



CoaguChek® XS PT Test – Optimized Test Strips Available

This customer letter has been updated to add expiration dates. Changes are indicated by black bars in the margin.

Introduction

This customer letter is a follow-up to Analyzer Bulletins 15-126 (dated 08/18/15) and 15-126U1 (dated 04/28/16), which communicated that CoaguChek XS PT Test Strip 2x24, CoaguChek XS PT Test Strip 6-count, and CoaguChek XS PT Test Strip 24-count were influenced by heparin concentrations for INR values ≥ 2.9 . The issue has been resolved with the optimization of the test strips.

The concentration of polybrene (an ingredient in the reagent intended to neutralize heparin in a patient's blood sample) in the above mentioned test strips was increased to ensure 100 percent heparin neutralization for all INR values.

Optimized Test Strips

Starting with the following strip lot numbers, the CoaguChek XS PT Test Strips may be used to test PT/INR patients with unfractionated heparin (UFH) concentrations up to 0.8 U/mL and low molecular weight heparins (LMWH) up to 2 IU/mL, regardless of the INR value; no alternative testing method is necessary:

| Product | Catalog Number | First Lot of Optimized Strips | Expiration Date |
|-------------------------------------|----------------|-------------------------------|-----------------|
| CoaguChek XS PT Test Strip 2x24 | 04625315160 | 12803712 | 10-31-2017 |
| CoaguChek XS PT Test Strip 6-count | 04625374160 | 12804321 | 10-31-2017 |
| CoaguChek XS PT Test Strip 24-count | 07797826160 | 12804312 | 10-31-2017 |



The strip lot numbers listed above are the first optimized lots. All subsequent lots are also optimized. This includes all lots with the expiration date of November 30, 2017 or later.

over...

- CoaguChek XS
- CoaguChek XS Plus
- CoaguChek XS Pro

Method Sheets

The current CoaguChek® XS PT Test Strip method sheets are accurate for the optimized test strips, so the method sheets will not be updated. Please refer to the following claim in the Limitations of Procedure section of the current method sheets:

Testing performed with the following in vitro spiked samples or native blood samples (triglycerides) indicated no significant effect on test results:

- Heparin concentrations up to 0.8 U/mL
- Low molecular weight heparins (LMWH) up to 2 IU anti-factor Xa activity/mL

Actions Required

- Refer to the CoaguChek XS PT Test Strip 2x24, CoaguChek XS PT Test Strip 6-count, and CoaguChek XS PT Test Strip 24-count method sheets for the insensitivity range of heparin within CoaguChek XS PT Test measurements.
- Discard Analyzer Bulletins 15-126, 15-126U1 and 16-145.

Questions

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

COAGUCHEK is a trademark of Roche.

All other product names and trademarks are property of their respective owners.