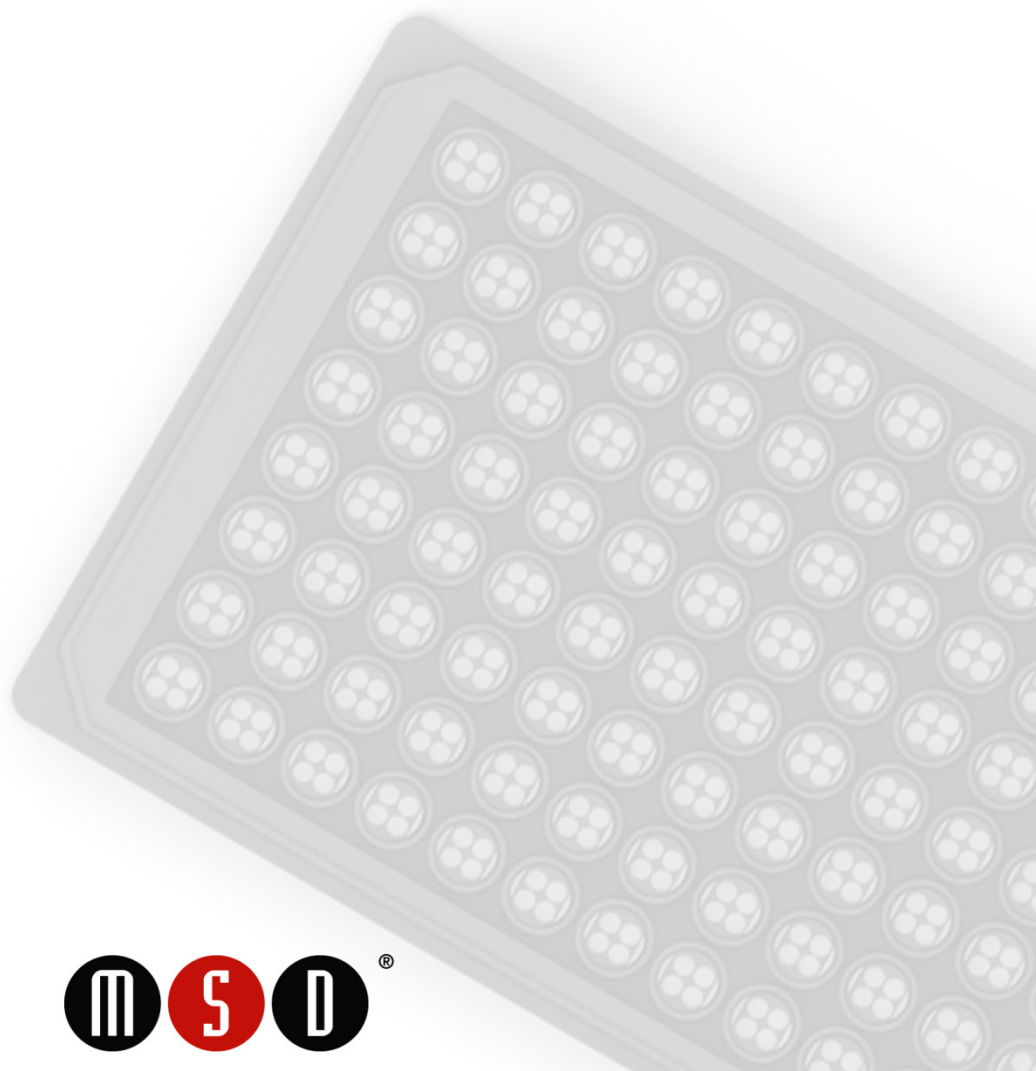


MSD[®] MULTI-SPOT Assay System

Performance Qualification Kit

SECTOR PR[®]

R21QQ-2



www.mesoscale.com[®]

MESO SCALE DISCOVERY®

Performance Qualification Kit

For use with SECTOR PR instruments

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

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MSD Scientific Support

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Introduction

The MSD Performance Qualification (PQ) Kit provides a rapid and convenient method for verifying the performance of SECTOR PR instruments (models 400 and 100). The qualification procedure measures signal, background, and dark (electronic) noise of the instrument.

The entire PQ test should take approximately 15–30 minutes and should be performed using the MSD reagents provided in the PQ Kit. Only those reagents from the lots specified in the kit 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 µL 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 L13XA-3
Free Tag ECL 15 000 R94AA-2	RT	1 bottle (250 mL)
Read Buffer T (1X) R92TA-2 (200 mL)	RT	1 bottle (200 mL)

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

Important:

- 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 reagents and plates 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 the SECTOR PR.

Free Tag ECL and Read Buffer T 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.

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 mean signal from the PQ kit C of A

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 Read Buffer T 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.
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 Read Buffer T. 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
Read Buffer T Mean Signal	300	100	25
Read Buffer T SD	40	25	0
Dark Noise Mean Signal	16	0	-16
Dark Noise SD	40	25	0

* See the C of A provided with the PQ kit for the kit-specific Free Tag mean signal.

Records and Results

Operator: _____

Date: _____

Records	Lot Number	Expiration Date	Mean Signal from C of A
Free Tag			
	Lot Number	Expiration Date	
Read Buffer T			
	Barcode	Incubation time (minutes)	
Plate 1			
Plate 2			
Plate 3			
	ID/Serial Number	Calibration Date	
Multichannel Pipettor			
	Serial Number		
Instrument			

Results	Mean Signal	Standard Deviation (SD)	%Coefficient variation (%CV)
Plate 1: Free Tag			
Plate 2: Read Buffer T			NA
Plate 3: Dark Noise			NA

Troubleshooting

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

1. Plates were not reused.
2. Reagents were properly stored.
 - Do not leave Free Tag and Read Buffer T bottles open for an extended period. Evaporation will alter the concentration of these reagents and will result in test failure.
 - 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.
3. The expiration dates of all reagents and plates 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 reagents and plates 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.