

Gamma-GT Classification

General Clinical Chemistry Programme

Dear Participant

It has come to our attention that some participants may be incorrectly classified for Gamma-GT, potentially leading to inappropriate statistics for comparison. In order to classify participants appropriately we would ask you to take the time to complete the attached questionnaire.

Many Thistle participants are registered in the IFCC-standardised carboxy method group. Generally, GGT reagents can be distinguished as Szasz-standardised assays or IFCC-standardised assays. Traditionally IFCC-standardised assays were aligned to the IFCC Reference Procedure for measuring GGT at 30°C, proposed in 1983. However, a newer IFCC Primary Reference Procedure for measuring GGT at 37°C was proposed in 2002. Some manufacturers align their GGT assays to the 1983 IFCC procedure and others to the 2002 IFCC procedure. **Results are different depending on the IFCC procedure used.** For this reason we would like all participants to thoroughly check their pack inserts.

Your pack insert may be used in order to determine which standard your assay is aligned to:

- 1) The **Assay Name, Summary or Principle** may state if it is Szasz- or IFCC-standardised.
- 2) The **Calibration Traceability** may state if the assay has been standardised to the IFCC 1983 or 2002 procedure.
- 3) **References or Bibliography** may list publications which relate to the IFCC procedures, for example:

Publications relating to the 1983 IFCC Procedure:

- a. *Shaw LM, Stromme JH, London JL et al. "Approved Recommendation (1983) on IFCC methods for the Measurement of Catalytic Concentrations of Enzymes. Part 4. IFCC Method for gamma-glutamyl transferase".*

Publications relating to the 2002 IFCC Procedure:

- b. *Schumann G et al. "IFCC Primary Reference Procedures for the Measurement of Catalytic Activity concentrations of Enzymes at 37°C - Part 6. Reference Procedures for the Measurement of Catalytic Concentrations of γ -glutamyltransferase".*
- c. *Kytzia H-J. "Reference Intervals for GGT according to the new IFCC 37°C reference procedure".*

If you cannot tell how your assay is standardised, please ask your manufacturer directly or send a copy to us with your laboratory Reference number stated clearly on it.

Note for Roche reagent users:

Customers using the IFCC-standardised assays (ACN219) may have received a bulletin from Roche requesting that they re-assign calibrator and QC values and to implement a new reference range. It is recommended that these instructions are followed, but if you have found reason not to do so, please tell us why, so that you can be classified appropriately. Customers using Szasz-standardised assays (ACN479) were advised by Roche not to make any changes.

Please return your completed questionnaires to us as soon as possible.

Kind regards

Marlize Albertse
General Manager - Thistle QA

Gamma-GT Classification Questionnaire

Please complete this questionnaire and return to Thistle QA as soon as possible.

Laboratory Participant Number: _____

Please state your Instrument: _____

Please state your reagent manufacturer: _____

Please state if you use theoretical factor or if you use a calibrator to establish a factor for GGT. If you use a calibrator, please state the manufacturer and if it is traceable to IFCC or another recommendation.

Please study our GGT pack insert, in particular the assay name, the Summary, Calibration and References sections then state the principle of your assay and it's alignment:

- Carboxy* assay standardised against Szasz
- Carboxy* assay standardised against IFCC, 1983 recommendations
- Carboxy* assay standardised against IFCC, 2002 recommendations
- Other, please give details: _____

* Gamma glutamyl - 3 - carboxy - 4 - nitroanalide method

The following should be completed by Roche reagent users only.

Please state if you received a bulleting form Roche regarding re-alignment of your assay to the 2002 IFCC standard.

Yes

No

If you received the bulleting but do not intend to re-align to the 2002 IFCC procedure, please state your reasons.
