



***Invitation for Submission of Expressions of Interest
To Providers of laboratory kit assembly services
for diagnostics and consumables
for diagnosis of TB using the Ziehl –Neelsen staining technique***

The Global Drug Facility (GDF), the procurement arm of the Stop TB Partnership, housed at the World Health Organization (WHO) in Geneva, Switzerland, intends to issue, via its appointed procurement agent, the Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ) GmbH, a restricted Invitation to Bid for assembly of a diagnostics consumables kit in countries serviced by GDF. It is planned to issue the ITB in Q4 2013.

GDF's mission is to ensure timely access to quality assured, affordable anti-tuberculosis (TB) medicines and diagnostics.

GDF supports implementation of the Stop TB Strategy in accordance with the Global Plan to Stop TB (2006 - 2015), supplemented by the Global MDR / XDR-TB Response Plan (2007 - 2008, as updated 2010). GDF facilitates global DOTS expansion or maintenance in support of the Stop TB Strategy. For a general background on GDF's services and operations, please refer to <http://www.stoptb.org/gdf/>.

For first line anti-TB medicines (FLMs) and drug-susceptible diagnostics, GDF offers two lines of services:

- A Grant Service for FLMs and diagnostics to support DOTS expansion or implementation; i.e. for countries and nongovernmental organizations (NGOs) that are donor-dependent for some or all of their drug supply and wish to expand or strengthen their DOTS programmes;
- A Direct Procurement Service for countries, NGOs and donors to purchase FLMs and diagnostics for use in DOTS programmes; i.e. for countries and NGOs that have sufficient finances but lack adequate procurement or quality assurance systems

GDF offers two types of diagnostic kits to countries:

- Brightfield microscopy
- LED microscopy using LED fluorescence technology

The kits respectively comprise a microscope, an equipment starter kit, a consumables kit and a sputum cup kit. While GDF is encouraging introduction of LED microscopy, it is continuing to provide brightfield microscopy for countries requesting such. For this purpose, GDF has recently revised and updated the composition and specifications of the brightfield kits and is screening submissions through this Expression of Interest (EOI). As the LED microscope is dual use also for brightfield microscopy and the equipment starter kit and sputum cups are identical for LED and brightfield microscopy, only the consumables kit is the subject of this EOI.

For the brightfield kits, these are intended to prepare solutions for microscopy using the Ziehl – Neelsen staining technique. Relevant SOPs are available here:

http://www.stoptb.org/wg/gli/assets/documents/18_light_microscope_fin.doc.docx
http://www.stoptb.org/wg/gli/assets/documents/22_reagents_for_microscopy_fin.doc
http://www.stoptb.org/wg/gli/assets/documents/26_ZN_staining_fin.doc
http://www.stoptb.org/wg/gli/assets/documents/09_disinfectants_fin.doc

A description of the required items and specifications for the diagnostics consumables kits is provided in Annex 1.

Providers are expected to attend to both sourcing of component products and assembly of the Kit. Component products must be manufactured in conformity with a generic, well-respected quality management system (e.g. ISO 9001 and ISO 13485, or equivalent) ¹ and registered in a highly regulated environment, such as in the US (US FDA), Japan or bear the CE marking or equivalent.

Evaluation

The purpose of this Call for Expressions of Interest (EOI) is to short-list potential providers of the above kits for an ITB to be conducted by GIZ, based on a technical assessment. The ITB will then be focussed on a quality / cost evaluation (best value for money). The successful bidder(s) will be awarded a one year long-term agreement, extendable for two further periods of one year each.

Submissions

All submissions will be assessed for acceptability to the GDF and providers will be notified in advance of the ITB.

All providers interested in participating in the planned GIZ ITB are requested to complete the detailed specification sheet filled with the bidder's specification – Annex 1.

Submissions are to be sent to the address listed hereunder no later than Monday, 16 September 2013. Data should be submitted in hard copy (paper) form in four (4) originals by registered courier and one copy on CD. Product samples may be requested at a later stage.

Subject: Expression of Interest - Diagnostics consumables kit – ZN Microscopy
 Attention: Mr. John Loeber
 Procurement Coordinator, Global Drug Facility
 Stop TB Department
 World Health Organization
 20 Avenue Appia
 1211 Geneva 27
 Switzerland

Enquiries / correspondence are kindly also directed by email only to:
 Mr. Thomas Verges, Global Drug Facility, email: vergest@who.int



Global TB Drug Facility / Stop TB Partnership

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The Stop TB Partnership Secretariat is housed by the World Health Organization

¹ For recommended quality management systems for medical devices and respective regulatory guidelines see <http://whqlibdoc.who.int/publications/2003/9241546182.pdf>