



DLT/FSN.001

16 November 2011

Field Safety Notice No. 1

Product: SD Bioline HIV-1/2 3.0
Product code: 03FK10
PQDx Number: PQDx 0027-012-00

The WHO Prequalification of Diagnostics programme has undertaken the WHO prequalification assessment for the SD Bioline HIV-1/2 3.0 (product code 03FK10) manufactured by Standard Diagnostics at 156-68, Hagal-dong, Giheung-ku, Yongin-si, Kyonggi-do 446-930 Republic of Korea. The laboratory evaluation showed unacceptably high rate (approximately 50%) of invalid test devices on two separate lot numbers (023419 and 023418B) with expiry dates 30 August 2013 and 2 August 2013, respectively.

The Partnership for Supply Chain Management (PSCM) has observed similar problems with the SD Bioline HIV-1/2 3.0 (product code 03FK16) lot number 023424B with expiry date 18 August 2013 and lot number 023425.

SD Bioline HIV-1/2 3.0 will be de-listed from the WHO e-catalogue and will therefore not be eligible for procurement by WHO and UN agencies, until further notice.

WHO has provided Standard Diagnostics with an appropriate course of action to guide their investigation of the problem and the company is cooperating fully with this request.

If you are experiencing similar problems, please complete the "User complaint form for reporting problems and/or adverse events related to diagnostic products" available on our webpages (http://www.who.int/diagnostics_laboratory/procurement/en/) and submit it to diagnostics@who.int. If you have any questions, please do not hesitate to contact the WHO Prequalification of Diagnostics programme by email (diagnostics@who.int).