Appendix 3: Part B

Decision on acceptance by the NRA to apply the Procedure to a specified WHO-prequalified in vitro diagnostic product and request for access to product-specific information and documentation

Please complete all fields marked with an *. For other fields, if there have been changes to the details provided in Part A above please also complete the relevant fields below. Where fields below are left blank, the data in Part A are considered to be valid.

Application details

Name of entity: _____ ("the Applicant")

Street: _____

City and country: _____

Telephone number: _____ (please include codes)

Email: _____

*Date of receipt of submission (dd/mm/yyyy): _____

Product name in national system (if known): _____

*National reference number (if known): _____

Product details for IVD

Product name:_ _____

Product code(s): _____

Regulatory version: _____

Manufacturer: _____

Manufacturing site(s): _____

Packaging: _____

WHO prequalification details

*WHO PQ reference number: _____

Date of prequalification (dd/mm/yyyy): _____

Name of WHO PQ holder: _____

Please complete either section A or section B below.

☐ **Section A**

The NRA agrees to conduct the assessment for accelerated registration of the above- mentioned product ("the Product") under the Procedure and requests access to product- specific information, in accordance with and subject to the terms of the Procedure and the Agreement between WHO and the NRA dated _____ (dd/mm/yyyy).

☐ **Section B**

The NRA has decided not to apply the Procedure to the above-mentioned Product for the following reasons:

_____

_____

_____

_____

***For the NRA of** _____ (indicate country)

Signature: _____

Name: _____

Title: _____

Place: _____

*Date (dd/mm/yyyy): _____