CONTRACTING AUTHORITY'S CLARIFICATION No. 1

"Supply of laboratory equipment for ensuring implementation of new laboratory analysis methods"

Publication ref: EC-ENEST/TGD/2025/EA-OP/0051

No.	Question	Answer
1.	(1) For Item 1.13 – Natural Convection Incubator, point 1.13.1 (*Temperature Settings: Adjustable temperature settings from +20°C to +80°C with a setting accuracy of ±0.1°C.)*: Please specify the operating range, because almost all manufacturers use standard incubators with natural convection with a temperature range from ambient +.	(1) Item 1.12[1]– Natural Convection Incubator: It is acceptable for the incubator to have an operating temperature range starting from ambient temperature +5°C to +80°C, with a setting accuracy of at least ±0.1°C.
	(2) Also for Item 1.13, point 1.13.2 *(Controller and Display: Equipped with a touchscreen display):* Please open specs to equipment with a LCD display which provides information about the current and set temperature.	(2) Item 1.12, point 1.12.2[2] - Controller and Display: Equipped with a touchscreen display: To allow greater participation and competition, a non-touch display showing both current and set temperature values would also be considered acceptable. The device must, however, ensure clear temperature control and basic operating functionality. **Corresponding specifications will be amended by means of Corrigendum No.2.**
	(3) For Item 1.14 – CO2 Incubator: Please confirm if you need humidity regulation. Additionally, could you please confirm the volume of this unit?	(3) Item 1.13 – CO2 Incubator; No, it is not required. The incubator should maintain a relative humidity as indicated in the specification, requiring a calibration certificate for conditions including +37°C, 5% CO_2, and 90% RH. The internal chamber volume should be a maximum of 200 litres. **Corresponding specifications will be added by means of Corrigendum No.2.**
	(4) In the Additional information about the Contract Notice in Selection criteria → Technical Capacity, for each lot it is requested:	(4) Technical capacity criteria remain as published. Namely, technical capacity domains stipulated under point 16.3.3 of Additional information about the Contract Notice were

[1] Please note that new numbering is established as per amended technical specifications through Corrigendum No. 2.

[2] As in footnote no. 2.

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	• Lot 1: The completed supplies are in the domain of supply of veterinary laboratory equipment. • Lot 2: The completed supplies are in the domain of supply of phytosanitary laboratory equipment. • Lot 3: The completed supplies are in the domain of supply of veterinary or health safety laboratory equipment. Please consider that the items requested for each lot can be used also in different sectors. We already have submitted these typologies of equipment but in different fields of specialization. To encourage the participation in the tender process of companies that have already implemented this instrumentation but not in a so specific field of application (which greatly restricts the participation of many competitors), we require to open the specifications considering only the high technology of the goods and the capacity to manage these.	identified having in mind specific nature of requested supplies and services in combination with the context of regular operations of beneficiary institutions which must meet rigorous technical, regulatory, and operational standards to ensure specific, accurate, reliable, and legally defensible results.
2.	(1) For Item 1.1 - Thermo Shaker for microplates: Would an orbit of 3mm instead of 2mm be acceptable? (2) For Item 1.5 – Microtome: please clarify the following: A) Do you need a manual, semi-automatic or automatic machine? B) The requirement for clamping options of standard cassette and super cassette are specific to one brand. Could you please specify an allowable range for the specimen dimensions?	(1) Item 1.1. Thermo Shaker for microplates, requirement 1.1.4: yes, as it is stated in TS "Unless otherwise specified, the requirements in these Technical Specifications are presented as a minimum standard that the offered goods (including ancillary services and works, if required) must meet. Any features superior to the minimum specifications or additional features offered should be clearly identified in the tenderer's offer". (2) Item 1.5 – Microtome: A) Either option is acceptable. B) The requirements for clamping options refer to the maximum dimensions vis-à-vis the physical space available in the laboratory. They do not indicate to a

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	(3) For Item 1.6 - Slide stainer: would a loading capacity of 10 slide racks instead of 11 be acceptable as long as all the other specifications are met? (4) For Item 1.8 - Water bath: please specify a range for the required water volume. Also, the 120mm maximum dimension for the height is extremely small and would correspond to a very small water bath. Is it possible to increase this dimension to at least 300mm? (5) For Item 1.13 – Natural Convection Incubator: please specify a range for the required capacity in litters. (6) For Item 1.14 – CO2 Incubator: please specify a range for the required capacity in litters. (7) Item 1.2 ELISA washer: Would a solution with both 8 and 12 way manifolds instead of 8 and 16 way be acceptable? (8) Item 1.4 Tissue processor: The number of reagent containers is very high and greatly limits the choice with no pertinent operational added value. Would a solution with 12 or more reagent containers be acceptable? (9) Item 3.1 Real-time PCR: a) The specified Maximum Block Ramp Rate of 9°C/Sec is extremely high, especially for interchangeable block format instruments. It is also not necessary even with a runtime lower than 30min. A value of 6°C/Sec ±1°C is sufficient. Please clarify if such ramp rate would be acceptable?	specific brand, since all clamps with lesser or equal to the provided dimensions (for both standard and super clamps) are acceptable. (3) Item 1.6 - Slide stainer: Answer is yes, i.e. corresponding requirement is set as maximum capacity, therefore Item with 10 slide racks is acceptable. (4) Item 1.8 - Water bath: We confirm that the maximum height can be increased to 300 mm. **Corresponding specifications will be amended by means of Corrigendum No.2.** (5) Item 1.12[3] – Natural Convection Incubator: required capacity in liters is maximum 180 litters. **Corresponding specifications will be modified by means of Corrigendum No.2.** (6) Item 1.13[4] – CO2 Incubator: The internal chamber volume should be maximum 200 liters. **Corresponding specifications will be amended by means of Corrigendum No.2.** (7) Item 1.2 - ELISA washer: Yes, a solution that includes both 8-way and 12-way manifolds could be considered fit for purpose. **Corresponding specifications will be amended by means of Corrigendum No.2.** (8) Item 1.4 - Tissue processor: No, for optimization of work currently specified number of reagent containers is considered as a minimum. (9) Item 3.1 – Real-time PCR with laptop:

[3] As in footnote no. 2.
[4] As in footnote no. 2.

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	Please clarify if such ramp rate would be acceptable? b) The lower limit of 1µL for the reaction volume for the 96-well block is very low and unusual. Would a limit of 10µL instead be acceptable? c) The "Self-Installable Optical Cartridges" requirement is specific to one model that is discontinued. Would it be possible to remove this requirement? (10) Item 3.4 Laboratory centrifuge: Would it be acceptable that the capacity, the maximum RPM and maximum RCF fall within ±10% of the specified values? (11) There is a problem with item 1.10 of lot 1: "Automated Inoculation Delivery System". The only compliant device is not registered for the Montenegrin Market and the manufacturer thus refuses to sell it (or even quote it) for this tender... Since there are no alternatives that match the specifications, could you either: 1/ remove this item from lot 1 of the tender.	(a) 6 °C/sec ±1 °C maximum block ramp rate may be considered fit for purpose—provided the system meets overall performance targets (e.g. ≤30 min runtime). **Corresponding specifications will be amended by means of Corrigendum No.2.** (b) The specification of a minimum reaction volume as low as 1 µL was included to reflect the flexibility and performance capabilities of modern real-time PCR systems, especially in terms of: reagent cost efficiency, particularly for high-throughput workflows, and compatibility with advanced chemistries. However, we acknowledge that a minimum volume of 1 µL is not a common operational requirement for most routine assays and that many robust systems operate optimally in the 10–20 µL range. Therefore, we confirm that a minimum reaction volume of 10 µL for the 96-well block may be considered fit for purpose, provided the system can reliably perform reactions with good thermal uniformity and detection sensitivity within that volume range. **Corresponding specifications will be amended by means of Corrigendum No.2.** c) The requirement for "Self-Installable Optical Cartridges" will be relaxed. Instead, the instrument should be designed to support flexible optical detection and allow for ease of service or upgrade, while ensuring compatibility with a broad range of commonly used fluorescent dyes. **Corresponding specifications will be amended by means of Corrigendum No.2.** (10) Item 3.4 - Laboratory centrifuge: Yes. **Corresponding specifications will be amended by means of Corrigendum No.2.** (11) According to the Corrigendum No. 2, Item 1.10 – Automated Inoculation Delivery System will be removed from Technical Specification.

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	2/ replace the specifications so that other alternatives can be proposed.	
3.	(1) For Item 2.2 -Automatic solvent evaporation system, point 2.2.5 (The temperature must be precise and uniform, with temperature control in place (± <0.5 °C)): We would like to point out that leading manufacturers of ASE systems typically ensure temperature control within ±2 °C, which is considered an industry standard and sufficient for ensuring uniformity and analytical reproducibility in routine applications. Could you please confirm: • whether the stated precision of ±<0.5 °C is correct and strictly required, or • whether systems offering temperature control within ±2 °C would also be considered acceptable?	(1) Regarding point 2.2.5 we confirm that the proposed modification is acceptable. Specifically, a temperature control precision within ±2 °C is sufficient to meet the requirements of the analytical methods we intend to use and will not negatively affect the accuracy, precision, or overall reliability of the laboratory results. Although there are instruments available on the market offering a range starting from 0.1 °C, we accept a precision of ±2 °C. Given the nature and robustness of the extraction methods applied, such a temperature range does not compromise the competence of the laboratory or compliance with the requirements of validated methods. Therefore, we consider that a system providing temperature control within ±2 °C would be fit for purpose. **Corresponding specifications will be amended by means of Corrigendum No.2**
	(2) Regarding Selection criteria for Lot 2: We kindly request clarification regarding the documentation requirements in case a third entity is involved in the offer, specifically for Lot 2. In our case, we intend to participate as the main tenderer and include a third entity to provide one of the requested instruments. This third entity will not contribute to the fulfilment of the selection criteria (economic, financial, or professional), **but will authorize our own technical staff to perform all necessary servicing and support for the equipment.** Considering this, could you please confirm:	(2) For entities not having the status of tenderer, member of a joint venture/consortium, capacity-providing entity or subcontractor, there is no obligation to provide the documentation required in point 3 of the Instructions to tenderer. Please note, however, that the tenderer has a legal obligation to clearly designate the role of each entity participating in their tender.

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	1. Which documents, if any, are required from such a third entity (e.g., Declaration on Honour, manufacturer's authorization, statement of collaboration, etc.)? 2. Would a written authorization from the third entity, confirming that our personnel are trained and authorized to service the equipment, be considered sufficient? 3. Can you confirm that, since the third entity is not contributing to the selection criteria, they are not required to submit financial or technical documentation, nor to assume any liability? (3) Regarding the tender specifications, specifically 2.2.8 ("The instrument supports glass/plastic vials of 7 mL and 15 mL capacity, ensuring compatibility with common sample volumes") and 2.2.10 ("The racks are adjustable to accommodate both 7 mL and 15 mL vials"), would it be acceptable to offer the instrument with 10 mL vials and a non-adjustable rack designed specifically for 10 mL vials, in order to allow for a wider range of offers?	(3) Regarding points 2.2.8 and 2.2.10 it is acceptable to offer an instrument compatible with 10 mL vials and a non-adjustable rack specifically designed for this vial size. This amendment is considered justifiable, as it does not affect the validity of the analytical results or compromise the accuracy and precision of measurements. While the technical specifications initially referred to 7 mL and 15 mL vials as a reference, this was intended to ensure compatibility with commonly used vial sizes in laboratory practice, rather than to limit the technical solutions offered by bidders. The use of 10 mL vials in this context does not represent a limitation. On the contrary, it offers additional flexibility without compromising the instrument's functionality or the reliability of analytical outcomes. Accordingly, this technical variation does not reduce the quality of laboratory analyses, as the proposed system fully meets all performance criteria in terms of precision, reproducibility, and usability in routine workflows. Moreover, we recognize that compatibility with a broader range of vial volumes can enhance operational flexibility. Therefore, it is expected that the layout and configuration of the vial rack be optimally aligned with the selected vial size, ensuring efficient and reliable use of the instrument. **Corresponding specifications will be amended by means of Corrigendum No.2**

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4.	(1) Instrument classification Question: Please clarify whether the required system must necessarily be: a) A medical device registered with competent authorities (FDA/CE-IVD) b) A laboratory instrument for research/general analysis RATIONALE: This distinction is fundamental as it significantly affects regulatory requirements, costs, and the range of eligible suppliers. (2). Intended use and validation Question: Please clarify whether: a) The system must be specifically pre-validated by the manufacturer for AST/MIC testing b) A generic liquid handling system is acceptable provided it is technically suitable, with internal validation by the user RATIONALE: High-quality generic systems can guarantee the same technical performance with greater operational flexibility and better cost-benefit ratio. (3). Technical specifications - clarifications Question: Regarding technical requirements, please specify: 3.1 Dosing Capability • Is technical compatibility with standard 96-well plates sufficient, or is specific certification required for this format? • Are systems supporting other formats (6, 24, 384, 1536-well) acceptable provided they are compatible with 96-well?	According to the Corrigendum No. 2, Item 1.10 – Automated Inoculation Delivery System is removed from Technical Specification. (4) Item 1.3 – Tissue Homogenizer We agree to broaden the requirements so **corresponding specifications will be amended by means of Corrigendum No.2.**

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	3.2 MIC/AST Testing • Is specific certification required for AST/MIC testing or is verifiable technical suitability sufficient? • Are generic systems acceptable provided they demonstrate precise and reproducible dispensing capability for microbiological testing? (4.) Item 1.3 - Tissue Homogenizer: CURRENT SPECIFICATIONS: • Maximum capacity: 24 tubes • Speed Range: Adjustable speed range 4,000 - 6,800 rpm • Locking System: Automated tube locking mechanism • Programmability: Multiple user-defined programs with automatic parameter saving • Cycle Options: Configurable for multiple cycles • Cycle Duration: Adjustable cycle times • Power supply: 220/230V, 50/60Hz REQUEST FOR CLARIFICATION: The specified speed range of 4,000 - 6,800 rpm creates a de facto monopolistic situation that appears to exclude all major tissue homogenizer manufacturers except one specific brand. This creates artificial barriers to entry for technically equivalent solutions, eliminates competitive pricing and innovation incentives and it's also scientifically groundless: the specific RPM range has no scientific basis - homogenization efficiency depends on multiple factors including bead technology, movement pattern, and processing time. PROPOSED MODIFICATION: We respectfully request that the speed range	

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	specification be modified to ensure fair competition and access to a broader range of technically equivalent solutions. We suggest one of the following alternatives: • Option A - Expanded Range: Speed Range: Adjustable speed range not less than 2,400 - 4,300 rpm (or equivalent linear velocity in m/s) • Option B - Performance-Based Specification: Speed Range: Sufficient speed range to achieve complete homogenization of biological samples including tough tissues (bone, cartilage, plant material) within 30-60 seconds, with adjustable speed control • Option C - Technology-Neutral Specification: Speed Range: Variable speed control suitable for processing samples from soft tissues to hard materials, with minimum speed range of 2,000 rpm and programmable speed increments ALTERNATIVE TECHNOLOGIES: Some manufacturers express speed in linear velocity (m/s) rather than RPM, which can achieve equivalent results. We suggest accepting either measurement unit with appropriate conversion factors. (5). Tissue Processor Requirements (Lot 1, Item 1.4) Current Specification Analysis The current specifications appear to be highly specific and may inadvertently limit the procurement to a single manufacturer or model. The combination of exact requirements including:	(5). Tissue Processor Requirements (Lot 1, Item 1.4) **Corresponding specifications will be amended by means of Corrigendum No.2.**

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	• Minimum 20 reagent containers with 4L capacity • Exactly 2 paraffin baths of 4L each • Specific vacuum range of 50-80 kPa • Specific pressure range of 30-60 kPa • Exact temperature ranges for different processes These precise specifications, when combined, significantly restrict the available options in the current tissue processor market. Market Analysis Our comprehensive market research indicates that while many leading manufacturers (including Leica, Sakura, Thermo Scientific, and others) offer high-quality tissue processors that meet the functional requirements for histological processing, the exact combination of specifications may exclude otherwise suitable equipment. Proposed Clarification We suggest modifying the specifications to focus on performance requirements rather than exact technical parameters. This approach would: • Ensure competitive bidding from multiple qualified manufacturers • Maintain high quality standards for histological processing • Provide better value for money • Allow access to the latest technological innovations Specific Recommendations: 1. Reagent Containers: "Minimum 12 reagent stations" (industry standard)	(6) Item 1.9 - Tissue Homogenizer: Microplate reader, point 1.9.1 Yes, systems with a minimum of 8 measurement channels with 1 reference channel could be considered fit for purpose, provided that all other specifications are met. **Corresponding specifications will be amended by means of Corrigendum No.2.**

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	2. Container Volume: "Minimum 3.5L capacity" (adequate for processing needs) 3. Paraffin Baths: "Minimum 2 paraffin baths" (without specifying exact volume) 4. Processing Capacity: Maintain "minimum 200 cassettes per cycle" 5. Vacuum/Pressure: "Appropriate vacuum and pressure systems for optimal tissue processing" (allowing manufacturer-specific optimized systems) These modifications would maintain the high performance standards required while ensuring a competitive procurement process. Request for Confirmation We respectfully request confirmation that the specifications will be reviewed to ensure they are not inadvertently restrictive and that functionally equivalent tissue processors from various manufacturers will be accepted. (6) Item 1.9 - Tissue Homogenizer: Microplate reader, point 1.9.1 (*Measurement Channels: 12 measurement channels with 1 reference channel*): CURRENT MARKET ANALYSIS: Our comprehensive market research indicates that the requirement for exactly 12 measurement channels significantly limits the available options in the current microplate reader market (actually, to 1 single manufacturer). The majority of manufacturers, including industry leaders such as BMG LABTECH, Molecular Devices, BioTek, and others, offer high-performance microplate readers with 8-channel optical systems as their standard configuration. TECHNICAL CONSIDERATIONS: We propose the following alternatives that would maintain or enhance the intended	

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	performance while ensuring competitive procurement: • Option 1: Accept 8-Channel Systems Modify the specification to accept "minimum 8 measurement channels" instead of exactly 12 channels. This would: - Maintain excellent analytical performance - Ensure competitive bidding from multiple qualified manufacturers - Provide access to the latest technological advancements - Offer better value for money • Option 2: Allow Monochromator-Based Systems as Equivalent Accept monochromator-based microplate readers as technically equivalent or superior to multi-channel filter-based systems. TECHNICAL SUPERIORITY OF MONOCHROMATOR SYSTEMS: Monochromator-based systems offer several technical advantages over traditional multi-channel filter systems: 1. Superior Flexibility: Monochromators enable selection of any wavelength within the instrument range (typically 200-1000 nm) without requiring physical filter changes, providing unlimited wavelength combinations for current and future assay requirements. 2. Enhanced Spectral Resolution: Monochromators provide better spectral resolution with narrow measurement bandwidths (typically 1-4 nm), resulting in reduced spectral cross-talk and enhanced sensitivity for assays with overlapping spectra.	

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	3. Precise Wavelength Selection: Fine-tuning capabilities allow optimization for specific dyes and custom assay development, which is critical for research applications. 4. Cost-Effective Operation: No need to purchase additional filters for new assays or applications, reducing long-term operational costs. 5. Spectral Scanning Capabilities: Ability to perform full excitation and emission spectrum analysis, valuable for assay development and characterization. 6. Future-Proof Technology: Adaptability to new fluorophores and assay technologies without hardware modifications. RECOMMENDED SPECIFICATION REVISION: We suggest modifying the current specification to: *"Measurement Channels: Minimum 8 measurement channels with 1 reference channel, OR monochromator-based optical system with variable wavelength selection capabilities across the specified wavelength range (340-750 nm) with spectral bandwidth ≤10 nm."* This revision would: • Maintain the high analytical standards required • Ensure competitive procurement process • Provide access to state-of-the-art technology • Offer better long-term value and flexibility REQUEST FOR CONFIRMATION: We respectfully request confirmation that either:	

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	1. The specification will be amended to accept 8-channel systems, or 2. Monochromator-based systems will be accepted as equivalent to the 12-channel requirement	
5.	Please advise: 1. Is it acceptable to submit CRPS as a proof of duly authorised signature of our executive director. 2. Is one written statement of supplier enough proof of a description of the warranty conditions and description of the organization of the commercial warranty in accordance with the conditions laid down in Article 32 of the Special conditions? 3. Which are supporting documents to the identification form that we need to deliver? 4. We have one identification form already filled and signed from our bank on 28.04.2025. Can we use it for this procedure, or we need to sign new one during this month? 5. We understood to submit proof of nonexistence of criminal record, and proof that all the taxes are paid. These documents are issued in Montenegrin language, is it acceptable? Do these documents need to be originals, or notarised copies, and are there any other documents needed in order to support the declaration of honour?	(1) In line with point 11, part 3 of the Instructions to tenders regarding attestation of the legal capacity of the person who signs the tender on behalf of the company, joint venture or consortium, acceptable proof must take a form of an official document such as statutes, power of attorney, or a notary statement. Under the assumption that under the term CRPS you're referring to the extract from the official register of economic operators established in Montenegro (i.e. Centralni registar privrednih subjekata Crne Gore), an extract issued by CRPS may be considered as an official document attesting the identity of the persons having the legal authority to act on behalf of a particular entity. In case you're applying as consortium/joint venture, please also take into consideration provisions of point 18.2 of Instructions to tenderers. (2) Please note that a description of the warranty conditions, which must be in accordance with the conditions laid down in Article 32 of the General conditions and description of the organisation of the commercial warranty in accordance with the conditions laid down in Article 32 of the Special conditions, including a detailed description of the organisation of the proposed service, as stipulated in point 11, part 3 - Documentation is to be elaborated by the tenderer in the free format. (3) Related to the Identification form for private or public law bodies, an indicative list of supporting documents is specified in the form itself, namely: - Public or private law body details: *copies of official supporting documents (Resolution, law, register(s) of companies, official gazette, VAT registration, etc.)* - Banking details: *it is preferable to attach a copy of a recent bank statement. With a bank*

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		statement, the stamp of the bank and the signature of the bank's representative are not required. Please note that the bank statement has to confirm all the information listed above under 'ACCOUNT NAME', 'IBAN/BANK ACCOUNT NUMBER' and 'BANK NAME'. *(4) Under the assumption that no changes have occurred in the meantime and that corresponding information is duly attested as correct and provided in the required form, the tenderer may rely on the previously issued Identification form.* (5) For detailed instructions for submission of evidence for attesting compliance with exclusions and selection criteria, please refer to point 20.7 of the Instructions to Tenderers.
6	(1) Specification 2.1.5.11 *Calibration curve generation and validation* Question: Can you give us a clarification regarding requested validation – does this part of the specification refer to IQOQ instrument and software validation? (2) Specification 2.1.5.13 - Report generation in PDF and Excel. Change proposal: 2.1.5.13 Report generation in PDF and Excel or Excel compatible data format Explanation: Changing the specification as stated represents an equivalent solution to the one originally requested. This will allow greater competition between multiple bidders so the customer can have better overview of the market and possible technical and economical solutions. For this	(1) Regarding technical specifications, sub-item 2.1.5.11 *Calibration curve generation and validation,* we confirm that the term "validation" in the context of "Calibration curve generation and validation" does not refer to IQ/OQ (Installation Qualification / Operational Qualification) of the instrument or software. Our intention was to emphasize the importance of the software's capability to verify and ensure the accuracy and reliability of the calibration curve as part of analytical performance. This refers specifically to the functional aspect of the software—its ability to internally assess, validate, and flag any potential inconsistencies in the calibration data or the model applied. (2) We agree with the proposed change to sub-item 2.1.5.13; the corresponding **change will be reflected in Corrigendum No.2.** Allowing report generation in PDF and Excel or Excel-compatible data format fully meets the technical and functional needs. This modification does not compromise the quality or usability of the reports and provides sufficient flexibility in selecting the software solution.

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	reason. please change the specification as stated. (3) Specification 2.1.5.14 Full-featured MS/MS spectral analysis Change proposal: 2.1.5.14 Software enables MS/MS spectral analysis Explanation: "Full featured" is a very broad term and softwares from different manufacturers have differently defined names of the same individual functions of chromatogram processing and overall MS/MS spectra processing. In order to enable equal competition between multiple bidders, please change the requested specification. (4) Specification 2.1.5.18 Backup options ensuring data integrity and avoiding loss of important results Question: Does the requested software have to be CFR Part 11 compliant or file based? (5) Specification 2.1.5.19 Support for External Data Interfacing: enabled import/export data in standard formats (e.g. csv, mzXML, raw) for further analysis or reporting in other software platforms Change proposal: 2.1.5.14 Support for External Data Interfacing: enabled import/export data in standard formats (e.g. cvs, mzXML) and export of raw data generated by mass spectrometer for further	(3) We acknowledge the explanation provided and agree with the proposed change to specification of Sub-item 2.1.5.14; change **will be addressed in the Corrigendum No.2.** (4) The clarification related to Sub-item 2.1.5.18 is as follows: 21 CFR Part 11 compliance is not explicitly required in this tender. The specification refers to the functional capability of the software to perform regular backups and ensure that stored data (including analysis results and related files) is protected from loss or corruption. The requirement can be fulfilled by a file-based backup system or another reliable method, as long as it ensures data integrity, traceability, and retrievability in case of system failure or data loss. The key objective is to safeguard important results, not to impose specific regulatory compliance such as 21 CFR Part 11 (5) We agree with the proposed change to specifications of Sub-item 2.1.5.19; change **will be addressed in the Corrigendum No.2.** The clarification provided highlights important differences in how various software solutions handle raw data export. Since not all manufacturers use the *.raw file extension but are still capable of exporting equivalent raw data (e.g., in ASCII or other compatible formats), the revised wording ensures functional equivalence without limiting technical solutions. This change supports fair and equal competition among bidders while preserving the intent of the original specification—to allow seamless import/export of data for further analysis or reporting in other software platforms.

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	analysis or reporting in other software platforms Explanation: In chromatography, a .raw file format represents the raw data generated by a mass spectrometer during an analysis with information about the mass-to-charge (m/z) ratios of ions detected, along with their intensities, scan times, and instrument settings. Softwares from different manufacturers can export raw data as described but doesn't necessarily have .raw file format. For example, raw data can be exported as ASCII text format which can later be opened in other platforms. Different softwares have different ways of doing the same operation so it is important to change specification as requested to enable equal and fair competition between bidders.	
	(6) Specification 2.18 Training Item No. 2.1 at IPH premises 5 persons, 2 training periods, 5 days each, the training should cover: Familiarization with the LCMS software (setting the method, i.e. starting the sample analysis; data processing- quantification (forming the calibration curve, forming the sequence, single analysis; UV spectra-training for determining spectrum purity; generating reports, etc.) Question: PDA/DAD detector is not listed in requested system configuration but in the training section UV spectra processing is required. it necessary to offer PDA/DAD detector in LC-MS/MS configuration?	(6) Regarding technical specifications, Sub-item 2.18 Training in connection to an Item No. 2.1 (at IPH premises), we would like to clarify that an error has occurred. The training does not refer to a detector different from the instrument being procured, i.e., the LC-MS/MS system. The training is intended exclusively for the operation of the instrument that is the subject of this procurement. **This error will be remedied through Corrigendum No.2.**
	(7) Specification 2.2.5. The temperature must be precise and uniform, with temperature control in place (± <0.5 °C).	(7) Regarding Sub-item 2.2.5 we confirm that the proposed modification is acceptable and will be reflected **through Corrigendum No.2.** Specifically, a temperature control precision within ± ≤2 °C is sufficient to meet the requirements of the analytical

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	Change proposal: 2.2.5. The temperature must be precise and uniform, _with temperature control in place (± ≤2 °C). Explanation: We propose amending the temperature specification from ± <0.5 °C to ± ≤2 °C, as this change does not compromise the quality, performance, or reliability of the evaporation system. International standards such as ISO, GLP, and GMP do not require tighter temperature accuracy for water bath in typical evaporation processes. A 12 °C tolerance is technically sufficient, widely accepted in practice, and allows for greater energy efficiency, lower maintenance, and more cost-effective solutions. This adjustment would enable fair market competition by allowing a broader range of qualified manufacturers to participate in the tender. Overall, it ensures a balanced, compliant, and economically responsible procurement process." (8) Suggestions, comments, and inquiries relate to the Cost Estimate, specifically LOT 2, item 2.2 Automatic Solvent Evaporation System: We propose that you divide the cost estimate into two separate groups, specifically separating 2.1 Ultra-High-Performance Liquid Chromatograph (UHPLC) with Triple Quadrupole (MS/MS) Mass Spectrometer from 2.2 Automatic Solvent Evaporation System. Namely, market research for this procedure clearly indicates that the detailed technical specifications for 2.2 are directed towards one specific manufacturer - Biotage, model Turbo Vap LV, which is not in accordance with the principles of competition and transparency prescribed by European legislation, especially in accordance with Article 42 of Directive 2014/24/EU on public procurement, which emphasizes the need to ensure equal	methods we intend to use and will not negatively affect the accuracy, precision, or overall reliability of the laboratory results. Although there are instruments available on the market offering a range starting from 0.1 °C, we accept a precision of ± ≤2 °C. Given the nature and robustness of the extraction methods applied, such a temperature range does not compromise the competence of the laboratory or compliance with the requirements of validated methods. Therefore, we consider that a system providing temperature control within ± ≤2 °C fulfills the technical and scientific criteria we require. (8) Modifications have been introduced to the specifications regarding item 2.2 which now allow for a broader competition, rendering the separation of the instruments into two different lots unnecessary.

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	access to all potential bidders. Item 2.1 Ultra-High-Performance Liquid Chromatograph (UHPLC with Triple Quadrupole (MS/MS) Mass Spectrometer is a measuring analytical device, while 2.2 Automatic Solvent Evaporation System is a sample preparation device, thus they do not fall into a related category of devices. Most potential bidders for analytical measuring devices do not simultaneously have the ability to offer sample preparation equipment, especially since a specific model from a particular manufacturer – Biotage, Turbo Vap LV, is specified here, which is exclusively represented by only one distributor in the region. It is important to emphasize that, given the high value of the procedure, the value of the disputed item 2.1 is 20 times greater than that of item 2.2. which further demonstrates the necessity for transparency in the procedure by separating them into two distinct groups of procurement items. In this specific case, it cannot be claimed that this is an indivisible unit, where dividing into groups would complicate contract execution due to technical difficulties and additional costs, or that contract execution would be inefficient and ineffective. Separating Automatic evaporator into separate group would lead to opening the market to a greater number of economic entities and manufacturers, which would result in a larger number of competitive, comparable, and favorable offers, leading to effective procurement and economical and purposeful spending of secured funds.	

No.	Question	Answer
7	(1) Tissue Processor (item 1.4) 1.4.1 Is it acceptable to offer a device with 19 reagent beakers? 1.4.3 Can the paraffin bath configuration be 4 × 2.5 L, plus one 2.5L additional bath for fresh paraffin? 1.4.8 Is a cleaning reagent temperature to 65°C acceptable? 1.4.9 Is a maximum processing capacity of 300 cassettes per cycle acceptable? (2) Slide Stainer (Item 1.6) 1.6.1 Is a maximum loading capacity of 12 slide racks acceptable? (3) Water Bath (Item 1.8) 1.8.1 Is a heating temperature of 60°C acceptable? (4) Natural Convection Incubator (Item 1.13) 1.13.5 Is it acceptable to offer a device with a maximum loading capacity of 25 kg per shelf? Total chamber loading capacity is 180 kg. LOT 3 In light of the restrictive specifications and the resulting exclusion from participation in Lot 3, we kindly request that the following amendments be made to the technical specifications in order to ensure compliance with the principles of transparency, non-discrimination, equal treatment, and effective competition.	(1) Tissue Processor (item 1.4) 1.4.1 Yes, this would be considered fit for purpose. **Corresponding specifications will be amended by means of Corrigendum No.2.** 1.4.3 **Corresponding specifications will be amended by means of Corrigendum No.2.** 1.4.8. Yes 1.4.9. Yes (2) Slide Stainer (Item 1.6) 1.6.1 Yes, please note that **corresponding specifications will be amended by means of Corrigendum No.2.** (3) Water Bath (Item 1.8) 1.8.1 The specification clearly indicates: "Heating temperature: 5°C - 75°C", in the form of required range. 60°C falls within specified heating range. (4) Natural Convection Incubator (Item 1.13) 1.13.5 Yes. **Corresponding specifications will be amended by means of Corrigendum No.2**

No.	Question	Answer
	(5)Real-time PCR system with laptop - Could you please clarify what is precisely meant by the specification 'Run Time < 30 min? - Your specification states that the system should include 8 filtered photodiodes. Could you please confirm whether a configuration with fewer filtered photodiodes—such as 6—would be considered acceptable? - According to your specification, the instrument should support both 96-well and 384-well blocks in an interchangeable format. Could you please clarify whether support for both formats is a strict requirement, or if a system with only a 96-well block would be acceptable? - Your specification mentions self-installable optical cartridges. Could you kindly clarify whether it would be acceptable for the system to have an integrated optical system instead of self-installable optical cartridges? - Does detection method which uses six filtered LEDs for illumination and differentially detects emission using six filtered photodiodes acceptable if this	(5) Item 3.1 Real-time PCR system with laptop - The specification "Run Time < 30 min" refers to the total time required to complete a standard quantitative PCR (qPCR) amplification protocol. This runtime is based on commonly used fast PCR protocols (e.g. 2-step or 3-step protocols for amplicons ≤200 bp), and assumes optimized reagents and reaction volumes. - A configuration with fewer than 8 filtered photodiodes (e.g., 6) may be considered fit for purpose, provided the system can support: a minimum of 5-plex detection per well with validated spectral discrimination; Compatibility with the listed dyes (FAM/SYBR Green, VIC/JOE/HEX, TAMRA, Texas Red, Cy5); Equivalent performance in terms of multiplexing capacity, sensitivity, and accuracy. **Corresponding specifications will be amended by means of Corrigendum No.2** - The requirement for interchangeable 96-well and 384-well blocks is intended to ensure maximum flexibility and scalability for different experimental needs. Therefore, support for both 96-well and 384-well blocks in an interchangeable format is a mandatory requirement. - A system with an integrated optical system is fit for purpose provided it meets other functional and performance criteria. **Corresponding specifications will be amended by means of Corrigendum No.2**

No.	Question	Answer
	method is equally fast, sensitive and accurate?	
		- Yes, a detection method using six filtered LEDs and six filtered photodiodes is acceptable, provided the system meets the required performance criteria, including: minimum 5-target multiplexing per well; sensitivity and accuracy comparable to specified systems; run time under 30 minutes; compatibility with required fluorescent dyes. **Corresponding specifications will be amended by means of Corrigendum No.2**
	(6) RNA/DNA extraction device - Is it acceptable that the extraction system has a magnetic beads-based system (built-in centrifuge and shaker are not required), and the procedure is performed by a pipetting arm?	(6) Item 3.2 – RNA/DNA extraction device: - A system that uses magnetic bead-based extraction performed by a pipetting arm is acceptable only if it provides full automation of all steps without requiring manual handling during the run. Systems that rely on manual steps or partial automation will not meet the requirements.
	- Your specification says 'Monitor runs remotely.' Is it acceptable that the system has electronic control via the main board (no additional PC is required)?	- Remote Monitoring: The goal of the requirement "Monitor runs remotely" is to enable users to track the progress of the run without being physically present at the device. A system with integrated electronic control via a main board is acceptable only if it includes a feature that allows remote access or monitoring (e.g., via mobile app, web interface, or remote notification system). **Corresponding specifications will be amended by means of Corrigendum No.2**
	- Is it acceptable that the pipetting range is 60–600 µl?	- No. The specified pipetting range of 5–900 µL reflects the volume requirements of standard and kit-based nucleic acid extraction protocols for plant material. These protocols typically involve high-volume steps

No.	Question	Answer
		(e.g. 400–900 µL for lysis and washing) and low-volume elution steps (e.g. 10–30 µL) to ensure high-quality, concentrated RNA/DNA. Therefore, this range is necessary to support full automation of all protocol steps without manual intervention.
	(7) Ultra low freezer Is it acceptable for the refrigerants to be R1270/R170, considering that R1270 also belongs to the group of green hydrocarbon-based cooling liquids?	(7) Item 3.5 Ultra-Low Temperature Freezer: Yes, the use of R1270 (propylene) in combination with R170 (ethane) is acceptable. R1270 is indeed a hydrocarbon-based refrigerant classified as a "green" alternative, similar to R290. **Corresponding specifications will be amended by means of Corrigendum No.2**
	(8) Laboratory centrifuge Regarding the technical specification for the laboratory centrifuge, we kindly request some clarification: The requirement specifies a maximum speed of 20,000 RPM and a maximum relative centrifugal force (RCF) of 35,000 × g, which are parameters typically associated with ultracentrifuges used for highly specialized applications (e.g., viral particle separation, subcellular fractionation, or DNA/RNA extraction from small volumes).Since such high specifications significantly impact both the cost and availability of suitable equipment on the market, it would be helpful if you could clarify the following: What type of samples are intended to be centrifuged? What specific procedure requires such high RPM and RCF values? Is there any flexibility in the specification, in case a device with slightly lower RPM/RCF—but greater market availability—can still meet the functional requirements?	(8) Item 3.4 – Laboratory centrifuge: Samples of plant material or soil are used for centrifugation after appropriate preparation. Yes, the specifications could be flexible in range ±10% for RPM and RCF values. **Corresponding specifications will be amended by means of Corrigendum No.2**
8	For Item 2.2 - Automatic solvent evaporation system, point 2.2.5 (*The temperature must be precise and uniform, with temperature control in place (± <0.5 °C)*): In reference to the technical specifications of evaporator provided in the tender documentation, it is stated that the required temperature control must have a	Regarding point 2.2.5 we confirm that the proposed modification is fit for purpose. Specifically, a temperature control precision within ±2 °C is sufficient to meet the requirements of the analytical methods we intend to use and will not negatively affect the accuracy, precision, or overall reliability of the laboratory results. Although there are

No.	Question	Answer
	tolerance of ± <0.5 °C. We would like to kindly ask whether it would be acceptable to offer a device with a temperature control accuracy of ±2 °C, considering it still provides stable and uniform performance.	instruments available on the market offering a range starting from 0.1 °C, we accept a precision of ±2 °C. Given the nature and robustness of the extraction methods applied, such a temperature range does not compromise the competence of the laboratory or compliance with the requirements of validated methods. Therefore, we consider that a system providing temperature control within ±2 °C fits the technical and scientific criteria we require. **The revised requirement will be published as part of Corrigendum No.2.**
9.	(1) LOT 1/LOT2/LOT3: Is the bid guarantee to be submitted individually for each lot, or is one bid guarantee covering all offered lots acceptable? (2) LOT 2: The tender documentation stipulates the following: "The candidate has completed supplies under at least 2 contracts implemented at any moment during the last four years before the submission deadline. • For each contract, the value of the supplies completed must not be less than EUR 250,000. • The completed supplies are in the domain of supply of phytosanitary laboratory equipment." Is it acceptable to submit a certificate for equipment with a value of no less than EUR 250,000, specifically for a device that has the same characteristics as the one that is the subject of the procurement? (3) LOT 1/LOT2/LOT3 :"If an interested tenderer wishes to submit an offer for all three lots in the following manner: two lots as a sole tenderer and one lot as part of a consortium, is the tenderer required to submit a separate offer for each lot, or is it acceptable to submit one single offer for all three lots together, or to submit one offer for the lots in which the tenderer participates independently and another offer for the lot in which the tenderer participates as part of a consortium?"	(1) As the contracts under this procedure may be awarded separately per each lot, you're advised to reflect mentioned logic by furnishing separate tender guarantee per each lot. *(2)* Contracting authority cannot prejudice decision about the compliance of the references with the technical criteria. In the context of this procedure, such decision can be made only by the evaluation committee during tender evaluation based on complete set of information. (3) Based on our understanding of described scenarios and pursuant to , a separate tender per distinct legal identity should be provided, meaning: - Separate offers where you participate as a sole tenderer - A separate offer for the lot where you participate as a consortium member.

No.	Question	Answer
	(4) LOT 1, Item 4. Tissue Processor (Position 1.4.1) The specification requires a minimum of 20 reagent bottles. Is it acceptable to offer a minimum of 17 reagent bottles? Tissue processing protocols never require such a large number of reagent changes, and an excessive number of bottles also leads to unnecessary chemical waste. (Position 1.4.3) The specification requires paraffin baths with a capacity of 4 L. Is it acceptable for the paraffin bath capacity to be 3.9 L? Such a small difference does not affect the quality of sample processing and allows more bidders to participate.	(4) As ammended in the Corrigendum No.2, at least 19 reagent bottles are necessary.
	(5) Item 5. Microtome (Position 1.5.5) The specification requires that the retraction setting range be from 10 microns to 100 microns. Is it acceptable for the retraction setting to be approximately 40 microns, as this is sufficient to ensure cutting quality and operational performance?	(5) The TS states: „Adjustable retraction in manual sectioning mode, 10 µm to 100 µm." and this should remain as such. If the question refers to a fixed retraction setting of approximately 40 µm, this is not acceptable, as the specification requires adjustable retraction (10–100 µm) to allow flexibility for different tissue types and sectioning conditions.
	(6) Item 8. Water Bath (Position 1.8.1) The specification requires a heating temperature range of 5 °C to 75 °C. Is it acceptable for the maximum heating temperature to be 60°C, given that the melting point of all types of paraffin used in pathology ranges between 52 °C and 58 °C?	(6) No, some of the protocols require higher temperatures.
	(7) LOT 2:"The tender documentation stipulates the following for item '2.2.5 The temperature must be precise and uniform, with temperature control in place (±< 0.5°C).' Is it acceptable for this item to offer "2.2.5 The temperature must be precise and uniform, with temperature control in place (± 2°C)"?	(7) Yes, **Corresponding specifications will be amended by means of Corrigendum No.2**

No.	Question	Answer
10.	Specification 2.2.5. "The temperature must be precise and uniform, with temperature control in place (±< 0.5°C)" Change proposal: 2.2.5. The temperature must be precise and uniform, with temperature control in place (accuracy ± ≤2°C). Explanation: After reviewing the market for automatic evaporators, we have determined that there is no automatic evaporator with temperature control of (±< 0.5°C) that meets all other required minimum technical specifications, and no bidder will be able to offer a device according to the required specifications. We assume that this is a random mistake and ask for a change in temperature control (accuracy ± ≤2°C).	Accepted, **Corresponding specifications will be amended by means of Corrigendum No.2**
11.	Specification: 2.2.4 - Water Temperature Range: Ambient to 80°C or more Proposal: 2.2.4 Water Temperature Range: Ambient to 60°C or more Explanation: Based on our extensive experience with similar systems, a water temperature of 60°C is sufficient to ensure optimal evaporation performance in most laboratory and industrial settings. Higher temperatures may not provide a proportional improvement in performance but do increase thermal stress and energy usage.	When defining the specification, primary consideration was given to the needs of the laboratory, followed by an assessment of the equipment offerings available on the market. Considering the complexity of certain laboratory methods and the use of high-boiling solvents such as acetonitrile or ethyl acetate, we believed that setting a maximum water temperature requirement of up to 80 °C would not negatively affect competitiveness. This assumption was verified, as there are a sufficient number of suppliers offering equipment with the required temperature range. However, given that the number of analytical methods requiring water temperatures near 80 °C is relatively small compared to the overall scope of testing, we accept the proposed change. **The revised requirement will be published in the Corrigendum No.2.**

No.	Question	Answer
	Many internationally recognized manufacturers design their systems to operate efficiently at or below 60°C. Limiting the specification to 80°C may unnecessarily restrict competition and exclude otherwise fully compliant and proven technologies.	