



Notification

Ref.: SBN-CPS-2018-014

15-11-2018

Product Name / GMMI	CoaguChek XS PT Test	04625315019; 04625358019
System	CoaguChek® XS system	
Production Identifier (Lot No./Serial No.)	CoaguChek XS PT Test	from #27216711 up to #33449812

Dear Valued Customer,

We are writing to inform you about your CoaguChek system and test strips. Please read this information carefully as details available with us indicate that you might be a recipient of the Lot No.(s) of the Product(s) mentioned above.

Roche Diagnostics does standardization of CoaguChek test strips against the standard from the World Health Organization (WHO) This standard was renewed in 2016. We switched to the new WHO standard (rTF/16) and became one of the first companies to deliver CoaguChek test strips calibrated towards this new standard from January 2018.

However, considering that other manufacturers might not have shifted the Reference Standardization to the new WHO Standard, Roche Diagnostics carried out a study which showed the following for CoaguChek test strips of the Lot No.(s) mentioned above:

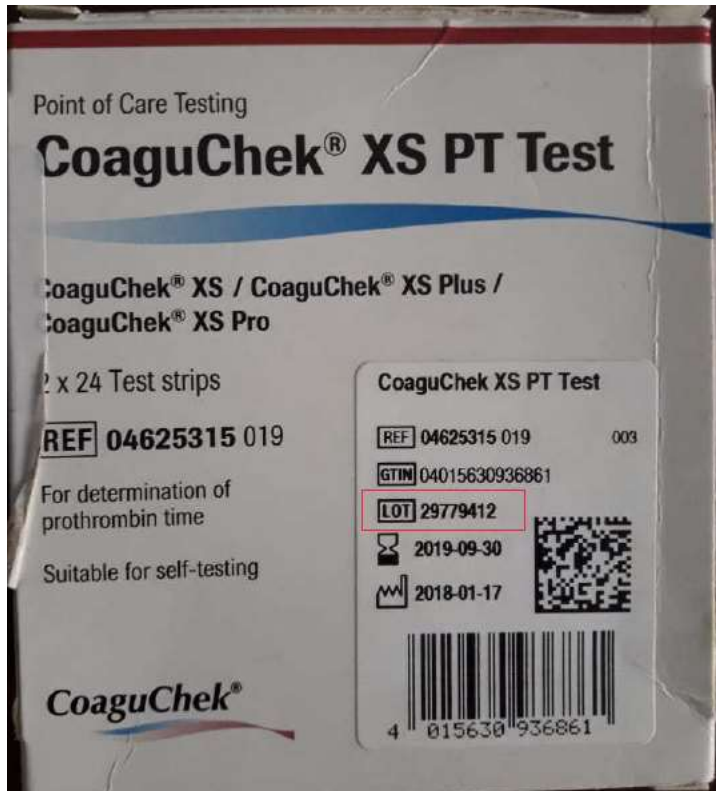
- For values between 0.8 and 4.5 INR: No significant differences are seen and your CoaguChek result is reliable.
- For values above 4.5 INR: the deviations to the other laboratory methods is possibly on account of difference in the Reference Standard used by the manufacturer

“What do I have to do if I have the mentioned Lot of CoaguChek strips?”

Please note that the medically used therapeutic range is \leq INR 4.5. Therefore, your CoaguChek system is delivering reliable results for your relevant therapeutic range. Please note that according to the package insert you should contact your physician every time you are out of your therapeutic range and all values above 4.5 INR as usual would require further consultation with a Healthcare Professional.

“How do I recognize which CoaguChek test strip Lot No. I have?”

The Lot No. is printed on the label, which is applied to the test strip box at manufacturing:



Lot No.

Roche Diagnostics is now making available new Lots based on the earlier WHO Standard. They would correlate well with the other Laboratory Methods even for values above therapeutic range of INR 4.5. These Lots are going to be available shortly.

We regret the inconvenience caused to you in this regard. Please communicate with us on the contact details below with your queries, if any:

Customer Support Centre

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Ensuring you of our best support!

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