



FDA MedWatch

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Terrific Care, LLC. / Medex Supply Dist, Inc. issues Nationwide Recall of CoaguChek Test Strips

Announcement

This announcement clarifies information included in Terrific Care, LLC's press release issued on 12/19/2018

On 12/19/2018, Terrific Care, LLC. / Medex Supply Dist, Inc. initiated a nationwide recall of Roche CoaguChek test strips distributed directly to U.S. consumers by Terrific Care, LLC. / Medex Supply Dist, Inc. This recall only includes CoaguChek test strips distributed directly to U.S. consumers by Terrific Care, LLC. / Medex Supply Dist, Inc via its website/phone calls/facsimil of All Catalog/REF Numbers that DO NOT END IN 160.

The products distributed by Terrific Care, LLC / Medex Supply Dist, Inc. have been found to inaccurately report high INR test results. 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.

All Catalog/REF Numbers that DO NOT END IN 160

Product	Catalog/REF Numbers	Affected Lot Numbers
CoaguChek XS Test Strips (All varieties sold by Terrific Care LLC. dba Medex Supply)	All Catalog/REF Numbers that do NOT end in 160 (see ex. image below)	27216700 through 33449899

This recall is related to the recent Roche Diagnostics Recall, the manufacturer of CoaguChek meters and test strips. The CoaguChek test strips distributed by Terrific Care LLC./Medex Supply Dist. Inc. include Catalog/REF numbers that were not included in the recent Roche recall because these items were not distributed by Roche Diagnostics in the United States.

Terrific Care, LLC. / Medex Supply Dist, Inc. began distributing impacted products between 12/27/2017 through 12/15/2018 directly to consumers via courier service.

Terrific Care, LLC. / Medex Supply Dist, Inc. voluntarily recalled product after becoming aware of consumer complaints.



Kidney Community Emergency Response



Actions Required:

Immediately stop using all CoaguChek XS Test Strips listed above and purchased directly from Terrific Care LLC. dba MedEx Supply.

Returns:

- Please send an E-Mail to RMA@medexsupply.com or call a customer service specialist at 888-433-2300 between the hours of 9:00 am - 5:00 pm, monday - thursday
- Return impacted strips directly to Terrific Care LLC. 61 Willet Street Passaic, NJ 07055-1971

Adverse reactions or quality problems experienced with the use of this product may be reported to 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.

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Product Photos

