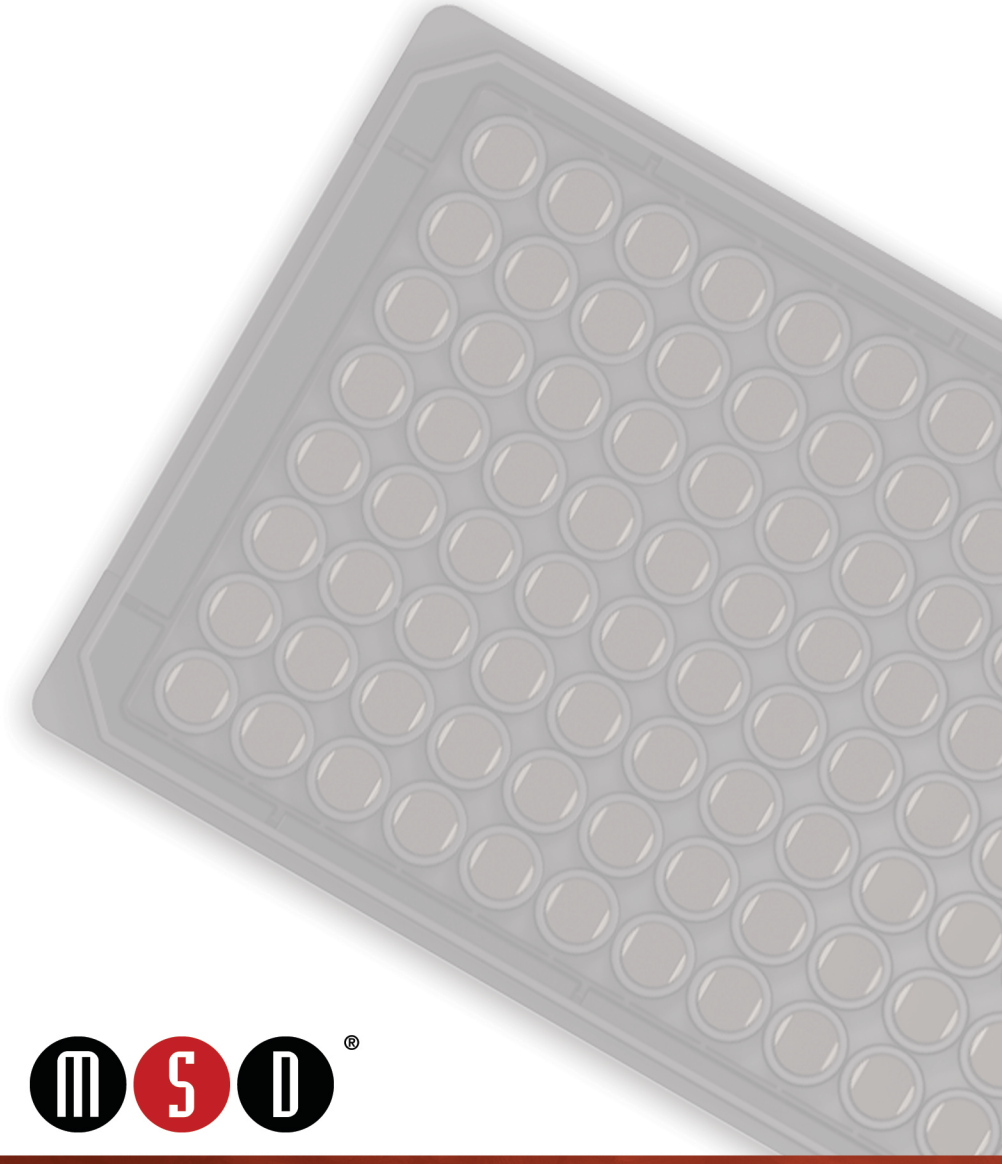
MSD® Performance Qualification Kits

S 600/600MM and SQ 120/120MM Performance Qualification Kit

R31QQ-3



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MESO SCALE DISCOVERY®

S 600/600MM and SQ 120/120MM Performance Qualification Kit

For use with the following MSD instruments: MESO® SECTOR S 600MM, MESO SECTOR® S 600, MESO QuickPlex® SQ 120MM, MESO QuickPlex SQ 120, SECTOR Imager 6000, SECTOR Imager 2400, and SECTOR Imager 2400A.

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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Introduction

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

The entire Performance Qualification (PQ) test should take approximately 15 to 30 minutes and should be performed using the MSD reagents provided in the PQ Kit. Only those components from the lots specified in the kit's certificate of analysis (COA) should be used for each test. Mixing components 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 SECTOR 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 COA is included in each kit.

Important:

- ❑ Testing should be performed at 20–26 °C.
- ❑ Do not leave the reagent bottles open for an extended period. Evaporation will alter the concentration of these reagents and may result in failure of the PQ.
- ❑ Exposing the unused MSD plates to the air for extended periods of time can affect the measured signal. Keep any unused plates in the original packaging and reseal the bag to prevent exposure to the air.
- ❑ Do not mix components from different kit lots.

Additional Materials and Equipment

- ❑ MSD electronic test 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.

Safety

Consult the *MSD Reader Safety Guide* 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 product-specific safety information is available in the applicable safety data sheet(s) (SDS), which can be obtained from MSD Customer Service or at www.mesoscale.com.

Test Protocol

Prior to testing, confirm the following:

- ❑ The instrument is powered.
- ❑ The instrument computer is powered and the operating system is fully initialized.
- ❑ The DISCOVERY WORKBENCH® or Methodical Mind™ 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.

Verify the operation of the instrument by running the electronic test plate. The following wells should have signals greater than 2,000 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 Obtained Mean Signal for the Free Tag and the PQ Low Control from the PQ kit COA
   - ❑ Pipettor information
   - ❑ Lab temperature and comments

   Note: Confirm that the lot numbers match those listed on the COA 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.

   Note: Use reverse pipetting technique and pipette to the bottom corner of the well to avoid creating bubbles.
3. Incubate plates 1 and 2 for 15 minutes (± 30 seconds) to allow the reagents and plates to equilibrate at 20–26 °C. Record the 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: Experimental mean signal and coefficent of variation (CV) values for the Free Tag. Enter the values in the Results table.
   - ❑ Calculate for plate #2: Experimental mean signal and standard deviation (SD) for the PQ Low Control. Enter the values in the Results table.
   - ❑ Calculate for plate #3: Experimental mean signal and SD for the Dark Noise. Enter the values in the Results table.
5. Compare the calculated results obtained in step 4 with the specifications in the Results table.
   - ❑ If all results are within the acceptable range, the test result is PASS.
   - ❑ If any one of the results is outside of the acceptable range, refer to the Troubleshooting section for guidance.

Records and Results

Operator:_____ Date:_____

Instrument Serial Number:_____

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

RESULTS TABLE	Description	Experimental Mean Signal	Signal Specification		PASS/FAIL
			Minimum Value	Maximum Value	
Plate 1	Free Tag		12,000	18,000	
Plate 2	PQ Low Control		25	100	
Plate 3	Dark Noise		-16	16	
	Description	**Calculated Value**	**%CV and SD Specification**		**PASS/FAIL**
Plate 1	Free Tag %CV		≤ 6 %		
Plate 2	PQ Low Control SD		≤ 25 counts		
Plate 3	Dark Noise SD		≤ 16 counts		

Troubleshooting

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

1. This PQ test should be performed in a lab where the temperature is within the operational range of the reader (20–26 °C). If the PQ kit was stored outside of this temperature range, reagents and plates should be equilibrated to 20–26 °C prior to use, as follows:
    - Incubate Free Tag and PQ Low Control bottles in a 20–26 °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 at 20–26 °C for ≥ 30 minutes.
2. Plates and reagents were properly stored.
    - Exposing the unused MSD plates to the air for extended periods of time can affect the measured signal. Keep any unused plates in the original packaging and reseal the bag to prevent exposure to the air.
    - Do not leave Free Tag and PQ Low Control bottles open for an extended period. Evaporation will alter the concentration of these reagents and may 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 µL.
    - There were no bubbles in the wells.
5. All lot numbers of plates and reagents used match those listed in the PQ kit COA.

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