

# GENERAL TERMS AND CONDITIONS OF Abbott Rapid Diagnostics Germany GmbH

## I. GENERAL PROVISIONS

- 1 Scope of application**  
Sales, deliveries and other services provided by Abbott Rapid Diagnostics Germany GmbH, Am Wassermann 28, 50829 Cologne, Germany (hereafter referred to as "ABBOTT") shall be governed solely by the following General Terms and Conditions (hereafter referred to as the "General Terms") which shall be deemed accepted by the Customer upon placing the order or by accepting the delivery. They also apply to all future business with the Customer. The application of the Customer's divergent or supplementary terms and conditions shall be excluded, even if ABBOTT does not expressly object to such terms and conditions.
- 2 Subject matter of the contract, conclusion of contract**  
2.1 ABBOTT's offers are without obligation. A contract is only concluded when ABBOTT issues a written order confirmation or if ABBOTT executes the order and this contract is exclusively oriented to the content of the order confirmation and these General Terms. When placing your order the order number, product name, shipping address and invoice recipient as well as any special delivery requests must be stated. Oral agreements or undertakings shall require confirmation in writing from ABBOTT in order to be deemed valid.  
2.2 The ID NOW™ instrument may contain or be delivered with certain open source software ("Open Source Software"). The rights of use applicable to the Open Source Software can be found under <https://www.alere.com/en/home/products-services/brands/id-now.html>  
2.3 The "Afinion" instrument may contain or be delivered with Data Point software. The access and use of the Data Point software by the Customer is subject to the Data Point terms and conditions available under <https://datapoint.abbott/SignIn/Login/#>  
2.4 ABBOTT reserves all rights to the offer documents (in particular images, drawings and details of weights and dimensions) and any patterns. They shall not be made available to third parties and must be returned to ABBOTT immediately on demand. Such documents may only be made accessible to third parties after prior consent by ABBOTT.  
2.5 The information provided by ABBOTT in its sales catalogues or with the offer - e.g. descriptions, drawings or pictures - only serves as a description of the products and is only approximately relevant unless such information has expressly been qualified as binding in writing.
- 3 Deadlines and dates for delivery**  
3.1 Times or terms of delivery and service are only binding in individual cases after written confirmation from ABBOTT and if the Customer has provided or made available all information and documentation required to carry out the delivery or service in good time to ABBOTT and has made any payments agreed in the manner agreed. Any times agreed shall commence on the date of ABBOTT's order confirmation. Delivery periods shall be extended correspondingly in the event of additional or supplementary orders issued later.  
3.2 Events which are unforeseeable, unavoidable and lie beyond the sphere of influence of ABBOTT and for which ABBOTT is not responsible, such as acts of god, war, natural catastrophes and labor disputes, release ABBOTT from its undertaking to make punctual delivery or performance for their duration. Agreed deadlines extend for the duration of the disruption; the Customer will be informed in an appropriate manner that the disruption has occurred. If the end of such disturbance is not foreseeable or should it continue for a period longer than two months, each party is entitled to rescind the contract.  
3.3 If ABBOTT is in default with its delivery or service, the Customer shall not be entitled to rescind the contract until a reasonable grace period set by the Customer has expired.
- 4 Prices, terms and conditions of payment**  
4.1 If the contracting parties have not agreed on a specific price, the price will be determined according to ABBOTT's price list which applies on the date the contract is concluded which ABBOTT submits to the Customer upon his request provided that the Customer has not been made aware of it.  
4.2 Within the scope of continuous obligations such as current supply contracts or service agreements ABBOTT reserves the right to make reasonable price increases. ABBOTT shall notify the Customer of any increase in prices at least eight weeks before the increase comes into force. The Customer has the right to annul the continuous obligations within four weeks after receipt of notification of the price increase.  
4.3 All prices of ABBOTT are invariably understood as plus the respective statutory turnover tax, possible customs duties, transportation and/or shipment costs which will be calculated separately.  
4.4 The contracting parties agree that all obligations to pay resulting from this contract will be valid in Euro.  
4.5 Each invoice shall be due for payment within 30 days from the date of invoice, without deduction. If this period passes unsuccessfully then the payment takes place in arrears in terms of § 286, section 3, sentence 1 Civil Code (BGB). Payments by the Customer shall not be deemed to have been made until ABBOTT has received the payment into its account.  
4.6 In the event that the Customer is in default (cf. article I. 4.5), ABBOTT shall be entitled to demand default interest on arrears as required by law. This shall be without prejudice to the assertion of further default damages.  
4.7 Bills of exchange and cheques in fulfillment of payment shall only be accepted by ABBOTT free of any costs or charges for ABBOTT.  
4.8 For deliveries to Customers outside of Germany, ABBOTT reserves the right to request advance payment in individual cases if there is an objectively justifiable reason.  
4.9 The Customer is only entitled to a set-off if its counterclaim is uncontested or legally binding.  
4.10 The Customer is only entitled to assert a right of retention to the extent that its counterclaim is based on the same contract, is uncontested or is legally binding.  
4.11 Should ABBOTT become aware of the risk of poor performance on the part of the Customer following conclusion of the contract, which thereby appear to endanger ABBOTT's entitlement to performance, ABBOTT shall be entitled to make outstanding deliveries or perform outstanding services against pre-payment only or in return for the provision of security; should this not be provided after a reasonable grace period, ABBOTT may, notwithstanding other rights, partially or completely rescind the

contract.

- 5 Limitations on liability and claim for damages**  
5.1 ABBOTT shall pay compensation for damages  
(i) caused to body, life and health;  
(ii) if ABBOTT has provided a guarantee concerning the particular quality of the contractual product or performance, the ability to procure them or any other guarantee, for damages arising from the non-fulfilment of said guarantee;  
(iii) for willful or grossly negligent damages caused by ABBOTT or persons employed to perform his obligation;  
(iv) in lieu of performance in the event of defective deliveries and performance based on considerable breaches of duty by ABBOTT;  
(v) in the event of the violation of material contractual obligations due to slight negligence, but limited to the foreseeable damage typical to such contract;  
(vi) in accordance with the German Pharmaceuticals Act, the product liability law or other mandatory liability provisions;  
(vii) in lieu of performance due to a culpable breach of a non-material contractual duty, if it would no longer be reasonable for the Customer to accept the performance or and if the delivery or performance is impossible for ABBOTT.  
5.2 In case that none of the provisions in article I. 5.1 is applicable, ABBOTT is not liable for damage compensation  
5.3 The provisions in article 5.1 shall apply to all claims to compensation for damages, irrespective of the legal grounds, and especially to liability in tort and for liability due to default during contract negotiations.  
5.4 The Customer shall be obliged to take appropriate measures to protect against damage and reduction in value.  
5.5 ABBOTT will not assume any liability for loss of data during service and/or repair works arising out the Customer, although requested to do so, not observing in terms of data protection its duty to collaborate.
- 6 Right of modification, General rules**  
6.1 ABBOTT reserves the right to modify these General Terms at any time at its sole discretion. ABBOTT shall inform the Customer in writing of any modifications to the General Terms at least eight weeks before the change takes effect. Provided the Customer does not object in writing to these modifications within 14 days, the amendments shall be deemed to have been approved.  
6.2 Should any provision of these General Terms be fully or partially void, this will not affect the effectiveness and enforceability of the remaining provisions.  
6.3 If the Customer is a merchant, a legal person under public law or a special fund under public law, the exclusive jurisdiction for all disputes arising or in connection with this contract shall be Wiesbaden.  
6.4 The laws of the Federal Republic of Germany shall apply to this contractual relationship with the exclusion of the UN Sales Convention (CISG).

## II. SPECIFIC RULES FOR THE SALE OF PRODUCTS

- 1 Modification, price increase, shipment, transfer of risk, insurances, default of acceptance, partial delivery**  
1.1 ABBOTT is entitled to modify the composition, the design and/or the appearance of the contractual product in so far as it is necessary for medical or technical reasons, it does not affect the product's functionality and if this is not considered unreasonable to the Customer.  
1.2 In case the delivery date agreed upon is more than four (4) months after the conclusion of the contract and in case ABBOTT has incurred cost increases with regard to the delivery product which were unforeseeable upon conclusion of the contract, ABBOTT is entitled at equitable discretion to increase the price agreed upon accordingly.  
1.3 In the case of sales by ABBOTT to entrepreneurs within the meaning of Section 14 of the German Civil Code (BGB), the delivery by ABBOTT shall, unless otherwise agreed in writing, be made in accordance with CIP to the Customer's registered office within Germany Incoterms 2020. The agreed place of fulfillment for delivery in this case shall be the respective first logistics center (goods distribution center) of the carrier in Germany that receives the products for transport to the Customer.  
1.4 In the case of sales by ABBOTT to entrepreneurs within the meaning of § 14 BGB, the risk shall pass to the Customer in accordance with the delivery clause agreed pursuant to section II. 1.3  
1.5 In the case of sales by ABBOTT to consumers within the meaning of § 13 BGB, the risk of accidental loss and accidental deterioration of the products shall pass to the Customer upon delivery to the Customer. In the event the Customer is in default of acceptance, the risk shall pass to the Customer upon default of acceptance. Orders with a net value of 250.00 Euros or more will be delivered free of charge by ABBOTT within Germany. If the net value of the products is less than 250.00 EUR, ABBOTT will charge a flat-rate delivery fee of 25.00 EUR for deliveries within Germany. The costs for deliveries abroad shall be borne by the Customer in the amount actually incurred.  
1.6 As a rule, the products will be delivered within 3 working days (Monday to Friday) from the date of the order was placed, unless the Customer requests a special delivery. In case the Customer requests a special delivery within Germany, ABBOTT will charge the following delivery costs in deviation from Section II 1.6:  
1.6.1 For express deliveries (delivery will be made on the working day following the day of the order), delivery costs of 40.00 EUR per delivery will be charged.  
1.7 If the Customer requests express delivery outside of Germany, Abbott shall, in deviation from Section II. 1.3 or 1.6, charge the costs for such express delivery according to actual expenditure.  
1.8 ABBOTT is entitled, should the Customer delay acceptance or infringe other duties to cooperate, to store the contractual products appropriately at the risk and the expense of the Customer. Without prejudice to its other rights, ABBOTT is entitled to rescind the contract if a reasonable grace period set by ABBOTT for the acceptance of delivery has expired without success. If the purchaser is in default of acceptance and during the default period the expiry date of the ordered product lapses, and without prejudice to ABBOTT's other rights, ABBOTT can require the payment of the contractually agreed purchase price minus any money saved on expenditure.  
1.9 ABBOTT may make partial deliveries for good reasons if the partial delivery is useable for the Customer within the framework of the contractual stipulation of purpose and the Customer does not accrue any material additional expenditures or additional costs hereby.

# GENERAL TERMS AND CONDITIONS OF Abbott Rapid Diagnostics Germany GmbH

- 2 Warranty, inspection duty, limitation for claims**
- 2.1 Details in catalogues, price lists, descriptions of the products and any other information material provided by ABBOTT to the Customer shall not be understood as guarantees for special qualities of the contractual product; such guarantees must be explicitly and in writing.
- 2.2 In the case of sales by ABBOTT to consumers within the meaning of § 13 BGB, the Customer shall be entitled to assert his statutory rights in respect of defects without limitation. In the case of the sale of a used product, however, the Customer may only assert the claims and rights due to a defect in the products within a warranty period of one year from delivery of the products.
- 2.3 In the case of sales by ABBOTT to entrepreneurs within the meaning of § 14 BGB, the following shall apply to the rights of the Customer:
- 2.3.1 The Customer must take delivery of forwarded contractual products even if they exhibit minor defects, without prejudice to its warranty rights.
- 2.3.2 Customer's warranty rights shall require that it inspects the products upon delivery without undue delay and notifies ABBOTT thereof in writing and without undue delay, but no later than two weeks following delivery; hidden defects must be notified to ABBOTT in writing without delay upon their discovery. It is no presupposed and/or customary use of the delivered product (in-vitro diagnostics) according to the sales contract if the Customer operates or uses the product contrary to the intended purpose provided by the manufacturer (in the meaning of § 3 para. 10 of the Medical Devices Act).
- 2.4 In the event of notifications of defects ABBOTT shall be entitled to inspect and test the respective contractual product. The Customer shall give ABBOTT the necessary period of time and opportunity for inspection. ABBOTT may also demand of the Customer that the respective product be returned to ABBOTT on ABBOTT's account. Should a notification of defects by the Customer transpire to be willfully or gross negligently unwarranted, the Customer shall be obliged to compensate ABBOTT for all expenses incurred in this connection.
- 2.5 If the contractual products have defects which are covered by warranty, ABBOTT shall be entitled, at ABBOTT's option, to remedy the defects or make a free-of-charge replacement delivery of the faulty part or the whole product.
- 2.6 Material, shipment and working costs in connection with the remedy of defects or replacement shall be borne by ABBOTT, unless article II. 2.4, sentence 4 applies.
- 2.7 The Customer has to give ABBOTT the necessary time and opportunity to remedy the defects or make a replacement delivery within 14 days. Only in urgent cases of endangering the safety of the business or for the purpose of averting disproportionately large damage or if ABBOTT is in default of remedying the defects, the Customer has the right upon prior notification to ABBOTT to carry out the remedy himself or have it done by a third party and demand compensation for the necessary costs from ABBOTT.
- 2.8 Parts replaced by ABBOTT are passed into the property of the Customer.
- 2.9 ABBOTT shall not assume any warranty for damages caused by inappropriate or improper use, incorrect warehousing, incorrect transport, faulty assembly, faulty operation, insufficient maintenance, incorrect handling, improper installation by the Customer, the use of inappropriate accessories or spare parts and natural abrasion.
- 2.10 If the elimination of a defect under warranty by repair or replacement fails, is unreasonable for the Customer or ABBOTT refuses such subsequent performance according to section 439 (3) German Civil Code ("BGB") then the Customer has the right to cancel the purchase or demand an appropriate reduction in the purchase price or demand compensation or demand compensation instead of performance or reimbursement of vain expenses.
- 2.11 The limitation period for the statutory warranty claim for the products shall be twelve (24) months from delivery. This limitation shall not apply to claims for damages arising from wrongful death, personal injury or health impairment or for losses arising from a malicious or grossly negligent breach of duty on the part of ABBOTT or by its legal representative or its vicarious agents shall become statute-barred in accordance with the legal provisions. In case the contractual product is sold for the intended use by the Customer or its indirect contractual partner to a consumer the recourse claims considering a longer limitation period according to section 479 BGB shall remain unaffected.
- 2.12 In the case of the sale of used products (including demo products) to entrepreneurs, all rights of the Customer due to defects are excluded except for any Customer's claims for damages and expenses (to which the above clauses apply).
- 2.13 Any other claims of the Customer shall be excluded, provided article I. 5 or sections 478, 479 BGB do not prescribe anything to the contrary.
- 3 Retention of title**
- 3.1 The delivered products shall remain ABBOTT's property until all receivables resulting from the business relationship with the Customer have been fully paid.
- 3.2 In case of current accounts, this retention of title shall be deemed to serve as security for the outstanding owing claim of ABBOTT.
- 3.3 The Customer shall only be permitted to effect the sale of the products subject to retention of ownership ("Retained Products") by way of due and proper commercial transactions. The Customer is not entitled to pledge the Retained Products, to transfer title as security or to take other actions endangering ABBOTT's ownership. The Customer assigns with immediate effect its receivables arising from the re-sale of the products, ABBOTT hereby accepts this assignment. In the event of the Customer selling the Retained Products after combining them with other goods or together with other goods, the cession of receivables shall only apply to the amount of the part that corresponds to the price agreed between the Customer and ABBOTT plus a safety margin of 10% of the price. The Customer is revocably entitled to collect the receivables ceded to ABBOTT for its account in its own name on a trust basis. ABBOTT may revoke such authorization and the right to resell the Retained Products if the Customer is in default of the performance of material obligations such as making payment to ABBOTT.
- 3.4 The Customer will provide ABBOTT at any time with all desired information on the Retained Products subject to reservation of ownership or on claims that have been assigned to ABBOTT. Attachments of or claims by third parties to the Retained Products shall immediately be reported to ABBOTT by the Customer and be accompanied by the necessary documents. Customer shall simultaneously inform the third party of ABBOTT's retention of title. The Customer bears the costs of defending against this type of access and claims.
- 3.5 The Customer is obliged to treat the Retained Products with care for the term of the retention of title.
- 3.6 If the realizable value of the securities due to ABBOTT exceeds ABBOTT's total claims by more than 10%, the Customer shall be entitled to demand a release to such extent.
- 3.7 Should the Customer be in default of material obligations such as payment to ABBOTT, ABBOTT may, irrespective of ABBOTT's other rights, take back the Retained Products and dispose of them in some other way in order to recover receivables due from the Customer. In such a case the Customer will grant ABBOTT or ABBOTT's representative immediate access to the Retained Products and shall return them.
- 3.8 In the event of shipments to other legal regimes in which the above-mentioned retention of title does not have the same effect in providing security as in Germany, the Customer shall undertake everything in order to provide ABBOTT with the appropriate rights to protection from risks. The Customer will cooperate in all measures, such as for instance registration or publication, which are necessary for and conducive to the validity and enforcement of such rights to protection from risks.
- 3.9 The Customer is required, at ABBOTT's request, to provide adequate insurance for the Retained Products, to provide ABBOTT with the appropriate evidence of insurance cover and to assign to ABBOTT claims under the insurance policy.
- 4 Product liability, withdrawal, non-assignment, data protection**
- 4.1 For medical reasons, the Customer shall not modify the delivered products nor its instructions of use, features or packaging, in particular, not change or remove any existing warnings related to the improper use of the products or any information concerning their correct use, contraindications, interactions with other drugs and dosing. The contractual products may be offered and/or sold in their unchanged original packing only, and not in partial quantities. If the Customer violates the above obligations, the Customer shall, internally, exempt ABBOTT from any product liability claims of third parties, provided that the Customer is responsible for the defect causing the liability.
- 4.2 In the event that ABBOTT is forced to recall the contractual products as a result of a defect thereof, the Customer as reseller shall support ABBOTT and take any reasonable measures requested of itself by ABBOTT. In such case, ABBOTT will reimburse the Customer for all necessary expenses resulting thereof.
- 4.3
- 4.4 Since the products delivered by ABBOTT generally require special storage conditions and the maintenance of a complete quality control in the interest of all customers, all deliveries are excluded from goodwill exchange. Any rights of the Customer due to defects of products as provided for in Section II. 2 remain unaffected. If the Customer is not a reseller, the Customer is not authorized to assign any contractual delivery claims to a third party.
- 5 Data Protection**
- 5.1 Capitalized words used but not defined in these General Terms shall have the meaning given to them in the EU General Data Protection Regulation (GDPR) as defined in section 5.3 hereunder).
- 5.2 Customer and, where necessary, its affiliates shall process business contact details of selected employees and contractors from ABBOTT (and its affiliates) only to enable the performance of the respective agreement.
- 5.3 Personal Data of the Customer, its employees and other individuals provided by the Customer as required for conclusion and performance of the respective agreement are processed by ABBOTT in compliance with the German Data Protection Act (Bundesdatenschutzgesetz) and the GDPR. Employees of ABBOTT which have professional access to Personal Data of the Customer are committed to confidentiality in accordance with GDPR. They may not use these Personal Data without permission; this also applies after they have left ABBOTT. To the extent the services provided by ABBOTT involve processing of Personal Data under the control of the Customer prior to such a processing starts a separate written data processing agreement shall be executed. The Supplier understands and acknowledges that the Personal Data required for the performance of a respective agreement may be transferred outside of the European Economic Area (EEA) which may include transfer to countries such as USA which may not be deemed to offer the same level of protection than the EEA does. In such situations, ABBOTT will apply all reasonable security measures to data and will comply with international transfer requirements laid down by applicable law.
- 5.4 Customers, who are Data Subjects in the meaning of the EU General Data Protection Regulation (GDPR), have, in accordance with the provisions of the GDPR, the right of access, which includes the right to obtain from ABBOTT information about and access to the Personal Data stored by ABBOTT about the Customer; the right of rectification, which includes the right to obtain from ABBOTT rectification of inaccurate or completion of incomplete Personal Data; the right to erasure, the right to restriction of processing and the right of receiving notification regarding rectification or erasure of Personal Data or restriction of processing and the right to object, which includes the right to object, on grounds relating to the Customer's particular situation, at any time to processing of Personal Data concerning the Customer. In some cases, Data Subjects may also have a right to data portability. In order to exercise a right as a Data Subject or in case of questions concerning data protection please contact ABBOTT Rapid Diagnostics Jena GmbH, c/o Datenschutzbeauftragter, Orlaweg 1, 07743 Jena, ARDx.datenschutz@abbott.com. Data Subjects also have the right to lodge a complaint with the corresponding supervisory authority. If a Data Subject asserts a right to erasure, to restriction or to object the performance of an agreement may be impeded. In such a case ABBOTT may have a right to terminate the agreement for cause.
- 6 Regulatory and Quality Requirements**
- 6.1 The Customer shall comply with the following:**
- 6.1.1 Use, store, preserve and handle all products received from ABBOTT in accordance with the storage conditions applicable to the product. The warehouse must be clean and dry, and the temperatures must be within the temperature range permitted for the relevant product. Calibrated refrigerators and freezers shall be used for storage between 2-8oC and <-18oC when required for specific products.

- 6.1.2 Ensure that products are transported to customers in accordance with the temperature requirements (according to product labeling).
- 6.1.3 Segregate products, both by product identity and lot number, to ensure accurate delivery.
- 6.1.4 Use a stock turnover system for products with an expiration date to prevent products from exceeding the expiration date.
- 6.1.5 Maintain sales documentation for delivered products, including the following items:
  - (a) Name and address of the products recipient
  - (b) Product name and code (catalog number)
  - (c) Delivery date
  - (d) Number of products delivered
  - (e) Lot number of products delivered (if the order was executed with products from more than one lot, also the lot numbers and number of the respective products from one lot).
- 6.1.6 Acting in accordance with the safety instructions or product recalls initiated by ABBOTT concerning regulatory or qualitative circumstances affecting the Product. This includes ensuring that such notices are communicated to customers and that defined product recall and replacement activities are carried out according to agreed schedules in the event of a recall.
- 6.2 Forward all complaints regarding products supplied by ABBOTT to ABBOTT as soon as possible and no later than within 1 working day.
- 6.3 Immediately and within 1 working day notify ABBOTT of any written, electronic or oral communication relating to: Alleged identity defects, the quality, durability, reliability, safety, effectiveness or performance of a device or biological product after it has been released for sale or distribution, any incident or event resulting in death or serious injury according to the European Medical Device Incident Reporting, and any indications of safety risks to users, patients or others associated with the product.
- 6.4 Follow all instructions of ABBOTT with respect to the promotion and advertising of the products. No promotional materials will be published on the internet or printed without the prior consent of Abbott.
- 6.5 Allow ABBOTT the inspection of the Customer's quality system as well as the Customer's compliance with these General Terms and Payment within normal working hours and after reasonable notice.
- 6.6 Insofar as Customer makes Abbott products available on the Union market, as defined in Regulation (EU) 2017/46 on in-vitro diagnostics (IVDR) and Regulation (EU) 2017/45 on medical devices (MDR), Switzerland or Turkey Customer acknowledges that it should comply with requirements applicable to distributors as Economic Operators under the IVDR and MDR and that it will cooperate with ABBOTT to achieve an appropriate level of traceability for the Abbott products.
- 7 Resale outside the European Economic Area, Compliance with the export control regulations**
- 7.1 Products shall not be resold or transferred for use or consumption to third parties outside the European Economic Area or Switzerland without ABBOTT's prior consent. The Customer is aware that ABBOTT is subject to the legal regulations the European Union as well as of the authorities of the United States of America, including but not limited to regulations of the U.S. Department of Treasury, which currently expressly prohibits any sale, export and forwarding of products to Iran, North Korea (Democratic People's Republic of Korea), Syria, the Crimea Region and Cuba.
- 7.2 The Customer commits itself not to sell, directly or indirectly, contractual products to third parties about whom it knows or must presume that they could supply the products to customers selling or exporting to the above-mentioned countries. Furthermore, all obligations of ABBOTT to supply the contractual products as well as technical information and support is subject to export control regulations of the European Union and U.S. statutes and regulations, including but not limited to the Export Administration Act of 1979 and its amended version and subsequent laws and provisions of the Department of Commerce and Bureau of Industry and Security, which regulate the licensing and supply of technologies and products to foreign countries of those individuals falling within the jurisdiction of the United States.
- 7.3 The Customer undertakes to cooperate with ABBOTT to observe all export control regulations applicable in this respect.
- 7.4 In the event of breaches of this chapter 6 ABBOTT shall be entitled to terminate all delivery contracts concluded with the Customer with immediate effect and reserves the right to cancel any order that has already been confirmed. In this case, the Customer does not have any claims for damages.