Attachment 5 – Test Instrument Log

Objective:

The objective of this section is to document the calibration of all test instruments that are used during the execution of the IQ/OQ protocol.

Procedure:

5. Fill out the table below for each test instrument used during execution of the IQ/OQ protocol.

Acceptance Criteria:

Documentation of the calibration of all test instruments that are used during the execution of the IQ/OQ protocol are identified, available, recorded and attached.

Result:

Have the acceptance criteria been met? (Y/N) _____ If Not, Deviation No: _____

Performed By: _____ Date: _____

Reviewed By: _____ Date: _____

Attachment 5 – Test Instrument Log (Cont.)

Instrument Description	Instrument ID	Calibration Date	Calibration Due Date	Cal Cert Attached?	Performed By / Date
Fluke Multimeter	2858	10Feb 20	10Feb 21	☑ Yes ☐ No	AR 10/07/2020
Hand held Laser Particle Counter	2640	10/29/2019	10/29/2020	☑ Yes ☐ No	AR 10/08/2020
RCS standart	2769	27 Jul 2020	27 Jul 2021	☑ Yes ☐ No	AR 10/08/2020
				☐ Yes ☐ No	
				☐ Yes ☐ No	
				☐ Yes ☐ No	
				☐ Yes ☐ No	
				☐ Yes ☐ No	
				☐ Yes ☐ No	
				☐ Yes ☐ No	

Comments:

_____

_____

Performed By: _____ Date: _____

Reviewed By: _____ Date: _____

Tektronix®

CMS 2/11/20

Certificate of Calibration

15356892

Instrument Identification

Company ID: 98203
APHENA PHARMA SOLUTIONS
CHERYL SCWARZ
7978 INDUSTRIAL PARK ROAD
EASTON, MD 21601

PO Number: 44804

COPY
TPR 10/07/2020

Instrument ID: 2858
Manufacturer: FLUKE
Description: TRUE RMS MULTIMETER

Model Number: 87 V
Serial Number: 38910207

Certificate Information

Reason For Service: ON-SITE CALIBRATION
Type of Cal: NORMAL
As Found Condition: IN TOLERANCE
As Left Condition: IN TOLERANCE
Procedure: 2102915 80 SERIES V CALIBRATION MANUAL; REV.1, 2/05
Remarks: *Refer to attached data.*

Technician: ERIC SPEARS
Cal Date 10Feb2020
Cal Due Date: 10Feb2021
Interval: 12 MONTHS
Temperature: 21.0 C
Humidity: 32.0 %

Tektronix certifies the performance of the above instrument has been verified using test equipment of known accuracy, which is traceable to the International System of Units (SI), National Metrology Institutes (NIST, NPL, PTB), derived from ratio type measurements, compared to reference materials or recognized consensus standards. The policies and procedures comply with ANSI/NCSL Z540.1-1994.
The quality system complies with ISO9001.

Approved By: ERIC SPEARS
Service Representative

Issue Date: 2/10/2020

Calibration Standards

T Traceable#	Inst. ID#	Description	Manufacturer	Model	Cal Date	Date Due
14922341	01-0544	HUMIDITY AND TEMPERATURE INDICATOR	VAISALA	HMI41/HMP46	21Aug2019	21Sep2020
14986670	01-1173	CALIBRATOR	FLUKE	5520A-SC1100/PC	16Sep2019	16Sep2020

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AR 10/07/2020

Tektronix®

Certificate Number: 15356892

Manufacturer: FLUKE
ID / Asset Number: 2858

Model Number: 87 V
Calibration Date: 10-Feb-2020

Function / Range	Nominal Value	As Found	Result	As Left	Result	Min	Max	Units
AC Voltage Tests								
600 mV Range @ 60 Hz	330.0	329.6	Pass	Same	Pass	327.3	332.7	mV
@ 13 kHz	600.0	602.4	Pass	Same	Pass	586.0	614.0	mV
6 V Range @ 60 Hz	3.300	3.298	Pass	Same	Pass	3.275	3.325	V
@ 20 kHz	3.300	3.282	Pass	Same	Pass	3.214	3.386	V
60 V Range @ 60 Hz	33.00	32.98	Pass	Same	Pass	32.75	33.25	V
@ 20 kHz	33.00	32.87	Pass	Same	Pass	32.14	33.86	V
600 V Range @ 60 Hz	330.0	329.9	Pass	Same	Pass	327.5	332.5	V
@ 2.5 kHz	330.0	330.1	Pass	Same	Pass	323.0	337.0	V
1000 V Range @ 60 Hz	500	500	Pass	Same	Pass	494	506	V
1000 V Range @ 1 kHz	1000	1002	Pass	Same	Pass	986	1014	V
Frequency Tests								
600 mV Range @ 150 mV	99.95	99.95	Pass	Same	Pass	99.93	99.97	kHz
600 mV Range @ 150 mV	199.50	199.50	Pass	Same	Pass	199.48	199.52	kHz
6 V Range @ 0.7 V	99.95	99.95	Pass	Same	Pass	99.93	99.97	kHz
60 V Range @ 7 V	99.95	99.95	Pass	Same	Pass	99.93	99.97	kHz
6 V Range, 3.4 V @ 1 kHz Sq	1000.0	1000.0	Pass	Same	Pass	999.8	1000.2	Hz
Duty Cycle Test								
6 V Range, 5 V @ 1 kHz Sq	50.0	50.0	Pass	Same	Pass	49.7	50.3	%
DC Voltage Tests								
6 V Range	3.300	3.300	Pass	Same	Pass	3.297	3.303	V
60 V Range	33.00	33.00	Pass	Same	Pass	32.97	33.03	V
600 V Range	330.0	330.0	Pass	Same	Pass	329.7	330.3	V
1000 V Range	1000	1000	Pass	Same	Pass	998	1002	V
600 mV Range	33.0	33.0	Pass	Same	Pass	32.9	33.1	mV
600 mV Range	330.0	330.0	Pass	Same	Pass	329.6	330.4	mV
Resistance Tests								
600 Ω Range	330.0	330.2	Pass	Same	Pass	329.1	330.9	Ω
6 kΩ Range	3.300	3.300	Pass	Same	Pass	3.292	3.308	kΩ
60 kΩ Range	33.00	33.01	Pass	Same	Pass	32.92	33.08	kΩ
600 kΩ Range	330.0	330.1	Pass	Same	Pass	327.9	332.1	kΩ
6 MΩ Range	3.300	3.301	Pass	Same	Pass	3.279	3.321	MΩ
50 MΩ Range	30.00	30.01	Pass	Same	Pass	29.67	30.33	MΩ
60 nS Range	0.00	-0.01	Pass	Same	Pass	-0.30	0.30	nS
60 nS Range	10.00	10.00	Pass	Same	Pass	9.60	10.40	nS
Diode Test								
6 V Range	3.000	2.999	Pass	Same	Pass	2.939	3.061	V
DC Current Tests								
600 µA Range	330.0	330.1	Pass	Same	Pass	328.9	331.1	µA
6000 µA Range	3300	3300	Pass	Same	Pass	3291	3309	µA
60 mA Range	33.00	33.00	Pass	Same	Pass	32.89	33.11	mA
400 mA Range	330.0	329.9	Pass	Same	Pass	329.1	330.9	mA
6 A Range	3.000	3.000	Pass	Same	Pass	2.990	3.010	A
10 A Range	10.00	10.00	Pass	Same	Pass	9.96	10.04	A
AC Current Tests								
600 µA Range @ 60 Hz	330.0	329.9	Pass	Same	Pass	326.5	333.5	µA
6000 µA Range @ 60 Hz	3300	3299	Pass	Same	Pass	3265	3335	µA
60 mA Range @ 60 Hz	33.00	32.98	Pass	Same	Pass	32.65	33.35	mA
400 mA Range @ 60 Hz	330.0	329.8	Pass	Same	Pass	326.5	333.5	mA
6 A Range @ 60 Hz	3.000	2.997	Pass	Same	Pass	2.968	3.032	A
Capacitance Tests								
Open Input	0.26	0.26	Pass	Same	Pass	0.21	0.31	nF
100 nF Range	5.00	5.00	Pass	Same	Pass	4.70	5.30	nF
100 µF Range	9.50	9.49	Pass	Same	Pass	9.20	9.80	µF
Low Pass Filter Test								

Tektronix®

Certificate Number: 15356892

Manufacturer: FLUKE
ID / Asset Number: 2858

Model Number: 87 V
Calibration Date: 10-Feb-2020

Function / Range	Nominal Value	As Found	Result	As Left	Result	Min	Max	Units
1000 V Range @ 400 Hz	400	391	Pass	Same	Pass	376	408	V
@ 800 Hz	400	279	Pass	Same	Pass	226	340	V
Peak Min/Max Test								
6 Vp-p, 2 kHz Sq (Max)	4.000	4.012	Pass	Same	Pass	3.897	4.103	V
6 Vp-p, 2 kHz Sq (Min)	-2.000	-2.006	Pass	Same	Pass	-2.102	-1.898	V
Temperature								
Type K	0.0	0.2	Pass	Same	Pass	-1.0	1.0	°C
Type K	100.0	100.3	Pass	Same	Pass	98.0	102.0	°C

Decision Rule 1 - Accredited Calibration Datasheets may contain measurements that are not covered by the Scope of Accreditation. These measurements are indicated by a pound sign(#). Measurement Uncertainty IS NOT taken into account for determining PASS or FAIL.

********END OF MEASUREMENT REPORT********

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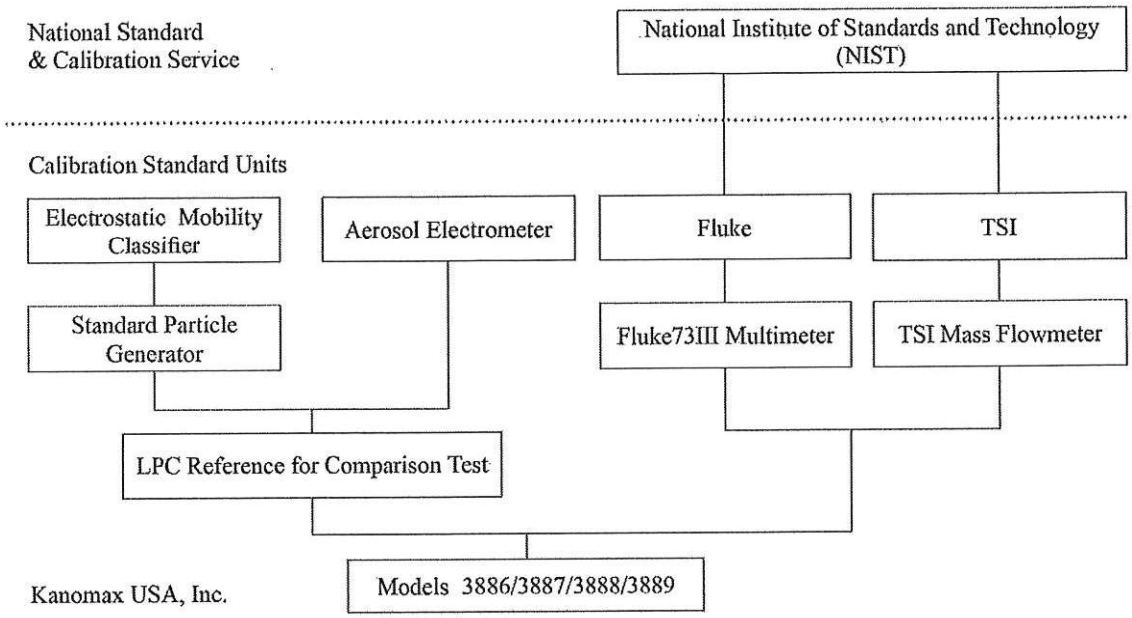
10/07/2020

ID-2640
cms
12/11/19

Traceability Certificate of Calibration
Handheld Laser Particle Counter



Standards	Model	S/N	Calibrator
LPC Reference for Comparison Test	3782-06	180806	Kanomax Japan Inc.
TSI Mass Flowmeter	4043	40431336011	TSI
Fluke Multimeter	Fluke73III	76876061	Innocal
Thermo Scientific 300 nm particles	3000 A/B	174664	Thermo Scientific
Thermo Scientific 500 nm particles	3500/A	209145	Thermo Scientific
Thermo Scientific 5000 nm particles	4205/A/C	200536	Thermo Scientific

Kanomax USA, Inc. (KUI) does hereby certify that all materials, components, and workmanship used in the manufacture of this equipment are in strict accordance ith the applicable specifications agreed upon by KUI and the customer and with all published specifications. The accuracy and stability of standards maintained by KUI are traceable to the National Institute of Standards and Technology, or have been derived from acceptable values of natural physical constants, or by the ratio type of self-calibration. This calibration has been performed in accordance with procedures and standards stipulated in JIS B-9921. Calibration results may drift from documented values prior to calibration due date attributable to various factors. Results obtained apply to the UUT only and are reflective of conditions at the time of this test.

KANOMAX USA, INC.

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10/02/2020

As Received

Cert # 102919.01

Test Sheet

Customer	Aphena Pharma Solutions
Model	3887 Particle Counter
Serial No.	025390
Cal Date	10/29/2019
Amb. Condition	22.5 ℃ 49.8 %RH
Atm. Pressure	1005 hPa
Next Cal	10/29/2020

Item	Procedure／Standard	Result	Judge
Sampling air flowrate	The flowrate should be within 2.83 L/min ±5%.	2.89 L/min	O.K
False count level	The count value should be below 1 count per 10 minutes when the zero-filter is put on the LPC inlet.	0 COUNTS	O.K
Threshold voltage	The threshold voltage for each particle size of Standard PSL particles should be less than 5V respectively.	V0.3= 0.922 V V0.5= 0.950 V V5.0= 0.594 V	O.K
Comparison Test	The ratio of the particle counts of the calibrated LPC to the standard one should be 100%+/- 10% for the 0.3 and 0.5 μm and 50%+/- 20% for 5um standard particles.	0.3 105.5% %	O K
		0.5 92.4% %	O K
		5.0 55.5% %	O K

10/29/2019

P Serio

Kanomax Usa
219 US Hwy 206
Andover, NJ 07821

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10/02/2020

Final Data Cert # 102919.01

Test Sheet

Customer	Aphena Pharma Solutions
Model	3887 Particle Counter
Serial No.	025390
Cal Date	10/29/2019
Amb. Condition	22.5 °C 49.8 %RH
Atm. Pressure	1005 hPa
Next Cal	10/29/2020

Item	Procedure／Standard	Result	Judge
Sampling air flowrate	The flowrate should be within 2.83 L/min ±5%.	2.89 L/min	O.K
False count level	The count value should be below 1 count per 10 minutes when the zero-filter is put on the LPC inlet.	0 COUNTS	O.K
Threshold voltage	The threshold voltage for each particle size of Standard PSL particles should be less than 5V respectively.	V0.3= 0.954 V V0.5= 0.900 V V5.0= 0.594 V	O.K
Comparison Test	The ratio of the particle counts of the calibrated LPC to the standard one should be 100%+/- 10% for the 0.3 and 0.5 µm and 50%+/- 20% for 5um standard particles.	0.3 101.3% %	O K
		0.5 103.1% %	O K
		5.0 55.5% %	O K

10/29/2019 P Serino

Kanomax Usa
219 US Hwy 206
Andover, NJ 07821

ID 2769

CMS 7/31/20

RCS Standard Certificate of Calibration

Customer Information:	Aphena Pharma Solutions 7978 Industrial Park Road Easton, MD 21601

Certificate Number
C8991185
Serial Number
27613

Unit Timing test – Acceptable Range of Tolerance at each setting is +/- 2%

As received				As Left			
Setting		As measured (in seconds)	Difference	Setting		As measured (in seconds)	Difference
8	min	481.47	0.31%	8	min	481.47	0.31%
4	min	241.11	0.46%	4	min	241.11	0.46%
2	min	120.68	0.57%	2	min	120.68	0.57%
1	min	60.44	0.73%	1	min	60.44	0.73%
0.5	min	30.32	1.07%	0.5	min	30.32	1.07%

Unit Speed (RPM) test – Acceptable Range of Tolerance from Standard value of 4096 RPM is +/- 2%

As received				As Left			
Standard		As measured (in RPM)	Difference	Standard		As measured (in RPM)	Difference
4096	RPM	4087	-0.22%	4096	RPM	4087	-0.22%

The performance of this instrument conforms with the manufacturer's specification: ☒ Yes ☐ No

Test Conditions:

Temperature (°C):	21.0	Relative Humidity (%):	61.0	Impeller condition:	OK

Test Equipment: Tools and standards used for calibration are traceable to National Institute of Standards and Technology (NIST) Standards.

Instrument	Manufacturer	Model	Serial Number	Calibration Due
Stopwatch	Control Company	1051	191887852	17 JAN 2021
Tachometer	Extech	461920	Z350444	24 JAN 2021
Hygrometer/ Thermometer	T&D	TR-73U	F80640C0	26 SEP 2020

The above serial numbered instrument has been calibrated and tested in accordance to the current standard operating procedure. Certificate completed according to document 00015374FM.

Calibrated by: _____ Date: 27 Jul 2020

Verified by: _____ Date: 27 JUL 2020

Calibration Performed:	27 JUL 2020
Next Calibration Due:	27 JUL 2021

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AR 10/02/2020

MilliporeSigma
80 Ashby Road, Bedford MA 01730 U.S.A.
Phone: 1-800-MILLIPORE (+1 800-645-5476) Email: na3customerservice@emdmillipore.com

Certificate of Decontamination 00005667FM – Equipment/Hardware

This form is intended for use with Equipment or Hardware (including rented or loaned equipment, Lab Water Systems, etc.) This form must be filled out in its entirety and signed by the end user of the product.

Trackwise Reference: _____

1. Customer (End User) Information			
Company Name:		**Contact Name:**	
Address:		**Job Title:**	
		Phone:	
		E-mail:	

2. Product Information			
Product Name:			
Catalog No:		**Serial No(s):**	
Lot No(s):		**Quantity:**	
☐ **Check here if product was not used. (Please skip to Section 5 of the form)**			

3. Material(s) that came into contact with the returned product	
Description:	70% IPA
pH of Mixture:	NA
Mixture Soluble In:	☐ **Water** ☐ **Ethanol** ☑ **Isopropyl Alcohol (IPA)** ☐ **Other (describe):**
	Source of solubility data: ☐ **SDS (attach)** ☐ **Other (describe):**
Biological Origin:	☐ **Human origin, humanized, or contains or expresses human DNA or RNA** ☐ **Non-human biological origin** ☑ **Non-biological origin**
	If biological origin (human or non-human), describe:
	If biological origin, enter safety level: ☐ **BSL 1** ☐ **BSL 2** ☐ **BSL 3** ☐ **BSL 4**
Radioactive:	**Mixture contains radioactive materials:** ☐ **Yes** ☑ **No** ***If Yes, please attach analysis showing product is not currently contaminated.***
Please describe the safety and environmental control measures used at your facility to handle the(se) material(s). You may attach a copy of the relevant risk assessment.	
Safety Data Sheet Attached:	☐ **Single SDS for Mixture (preferred)** ☐ **Multiple SDS for components** ☑ **No SDS (additional info may be needed)**

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10/02/2020