Urgent *Field Safety Notice*

Affected product: ***Cascade Abrazo c-ACT-LR cards***

FSCA Id.: FSCA 2017-03-10

Type of action: FSCA – Device destruction

Date: April 5, 2017

Attention: (User Addressee)

Details of affected device: **Cascade Abrazo c-ACT-LR cards** lot **1-16-5701**, for activated clotting time, ACT – manufactured by Helena Laboratories.

Description of problem: Some cards in this lot have shown occasional shorter or longer clot times than expected variation, as evidenced investigation by variations in wave form. This variation could have a different ACT value presentation than may be expected based on patient treatment and conditions.

Risk to Health: This should not likely have a detrimental effect on patients, even in the POC setting, as health care personnel monitoring the patient would base decisions primarily on the amount of medication (heparin, or protamine) given and patient conditions presented, rather than strictly relying on the ACT value. Additionally, if an aberrant value is displayed, device IFU indicates the specimen – *patient, or control* – should be re-run. If an unexpected value is repeated: a) for a control, the run would be considered *invalid*, and require a repeated testing, b) if for a patient, a **control** set should also be tested, before repeating the patient sample, or c) an alternative method used for diagnostic evaluation.

Advise on action to be taken by user: Though no actual complaints occurred on this lot, we chose this **"removal and destruction"** action, to proactively prevent quality problems that may complicate user-patient situation.

Transmission of this Field Safety Notice: This notice needs to be passed on to all those who need to be aware within your organisation or any organisation where the potentially affected devices have been transferred. Please transfer this notice to other organisations on which this action has an impact. Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. An acknowledgement form, attached. The completed forms are all to be returned to the USA.

Contact reference person: Jessica Jones, MD, MPH c/o Helena Laboratories, 1530 Lindbergh Dr. Beaumont, TX (USA) 77704. JJones@helena.com

The undersigned confirms that this notice has been notified to the appropriate Regulatory Agency

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April 5 , 2017

WITHDRAWAL NOTIFICATION

for REMOVAL of PRODUCT from INVENTORY

PRODUCT*: ***Cascade Abrazo c-ACT-LR*** **Lot:** ***1-16-5701***

This lot is to be handled by Distributors/Users, as follows:

___Prevent any shipments or scheduled demonstrations with this lot
___Remove this lot from Available Inventory and discard the cards
___Place cards in Quarantine – pending disposal
___Contact Helena's International Sales for credit and replacement

Verify amount REMOVED FROM STOCK:

Total number pulled: _____ Date _____

The following signifies written certification that this lot has been disposed:

Verified by: _____

Please complete this form and return to Helena Laboratories, USA via: FAX: 409-842-1874 or e-mail to jjones@helena.com – For questions, contact Jessica W. Jones, MD, MPH – Mgr., Technical Services at: 1 (409) 842-3714 ext. 1177

***Reason for removal:** Some cards in this lot are experiencing variations in values (verified by wave form), resulting in possible shorter, or longer, times than expected. While this issue, if present, should be found via use of the Quality Control materials, due to its intermittent nature in the cards, this alone cannot be relied upon.