

## TEST CHANGE

**NOTIFICATION DATE:** June 21, 2021

**EFFECTIVE DATE:** July 6, 2021

## PROTIME/INR 487/85610.0

## **QUICK REFERENCE**

On July 6, 2021, Allina Health Laboratory will be transitioning to a new lot of Prothrombin Time reagent, which requires thorough validation testing to establish a new mean normal reference time. The new normal Protime is used to calculate the International Normalized Ratio (INR) for each new lot of thromboplastin. This process occurs approximately every 12 months when a new lot of reagent has been made available by the instrumentation reagent vendor.

## **DETAILS**

As we prepare for changing to a new Protime reagent lot, Allina Health Laboratories Coagulation Department undertakes a new "normal range" study using 25 specimens from persons known to be free of coagulation abnormalities and not on any current medications. These samples are run at every site, on each analyzer to give us a large volume dataset and a thorough representation of instrument comparability.

These normal Protime results are compiled to establish a reference time for the INR calculation. They also provide data that can be used for a new normal reference range.

Current Protime Reference range	12.0 – 14.6 sec
NEW Protime Reference range	11.8 – 13.9 sec

QUESTIONS: Contact your Allina Health Laboratory account representative, or our Client Services department