



SAGE SCIENCE INC

SageHLS IQ/OQ

460041 Rev. A
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Sheet **1** of **11**

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SUMMARY

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

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Table of Contents

1.0	INTRODUCTION	3
1.1	Purpose.....	3
1.2	Scope.....	3
1.3	Reference Documents	3
1.4	Responsibilities.....	3
2.0	INSTALLATION QUALIFICATION (IQ)	4
2.1	Instrument Origin and Identification	4
2.2	Instrument Delivery and Documentation.....	5
2.3	Environment and Siting	6
2.4	IQ Signature	7
3.0	OPERATIONAL QUALIFICATION (OQ)	8
3.1	Powering On the Instrument	8
3.2	Optical Calibration.....	9
3.3	Current Test	10
3.4	OQ Signature	11

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 SageHLS upon installation, and ongoing operation.

1.3 Reference Documents

460033, SageHLS Installation Guide, 460034 SageHLS 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:	SageHLS System
Instrument Description:	Agarose Gel Electrophoresis, DNA Extraction, Fragmentation, and Size Selection
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.

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



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, SageHLS Installation Guidelines Rev A 460033
Installed by:**

User Sage Science Representative

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

Comments:

3.0 OPERATIONAL QUALIFICATION (OQ)

3.1 Powering On the Instrument

Refer to the SageHLS Operations Manual, page 2-2.

Are the instrument and LCD display connected to power outlets ? 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 SageHLS 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 Current Test

Refer to SageHLS Operations Manual

Load the “Temp Test” workflow file (Section 6.5 and 6.6)

Prepare two gel cassettes as outlined in Section 12 (pages 12-4 to 12-6)

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

Run the Current Test (Section 6.7)

Has the “Temp Test” workflow file been loaded? Yes No

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

Is the lid closed? Yes No

Have all four sample lanes been selected in the Nest Configuration? Yes No

Press the “Clear Run Data” Button (if necessary)

Press the “Check Current” Button

Press “Start” in the Current Check pop up window

Did all lanes pass the Separation Test Result? Yes No

Did all lanes pass the Elution Test Result? Yes No

Press the “Return” in the Current Check Window and proceed to the Temperature Test (next section)

Comments:

3.3 Temperature Test

Refer to the SageHLS Operations Manual (Section 6.8, Running a Workflow)

Press the “Run Workflow” Button

Press “Start”

Wait for the Temperature Test to complete: 9 minutes.

Did the temperature test complete without an error warning?

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: