The Global Fund

VERSION 20, 2 March 2017

# LIST OF ISO 17025 QUALITY CONTROL LABORATORIES COMPLIANT WITH 'THE GLOBAL FUND QA REQUIREMENTS

## A/ WHO-PREQUALIFIED QUALITY CONTROL LABORATORIES

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| *To obtain the list of WHO prequalified quality control laboratories click at the link provided herewith* | http://www.who.int/prequal/lists/PQ_QCLabsList.pdf |

## B/ ISO/IEC 17025-CERTIFIED QUALITY CONTROL LABORATORIES

*1. The Quality Control Laboratories have been listed below following the response to a technical questionnaire and subsequently on the verification of credentials submitted along with it. The listed Quality Control Laboratories are capable of performing Quality control testing of Finished Pharmaceutical products listed in Global Fund list, as part of the monitoring activities described in the* ***Global Fund's QA Policy***

*2. Only the laboratories that responded to the questionnaire and expressed their interest to be listed on the Global Fund website have been listed below. The laboratories that wish to be listed in this list shall respond to the* ***questionnaire*** *which can be downloaded from the* ***Global Fund website***

| | Details of laboratory | | | | Testing capabilities | | Remarks |
|---|---|---|---|---|---|---|---|
| COUNTRY | Name and location | STATUS | Physical Address (see WHO website or laboratory website) | Contact person | Physical/ chemical analysis | Microbiological tests (sterility test, bacterial endotoxin test and microbial count) | ADDITIONAL INFORMATION IF ANY |
| AZERBAIJAN | Azerbaijan Republic Ministry of Health Analytical Expertise centre | ISO/IEC 17025 (Date of issue: 04 Dec 2012) | 34 J.Jabbarli Str Baku AZ1065 Tel:+99412-596-05-20 | Farid Aliyev lab@pharma.az | YES | YES | |
| BELARUS | The Republican Control Analytical laboratory | ISO/IEC 17025 (Date of issue: 09 July 2010) | Prityskogo street, 78, Minsk, 220140 Tel:017 3349789 | Mrs. Marina Kravez, rcal@rceth.by | YES | YES | |
| BELGIUM | CHEMIPHAR NV | ISO/IEC 17025 (Date of issue: (06 October 2009) | Lieven Bauwensstraat 4, 8200 Brugge | Jan Cordonnier jan.cordonnier@chemiphar.com | YES | YES (Out sourced to LEC QC LAB Belgium) | |
| BELGIUM | Laboratoire de Contrôle et d'Analyse S.A.(LCA) | ISO/IEC 17025 (Date of issue: 01 June 2012) | Avenue Jean Jaures, 46 B-1030 Schaarbeek TEL:+32494578205 | Seppe De Gelas Seppe.degelas@lca.be | YES | YES | |
| BOSNIA AND HERZEGOVINA | The Control laboratory of the Agency on Medicines and Medical Devices. web site: http://www.alims.gov.ba/ | ISO/IEC 17025 (Date of issue: 20 March 2009) | Maršala Tita 9, Sarajevo Tel: +387 33 279 351/369, Fax: +387 33 211 279 | Mr. Seherzada Hadzidedic s.hadzidedic@alims.gov.ba ljkudra@alims.gov.ba | YES | YES | |
| CANADA | HEALTH CANADA HPFB Inspectorate | ISO/IEC 17025 (Date of issue: 15 October 2009) | 1001, rue Saint-Laurent Ouset Longueuil, QC J4K1C7 Tel: +16132383222 | M. Jacques Gagnon jacques_gagnon@hc-sc.gc.ca | YES | YES | |
| CAPE VERDE | Inlab Laboratoria de control de qualidade Inpharma | ISO/IEC 17025 (Date of issue: 19 October 2008) | Z.I de tira chapeu CP 472 Praia Cap Vert Tel:(00238)2627162 | Elisete LIMA emlima@inpharma.cv inlab@inpharma.cv | YES | NO | |

| | Details of laboratory | | | | Testing capabilities | | Remarks |
|---|---|---|---|---|---|---|---|
| COUNTRY | Name and location | STATUS | Physical Address (see WHO website or laboratory website) | Contact person | Physical/ chemical analysis | Microbiological tests (sterility test, bacterial endotoxin test and microbial count) | ADDITIONAL INFORMATION IF ANY |
| CHINA | Beijing Institute for Drug Control www.bidc.org.cn | ISO/IEC 17025 (Date of issue: 20 Oct 2012) | No.13 Shuiche Lane Xinjiekou St.Xicheng District,Beijing Tel: 010-83228397/010-83228397 | Wang zhibin | YES | YES | |
| CHINA | SGS-LIFE SCIENCE SERVICES LAB CSTC Standards Technical services, Shanghai CO Ltd. | ISO/IEC 17025 (Date of issue: 31 August 2009) | 3rd building, No889, Yishan Road, Xuhui District, 200233 Shanghai | SGS Nederland B.V., Leanne Ruitenbeek Leanne.Ruitenbeek@sgs.com | YES | YES | |
| ETHIOPIA | The Etiopian Food, Medicine and Health care Administration and Control Authority (FMHACA) | ISO/IEC 17025 (Date of issue: 27 Nov 2011) | Gullelle Sub-City- Kebele 10- House No:622, Patriot road PO BOX 5681, Addis Ababa, Tel:+251112776984 | Bikila Bayassa Bikubf2007@yahoo.com | YES | NO | |
| GHANA | Centre for Pharmaceutical Advancement and Training (CePAT) | ISO/IEC 17025 (Date of issue: 17 July 2014) | PO Box WY1204 Kwabenya Accra | cepat@usp.org kpb@usp.org | YES | NO | |
| GHANA | FOOD AND DRUG AUTHORITY LABORATORY | ISO/IEC 17025 (Date of issue: 06 April 2014) | PO Box CT 2783 Cantonment, Accra | fda@fdaghana.gov.gh Eric Karikari Boateng | YES | NO | |
| INDIA | CHOKSI LABORATORIES LIMITED website: www.choksilab.com | ISO/IEC 17025 (Date of issue: 23 Dec 2010) | 6/3, Manorama Ganj, Indore 452001 Tel:+917314243888 | Vyangesh Choksi v.choksi@choksilab.com amreesh.beohar@choksilab.com | YES | NO | |
| INDIA | PRK Pharmanalyst Pvt Ltd | ISO/IEC 17025 (Date of issue: 12 Jan 2011) | Flat Nos 201-205, Bluechip Arcade, Himayatnagar, Hyderabad 500029 | Mr.M.SRINIVAS RAO prklab@gmail.com | YES | NO | |
| INDIA | ARBRO PHARMACEUTICALS Ltd ANALYTICAL DIVISION web site: http://arbropharmaindia.com/ | ISO/IEC 17025 (Date of issue: 24 November 2008) | 4/9, Kirti nagar Industrial Area, New Delhi-110015 Tel: + 91 11 45754575 Fax: + 91 11 45754545 | Dr.Saurabh Arora arbro@arbropharma.com sa@arbropharma.com | YES | YES | Laboratory Conforms to ISO9001:2000 specification |
| INDONESIA | National Quality Control Laboratory of Drug and Food Control (NQCLDF). – National Agency of Drug and Food Control (NADFC) | ISO/IEC 17025 (Date of issue: 02 May 2012) | Jalan Percetakan Negara no. 23 (Street); Jakarta 10560 | Drs. Syamsudin, Msi., Apt. (Director) Tel. +62 - 21 4245075; nqcldf@yahoo.com | YES | NO | |
| KYRGYZ REPUBLIC | Central Control and Analytical Laboratory of the Department for Drug Supply and Medical Devices | ISO/IEC 17025 (Date of issue: 03 Feb 2014) | Bishkek, 3rd Line Str., 25 Akhunbaev Str., 186 | ckal70@gmail.com | YES | NO | Currently the laboratory is not in a position to perfrom water content and endotoxin test |
| NEPAL | ZEST LABORATORIES PRIVATE LIMITED | ISO/IEC 17025:2005 (Date of issue: 22 /04/2016) | Hanumante marg, Balkot -2, Anantalingeswor Municipality, Bhaktapur | Shobha Basnet at Shobha@zestlab.com.np ; mail@zestlab.com.np | YES | YES (Microbial count and Bacterial Endotoxin) | Accredited for Condom Testing For detailed scope of accreditation, Please consult directly. |

| | Details of laboratory | | | | Testing capabilities | | Remarks |
|---|---|---|---|---|---|---|---|
| COUNTRY | Name and location | STATUS | Physical Address (see WHO website or laboratory website) | Contact person | Physical/ chemical analysis | Microbiological tests (sterility test, bacterial endotoxin test and microbial count) | ADDITIONAL INFORMATION IF ANY |
| PHILIPPINES | FOOD AND DRUG ADMINISTRATION LABORATORY SERVICES DIVISION http://www.fda.gov.ph | ISO/IEC 17025 (Date of issue: 08 April 2010) | Civic Drive Filinvest Corporate City, Alabang, Muntinlupa City | info@fda.gov.ph<br>Maria Victoria P. Calub<br>Jocelyn E. Balderrama | YES | YES | |
| UKRAINE | State Institution "O.M. Marzeiev Institute for Hygiene and Medical Ecology of the National Academy of Medical Sciences of Ukraine" | ISO/IEC 17025 (Date of issue: 27 May 2014) | 02660 Kyiv, str. Popudrenko, 50 | 3526309@ukr.net<br>Natalia Ostanina | YES | YES | |
| UZBEKISTAN | Test Centre in the Structure of The State Centre of Examination and Standadisation of Medical Products | ISO/IEC 17025:2005 (Date of issue: 22 Aug 2011) | 16, Ozod Str Umarov pass 100002 Tashkent | Jalilov Kh.K | YES | YES | |
| ZIMBABWE | Medicine Control Authority of Zimbabwe (MCAZ) | ISO/IEC 17025 (Date of issue: 30 April 2010) | 106 Baines Avenue Box 10559 Harare | Bridget Dube bdube@mcaz.co.zw | YES | NO | |

*1. Global Fund Grant Recipients are allowed to use any other ISO 17025 certified than listed, provided the Grant Recipients verify, prior to using the laboratory, various aspects of the testing capabilities, including Participation in any Proficiency Testing Schemes (PTS) conducted by any internationally acclaimed organisation that performs PTS, though not mandatory, will be considered an added value for selection. but not limited to technical capacity and if equipped adequately to test all products listed in Global Fund lists. Assistance will be provided by the Global Fund Secretariat in this regard.*

*2. A QC lab that is not equipped to undertake microbiological testing (sterility test, bacterial endotoxin test and microbial count) can be used, provided the laboratory will undertake the responsibility to perform the microbiological tests in another QC lab that fulfills Global Fund Quality standards as shown in the questionnaire posted on the Global Fund website (http://www.theglobalfund.org/documents/psm/communication/Questionnaire_for_QC_labs.doc). Alternatively the grant recipients can choose to use two QC labs, one for microbiological tests and another for other tests, but should be aware fo the logistic and time constraints.*

*3. There should be an agreement between the Grant Recipients and the laboratory indicating the responsibilities of both parties.*

*4. The Grant Recipients should ensure that the testing of products by the laboratories would not be in breach of their national legislation, including patent restrictions.*

*5. The Grant Recipient should ensure that the laboratories declare any possible conflict of interest in testing product samples prior to agreeing to perform work on behalf of the contract-giver.*

*6. The list does not constitute any guarantee for the use of the laboratories mentioned . The assessment was made on the informations provided by the laboratory. No site inspection has been performed.*

*7. Quality control laboratories are added to the list when found to meet the norms and standards for use only by the grant recipients of the Global Fund.*

*8. Global Fund cannot represent that the listed laboratories will continue to meet the above-mentioned standards. Any laboratory found no longer to meet the required standards will be delisted.*

*9. The list is not exhaustive.*

*10. The list may not be used by laboratories for commercial or promotional purposes.*

## Disclaimer to the List of Quality Control Laboratories:

*1. Inclusion in the list does not constitute an endorsement, or warranty of the fitness, of any laboratory for a particular purpose.*
*2. Global Fund does not furthermore warrant or represent that:*
*a) the list is complete or error free; and/or that*
*b) the laboratories which have been found to meet the standards will continue to do so; and/or that*
*c) the laboratories listed have obtained regulatory approval for use for testing drugs, or that their activities are in accordance with the national laws and regulations of any country, including but not limited to patent laws.*