Magnisense SE
16 avenue Hoche
75008 Paris

17th June 2019,

[redacted]

Dear [redacted]

[redacted]

"We have observed a lack of sensitivity of the test MiAG|cTnI which may lead to false results. Investigations are underway in our Research and Development department in order to find the origin of this anomaly and to implement corrective actions. However, pending the resolution of this problem, we are obliged to take the decision to suspend the marketing of the MiAG|cTnI in vitro diagnostic kit.

However, risk related to patient health and safety was assessed as near zero because the MiAG|cTnI kit distributed was only used in the evaluation framework (comparison with the results obtained from [redacted]) and are not used to make any medical decision."

Yours faithfully,

STIG VISTI ANDERSEN
CEO