Centre for Environment Fisheries & Aquaculture Science

Cefas

Conditions of Contract

Short Form Enhanced

CEFAS24-05 – Contract for provision of a tissue processor under the Ocean Country Partnership Programme.

Contents

Centre for Environment
Fisheries & Aquaculture
Science

Cefas

Shandon Diagnostics Ltd t/a Epredia
Manor Park
Tudor Road
Runcorn
Cheshire
WA7 1TA

[redacted]

Date: 20 February 2024
Our ref: **CEFAS24-05**

Dear [redacted]

Supply of a tissue processor under the Ocean Country Partnership Programme.

Following your tender/ proposal for the supply of a tissue processor under the Ocean Country Partnership Programme to **The Secretary of State for Environment, Food and Rural Affairs** acting as part of the Crown through the **Centre for Environment, Fisheries and Aquaculture Science**, we are pleased confirm our intention to award this contract to you.

The attached contract details ("**Order Form**"), contract conditions and the **Annexes** set out the terms of the contract between **Centre for Environment, Fisheries and Aquaculture Science** and **Shandon Diagnostics Ltd t/a Epredia** for the provision of the deliverables set out in the Order Form.

We thank you for your co-operation to date and look forward to forging a successful working relationship resulting in a smooth and successful delivery of the deliverables. Please confirm your acceptance of the Conditions by signing and returning the Order Form within **7** days from the date of this letter, which will create a binding contract between us. No other form of acknowledgement will be accepted. Please remember to include the reference number above in any future communications relating to this contract.

We will then arrange for the Order Form to be countersigned so that you have a signed copy of the Order Form for your records.

Yours faithfully,

[redacted]

[redacted]
Pakefield Road,
Lowestoft,
Suffolk,
NR33 0HT, UK
[redacted]
[redacted]

Order Form

1. Contract Reference	CEFAS24-05 Contract for provision of a tissue processor under the Ocean Country Partnership Programme.
2. Date	29 February 2024
3. Authority	Cefas Pakefield Road Lowestoft Suffolk NR33 0HT
4. Supplier	*Shandon Diagnostics Limited t/a Epredia* *Manor Park* *Tudor Road* *Runcorn* *Cheshire* *WA7 1TA* *00330973*
4a. Supplier Account Details	[redacted]
5. The Contract	The Supplier shall supply the Deliverables described below on the terms set out in this Order Form and the attached contract conditions ("**Conditions**") and any Annexes. Unless the context otherwise requires, capitalised expressions used in this Order Form have the same meanings as in Conditions. In the event of any inconsistency between the provisions of the Order Form, the Conditions and the Annexes, the inconsistency shall be resolved by giving precedence in the following order: 1. Order Form, Annex 2 (Specification) and Annex 3 (Charges) with equal priority. 2. Conditions and Annex 1 (Authorised Processing Template) with equal priority. 3. Annexes 4 (Tender Submission) and 5 (Sustainability). In the event of any inconsistency between the provisions of Annexes 4 and 5, Annex 5 shall take precedence over Annex 4. **Please do not attach any Supplier terms and conditions to this Order Form as they will not be accepted by the Authority and may delay conclusion of**

	the Contract.	
6. Deliverables	**Goods**	Delivered in accordance with the following instructions: Delivery Address: [redacted] Belize agricultural health authority Central veterinary diagnostic laboratory central farm Cayo district Belize Date of Delivery: 28/03/2024 (Estimated) Packaging Instructions: As per Tender Submission.
	Services	To be performed at: Belize agricultural health authority Central veterinary diagnostic laboratory central farm Cayo district Belize
7. Specification	The specification of the Deliverables is as set out in Annex 2.	
8. Term	The Term shall commence on **1 March 2024** (or as soon as possible) (the **Start Date)** and the Expiry Date shall be **1 March 2027** unless it is otherwise extended or terminated in accordance with the terms and conditions of the Contract. The Authority may extend the Contract for 2 further periods of up to 12 months' each by giving not less than 1 months' notice in writing to the Supplier prior to the Expiry Date. The terms and conditions of the Contract shall apply throughout any such extended period.	
9. Charges	The Charges for the Deliverables shall be as set out in Annex 3.	
10. Payment	The Authority's preference is for all invoices to be sent electronically, quoting a valid Purchase Order Number (PO Number), to: Finance@cefas.gov.uk Alternatively, you may post to: Cefas Pakefield Road Lowestoft Suffolk NR33 0HT Within **10** Working Days of receipt of your countersigned copy of this Order Form, we will send you a unique PO Number. You must be in receipt of a valid PO Number before submitting an invoice. To avoid delay in payment it is important that the invoice is compliant with Annex 3 Non-compliant invoices will be sent back to you, which may lead to a delay in	

	payment. If you have a query regarding an outstanding payment please contact the Authority's Authorised Representative(s).	
11. Authority Authorised Representative(s)	For general liaison your contact will continue to be [redacted] [redacted] [redacted]	
12. Address for notices	Authority: Cefas Pakefield Road Lowestoft Suffolk NR33 0HT [redacted]	Supplier: Shandon Diagnostics Limited t/a Epredia Manor Park Tudor Road Runcorn Cheshire WA7 1TA [redacted]
13. Key Personnel	Authority: Cefas Pakefield Road Lowestoft Suffolk NR33 0HT [redacted]	Supplier: Shandon Diagnostics Limited t/a Epredia Manor Park Tudor Road Runcorn Cheshire WA7 1TA [redacted]

14. Procedures and Policies	For the purposes of the Contract the applicable policies and procedures are available at: Policies, plans, reports and quality - Cefas (Centre for Environment, Fisheries and Aquaculture Science) For the avoidance of doubt, if other policies of the Authority are referenced in the Conditions and Annexes, those policies will also apply to the Contract on the basis described therein. The Authority may require the Supplier to ensure that any person employed in the delivery of the Deliverables has undertaken a Disclosure and Barring Service check. The Supplier shall ensure that no person who discloses that they have a conviction that is relevant to the nature of the Contract, relevant to the work of the Authority, or is of a type otherwise advised by the Authority (each such conviction a "Relevant Conviction"), or is found by the Supplier to have a Relevant Conviction (whether as a result of a police check, a Disclosure and Barring Service check or otherwise) is employed or engaged in the provision of any part of the Deliverables.
15. Limitation of Liability	As per Clause 12.1
16. Insurances	The Supplier shall hold the following insurance cover for the duration of the Contract in accordance with this Order Form. - Employers Liability insurance with cover for a single event or multiple with an aggregate of not less than £5 million; - Product Liability insurance with cover for a single event or multiple with an aggregate of not less than £500,000

Signed for and on behalf of the **Supplier**	Signed for and on behalf of the **Authority**
Name: [redacted]	Name:
Date: 29/02/2024	Date: 1 March 2024

[redacted]

Annex 1 – Authorised Processing Template

N/A

Annex 2 – Specification

Background:
The OCPP was announced in 2021 as a key bilateral aid programme under the £500m Blue Planet Fund.

The OCPP is a UK Government-led programme delivered under the Blue Planet Fund. Through this programme, Cefas, in partnership with JNCC and MMO, provide technical assistance to support countries in tackling marine pollution, support sustainable seafood practices, and establish designated, well-managed and enforced Marine Protected Areas (MPAs).

OCPP objectives are to support countries to tackle marine pollution, support sustainable seafood practices and establish designated, well-managed and enforced MPAs.

From 2021-26, Cefas will lead delivery of the Marine Pollution and Sustainable Seafood themes of OCPP, working in partnership with experts from the Joint nature Conservancy Council (JNCC) and the Marine Management Organisation (MMO).

This work includes the provision of equipment for the set up of a laboratory in Belize as part of the improvement of scientific capacity in the field of Histology.

Requirement:
Cefas require provision of a carousel-rotary style tissue processor, with the following specifications:

1. Capable of processing between 100 and 200 specimens housed in Tissue cassettes.
2. Electrical Configurations 120V, 60Hz, AC and work with appropriate type A, B or C plugs.
3. A fume control system is required to eliminate harmful fumes. Ideally there will be a facility to fit a carbon filter. 4x Spare filters should be included as part of the bundle. There must be a facility to easily buy replacement filters.
4. Ideally 8 or more reagent stations. These must be resistant to xylene and alcohol. Each station must be easily removed and cleanable. If the stations are considered as additional consumables, these must be included in the quotation.
5. At least 3 heated wax stations.
6. Built-in specimen basket agitation and/or reagent mixing facilities.
7. An integrated computer control system with a keypad and display.
8. Ideally a method of recoding faults so that engineers can be made aware of issues by sending logs or error codes.
9. Ability to programme user defined processing schedules, and there must be a memory cache to allow for multiple programs to be saved on the instrument.
10. Pre-set programs available to use, as well as free editing of station parameters such as mixing, immersion time, drip time (to avoid reagent carry over), and temperature control for wax baths.
11. The capacity to inform the user of the status of the instrument programmes with the

following parameters:

- Adjustable start time and delayed start time adjustable as required by the user.
- Total program run time, predicted end time must be displayed on demand.
- Ideally multiple baskets could be processed at the same time and for these to be detailed on the display so the progress and end time can be checked for each basket.
- Audible alarms, error messages and warning codes for when paraffin wax is un-melted and in solid state. In addition, automatic reheating of wax before basket is transferred to a wax bath.
- Warning and alarms if the power has been lost or if there has been a fault.
- Manual operation and overrides are essential.
- A battery backup to allow for power outages and retaining of instrument memory. Please include in quotation if this is not supplied as standard.
- Ability to remove specimens from the instrument if there is a mains or battery failure.
- Failsafe conditions such as automatic immersion of tissue basket in a station, in case of mains power failure.

12. If an uninterrupted power supply device is required to use the equipment, please specify and include in quotation.

13. All required leads and connectors must be included.

On-site installation and training

- Installation on-site is a requirement to tender.
- Ideally a training package will be included, to be delivered to relevant in-country users. Suppliers should indicate the options available, whether through the use of a virtual platform or face-to-face in-country.

Please note that installation and training can take place at a later date following delivery – this will be no later than 3 months after delivery date. **Cefas require the equipment to be delivered as soon as possible, ideally before the end of March 2024.**

Warranties/Guarantees/Servicing and Technical Support

- A 12 month warranty as standard – please include detail of what is included.
- A service contract for the first 12 month warranty period, plus an additional 2 years' support following (total 3 years), which must include the following support:
    a. Technical support by e-mail and by telephone.
    b. Engineer visits for planned annual maintenance.
    c. Engineer visits for repairs or breakdowns.

Please indicate the options available and what is included and include costs in quotation.

Environmental Considerations

- Unit should have a low power consumption.
- Unit should be designed for reuse/recycle and of regenerative nature to eliminate waste where possible.
- Consideration of how packaging will be managed. Ideally at the time of installation the supplier will remove packaging and dispose of by ethical and environmentally friendly methods. Where possible packaging is to be re-used or recycled.
- Consideration of whole life costing for use of the unit.

Quantity: 1

Delivery Date: Cefas require the equipment to be delivered as soon as possible, with a strong preference for delivery before the end of March 2024.

Location for goods to be delivered/services to be undertaken:
To: Ms. Sylvia Mendez
Belize agricultural health authority
Central veterinary diagnostic laboratory
central farm
Cayo district
Belize

Delivery Requirements
The Tenderer is required to provide details on their capability and recent experience of shipping internationally to INCOTERM DDP, specifically to Sri Lanka and/or in the South Asian region.

Pricing should be provided for both of the following options:

1.1. Total cost for the required equipment including all associated costs for installation and training but **excluding delivery**

1.2. Total cost for the required equipment including all associated costs for installation and training but **including delivery to INCOTERM DDP**

Cefas is currently working with the Belize government regarding customs duties. It is possible that the equipment will be exempt from all import duties. A customs declaration will be produced at confirmation of purchase and near the expected shipping dates. These details will be confirmed by Cefas as soon as possible.

Annex 3 – Charges

Defined terms within this Annex:

E-Invoicing: Means invoices created on or submitted to the Authority via the electronic marketplace service.

Electronic Invoice: Means an invoice (generally in PDF file format) issued by the Supplier and received by the Authority using electronic means, generally email

1. **How Charges are calculated**

1.1 The Charges:

1.1.1 shall be calculated in accordance with the terms of this Annex 3;

1.2 Any variation to the Charges payable under the Contract must be agreed between the Supplier and the Authority and implemented using the procedure set out in this Annex.

2. Rates and Prices

Goods or Services Required	Unit	Qty	Total Cost (ex VAT)	VAT (if applicable)
1 x tissue processor as per all requirements in Technical Specification in RFQ Part 1 Technical **INCLUSIVE of delivery to the provided address to INCOTERM DDP**	Total Fixed Cost	1	£43,841.92	£8,768.38
		Total Cost:	£43,841.92	£52,610.30

UNIT COST ONLY 1 x tissue processor as per all requirements in Technical Specification in RFQ Part 1 Technical **(excluding delivery)**	Total Fixed Cost	1	£36,303.00	£7,200.00
		Total Cost:	£36,303.00	£43,503.00

Cefas is currently working with the Belize government regarding customs duties. It is possible that the equipment will be exempt from all import duties. A customs declaration will be produced at confirmation of purchase and near the expected shipping dates. These details will be confirmed by Cefas as soon as possible.

Payment Schedule

Deliverable	Delivery Date	Invoice (ex VAT)
Evidence that item has arrived at the provided address and has been checked/ signed-off by BAHA staff	TBC on Contract award	£43,841.92

3. CURRENCY

All Supplier invoices shall be expressed in sterling or such other currency as shall be permitted by the Authority in writing.

4. Variations

The Authority may make reasonable changes to its invoicing requirements during the Term after providing 30 calendar days written notice to the Supplier.

5. Electronic Invoicing

5.1 The Authority shall accept for processing any electronic invoice that it is valid, undisputed and complies with the requirements of the Authority's e-invoicing system:

5.2 The Supplier shall ensure that each invoice is submitted in a PDF format and contains the following information:

5.2.1 the date of the invoice;

5.2.2 a unique invoice number;

5.2.3 the period to which the relevant Charge(s) relate;

5.2.4 the correct reference for the Contract

5.2.5 a valid Purchase Order Number;

5.2.6 the dates between which the Deliverables subject of each of the Charges detailed on the invoice were performed;

5.2.7 a description of the Deliverables;

5.2.8 the pricing mechanism used to calculate the Charges (such as fixed price, time and materials);

5.2.9 any payments due in respect of achievement of a milestone, including confirmation that milestone has been achieved by the Authority's Authorised Representative

5.2.10 the total Charges gross and net of any applicable deductions and, separately, the amount of any reimbursable expenses properly chargeable to the Authority under the terms of this Contract, and, separately, any VAT or other sales tax payable in respect of each of the same, charged at the prevailing rate;

5.2.11 a contact name and telephone number of a responsible person in the Supplier's finance department and/or contract manager in the event of administrative queries; and

5.2.12 the banking details for payment to the Supplier via electronic transfer of funds (i.e. name and address of bank, sort code, account name and number);

5.3 The Supplier shall submit all invoices and any requested supporting documentation through the Authority's e-invoicing system or if that is not possible to: Finance@cefas.gov.uk or Cefas, Pakefield Road, Lowestoft, Suffolk NR33 0HT with a copy (again including any supporting documentation) to such other person and at such place as the Authority may notify to the Supplier from time to time.

Annex 4 – Tender Submission

See end of Contract document

Annex 5 – Sustainability

1 Sustainability

1.1 The Supplier must comply with the Authority's Sustainability Requirements set out in this Contract. The Supplier must ensure that all Supplier Staff and subcontractors who are involved in the performance of the Contract are aware of these requirements in accordance with clauses 8.1(c) and 13.2.

1.2 The Authority requires its suppliers and subcontractors to meet the standards set out in the Supplier Code of Conduct in accordance with clause 13.1(c).

1.3 The Supplier must comply with all legislation as per clause 13.1.

2 Human Rights

2.1 The Authority is committed to ensuring that workers employed within its supply chains are treated fairly, humanely, and equitably. The Authority requires the Supplier to share this commitment and to take reasonable and use reasonable and proportionate endeavours to identify any areas of risk associated with this Contract to ensure that it is meeting the International Labour Organisation International Labour Standards which can be found online - Conventions and Recommendations (ilo.org) and at a minimum comply with the Core Labour Standards, encompassing the right to freedom of association and collective bargaining, prohibition of forced labour, prohibition of discrimination and prohibition of child labour.

2.2 The Supplier must ensure that it and its sub-contractors and its [or their] supply chain:

2.2.1 pay staff fair wages and

2.2.2 implement fair shift arrangements, providing sufficient gaps between shifts, adequate rest breaks and reasonable shift length, and other best practices for staff welfare and performance.

3 Equality, Diversity and Inclusion (EDI)

3.1 The Supplier will support the Authority to achieve its Public Sector Equality Duty by complying with the Authority's policies (as amended from time to time) on EDI. This includes ensuring that the Supplier, Supplier Staff, and its subcontractors in the delivery of its obligations under this Contract:

3.1.1 do not unlawfully discriminate either directly or indirectly because of race, colour, ethnic or national origin, disability, sex, sexual orientation, gender reassignment, religion or belief, pregnancy and maternity, marriage and civil partnership or age and without prejudice to the generality of the foregoing the Supplier shall not unlawfully discriminate within the meaning and scope of the Equality Act 2010;

3.1.2 will not discriminate because of socio-economic background, working pattern or having parental or other caring responsibilities;

3.1.3 eliminates discrimination, harassment, victimisation, and any other conduct that is prohibited by or under the Equality Act 2010;

3.1.4 advances equality of opportunity between people who share a protected characteristic and those who do not;

3.1.5 foster good relations between people who share a protected characteristic and people who do not share it;

3.1.6 identifies and removes EDI barriers which are relevant and proportionate to the requirement; and

3.1.6 shall endeavour to use gender-neutral language when providing the Deliverables and in all communications in relation to the Contract.

4 Environment

4.1 The Supplier shall ensure that any Goods or Services are designed, sourced, and delivered in a manner which is environmentally responsible and in compliance with paragraph 1.3 of this Annex;

4.2 In performing its obligations under the Contract, the Supplier shall to the reasonable satisfaction of the Authority ensure the reduction of whole life cycle sustainability impacts including;

4.2.1 resilience to climate change;

4.2.2 eliminating and/or reducing embodied carbon;

4.2.3 minimising resource consumption and ensuring resources are used efficiently;

4.2.4 avoidance and reduction of waste following the waste management hierarchy as set out in Law and working towards a circular economy;

4.2.5 reduction of single use consumable items (including packaging), and avoidance of single use plastic in line with Government commitments;

4.2.6 environmental protection (including pollution prevention, biosecurity and reducing or eliminating hazardous substances; and

4.2.7 compliance with Government Buying Standards applicable to Deliverables and using reasonable endeavours to support the Authority in meeting applicable Greening Government Commitments.

5 Social Value

5.1 The Supplier will support the Authority in highlighting opportunities to provide wider social, economic, or environmental benefits to communities though the delivery of the Contract.

5.2 The Supplier will ensure that supply chain opportunities are inclusive and accessible to:

5.2.1 new businesses and entrepreneurs;

5.2.2 small and medium enterprises (SMEs);

5.2.3 voluntary, community and social enterprise (VCSE) organisations;

5.2.4 mutuals; and

5.2.5 other underrepresented business groups.

Short Form Terms

1. Definitions used in the Contract

In this Contract, unless the context otherwise requires, the following words shall have the following meanings:

"Authority"	means the authority identified in paragraph 3 of the Order Form;
"Authority Data"	a) the data, text, drawings, diagrams, images or sounds (together with any database made up of any of these) which are embodied in any electronic, magnetic, optical or tangible media, including any of the Authority's confidential information, and which: i) are supplied to the Supplier by or on behalf of the Authority; or ii) the Supplier is required to generate, process, store or transmit pursuant to the Contract; or b) any Personal Data for which the Authority is the Data Controller;
"Authority Cause"	any breach of the obligations of the Authority or any other default, act, omission, negligence or statement of the Authority, of its employees, servants, agents in connection with or in relation to the subject-matter of the Contract and in respect of which the Authority is liable to the Supplier;
"Central Government Body"	for the purposes of this Contract this means a body listed in one of the following sub-categories of the Central Government classification of the Public Sector Classification Guide, as published and amended from time to time by the Office for National Statistics: • Government Department; • Non-Departmental Public Body or Assembly Sponsored Public Body (advisory, executive, or tribunal); • Non-Ministerial Department; or • Executive Agency;
"Charges"	means the charges for the Deliverables as specified in the Order Form and Annex 3;
"Confidential Information"	means all information, whether written or oral (however recorded), provided by the disclosing Party to the receiving Party and which (i) is known by the receiving Party to be confidential; (ii) is agreed by the Parties to be confidential;

"Contract"	means this contract between (i) the Authority and (ii) the Supplier which is created by the Supplier signing the Order Form and returning it to the Authority.
"Controller"	has the meaning given to it in the “UK GDPR”;
“Crown Body”	means any department, office or agency of the Crown, including any and all Local Authority bodies;
"Data Loss Event"	any event that results, or may result, in unauthorised access to Personal Data held by the Supplier under this Contract, and/or actual or potential loss and/or destruction of Personal Data in breach of this Contract, including any Personal Data Breach;
"Data Protection Impact Assessment"	an assessment by the Controller of the impact of the envisaged processing on the protection of Personal Data;
"Data Protection Legislation"	(i) the UK GDPR and any applicable national implementing Laws as amended from time to time; (ii) the Data Protection Act 2018 to the extent that it relates to Processing of personal data and privacy; (iii) all applicable Law about the Processing of personal data and privacy;
"Data Protection Officer"	has the meaning given to it in the GDPR;
"Data Subject"	has the meaning given to it in the GDPR;
"Data Subject Access Request"	a request made by, or on behalf of, a Data Subject in accordance with rights granted pursuant to the Data Protection Legislation to access their Personal Data;
"Date of Delivery"	means that date by which the Deliverables must be delivered to the Authority, as specified in the Order Form;
"Deliver"	means handing over the Deliverables to the Authority at the address and on the date specified in the Order Form, which shall include unloading and any other specific arrangements agreed in accordance with Clause 4. Delivered and Delivery shall be construed accordingly;
"Deliverables"	Goods and/or Services that may be ordered under the Contract including the Documentation;

"Documentation"	descriptions of the Services, technical specifications, user manuals, training manuals, operating manuals, process definitions and procedures, system environment descriptions and all such other documentation (whether in hardcopy or electronic form) that is required to be supplied by the Supplier to the Authority under the Contract as: a) would reasonably be required by a competent third party capable of Good Industry Practice contracted by the Authority to develop, configure, build, deploy, run, maintain, upgrade and test the individual systems that provide the Deliverables b) is required by the Supplier in order to provide the Deliverables; and/or c) has been or shall be generated for the purpose of providing the Deliverables;
"Existing IPR"	any and all intellectual property rights that are owned by or licensed to either Party and which have been developed independently of the Contract (whether prior to the date of the Contract or otherwise);
"Expiry Date"	means the date for expiry of the Contract as set out in the Order Form;
"FOIA"	means the Freedom of Information Act 2000 together with any guidance and/or codes of practice issued by the Information Commissioner or relevant Government department in relation to such legislation;
"Force Majeure Event"	any event, occurrence, circumstance, matter or cause affecting the performance by either Party of its obligations under the Contract arising from acts, events, omissions, happenings or non-happenings beyond its reasonable control which prevent or materially delay it from performing its obligations under the Contract but excluding: i) any industrial dispute relating to the Supplier, the Supplier Staff (including any subsets of them) or any other failure in the Supplier or the subcontractor's supply chain; ii) any event, occurrence, circumstance, matter or cause which is attributable to the wilful act, neglect or failure to take reasonable precautions against it by the Party concerned; and iii) any failure of delay caused by a lack of funds;
"Goods"	means the goods to be supplied by the Supplier to the Authority under the Contract;
"Good Industry Practice"	standards, practices, methods and procedures conforming to the law and the exercise of the degree of skill and care, diligence, prudence and foresight which would reasonably and ordinarily be expected from a skilled and experienced person or body engaged within the relevant industry or business sector;
"Information"	has the meaning given under section 84 of the FOIA;

"Information Commissioner"	the UK's independent authority which deals with ensuring information relating to rights in the public interest and data privacy for individuals is met, whilst promoting openness by public bodies;
"Insolvency Event"	occurs in respect of a legal person (for example an individual, company or organisation): i) if that person is insolvent; ii) if an order is made or a resolution is passed for the winding up of the person (other than voluntarily for the purpose of solvent amalgamation or reconstruction); iii) if an administrator or administrative receiver is appointed in respect of the whole or any part of the persons assets or business; or iv) if the person makes any arrangement with its creditors or takes or suffers any similar or analogous action to any of the actions detailed in this definition as a result of debt in any jurisdiction whether under the Insolvency Act 1986 or otherwise;
"IP Completion Day"	has the meaning given to it in the European Union (Withdrawal) Act 2018;
"Key Personnel"	means any persons specified as such in the Order Form or otherwise notified as such by the Authority to the Supplier in writing;
"Law"	means any law, statute, subordinate legislation within the meaning of Section 21(1) of the Interpretation Act 1978, bye-law, right within the meaning of Section 4(1) EU Withdrawal Act 2018 as amended by EU (Withdrawal Agreement) Act 2020, regulation, order, regulatory policy, mandatory guidance or code of practice, judgment of a relevant court of law, or directives or requirements of any regulatory body with which the Parties are bound to comply;
"New IPR"	all and any intellectual property rights in any materials created or developed by or on behalf of the Supplier pursuant to the Contract but shall not include the Supplier's Existing IPR;
"Order Form"	means the letter from the Authority to the Supplier printed above these terms and conditions;
"Party"	the Supplier or the Authority (as appropriate) and "Parties" shall mean both of them;
"Personal Data"	has the meaning given to it in the UK GDPR;
"Personal Data Breach"	has the meaning given to it in the UK GDPR;
"Processing"	has the mean given to it in the UK GDPR;
"Processor"	has the meaning given to it in the UK GDPR;
"Purchase Order Number"	means the Authority's unique number relating to the order for Deliverables to be supplied by the Supplier to the Authority in accordance with the terms of the Contract;

"Regulations"	the Public Contracts Regulations 2015 and/or the Public Contracts (Scotland) Regulations 2015 (as the context requires) as amended from time to time;
"Request for Information"	has the meaning set out in the FOIA or the Environmental Information Regulations 2004 as relevant (where the meaning set out for the term "request" shall apply);
"Services"	means the services to be supplied by the Supplier to the Authority under the Contract;
"Specification"	means the specification for the Deliverables to be supplied by the Supplier to the Authority (including as to quantity, description and quality) as specified in Annex 2;
"Staff Vetting Procedures"	means vetting procedures that accord with good industry practice or, where applicable, the Authority's procedures for the vetting of personnel as provided to the Supplier from time to time;
"Start Date"	Means the start date of the Contract set out in the Order Form;
"Subprocessor"	any third Party appointed to process Personal Data on behalf of the Supplier related to the Contract;
"Supplier Staff"	all directors, officers, employees, agents, consultants and contractors of the Supplier and/or of any subcontractor engaged in the performance of the Supplier's obligations under the Contract;
"Supplier"	means the person named as Supplier in the Order Form;
"Sustainability Requirements"	means any relevant social or environmental strategies, policies, commitments, targets, plans or requirements that apply to and are set out in the Annex 5;
Tender Submission	means the Supplier's response to the invitation to the bidder pack (including, for the avoidance of doubt, any clarification provided by the Supplier).
"Term"	means the period from the Start Date to the Expiry Date as such period may be extended in accordance with the Order Form or terminated in accordance with Clause 11;
"UK GDPR"	means Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation) (United Kingdom General Data Protection Regulation), as it forms part of the law of England and Wales, Scotland and Northern Ireland by virtue of section 3 of the European Union (Withdrawal) Act 2018 (and see section 205(4);

"VAT"	means value added tax in accordance with the provisions of the Value Added Tax Act 1994;
"Workers"	any one of the Supplier Staff which the Authority, in its reasonable opinion, considers is an individual to which Procurement Policy Note 08/15 (Tax Arrangements of Public Appointees) (https://www.gov.uk/government/publications/procurement-policynote-0815-tax-arrangements-of-appointees) applies in respect of the Deliverables;
"Working Day"	means a day (other than a Saturday or Sunday) on which banks are open for business in the City of London.

2. Understanding the Contract

In the Contract, unless the context otherwise requires:

2.1 references to numbered clauses are references to the relevant clause in these terms and conditions and references to numbered paragraphs are references to the paragraph in the relevant Annex;

2.2 any obligation on any Party not to do or omit to do anything shall include an obligation not to allow that thing to be done or omitted to be done;

2.3 the headings in this Contract are for information only and do not affect the interpretation of the Contract;

2.4 references to "writing" include printing, display on a screen and electronic transmission and other modes of representing or reproducing words in a visible form;

2.5 the singular includes the plural and vice versa;

2.6 a reference to any law includes a reference to that law as amended, extended, consolidated or re-enacted from time to time and to any legislation or byelaw made under that law;

2.7 any reference in this Contract which immediately before the IP Completion Day (or such later date when relevant EU law ceases to have effect pursuant to Section 1A of the European Union (Withdrawal) Act 2018) is a reference to (as it has effect from time to time):

i. any EU regulation, EU decision, EU tertiary legislation or provision of the European Economic Area ("**EEA**") agreement ("EU References") which is to form part of domestic law by application of Section 3 of the European Union (Withdrawal) Act 2018 and which shall be read on and after IP Completion Day as a reference to the EU References as they form part of domestic law by virtue of Section 3 of the European Union (Withdrawal) Act 2018 as modified by domestic law from time to time; and

ii. any EU institution or EU authority or other such EU body shall be read on and after the date of exit from the EU as a reference to the UK institution, authority or body to which its functions were transferred.

2.8 the word ‘including’, "for example" and similar words shall be understood as if they were immediately followed by the words "without limitation";

2.9 a person includes a natural person, corporate or unincorporated body (whether or not having separate legal personality);

2.10 any Annexes form part of this Contract and shall have effect as if set out in full in the body of this Contract. Any reference to this Contract includes the Annexes; and

2.11 all undefined words and expressions are to be given their normal English meaning within the context of this Contract. Any dispute as to the interpretation of such undefined words and expressions shall be settled by reference to the definition in the Shorter Oxford English Dictionary.

3. How the Contract works

3.1 The Order Form is an offer by the Authority to purchase the Deliverables subject to and in accordance with the terms and conditions of the Contract.

3.2 The Supplier is deemed to accept the offer in the Order Form when the Authority receives a copy of the Order Form signed by the Supplier.

3.3 The Supplier warrants and represents that its Tender Submission and all statements made and documents submitted as part of the procurement of Deliverables are and remain true and accurate.

4. What needs to be delivered

4.1 All Deliverables

(a) The Supplier must provide Deliverables: (i) in accordance with the Specification and Tender Submission; (ii) to a professional standard; (iii) using all reasonable skill and care; (iv) using Good Industry Practice; (v) using its own policies, processes and internal quality control measures as long as they don’t conflict with the Contract; (vi) in accordance with such policies and procedures of the Authority (as amended from time to time) that may be specified in the Contract (vii) on the dates agreed; and (viii) in compliance with all applicable Law.

(b) Without prejudice to the Specification the Supplier must provide Deliverables with a warranty of at least 12 months (or longer where the Supplier offers a longer warranty period to the Authority) from Delivery against all obvious damage or defects.

4.2 Goods clauses

(a) All Goods Delivered must be capable of meeting the requirements set out in the Specification and be either (i) new and of recent origin, (ii) reused or (iii) recycled.

(b) All manufacturer warranties covering the Goods will be assigned to the Authority on request and for free.

(c) The Supplier transfers ownership of the Goods on completion of Delivery (including off-loading and stacking) or payment for those Goods, whichever is earlier.

(d) Risk in the Goods transfers to the Authority on Delivery but remains with the Supplier if the Authority notices any damage or defect following Delivery and lets the Supplier know within three Working Days of Delivery.

(e) The Supplier must have full and unrestricted ownership of the Goods at the time of transfer of ownership.

(f) The Supplier must Deliver the Goods on the date and to the specified location during the Authority's working hours.

(g) The Supplier, its subcontractor(s) and supply chain must minimise packaging used whilst providing sufficient packaging for the Goods to reach the point of Delivery safely and undamaged. The Supplier must take back any primary packaging where it is possible to do so. Packaging must be 100% re-usable, recyclable or compostable, use recycled content where reasonably practicable and support the Government's commitment to eliminate single use plastic.

(h) All Deliveries must have a delivery note attached that specifies the order number, type, quantity of Goods, contact and details of traceability through the supply chain.

(i) The Supplier must provide all tools, information and instructions the Authority needs to make use of the Goods. This will include, where appropriate, any operation manuals which, unless specified otherwise, will be written in English and provided in electronic form.

(j) The Supplier will notify the Authority of any request that Goods are returned to it or the manufacturer after the discovery of safety issues or defects that might endanger health or hinder performance and shall indemnify the Authority against the costs arising as a result of any such request. Goods must be disposed of in line with the waste management hierarchy as set out in Law. The Supplier will provide evidence and transparency of the items and routes used for disposal to the Authority on request.

(k) The Authority can cancel any order or part order of Goods which have not been Delivered. If the Authority gives less than 14 calendar days' notice then it will pay the Supplier's reasonable and proven costs already incurred on the

cancelled order as long as the Supplier takes all reasonable steps to minimise these costs.

(l) The Supplier must at its own cost repair, replace, refund or substitute (at the Authority's option and request) any Goods that the Authority rejects because they don't conform with clause 4.2. If the Supplier doesn't do this it will pay the Authority's costs including repair or re-supply by a third party.

(m) The Authority will not be liable for any actions, claims, costs and expenses incurred by the Supplier or any third party during Delivery of the Goods unless and to the extent that it is caused by negligence or other wrongful act of the Authority or its servant or agent. If the Authority suffers or incurs any damage or injury (whether fatal or otherwise) occurring in the course of Delivery or installation then the Supplier shall indemnify from all losses, damages, costs or expenses (including professional fees and fines) which arise as a result of or in connection with such damage or injury where it is attributable to any act or omission of the Supplier or, where related to the Contract, any of its subcontractors or suppliers.

4.3 Services clauses

(a) Late delivery of the Services will be a breach of the Contract.

(b) The Supplier must co-operate with the Authority and third party suppliers on all aspects connected with the delivery of the Services and ensure that Supplier Staff comply with any reasonable instructions including any security requirements.

(c) The Authority must provide the Supplier Staff with reasonable access to its premises at such reasonable times agreed with the Authority for the purpose of supplying the Services.

(d) The Supplier must at its own risk and expense provide all equipment required to deliver the Services. Any equipment provided by the Authority to the Supplier for supplying the Services remains the property of the Authority and is to be returned to the Authority on expiry or termination of the Contract.

(e) The Supplier must allocate sufficient resources and appropriate expertise to the Contract.

(f) The Supplier must take all reasonable care to ensure performance does not disrupt the Authority's operations, employees or other contractors.

(g) On completion of the Services, the Supplier is responsible for leaving the Authority's premises in a clean, safe and tidy condition and making good any damage that it has caused to the Authority's premises or property, other than fair wear and tear and any pre-existing cleanliness, safety or tidiness issue at the Authority’s premises that existed before the commencement of the Term.

(h) The Supplier must ensure all Services, and anything used to deliver the Services, are of the required quality and free from damage or defects.

(i) The Authority is entitled to withhold payment for partially or undelivered Services or for Services which are not delivered in accordance with the Contract but doing so does not stop it from using its other rights under the Contract.

5. Pricing and payments

5.1 In exchange for the Deliverables delivered, the Supplier shall be entitled to invoice the Authority for the charges in Annex 3. The Supplier shall raise invoices promptly and in any event within 90 days from when the charges are due.

5.2 All Charges:

(a) exclude VAT, which is payable on provision of a valid VAT invoice and charged at the prevailing rate;

(b) include all costs connected with the supply of Deliverables.

5.3 The Authority must pay the Supplier the charges within 30 days of receipt by the Authority of a valid, undisputed invoice, in cleared funds to the Supplier's account stated in the Order Form.

5.4 A Supplier invoice is only valid if it:

(a) includes all appropriate references including the Purchase Order Number and other details reasonably requested by the Authority as set out in Annex 3; and

(b) includes a detailed breakdown of Deliverables which have been delivered (if any).

Details of the Authority's requirements for a valid invoice at the Start Date are set out in Annex 3.

5.5 If there is a dispute between the Parties as to the amount invoiced, the Authority shall pay the undisputed amount. The Supplier shall not suspend the provision of the Deliverables unless the Supplier is entitled to terminate the Contract for a failure to pay undisputed sums in accordance with clause 11.6. Any disputed amounts shall be resolved through the dispute resolution procedure detailed in clause 35.

5.6 If any sum of money is recoverable from or payable by the Supplier under the Contract (including any sum which the Supplier is liable to pay to the Authority in respect of any breach of the Contract), that sum may be deducted unilaterally by the Authority from any sum then due, or which may become due, to the Supplier under the Contract or under any other agreement or contract with the Authority. The Supplier shall not be entitled to assert any credit, set-off or counterclaim against the Authority in order to justify withholding payment of any such amount in whole or in part.

5.7 The Supplier must ensure that its subcontractors and supply chain are paid, in full, within 30 days of receipt of a valid, undisputed invoice. If this doesn't happen, the Authority can publish the details of the late payment or non-payment.

6. The Authority's obligations to the Supplier

6.1 If the Supplier fails to comply with the Contract as a result of an Authority Cause:

(a) the Authority cannot terminate the Contract under clause 11 on account of the failure to comply, provided this will not prejudice the Authority's right to terminate for another cause that may exist at the same time;

(b) the Supplier will be relieved from liability for the performance of its obligations under the Contract to the extent that it is prevented from performing them by the Authority Cause and will be entitled to such reasonable and proven additional expenses that arise as a direct result of the Authority Cause;

(c) the Supplier is entitled to any additional time needed to deliver the Deliverables as a direct result of the Authority's Cause;

(d) the Supplier cannot suspend the ongoing supply of Deliverables.

6.2 Clause 6.1 only applies if the Supplier:

(a) gives notice to the Authority within 10 Working Days of becoming aware of an Authority Cause, such notice setting out in detail with supporting evidence the known reasons for the Authority Cause;

(b) demonstrates that the failure only happened because of the Authority Cause;

(c) has used all reasonable endeavours to mitigate the impact of the Authority Cause.

7. Record keeping and reporting

7.1 The Supplier must ensure that suitably qualified (and authorised) representatives attend progress meetings with the Authority and provide progress reports when specified in Annex 2.

7.2 The Supplier must keep and maintain full and accurate records and accounts on everything to do with the Contract for seven years after the date of expiry or termination of the Contract.

7.3 The Supplier must allow any auditor appointed by the Authority access to their premises to verify all contract accounts and records of everything to do with the Contract and provide copies for the audit.

7.4 The Supplier must provide information to the auditor and reasonable co-operation at their request.

7.5 If the Supplier is not providing any of the Deliverables, or is unable to provide them, it must immediately:

(a) tell the Authority and give reasons;

(b) propose corrective action;

(c) agree a deadline with the Authority for completing the corrective action.

7.6 If the Authority, acting reasonably, is concerned either:

(a) as to the financial stability of the Supplier such that it may impact on the continued performance of the Contract; or

(b) as to the sustainability or health and safety conduct of the Supplier, subcontractors and supply chain in the performance of the Contract;

then the Authority may:

(i) require that the Supplier provide to the Authority (for its approval) a plan setting out how the Supplier will ensure continued performance of the Contract (in the case of (a)) or improve its sustainability conduct or performance (in the case of (b)) and the Supplier will make changes to such plan as reasonably required by the Authority and once it is agreed then the Supplier shall act in accordance with such plan and report to the Authority on demand

(ii) if the Supplier fails to provide a plan or fails to agree any changes which are requested by the Authority or materially fails to implement or provide updates on progress with the plan, terminate the Contract immediately for material breach (or on such date as the Authority notifies).

8. Supplier staff

8.1 The Supplier Staff involved in the performance of the Contract must:

a) be appropriately trained and qualified;

b) be vetted using Good Industry Practice and in accordance with the instructions issued by the Authority in the Order Form;

c) comply with the Authority's conduct requirements when on the Authority's premises including, without limitation, those Sustainability Requirements relating to Equality, Diversity & Inclusion (EDI) contained in Annex 5; and

d) be informed about those specific requirements referred to in Clause 13.2.

8.2 Where an Authority decides one of the Supplier's Staff isn't suitable to work on the Contract, the Supplier must replace them with a suitably qualified alternative.

8.3 If requested, the Supplier must replace any person whose acts or omissions have caused the Supplier to breach clause 8.

8.4 The Supplier must provide a list of Supplier Staff needing to access the Authority's premises and say why access is required.

8.5 The Supplier indemnifies the Authority against all losses, damages, costs or expenses (including professional fees and fines) arising from claims brought against it by any Supplier Staff caused by an act or omission of the Supplier or any other Supplier Staff.

8.6 The Supplier shall use those persons nominated in the Order Form (if any) to provide the Deliverables and shall not remove or replace any of them unless:

(a) requested to do so by the Authority;

(b) the person concerned resigns, retires or dies or is on maternity, adoption, shared parental leave or long-term sick leave; or

(c) the person's employment or contractual arrangement with the Supplier or any subcontractor is terminated.

9. Rights and protection

9.1 The Supplier warrants and represents that:

(a) it has full capacity and authority to enter into and to perform the Contract;

(b) the Contract is executed by its authorised representative;

(c) it is a legally valid and existing organisation incorporated in the place it was formed;

(d) there are no known legal or regulatory actions or investigations before any court, administrative body or arbitration tribunal pending or threatened against it or its affiliates that might affect its ability to perform the Contract;

(e) it maintains all necessary rights, authorisations, licences and consents to perform its obligations under the Contract;

(f) it doesn't have any contractual obligations which are likely to have a material adverse effect on its ability to perform the Contract; and

(g) it is not impacted by an Insolvency Event.

9.2 The warranties and representations in clause 9.1 are repeated each time the Supplier provides Deliverables under the Contract.

9.3 The Supplier indemnifies the Authority against each of the following:

(a) wilful misconduct of the Supplier, any of its subcontractor and/or Supplier Staff that impacts the Contract;

(b) non-payment by the Supplier of any tax or National Insurance.

9.4 If the Supplier becomes aware of a representation or warranty that becomes untrue or misleading, it must immediately notify the Authority.

9.5 All third party warranties and indemnities covering the Deliverables must be assigned for the Authority's benefit by the Supplier.

10. Intellectual Property Rights (IPRs)

10.1 Each Party keeps ownership of its own Existing IPRs. The Supplier gives the Authority a non-exclusive, perpetual, royalty-free, irrevocable, transferable worldwide licence to use, change and sub-license the Supplier's Existing IPR to enable it and its sub-licensees to both:

(a) receive and use the Deliverables;

(b) use the New IPR.

10.2 Any New IPR created under the Contract is owned by the Authority. The Authority gives the Supplier a licence to use any Existing IPRs for the purpose of fulfilling its obligations under the Contract and a perpetual, royalty-free, non-exclusive licence to use any New IPRs.

10.3 Where a Party acquires ownership of intellectual property rights incorrectly under this Contract it must do everything reasonably necessary to complete a transfer assigning them in writing to the other Party on request and at its own cost.

10.4 Neither Party has the right to use the other Party's intellectual property rights, including any use of the other Party's names, logos or trademarks, except as provided in clause 10 or otherwise agreed in writing.

10.5 If any claim is made against the Authority for actual or alleged infringement of a third party's intellectual property arising out of, or in connection with, the supply or use of the Deliverables (an "**IPR Claim**"), then the Supplier indemnifies the Authority against all losses, damages, costs or expenses (including professional fees and fines) incurred as a result of the IPR Claim.

10.6 If an IPR Claim is made or anticipated the Supplier must at its own expense and the Authority's sole option, either:

(a) obtain for the Authority the rights in clauses 10.1 and 10.2 without infringing any third party intellectual property rights;

(b) replace or modify the relevant item with substitutes that don't infringe intellectual property rights without adversely affecting the functionality or performance of the Deliverables.

11. Ending the contract

11.1 The Contract takes effect on the date of or (if different) the date specified in the Order Form and ends on the earlier of the date of expiry or termination of the Contract or earlier if required by Law.

11.2 The Authority can extend the Contract where set out in the Order Form in accordance with the terms in the Order Form.

Ending the Contract without a reason

11.3 The Authority has the right to terminate the Contract at any time without reason or liability by giving the Supplier not less than 90 days' written notice and if the Contract is terminated, clause 11.5(b) to 11.5(g) applies.

When the Authority can end the Contract

11.4 (a) If any of the following events happen, the Authority has the right to immediately terminate its Contract by issuing a termination notice in writing to the Supplier:

(i) there is a Supplier Insolvency Event;

(ii) if the Supplier repeatedly breaches the Contract in a way to reasonably justify in the Authority's opinion that the Supplier's conduct is inconsistent with it having the intention or ability to give effect to the terms and conditions of the Contract;

(iii) if the Supplier is in material breach of any obligation which is capable of remedy, and that breach is not remedied within 30 days of the Supplier receiving notice specifying the breach and requiring it to be remedied. Where a material breach is not capable of remedy, the Authority has the right to immediately terminate the Contract;

(iv) there is a change of control (within the meaning of section 450 of the Corporation Tax Act 2010) of the Supplier which isn't pre-approved by the Authority in writing;

(v) if the Authority discovers that the Supplier was in one of the situations in 57 (1) or 57(2) of the Regulations at the time the Contract was awarded;

(vi) the Supplier or its affiliates embarrass or bring the Authority into disrepute or diminish the public trust in them;

(vii) where a right to terminate described in clause 27 occurs;

(viii) the Supplier is in breach of any of its health, safety and well-being obligations under clause 28.1(a); and

(ix) where, in accordance with clause 33.3, there is or may be an actual or potential conflict of interest. .

(b) If any of the events in 73(1) (a) to (c) of the Regulations (substantial modification, exclusion of the Supplier, procurement infringement) happen, the Authority has the right to immediately terminate the Contract and clause 11.5(a) to 11.5(g) applies.

11.5 What happens if the Contract ends

Where the Authority terminates the Contract under clause 11.4 all of the following apply:

(a) the Supplier is responsible for the Authority's reasonable costs of procuring replacement deliverables for the rest of the Term ;

(b) the Authority's payment obligations under the terminated Contract stop immediately;

(c) accumulated rights of the Parties are not affected;

(d) the Supplier must promptly delete or return the Authority Data except where required to retain copies by law;

(e) the Supplier must promptly return any of the Authority's property provided under the Contract;

(f) the Supplier must, at no cost to the Authority, give all reasonable assistance to the Authority and any incoming supplier and co-operate fully in the handover and re-procurement;

(g) the following clauses survive the termination of the Contract: 3.3, 7,2, 7.3, 7.4, 9, 10, 12,13.3, 14, 15, 16, 17, 18, 19, 20, 32, 35, 36 and any clauses or provisions within the Order Form or the Annexes which are expressly or by implication intended to continue.

11.6 When the Supplier can end the Contract

(a) The Supplier can issue a reminder notice if the Authority does not pay an undisputed invoice on time. The Supplier can terminate the Contract if the Authority fails to pay an undisputed invoiced sum due and worth over 10% of the total Contract value or £1,000, whichever is the lower, within 30 days of the date of the reminder notice.

(b) If a Supplier terminates the Contract under clause 11.6(a):

(i) the Authority must promptly pay all outstanding charges incurred to the Supplier;

(ii) the Authority must pay the Supplier reasonable committed and unavoidable losses as long as the Supplier provides a fully itemised and costed schedule with satisfactory evidence - the maximum value of this payment is limited to the total sum payable to the Supplier if the Contract had not been terminated;

(iii) clauses 11.5(d) to 11.5(g) apply.

11.7 Partially ending and suspending the Contract

(a) Where the Authority has the right to terminate the Contract it can terminate or suspend (for any period), all or part of it. If the Authority suspends the Contract it can provide the Deliverables itself or buy them from a third party.

(b) The Authority can only partially terminate or suspend the Contract if the remaining parts of it can still be used to effectively deliver the intended purpose.

(c) The Parties must agree (in accordance with clause 25) any necessary variation required by clause 11.7, but the Supplier may neither:

(i) reject the variation; nor

(ii) increase the Charges, except where the right to partial termination is under clause 11.3.

(d) The Authority can still use other rights available, or subsequently available to it if it acts on its rights under clause 11.7.

12. How much you can be held responsible for

12.1 Each Party's total aggregate liability under or in connection with the Contract (whether in tort, contract or otherwise) is no more than 10 times the value of the Contract, unless specified in the Order Form.

12.2 No Party is liable to the other for:

(a) any indirect losses;

(b) loss of profits, turnover, savings, business opportunities or damage to goodwill (in each case whether direct or indirect).

12.3 In spite of clause 12.1, neither Party limits or excludes any of the following:

(a) its liability for death or personal injury caused by its negligence, or that of its employees, agents or subcontractors;

(b) its liability for bribery or fraud or fraudulent misrepresentation by it or its employees;

(c) any liability that cannot be excluded or limited by law.

12.4 In spite of clause 12.1, the Supplier does not limit or exclude its liability for any indemnity given under clauses 4.2(j), 4.2(m), 8.5, 9.3, 10.5, 13.3, 15.28(e) or 31.2(b).

12.5 Each Party must use all reasonable endeavours to mitigate any loss or damage which it suffers under or in connection with the Contract, including where the loss or damage is covered by any indemnity.

12.6 If more than one Supplier is party to the Contract, each Supplier Party is fully responsible for both their own liabilities and the liabilities of the other Suppliers.

13. Obeying the law

13.1 The Supplier must, in connection with provision of the Deliverables:

(a) comply with all applicable Law;
(b) comply with the Sustainability Requirements
(c) use reasonable endeavours to comply and procure that its subcontractors comply with the Supplier Code of Conduct appearing at:

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/779660/20190220-Supplier_Code_of_Conduct.pdf

13.2 The Sustainability Requirements and the requirements set out in Clause 27, 28 and 30 must be explained to the Supplier's Staff, subcontractors and suppliers who are involved in the performance of the Supplier's obligations under the Contract and where it is relevant to their role and equivalent obligations must be included in any contract with any suppliers or subcontractor that is connected to the Contract.

13.3 The Supplier indemnifies the Authority against all losses, damages, costs or expenses (including professional fees and fines) resulting from any default by the Supplier relating to any applicable Law to do with the Contract.

13.4 The Supplier must appoint a Compliance Officer who must be responsible for ensuring that the Supplier complies with the Law and its obligations under the Contract.

13.5 "Compliance Officer" the person(s) appointed by the Supplier who is responsible for ensuring that the Supplier complies with its legal and other obligations under the Contract.

13.6 The Supplier will provide such evidence of compliance with its obligations under this Clause 13 as the Authority reasonably requests.

14. Insurance

14.1 The Supplier must, at its own cost, obtain and maintain the required insurances as set out in the Order Form.

14.2 The Supplier will provide evidence of the required insurances on request from the Authority.

15. Data protection

15.1 The Authority is the Controller and the Supplier is the Processor for the purposes of the Data Protection Legislation.

15.2 The Supplier must process Personal Data and ensure that Supplier Staff process Personal Data only in accordance with this Contract.

15.3 The Supplier shall take all reasonable measures relating to the security of processing which are required pursuant to Article 32 of the UK GDPR including, without limitation, those security measures specified in this clause 15.

15.4 The Supplier must not remove any ownership or security notices in or relating to the Authority Data.

15.5 The Supplier must make accessible back-ups of all Authority Data, stored in an agreed off-site location and send the Authority copies every six Months.

15.6 The Supplier must ensure that any Supplier system holding any Authority Data, including back-up data, is a secure system that complies with the security requirements specified in writing by the Authority.

15.7 If at any time the Supplier suspects or has reason to believe that the Authority Data provided under the Contract is corrupted, lost or sufficiently degraded, then the Supplier must notify the Authority and immediately suggest remedial action.

15.8 If the Authority Data is corrupted, lost or sufficiently degraded so as to be unusable the Authority may either or both:

(a) tell the Supplier to restore or get restored Authority Data as soon as practical but no later than five Working Days from the date that the Authority receives notice, or the Supplier finds out about the issue, whichever is earlier;

(b) restore the Authority Data itself or using a third party.

15.9 The Supplier must pay each Party's reasonable costs of complying with clause 15.8 unless the Authority is at fault.

15.10 Only the Authority can decide what processing of Personal Data a Supplier can do under the Contract and must specify it for the Contract using the template in Annex 1 of the Order Form (*Authorised Processing*).

15.11 The Supplier must only process Personal Data if authorised to do so in the Annex to the Order Form (*Authorised Processing*) by the Authority. Any further written

instructions relating to the processing of Personal Data are incorporated into Annex 1 of the Order Form.

15.12 The Supplier must give all reasonable assistance to the Authority in the preparation of any Data Protection Impact Assessment before starting any processing, including:

(a) a systematic description of the expected processing and its purpose;

(b) the necessity and proportionality of the processing operations;

(c) the risks to the rights and freedoms of Data Subjects;

(d) the intended measures to address the risks, including safeguards, security measures and mechanisms to protect Personal Data.

15.13 The Supplier must notify the Authority immediately if it thinks the Authority's instructions breach the Data Protection Legislation.

15.14 The Supplier must put in place appropriate Protective Measures to protect against a Data Loss Event which must be approved by the Authority.

15.15 If lawful to notify the Authority, the Supplier must notify it if the Supplier is required to process Personal Data by Law promptly and before processing it.

15.16 The Supplier must take all reasonable steps to ensure the reliability and integrity of any Supplier Staff who have access to the Personal Data and ensure that they:

(a) are aware of and comply with the Supplier's duties under this clause 15;

(b) are subject to appropriate confidentiality undertakings with the Supplier or any Subprocessor;

(c) are informed of the confidential nature of the Personal Data and do not provide any of the Personal Data to any third party unless directed in writing to do so by the Authority or as otherwise allowed by the Contract;

(d) have undergone adequate training in the use, care, protection and handling of Personal Data.

15.17 The Supplier must not transfer Personal Data outside of the EU unless all of the following are true:

(a) it has obtained prior written consent of the Authority;

(b) the Authority has decided that there are appropriate safeguards (in accordance with Article 46 of the UK GDPR);

(c) the Data Subject has enforceable rights and effective legal remedies when transferred;

(d) the Supplier meets its obligations under the Data Protection Legislation by providing an adequate level of protection to any Personal Data that is transferred;

(e) where the Supplier is not bound by Data Protection Legislation it must use its best endeavours to help the Authority meet its own obligations under Data Protection Legislation; and

(f) the Supplier complies with the Authority's reasonable prior instructions about the processing of the Personal Data.

15.18 The Supplier must notify the Authority immediately if it:

(a) receives a Data Subject Access Request (or purported Data Subject Access Request);

(b) receives a request to rectify, block or erase any Personal Data;

(c) receives any other request, complaint or communication relating to either Party's obligations under the Data Protection Legislation;

(d) receives any communication from the Information Commissioner or any other regulatory authority in connection with Personal Data processed under this Contract;

(e) receives a request from any third party for disclosure of Personal Data where compliance with the request is required or claims to be required by Law;

(f) becomes aware of a Data Loss Event.

15.19 Any requirement to notify under clause 15.17 includes the provision of further information to the Authority in stages as details become available.

15.20The Supplier must promptly provide the Authority with full assistance in relation to any Party's obligations under Data Protection Legislation and any complaint, communication or request made under clause 15.17. This includes giving the Authority:

(a) full details and copies of the complaint, communication or request;

(b) reasonably requested assistance so that it can comply with a Data Subject Access Request within the relevant timescales in the Data Protection Legislation;

(c) any Personal Data it holds in relation to a Data Subject on request;

(d) assistance that it requests following any Data Loss Event;

(e) assistance that it requests relating to a consultation with, or request from, the Information Commissioner's Office.

15.21 The Supplier must maintain full, accurate records and information to show it complies with this clause 15. This requirement does not apply where the Supplier employs fewer than 250 staff, unless either the Authority determines that the processing:

(a) is not occasional;

(b) includes special categories of data as referred to in Article 9(1) of the UK GDPR or Personal Data relating to criminal convictions and offences referred to in Article 10 of the UK GDPR;

(c) is likely to result in a risk to the rights and freedoms of Data Subjects.

15.22 The Supplier will make available to the Authority all information necessary to demonstrate compliance with clause 15 and allow for and contribute to audits, including inspections, conducted by the Authority or another auditor appointed by the Authority.

15.23 The Supplier must appoint a Data Protection Officer responsible for observing its obligations in this Contract and give the Authority their contact details.

15.24 Before allowing any Subprocessor to process any Personal Data, the Supplier must:

(a) notify the Authority in writing of the intended Subprocessor and processing;

(b) obtain the written consent of the Authority;

(c) enter into a written contract with the Subprocessor so that this clause 15 applies to the Subprocessor;

(d) provide the Authority with any information about the Subprocessor that the Authority reasonably requires.

15.25 The Supplier remains fully liable for all acts or omissions of any Subprocessor.

15.26 At any time the Authority can, with 30 Working Days' notice to the Supplier, change this clause 15 to:

(a) replace it with any applicable standard clauses (between the controller and processor) or similar terms forming part of an applicable certification scheme under UK GDPR Article 42;

(b) ensure it complies with guidance issued by the Information Commissioner's Office.

15.27 The Parties agree to take account of any non-mandatory guidance issued by the Information Commissioner's Office.

15.28 The Supplier:

(a) must provide the Authority with all Authority Data in an agreed open format within 10 Working Days of a written request;

(b) must have documented processes to guarantee prompt availability of Authority Data if the Supplier stops trading;

(c) must securely destroy all storage media that has held Authority Data at the end of life of that media using Good Industry Practice;

(d) must securely erase or return all Authority Data and any copies it holds when asked to do so by the Authority unless required by Law to retain it;

(e) indemnifies the Authority against any and all losses, damages, costs or expenses (including professional fees and fines) incurred if the Supplier breaches clause 15 and any Data Protection Legislation.

16. What you must keep confidential

16.1 Each Party must:

(a) keep all Confidential Information it receives confidential and secure;

(b) not disclose, use or exploit the disclosing Party's Confidential Information without the disclosing Party's prior written consent, except for the purposes anticipated under the Contract;

(c) immediately notify the disclosing Party if it suspects unauthorised access, copying, use or disclosure of the Confidential Information.

16.2 In spite of clause 16.1, a Party may disclose Confidential Information which it receives from the disclosing Party in any of the following instances:

(a) where disclosure is required by applicable law, permitted in respect of an audit pursuant to clause 7.3, or by a court with the relevant jurisdiction if the recipient Party notifies the disclosing Party of the full circumstances, the affected Confidential Information and extent of the disclosure;

(b) if the recipient Party already had the information without obligation of confidentiality before it was disclosed by the disclosing Party;

(c) if the information was given to it by a third party without obligation of confidentiality;

(d) if the information was in the public domain at the time of the disclosure;

(e) if the information was independently developed without access to the disclosing Party's Confidential Information;

(f) to its auditors or for the purposes of regulatory requirements;

(g) on a confidential basis, to its professional advisers on a need-to-know basis;

(h) to the Serious Fraud Office where the recipient Party has reasonable grounds to believe that the disclosing Party is involved in activity that may be a criminal offence under the Bribery Act 2010.

16.3 The Supplier may disclose Confidential Information on a confidential basis to Supplier Staff on a need-to-know basis to allow the Supplier to meet its obligations under the Contract. The Supplier Staff must enter into a direct confidentiality agreement with the Authority at its request.

16.4 The Authority may disclose Confidential Information in any of the following cases:

(a) on a confidential basis to the employees, agents, consultants and contractors of the Authority;

(b) on a confidential basis to any other Central Government Body, any successor body to a Central Government Body or any organisation that the Authority transfers or proposes to transfer all or any part of its business to;

(c) if the Authority (acting reasonably) considers disclosure necessary or appropriate to carry out its public functions;

(d) where requested by Parliament; and/or

(e) under clauses 5.7 and 17.

16.5 For the purposes of clauses 16.2 to 16.4 references to disclosure on a confidential basis means disclosure under a confidentiality agreement or arrangement including terms as strict as those required in clause 16.

16.6 Information which is exempt from disclosure by clause 17 is not Confidential Information.

16.7 The Supplier must not make any press announcement or publicise the Contract or any part of it in any way, without the prior written consent of the Authority and must take all reasonable steps to ensure that Supplier Staff do not either.

16.8 Where essential to comply with or carry out their statutory functions the Authority may disclose Confidential Information.

17. When you can share information

17.1 The Supplier must tell the Authority within 48 hours if it receives a Request For Information.

17.2 Within the required timescales the Supplier must give the Authority full co-operation and information needed so the Authority can:

(a) comply with any Freedom of Information Act (FOIA) request;

(b) comply with any Environmental Information Regulations (EIR) request.

17.3 The Authority may talk to the Supplier to help it decide whether to publish information under clause 17. However, the extent, content and format of the disclosure is the Authority's decision, which does not need to be reasonable.

18. Invalid parts of the contract

If any part of the Contract is prohibited by Law or judged by a court to be unlawful, void or unenforceable, it must be read as if it was removed from that Contract as much as required and rendered ineffective as far as possible without affecting the rest of the Contract, whether it's valid or enforceable.

19. No other terms apply

The provisions expressly incorporated into the Contract are the entire agreement between the Parties. The Contract replaces all previous statements and agreements whether written or oral. No other provisions apply.

20. Other people's rights in a contract

No third parties may use the Contracts (Rights of Third Parties) Act 1999 (CRTPA) to enforce any term of the Contract unless stated (referring to CRTPA) in the Contract. This does not affect third party rights and remedies that exist independently from CRTPA.

21. Circumstances beyond your control

21.1 Any Party affected by a Force Majeure Event is excused from performing its obligations under the Contract while the inability to perform continues, if it both:

(a) provides written notice to the other Party;

(b) uses all reasonable measures practical to reduce the impact of the Force Majeure Event.

21.2 Either party can partially or fully terminate the Contract if the provision of the Deliverables is materially affected by a Force Majeure Event and the impact of such event lasts for 90 days continuously.

21.3 Where a Party terminates under clause 21.2:

(a) each party must cover its own losses;

(b) clause 11.5(b) to 11.5(g) applies.

22. Relationships created by the contract

The Contract does not create a partnership, joint venture or employment relationship. The Supplier must represent themselves accordingly and ensure others do so.

23. Giving up contract rights

A partial or full waiver or relaxation of the terms of the Contract is only valid if it is stated to be a waiver in writing to the other Party.

24. Transferring responsibilities

24.1 The Supplier cannot assign the Contract, or any rights under it, without the Authority's written consent.

24.2 The Authority can assign, novate or transfer its Contract or any part of it to any Crown Body, any contracting authority within the meaning of the Regulations or any private sector body which performs the functions of the Authority.

24.3 When the Authority uses its rights under clause 24.2 the Supplier must enter into a novation agreement in the form that the Authority specifies.

24.4 The Supplier remains responsible for all acts and omissions of the Supplier Staff as if they were its own.

24.5 If the Authority asks the Supplier for details about its subcontractors and/or supply chain, the Supplier must provide such details as the Authority reasonably requests including, without limitation:

(a) their name;
(b) the scope of their appointment; and
(c) the duration of their appointment.

25. Changing the contract

25.1 Either Party can request a variation to the Contract which is only effective if agreed in writing and signed by both Parties. No oral modifications to the Contract shall be effective. The Authority is not required to accept a variation request made by the Supplier.

26. How to communicate about the contract

26.1 All notices under the Contract must be in writing and are considered effective on the Working Day of delivery as long as they’re delivered before 5:00pm on a Working Day. Otherwise the notice is effective on the next Working Day. An email is effective when sent unless an error message is received.

26.2 Notices to the Authority or Supplier must be sent to their address in the Order Form.

26.3 This clause does not apply to the service of legal proceedings or any documents in any legal action, arbitration or dispute resolution.

27. Preventing fraud, bribery and corruption

27.1 The Supplier shall not:

(a) commit any criminal offence referred to in the Regulations 57(1) and 57(2);

(b) offer, give, or agree to give anything, to any person (whether working for or engaged by the Authority or any other public body) an inducement or reward for doing, refraining from doing, or for having done or refrained from doing, any act in relation to the obtaining or execution of the Contract or any other public function or for showing or refraining from showing favour or disfavour to any person in relation to the Contract or any other public function.

27.2 The Supplier shall take all reasonable steps (including creating, maintaining and enforcing adequate policies, procedures and records), in accordance with good industry practice, to prevent any matters referred to in clause 27.1 and any fraud by the Supplier, Supplier Staff (including its shareholders, members and directors), any subcontractor and the Supplier's supply chain in connection with the Contract. The Supplier shall notify the Authority immediately if it has reason to suspect that any such matters have occurred or is occurring or is likely to occur.

27.3 If the Supplier or the Supplier Staff engages in conduct prohibited by clause 27.1 or commits fraud in relation to the Contract or any other contract with the Crown (including the Authority) the Authority may:

(a) terminate the Contract and recover from the Supplier the amount of any loss suffered by the Authority resulting from the termination, including the cost reasonably incurred by the Authority of making other arrangements for the supply of the Deliverables and any additional expenditure incurred by the Authority throughout the remainder of the Contract; or

(b) recover in full from the Supplier any other loss sustained by the Authority in consequence of any breach of this clause.

28. Health, safety and wellbeing

28.1 The Supplier must perform its obligations meeting the requirements of:

(a) all applicable Law regarding health and safety;
(b) the Authority's current health and safety policy and procedures while at the Authority's premises, as provided to the Supplier.
(c) the Authority's current wellbeing policy or requirements while at the Authority's premises as provided to the Supplier.

28.2 The Supplier and the Authority must as soon as possible notify the other of any health and safety incidents, near misses or material hazards they're aware of at the Authority premises that relate to the performance of the Contract.

28.3 Where the Services are to be performed on the Authority's premises, the Authority and Supplier will undertake a joint risk assessment with any actions being appropriate, recorded and monitored.

28.4 The Supplier must ensure their health and safety policy statement and management arrangements are kept up to date and made available to the Authority on request.

28.5 The Supplier shall not assign any role to the Authority under the Construction (Design and Management) Regulations 2015 (as amended) (the 'CDM Regulations') without the Authority's prior express written consent (which may be granted or withheld at the Authority's absolute discretion). For the avoidance of doubt so far as the Authority may fall within the role of client as defined by the CDM Regulations in accordance with CDM Regulation 4(8) the parties agree that the Supplier will be the client.

29. Business Continuity

29.1 The Supplier will have a current business continuity plan, which has assessed the risks to its business site/s and activities both directly and with regards to reliance on the supply chain and will set out the contingency measures in place to mitigate them and adapt. As part of this assessment, the Supplier will take into account the business continuity plans of the supply chain. The Supplier's business continuity plan must include (where relevant), an assessment of impacts relating to extreme weather, a changing average climate and/or resource scarcity.

29.2 The Supplier's business continuity plan will be reviewed by the Supplier at regular intervals and after any disruption. The Supplier will make the plan available to the Authority on request and comply with reasonable requests by the Authority for information.

30. Whistleblowing

30.1 The Authority's whistleblowing helpline must be made available to the Supplier and Supplier Staff, subcontractors and key suppliers in the supply chain in order to report any concerns.

30.2. The Supplier agrees:

(a) to insert the following wording into their whistleblowing policy and communicate to all staff:

"If you feel unable to raise your concern internally and it relates to work being carried out for which the ultimate beneficiary (through a contractual chain or otherwise) is Defra group, please email CMBOffice@cefas.co.uk."

(b) to ensure that their Sub-contractors have free access to the Authority's whistleblowing policy.

31. Tax

31.1 The Supplier must not breach any tax or social security obligations and must enter into a binding agreement to pay any late contributions due, including where applicable, any interest or any fines. The Authority cannot terminate the Contract where the Supplier has not paid a minor tax or social security contribution.

31.2 Where the Supplier or any Supplier Staff are liable to be taxed or to pay National Insurance contributions in the UK relating to payment received under this Contract, the Supplier must both:

(a) comply with the Income Tax (Earnings and Pensions) Act 2003 and all other statutes and regulations relating to income tax, the Social Security Contributions and Benefits Act 1992 (including IR35) and National Insurance contributions;

(b) indemnify the Authority against any Income Tax, National Insurance and social security contributions and any other liability, deduction, contribution, assessment or claim arising from or made during or after the Term in connection with the provision of the Deliverables by the Supplier or any of the Supplier Staff.

31.3 If any of the Supplier Staff are Workers who receive payment relating to the Deliverables, then the Supplier must ensure that its contract with the Worker contains the following requirements:

(a) the Authority may, at any time during the term of the Contract, request that the Worker provides information which demonstrates they comply with clause 31.2, or why those requirements do not apply, the Authority can specify the information the Worker must provide and the deadline for responding;

(b) the Worker's contract may be terminated at the Authority's request if the Worker fails to provide the information requested by the Authority within the time specified by the Authority;

(c) the Worker's contract may be terminated at the Authority's request if the Worker provides information which the Authority considers isn't good enough to demonstrate how it complies with clause 31.2 or confirms that the Worker is not complying with those requirements;

(d) the Authority may supply any information they receive from the Worker to HMRC for revenue collection and management.

32. Publicity

32.1 The Supplier and any subcontractor shall not make any press announcements or publicise this Contract or its contents in any way; without the prior written consent of the Authority.

32.2 Each Party acknowledges to the other that nothing in this Contract either expressly or by implication constitutes an endorsement of any products or services of the other Party and each Party agrees not to conduct itself in such a way as to imply or express any such approval or endorsement.

33. Conflict of interest

33.1 The Supplier must take action to ensure that neither the Supplier nor the Supplier Staff are placed in the position of an actual or potential conflict between the financial or personal duties of the Supplier or the Supplier Staff and the duties owed to the Authority under the Contract, in the reasonable opinion of the Authority.

33.2 The Supplier must promptly notify and provide details to the Authority if a conflict of interest happens or is expected to happen.

33.3 The Authority can terminate its Contract immediately by giving notice in writing to the Supplier or take any steps it thinks are necessary where there is or may be an actual or potential conflict of interest.

34. Reporting a breach of the contract

34.1 As soon as it is aware of it the Supplier and Supplier Staff must report to the Authority any actual or suspected breach of Law or breach of its obligations under the Contract.

34.2 Where an actual or suspected breach is notified to the Authority under clause 34.1, the Supplier will take such action to remedy any breach as the Authority may reasonably require. Where the breach is material, the Authority has the right to terminate under clause 11.4.

34.3 The Supplier must not retaliate against any of the Supplier Staff who in good faith reports a breach listed in clause 34.1.

35. Resolving disputes

35.1 If there is a dispute between the Parties, their senior representatives who have authority to settle the dispute will, within 28 days of a written request from the other Party, meet in good faith to resolve the dispute.

35.2 If the dispute is not resolved at that meeting, the Parties can attempt to settle it by mediation using the Centre for Effective Dispute Resolution (CEDR) Model Mediation Procedure current at the time of the dispute. If the Parties cannot agree on a mediator, the mediator will be nominated by CEDR. If either Party does not wish to use, or continue to use mediation, or mediation does not resolve the dispute, the dispute must be resolved using clauses 35.3 to 35.5.

35.3 Unless the Authority refers the dispute to arbitration using clause 35.4, the Parties irrevocably agree that the courts of England and Wales have the exclusive jurisdiction to:

(a) determine the dispute;

(b) grant interim remedies;

(c) grant any other provisional or protective relief.

35.4 The Supplier agrees that the Authority has the exclusive right to refer any dispute to be finally resolved by arbitration under the London Court of International Arbitration Rules current at the time of the dispute. There will be only one arbitrator. The seat or legal place of the arbitration will be London and the proceedings will be in English.

35.5 The Authority has the right to refer a dispute to arbitration even if the Supplier has started or has attempted to start court proceedings under clause 35.3, unless the Authority has agreed to the court proceedings or participated in them. Even if court proceedings have started, the Parties must do everything necessary to ensure that the court proceedings are stayed in favour of any arbitration proceedings if they are started under clause 35.4.

35.6 The Supplier cannot suspend the performance of the Contract during any dispute.

35.7 The provisions of this clause 35 are without prejudice to the Authority's right to terminate or suspend the Contract under clause 11.

36. Which law applies

36.1 This Contract and any issues arising out of, or connected to it, are governed by English law.

36.2 The courts of England and Wales shall have jurisdiction to settle any dispute or claim (whether contractual or non-contractual) that arises out of or in connection with the Contract or its subject matter or formation.

Excelsior AS

Tissue Processor

Operator Guide

A82310100 Issue 15A March 2022

REF
A82300001
A82300002

epredia

Our mission is to **improve lives** by **enhancing cancer diagnostics.**

To every one of us at Epredia, this mission is personal. Many of us have loved ones and family who have been affected by cancer.

You are on the front line of this fight, and our pledge is to arm you with the most innovative tools to enable early detection and diagnosis of this disease.

Learn more at **epredia.com**

epredia

Company Information

Epredia makes every attempt to ensure that the information contained in this supporting document is correct and clearly stated but does not accept responsibility for any errors or omissions. The development of Epredia products and services is an ongoing process. Please ensure that any published information you use as a reference is up to date and relates to the condition of the product. If necessary, check with your local Epredia representative.

This document may not, in whole or in part, be copied, photocopied, reproduced, translated, or converted to any electronic or other form without prior written consent of Epredia. All information contained in this manual is proprietary and confidential, and the exclusive property of Epredia and is protected by copyright.

Contact address

Shandon Diagnostics Limited, a subsidiary of Epredia
Tudor Road, Manor Park, Runcorn
Cheshire, WA7 1TA, UK

Tel: +44 (0) 1928 534000
Fax: +44 (0) 1928 534001
Web: www. epredia.com

USA Distributor

Richard-Allan Scientific LLC, a subsidiary of Epredia
4481 Campus Drive
Kalamazoo, MI 49008, USA

Tel: 1-800-522-7270
Fax: +1 269-372-2674
Web: www. epredia.com

CE IVD

These instruments conform to the general safety and performance of:

- EU IVDR 2017/746

Symbols

The following symbols and conventions may be used throughout this document and on the instrument:

This symbol is used on the equipment, or in a document, to indicate that instructions must be followed for safe and correct operation.

This symbol is also used on the instrument, or in a document, to indicate that irritants or potentially harmful chemicals are present. Refer to the Material Safety Data Sheets for the products, and always use Good Laboratory Practice.

If this symbol appears on the instrument always refer to the operator guide.

This symbol indicates that a surface is hot. If this symbol appears on the instrument or in the documentation always refer to the operator guide. Take suitable precautions.

This symbol is utilised on the instrument, or in a document, to indicate that there are potential biological risks associated with the instrument and / or with instrument use. Always use Good Laboratory Practice.

Manufacturer

This symbol is used on the instrument or in a document to indicate that the instructions must be followed.

A warning is given in the documentation if there is a potential risk of injury, equipment failure or poor tissue sample processing outcome.

Note

Notes give additional information about a job or instruction, but do not form part of the instruction.

Safety Information

Introduction

Epredia instruments are designed for convenient and reliable service; however, improper use or handling by a user may damage the instrument or cause a hazard to health. The instrument must not be used in a manner not specified by Epredia. Correct maintenance procedures are essential for consistent performance. It is recommended that users secure a maintenance contract with our service department.

To remain compliant with regulatory requirements, and to ensure that mandatory safety upgrades are performed at the earliest opportunity, it is strongly recommended that all service activities are performed by Epredia-factory trained Engineers. Warranty may be voided if service is performed by non-factory trained Engineers.

Maintenance or repairs that are not performed by Epredia trained Engineers with proven training may affect the safety, performance and compliance of the equipment.

Please consult your local sales or support teams for more information about service contracts

The following sections contain important information for the safe setup and use of the instrument and should be read and understood by the user before using the instrument.

General Safety

This instrument, as supplied, conforms to IEC61010-1 and IEC61010-2-101; however, the addition of chemicals introduces potential hazards. Good Laboratory Practice must be employed, and consideration must be given to the potential for hazard when dealing with these chemicals.

Do not use the instrument in close proximity to strong electromagnetic radiation, as these may interfere with the proper operation. The electromagnetic environment should be evaluated prior to operation of the device.

Good Laboratory Practice must be used when handling tissue samples to prevent cross contamination and infection. The user should complete a risk assessment to determine any potential hazards related to tissue handling.

- Do not introduce any source of ignition into, or near, the instrument once it has been loaded with reagents.
- Do not remove any panels or access covers, unless specifically instructed to do so. The instrument does not have any user serviceable parts. Potentially lethal voltages are present inside the instrument.
- The instrument must be properly connected to a good earth, (ground) via the Mains input supply and positioned such that it is possible to interrupt the Mains supply at the source by removing the plug from the socket.
- Use only factory approved accessories or replacement parts within the instrument.
- Only use reagents recommended in the operator guide.
- If the Excelsior AS is used in a manner not specified by Epredia, the protection provided by the instrument may be impaired.

Disposal of Sealed Lead Acid Batteries

The sealed lead acid batteries within this instrument need to be replaced every 2 years.

Notes:

If the instrument has been operated in temperatures above 30°C for much of the time, or has been exposed to frequent mains failures, the batteries should be replaced every year.

The batteries in the Excelsior AS should only ever be changed as a pair.

The battery manufacturers advise their customers to comply with the relevant regulations within their particular country regarding disposal of this type of battery.

The battery used within this instrument is:

- 12 V 12 Ah, valve regulated, sealed, lead acid type, rechargeable battery.

  This battery is classified as "Class 8 & Group III UN No 2800 Batteries, wet, non-spillable, electric storage, special provision A67", and meets all requirements of the International Air Transport Association (I.A.T.A) Dangerous Goods Regulations.

Batteries cannot be accessed by the customer and must only be replaced by trained service personnel.

Chemical Safety

The introduction of chemicals creates potential hazards. Epredia has adopted the following position with regard to the subject of volatile chemicals used in laboratories:

- Customers using non-specified chemicals in the instrument, do so at their own risk.

- All chemicals recommended by Epredia have auto-ignition temperatures considerably above any surface temperatures that can be reached during a single fault failure on the instrument.
- The instrument contains no source of ignition in any areas of the instrument where chemicals are stored, or likely to leak into, in a single fault condition.
- The operator is fully aware of the contents of the specification documents detailing the properties of the chemicals they are using.
- The operator has carried out any legally required assessment of chemicals used and is using Good Laboratory Practice.
- Some chemicals which may be used during operation are flammable - do not use sources of ignition in the vicinity of the instrument when it is loaded with reagents.
- Harmful chemical vapours such as Xylene or Toluene (others) may be emitted during the normal operation of some instruments and the operator should be aware of suitable precautions and safety measures. The short-term exposure limits for Xylene and Toluene will be no greater 100 ppm
- Do not use consumables past their expiration date.
- Do not use the instrument in hazardous atmospheres and with hazardous materials for which the instrument is not designed.
- Ensure you use the correct waste wax container when disposing of waste wax out of the instrument.

EMC Statement

This IVD equipment complies with the emissions and immunity requirements of IEC 61326-2-6.

This equipment has been designed and tested to CISPR 11 Class A.

It is intended for use in a laboratory environment by a trained and qualified professional. In a domestic environment it may cause radio interference, in which case it may be necessary to take measures to mitigate the interference.

Environment

This instrument is required to comply with the European Union's Waste Electrical and Electronic Equipment (WEEE) Directive 2012/19/EU. It is marked with the following symbol:

Epredia has contracts with one or more recycling / disposal companies in each EU Member State, and this product and packaging should be disposed of or recycled through them. For further information, contact your Epredia service representative.

Warranty Statement

Epredia is proud of their quality, reliability and of our after-sales service. We continuously strive to improve our service to our customers.

Please ask your distributor or Epredia representative about service contracts which can help maintain your instrument in an optimal operating condition.

Warranty provisions necessarily vary to comply with differences in national and regional legislation. Specific details can be found in the delivery documentation or from your dealer or representative.

Please note that your warranty may be invalidated if:

- This instrument is modified in any way, or not used as intended by Epredia.
- Accessories and reagents which have not been approved by Epredia are used.
- The instrument is not operated or maintained in accordance with instructions.
- The installation of the instrument was not conducted by a certified Epredia representative.

Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user/or the patient resides.

Enhancing precision
cancer diagnostics

www.epredia.com

Tudor Road, Manor Park
Runcorn, WA7 1TA
United Kingdom
+44 (0) 800 018 9396
+44 (0) 1928 534 000

4481 Campus Drive
Kalamazoo, MI 49008
United States
+1 (800) 522-7270

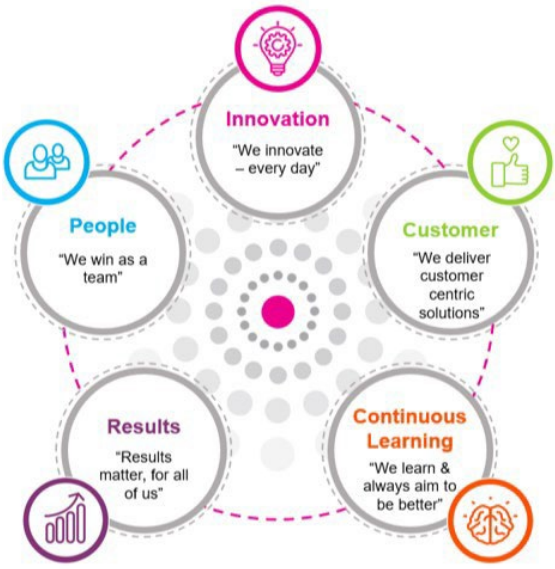
epredia
Enhancing precision cancer diagnostics

 A82310100 Issue 15A

POWERED BY SHANDON MICROM MENZEL-GLÄSER Richard-Allan Scientific

Fair work First

At Epredia, we embrace DIVERSE perspectives and inspire each other. We foster employee wellbeing by integrating safety, flexibility, health, and BELONGING in our work environment. Our mission is to improve lives by enhancing cancer diagnostics. Our vision is to deliver best-in-class customer experiences and to be seen as the highest quality partner in enhancing diagnostics. That begins with our people. With empathy and humility, we seek win- for - all solutions, teamwork is about all of us working better together.



Epredia
Manor Park
Tudor Road
Runcorn
Cheshire
WA7 1TA

www.epredia.com

The Mission, Vision and Values are an important part of what Epredia's stands for as a company. The mission describes the unique purpose that justifies our organization, the vision defines what we aspire to become, and the values set a standard for how our employees should act and how we want to operate our business. When we follow these guiding principles, we are able to drive towards common goals and collective future success as an organization. We believe these elements can set us apart from our competitors and define who we are and who we want to become over the coming years.

To every one of us at Epredia™, this mission is personal. Many of us have loved ones and family who have been affected by cancer. We are working to provide pathologists and healthcare professionals with the most innovative tools to enable early detection and diagnosis of this disease.

At Epredia, from our values we promote to support and strengthen local supply chains and to develop social value with ALL Government policies for driving good quality and fair work Globally. We continuously innovate better instrumentation and consumables for the economy, we procure supplies with reputable third parties who engage in legitimate business activities and do not engage in business relationships with individuals or entities that are or have been involved with anti-social forces. Identifying modern slavery is not an operating risk, Epredia will provide all the appropriate checks aligned to our Code of Conduct within our supply chain. We employ workforce directly from all over the world where we invest in their development, no offerings of inappropriate use of zero hours contracts in the UK, so that Epredia provides fair pay for all workers and we are tackling the gender pay gap Globally for a more diverse and inclusive workforce that falls within our Code of Conduct. Appropriate channels for effective voices are exercised through a platform called MyHR, therefore every decision, no matter how big or small is aimed at ensuring our customers have our best products, services and partnerships (internal and external). Epredia are persistent in balancing everyone's working experience by offering flexible and family friendly working practices for all employees from the contract start date of employment. There will also be more implemented through the journey of supply and service for social value as we evolve in partnership with all medical organisations.

Please see below more information relating to Epredia's Third Party Code of Conduct;

Epredia Third Party Code of Conduct.pdf

Epredia
Manor Park
Tudor Road
Runcorn
Cheshire
WA7 1TA

www.epredia.com

epredia
Enhancing precision cancer diagnostics

Modern Slavery Statement

Shandon Diagnostics Limited Modern Slavery Act Statement
for the financial year ending 31st March 2022

This statement ("Statement") is made pursuant to Section 54 of the United Kingdom Modern Slavery Act 2015 (the "Act"), and sets out the policies Shandon Diagnostics Limited adopted to prevent slavery and human trafficking in our supply chains and in any part of our business. For purposes of this Statement, Shandon Diagnostics Limited shall be referred to as "Shandon." Shandon Diagnostics Limited is a fully owned subsidiary of Epredia Holdings Corporation, a member of the PHC Group.

INTRODUCTION

Shandon seeks to combat the risks of modern slavery and human trafficking within our supply chains and operations. We expect our contractors, suppliers, and other business partners to provide their services ethically and to the same high standards of integrity. Shandon supports and endeavors to adhere to the Act and equivalent anti-slavery and human trafficking laws in effect in the countries where we operate and provide our products.

OUR STRUCTURE AND SUPPLY CHAINS

As part of our mission to improve patient lives, Shandon manufactures and sells instruments and consumables for precision cancer diagnostics worldwide through distributor and intercompany sales channels.

We are committed to acting ethically and respecting human rights throughout our organization and in ou business relationships.

The supply chain that supports our business comprises a wide range of suppliers, from small/medium enterprises (SMEs) to global corporates, including products and services from manufacturing, IT hardware and software, maintenance, recruitment agents, and cleaning services.

The range of products/services in our supply chain and the wide range of jurisdictions in which these are sourced mean that we consider the tiers below our immediate suppliers to be our primary area of risk from a forced labour perspective.

OUR POLICIES

To uphold and embed our commitment to respecting human rights throughout our organization and in our business relationships, Shandon adheres to the following principles when conducting its business activities and expects its suppliers to abide by the same:

- Compliance with Applicable Laws: We comply with all applicable laws, regulations, rules, guides, ordinances, and legal standards.
- Child Labour: We do not employ or use under-aged labour as described in Minimum Age Convention 138 and Worst Forms of Child Labour Convention 182 of the International Labour Convention.
- Forced Labour/ Prison Labour/ Trafficking In Persons:

- We do not make use of forced or compulsory labour as described in Article 2 in the Forced Labour Convention 29 and Article 1 in the Abolition of Forced Labour Convention 105 of the International Labour Organization.
    - We comply with all applicable labour laws, rules, and regulations, including but not limited to, all laws forbidding the solicitation, facilitation, or any other use of slavery, servitude, forced or compulsory labour or human trafficking, or sex trafficking, as those terms are used in the US laws, California Transparency in Supply Chains Act of 2010, California Civil Code, section 1714.43, the UK Modern Slavery Act 2015, and FAR 52.222-50, Combating Trafficking in Persons.
    - We do not retain or withhold any worker's original identity documents or restrict access to such documents or require workers to pay any monetary deposits for the purpose of obtaining employment. If any personal loans are offered to workers as part of their compensation or pursuant to company policy, the repayment terms should not be construed as debt bondage or forced labour.
- Fair Treatment: We provide a workplace free of harsh and inhumane treatment, including any sex harassment, sexual abuse, corporal punishment, mental or physical coercion or verbal abuse an no threat of any such treatment.
- Wages, Benefits and Working Hours: We pay workers according to applicable wage laws, including minimum wages, overtime hours and mandated benefits. We communicate with the worker the basis on which they are being compensated in a timely manner and communicate with the worker whether overtime is required and the wages to be paid for such overtime.
- Freedom of Association:
    - We encourage open communication and direct engagement with workers to resolve workplace and compensation issues.

- Workers are able to communicate openly with management regarding working conditions without threat of reprisal, intimidation or harassment.
- We respect the rights of workers, as set forth in local laws, to associate freely, join or not join labour unions, seek representation and join workers' councils.
- We respect, within the framework of local laws and established practices, the principles of Article 2 in the Freedom of Association and Protection of the Right to Organize Convention 87 and Articles 1 and 2 in the Right to Organize and Collective Bargaining Convention 98 of the International Labour Organization.

DUE DILIGENCE PROCESSES

Shandon endeavors to develop and monitor its policies and procedures that are aimed at enhancing integrity and ethical behavior to be consistent with the contemporary state of applicable laws and regulations, as well as good industry practice. Additionally, our standard contracts with suppliers and business partners include provisions that all parties will comply with all applicable laws. Shandon also implements third party due diligence screenings of certain new and current suppliers, distributors, and other business partners to confirm none have been convicted of offenses related to modern day slavery or human trafficking, and to assess whether suppliers, distributors, and other business partners have appropriate policies in place.

Shandon encourages all workers to report any suspected violations and concerns in the workplace without threat of reprisal, intimidation, or harassment. We require suppliers to investigate and take corrective action on reported concerns if needed.

RISK ASSESSMENT AND MANGEMENT

In addition to the aforementioned policies, Shandon performs factory audits as necessary and when working with a new supplier. During these audits, which are conducted in conjunction with engineering and supplier quality, Shandon reviews whether suppliers can demonstrate compliance with the principles set forth above.

MEASURING EFFECTIVENESS

To ensure Shandon and its business partners are committed to protecting and advancing human rights,

- review our current supply chains and re-evaluate risks;
- conduct audits where suppliers demonstrate their adherence to Shandon policies;
- maintain a robust internal reporting system through a compliance helpline, which is readily available to all employees;

require internal training on protecting human rights; and

- expect our suppliers to continually improve by setting performance objectives, executing implementation plans and taking necessary corrective actions for deficiencies identified by internal or external assessments, inspections and management reviews.

TRAINING

As part of Shandon's commitment to combat modern day slavery and human trafficking throughout our organization and supply chains, we provide regular trainings to personnel to ensure that our values are fully communicated and adhered to. Some of these trainings are mandatory and interactive. These trainings include online modules that educate Shandon personnel on the Act itself, how to recognize modern slavery, and how to take action against it.

CONCLUSION

Shandon is committed to upholding the highest respect for human rights throughout its business operations and supply chains. As part of PHC Holdings Corporation, a continuous improvement company, we will update and improve our policies and procedures on an ongoing basis. We will also report on our progress through subsequent versions of this Statement on a yearly basis.

This Statement has been reviewed and approved by the Shandon Board on 10th May 2023.

Ian Weir
Director, Shandon Diagnostics Limited

Give Feedback

SCOPE

This Environmental Policy applies to Shandon Diagnostics Ltd, all employees across all departments, contractors, and stakeholders associated with its operations and activities.

PURPOSE

The purpose of this document is to establish and communicate our commitment to environmental sustainability, outlining the principles, objectives, and responsibilities for achieving environmental performance excellence in accordance with ISO 14001:2015 Clause 5.2. It also outlines the framework for defining and assigning organisational roles, responsibilities, and authorities as required by ISO 14001:2015, Clause 5.3.

POLICY STATEMENT

Shandon Diagnostics Ltd is dedicated to environmental sustainability and acknowledges its responsibility to protect the environment, prevent pollution, and continually improve its environmental performance.

We are committed to complying with applicable environmental laws, regulations, and other requirements, as well as to setting and achieving environmental objectives and targets.

We will strive to:

- Minimise our environmental impact by conserving resources, reducing waste, and preventing pollution.
- Integrate environmental considerations into our decision-making processes, from product design to procurement and operational activities.
- Promote environmental awareness and responsibility among our employees, contractors, and stakeholders through education and training.
- Regularly review our environmental objectives and targets to ensure they remain relevant and achievable.
- Communicate openly and transparently about our environmental performance, fostering dialogue with stakeholders.
- Continually improve our environmental management system through regular reviews, audits, and corrective actions.
- Support sustainable practices within our supply chain and collaborate with partners who share our commitment to the environment.

Ian Weir
Site Lead
August 2023

Excelsior AS

Tissue Processor

Operator Guide

A82310100 Issue 15A March 2022

REF
A82300001
A82300002

epredia

Our mission is to **improve lives** by **enhancing cancer diagnostics.**

To every one of us at Epredia, this mission is personal. Many of us have loved ones and family who have been affected by cancer.

You are on the front line of this fight, and our pledge is to arm you with the most innovative tools to enable early detection and diagnosis of this disease.

Learn more at **epredia.com**

epredia

Company Information

Epredia makes every attempt to ensure that the information contained in this supporting document is correct and clearly stated but does not accept responsibility for any errors or omissions. The development of Epredia products and services is an ongoing process. Please ensure that any published information you use as a reference is up to date and relates to the condition of the product. If necessary, check with your local Epredia representative.

This document may not, in whole or in part, be copied, photocopied, reproduced, translated, or converted to any electronic or other form without prior written consent of Epredia. All information contained in this manual is proprietary and confidential, and the exclusive property of Epredia and is protected by copyright.

Contact address

Shandon Diagnostics Limited, a subsidiary of Epredia
Tudor Road, Manor Park, Runcorn
Cheshire, WA7 1TA, UK

Tel: +44 (0) 1928 534000
Fax: +44 (0) 1928 534001
Web: www. epredia.com

USA Distributor

Richard-Allan Scientific LLC, a subsidiary of Epredia
4481 Campus Drive
Kalamazoo, MI 49008, USA

Tel: 1-800-522-7270
Fax: +1 269-372-2674
Web: www. epredia.com

CE IVD

These instruments conform to the general safety and performance of:

- EU IVDR 2017/746

Symbols

The following symbols and conventions may be used throughout this document and on the instrument:

This symbol is used on the equipment, or in a document, to indicate that instructions must be followed for safe and correct operation.

This symbol is also used on the instrument, or in a document, to indicate that irritants or potentially harmful chemicals are present. Refer to the Material Safety Data Sheets for the products, and always use Good Laboratory Practice.

If this symbol appears on the instrument always refer to the operator guide.

This symbol indicates that a surface is hot. If this symbol appears on the instrument or in the documentation always refer to the operator guide. Take suitable precautions.

This symbol is utilised on the instrument, or in a document, to indicate that there are potential biological risks associated with the instrument and / or with instrument use. Always use Good Laboratory Practice.

Manufacturer

This symbol is used on the instrument or in a document to indicate that the instructions must be followed.

A warning is given in the documentation if there is a potential risk of injury, equipment failure or poor tissue sample processing outcome.

Note

Notes give additional information about a job or instruction, but do not form part of the instruction.

Safety Information

Introduction

Epredia instruments are designed for convenient and reliable service; however, improper use or handling by a user may damage the instrument or cause a hazard to health. The instrument must not be used in a manner not specified by Epredia. Correct maintenance procedures are essential for consistent performance. It is recommended that users secure a maintenance contract with our service department.

To remain compliant with regulatory requirements, and to ensure that mandatory safety upgrades are performed at the earliest opportunity, it is strongly recommended that all service activities are performed by Epredia-factory trained Engineers. Warranty may be voided if service is performed by non-factory trained Engineers.

Maintenance or repairs that are not performed by Epredia trained Engineers with proven training may affect the safety, performance and compliance of the equipment.

Please consult your local sales or support teams for more information about service contracts

The following sections contain important information for the safe setup and use of the instrument and should be read and understood by the user before using the instrument.

General Safety

This instrument, as supplied, conforms to IEC61010-1 and IEC61010-2-101; however, the addition of chemicals introduces potential hazards. Good Laboratory Practice must be employed, and consideration must be given to the potential for hazard when dealing with these chemicals.

Do not use the instrument in close proximity to strong electromagnetic radiation, as these may interfere with the proper operation. The electromagnetic environment should be evaluated prior to operation of the device.

Good Laboratory Practice must be used when handling tissue samples to prevent cross contamination and infection. The user should complete a risk assessment to determine any potential hazards related to tissue handling.

- Do not introduce any source of ignition into, or near, the instrument once it has been loaded with reagents.
- Do not remove any panels or access covers, unless specifically instructed to do so. The instrument does not have any user serviceable parts. Potentially lethal voltages are present inside the instrument.
- The instrument must be properly connected to a good earth, (ground) via the Mains input supply and positioned such that it is possible to interrupt the Mains supply at the source by removing the plug from the socket.
- Use only factory approved accessories or replacement parts within the instrument.
- Only use reagents recommended in the operator guide.
- If the Excelsior AS is used in a manner not specified by Epredia, the protection provided by the instrument may be impaired.

Disposal of Sealed Lead Acid Batteries

The sealed lead acid batteries within this instrument need to be replaced every 2 years.

Notes:

If the instrument has been operated in temperatures above 30°C for much of the time, or has been exposed to frequent mains failures, the batteries should be replaced every year.

The batteries in the Excelsior AS should only ever be changed as a pair.

The battery manufacturers advise their customers to comply with the relevant regulations within their particular country regarding disposal of this type of battery.

The battery used within this instrument is:

- 12 V 12 Ah, valve regulated, sealed, lead acid type, rechargeable battery.

  This battery is classified as "Class 8 & Group III UN No 2800 Batteries, wet, non-spillable, electric storage, special provision A67", and meets all requirements of the International Air Transport Association (I.A.T.A) Dangerous Goods Regulations.

Batteries cannot be accessed by the customer and must only be replaced by trained service personnel.

Chemical Safety

The introduction of chemicals creates potential hazards. Epredia has adopted the following position with regard to the subject of volatile chemicals used in laboratories:

- Customers using non-specified chemicals in the instrument, do so at their own risk.

- All chemicals recommended by Epredia have auto-ignition temperatures considerably above any surface temperatures that can be reached during a single fault failure on the instrument.
- The instrument contains no source of ignition in any areas of the instrument where chemicals are stored, or likely to leak into, in a single fault condition.
- The operator is fully aware of the contents of the specification documents detailing the properties of the chemicals they are using.
- The operator has carried out any legally required assessment of chemicals used and is using Good Laboratory Practice.
- Some chemicals which may be used during operation are flammable - do not use sources of ignition in the vicinity of the instrument when it is loaded with reagents.
- Harmful chemical vapours such as Xylene or Toluene (others) may be emitted during the normal operation of some instruments and the operator should be aware of suitable precautions and safety measures. The short-term exposure limits for Xylene and Toluene will be no greater 100 ppm
- Do not use consumables past their expiration date.
- Do not use the instrument in hazardous atmospheres and with hazardous materials for which the instrument is not designed.
- Ensure you use the correct waste wax container when disposing of waste wax out of the instrument.

EMC Statement

This IVD equipment complies with the emissions and immunity requirements of IEC 61326-2-6.

This equipment has been designed and tested to CISPR 11 Class A.

It is intended for use in a laboratory environment by a trained and qualified professional. In a domestic environment it may cause radio interference, in which case it may be necessary to take measures to mitigate the interference.

Environment

This instrument is required to comply with the European Union's Waste Electrical and Electronic Equipment (WEEE) Directive 2012/19/EU. It is marked with the following symbol:

Epredia has contracts with one or more recycling / disposal companies in each EU Member State, and this product and packaging should be disposed of or recycled through them. For further information, contact your Epredia service representative.

Warranty Statement

Epredia is proud of their quality, reliability and of our after-sales service. We continuously strive to improve our service to our customers.

Please ask your distributor or Epredia representative about service contracts which can help maintain your instrument in an optimal operating condition.

Warranty provisions necessarily vary to comply with differences in national and regional legislation. Specific details can be found in the delivery documentation or from your dealer or representative.

Please note that your warranty may be invalidated if:

- This instrument is modified in any way, or not used as intended by Epredia.
- Accessories and reagents which have not been approved by Epredia are used.
- The instrument is not operated or maintained in accordance with instructions.
- The installation of the instrument was not conducted by a certified Epredia representative.

Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user/or the patient resides.

Enhancing precision
cancer diagnostics

www.epredia.com

Tudor Road, Manor Park
Runcorn, WA7 1TA
United Kingdom
+44 (0) 800 018 9396
+44 (0) 1928 534 000

4481 Campus Drive
Kalamazoo, MI 49008
United States
+1 (800) 522-7270

epredia
Enhancing precision cancer diagnostics

 A82310100 Issue 15A

POWERED BY SHANDON MICROM MENZEL-GLÄSER Richard-Allan Scientific

epredia Enhancing precision cancer diagnostics

Sustainability Statement

In July, Shandon Diagnostics Ltd [a subsidiary of Epredia] published the Carbon Reduction Plan [CRP], in line with the Government Climate Change Act of 2008, to conform to the 2019 Amendment for a net UK carbon account, or "Net Zero" by 2050. Shandon Diagnostics is committed to achieving Net Zero emissions by 2040. The CRP sets to establish the most cost-effective route to an economically and environmentally sustainable future by outlining the strategies and actions that will be implemented or are already in place to mitigate Scope 1 and Scope 2 emissions only at this time. Shandon Diagnostics is addressing the Scope 3 emissions and by obtaining the necessary data to capture and address them effectively. The obligations are recognised and central to ongoing policy in contributing to both a sustainable future and achieving the carbon reduction goals.
The baseline Scope 1 emissions for the year ending 31/03/23 are publishable and Scope 2 data is being gathered and processed. The accompanying strategies are evolving and becoming policy. Additionally, the wider global group statement will follow in September, from there, the detail of the CRP will begin to take shape.
Epredia will consistently and actively engage with all customers, partners and stakeholders to share data and meet common objectives, to build resource resilience and stronger alliances into the future. Epredia are currently working towards obtaining the accreditation of ISO 14001.

Please see explained breakdown of the below documents attached;

Scope 1:
Co2e inclusions;

- Runcorn Van/LGV (516litres of Diesel)
- Back-up Generator (800litres of Diesel)
- Gas used on site (227460 kWh)

Scope 2:
Electric purchased (861,705 kWh) ***From 100% Renewable Sources***

The attached data of the CRP makes up the attached report 'Normative'.

EHS-GHG-0001 - Carbon Reduction Pla

normative.pdf

Please explore our mother company ambitions for future state that all the operating companies will be required to adopted.

Environmental Activities | Environmental Sustainability | Sustainability | PHC Holdings Corporation (phchd.com)

Epredia
Manor Park
Tudor Road
Runcorn
Cheshire
WA7 1TA

www.epredia.com

Environmental Initiatives

Epredia are currently in the process of improving our services by introducing a warehouse at our facilities in Runcorn, where we will be storing minimal stock of our instruments, parts and consumables for reduced delivery times and to be environmentally sustainable.

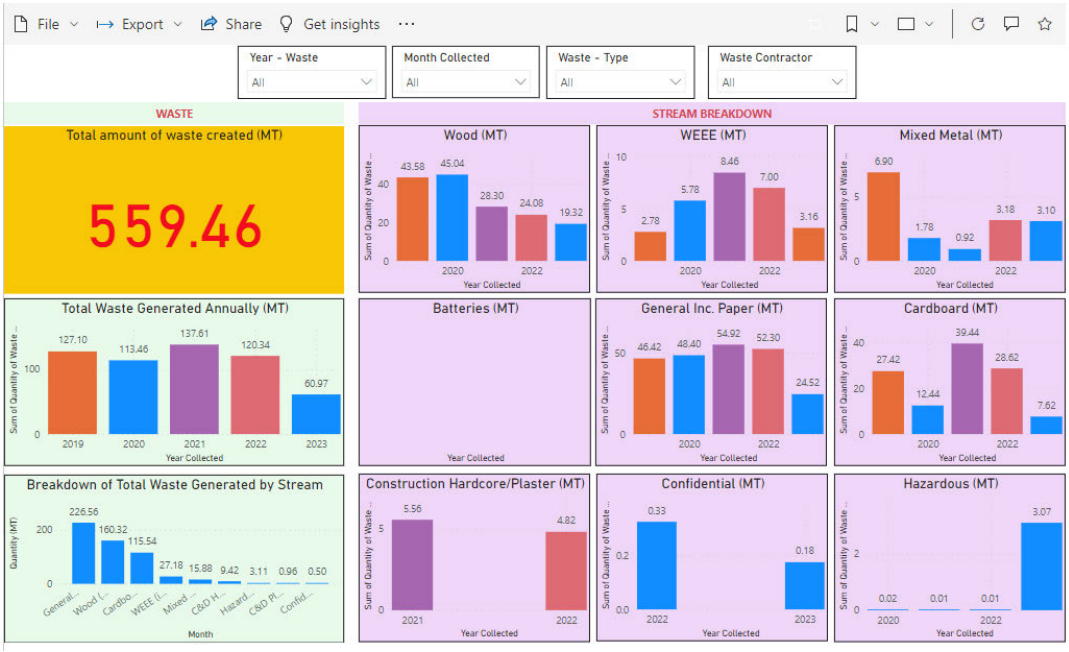
The Runcorn head office has introduced sensor lighting. Reusable or recyclable packaging for all saleable products as part of our ISO 14001 accreditation (See attached below) to improve our environmental performance through more efficient use of resources and reduction of waste.

PDF

Shandon Diagnostics Limited_EMS 793518

As part of ISO 14001 accreditation Shandon Diagnostic Ltd t/a Epredia have initiated recordings of year-on-year waste trends, so that we can report our waste reduction as part of the suppliers business responsibility to the environment.

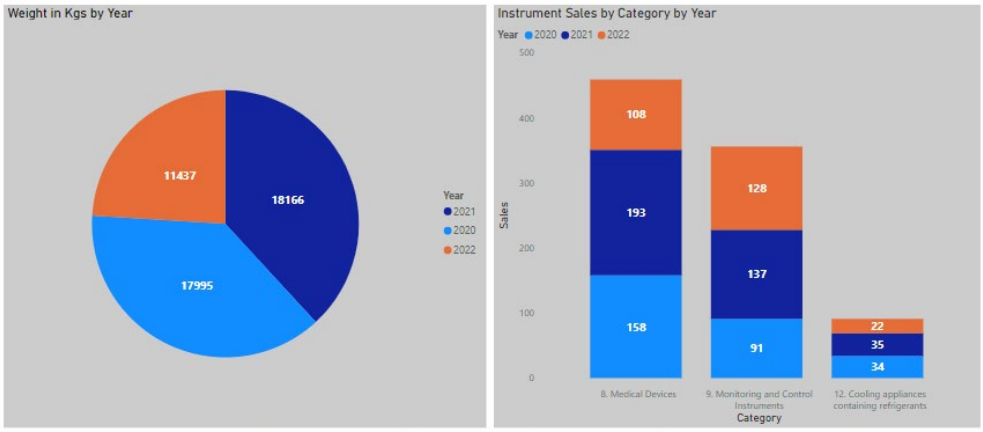
Waste Overview;



Epredia
Manor Park
Tudor Road
Runcorn
Cheshire
WA7 1TA

www.epredia.com

WEEE UK Compliance Scheme;

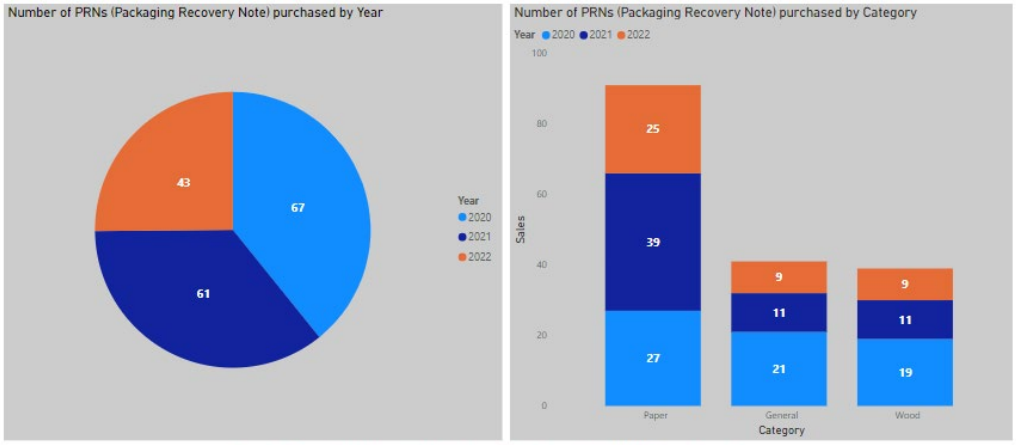


Shandon Diagnostics Ltd appoints B2B Compliance to register them in their UK WEEE registration scheme.
Shandon Diagnostics Ltd are subject to an annual registration frequency, [1st > 15th Jan window].
Registration is based upon sales data, which is provided through PowerBi Dashboard ***'Quality KPI Reporting'*** Location ***SAP_DataSets***

Certificate attached below;

Shandon Diagnostics Ltd 2023 Compliance

Packaging Waste UK Compliance Scheme;



Shandon Diagnostics Ltd appoints Veolia to register them in their UK WEEE registration scheme.
Shandon Diagnostics Ltd are subject to an annual registration frequency, [1st January > 31st December].
Registration is based upon i) sales data, which is provided through PowerBi Dashboard ***'Quality KPI Reporting'*** Location ***SAP_DataSets***, ii) Packaging purchased see McFarlanes Figures and iii) Waste Reports, see ASH Waste Monthly reports.

Certificate attached below;

EA-1110 Shandon Diagnostics Ltd - Men

Epredia
Manor Park
Tudor Road
Runcorn
Cheshire
WA7 1TA

www.epredia.com

Majority of our fleet has now switched to hybrid or electric vehicles only. They are used for sales representatives and staff that can contractually benefit for a company car.

Epredia has also introduced a benefit to all employees to apply for an electric vehicle. This is a salary sacrifice benefit, which allows you to lease a fully electric, brand new vehicle for an agreed period of time via a tax efficient repayment method. You can save up to 40% off the cost of an electric car with this salary sacrifice scheme.
Octopus Electric Vehicles' salary sacrifice scheme provides the whole package. You get the car, charger, energy, insurance, servicing, maintenance, breakdown and tyres.
For more information click on www.octopusev.com

Epredia
Manor Park
Tudor Road
Runcorn
Cheshire
WA7 1TA

www.epredia.com

epredia Enhancing precision cancer diagnostics

Tissue Processor

The Excelsior AS™ tissue processor is a rotational chamber processor that allows customers to reduce tissue processing time, create a safe user environment, decrease maintenance time and reagent usage while producing exceptional tissue quality. Engineered for reliability and peace of mind, the processors UK install bases is being used widely across the UK in clinical laboratories for over a decade of service history.

The Excelsior AS™ tissue processor is a fully enclosed, automated, compact and a free-standing tissue processor.
This will include standard cassette processing baskets, paraffin scraper, x3 filters (as standard) and x5 waste wax trays required to operate the machine.

1. Capable of processing between 100 and 200 specimens housed in Tissue cassettes.

The cassette capacity is:
Organized basket 6 sections: total 222 standard cassettes
High volume organized basket 6 sections: total 300 cassettes

2. Electrical Configurations 120V, 60Hz, AC and work with appropriate type A, B or C plugs.

Power requirements are:
100-240 Vac; 50/60 Hz; 1300 VA (max.), 300 VA (typical) and works with appropriate type A, B or C plugs

3. A fume control system is required to eliminate harmful fumes. Ideally there will be a facility to fit a carbon filter. 4x Spare filters should be included as part of the bundle. There must be a facility to easily buy replacement filters.

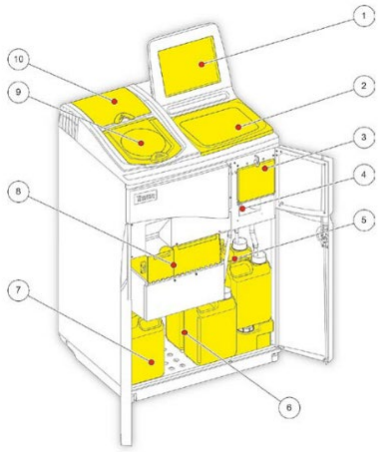
Epredia generally only provides 3 with an install, however, we will accommodate by providing 1 extra pack to fulfil the requirement.

Epredia
Manor Park
Tudor Road
Runcorn
Cheshire
WA7 1TA

www.epredia.com

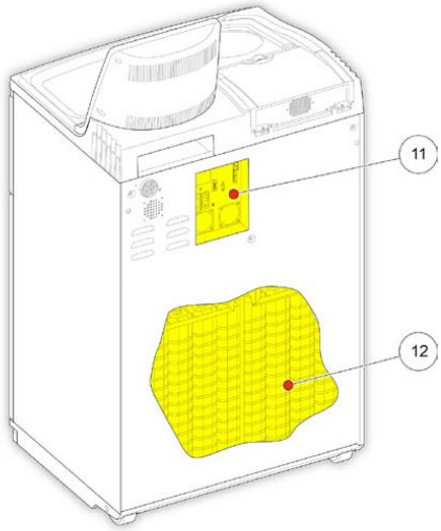
4. Ideally 8 or more reagent stations. These must be resistant to xylene and alcohol. Each station must be easily removed and cleanable. If the stations are considered as additional consumables, these must be included in the quotation.

At the front of the machine there are two exchange positions for alcohol and xylene, one in and one out. There are two formalin fixative bottles and three flush reagent bottles, which include x1 Alcohol, x1 xylene and x1 water. These 7 bottles are accessible for the user and can be cleaned and replaced when required. Labelled 5, 6 and 7 in the diagram below.



1	Touch screen
2	Removable tray
3	Filter compartment
4	USB port
5	Flush reagent bottles
6	Exchange bottles
7	Fixative bottles
8	Wax baths and waste wax tray
9	Reaction Chamber
10	Downdraft filter compartment

All the remaining x9 bottles are stored away in the back of the machine and are concealed. These consist of reagent bottles for x6 Alcohol and x3 Xylene. These are only accessible for engineers through removing the back panel and these are cleaned during the annual maintenance of the machine.



11	Electrical connections panel
12	Concealed reagent bottles

5. At least 3 heated wax stations.

The Excelsior AS™ processor includes x3 paraffin wax tanks. The wax tanks store up to 5.6L in each wax tank.
The temperature range between 50-70 degrees Celsius

Epredia
Manor Park
Tudor Road
Runcorn
Cheshire
WA7 1TA

www.epredia.com

6. Built-in specimen basket agitation and/or reagent mixing facilities.

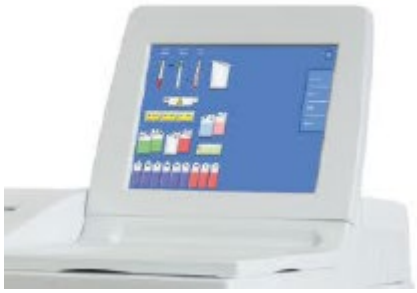
The Excelsior AS™ built-in specimen basket agitation moves through the process steps, drawing in reagents in turn and agitating the baskets to stir reagent around the specimens. Tissue Processing utilizing simple immersion & agitation of the baskets.

7. An integrated computer control system with a keypad and display.

The Excelsior AS™ has a compact and informative user interface that displays the following information:

- The all-new touch-screen interface is intuitive and easy to learn
- With intelligent software, it's easier to avoid mistakes that affect tissue quality
- Context sensitive help
- Reaction Chamber status, program details and process status
- Graphics, showing processing and reagent movement in real time

The touch screen user interface is used to initiate processing and set system preferences and settings.

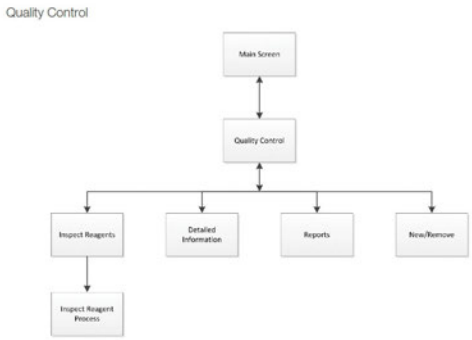


The on-screen keyboard

The on-screen number pad

8. Ideally a method of recoding faults so that engineers can be made aware of issues by sending logs or error codes.

The Excelsior AS logs any faults/error codes that occur and stores reports within the memory for engineers awareness and if set up can be sent remotely via the LIMS connectivity.



Epredia
Manor Park
Tudor Road
Runcorn
Cheshire
WA7 1TA

www.epredia.com

9. Ability to programme user defined processing schedules, and there must be a memory cache to allow for multiple programs to be saved on the instrument.

The Excelsior AS can store up to 8 full configurable tissue processing programmes. The user can select the time required, optional vacuum, the temperature of the alcohol, formalin, or Xylene in use and the drain time after the process.

10. Pre-set programs available to use, as well as free editing of station parameters such as mixing, immersion time, drip time (to avoid reagent carry over), and temperature control for wax baths.

The Excelsior AS fully complies with having pre-set programs available, as well as free editing of station parameters such as mixing, immersion time, drip time, and temperature control for wax baths.

11. The capacity to inform the user of the status of the instrument programmes with the following parameters:
    - Adjustable start time and delayed start time adjustable as required by the user.

      A program can be started when specimens and baskets are loaded, and the fill level has been set (if applicable). The program will either start immediately or after a delay in fixative or alcohol. The length of the delay will vary according to the specified end time of the program.

    - Total program run time, predicted end time must be displayed on demand.

      For running an overnight program with a delayed start, the Reaction Chamber will fill with the delay step reagent and then hold until active processing starts to complete at the specified end time.

    - Ideally multiple baskets could be processed at the same time and for these to be detailed on the display so the progress and end time can be checked for each basket.

      3 baskets can be processed at the same time which can be detailed on display so the progress and end time can be checked for each basket.

    - Audible alarms, error messages and warning codes for when paraffin wax is un-melted and in solid state. In addition, automatic reheating of wax before basket is transferred to a wax bath.

      There are audible alarms, error messages and codes if the paraffin is un-melted. The paraffin is constantly heated in the bath.

      The machine has a 'Wax not ready' warning that will stop the machine from advancing until the wax is melted and at the temperature required to reach the chamber and work with the tissue. Also there is also a level sensor in each wax tank that ensures there is enough wax at each stage.

      The basket transferring to the wax bath but the way the machine works the reagents always remain in the chamber and the wax is drew into the chamber via the heated wax pipes.

- Warning and alarms if the power has been lost or if there has been a fault.

  Excelsior AS monitors various system events which can be used to trigger audio and remote alarms. For example, audio alarms can be set to alert operators that the instrument is on hold (the lid has been opened when processing has started) or a program has ended.

- Manual operation and overrides are essential.

  Ability to override QC warnings and postpone rotation.

- A battery backup to allow for power outages and retaining of instrument memory. Please include in quotation if this is not supplied as standard.

  An Excelsior AS has 2 x 12V batteries that will activate if the power is lost during a process or engineering test. These batteries allow time for the process to continue into mains power is restored. If mains power is not restored, the instrument will leave itself in a stable state (Either Wax or Formalin) . This is dependent on how far the process has ran. These batteries are changed by the machine when mains power is active to ensure the batteries are charged in case of power failure.

  There has never been an official figure on the amount of time that it will keep going for. This is because its very difficult to give an accurate figure. The time it can run on battery power is highly dependent on the following things:
  - The protocol that is running – required reagent temperatures in the chamber, fill level (time pump is running), whether vacuum is being cycled on the chamber during processing (pump time again).
  - Ambient temperature
  - Age/health of the batteries. Excelsior batteries should be changed at least every 3 years.

- Ability to remove specimens from the instrument if there is a mains or battery failure.

  How do I retrieve my tissues if an instrument malfunction occurs while the instrument is under vacuum?
  - Press the Lid Release or Stop / Abort options, if available. If these options are not available, open the right door, remove the metal baffle plate and pull the red emergency vacuum release. For details, see Fitting the Filters.

  - Remove all specimens from the Reaction Chamber.

- Failsafe conditions such as automatic immersion of tissue basket in a station, in case of mains power failure.

  This is covered in the battery backup which last for up to 4 hours Where the machine continues to function on batteries and then gets itself in a safe state.

Epredia
Manor Park
Tudor Road
Runcorn
Cheshire
WA7 1TA

www.epredia.com

EXCELSIOR AS™ unique features:

- Unique basket design which improves exposure to fluid and better tissue penetration
- Triple filtration: Downdraft and cabinet ventilation for maximum user safety
- Alcohol quality measurement enables you to extend your reagent life and provides significant cost savings
- Disposable single-use wax trays
- Power outages are no longer a concern with enhanced backup batteries of up to 4 hours.

The EXCELSIOR AS™ reagent management system is also unique.

This works by monitoring the alcohol level in the first alcohol step of the protocol. When this is judged to be of a certain non-acceptable level by the EXCELSIOR AS™, the first alcohol is then discarded by the machine, and only a pure alcohol is then added to step six, and all other.

- Eliminates the need to pour chemicals from one bottle to another.
- Competitive systems have up to 16 bottles – The Excelsior AS™ only has 3.
- No interruption to daily workflow
- Increased instrument up-time
- Minimal exposure to hazardous fumes
- Minimal lifting of heavy reagent bottles

Why should you choose EXCELSIOR AS™ rapid tissue processor for your laboratory?
Rotational Processing?

Decrease fatty tissue processing time without the use of a pre-treatment.
Process without the use of heat, satisfying IHC and Molecular studies.

Intelligent alcohol monitoring system

- Density meter measurement of alcohol quality every run, saving almost 3x the monthly reagent costs vs competitors.

- In process reagent exchanges can save Laboratories almost 3x the monthly laboratory technician time vs. competitors.

Epredia
Manor Park
Tudor Road
Runcorn
Cheshire
WA7 1TA

www.epredia.com

LAB and user safety

Downdraft ventilation at chamber as well as dual filtration inside reagent cabinet promotes a safe environment for your staff.
Waste was trays for paraffin disposable creates fast safe removal of molten paraffin.
Ready to use 5L reagent design eliminates decanting.

For more information, please click on the attached Brochure, Operational Guide, Declaration of Conformity and case studies on the EXCELSIOR AS™;


Excelsior_AS_Brochure.pdf


Excelsior_Op-Guide.pdf


Excelsior AS - EU IVDR Declaration of C


Excelsior Univ Hospital of Wales Cas


Excelsior Xylene Free Processing Case Study


Excelsior AS vs VIP Study Brief EN.pdf

Epredia
Manor Park
Tudor Road
Runcorn
Cheshire
WA7 1TA

www.epredia.com

Training

Instrument	Course Name	Training Level (Key Operator or Basic)	Duration	Course Description	No. of places offered	Certificate
Epredia Excelsior Tissue Processor	Excelsior	Super user and basic training can be provided	2 hours	How to use the Excelsior processor & make changes to the protocols/setup plus maintenance tasks	Training offered to all	Certificates provided and registered

The training that is provided as part of the contract is the Super User training and/or Basic training, as part of this training, it is recommended that the newly trained Super Users are actively involved in the training of the Basic Users within the laboratory, this improves Super User confidence in using the instruments and means that the laboratory will have a high level of competency and self-sufficiency to perform their own in-house training when staffing changes. We provide various levels of training to your different users within the lab in 2 levels, super user, advanced and basic with a schedule worked out before starting with certification supplied after for each staff member.

Scientific Supplies & Technology Int'l have worked as distribution partners with Epredia for over 10 years and they are trained and certified to carry out all the installation and training required, Epredia usually recommend 2 hours with each super user initially with 1 hour spent on basic user training, however, dependent on SST Int'l schedule there might be a few differences on how they provide this, however, similarly it is standard across the board. This will be topped up during the verification period of the instruments with additional training provided specific to the laboratory and workflow of the individual site.

An individual training plan will be provided as well as user guides once the number of staff for training on site is known, usually 1 day is scheduled for this, but it can be increased as needed.

We also provide Webinar's and Live Lab Demo's which maybe useful for users for recap information, please click on the links below to explore and/or register;

Epredia Education Webinars for Anatomical Pathology Lab | Epredia

Pathology Lab Product Demo | Epredia

Epredia Instrument platform Go-Live

The Epredia instrument is ready to go live once the laboratory has successfully completed their validation paperwork. Once the instruments has gone Live, Epredia will fill in a Certificate of Completion, to be signed by the Laboratory Manager to indicate that they are satisfied with the installation, optimisation and training and are happy to use the Instrument for routine diagnostic use.

Epredia
Manor Park
Tudor Road
Runcorn
Cheshire
WA7 1TA

www.epredia.com

Warranty

Epredia Instrument Service Level Agreement

The Excelsior AS™ tissue processor is covered under an initial 12-month warranty, however all servicing and training will be covered by our distribution partner Scientific Supplies & Technology, 7245 NW 43rd St, Miami, FL 33166, USA.

SST Int'l have quoted for year 2 & 3 for service as requested within the ITT specification.

Scientific Supplies & Technology Int'l Service Statement

SST Int'l. provides comprehensive service solutions to our customers timely and efficiently, including technical support, spare parts support, training, field service, upgrade, warranty service, service contract and on demand service. All of our Field Service Engineers and Application Specialists are factory trained and certified, and because they are located in Miami, Belize, Jamaica, St. Lucia, and Guyana, we are able to ensure quick response times for all equipment service issues.

Technical Support

SST provides technical support via phone, email, orally, WhatsApp, or by any means during the entire life cycle of instruments sold by SST.

Spare Parts Support

SST carries spare parts for MOST products that we offer. If for any reason we do not have the required part needed, we will endeavor to work with Epredia to obtain the part in a quick, reliable timeframe.

Training

SST provides multiple levels of training to our customers whether in our Miami office or in-lab during installation. Our various types of training include: web-based, on-site or internal, scheduled and on demand.

Field Service

SST Field Service Engineers provide preventive maintenance, calibration, breakdown repair and other field services on request or as scheduled as necessary.

For service inquiries:
Phone: 305-593-21-37
Email: service@sst-intl.com

Epredia
Manor Park
Tudor Road
Runcorn
Cheshire
WA7 1TA