

# In-Vitro Diagnostics Service Terms ("IVD Service Terms")

(Version: 17.05.2024)

These IVD Service Terms govern the provision of maintenance services for Hardware and Software of the in-vitro diagnostic portfolio distributed by Siemens Healthineers in addition to (i) the Commercial Form and (ii) the General Terms, the Supplemental General Terms and the IVD Terms or IVD-CPR-Terms as applicable (together "Terms"). These IVD Service Terms shall be read as complementary to the Terms and prevail in case of conflict.

## 0. Definitions

In addition to the definitions in the Terms the following definitions apply:

- 0.1. "Customer Replaceable Parts" means those wear and tear parts which are in the operators guide and/or instruction manual of the analyzer/system labelled as Customer Replaceable Part.
- 0.2. "Instrument" means Hardware including preinstalled Software which is capable of performing or facilitating diagnostic routines.
- 0.3. "Maintenance" means non-periodic repair services as well as periodic servicing and inspections of the Hardware including preventive maintenance, exchange of parts and provision of replacement parts - excluding Customer Replaceable Parts all as per specifications of the original equipment manufacturer.
- 0.4. "Principal Coverage Period or PCP" means the period during which Siemens Healthineers will provide the Services as set out in the Commercial Form excluding public holidays in the Territory.
- 0.5. "Remote Services" means the provision of Services via a secured telecommunications link.
- 0.6. "Service Agreement" means the part of the Agreement relating to the Services.
- 0.7. "teamply Fleet" means an online service portal and/or an app for Hardware fleet management of Siemens Healthineers.
- 0.8. "Territory" means the country/federal state of Siemens Healthineers or any other country or area as designated in the Commercial Form.

## 1. Maintenance Services

- 1.1. Siemens Healthineers will provide Maintenance under this Service Agreement as detailed in the Commercial Form, including, unless specified otherwise, all labor and parts (excluding consumables, electrodes and certain other parts) as are necessary to keep Hardware in good working order.
- 1.2. Any rescheduling of scheduled maintenance visits at the request of the Customer will exempt Siemens Healthineers from any commitment in the provision of the same, e.g. with respect to duration or frequency and in the impact that such rescheduling has on other agreed Services and/or usability and proper functioning of Deliverables.
- 1.3. In the event that Customer requires maintenance or repair in addition to the agreed Services these additional services are subject to terms and conditions agreed in this Service Agreement, additional cost and explicit confirmation by Siemens Healthineers.

## 2. Customer's Duties of Cooperation

- 2.1. To the extent required or deemed advisable for the performance of the Services, Customer shall perform the following obligations in time and free of charge:
  - 2.1.1. Provision of briefings and site rules, if any.
  - 2.1.2. Provision of general information relevant to the Services, the surroundings and the local situation, as well as on the applicable safety regulations of Customer.
  - 2.1.3. Implementation of the required operational and legal safety measures, provision of a safe working environment, provision of (special) protective clothing and devices as well as the provision of security or personnel to escort the service technicians in accordance with the requirements of work safety,

and upon Siemens Healthineers' request the provision of a second person required for reasons of accident safety.

- 2.1.4. User and operator maintenance of the Deliverables in compliance with the Instructions for Use to the extent not covered by this Service Agreement
- 2.1.5. Establishment of the operating conditions and infrastructural requirements necessary for the intended performance of the Services.
- 2.1.6. Provision and attendance of appropriate personnel during the performance of the Services with the necessary experience and know-how concerning the provision of the Services. Such personnel of Customer must be able to make and implement any necessary decisions concerning the Services.
- 2.1.7. Ensure that all personnel dealing with the Software and or Hardware are adequately trained on all aspects of the Software or Hardware including security.
- 2.1.8. Provision of up-to-date documents and information relevant for the Service Provision (e.g. documents on the Hardware, the configuration drawings, the list of available service parts at Customer's site).
- 2.1.9. Provision of technical production resources and materials (e.g. electricity, water, adequate plumbing, compressed air, telephone and Internet).
- 2.1.10. Provision of Customer Replaceable Parts with the quality, quantity, standards and recommendations of the original equipment manufacturer. Customer is responsible for the provision and stocking of Customer Replaceable Parts.
- 2.1.11. Current data back-up including the stored data and the system parameters on an appropriate data carrier as well as the provision of a copy of the respective data carrier.
- 2.1.12. Execution of the data back-up required for Customer and retrieval of data if necessary.
- 2.1.13. Upon request Siemens Healthineers will dispose of any waste brought on site by Siemens Healthineers in the course of the Service provision against separate payment.
- 2.1.14. Obtaining of any permits, approvals, consents or authorizations from any relevant authority, except to the extent that these are only to be obtained by Siemens Healthineers.
- 2.1.15. Establishment and maintenance of such recovery and data retention procedures as Customer considers necessary when Customer grants system access (including remote access) to Siemens Healthineers.
- 2.1.16. In so far as they relate to the Software, follow any documents issued by Siemens Healthineers that are made available via teamply Fleet or otherwise, including but not limited to any vulnerability assessment and security advisories regularly published in teamply Fleet, as amended from time to time.
- 2.1.17. Handling of all systems, reagents and consumables supplied by Siemens Healthineers with due care and efficiently.
- 2.2. At Siemens Healthineers' request and to the extent necessary, Customer shall timely and diligently support Siemens Healthineers free of charge in any problem analysis. Customer shall promptly provide incident reports and error messages as well as data and protocols appropriate for analyzing the failure.

### 3. Separate Charges

- 3.1. Siemens Healthineers performs the agreed Services during the Principal Coverage Period. If Customer requires Siemens Healthineers to provide Services outside of the agreed Principal Coverage Period, such Services will be separately charged at Siemens Healthineers' rates, terms and conditions then in effect.
- 3.2. Unless specifically otherwise agreed or where the claim or liability is caused by the negligence of or due to a breach of the Terms by Siemens Healthineers, the Service Agreement excludes labor, parts and expenses necessary to maintain, repair or reset the Hardware:
  - 3.2.1. damaged by fire, accident, theft misuse, abuse, negligence, improper application or alteration, improper storage, exploitation of IT vulnerabilities or by any other incident outside Siemens Healthineers' control;
  - 3.2.2. due to Customer's failure to comply with its obligations under this Service Agreement, particularly in Section 2 and Section 1.2 of the IVD Terms;
  - 3.2.3. defective or changed due to unauthorized attempts to repair, relocate, maintain, service, access or modify the Hardware by Customer or any third party, not authorized by Siemens Healthineers, or due to the attachment and/or use of non-Siemens Healthineers supplied parts, equipment or software without Siemens Healthineers' prior written approval during the term of the Service Agreement;
  - 3.2.4. failing due to causes of non-Siemens Healthineers supplied equipment, parts or software including, but not limited to, problems with the Customer's network;
  - 3.2.5. defective due to any repair or service performed by Customer or any third party prior to the commencement of the term of this Service Agreement.
  - 3.2.6. use of supplies, disposables, consumables or reagents not recommended in writing by the Hardware manufacturer, or accessories which the Hardware manufacturer has not specifically designated in writing as compatible with the Hardware; or
  - 3.2.7. Customer owned Instrument de-installation, decontamination, re-installation.
- 3.3. Unless specifically otherwise agreed, Service further excludes the following:
  - 3.3.1. furnishing of batteries, fuses, lamps, hoses, tubing, filters, disconnected fittings, electrodes, computer software, test patterns, calibration standards, report forms, printers, printer paper, pen styli, ink pens, or hollow cathode;
  - 3.3.2. Hardware peripherals such as uninterruptable power sources; and
  - 3.3.3. supply of parts defined as 'Supplies', 'Supplies list', 'Supplies and Replacement Parts', 'Consumables and Accessories', 'Orderable Parts', or 'Customer Replaceable Parts' within the Operator's Guide, Instructions for Use, or Operating Manual.

### 4. Availability and Accessibility of Instrument

- 4.1. In order to provide the Services covered by this Agreement Siemens Healthineers has to access certain information pertaining to Hardware and Software via the remote connection, particularly asset and configuration data, utilization data and technical status information.
- 4.2. If the Hardware and/or Software is not made available onsite or remotely at the appointed time, waiting time beyond a reasonable time may be charged at Siemens Healthineers' per-call rates and terms then in effect.

### 5. Sustainable Use of Service Parts

This Service Agreement is offered on the basis that Siemens Healthineers may use exchanged service parts for the purpose of root cause analysis or as the case may be for re-using them after refurbishment. Thus exchanged service parts which are removed from the Hardware and taken back by Siemens Healthineers or which are requested to be returned to Siemens

Healthineers, shall, unless already owned by Siemens Healthineers, upon the earlier of take back or request become the property of Siemens Healthineers. Customer warrants that it will transfer clear and free title to Siemens Healthineers.

### 6. IT and Software Maintenance

- 6.1. Siemens Healthineers may update the Software and/ or computing hardware when it deems appropriate to maintain the Hardware according to the intended configuration and use. These updates are determined solely and exclusively by Siemens Healthineers. The update may also include any implementation of new functions and performance improvement of the Hardware.
- 6.2. Customer represents and warrants that it will only use Software that has been validly licensed to it by Siemens Healthineers or its authorized partners. Any Software not duly licensed from Siemens Healthineers or its authorized partners constitutes unauthorized software. If Customer downloads, installs and/or uses unauthorized software, then Siemens Healthineers may, in addition to any other rights Siemens Healthineers may have in such case, (i) remove unauthorized software and reset the system at Customer's cost and/or (ii) terminate this Service Agreement and/or (iii) claim damages from Customer.

### 7. Guarantees

- 7.1. If an Uptime Guarantee has been agreed the following shall apply.
- 7.2. "Uptime Guarantee" or "Uptime" means the capability of the Hardware to be utilized and process samples in accordance with the Instructions for Use and to generate test results.
- 7.3. Unless explicitly agreed otherwise, any Uptime Guarantee shall (i), if agreed as a percentage, be based on 9 hours per day and five days per week, and (ii) be calculated in relation to the relevant type of Hardware – not by individual unit.
- 7.4. The following shall not count as downtime and therefore would not constitute a violation of the Uptime Guarantee:
  - 7.4.1. Scheduled predetermined preventive maintenance;
  - 7.4.2. Routine maintenance;
  - 7.4.3. Condition based maintenance;
  - 7.4.4. Installation of software updates;
  - 7.4.5. Implementation of computing hardware exchanges as per Section 6.1 or hardware as per Section 1.4 of the IVD Terms;
  - 7.4.6. Preventive replacement of service parts;
  - 7.4.7. Scheduled remedy of partial failures and impairments, facilitating restricted use of the Hardware and/or Software;
  - 7.4.8. Elimination of malfunctions and damage resulting from incorrect operation;
  - 7.4.9. Measures to avoid exploitation of IT vulnerabilities;
  - 7.4.10. Extraordinary contamination;
  - 7.4.11. Customer is not providing access to the Hardware as agreed in Section 7.5 of the General Terms.
  - 7.4.12. Customer failure to comply with its obligations to efficiently manage its use of Instrument, reagents and or consumables; and
  - 7.4.13. Exclusions under Section 3.2.
- 7.5. Any Uptime Guarantee shall not apply if and for as long as Customer fails to implement any update of Instrument Software that addresses malfunctions or deficiencies in the quality or safety of an Instrument and is reasonably categorized by Siemens Healthineers as a mandatory update. The same shall apply if the Customer fails to enable access to an Instrument for Siemens Healthineers, if Siemens Healthineers determined, in its sole discretion, that an on-site implementation is required.
- 7.6. If Siemens Healthineers fails to achieve the agreed Uptime or any other key performance indicator and there is no specific regulation regarding the remedy for such failure in the Commercial Form, Siemens Healthineers shall issue a credit note as described in the Commercial Form with a value equal to

the documented costs for any samples to have been processed by a third party. The credit amount shall be deducted from the next invoice in the payment cycle under this Service Agreement. The credit note shall be limited to a maximum of 10% of the fee paid for reagents in the preceding month or, if lower, a maximum amount of \$500 per Instrument per contract year (any 12-months period from the effective date of the Agreement).

- 7.7. The foregoing states Siemens Healthineers' entire obligation and liability, and the Customer's sole remedy, for Siemens Healthineers' failure to meet the Uptime Guarantee or other key performance indicator unless explicitly otherwise agreed.
- 7.8. If the Hardware is not fully operational, Customer must immediately notify the Siemens Healthineers Customer Care Center. Downtime will not commence until such notification is given to Siemens Healthineers. Customer must accept all technical assistance that is offered by Siemens Healthineers, including, but not limited to, telephone support and remote diagnostics. For any period of time that Customer does not seek and accept technical assistance from Siemens Healthineers, the Hardware shall be considered to be operational.
- 7.9. If the Hardware is moved from the original Customer location without the prior written consent of Siemens Healthineers or if Customer fails to comply with its obligations for the provision and maintenance of a remote connection 24 hours per day, 7 days a week, then the Uptime Guarantee shall not apply.

**8. Throughput Based Service**

If the anticipated Throughput of an Instrument has been agreed as basis for selecting the appropriate annual Throughput Classification, the following shall apply:

- 8.1. For this Section 8 the following definitions shall apply.
  - 8.1.1. "Throughput" means all processing routines performed by the covered Instrument. Throughput is not limited to testing patient samples.
  - 8.1.2. "Throughput Classification" means the classification based on annual Throughput of tests. Low volume, mid volume and high volume classifications are available.

- 8.2. Instrument's actual Throughput will be monitored and finally determined on an annual basis to define the appropriate Throughput Classification to maintain performance of the Instrument. If the actual Throughput falls outside of the contracted Throughput Classification, Customer will be offered the opportunity to upgrade (or downgrade) its annual Throughput Classification for the next 12 months period to reflect the actual Throughput. If Customer elects not to upgrade to the applicable Throughput Classification in case of elevated Throughput, Siemens Healthineers may refuse the provision of any service required beyond the then current Throughput Classification (both preventive and reactive service) or invoice the Customer for additional services on a time and materials basis at the then applicable rates. Any upgrade or downgrade of Throughput Classification shall only apply prospectively from the end of the relevant 12 months period and Siemens Healthineers shall not be entitled to claim additional service fees or obliged to make any refund of fees in relation to services rendered during such 12 months period.

- 8.3. In order to allow the monitoring and determination of actual Throughput, the Customer shall ensure that relevant Instruments are and remain connected to a remote connection defined by Siemens Healthineers and the auto-reporting function of such Instruments remains activated at all times. If the relevant Throughput data for any given 12 months period should not be completely available via such remote connection for reasons not attributable to Siemens Healthineers, Siemens Healthineers may determine the applicable Throughput Classification for the subsequent 12 months period in its reasonable discretion unless a different actual Throughput can be proven by the Customer.

**9. Extended Service**

Prior to the expiration of the term of the Service Agreement, based on mutual agreement, Customer, may purchase additional years of service for the Hardware. Details of the then applicable fee are described in the Commercial Form. Such fee is based upon the configuration of the Hardware as of the effectiveness of this Agreement and is subject to change in the event that changes to the configuration of the Hardware are made after effectiveness of this Agreement. Service will be performed at the same terms and condition agreed herein subject to any updated terms and conditions of Siemens Healthineers.