

RDNZ Customer Bulletin

DATE: February 19th 2008

REFERENCE: CB 08/03

Reduced stability of Thyroglobulin in PreciControl Universal

Current Situation:

Internal investigation has revealed that the Level 2 material in PreciControl Universal, (Lot # 178500, Bottle Lot 177963) does not meet one of the stated stability claims in the package insert for Elecsys Thyroglobulin. In particular, stability at 2-8°C is adversely affected.

Actions Required:

When using this lot # of PreciControl Universal to control Thyroglobulin, please note the following revised stability claims:

- Up to 5h on board the analyser
- Up to 5h at 20-25°C
- One month at -20°C (freeze only once)
- **DO NOT STORE AT 2-8°C** after reconstitution

Please Note: No warning note will be included with the reagent or control material. This modified stability claim is applicable to this lot # of PreciControl Universal only at this stage.

We apologise for any inconvenience. Please contact us on Techline if you would like to discuss this further, or require any additional information. .