

# CustomerLetter

## CoaguChek® PT Test Strips and CoaguChek XS PT Test Strips – Use With Patients Who May Have Anti-phospholipid Antibodies Present

### Information

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This Customer Letter provides additional information regarding the use of CoaguChek PT Test Strips and CoaguChek XS PT Test Strips in patients who may have anti-phospholipid antibodies (APAs) present.

The package inserts for both CoaguChek PT Test Strips and CoaguChek XS PT Test Strips state:

*The presence of anti-phospholipid antibodies (APAs) such as Lupus antibodies (LA) can potentially lead to long clotting times, i.e., elevated INR values. A comparison to an APA-insensitive laboratory method is recommended if the presence of APAs is known or suspected.*

The role that APAs can play in PT/INR testing can be further explained as follows:

The active thromboplastin ingredient used to initiate clotting in these test strips contains phospholipids. Anti-phospholipid antibodies can interact with the thromboplastin, preventing it from initiating the clotting cascade. As a result, the overall clotting process would be slowed, and it would appear that the patient has a higher INR than he/she would have if no antiphospholipid antibodies were present. You would expect to see higher-than-normal INR values on CoaguChek PT and CoaguChek XS systems when there is interference from anti-phospholipid antibodies. However, there is a significant amount of data that shows that impact of these antibodies on PT/INR results is highly dependent on the patient. Therefore, we cannot tell how individual patient PT/INR results might be affected by the thromboplastin on CoaguChek PT and CoaguChek XS PT Test strips.

The following publications are recommended for additional information:

- Moll, S and Ortel, TL, “Metering Warfarin Therapy in Patients with Lupus Anticoagulants.” *Annals of Internal Medicine* 1997; 127: 177-185.
- Robert, A et al., “Control of Oral Anticoagulation in Patients with the Antiphospholipid Syndrome – Influence of the Lupus Anticoagulant on International Normalized Ratio.” *Thromb. Haemost.* 1998; 80: 99-103.

For the reasons listed above, Roche continues to recommend that a comparison to an APA-insensitive laboratory method be performed if the presence of APAs is known or suspected.

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CoaguChek XS Plus	CoaguChek XS Pro	CoaguChek XS Professional	CoaguChek Vantus
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**Questions**

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Please contact Roche Diagnostics Point-of-Care Technical Service at 1-800-428-4674 if you have questions about the information in this Customer Letter.

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