



RFE MEMO


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Product Description(s): MSD GOLD™ 96-well Small Spot Streptavidin SECTOR® Plate

Catalog Number(s) / Size(s): L45SA-Series

Lot Number: Z0021317

Based on additional testing, the original date of expiration for this plate has been extended by 12 months. The expiration date of Z0021317 has been extended to 31 DEC 2020.

Function	Name	Signature	Date
Quality	Karen Hamilla		09 MAR 2020

This memo supersedes all other statements regarding date of expiration for this product.



CERTIFICATE OF ANALYSIS: TITRATION PLATES

COA - 8533

Product Description: MSD GOLD™ 96-Well Small Spot Streptavidin SECTOR® Plate

Catalog #: L45SA-1 (1 plate); L45SA-2 (5 plates); L45SA-5 (30 plates);
L45SA-6 (120 plates); L45SA-7 (510 plates)

Lot Number: Z0021317

Expiration date: 31 DEC 2019

Statement: This product was manufactured and tested according to approved MSD Standard Operating Procedures.

This product has an approximate binding capacity of 0.075 pmoles of biotinylated IgG. For optimal assay results, the amount of biotinylated reagent used in the assay should not exceed this binding capacity.

Titration plates were tested using tagged BTI lot: R0010578

Concentration of SULFO-TAG™ Conjugated Biotinylated IgG (BTI)	Mean ECL spec and tolerance range	Pass/Fail?
1.5 nM (0.075 pmole)	45,472 counts ± 15%	Pass
1.0 nM (0.05 pmole)	34,498 counts ± 15%	Pass
0.5 nM (0.025 pmole)	18,826 counts ± 15%	Pass
0 nM (0.0 pmole)	Not to exceed 100 counts	Pass

Concentration of SULFO-TAG™ Conjugated Biotinylated IgG (BTI)	Intraplate CV or SD spec	Pass/Fail?
1.5 nM (0.075 pmole)	≤10%	Pass
1.0 nM (0.05 pmole)	≤10%	Pass
0.5 nM (0.025 pmole)	≤10%	Pass
0 nM (0.0 pmole)	≤15 count SD	Pass



CERTIFICATE OF ANALYSIS: UNIFORMITY PLATES

COA -

This product has an approximate binding capacity of 0.075 pmoles of biotinylated IgG. For optimal assay results, the amount of biotinylated reagent used in the assay should not exceed this binding capacity.

Metric	Specification	Pass/Fail?
Mean Intraplate CV	$\leq 6\%$	
Intraplate CV	$\leq 8\%$ for at least 91.5% of plates	
Number of plates with intraplate CV $>12\%$	0 plates	
Interplate CV	$\leq 8\%$	
Plates where signal $> 20\%$ from plate mean occurs in same well on multiple plates	0 plates	
Wells with signal $> 50\%$ from plate mean	0 plates	
Median signal for concentric rings, min to max range	$\leq 10\%$ for all plates	
Median signal for columns, min to max range	$\leq 10\%$ for at least 91.5% of plates	
Median signal for columns, min to max range	$\leq 15\%$ for all plates	
Median signal for rows, min to max range	$\leq 10\%$ for at least 91.5% of plates	
Median signal for rows, min to max range	$\leq 15\%$ for all plates	
Number of plates sampled (N)	Lot size dependent; see SOP 3-2000-6P0002	Pass

The above product is intended for research use only. Not for use in diagnostic procedures.

	Name	Function	Signature	Date
Review/Approval	Carissa Hubbard	Quality Control		24 JUL 2017
Review/Approval	Vanessa Castleberry	Quality Assurance		25 JUL 2017