INTRODUCTION

Bone turnover markers are frequently used as pharmacodynamic biomarkers in clinical studies. Serum samples used to assess bone markers are collected at clinical sites, frozen, and subsequently sent to central laboratories in polystyrene boxes on dry ice. Upon arrival, serum samples are stored in -70°C freezers before being measured in batches.

In the first study, we investigated the stability of the bone markers CTX-I (carboxy-terminal telopeptide of type I collagen), PINP (procollagen I amino-terminal propeptide), OC (Osteocalcin), BSAP (bone-specific alkaline phosphatase), iPTH (intact parathyroid hormone) and TRACP 5b (tartrate-resistant acid phosphatase isof orm 5b) after a simulation of freezer temperature increase caused by power or equipment failure.

In the second study, we investigated the stability of the same markers after a simulation of a shipment in dry ice, until reaching room temperature after complete evaporation.

METHODS

Stability -70°C freezer:
Several aliquots of 6 different serum pools were stored in a full -70°C freezer for 20 days. Then, electricity failure was simulated and the resulting temperature increase was monitored over the following 60 hours. One aliquot of each serum pool was taken out of the freezer after 8, 24, 32 and 60 hours respectively and refrozen at -70°C until analysis. The 60 hours aliquots were additionally fully thawed before being refrozen.

Stability dry ice shipping:
Several aliquots of 4 different serum pools were stored in a package containing 6 kg of dry ice. One aliquot of each serum pool was taken out of the package after 24, 48, 72 and 76 hours respectively and refrozen at -70°C until analysis. The 76 hours aliquots were additionally fully thawed before being refrozen.

RESULTS

CONCLUSION

A freezer temperature failure for over 60 hours or a prolonged dry ice shipment for over 76 hours do not affect the validity of the data generated for the bone turnover markers tested.

However, when samples are received defrosted in the analyzing laboratory, special care based on the sensitivity of the biomarker must be taken.

Conflict of interest disclosure: All authors are employees of BioClinica Lab and have no conflicts of interest.

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