

Recall detail

Type of Product ⁱ	Medical Device
TGA Recall Reference ⁱⁱ	RC-2016-RN-00024-2
Product Name/Description ⁱⁱⁱ	One Step HCG Urine Pregnancy Test. An in vitro diagnostic medical device (IVD) Batch Numbers: 20140406 and 20150314 ARTG number: 260088
Recall Action Level ^{iv}	Retail
Recall Action Classification ^v	Class II
Recall Action Commencement Date ^{vi}	8/01/2016
Responsible Entity ^{vii}	Murray International Trading Pty Ltd
Reason / Issue ^{viii}	Subsequent to complaints regarding false negative results by the users, results of the testing undertaken by the TGA for the above batches have showed that these batches do not comply with the claim in the Instructions for Use which specify that "In less than 5 minutes, levels of HCG as low as 25mIU/ml can be detected". Batch # 20150314 has failed to detect hCG in human urine at concentrations of 10, 25, and 50 mIU/mL levels while batch # 20140406 has failed at hCG concentrations of 10, 25, 50 and 100 mIU/mL . The TGA is undertaking further investigation to ascertain if any further actions are required. False negative results in the worst case can result in misdiagnosis and significant harm.
Recall Action ^{ix}	Recall
Recall Action Instructions ^x	Customers are advised to quarantine any unused stock from the above batches and return it to Murray International Trading Pty Ltd.
Contact Information ^{xi}	hysy07@murrayit.net

Footnotes

ⁱ Type of Product: Medicine, Medical Device, or Biological

ⁱⁱ TGA Recall Reference: Unique number given by the TGA

ⁱⁱⁱ Product Name/Description: Brand name (including active ingredient for medicines) and may include generic reference for the kind of medical devices. Includes all necessary information such as affected: catalogue / model and / or batch / serial numbers.

^{iv} Recall Action Level: The level to which the recall action is to be undertaken. This is based on the significance of the risk and the channels through which the goods have been distributed. The recall action levels are / Wholesale / Hospital / Retail / Consumer.

◦ Wholesale - includes wholesalers and state purchasing authorities.