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Important Recall Notice

DATE: 22 September 2017
TO: Investigators and Study Coordinators
FROM: Covance Site Communications
RE: Becton Dickinson (BD) 2mL K2 EDTA Blood Collection Tube Recall - Lot # 6279849

Covance Central Laboratory Services (Covance CLS) would like to inform your site that BD is conducting a voluntary recall of the 2 mL K2 EDTA purple-top Blood Collection Tube specific to Lot # 6279849. This tube is pictured below and is included in some of your site's Covance collection kits:



The manufacturer's recall notice states:

"BD has confirmed that a limited portion of the lot was manufactured with less than the required amount of K2 EDTA additive, an anticoagulant, which may cause erroneous results that could lead to specimen recollection and potential delay of treatment or misdiagnosis/mismanagement of treatment and serious complications, such as failure to detect thrombocytosis or postponing surgery. No adverse events have been reported for this issue at this time."

Tubes with less than the required K2 EDTA are vulnerable to platelet aggregation (which would decrease the reported platelet count); specimen clotting (which would cause test cancellation) or microclots (which could affect platelet count and other CBC parameters if undetected). CBC instrumentation includes clot filters and flags platelet aggregation for microscopic slide review. Covance Central Laboratories has added an additional processing step for these tubes, inspecting each tube for small clots.

For Covance use:

NA;; LATAM: ; EMEA:; SGP:; CHN: ; JPN:;

Site:

Language: English

Letter # 40766

31 August 2017/JS

Your site has been identified as having collection kits on hand which include the impacted lot of BD 2 mL K2 EDTA collection tubes. Covance is asking that you please dispose of the Lot # 6279849, 2 mL K2 EDTA collection tubes included in your collection kits, and carefully follow the instructions described in this letter.

Within the next 3 weeks, you will receive a site specific letter including a study-specific listing of the impacted visit kits, with Covance accession included for greater ease in identifying the impacted collection tubes. In parallel, you are being shipped replacement supplies in order to allow you to replace the 2 mL K2 EDTA collection tubes included in this recall.

Replacement Collection Kits:

- Where required due to local import permit requirements, Covance CLS will provide a 1:1 replacement of any visit kit containing the Lot #6279849, 2 mL K2 EDTA collection tube which our records indicate you have on hand based on a recent review of kits shipped and received at Covance CLS.
- These will be received within the next 15-20 business days.
- Upon receipt, please follow local practices to discard/destroy any of the applicable visit kits, which include the Lot #6279849, 2 mL K2 EDTA collection tube, for which replacement kits are sent.

In the event that local requirements allow, you will instead receive a bulk supply of the 2 mL K2 EDTA collection tubes:

Replacement Collection Tubes:

- A bulk supply of replacement 2 mL K2 EDTA collection tubes will follow this notification in the next 10-15 business days. The bulk supply should be used as a 1:1 replacement of each 2 mL K2 EDTA tube in the impacted collection kits.
- **In the event that you do not receive the resupply (kits or bulk supply) in advance of the need for use of an impacted visit kit, follow the same instructions as noted below, using a local supply of the 2 mL K2 EDTA collection tubes.**
- If using blank labels, when collecting more than two, 2 mL K2 EDTA tubes your staff will also need to record the accession number from the kit on the tube label. It is imperative that this is done, so that the sample can be correctly linked to the Sponsor, Protocol, Investigator, Patient and Visit.

Labelling Replacement Tubes:

It will be critical that your site staff follow the below instructions for the labelling of the replacement tubes for proper processing upon receipt at Covance CLS:

- There are two extra barcode labels included in each of your existing Covance collection kits. Please use one of the two extra barcode labels from the kit and place the label onto the replacement 2 mL K2 EDTA tube.
- If two tubes within one kit require replacement, please use the second extra barcode label from the kit and place this label onto the second replacement 2 mL K2 EDTA tube for that kit.
- When using the extra barcode labels from each kit, you must print:
 - The test name, i.e. Hematology
 - The protocol specific patient ID.
- Remember, someone else will be interpreting what you record, so it is critical that you write legibly to avoid holds and/or queries. Please see below for an example of how a completed extra barcode label should appear prior to sending to Covance:



Thank you for your attention to this information. If you have any questions regarding the information in this notice, please contact Covance Investigator Support at the toll-free number located in the Contacts' Section of your laboratory manual or at the appropriate phone number for your location as listed in the header above.

Please retain a copy of this notice in your study files for documentation purposes.