

# Field Safety Notice



## GGT/IFCC Granulate System Kits for Roche/Hitachi and Modular P Analyzers

Dear customer,

We regret to inform you that falsely low results have been reported with two lots of the GGT IFCC granulate reagent when hemolyzed serum/plasma samples were analyzed. The effect may even produce negative results depending on the Hemoglobin concentration in the sample.

### Example:

With an H Index of 100 (100 mg/dl Hb) the recovery of GGT is approximately 40 U/L lower.

The problem is most likely related to a specific lot of raw material used for manufacturing the below listed two lots. Studies to identify the interfering component and to eliminate the problem are in progress.

The affected products are:

**Cat. no. 11730169 216 for Roche/Hitachi 902/904/911/912, lot no. 675900**

**Cat. no. 11730053 216 for Roche/Hitachi 917/Modular P, lot no. 675913**

As an immediate consequence the delivery of the affected reagent kits has been stopped.

In order to avoid inappropriate medical decisions based on possibly falsely low GGT results, Roche Diagnostics decided to recall the defective reagent kits from customers' sites. Therefore, the kits out of these two lots must not be longer used but have to be destroyed locally.

For substitution of the defective kits we can immediately offer liquid GGT/IFCC reagents:

**Cat. no. 12016788 216 for Roche/Hitachi 902/904/911/912**

**Cat. no. 12016958 216 for Roche/Hitachi 917/Modular P**

The liquid GGT reagent is standardized on the same basis as the granulate method. Both reagents are standardized against the original formulation and procedures

recommended by the IFCC. There is no difference in patient test results.

Please address your local Roche affiliate accordingly.

We apologize for any inconvenience this problem may cause you.

Kind regards,