

## **Cholestech Technical Bulletin 007 - GDX Test**

### **GDX Cartridge Transport and Storage**

#### **Product Information**

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This is a reminder that the reagents in the GDX Test Cartridge are affected by temperatures above the labelled upper storage limit of 25°C. The GDX instructions for use state that:

**“the Cholestech GDX A1c Test Cartridges are stable until the expiration date when stored between 2-25°C (36-77°F). Do not freeze. Test cartridges stored refrigerated should be allowed to equilibrate at room temperature for at least one hour prior to use”.**

In order to comply with these instructions and obtain the best possible results, transport and storage should be kept within this range. However, provided that transport takes place at not more than 40°C for not more than 3 days there should be no adverse effect on the product.

If the product is transported or stored outside these recommended temperatures (ie >25°C for prolonged periods) the product will be compromised and the HbA1c values will be reduced. Should customers find unexpectedly low values with controls and patient samples the temperature of transport and/or storage should be examined.

Customers are also reminded that Cholestech GDX A1C Controls are available from Cholestech. As stated in the Instructions for Use, these controls must be run:

- With each new shipment of test cartridges (even if cartridges are from the same lot previously received)
- With each new lot of test cartridges

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**This Technical Bulletin is intended to inform or remind the user of this Product of the recommended ways in which the Product should, or should not, be used, maintained or stored. If the Product is not used, maintained or stored as recommended, the performance of the Product will be affected. The manufacturer cannot accept any responsibility for any such affected performance caused by use, maintenance or storage of the Product in a way that is contrary to recommendations in this Technical Bulletin.**