



**Australian Government**  
**Department of Health and Ageing**  
**Therapeutic Goods Administration**

## **Safety Advisory - Optium blood glucose test strips**

**7 January 2011**

The Therapeutic Goods Administration (TGA) has been advised by Abbott Diabetes Care that routine Quality Assurance monitoring has identified a problem associated with the slow filling with certain lots of Optium blood glucose test strips. The affected products are:

- Optium Point of Care Glucose Test Strips 100s (G3cH)
- Optium Glucose Test Strips 100s (G3c)
- Optium Glucose Test Strips 10s (G3c)

The affected test strips may give falsely low blood glucose readings if exposed to high temperatures for extended periods of time.

Abbott Diabetes Care has advised that:

- An inaccurately low blood glucose reading may occur if the test strip takes longer than 5 seconds to 'fill'; and
- If this occurs then the strip should be discarded and the test repeated.

### ***Information for consumers***

Consumers are being alerted to this problem as a precautionary measure. The TGA and Abbott Diabetes Care consider that the risk to Australian consumers is low, as affected test strips may be readily identified to that the slow fill time.

However, users of these test strips are advised to observe the instructions for use regarding appropriate storage. Strips should be stored at a temperature between 4 and 30 degrees centigrade, and fill time should be monitored (no longer than 5 seconds). Should a test strip take longer than normal to fill, it should be discarded and the test repeated.

*Abbott Diabetes Care has advised that consumers in possession of test strips with any of the **lot numbers** identified below and who have observed that these are not filling correctly, may contact Abbott Australasia on their Customer Service Line on **1800 801 478** and the product will be replaced.*

The TGA will continue to closely monitor the three affected Optium blood glucose test strip products supplied in Australia. Any Suspected adverse events of any type should be reported to TGA.

Information on how on how to report a suspected problem with a medicine or medical device to the TGA can be found on the TGA website at '[Report a problem with a therapeutic product](http://www.tga.gov.au/problem/index.htm)'  
<http://www.tga.gov.au/problem/index.htm>.

### ***Affected product lot numbers***

The affected Optium blood glucose test strip products and their lot numbers are:

Product Name	Lot Numbers

Optium Point of Care Glucose Test Strips 100s (G3cH)	45503, 45510, 45515, 45520, 45545, 45564, 45695, 45805, 45836, 45883, 45898, 45928, 45964, 45965, 45993, 45998, 46097, 46146, 46189, 46205, 46236, 46334, 46402, 48030, 48036, 48087
Optium Glucose Test Strips 100s (G3c)	45001A121, 45001A122, 45001A123, 45001A139, 45001A147, 45001A189, 45001A196, 45001A198, 45001A201, 45001A210, 45001A215, 45001A225, 45001A248, 45001A253, 45001A257, 45001A260, 45001A299, 45001A303, 45001A321, 45001A322, 45001A324, 45001A327, 45001A359, 45001A396, 45001A399, 45001A404, 45001A421, 45001A427, 45001A448, 45001A468, 45001A518, 45001A531, 45001A555, 45001A571, 45001A611, 45001A640, 45001A642, 45001A651, 45001A689, 45001A705, 45001A715, 45001A734, 45001A745, 45001A746, 45001A762, 45001A764, 45001A787, 45001A802, 45001A804, 45001A836, 45001A881, 45001A883, 45001A923, 45001A927, 45001A928, 45001A939, 45001A955, 45001A969, 45001A971, 45001C014, 45001C041, 45001C051, 45001G019, 45001G034, 45001G057, 45001G058, 45001G088
Optium Glucose Test Strips 10s (G3c)	45001A133, 45001A338, 45001A568, 45001A641, 45001A770, 45001A774, 45001A911, 45001G013, 45001G076, 45001G244

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URL: <http://www.tga.gov.au/alerts/devices/optium-glucose-strips.htm>

PDF: <http://www.tga.gov.au/alerts/devices/optium-glucose-strips.pdf>