Fourth information update on SD Bioline HIV-1/2 3.0

Product codes: 03FK10, 03FK16 (PQDx reference number 0027-012-00)

Background:

1. The first inspection of manufacturing of the above mentioned product was conducted by the WHO Prequalification of Diagnostics Programme from 28 September-1 October 2010 at Standard Diagnostics Inc. (SD). A re-inspection at 156-68 Hagal-dong Giheung-gu, Yongin-si, Kyonggi-do 446-930, Republic of Korea and an inspection of the newly acquired site at 473-4 Bora-dong Giheung-gu, Yongin-si, Kyonggi-do, 446-904, Republic of Korea, took place 6-9 March 2012.

2. With the findings of major product failure of SD BIOLINE HIV-1/2 3.0 during the WHO laboratory evaluation (WHO Field Safety Notice, 16 November 2011), SD took the decision to recall the following lots: 023418, 023418B, 023419, 023424, 023424B, 023425B, 023426B, 023427, 023427B, 023428, 023428B, 023429B, 023430, 023430B.

3. Given the above point 2, WHO undertook a first re-inspection in March 2012 where a number of critical nonconformities were noted, subsequently WHO issued a Notice of Concern on 11 July 2012.

4. A second re-inspection took place 26-29 November 2012, to determine if the critical nonconformities found in March 2012 had been addressed and if confidence in the performance of the product could be restored.

5. The second re-inspection in November 2012 found that SD was to be commended for applying significant improvements in their quality system in many areas. However, the remaining critical concern was the ability to adequately assure the quality of lots released to end users.

6. On 15 February 2013, WHO received the report from SD regarding the corrective actions taken for the remaining critical nonconformity which WHO subsequently considered to be acceptable. The manufacturer was then notified that the inspection process had been finalized with satisfactory results.

7. Consequently, the WHO Notice of Concern was removed on 20 February 2013.

Update:

8. The WHO prequalification assessment of SD BIOLINE HIV-1/2 3.0 has now been concluded with satisfactory dossier review and site inspection, and acceptable results in laboratory evaluation.

9. SD Bioline HIV-1/2 3.0 was therefore WHO prequalified on 20 May 2013 and is eligible for WHO and UN procurement.

10. Results of the USAID/CDC laboratory evaluation and dossier review by CDC/International Laboratory Branch were also made available to WHO and all parties agreed to re-instating eligibility for global procurement.

11. This information update dated 15 May 2013 supersedes the previous versions dated (6 January 2012, 6 July 2012, 1 March 2013). For further information, please contact diagnostics@who.int.