rise of 27.4%.
• Oxycodone showed the least increase with nine samples confirming positively (16.0% increase).
• Analyzing specimens below the 20µg/L concentration resulted in six more oral fluid specimens being identified for 6-AM as well as more positives for codeine and morphine.

Objective

• To analyze these previously screened negative samples in order to indicate the number that may confirm positively for opioids if the cut-off concentrations for both screening and confirmation were reduced.

Data Summary

<table>
<thead>
<tr>
<th>Opiate</th>
<th>HYC</th>
<th>OXYC</th>
<th>COD</th>
<th>6-AM</th>
<th>MOR</th>
<th>HYM</th>
<th>Total # Opiate Positives</th>
</tr>
</thead>
<tbody>
<tr>
<td>LPC ≤ x ≤ cut-off</td>
<td>73</td>
<td>56</td>
<td>11</td>
<td>10</td>
<td>4</td>
<td>2</td>
<td>156</td>
</tr>
<tr>
<td>4ug/L confirm</td>
<td>20</td>
<td>9</td>
<td>4</td>
<td>0</td>
<td>2</td>
<td>0</td>
<td>35</td>
</tr>
<tr>
<td>% increase</td>
<td>27.4</td>
<td>47.5</td>
<td>8.9</td>
<td>0.0</td>
<td>25</td>
<td>0.0</td>
<td>22.2</td>
</tr>
<tr>
<td>LPC ≤ x ≤ cut-off 20ug/L confirm</td>
<td>15</td>
<td>5</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>22</td>
</tr>
<tr>
<td>% increase</td>
<td>20</td>
<td>5.6</td>
<td>0.0</td>
<td>5.0</td>
<td>0.0</td>
<td>0.0</td>
<td>14.1</td>
</tr>
</tbody>
</table>

Conclusion

• Since oral fluid serves as a good matrix in identifying users of pain management drugs, it is imperative that we use this to our advantage in distinguishing users from non-users. If the cut-off is too high, it may produce false negative results.
• A reduction in the cut-off concentration for both screening (from 40µg/L to 20µg/L) and confirmation of opioids in oral fluid should be considered to increase the number of true opioid positives detected.

SOFT, San Francisco, 2011