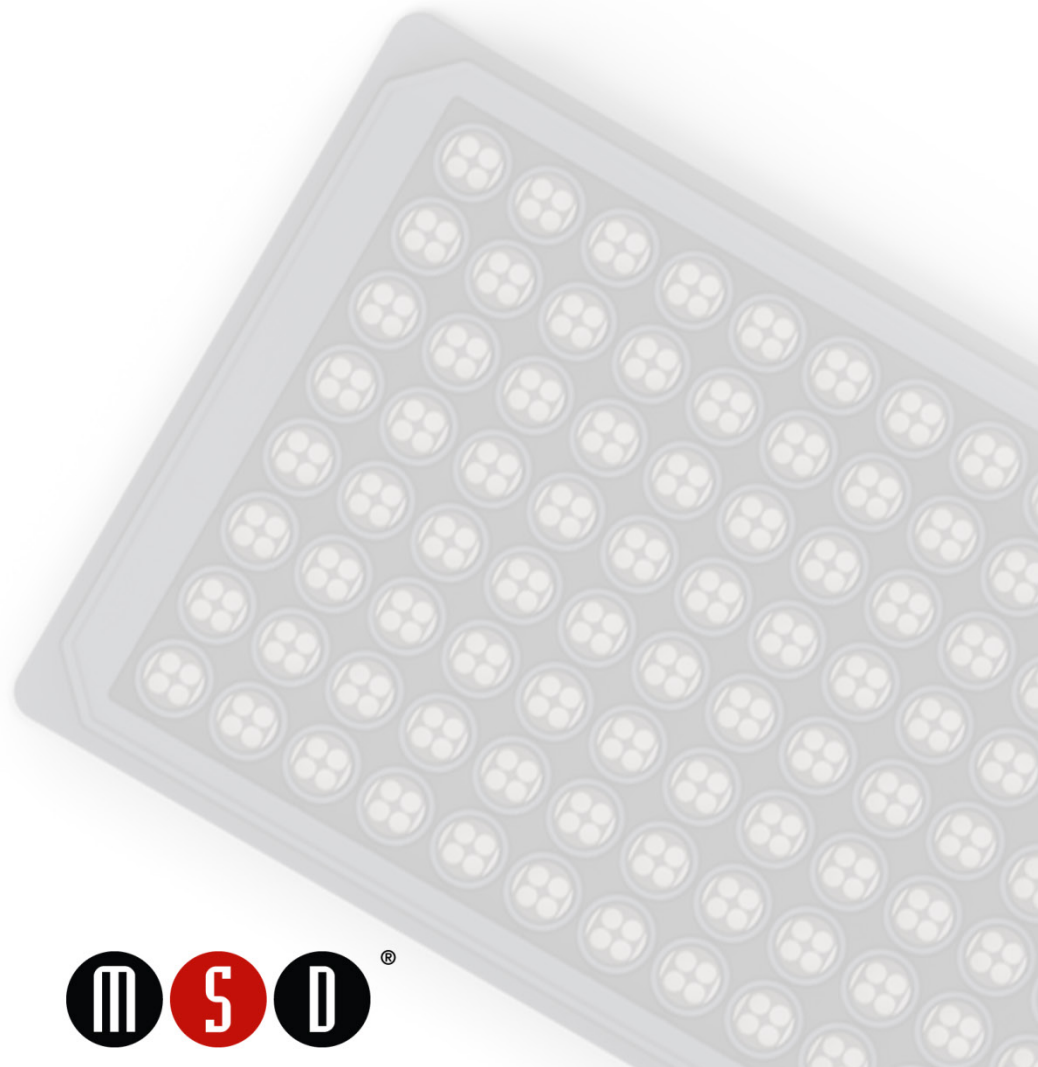


MSD[®] MULTI-SPOT Assay System

SECTOR[®] Imager Performance Qualification Kit

R31QQ-3



www.mesoscale.com[®]

MESO SCALE DISCOVERY®

SECTOR Imager Performance Qualification Kit

For use with SECTOR Imager 6000, SECTOR Imager 2400, SECTOR Imager 2400A, MESO™ SECTOR S 600, and the MESO QuickPlex™ SQ 120 instrument

This package insert must be read in its entirety before using this product.

FOR RESEARCH USE ONLY.

NOT FOR USE IN DIAGNOSTIC PROCEDURES.

MESO SCALE DISCOVERY

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Ordering Information

MSD Customer Service

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MSD Scientific Support

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Introduction

The SECTOR Imager Performance Qualification (PQ) Kit provides a rapid and convenient method for verifying the performance of SECTOR Imager (6000, 2400, 2400A), MESO SECTOR S 600, and MESO QuickPlex (SQ 120) instruments. The qualification procedure measures consistency of signals across a plate read, and dark (electronic) noise of the instrument.

The entire PQ test should take approximately 15 to 30 minutes and should be performed using the MSD reagents provided in the PQ Kit. Only those reagents from the lots specified in the kit's certificate of analysis (C of A) should be used for each test. Mixing reagents from different manufacturing lots may compromise performance.

Mean signal, standard deviation, and %CV values are calculated and compared with specifications. Dark noise is measured as a standard deviation of the signal values from wells in which no electrochemiluminescence is occurring (i.e. empty wells). The source of these signals is electronic noise in the analog to digital conversion.

All performance information, including standard signal levels, is based on 150 μ L read volume in 96-well MULTI-ARRAY[®] microplates using standard read parameters in the specified operating environment.

The intervals for conducting the PQ are defined by the operator and the quality system of the lab in which the instrument is being used.

The PQ procedure can only verify that the instrument is performing within specifications.

Reagents Supplied

Product Description	Storage	Quantity per Kit
MULTI-ARRAY [®] 96-Well Plate	RT	10 plates L15XA-3
Free Tag ECL 15 000	RT	1 bottle (250 mL)
PQ Low Control	RT	1 bottle (200 mL)

A lot-specific C of A is included in each kit.

Important:

- Testing should be performed at 20-26° C (68-78° F).
- Do not leave the reagent bottles open for an extended period. Evaporation will alter the concentration of these reagents and will result in failure of the PQ.
- Do not leave the plates exposed for an extended period. Keep all unused plates in their original packaging and reseal the bag as instructed on the label.
- Do not mix plates and reagents from different kit lots.

Required Material and Equipment (not supplied)

- ❑ MSD demonstration plate (provided at the time of instrument installation).
- ❑ Multi-channel pipettor, capable of dispensing 150 μL /well into a 96-well microtiter plate. Make sure that the pipettor is calibrated and within specification ($\pm 10\%$ of 150 μL).

Safety

Consult the instrument manual for safety precautions and regulations concerning the handling of materials and the instrument's electrical and mechanical components before working with MSD plate readers.

Free Tag ECL and PQ Low Control are chemical solutions and should be handled appropriately. Proper care should be taken to prevent spills. Use safe laboratory practices and wear gloves, safety glasses, and lab coats when handling kit components. Handle and dispose of all hazardous samples properly in accordance with local, state, and federal guidelines.

Additional safety information is available in the product safety data sheet (SDS), which can be obtained from MSD Customer Service.

Test Protocol

Prior to testing, confirm the following:

- The instrument is powered.
- The instrument computer is powered and the operating system is fully initialized.
- MSD DISCOVERY WORKBENCH® software is running.
- The instrument camera is at operating temperature.
- The testing environment (lab) is within the recommended operating temperature for the instrument: 20-26° C (68-78° F).

Verify operation of the instrument by running the demonstration plate. The following wells should have signals greater than 2000 counts: A9, B10, C11, D12, H1, G2, F3, and E4. All other wells should have signals lower than 200 counts.

1. Record the following items in the Records table provided below:

- Lot numbers and expiration dates of all reagents
- Plate barcodes
- The expected Free Tag and PQ Low Control mean signal from the PQ kit C of A
- Pipettor information
- Lab temperature and comments

Confirm that the lot numbers match those listed on the C of A for this PQ kit.

2. Prepare 3 plates as follows:

- Fill plate #1 with 150 µL of Free Tag in each well.
- Fill plate #2 with 150 µL of PQ Low Control in each well.
- Leave plate #3 empty.

Use reverse pipetting technique and pipette to the bottom corner of the well to avoid creating bubbles.

3. Incubate for 15 minutes (\pm 5 min) to allow the reagents and plates to equilibrate and come to room temperature. Record incubation time in the Records table.

4. Read plates 1, 2, and 3 on the instrument one at a time and record the appropriate details in the Results table provided below.

- Calculate for plate #1: Mean and CV values for Free Tag. Enter the values in the Results table.
- Calculate for plate #2: Mean and standard deviation for PQ Low Control. Enter the values in the Results table.
- Calculate for plate #3: Mean and standard deviation for dark noise. Enter the values in the Results table.

5. Compare the calculated results obtained in step 4 with the specifications listed below.

- If all results are within the acceptable range (min and max), the test result is PASS.
- If any one of the results is outside of the acceptable range, refer to the Troubleshooting section for guidance.

Specifications

	Max	Nominal	Min
Free Tag Mean Signal	18000	15000*	12000
Free Tag %CV	6.0	3.0	0
PQ Low Control Mean Signal	100	50*	25
PQ Low Control SD	25	10	0
Dark Noise Mean Signal	16	0	-16
Dark Noise SD	16	10	0

* See the C of A provided with the PQ kit for the kit-specific Free Tag and PQ Low Control mean signals.

Records and Results

Operator: _____

Date: _____

Instrument Serial Number: _____

RECORDS TABLE	Lot Number	Expiration Date	Mean Signal from C of A
Performance Qualification Kit			
Free Tag			
PQ Low Control			
	Barcode	Incubation Time (Minutes)	
Plate 1			
Plate 2			
Plate 3			
	ID/Serial Number	Calibration Date	
Multichannel Pipettor			
	Ambient Temperature (°C)	Within Range *20-26°C (Y/N)? If no, please provide comments	
Lab Temperature			

*Equates to 68-78° F

RESULTS TABLE	Description	Mean Signal	Standard Deviation (SD)	% Coefficient of Variation (CV)
Plate 1	Free Tag			
Plate 2	PQ Low Control			NA
Plate 3	Dark Noise			NA

Troubleshooting

If the performance qualification test does not meet specifications, repeat the test after confirming the following:

1. Verify lab temperature is 20-26°C (68-78° F). For labs where temperature is outside of the recommended temperature ranges for testing, reagents and plates should be equilibrated to room temperature prior to use.
 - Incubate Free Tag and PQ Low Control bottles in a room temperature (23°C) water bath for ≥ 30 minutes. Submerge the bottles in the water bath, keeping the cap of the bottles above water level. Place the test plates in a room temperature incubator for the same period of time.
 - After the addition of reagents to the test plates, the test plates can also be placed in a room temperature incubator for the 15 minutes (± 5 min) incubation step.
2. Plates and reagents were properly stored.
 - Do not leave the plates exposed for an extended period. Keep all unused plates in their original packaging and reseal the bag as instructed on the label.
 - Do not leave Free Tag and PQ Low Control bottles open for an extended period. Evaporation will alter the concentration of these reagents and will result in test failure.
3. The expiration dates of all plates and reagents are not past due.
4. The correct protocol was followed.
 - The incubation time of Free Tag should be between 10 and 20 minutes.
 - The volume of reagent per well should be 150 μ L.
 - There were no bubbles in the wells.
5. All lot numbers of plates and reagents used match those listed in the PQ kit C of A.

If the specifications are not met when the PQ test is repeated, please contact scientificsupport@mesoscale.com.