*Instructions: Adjust sections in blue as applicable, including manufacturing steps section as needed. Delete comments highlighted in yellow. Submit alongside other documents*

**Letter of Intent**

[Date]

**To**

**Global Fund,**

**Global Health Campus, Le Pommier 40**

**CH-1218 Grand-Sacconnex**

**Geneva, Switzerland**

To whom this may concern,

This letter serves as [Manufacturer]’s commitment to make best efforts to expand the manufacturing steps conducted in African sites for [Product] to achieve end-to-end manufacturing in African sites within the next 10 years. This may include expanding from [packaging of finished test kits/ production of finished test kits], with the aim of achieving [fully integrated manufacturing starting with reagent raw materials] by [year].

*[Note: Manufacturer to adjust manufacturing steps above as applicable]*

Please find attached a Business Plan describing these plans in more detail.

*[Action: Manufacturer to attach business plan]*

As a duly authorized officer of the [Manufacturer], I represent, on behalf of [the Manufacturer], that the [Manufacturer’s] materials, proposal and the schedules attached herein do not contain any untrue statement of a material fact or omit any material fact which is necessary in order to make the statements therein not misleading.

I consent to this letter and attached Business Plan to being shared with PEPFAR, Unitaid and FIND representatives.

Sincerely,

\_\_\_\_\_\_\_[Sender signature]\_\_\_\_\_\_\_\_

[Sender’s name], [Manufacturer]

Annex 1: Key definitions

|  |  |
| --- | --- |
| **Production of uncut sheets** | All manufacturing operations to produce uncut sheets from all raw materials (raw material procurement, storage, preparation, conjugating, membrane coating, laminating) and lot release. |
| **Production of finished tests** | All manufacturing operations to produce finished Rapid Diagnostics Tests from uncut sheets (cut sheets, molded components, and any assembly into cartridge/ final format) and lot release. |
| **Packaging of finished test kits** | All manufacturing operations to produce final Rapid Diagnostic Kits from finished Rapid Diagnostic Tests (pouching, sealing, kitting, labelling, IFU’s, final cartooning) and lot release. |
| **Uncut sheet** | Semi-finished product in the form of laminated cards (for lateral flow) ready for stripping and assembling. |
| **Manufacturing In African sites** | Manufacturing operations happening in a site located in one of the 55 member states of the African Union |