Door

Check gasket sealing (with trolley in cavity)

Check alignment of trolley front bottom plate with façade gasket (adjust as required) 🗵

Electric Compartment

Cleanness: Effective Wear and Tear: No

Overheating: No Oxidations: No

Cleanness Internal

Cavity Cleanness: Effective

Cavity Fan area behind suction wall: Effective

If either are poor, cavity should be cleaned and reassessed.

Operating System

Confirm correct OS Version:

Confirm Heat Inactivation Program Steps: ⊠

Confirm Oven Security in place:

Installation Observations or comments:

Click or tap here to enter text.

The system has been installed and commissioned in line with the system specification.

The system has passed Installation Qualification:



Operation Qualification

The operation qualification (OQ) ensures that the system operates within the specified limits consistently.

The OQ is carried out using a 17-point temperature mapping exercise using UKAS calibrated temperature probes. The system will run at two different temperatures and the cavity variance

calculated. The probe locations shall be detailed on the certificate and shall be distributed as follows:

Tray 1 - Top	5 Probes – Corners and center
Tray 3	1 Probe – Center
Tray 5	5 Probes - Corners and center
Tray 7	1 Probe - Center
Tray 10 - Bottom	5 Probes - Corners and center

Raw data will be supplied as a comma-delimited file.

Acceptance Criteria

Setpoint 85°C - Preheat Stage

- The system shall achieve setpoint +/- 10% measured over of a stable period >= 15 minutes.
- The maximum temperature difference between probes for each read shall be < 5.5°C

Setpoint 70°C - Inactivation Stage

- The system shall achieve setpoint +/- 6% measured over of a stable period >= 15 minutes.
- The maximum temperature difference between probes for each read shall be < 3°C

Operation Qualification

OQ date: 17/01/2022

OQ operators:

TMS Europe: Duncan Couch

BiologIC Technologies: Colin Barker

Issued Certificate Number: 62032

Acceptance criteria met: 🛛

Operation Qualification Observations or Comments:

Initial testing showed an elevation of the indicated temperature at 70 °C. The temperature was calibrated and remapped and met the acceptance criteria.

Outcome

The system has been tested in line with the OQ acceptance criteria.

The system has passed Operation Qualification:



Performance Qualification

The performance qualification (PQ) ensures that the system executes the intended process correctly when operated as intended.

The PQ is carried out using UKAS calibrated thermocouples attached to diagnostic probes and overpacked to UN3733. These probes are analogues of diagnostic samples and have been shown as appropriate in the original design and validation of the heat inactivation process.

Eight sample analogue probes are run in the system alongside dummy samples to form "complete" trays of 25 samples. The system is run using the "Heat Inactivation" program and the data analysed.

The probes are distributed evenly throughout the samples.

Raw data will be supplied as a comma-delimited file.

Acceptance criteria

- · The heat inactivation program should run without error.
- All probes should achieve >=65°C for >10 minutes.
- . A temperature >80 °C should not be exceeded for each diagnostic probe.

Performance Qualification

PQ date: 07/01/2022

PQ operator (BiologIC Technologies):

Probes Calibration Certificate Number: 55452

Acceptance criteria met:

Performance Qualification Observations or Comments:

Ideally the system is filled with dummy samples to represent a full load; however, these samples were not available. The risk is mitigated as these ovens have been previously validated for Heat Inactivation using this protocol and operated under mixed load levels (circa 750,000 samples have been processed between three ovens). This PQ represents a verification rather than primary validation. The oven has been shown to operate whilst being well below maximum capability in terms of heating power and so there is sufficient headroom to accommodate the thermal load represented by a full oven.

Outcome

The system has been tested in line with the PQ acceptance criteria.

The system has passed Performance Qualification:



System Release for Use

The system has undergone IQ, OQ, and PQ.

Assessment	Status
Installation Qualification	Pass
Operation Qualification	Pass
Performance Qualification	Pass

The results show the system to be behaving as expected and support the application of the system in the validated heat inactivation process i.e. heating 260 samples of a validated type to >65°C for more than 10 minutes.

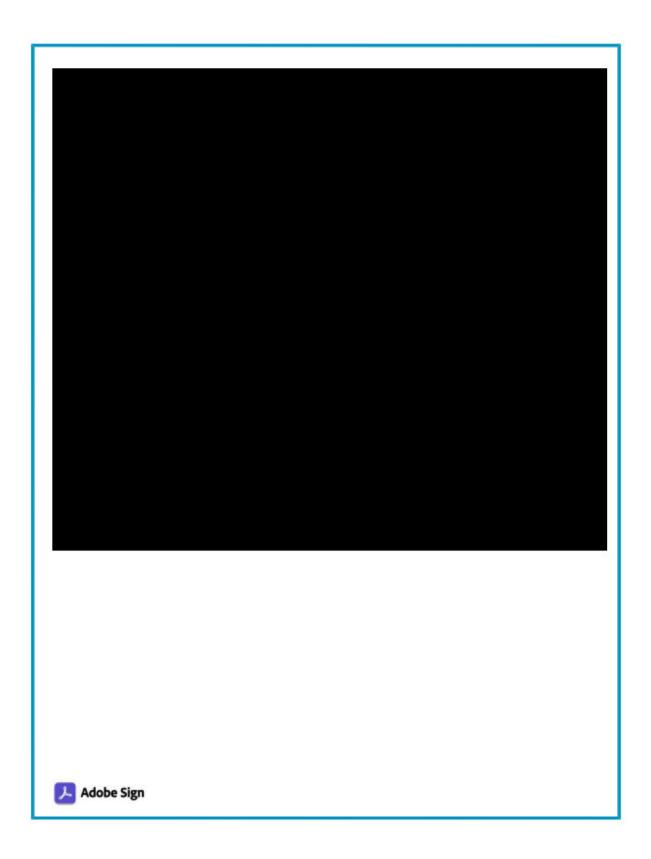
We recommend that the oven may be put into use subject to the following notes:

- This recommendation is restricted to the validated sample types and assumes there is no modification to the oven or process.
- The system must undergo preventative maintenance at regular intervals not less than twice a year. Failure to maintain may void warranty and lead to increased risk of exposure to live virus.
- The system must be revalidated after maintenance or repair. Repairs or maintenance may result in incomplete heat inactivation and lead to increased risk of exposure to live virus.
- The protocol for heat inactivation of Covid-19 has been validated at >65°C for more than 10 minutes. It is wholly the responsibility of DHSC to ensure that the protocol and its full implementation is fit for the ultimate purpose of inactivating viral samples, with no liability to BiologIC





 $Adobe\ Sign\ Transaction\ Number:\ CBJCHBCAABAAyz Fn IngXxu8AdPbhtBttuJXVNEARJSgU$



Appendix 9: PPM Acceptance Job Sheet



Service Report for a BiologIC Heat Inactivation system for Covid-19 Diagnostic samples.

This document is a record of the annual servicing of a bulk heat inactivation process for diagnostic samples based on a modified Electrolux Professional Skyline oven.

System Identification

For the purpose of traceability, the system shall be identified by the serial number of the oven.

Location: Click or tap here to enter text.

Oven Identity Card: PNC: Click or tap here to enter text. Serial: Click or tap here to enter text.

Operation Qualification

The operation qualification (OQ) ensures that the system operates within the specified limits consistently.

The OQ is carried out using a 17-point temperature mapping exercise using calibrated temperature probes. The system will run at two different temperatures and the cavity variance calculated. The probe locations shall be detailed on the certificate and shall be distributed as follows:

Tray 1 - Top	5 Probes – Corners and center
Tray 3	1 Probe – Center
Tray 5	5 Probes – Corners and center
Tray 7	1 Probe - Center
Tray 10 – Bottom	5 Probes – Corners and center

Raw data will be supplied as a comma-delimited file.

Acceptance Criteria

Setpoint 85°C - Preheat Stage

- The system shall achieve setpoint +/- 10% measured over of a stable period >= 15 minutes.
- The maximum temperature difference between probes for each read shall be < 5.5°C

Setpoint 70°C - Inactivation Stage

- The system shall achieve setpoint +/- 6% measured over of a stable period >= 15 minutes.
- The maximum temperature difference between probes for each read shall be < 3°C

Operation Qualification

OQ date: Click or tap to enter a date.

OQ	O	ne	ra	to	rs:
\sim	0	\sim	ıu	w	o.

BiologIC Technologies: Click or tap here to enter text.

Issued Certificate Number: Click or tap here to enter text.

Acceptance criteria met: □

Operation Qualification Observations or Comments:

Click or tap here to enter text.

Outcome

The system has been tested in line with the OQ acceptance criteria.

The system has passed Operation Qualification:

For BiologIC Technologies

Signature:

Name: Click or tap here to enter text.

Role:

System Release for Use

The results show the system to be behaving as expected and support the application of the system in the validated heat inactivation process i.e. heating 260 samples of a validated type to >65°C for more than 10 minutes.

We recommend that the oven may be put into use subject to the following notes:

- This recommendation is restricted to the validated sample types and assumes there is no modification to the oven or process.
- The system must undergo preventative maintenance at regular intervals not less than twice a year. Failure to maintain may void warranty and lead to increased risk of exposure to live virus.
- The system must be revalidated after maintenance or repair. Repairs or maintenance may result in incomplete heat inactivation and lead to increased risk of exposure to live virus.
- The protocol for heat inactivation of Covid-19 has been validated at >65°C for more than 10 minutes. It is wholly the responsibility of DHSC to ensure that the protocol and its full implementation is fit for the ultimate purpose of inactivating viral samples, with no liability to BiologIC

For BiologIC Technologies

Signature:

Name: Click or tap here to enter text. Role: Click or tap here to enter text. Date: Click or tap to enter a date.

Declaration by Customer

I declare that I accept the contents of this report and recognise the service as complete. For and on behalf of the Customer:

Name:		
Role:		
Organisation:		
Date:		
Signature:		

Appendix 10: MI Template (Example)

		CONTRACT DETAILS							_					
Contract Ref	PO#	Product Description	Qty ordered	PO end date	PO Value	Invoice Number	Invoice Date	Invoice Paid Yes / No						
C****	Роххх	HEATINACTIV OVEN	1											
C****	Poxxxx	Electolux Service Contract Year 1	3											
C****	Poxxxx	B ologIC Service Contract Year 1	3											
'		-			•				-					
		BiologIC Service Agreement												
Contract Ref	PO#	Instrument	Contract Type	Serial Number	Biologic Service Period	Biologic Requal fication Date (Booked after 2nd Electrolux PM visit)	Site Signed Checklist/Jobsheet Provided?	Signed By (Name)	Call Out 1 - Date Used	Site Signed Check ist/Jobsheet Provided?	Signed By (Name)	Call Out 2 - Date Used	Site Signed Checklist/Jobsheet Provided?	Signed By (Name)
C96148	Pxxxxxx	Electrolux Oven 1 - SLS Supplied	Electrolux Maintenance	13720001	19/12/2023									
	Pxxxxxx	Electrolux Oven 2	Electrolux Maintenance	2820001	19/12/2023									
	Pxxxxxx	Electrolux Oven 3	Electrolux Maintenance	620001	19/12/2023									
		Electrolux Service Agreement			T.				1			_		
	PO#	Instrument	Contract Type	Serial Number	Electrolux Service Period	Preventative Mainenance Visit Date -	Site Signed Checklist/Jobsheet Provided?	Signed By (Name)	Preventative Mainenance Visit Date - 2	Site Signed Check ist/Jobsheet Provided?	Signed By (Name)			
Contract Ref	Pxxxxxx	Electrolux Oven 1 - SLS Supplied	Electrolux Maintenance	13720001	19/12/2023									
C96148	Pxxxxxx	Electrolux Oven 2	Electrolux Maintenance	2820001	19/12/2023									
C96148	Pxxxxxx	Electrolux Oven 3	Electrolux Maintenance	620001	19/12/2023									
		NON CHARGABLE AD HOC CALLOUTS	1											
Contract Ref	PO#	Instrument	Serial Number	Date Callout Requested	Target Date for Resolution	Call Out Details	Site Contact	Site Contact Details	Date Callout Completed	Location				
C96148	Pxxxxxx	Electrolux Oven 1 - SLS Supplied	13720001					·		RFL				
	Pxxxxxx	Electrolux Oven 2	2820001							RFL				
	Pxxxxxx Pxxxxxx	Electrolux Oven 2 Electrolux Oven 3	2820001 620001							RFL RFL				

Appendix 11 - Key Performance Indicators

• Supplier:

- a. Goods delivered on time and confirmation received from the Authority of Acceptance.
- b. Initial Services are performed in accordance with Appendix 2, sub-heading The Specification of Requirements sub-clauses 2, 3, 4, and 5.
- c. A management report in accordance with Appendix 10 of this Contract submitted to the Authority's Contract Manager, or other authorised representative, monthly, 2 (two) Business Days prior to each contract management meeting,
- d. Compliant invoices are issued to the Authority in accordance with clause 7.3 of this contract in a timely manner.
- e. Callouts in relation to either Sub-contractor are arranged and take place in accordance with agreed timescales with the Authority's Delivery Contact during the term of the Initial Services and any or all terms of the Optional Services.
- f. Confirmation of call-out arrangements confirmed by the Supplier in email to the Authority's Delivery Contact or other authorised representative, as may be advised from time to time, in a timely manner after notification received of the need for such callouts during the term of the Initial Services and any or all terms of the Optional Services.
- g. Any and all charges not covered by this Contract are advised to and agreed with the Authority in accordance with Appendix 2 sub-heading The Specification of Requirements sub-clause 10.

• Authority:

a. Payment of compliant invoices in accordance with clause 7.3 of this Contract.

Appendix 12 - Change Control Register (Template)

UK Sec Age	Contract Management Guide K Health ecurity gency Change Control Register											
Contract N	ntract Name: C102881 Provision of Heat Inactivation Oven and Preventative Maintenance for 3 Ovens at RFL.									Supplier:	SCIENTIFIC LABORATOR	Y SUPPLIES LTD (SLS)
	Cha	nge Details				Change Initiatio	n				Sign Off	
							Impact o	f Change				
Change Ref. No.	Status (choose from Drop down menu)	Description of Change	Change Raised by (organisation/ name/ title/ team)	Reason for change (e.g. changing needs, savings initiative, issues with original contract provision etc.)	Change approved in principle by:	Change notice sent to supplier (date)	Cost (provide total cost of change)	Time (insert date of any extension to the original contract term or programme)	Change Progress comments	Change approved for implementation by: (name / title)	Change sign off date (date of sign off of the amended contract documentation)	Change implementation date (start of new/ amended provision by supplier)
1												
2												
3												
5												
6												
7												
8												
10												
11												
12												
13 14												
15											 	
16												
17												
18 19												
20											 	
21	 										<u> </u>	
22												
23												
24												-
25 26	 					-				-	 	
27											 	
28												
29								1				



Appendix 13 – Risk Register and Issues Log (Templates)



Risk Register

Date	13/09/2022
Contract Title:	Provision of Heat Inactivation Oven and Preventative Maintenance for 3 Ovens at RFL.
Contract Atamis Reference No:	C102881
Commercial Contract Manager (CCM) Name	Geoff Johnston

												Post Mitigation			
Risk ID	Risk description	Risk consequence (Impact)	Date raised	Owner	Likelihood (1 5)	Impact (1 5)	Risk exposure (L x I)	Movement of Risk	Risk Status	Risk Response	Action required	Likelihood (1 5)	Impact (1 5)	Risk exposure (L x I)	Action Target Date
							0							0	
							0							0	
							0							0	
							0							0	
							0							0	
							0							0	
							0							0	1
							0							0	
							0							0	
							0							0	
							0							0	





Issue Log

Contract Title:	Provision of Heat Inactivation Oven and Preventative Maintenance for 3 Ovens at RFL.	Date	13/09/2022	Commercial Contract Manager Name	Geoff Johnston
Contract					
Atamis Reference No:	C102881				
Reference No:					

Issue ID	Issue and description	Category eg. performance specific goods/ service area etc.	Description	RAG	Raised By	Issue Owner	Associated Risk Ref No	Progress to date (include dates)	Status	Date Closed	Comments