FIELD SAFETY NOTICE

Urgent

Object : Return of TROPONIN I-CHECK-1 device to VEDALAB premises.

Lot(s) : 19084, 02064, 17094 & 17114.

Information about the product recall :

These lots show problem of sensitivity due to wrong calibration due to variation of commercial controls used for the internal quality control of the lots performances. Therefore the lots indicated above, which have been calibrated using these commercial controls, must be withdrawn from your market and returned to VEDALAB. Information about the return is indicated below.

As an immediate correction, the diluent solution has been replaced to correct the sensitivity problem. The lots must be recalled by IMCARMED and the diluent vials must be replaced by diluent **lot 06025**.

As the corrective action n° 21502400, the calibration procedure has been modified and implemented immediately. The troponin I devices lots will be calibrated against the N.I.S.T. reference material n° 2921.

Sorry for any inconvenience

With our Best regards

[redacted] [redacted]

Quality Assurance/Regulatory Affairs manager C.E.O.

[redacted]

ISO 9001 Certified ISO 13485

Siège Social : Rue de l'Expansion - ZAT du Londeau - CERISÉ - B.P. 181
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Etablir une fiche d'avertissement par dispositif et la joindre à la correspondance client

Dispositif médical DIV/Medical device DIV :	TROPONIN I –CHECK-1 ref. 28081
Lot(s) :	19084 (device)/19084 (Diluent)
Fiche établie suite à /Notice issued due to	
■ ACP en cours/Pending Corrective or preventive action **N° 21502400**	■ Réactovigilance/Vigilance (FSN attached)

Cocher les mentions concernées Tick all appropriate box(es)	Informations et recommandations Information and recommendations
❑ **Utilisation d'un dispositif médical DIV/Medical device DIV use**	NA
■ **Modification d'un dispositif médical DIV/Medical device DIV modification**	The complaint n° **21501106** has been opened to assess the performances of this lot which sensitivity was reported as slightly lower from the field. The investigation performed on the retained devices samples by Vedalab technical department has confirmed a problem of calibration which lowered the sensitivity of the test. A corrective action n°**21502400** has been opened to identify the root causes and eliminate them. VEDALAB requires all the devices lots (as specified in **FSN**) from TROPONIN I-CHECK-1 must be withdrawn from the German market and diluent vials replaced with lot **06025.**
❑ **Retour à VEDALAB d'un dispositif médical DIV/Medical device DIV Return to VEDALAB**	NA
❑ **Destruction d'un dispositif médical DIV/Medical device DIV disposal**	NA

Date & Visa DIRECTION :	**Cachet VEDALAB/VEDALAB Stamp :**
February 6th 2015 [redacted]	VEDA.LAB Rue de l'Expansion ZAT du Londeau - Cerisé - BP 181 61006 Alençon cedex – France ☎ (33) 2 33 27 56 25 – 🖷 (33) 2 33 27 70 60 SIRET 382 394 559 00027