

ANNEXURE- A

BMSIC/MEDICAL DEVICE/CONSUMABLE/19-03

Clarification in the light of queries/suggestions received from various firms during and after Pre-Bid Meeting held on 30/09/2019

S.N.	Name of the Firm	Bidders Queries	Present Clause	Clarification/Amendment
1	M/s Mediclone Biotech Pvt. Ltd.	1. The Assay maybe based on Rapid Test Principles- Reg :- Please do update if the Assay is Immunochromatographic Assay Based As well.	1. The assay may be based on any of the rapid test principles: (Immunoconcentration /Dot blot immunoassay (vertical flow), dip stick and comb assay.	The assay may be based on any of the rapid test principles: (Immunoconcentration / Immunochromatographic/ Dot blot immunoassay (vertical flow/ lateral flow), card/ cassette based)
		2. Positive and negative Controls- Reg :- The Controls can be Provided as requested for 10% of the Tests to be performed, but we would like it to be separately shipped as they are 2°C to 8°C products, packing them separately would also have little space occupancy in the Warehouse Cold-storage, as the Rapid cards as kits with controls occupy much space and the cards are usually kept at Room- Temperature.	2. The assay should have reactive and non-reactive controls with each kit in adequate volume (minimum 10% of pack size). The manufacturer / importer should ensure maintenance of cold chain during storage and transport of kits at 2°C to 8°C.	2. The assay should have reactive and non-reactive controls with each kit in adequate volume (minimum 10% of pack size). The manufacturer/ importer should ensure maintenance of cold chain of the control reagents during storage and transport at 2°C to 8°C. The POC kit containing the required accessories as per the mentioned specification excluding the control reagents may be shipped at ambient temperature.
		3. The Assay Sensitivity and Specificity Statements and Certificate from NIB :- The Assay sensitivity and specificity statements to be enclosed with In-House Test Reports or NABL Accredited Test Reports.	3. The assay should have sensitivity of 99% or more and specificity of 95% or more and the same should be supported by statements in kit insert and certificate from National Institute of Biological Sciences.	The assay should have sensitivity of 99% or more and specificity of 95% or more and the same should be supported by statements in kit insert and certificate from National Institute of Biological Sciences/ Independent NABL Accredited Test Reports along with In-House Test Reports.

		4. Transportation of Kits - Reg :- The Rapid cards and the accessories mentioned are usually transported in Normal Temperature. As the Products are being packed in Silica Gel to protect from Moisture. The maximum Temperature the Products can be safely stored is 30°C. Hence, request to amend the necessity of Cold-chain Transportation.	4. The assay should have an in-built positive and negative control for testing the validity of the test kits.	The manufacturer/ importer should ensure maintenance of cold chain of the control reagents during storage and transport at 2°C to 8°C. The POC kit containing the required accessories as per the mentioned specification excluding the control reagents may be shipped at ambient temperature.
		5. Accessories - Reg :- Please request to amend the Auto retractable lancets to Sterile single use Lancets.	• The test kit should be supplied with sterile auto retractable disposable lancet one for each test (card). Each kit box will contain 50 (fifty) such lancets.	No Change