

Aldevron GMP-Source Certificate of Analysis Lot 85475 Revision 2



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Organization:	Protein Name:
Aldevron	sNLS-SpCas9-sNLS Nuclease
Storage Temperature:	Final Buffer:
-10 to -30 °C	25 mM Tris, 0.3 M NaCl, 0.1 mM EDTA, 50% glycerol, pH 7.4
Fill Volume:	Total Vials Released:
5.0 mL	21 vials

Assay	Method	Specifications	Results
Purity, RP-HPLC <i>SOP_QC_1580</i>	RP-HPLC method	≥95%	Pass Value: 99%
Purity, SDS-PAGE <i>SOP_QC_1565</i>	Densitometry SYPRO Orange	≥95%	Pass Value: 97%
Aggregation <i>SOP_QC_1624</i>	Analytical SEC	≤5% aggregate	Pass Value: <LOD (0.673%)
Concentration <i>SOP_QC_1578</i>	UV VIS 280 nm	10.0 mg/mL +/- 10%	Pass Value: 10.7 mg/mL
Endotoxin <i>Lancaster Laboratories</i>	Kinetic chromogenic LAL assay Ph. Eur. 2.6.14 USP <85>	≤10 EU/mg	Pass Value: 0.0723 EU/mg
Residual DNase <i>PPD</i>	Ambion DNaseAlert	<LOQ	Pass Value: <LOQ
Residual RNase <i>PPD</i>	Ambion RNaseAlert	<LOQ	Pass Value: <LOQ
Appearance <i>SOP_QC_0253</i>	Visual Inspection	Clear, colorless	Pass Clear, colorless
Residual Host Protein <i>SOP_QC_1584</i>	Cygnus <i>E. coli</i> HCP ELISA Kit	≤200 ng/mL	Pass Value: 71 ng/mL
Residual Host Genomic DNA <i>SOP_QC_1622</i>	Quantitative PCR with Proteinase K digestion	<1% (w/w)	Pass Value: 0% gDNA
Activity Assay, in vitro <i>SOP_QC_1623</i>	Cas9-mediated cleavage of reference DNA	≥80% of uncut reference DNA converted to cleavage products	Pass Value: 97% activity
Microbiological Examination of Non-Sterile Products <i>BioReliance</i>	Ph. Eur. 2.6.12, USP <61> microbial enumeration	<1 CFU/mL	Pass Value: <1 CFU/mL total aerobic microbial count Value: <1 CFU/mL total combined yeasts and molds count

Quality Control: Jessie Breyer Date: Nov 27, 2017
Jessie Breyer (Nov 27, 2017)

Quality Assurance: Naomi Lucht Date: Nov 27, 2017
Naomi Lucht (Nov 27, 2017)

Aldevron GMP Certificate of Analysis Lot 79866 Revision 2



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Organization:	Protein Name:
Aldevron	sNLS-SpCas9-sNLS Nuclease
Storage Temperature:	Final Buffer:
-10 to -30 °C	25 mM Tris, 0.3 M NaCl, 0.1 mM EDTA, 50% glycerol, pH 7.4
Fill Volume:	Total Vials Released:
5.0 mL	53 vials

Assay	Method	Specifications	Results
Purity, RP-HPLC <i>SOP_QC_1580</i>	RP-HPLC method	≥95%	Pass Value: 99%
Purity, SDS-PAGE <i>SOP_QC_1565</i>	Densitometry SYPRO Orange	≥95%	Pass Value: 98%
Aggregation <i>SOP_QC_1624</i>	Analytical SEC	≤5% aggregate	Pass Value: <LOD (0.673%)
Concentration <i>SOP_QC_1578</i>	UV VIS 280 nm	10.0 mg/mL +/- 10%	Pass Value: 10.0 mg/mL
Endotoxin <i>Lancaster Laboratories</i>	Kinetic chromogenic LAL assay Ph. Eur. 2.6.14 USP <85>	≤10 EU/mg	Pass Value: <0.0500 EU/mg
Residual DNase <i>PPD</i>	Ambion DNaseAlert	<LOQ	Pass Value: <LOQ
Residual RNase <i>PPD</i>	Ambion RNaseAlert	<LOQ	Pass Value: <LOQ
Appearance <i>SOP_QC_0253</i>	Visual Inspection	Clear, colorless	Pass Clear, colorless
Residual Host Protein <i>SOP_QC_1584</i>	Cygnus <i>E. coli</i> HCP ELISA Kit	≤200 ng/mL	Pass Value: 71 ng/mL
Residual Host Genomic DNA <i>SOP_QC_1622</i>	Quantitative PCR with Proteinase K digestion	<1% (w/w)	Pass Value: 0% gDNA
Activity Assay, in vitro <i>SOP_QC_1623</i>	Cas9-mediated cleavage of reference DNA	≥80% of uncut reference DNA converted to cleavage products	Pass Value: 98% activity
Microbiological Examination of Non-Sterile Products <i>BioReliance</i>	Ph. Eur. 2.6.12, USP <61> microbial enumeration	<1 CFU/mL	Pass Value: <1 CFU/mL total aerobic microbial count Value: <1 CFU/mL total combined yeasts and molds count

Quality Control:

Jessie Breyer
 Jessie Breyer (Nov 27, 2017)

Date: Nov 27, 2017

Quality Assurance:

Naomi Lucht
 Naomi Lucht (Nov 27, 2017)

Date: Nov 27, 2017