

## 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	
<b>Device Name</b>	Advia Centaur XPT HBsII Kits
<b>Lot No.</b>	34096220
<b>Manufacturer</b>	Siemens
<b>Country of Origin</b>	USA
<b>Reference</b>	<a href="https://fscs.swissmedic.ch/mep/api/publications/Vk_20200925_10/documents/1">https://fscs.swissmedic.ch/mep/api/publications/Vk_20200925_10/documents/1</a>
<b>Reason of Recall</b>	NHRA initiates this FSN due to inability to calibrate the ADVIA Centaur HBsAg Confirmatory (Conf) assay on the ADVIA Centaur XPT when using Master Curve Cards (MCCs) provided in the ADVIA Centaur HBsAgII kit lots listed in Table 1 in the above link. The inability to calibrate the ADVIA Centaur HBsAg Conf assay on the ADVIA Centaur XPT prevents the generation of HBsAg Conf results and could delay reporting of Conf results. This issue is observed only on the ADVIA Centaur XPT. Customers can continue to generate HBsAgII results with kit lots ending in 220 and 223 on ADVIA Centaur XPT.
<b>Action should be taken</b>	Please stop using the above defected medical device and contact the authorized representative <b>Wael Pharmacy</b> at <a href="mailto:vincent@waelpharmacy.com">vincent@waelpharmacy.com</a> to take necessary action for replacement.

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

For more information please contact [Medical\\_Devices@nhra.bh](mailto:Medical_Devices@nhra.bh)