

Medical Devices Safety Notice

The National Health Regulatory Authority would like to alert all governmental and private healthcare facilities, local agents and distributors that the below medical device:

| Device Details | |
|------------------------|---|
| Device Name | Quo-Lab A1C test kit |
| Lot No. | 026246 to 026403 |
| Manufacturer | EKF DIAGNOSTICS |
| Country of Origin | GERMANY |
| Reference | Link |
| Reason of Recall | NHRA initiates this FSN due to identification of stability specification failures in retention samples stored for over six months, with risks of false low measurements. |
| Action should be taken | Please stop using the above mentioned medical device and contact the authorized representative Gulf corporation for Technology at quality@gctbahrain.com to take the necessary action for recall. |

Your cooperation is highly appreciated in improving health services in the Kingdom of Bahrain.

For more information please contact Medical_Devices@nhra.bh