TERMS OF REFERENCE FOR THE R&D PROJECT

***In-vitro* Diagnostic Medical Devices and Biological Evaluation of Medical Devices Sectional Committee MHD 19**

1. **Title**: Methodology for performance evaluation of HIV Diagnostic Test Kit

2. **Background:**

The Minister of Health and Family Welfare MOHFW has been working towards the goal of 'ending the AIDS epidemic as a public health threat by 2030'. HIV Testing is a critical intervention in supporting the National AIDS Control Programme (NACP) of NACO National AIDS Control Organization. It is important that the standard test methods are defined for safe use of HIV Diagnostic Test Kit to support the vision of the nation.

3. **Objective:**

The Objective of the project is to study and define the test methodology for essential performance evaluation of the HIV Diagnostic test kit. The project is intended to extensively study the various product technologies in the HIV Diagnostic Test Kit and define test methodologies for evaluating the performance of the various types of HIV Diagnostic Test Kit.

4. **Scope:**

4.1 Comprehensive **study of existing literature** which includes international standards, journals, research papers, any SoPs/ guidance/ instructions issued by the Ministries/ regulators concerned and any other study

4.2 Collection of **scale-wise data on manufacturing base** through government sources (websites, reports) or industry associations

4.3 Analysis of the **import and export data** and conduct analytical study of the technical regulations on the product in various countries

4.4 Analytical study on availability of **test facilities** in the country

4.5 Collection of data on the following through visits to 2 large scale industries, total 2 Medium/ small/ micro, 1 government and 1 NABL accredited private testing facility:

- Manufacturing process,
- Product varieties,
- Reagent Stability requirements,
- Sampling Plan requirements,
- Panel requirements,
- Performance test methodology and parameters
    - Precision
    - Linearity
    - Limit of Detection
    - Performance panel requirements
    - Diagnostic specificity
    - Diagnostic sensitivity
    - Clinical specificity
    - Clinical sensitivity

5. Research Methodology:

The project will involve the following research methodologies:

(a) Study the literature and analyse it in respect to the scope

(b) Survey the market through structured questionnaires for collecting information in respect to the scope

(c) Contact the relevant organizations and associations (Industry/ user associations) for gathering the data

(d) Visits to the manufacturing units to collect data as per the scope and observe the following:

1. Manufacturing processes,
2. In-process controls,

(e) Discussion with focused groups (Quality control personnel and person responsible for manufacturing) through structured questionnaires on the test methodologies

(f) Samples to be tested inhouse for functional and safety requirements during the visits to industries. Samples shall be tested in such a manner that there is sufficient data to compare the performance and the range of varieties being manufactured by any particular manufacturer. For this purpose, samples from the lowest, middle, highest range shall be preferably considered for testing. In case of non-availability of samples during the visit or tests are time consuming in nature, the test results of the samples already tested and documented by the manufacturer may be collected for the purpose of analysis.

(g) Comprehensive reporting on all aspects.

6. Delivery Milestones and Review Process:

The duration of the project is 6 months from the date of award of the project. The proposed indicative timeline stage-wise is given below:

- An interim report indicating the review of the literature, desktop research, questionnaires collected and sampling plan shall be submitted in 2 Months from award of the project.
- Draft report shall be submitted by the end of 4 Months from award of the project.
- Final report shall be submitted within 6 Months from award of project, including all the deliverables mentioned in ITEM 4 and following the ITEM 5.

7. Support from BIS:

BIS shall support the project by providing access to Indian standards, international standards, BIS Licensee details, BIS Laboratory details.

8. Nodal Point:

Ms. Nagavarshini M., Scientist B/ Assistant Director, Member Secretary, MHD 19 may be contacted for more clarification on the R&D project (Email address: mhd@bis.gov.in)