The LumiraDx Platform INR Test: Performance and ease of use in an anticoagulation clinic setting

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The LumiraDx Platform INR Test provides reliable INR monitoring when used by healthcare professionals at the point of care.

BACKGROUND

• Patients treated with vitamin K antagonist therapy require regular monitoring of international normalized ratio (INR) to maintain optimal anticoagulation.
• The LumiraDx Platform is a new point-of-care in vitro diagnostic system that enables INR testing using fingerstick capillary blood samples.

AIM

• To evaluate the accuracy, precision and ease of use of the LumiraDx Platform INR Test.

METHODS

• The LumiraDx INR Test is an assay in which emitted fluorescence reflects the degree of thrombin activation.
• Precision was assessed by correlating paired replicate samples from three Test Strip Lots in multiple clinic sites.
• Accuracy was determined by comparing LumiraDx INR Test results with INR measured by a laboratory reference method, the ACL Elite Pro.
• Feedback was collected from healthcare professionals via a questionnaire.

RESULTS

• Mean paired replicate precision of the LumiraDx INR Test results (% coefficient of variation) was <4.0 when paired samples were applied by either direct application or via a capillary transfer pipette.
• The LumiraDx INR results showed a strong correlation (r = 0.965) with the laboratory reference method.
• User feedback indicated that the instructions given by the LumiraDx system were easy to follow.

SUMMARY/CONCLUSION

• The LumiraDx Platform INR Test is capable of providing accurate and reliable INR analysis.

Demographic data of recruited individuals

<table>
<thead>
<tr>
<th>VKA</th>
<th>n</th>
<th>Mean Age (years)</th>
<th>INR (laboratory reference method)</th>
<th>Mean INR</th>
<th>Mean CV (%)</th>
<th>1st Quartile</th>
<th>Median</th>
<th>3rd Quartile</th>
<th>INR max</th>
</tr>
</thead>
<tbody>
<tr>
<td>Warfarin</td>
<td>340 (F=146; M=194)</td>
<td>71</td>
<td>30</td>
<td>94</td>
<td>2.48</td>
<td>2.07</td>
<td>3.02</td>
<td>7.51</td>
<td></td>
</tr>
<tr>
<td>No therapy</td>
<td>26 (F=17; M=9)</td>
<td>53</td>
<td>29</td>
<td>81</td>
<td>0.92</td>
<td>0.90</td>
<td>0.94</td>
<td>1.03</td>
<td></td>
</tr>
</tbody>
</table>

F, female; INR, international normalized ratio; M, male; n, number of patients; VKA, vitamin K antagonist

Precision of INR measurements of samples directly applied to the test strip or by transfer pipette, using three test strip lots

<table>
<thead>
<tr>
<th>Lot</th>
<th>Direct application</th>
<th>Transfer pipette</th>
<th>Combined</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>Mean INR</td>
<td>Mean CV (%)</td>
</tr>
<tr>
<td>5000003</td>
<td>85</td>
<td>2.396</td>
<td>3.19</td>
</tr>
<tr>
<td>5000004</td>
<td>108</td>
<td>2.667</td>
<td>3.81</td>
</tr>
<tr>
<td>5000006</td>
<td>91</td>
<td>2.518</td>
<td>3.30</td>
</tr>
<tr>
<td>All</td>
<td>284</td>
<td>2.538</td>
<td>3.46</td>
</tr>
</tbody>
</table>

CV, coefficient of variation; INR, international normalized ratio; n, number of duplicate capillary blood samples.

Method comparison of INR measurements of samples directly applied to the test strip

y = 0.967x - 0.001
Slp CI (0.945, 0.990)
Int CI (-0.060, 0.054)
r = 0.965

ACL ELITE Pro, IL ACL Elite Pro (Instrumentation Laboratory; Bedford, MA, USA); Int CI, intercept confidence interval; Slp CI, slope confidence interval.

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