



## **SAGE SCIENCE INC**

PippinHT IQ/OQ

**UOC-460006 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 PippinHT 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 PippinHT upon installation, and ongoing operation.

### **1.3 Reference Documents**

460004, PippinHT Installation Guide, 460005 PippinHT 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

<b>Instrument:</b>	PippinHT DNA Size Selection System
<b>Instrument Description:</b>	Automated Preparative Agarose Gel Electrophoresis
<b>Manufacturer:</b>	Sage Science, Inc. 500 Cumming Center Suite 2400 Beverly, MA 01915 617.922.1832 www.sagescience.com
<b>Service Contact:</b>	Tel: 888.744.0144 Email: support@sagescience.com
<b>Serial Number:</b> (see back panel)	
<b>Date Received:</b>	
<b>Installation Location:</b>	
<b>Purchase Order Number:</b>	
<b>ID or Asset Number:</b>	

## **2.2 Instrument Delivery and Documentation**

Verify that the following items have been received.

<b>PippinHT Instrument</b>	
Power Supply	
Power Cord	
<b>Documentation</b>	
Operations Manual	
<b>Accessories</b>	
USB Computer Keyboard	
USB Mouse	
Mouse Pad	
USB Flash Drive	
Calibration Fixture 1	
Calibration Fixture 2	
Rinse Cassette 1	
Rinse Cassette 2	
<b>LCD Display</b>	
LCD Display	
Power Supply	
Power Cord	
HDMI/VGA video cable	



Calibration fixtures  
with protective covers.



Rinse Cassettes

**Comments:**

**2.4 IQ Signature**

**Refer to Installation Guide, 460004 Rev.B**

**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 PippinHT software successfully launch (Main Tab)? Yes ☐ No ☐

*Click the PippinHT logo on the bottom right of the Main screen 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 both the detector arrays ?

Yes ☐ No ☐

Is the lid closed?

Yes ☐ No ☐

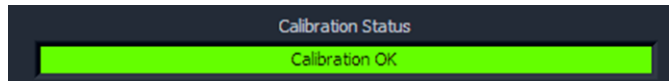
*Go to the Main screen*

*Press the CALIBRATE button (opens the calibration pop-up window)*

*Press the CALIBRATE button in the pop-up window*

Does the Calibration Status window display “Calibration OK”:

Yes ☐ No ☐



**Comments:**

### 3.3 Continuity Test

Refer to PippinHT Operations Manual (pages 7-1 to 7-3 for the gel preparation procedure, and 8-1 to 8-2 for the Continuity Test.)

Prepare two gel cassettes as outlined in Section 7 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 ☐

*Go to the Main screen*

*Press the TEST button (opens the continuity test pop-up window)*

*Press the CALIBRATE button in the 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:**