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IQ/OQ Protocol
Installation Qualification/ Operation Qualification

CentriVap® DNA Systems

Labconco No. – 1058801, Rev. D, ECO L395
Available at **labconco.com**

Purpose and Scope IQ and OQ

This Qualification Protocol is solely intended to be used with Labconco CentriVap DNA Systems, which are new or relocated. CentriVap Mobile Console and other systems are covered in a separate document, #1058800.

Models: **CentriVap DNA Systems**

7970010	*7970011*

It is written to assist the end-user in validation of predetermined specifications. The protocol begins with planning the site for the piece of equipment and therefore is of value prior to receipt of delivery.

The use of this document does not replace the need for the CentriVap DNA Systems User's Manual (#7397604). Information within the User's Manual is required to complete this IQ/OQ Protocol. If the manual has been misplaced, copies can be obtained from the manufacturer or down-loaded from their website, www.labconco.com

Responsibilities

End-User – The ultimate user or otherwise appointed personnel in the lab is responsible to ensure the Concentrator is installed and operating properly. This document can assist in that validation. This document cannot however anticipate every application or unique situation encountered with the installation and operation. It is therefore essential that users, lab managers and safety officers work together to broaden the scope of this document through careful forethought.

End-User Employer – The employer is responsible for supporting the validation through adequate resources and training. The organization shall also ensure the validation process has been fully carried out prior to applying the Concentrator. Records should be stored in a safe, easily retrievable location. The location of the equipment and required validation should be included in the company's quality system.

Manufacturer – Labconco Corporation, certified ISO-9001, is responsible to fully test each CentriVap DNA System prior to shipment. The manufacturer must retain these records. Labconco's staff of Product Service Representatives and Product Specialists can assist with information on the purchase, delivery and installation. Labconco is not responsible for the actual installation or validation processes.

Performance Qualification

Once the Concentrator has been checked for proper installation and operation, its performance can be validated. Labconco cannot recommend specific procedures to do this. The performance validation should be designed to meet the specifications and accuracy required of the application.

In general this requires establishing acceptance criteria, making several runs and testing the results with calibrated equipment and qualified personnel.

A. Installation Qualification

Step	Description	Specification or Acceptance Criteria	Result	
			YES	NO
1	**Site Planning**			
1a	Space Requirements	Refer to Appendix B in User's Manual for dimensions of the model you have chosen. Has adequate counter space been provided for placement of the equipment?	Y	N
1b	Electrical Service	Refer to the User's Manual for a list of model numbers and their corresponding electrical requirements. Are services available for the equipment to be connected to an electrical circuit of adequate size and the proper voltage?	Y	N
		Does the service outlet match the power cord plug?	Y N/A	N
1c	Exhaust Requirements	Refer to the User's Manual. Have accommodations been made to vent the CentriVap safely?	Y	N
2	**Prior to Operation**			
2a	Damage Claims	Have the delivered products been inspected for any signs of damage that may have occurred while in transit? Keep packaging materials until inspection is complete. If damaged, refer to the User's Manual for information on shipping damage claims.	Y	N
2b	Rotor	Does the rotor match the size of tubes you wish to use in this Concentrator?	Y	N
		Has the rotor been placed into the Concentrator's chamber so that the hub is seated all the way down on the drive pin?	Y	N
2c	Handling Solvents	Has the Safety Officer or equivalent reviewed the safe handling, venting and disposal of solvents trapped?	Y N/A	N
2d	Glass Lid	If the solvents used attack acrylic, has the	Y	N

		optional glass lid been considered?	N/A	
2e	Secondary Trap	The Secondary Trap is an optional accessory. If necessary, has the appropriate type of chemical cartridge been procured for the samples to be run? Refer to the User's Manual.	Y N/A	N

B. Operational Qualification

Step	Description	Specification or Acceptance Criteria	Result	
			YES	NO
1	**Concentrator**			
1a	Preheat	Activate the Preheat feature. With the lid closed, does the chamber heat up?	Y	N
1b	Heat and Run	Select any program and set a higher than ambient temperature and set the Run Time to one minute to check operation. Does the rotor turn and the chamber heat when the lid is closed?	Y	N
1c	Run Timer	Did the alarm sound and rotor stop after one minute?	Y	N
1d	Interrupt Cycle Rotor Brake	Repeat the one-minute cycle, except this time: press the STOP button to interrupt the cycle. Did the rotor stop? When Run is pressed, did the cycle resume?	Y	N
1e	Shaft Speed	If rotor shaft speed is important to your work, measure with a calibrated tachometer. To do this, remove the rotor and measure the shaft rotation through the closed lid. (Typically reflective tape is attached to the top surface of the drive shaft.) Does the speed measure at least: 1650 RPM for the 115V, 1350 RPM for the 230V? Speed _____RPM's Measured with _____	Y N/A	N
2	**Vacuum Pump**			
2a	Start of Vacuum	Close the lid to the CentriVap. Press RUN. Did the vacuum pump start after the rotor reached operating speed?	Y	N

2b	Vacuum Level of the Pump	To check the vacuum level of the pump, place a stopper with a hole in the port in the rear of the chamber. Attach a vacuum gauge to the stopper. Vacuum should be at least 15 mbar. Gauge reading? _____ Type of gauge used? _____	Y N/A	N
3	**Personnel Training**			
3a	User Training	Have personnel that use the CentriVap DNA System been adequately trained? Are personnel familiar with: Volume limits of samples in vials; Symmetric loading of vials in rotor; Safe handling of solvents and vapors; Programming time and temp. parameters; Cleaning of the CentriVap and emptying the liquid trap?	Y	N

C. Summary

Labconco CentriVap DNA System IQ/OQ Document 1058801 Revision D

Equipment Location _____

CentriVap Ser. No. _____ Model No._____

User Protocol _____ Revision (or Date published) _____

Contact (print name):_____
Title: _____

Review the "Response" columns for answers of "NO." Use the area below to describe the deficiency or unacceptable results. Those deficiencies are to be followed with an instruction for "Corrective Actions." Once acceptable results are obtained, the deficiency is "accepted" by initialing the Corrective Action.

Step	Deficiency followed by Corrective Action	Initial