E. INVESTIGATION INFORMATION

CONCLUSION

In the complaint laboratory, on the retain kit VIDAS TNHS batch 1007570460 / 200709-0,we did not reproduce the customer's anomaly .

There is no anomaly highlighted with the control chart, the analysis of quality data and the tests performed with the retain kit VIDAS TNHS lot 1007570460 / 200709-0.

Performance of VIDAS TNHS lot 1007570460 / 200709-0 are within specifications.

As a reminder, in order to restrain the potential issues, it is important to follow the pre-analytical steps especially for high sensitive Assays.

1°) Sampling/ Coagulation :

According to the Good Practices Laboratory, always refer to the tube manufacturer recommendations .

- Plasma :
- Respect ratio between the anticoagulant and the sample.
- The filled tube must be turned upside down in order to mix the sample with the anticoagulant. Those steps are essentials to stop the coagulation and avoid the formation of micro clots.
- Serum :
- Wait for the complete formation of the clot before performing a centrifugation, at least 30 minutes, and more if the patient is under anticoagulant treatment.

2°) Centrifugation:

According to the WHO recommendations (WHO/DIL/LAB/99.1 Rev.2):

• "1.3.2.1. Plasma

Centrifuge the anticoagulated blood for at least 15 minutes at 2000 to 3000 g to obtain cell-free plasma.

• 1.3.2.2. Serum

When plasma coagulation is complete, centrifuge the sample for at least 10 minutes at a minimum speed of 1500 g.

When separating serum or plasma, the temperature should not drop below 15 °C or exceed 24 °C.°"

INSTRUMENT MAINTENANCE REMINDER

It is necessary to perform regular instrument maintenance in order to ensure the mini VIDAS®, VIDAS® and VIDAS 3® are functioning correctly and ensure the quality of your daily results. These procedures are described in the mini VIDAS®, VIDAS® or VIDAS 3® User Manuals.

According to the recorded data, for all lots the outliers rate is remaining at a low level, within the specifications, since the VIDAS® TNHS launch.

Those data confirm that VIDAS TNHS assay is at the state of the art regarding its performance. Please note that Negative Predictive Value (NPV) is not impacted by critical outliers (*). This parameter is one of key clinical performances of assay, allowing to rule-out a myocardial infarction.

(*)critical outlier: For VIDAS® High sensitive Troponin I, critical outliers are non-repeatable high values which are higher than the medical decision level of 19 ng/L (99th percentile of normal reference population), whereas the sample median is below this decision level. Only critical outliers have an impact on specificity and positive predictive value estimation.

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Reminder from package insert: "LIMITATIONS OF THE METHOD Interference may be encountered with certain samples containing antibodies directed against reagent components. For this reason, assay results should be interpreted taking into consideration the patient's clinical history, and the results of any other tests performed."