



Indianapolis, October 31, 2018

Roche Diagnostics to replace CoaguChek® XS PT Test Strips

Roche (SIX: RO, ROG; OTCQX: RHHBY): This notification supplements previous Urgent Medical Device Correction (UMDC) communications initially issued by Roche Diagnostics on September 12, 2018 and updated on October 17, 2018.

Roche Diagnostics will be proactively replacing all CoaguChek XS PT Test Strips in the United States.

- Patient Self-Testers (PST) will receive replacement test strips from their self-testing service providers.
- Professional / Healthcare Providers will receive their replacement test strips through Roche.

The affected CoaguChek XS PT Test Strips are used with the following CoaguChek professional and patient self-testing point-of-care meters listed in the table below.

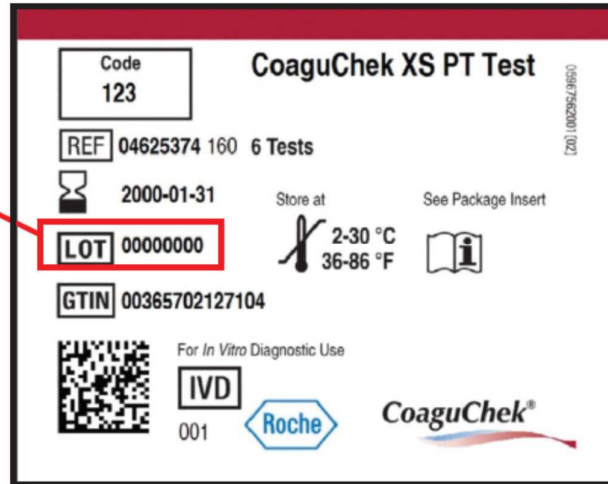
Healthcare Providers (professional)	Patient Self-Testers
CoaguChek XS Professional	CoaguChek XS PST
CoaguChek XS Pro	CoaguChek Vantus
CoaguChek XS Plus	

Roche Diagnostics, the manufacturer of CoaguChek meters and test strips, recently calibrated the CoaguChek XS PT Test Strips to the most recent International Normalized Ratio (INR) Standard. Since calibrating to this new standard, Roche Diagnostics has been informed of patients experiencing inaccurately high INR test results when testing with the affected lots of CoaguChek XS PT Test Strips listed in the table below.

Product	Catalog numbers	Affected lot numbers	
CoaguChek XS PT Test 2x24 Strips	04625315160	28124111	30497423
		28124121	30497515
CoaguChek XS PT Test 6 Strips	04625374160	28631911	31404314
		28631921	31404821
CoaguChek XS Test 24 Tests USA	07797826160	28631924	32264116
		28632021	32264212
		28632213	32264316
		28632312	32264317
		28632412	32264411
		29415113	32264421
		29415123	33045913
		29494221	33046011
		29494312	33046113
		29494613	33046312
		29494711	33046314
		29778721	33046321
		29779012	33046322
		29779213	33449612
		29779214	33449712
30497213	33449723		
30497311	33449817		
		30497413	

The lot number is printed on the test strip label, which is applied to the test strip vial. See the picture below for an example of the location of the lot number on the test strip vial.

**Location of Lot Number
on the Test Strip Vial**



Patients taking warfarin who receive inaccurate INR results above their target therapeutic range may be at risk for inappropriate therapeutic measures such as a warfarin dose reduction, interruption of warfarin use, or administration of vitamin K.

The affected test strips in the table above will be replaced with new CoaguChek XS PT Test Strips, which are not impacted by the Urgent Medical Device Correction (UMDC) and can be used without the need for confirmatory measurements with a laboratory method.

Action Required – Patient Self-Testers:

Stop using and discard any CoaguChek XS PT Test Strips listed in the table above. As of October 29, 2018, Roche started shipping newly calibrated test strips to healthcare providers and patient self-testing service providers. These test strips have been calibrated to the previous INR standard. For questions regarding when you will receive your new test strips, please contact your test strip provider. If you have any questions regarding your testing schedule, please contact your healthcare provider.

Action Required – Health Care Providers:

Stop using and discard any CoaguChek XS PT Test Strips listed in the table above. Also, please advise your self-testing patients to do the same (see above). Roche Diagnostics has started shipping unaffected test strips to healthcare providers, patient self-testing service providers and distribution partners.

Roche Diagnostics is notifying its healthcare providers, patient self-testing service providers, and distribution partner customers to arrange for replacement of all affected CoaguChek XS PT Test Strips listed in the table above. This will be executed through an updated Urgent Medical Device Correction (UMDC).

Healthcare providers and patients (self-testing customers) with questions may contact Roche Diagnostics Point of Care Technical Service by telephone at 1-800-428-4674.

Adverse reactions or quality problems experienced with the use of this product may be reported to Roche Diagnostics Point of Care Technical Service at 1-800-428-4674 and the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report Online: www.fda.gov/medwatch/report.htm
- Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.

About Roche

Roche is a global pioneer in pharmaceuticals and diagnostics focused on advancing science to improve people's lives. The combined strengths of pharmaceuticals and diagnostics under one roof have made Roche the leader in personalized healthcare – a strategy that aims to fit the right treatment to each patient in the best way possible.

Roche is the world's largest biotech company, with truly differentiated medicines in oncology, immunology, infectious diseases, ophthalmology and diseases of the central nervous system. Roche is also the world leader in in vitro diagnostics and tissue-based cancer diagnostics, and a frontrunner in diabetes management.

Founded in 1896, Roche continues to search for better ways to prevent, diagnose and treat diseases and make a sustainable contribution to society. The company also aims to improve patient access to medical innovations by working with all relevant stakeholders. Thirty medicines developed by Roche are included in the World Health Organization Model Lists of Essential Medicines, among them life-saving antibiotics, antimalarials and cancer medicines. Roche has been recognized as the Group Leader in sustainability within the Pharmaceuticals, Biotechnology & Life Sciences Industry nine years in a row by the Dow Jones Sustainability Indices (DJSI).

The Roche Group, headquartered in Basel, Switzerland, is active in over 100 countries and in 2017 employed about 94,000 people worldwide. In 2017, Roche invested CHF 10.4 billion in R&D and posted sales of CHF 53.3 billion. Genentech, in the United States, is a wholly owned member of the Roche Group. Roche is the majority shareholder in Chugai Pharmaceutical, Japan. For more information, please visit www.roche.com.

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