MEMORANDUM

DATE: 11-7-18

TO: NPL Clients

FROM: Rhonda Burgard, MT (ASCP), BB, MPA

RE: CoaguChek Recall

The FDA has issued a Class 1 recall of some lot numbers of the Roche CoaguChek XS Pt test strips. A Class 1 recall is the most serious type of recall. According to the FDA, use of these devices may cause serious injuries or death.

The recall of the CoaguChek XS test strips is due to inaccurate INR test results at INR values of > 4.5 INR, when compared to laboratory results. The company will supply new test strips sometime within the next month. Until the new strips are received, stop using the affected test strips/ Protime/INR monitoring should be done via blood drawn from the vein and tested by a laboratory. Patients should are encouraged to contact their health care providers before making any changes to their warfarin dose. Attached is a link to the FDA website giving additional information https://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm624822.htm

If you have any questions or concerns, please contact the Northern Plains Client Services at 701-530-5700. Please share this information with your providers.