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EQA CONTROL MATERIALS FOR GLYCATED HEMOGLOBIN (HbA_{1c})
COMMUTABILITY EVALUATION

Aim of the study: The blood measurement of glycated haemoglobin (HbA_{1c}) is the most important laboratory test for monitoring the glycemic state in diabetic patients and for a prediction of complication. It's therefore necessary that methods available for this analyte be standardized and checked with suitable EQA programs with materials of proved commutability and with target values assigned by a reference method.

Manufacturer's home is willing to prepare and develop control materials (lyophilized control from human blood) in agreement with the above-mentioned features for EQA programs.

Aim of this study is the preliminary evaluation of their commutability.

Materials: 2 lots of XXX control materials will be tested. Each lot consist of (2,3 ...) levels of concentration. Lyophilized materials will be reconstituted according to manufactures instructions.

Methods: In order to check the commutability of above-mentioned materials, their behaviour will be compared with that of 20 EDTA blood samples with HbA_{1c} concentrations included in the interval 4-10%. These samples will be collected, aliquoted, and stored at -20 °C until their use.

1. Certification of HbA_{1c} concentration

Certification of materials and biological samples will be executed by the IFCC- HPLC/Capillary Electrophoresis reference method, performed in duplicate (¹)

2. Commutability Evaluation

The commutability of materials will be evaluated by the following methods:

- HPLC methods: Tosoh G7 and Bio-Rad Variant II dual kit,
- Immunochemical methods: Bayer DCA 2000 and Roche Integra
- Affinity chromatography: Afinion

Control materials and biological samples will be assayed in duplicate with every analytical system.

Evaluation: Commutability of control materials will be evaluated by applying limits of $\pm 2,5\%$ the mean percentage difference found on blood samples between commercial system and reference method (²).

References

¹ Jeppsson JO, Kobold U, Barr J, Finke A, Hoelzel W, Hoshino T, Miedema K, Mosca A, Mauri P, Paroni R, Thienpont L, Umemoto M, Weykamp C. Approved IFCC reference method for the measurement of Hb A1c in human blood. Clin Chem Lab Med 2002;40:78-89.

² Ponzo P, Dolci A, Scapellato L, Milano M, Paleari R, Mosca A, Panteghini M. Valutazione della commutabilità per il sistema analitico Cobas Integra dei materiali di controllo utilizzati nella VEQ per l'emoglobina glicata. Biochimica Clinica 2008;32:44-7.