Urgent Field Safety Notice

Commercial name of the affected product: CLUNGENE hCG Pregnancy Test
FSCA-identifier: 20140820
Type of action: a device modification (permanent changes to the instructions for use).

Date: 2014-10-12

Attention: ////////////////

Details on affected devices:
The affected products are come from Hangzhou Clongene Biotech Co., Ltd. The name is CLUNGENE hCG Pregnancy Test and the types are Strip, Cassette and Midstream.

Description of the problem:
The instruction for use existed some defects and had to be revised.
The reason for FSN is that the CLUNGENE hCG Pregnancy Test Midstream (lot 13122001 and 14060301) gave 11 false positive results at 5 Ireland healthcare facilities from 12th June 2014 to 18th August 2014. We tested the reserved samples of Lot13122001, Lot14060301 in the factory and returned 20pcs sticks from distributor, all test results are passed. As of right now, we can draw a conclusion that the accuracy of the CLUNGENE hCG Pregnancy Test Midstream is more than 99% from the current complaints.
The CLUNGENE hCG Pregnancy Test is a Immuno-chromatographic qualitative assay designed for the rapid detection of human chorionic gonadotropin (hCG) in urine, aid for early detection of pregnancy. It only provides a presumptive diagnosis for pregnancy, the clinical diagnostic accuracy is about 99%. Occasionally urine specimens containing less than 25mIU/ml hCG also yield positive results. Based on the above reasons, we recommend that if the test result is positive, it is better to go to the hospital for further diagnosis with other clinical methods, such as a quantitative assay for detection of hCG is recommended. And the patient should not take any decision of medical relevance without first consulting her medical practitioner. We revised the Package insert as the old version didn't state it unequivocal. Sometimes, certain medications and endogenous substances in urine can lead to false positive results. The potentially interfering substances which will not interfere the assay when below a certain concentration were added in the new package insert as well.

Advise on action to be taken by the user:
Please check the products in your possession. If you have the same type products, please contact the distributors or manufacturer to get the revised instruction for use. Distributors should inform their customers of the updated information which has been revised in the instruction for use. End users are recommended to consult with their doctor for further diagnosis with other clinical methods, such as a quantitative assay for detection of hCG if she gets a positive result, and should not take any decision of medical relevance without first consulting the medical practitioner.

Transmission of this Field Safety Notice:
This notice needs to be passed to all distributors which sell these types in the market of EEA member states.

Contact reference person:
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The under sign confirms that this notice has been notified the appropriate Regulatory Agency.

Signature: Shujian Zheng