

GeneXpert Service Level Agreement
Between
Cepheid HBDC SAS
and [Insert Ministry of Health entity or Global Fund principal recipient
as applicable]

Between Cepheid HBDC SAS located at Vira Solelh, 81470 Maurens Scopont, France, hereinafter referred to as the “Service Provider” and [Insert Ministry of Health entity or Global Fund principal recipient as applicable] located at [Insert address, country], hereinafter referred to as the “Customer” in this contract.

Whereas the Service Provider is committed to provide to the Customer the described services, this contract shall be governed by the following conditions:

1. Purpose of the agreement

This service level agreement (SLA) describes the necessary technical support (including but not limited to service and maintenance) that the Customer will receive from the Service Provider. The necessary technical support to be provided includes installation, training, preventative maintenance and unscheduled repairs for the Cepheid equipment, hereinafter referred to as “analyzer” and/or “analyzers” as listed in “Annexe A – List of Analyzers Under Coverage”. The analyzers under coverage are the Cepheid instruments including its desktop computer with monitor or laptop computer and bar code reader.

2. Terms

- a) Under this SLA, where covered by the Service Level indicated in Annexe E, the Service Provider undertakes the execution by its technical staff of the scheduled Preventative Maintenance according to the instructions, which are described in “Annexe B – Yearly Maintenance Checklist” for each year of the SLA contract duration.
- b) The Service Provider will provide the XpertCheck kits necessary to perform the Preventative Maintenance required for all analyzers for each year of the SLA contract duration.
- c) Where covered by the Service Level indicated in Annexe E, the Service Provider will swap modules that have failed XpertCheck at the time of the Preventative Maintenance. When possible, the staff of the Service Provider will have the replacement modules in his/her person during the Preventative Maintenance so that any module failure can be solved immediately. The Service Provider agrees to replace modules which have failed within the Service Level maximum delay set out in Annexe E, Table 1.
- d) Where covered by the Service Level indicated in Annexe E, the Service Provider will inform the Customer, at least one week in advance, before proceeding with each scheduled Preventative Maintenance.

- e) In addition to the Preventative Maintenance (where covered by the Service Level indicated in Annexe E), the SLA also covers all unscheduled repairs related to the analyzers' malfunctions without any additional costs to the Customer. This includes replacement of faulty modules, modules that fail calibration, and analyzers or parts that are not functioning properly. The Service Provider agrees to replace modules which have failed within the Service Level maximum delay set out in Annexe E, Table 1. The Service Provider agrees to replace components, other than modules, which have failed within the Service Level maximum delay set out in Annexe E, Table 1. If there is need for removal of the Cepheid analyzer or any analyzer component from the site, such operation will be performed by the Service Provider to ensure proper removal. In the event of total analyzer malfunction and where such coverage is included in the Service Level conditions set out in Annexe E, Table 1, the Service Provider will ensure that while the analyzer is being repaired, the Service Provider will provide a temporary replacement device to the site within 10 working days at no extra cost to the Customer. If the Service Provider determines that the analyzer under warranty cannot be repaired, the Service Provider will exchange the malfunctioning analyzer with a replacement device. In addition, the Service Provider shall not levy any additional cost for the repair or replacement of the desktop computer or laptop under warranty.
- f) Where seven or more years have passed since the date of invoicing of an instrument, only module replacement will continue to be covered by this SLA.
- g) The Service Provider assumes all costs related to labor, travel and accommodation costs, and having spare parts, including shipping (Delivery Duty Paid [DDP]), clearance and other related costs.
- h) When determined necessary by Cepheid Technical Services, the Service Provider may request the transport of any part(s) of or the entire analyzer to its technical support facilities for repair purposes. All transportation costs (including international shipments where necessary) are the responsibility of the Service Provider.
- i) The Service Provider agrees to ensure that each analyzer's computer has the necessary version of the Cepheid software to run all Xpert cartridges procured by the Customer at no additional cost to the Customer. The Service Provider will also provide Cepheid-validated patches and bug fixes to the Cepheid operating software.
- j) Prior to installation of analyzers, the Service Provider will be available to provide off-site advice on environmental and infrastructure prerequisites (e.g., need for air conditioning, uninterrupted power supply, extended batteries, voltage stabilizer, cables, etc.) and provide performance standard recommendations to enable the Customer to identify suitable locally available ancillary equipment and vendors.
- k) Upon request of Customer, the Service Provider will install any new analyzers in accordance with the Service Level defined in Annexe E, Table 1.
- l) Upon request of Customer, the Service Provider will conduct Trainings of Trainers (ToTs), initial and refresher trainings on GeneXpert use and basic maintenance, in accordance with the Service Level defined in Annexe E, Table 1.

3. Customer support

- a) The Service Provider will provide remote technical support (including online support) and accept service requests from the Customer by phone and by email. Contact information of the Service Provider is provided in Annexe C.
- b) A local phone number will be available on all working days in accordance with the Service Level defined in Annexe E, Table 1.
- c) All service requests will be acknowledged and a follow-up plan articulated to the customer (by phone or email) **within 48 hours** (2 working days).

4. Customer responsibilities

- a) In order to facilitate the support process, customers are required to:
 - i. Make service requests through the appropriate channels as described in Annexe C.
 - ii. Provide detailed information at the time of the service request and make every effort to be available to communicate with the technical support technician if required.
 - iii. Notify technical support in advance of any pre-determined required assistance.
 - iv. The Customer is responsible for ensuring full and unfettered access to the Service Provider's engineer to the instrument. The Service Provider shall not be deemed responsible for any delays incurred to repairs on inaccessible instruments. The Customer may be invoiced for lost time and travel expenses resulting.
- b) It is the Customer's sole responsibility to complete a backup of all existing data on the supported analyzers prior to the Service Provider performing any services.
- c) The customer is responsible for basic daily, weekly, monthly and quarterly maintenance of the instrument as described in Annexe G. Where covered by the Service Level indicated in Annexe E, the Service Provider is responsible for the yearly maintenance; otherwise it is the customer's responsibility.
- d) Customers will assist the Service Provider by completing the Pre-Installation Report in Annexe F.
- e) This SLA does not cover malfunction or failures resulting from use of the analyzer for purposes other than that which it was designed, unauthorized attachments, acts of nature, unusual physical or electrical stress, accidents, or modifications or repairs done by other than the Service Provider.
- f) Where coverage of sites in hazardous regions is included in the agreement and to ensure the continuity of testing, the customer agrees:
 - i. To permit the rotation of instruments so as to allow swapping to occur without the need to swap back instruments once repaired.
 - ii. To ensure the timely return of any swapped modules, computers or instruments.

- iii. To purchase sufficient modules and spare instruments to allow swapping of modules and systems to occur.

5. Monitoring service requests and Service Provider performance

- a) The Service Provider will maintain an online Service and Maintenance tracking tool for the Customer including all analyzer users and managers, the Customer's procurement agent, and Global Fund principal recipient [insert or revise entities as appropriate] to check current status of module replacements, warranty status per device, annual module XpertCheck due dates, and log of service requests with current status (e.g., under analysis, in progress, resolved).
- b) The Service Provider must provide monthly via email a Service Provider Monthly Performance Report, a template of which is provided in Annexe D, to the Customer, the Customer's procurement agent, and the Global Fund principal recipient [insert or revise recipients as appropriate]. The Customer will have 10 working days from the date of receipt of the report to dispute any of the information provided in the report.
- c) On a quarterly basis the Service Provider and Customer will agree to review together the Service Provider performance and identify any corrective actions needed to improve performance.
- d) On an annual basis the Service Provider must conduct a customer satisfaction survey with analyzer users and site managers and share the results with the Customer, the Customer's procurement agent, and the Global Fund [insert or revise recipients as appropriate].

6. Services excluded from the SLA

- a) All interventions due to malfunctions caused by accident, theft, fire or natural disasters
- b) Procurement and distribution of consumables and ancillary equipment, including test cartridges, printers, paper, uninterrupted power supply, air conditioning units, extended batteries, voltage stabilizers, cables and solar panels.
- c) Infrastructure changes at planned analyzer sites to accommodate equipment
- d) [Delete if included above as a covered service: On-site installation of equipment and trainings outside of city(ies) of Service Provider's office(s)]
- e) Preventive and curative maintenance site-visits in regions deemed by mutual agreement to be hazardous through, but not limited to, civil unrest, insurgent activity, kidnap, disease, etc. Sites presenting such a risk are indicated in Annexe A.

7. Validity and renewal

- a) This SLA will be valid from [enter start date] to [enter end date].
- b) This SLA may be subject to renewal, with refinement to the test cartridge surcharge cost based on performance of the Service Provider, any changes to anticipated

numbers of test cartridges to be procured, and any changes to the proportion of analyzers covered that are under initial warranty.

- c) In case the Customer wishes to add any services to the contract during the term, there shall be made an addendum to the respective information and the price will be adjusted taking into consideration the added services and the time remaining within the term of the contract. Alternatively any requested additional services out of the scope of the contract may, upon mutual agreement, be invoiced separately.

8. Price, payment terms and penalties

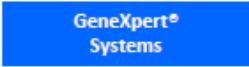
- a) The test cartridge surcharge for the contract duration will be [enter cost] per cartridge, for all cartridge types offered by Cepheid. This surcharge is based on the anticipated use of approximately XXX,XXX cartridges inclusive of all cartridge types in the analyzers listed in Annexe A during the SLA contract duration.
- b) Payment of the surcharge for supplied cartridges will be made by the Customer's procurement agent, in accordance with the terms of the procurement agent's agreement with Cepheid HBDC.

9. Force Majeur

- c) The Service Provider shall be held innocent of all delays occasioned through war, adverse weather conditions, industrial action, customs delays and any other events beyond the control of the Service Provider.

[Insert name of Customer]	Cepheid HBDC SAS
Name:	Name:
Address:	Address:
Title:	Title:
Date:	Date:
Signature:	Signature:

Annexe B – Yearly Maintenance Checklist



Document Number: D 21805
Attachment
Rev: A.1
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Page 1 of 1

Yearly Maintenance check-list

Institute name		System serial	
Institute address		Instrument configuration	
Institute contact		Software version	

LEVEL 1: CLEANING

- Back-up system files, then Power down GX _____ Done N/A
- Complete system inspection and clean: Filters, inside, outside, electrical, etc. _____ Done N/A
- Inspect modules cartridge bay, clean. Replace doors if needed _____ Done N/A
- Remove stains caused by buffer _____ Done N/A
- Check and replace hotline sticker if needed _____ Done N/A
- Clean optic's using brush (300-8330) _____ Done N/A

Comments

LEVEL 2: TECHNICAL ASPECTS

- Check if archiving has been done correctly _____ Done N/A
- Review System Log for last 3 months and check for unexpected errors _____ Done N/A
- Computer assessment _____ Done N/A
- Update GXDX software if applicable _____ Done N/A

Comments

LEVEL 3: MODULE CHECK

- Perform Xpert Check and replace failed modules if needed _____ Done N/A
- Print IQ report and check it entirely _____ Done N/A

Comments

Laboratory
Name & Signature

Cepheid FSE
Date, Name & Signature

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Cepheid Confidential Date Printed: 7/17/2018 11:45:37

Annexe C – Contact information of the Service Provider

[Insert details]

Annexe D – Service Provider Monthly Performance Report

Month and year:		Number
a.	Cumulative number of installed analyzers in the country covered by the SLA (with updated Annexe A if applicable)	
b.	Number of modules that were swapped in the past month, within the target delay (Annexe E, Table 1) from date when module failure was notified to Cepheid Technical Support	
c.	Number of modules that were swapped in the past month, in excess of the target delay (Annexe E, Table 1) from date when module failure was notified to Cepheid Technical Support	
d.	Number of failed modules that were not working at the end of the month and have not been working for more than the target delay (Annexe E, Table 1)	
Percentage of module swaps that were timely (within the target delay indicated in Annexe E, Table 1). Calculated as: $b. / (b. + c. + d.)$		
e.	Number of other failed parts or equipment that were replaced or repaired in the past month, within the target delay (Annexe E, Table 1) from date when the failure was notified to Cepheid Technical Support	
f.	Number of other failed parts or equipment that were replaced or repaired in the past month, within the target delay (Annexe E, Table 1) from date when the failure was notified to Cepheid Technical Support	
g.	Number of other failed parts or equipment that were pending replacement or repair at the end of the month, and have been pending for more than the target delay (Annexe E, Table 1)	
Percentage of other repairs and replacements that were timely (≤ 20 working days). Calculated as: $e. / (e. + f. + g.)$		
h.	Number of GeneXperts that underwent XpertCheck in the past month, according to schedule (no more than 30 working days past annual scheduled date)	
i.	Number of GeneXperts that underwent XpertCheck in the past month, with a delay (more than 30 working days past annual scheduled date)	
j.	Number of GeneXperts at the end of the month that were overdue for XpertCheck (more than 30 working days past annual scheduled date)	
Percentage of XpertCheck preventative maintenance activities that were timely (≤ 30 working days past annual scheduled date). Calculated as: $h. / (h. + i. + j.)$		
k.	Number of requests received in the past month which received a timely response (requests acknowledged and follow-up plan articulated within 2 working days)	
l.	Number of requests received in the past month which did not receive a timely response	
Percentage of requests that received a timely response (≤ 2 working days) Calculated as: $k. / (k. + m.)$		
m.	Description of any trainings provided by the Service Provider in the month, including location(s) and numbers of participants:	
n.	Number of analyzers installed in the past month with training completed	
o.	Total number of individuals in-country currently contracted by the Service Provider or its distributor or authorized service provider and who have completed a training programme at a Cepheid training center	

Comments:

Annexe E

Service Level:(A, B, C, D,)

Preventive Maintenance: (included / excluded)

Hazardous Region Cover: (included / excluded)

Table 1: Service Level Definition

Service Level	A	B	C	D
Description	Service Centre	Local Partner	Local Partner with buffer stock of modules	Without Local Partner
Maximum Service Delay (in working days) and Key Performance Indicators (KPI)²				
Module Replacement / With C360	5 days / 4 days KPI 95%	20 days / 15 days KPI 90%	10 days / 8 days KPI 90%	25 days / 20 days KPI 80%
Component Replacement / With C360	15 days / 10 days KPI 90%	20 days / 15 days KPI 90%	20 days / 15 days KPI 90%	30 days / 25 days KPI 90%
Complete Instrument / With C360	20 days / 15 days KPI 100%	20 days / 15 days KPI 98%	20 days / 15 days KPI 98%	20 days / 15 days KPI 95%
Temporary Loan Instrument ¹	3 days KPI 95%	10 days KPI 95%	15 days KPI 90%	Not Available
Response to service requests with follow-up plan articulated	2 days KPI 95%	2 days KPI 95%	2 days KPI 95%	2 days KPI 95%
Preventive Maintenance	Available	Service Provider Dependent	Service Provider Dependent	Not Available
Training of Trainers	Available at central locations twice annually	Available at central locations twice annually	Available at central locations twice annually	Available at Cepheid locations

System Installation	10 days	10 days	10 days	By arrangement
Telephone Hotline	Local Cepheid or service centre operator	As available from Distributor	As available from Distributor	Direct to Cepheid Tech Support
	Cepheid WhatsApp (under development)			

Notes:

1: One temporary loan instrument will be made available for every 2,000 modules installed (excluding GeneXpert Infinity systems). Where coverage of sites in high-risk regions is included in the agreement, repairs will be carried out by system swap, the timings of which are excluded from the KPIs.

2: Instruments requiring repair on the start date of the agreement are not included in the Key Performance Indicators unless the agreement is a renewal. Delays introduced by repair of pre-existing instrument failures will not be included in KPIs.

3: Assumes a single instrument at a fully prepared site. Where installations are to be made at multiple-sites, installation schedules to be agreed between the Customer and the Service Provider.

Annexe F: Pre-Installation Report

Annexe G: System Maintenance Log

GeneXpert® System Maintenance Log

Name of Institution: GeneXpert Serial Number: Month and Year:

Last Calibration Check Date: FAS Installation Date:

Instructions: 1. Enter the name of your institution, GeneXpert Serial Number, current Month and Year, Last Calibration Check date, and FAS Installation Date in the fields above.
 2. For each maintenance activity listed below check the box(es) under the day of the month that the activities were performed and enter your initials (2 characters maximum) in the bottom row.
 3. Save the file after entering the data. We recommend saving one file each month for a complete record of activities.

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Daily Maintenance	<input type="checkbox"/>																														
Clean work area	<input type="checkbox"/>																														
Close all module doors	<input type="checkbox"/>																														
Discard used cartridges	<input type="checkbox"/>																														
Weekly Maintenance	<input type="checkbox"/>																														
Power down the GeneXpert instrument ¹	<input type="checkbox"/>																														
Power down the GeneXpert computer ¹	<input type="checkbox"/>																														
Monthly Maintenance	<input type="checkbox"/>																														
Archive tests ²	<input type="checkbox"/>																														
Purge tests ²	<input type="checkbox"/>																														
Replace fan filters ¹	<input type="checkbox"/>																														
Quarterly Maintenance	<input type="checkbox"/>																														
Clean plunger rod and cartridge trays ¹	<input type="checkbox"/>																														
Clean instrument surfaces ¹	<input type="checkbox"/>																														
Yearly Maintenance	<input type="checkbox"/>																														
Check annual instrument maintenance ¹	<input type="checkbox"/>																														
As Necessary	<input type="checkbox"/>																														
Print system log report ¹	<input type="checkbox"/>																														
Back up database ²	<input type="checkbox"/>																														
Technician Initials (Two Letters)	<input type="checkbox"/>																														

1. Refer to Chapter 9 (Service and Maintenance) in the Operator Manual for detailed procedure.
 2. Refer to Chapter 3 (Operating Instructions) in the Operator Manual for detailed procedure.
 These are minimum recommendations for cleaning. Your institution may require that maintenance be performed on a more frequent basis.

Reference: GeneXpert GX Dx Operator Manual (P/N 301-0045, Rev. K)

