

# The Effect of Freeze/Thaw of Whole Blood on PTH Test Values—PTH Specimen Transportation Study

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At the majority of dialysis clinics throughout the United States, current practice does not follow manufacturers' instructions for PTH tests, requiring centrifugation and separation of plasma from patient blood samples within 2 hours. Indeed, most dialysis patient PTH samples are shipped cross-country as whole blood on two flights, including through the distribution hub. Moreover, some whole blood PTH samples travel via ground transport under uncontrolled temperature conditions. Winter conditions, uncontrolled temperatures in air cargo holds and ground transport as well as direct contact with ice packs removed from a freezer and placed in the shipping container could freeze the whole blood PTH specimens. Therefore, we investigated the effects of freezing whole blood PTH specimens on the PTH test value. A single tube of EDTA whole blood was drawn from 30 dialysis patients. Each sample of whole blood was divided into 2 portions. The plasma from one portion was separated within 2 hours of blood draw and then frozen in accordance with common PTH test manufacturer's FDA cleared instructions. The whole blood from the other sample was placed in a Styrofoam container in direct contact with an ice pack removed from a household freezer. All of the whole blood samples in contact with the ice packs froze. After 24 hours the whole blood samples were thawed and the plasma was separated from the cells, simulating common, yet not compliant with test manufacturer's FDA cleared instructions, shipping and handling conditions. Both samples were tested for both intact PTH and 1-84 PTH. Freezing the whole blood resulted in a mean decrease in PTH by 58% for the intact PTH assay and a decrease of 50% for the 1-84 PTH assay as compared to the sample of plasma that was separated from cells within 2 hours and then frozen. Thus, not immediately separating the plasma from the cells exposes the sample to the risk of freezing whole blood and freezing whole blood results in unreliable PTH assay results.

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