

Further guidance for the management of high or out-of-range INR result

We have been made aware that there have been occurrences where some patients with a high or out-of-range INR measured using a point of care capillary test are then subsequently measuring significantly different venous INR test.

Some variance between the difference sampling methods is as expected. Lumira report this can be as high as $\pm 30\%$ or ± 1.2 INR units if the average INR result is 4.0^1 . Variation decreases as INR decreases; for an average INR of 2.0 accepted variance is ± 0.4 INR units or 20%.

Current advice for patients with an out-of-range result (>4.5) is to repeat the capillary test and, if the second result remains high or out-of-range, obtain a venous sample. Using a venous sample to dose has reportedly led to some difficulties with dosing and stabilising patients using INRStar.

We have approached Lumira for further guidance who have advised for out-of-range INR results to dose against the point of care capillary test rather than venous sample.

Advice is as follows:

For patients with a high or out-of-range capillary INR result (>4.5 INR units):

1. Repeat the capillary sample using the LumiraDx machine
2. If the second capillary sample result remains >4.5 **refer to a clinician** for further advice.
3. The capillary sample result should be used to dose but be aware of the increased risk of bleeding and any subsequent action that may be required i.e. counselling patient on bleeding risks and signs of bleeding, vitamin K administration etc. Consider and investigate any reasons for a raised INR, for example medication changes.

Please note – LumiraDx will not record an INR if the result is >7.5 . A venous sample must always be obtained; this result should be used to dose within INRStar.

References

1. LumiraDx. Comparing results across different methodologies – why do INR results differ?