

ADVISORY NOTICE

ECL 760 – TT EC error

TO WHOM IT MAY CONCERN

According to our records, you are an ECL 760 and Erba Thrombin Time reagent (ref. EHL00007 and EHL00026) user.

Following complaints we received from some customers, Erba has investigated and confirmed a potential non-systematic error of Thrombin Time (TT) test in patient samples, using ECL 760 with Software version 1.9.

The root cause investigations are still unclear, but we identify that TT samples analysis could be impacted by EC error (Early Clot) with no possibility to receive a result.

Erba is working to a solution, but until today wasn't possible now to deliver a successful resolution. For this reason, we wanted to inform you formally about the current situation.

Actions:

- Option 1: Rerun the sample (but if the result EC error persist -> Option 2)
- Option 2: Run the sample in other system: ECL 105 or ECL 412

According to our risk analysis, as patient results are interpreted in a global biological and clinical context, this defect has not a significant clinical impact.

We regret the discomfort we may bring you, and we thank you in advance for your support. We continue to work towards bringing a solution in the shortest possible time.

Yours sincerely,

Erba Lachema s.r.o.

Technical product management

Erba Lachema s.r.o.

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