**Summary and Explanation of the Test**

The LumiraDx INR Test is an immunonephelometric assay that uses fresh capillary blood. It is intended for use in professional use which is used for in vitro diagnostic tests.

**Materials Required but not Provided with the Test Strip**

- Clean Transfer Tube
- Lancet
- Clean Tissue
- Medical Sterile Lancets
- Blood Collection Device

**Handling the Test Strip**

- The Test Strip must be handled carefully to avoid contamination. Do not touch the reagent cap or the sample application area.

**Specimen Sample Collection and Preparation**

1. Place the sample on the selected finger to obtain a good drop of blood.
2. Clean the patient's finger with a clean tissue.
3. Dispose of lancet and Test Strip in the bio-waste disposal container.
4. Punch the finger to obtain a fresh drop of blood.
5. Into the tube. Then hold the transfer tube over the Sample Application Area of the inserted Test Strip you must transfer the LumiraDx Lot Calibration Strip you must transfer the LumiraDx Lot Calibration Strip.
6. Immediately apply the sample.

**Expected Results**

- The expected result will be presented on the Instrument touch-screen. For rejects or abnormal results, it will be determined by local guidelines. Refer to the Instrument manual for further information on testing procedure for the LumiraDx INR Quality Controls pack insert.

**Limitations of the Procedure**

- There may be a significant increase or decrease in the patient's INR level due to a clotting disorder.
- Changes in the patient's diet (e.g. alcohol, anti-virals, fibrates, glucosamine, non-steroidal anti-inflammatory drugs) can lead to unusually low or high INR results.
- Certain medications (for example such as congestive heart failure, anti-platelet agents, anti coagulants, and antihypertensive agents) can significantly affect test results.

**Interference**

- Unfractionated Heparin
- Daptomycin
- Lipemia (Triglycerides)
- Coagulation Analyser with HemosIL RecombiPlastin II
- ACL
- ACL Elite with HemosIL RecombiPlastin II
- ACL Elite Pro with HemosIL RecombiPlastin II
- CoaguChek
- HI-5
- Roche
- ACL Top with HemosIL RecombiPlastin II
- PT-1
- PASS (for example such as congestive heart failure, anti-platelet agents, anti coagulants, and antihypertensive agents) can lead to unusually low or high INR results.

**References**

- Summary and Explanation of the Test
- Materials Required but not Provided with the Test Strip
- Handling the Test Strip
- Specimen Sample Collection and Preparation
- Expected Results
- Limitations of the Procedure
- Interference

**For product enquiries please contact LumiraDx Customer Services.**

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