



SageELF IQ/OQ

UOC-460002 Rev. A

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Sheet **1** of **11**

Prepared by: AlexVira

SUMMARY

This document provides instructions and records for Installation Qualification (IQ) and Operational Qualification (OQ) for the SageELF platform .

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1.0 INTRODUCTION

1.1 Purpose

This guideline documents requirements and procedures for users or Sage Science Staff for installation qualifications and operational qualification (IQ/OQ)

1.2 Scope

This document provides a checklist of items and procedures to qualify the correct function of the SageELF upon installation, and ongoing operation.

1.3 Reference Documents

460001, SageELF Installation Guide, 460003 SageELF Operations Manual

All at the latest revision.

1.4 Responsibilities

The Applications Lab Director or designee will be responsible to ensure that this procedure is implemented.

2.0 INSTALLATION QUALIFICATION (IQ)

2.1 Instrument Origin and Identification

Instrument:	SageELF Fractionator
Instrument Description:	Agarose Gel Electrophoresis, Preparative Fractionation of DNA or protein samples.
Manufacturer:	Sage Science, Inc. 500 Cumming Center Suite 2400 Beverly, MA 01915 617.922.1832 www.sagescience.com
Service Contact:	Tel: 888.744.0144 Email: support@sagescience.com
Serial Number: (see back panel)	
Date Received:	
Installation Location:	
Purchase Order Number:	
ID or Asset Number:	

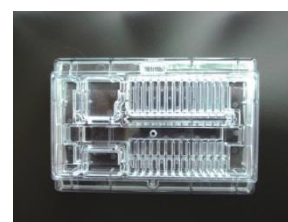
2.2 Instrument Delivery and Documentation

Verify that the following items have been received.

SageELF Instrument	
Power Supply	
Power Cord	
Documentation	
Operations Manual	
Accessories	
USB Computer Keyboard	
USB Mouse	
Mouse Pad	
USB Flash Drive	
Calibration Fixture 1	
Calibration Fixture 2	
Rinse Cassette 1	
Rinse Cassette 2	
LCD Display	
LCD Display	
Power Supply	
Power Cord	
HDMI/RS232 video cable	



Calibration Fixtures



Rinse Cassette

2.2 Instrument Delivery and Documentation (cont'd)

Is there any damage to the instrument or accessories?

Yes ☐ No ☐ **Comments:**

Has the manufacturer been informed of damage or missing items?

Yes ☐ No ☐ **If yes, corrective action taken::**

2.3 Environment and Siting

Manufacturers Recommendations	
Ambient Temperature between 17-25°C	
~30 x 30 in. bench space	
Proximity to 2 x 110V or 220V outlets	

Comments:

2.4 IQ Signature

Refer to Installation Guide, SSIXXMXXXX Rev.A
Installed by:

User ☐ Sage Science Representative ☐

IQ Completed By: _____ **Date:** _____

Comments:

3.0 OPERATIONAL QUALIFICATION (OQ)

3.1 Powering On the Instrument

Refer to Operations Manual (page 3-2)

Are the instrument and LCD display connected to power outlets ? Yes ☐ No ☐

Are the blue LEDs on the Cassette nests activated? Yes ☐ No ☐

Is the LCD Display on ? Yes ☐ No ☐

*Press power switch located on the rear of the instrument, and wait for software to launch
(approximately 30 seconds)*

Is the blue LED on the front panel activated? Yes ☐ No ☐

Did the SageELF software successfully launch (Main Tab)? Yes ☐ No ☐

Press the "Display Info" button to pop up the Information Window.

Software version: _____

Click the pop up window to exit.

3.2 Optical Calibration

Refer to Operations Manual (pages 6-1 and 6-2)

Have both calibration fixtures been placed over the detectors ?

Yes ☐ No ☐

Is the Lid Closed?

Yes ☐ No ☐

Press the "Clear Run Data" Button

Press the "Calibrate Detector" Button

Select both nests in the Detector Calibration pop up window

Press "Start"

Did both nests pass the Calibration Test

Yes ☐ No ☐

Comments:

3.3 Current Test

Refer to Operations Manual (pages 8-1 and 8-2, and 9-1 to 9-4)

Prepare two gel cassettes as outlined in Section 8 of the Operations Manual

Place the two gel cassettes onto the instrument Nests 1 and 2 and close the lid.

Have the cassettes been prepared and the adhesive tape removed ? Yes ☐ No ☐

Is the lid closed? Yes ☐ No ☐

Press the “Clear Run Data” Button

Press the “Check Current” Button

Select both cassette in the Current pop up window

Press “Start”

Did both cassettes pass the Separation Test Result? Yes ☐ No ☐

Did both cassettes pass the Elution Test Result? Yes ☐ No ☐

Comments:

3.4 OQ Signature

Assessed by:

User ☐ Sage Science Representative ☐

OQ Completed By: _____ **Date:** _____

Serial Number: _____

Have there been any deviations?

Yes ☐ No ☐ **Comments:**

Has the manufacturer been informed of the deviations?

Yes ☐ No ☐ **If yes, corrective action taken::**

Comments: