

# The way forward in digital PCR

## resDNASEQ dPCR CHO DNA Kit

Residual DNA quantitation

### Highly sensitive dPCR assay for quantitation of residual CHO host-cell DNA

The Applied Biosystems™ resDNASEQ™ dPCR CHO DNA Kit is a powerful digital PCR (dPCR) solution for quantitating residual DNA from CHO expression systems, which are commonly utilized for the production of monoclonal antibodies (mAbs). By harnessing the capabilities of high-performance Applied Biosystems™ TaqMan™ chemistry, the resDNASEQ CHO assay provides a rapid and reliable approach for accurately quantifying residual CHO DNA (Table 1). This assay offers exceptional sensitivity and specificity, helping ensure that the quantitation data obtained from a wide range of sample types, including in-process samples with varying sample matrices and final product formulations, is reliable and consistent.

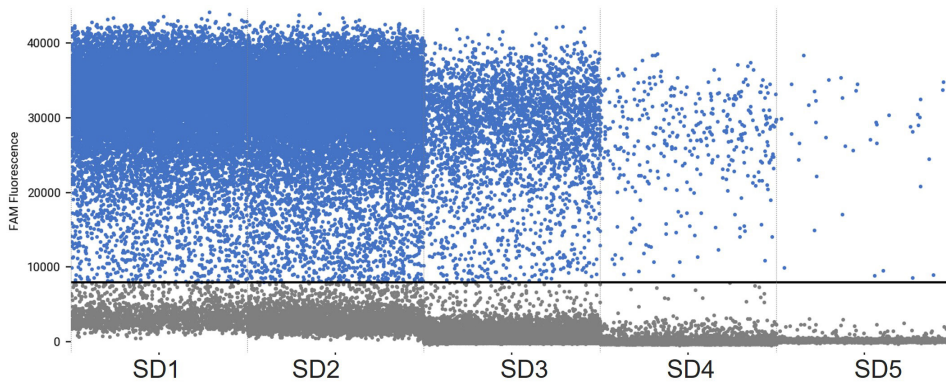
- Accurate, absolute quantitation of residual CHO DNA
- Easy-to-use, integrated sample-to-results system features Applied Biosystems™ TaqMan™ digital PCR master mix and TaqMan™ primer/probe set
- Highly sensitive quantitation delivers results in about 3 hours
- Optional manual or automated sample preparation, optimized for quantitative recovery of samples from complex matrices



**Table 1. Sensitive and specific quantitation of CHO DNA using the ResDNASEQ dPCR CHO DNA Kit.**

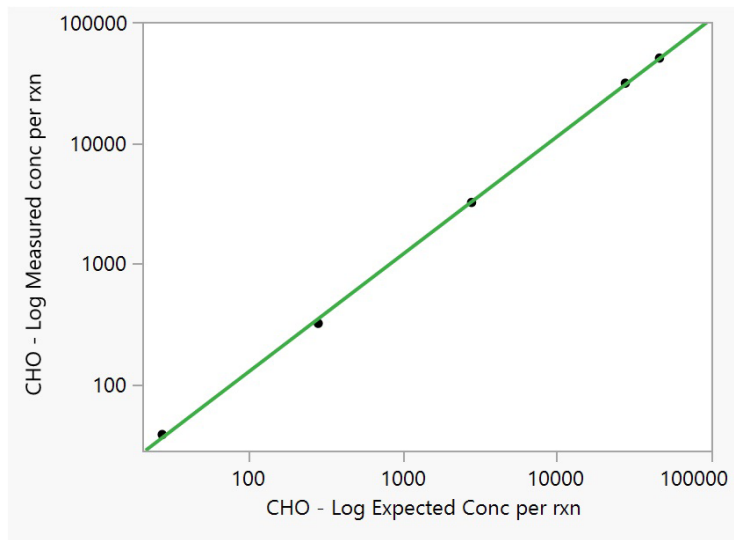
Specifications	
Linearity	$R^2 \geq 0.99$
Precision	$CV \leq 30\%$
Limit of detection (LOD)	1 copy/ $\mu$ L; 0.6 fg/rxn
Limit of quantitation (LOQ)	3 copies/ $\mu$ L; 1.8 fg/rxn
Slope	0.95-1.05

The dPCR fluorescence plot illustrates the sensitivity of the assay down to very low quantities of residual CHO DNA (Figure 1). The powerful software algorithms are able to consistently and accurately quantitate DNA even at higher concentrations of the linear range.



**Figure 1. 1D dot plots displaying dPCR-based quantification of CHO from serially diluted samples.** Using the QuantStudio Absolute Q Digital PCR System, absolute quantification of CHO copies across serially diluted samples is possible by counting the total number of microchambers positive for the fluorescent label.

The linear range allows testing of a wide range of samples containing CHO DNA (Figure 2).



**Figure 2. High sensitivity and broad dynamic range.** Linear range was generated using serial dilutions ranging from 5,000 copies/ $\mu\text{L}$  ( $\text{cp}/\mu\text{L}$ ) (SD1) to 3 copies/ $\mu\text{L}$  (SD5) of CHO DNA. Linearity:  $R^2 > 0.99$ ; slope = 1.01.

**Table 2: resDNASEQ dPCR CHO DNA Kit performance summary demonstrates assay accuracy and precision among triplicate reactions.**

CHO	w Conc.			Ave. Conc.	Ave. Conc.	Relative Accuracy	SD	CV%
	( $\text{cp}/\mu\text{L}$ )	( $\text{fg}/\mu\text{L}$ )	( $\text{fg}/\text{rxn}$ )	( $\text{cp}/\mu\text{L}$ )	( $\text{fg}/\mu\text{L}$ )	(%)		
SD1(ULOQ)	5000	<b>328.21</b>	2953.9	4711.3	<b>309.26</b>	94.23	86.1	1.83%
SD3	300	<b>19.69</b>	177.2	278.3	<b>18.27</b>	92.75	2.62	0.94%
SD4	30	<b>1.97</b>	17.7	27.7	<b>1.82</b>	92.17	0.87	3.13%
SD5(LOQ)	3	<b>0.20</b>	1.8	2.7	<b>0.18</b>	91.11	0.13	4.77%

**Table 3. Summary of assay LOD for the resDNASEQ dPCR CHO DNA Kit.**

Test Item	Expected Conc. of LOD (cp/μL)	Ave. Conc. of LOD (cp/μL)	Ave. Conc. of NTC (cp/μL)	SD of NTC (cp/μL)	Conc. of NTC + 3 SD (cp/μL)
CHO	1.00	0.94	0.01	0.03	0.09

### Digital PCR workflow

The resDNASEQ dPCR CHO DNA Kit is part of an integrated digital PCR workflow for impurity testing during biopharmaceutical manufacturing (Figure 3). Optional use of the Thermo Scientific™ Pharma KingFisher™ Apex 96 Deep-Well Magnetic Particle Processor with the Applied Biosystems™ PrepSEQ™ Nucleic Acid Sample Preparation Kit helps ensure high recovery of residual DNA with less labor and error than manual processing. The Pharma KingFisher Apex instrument can process up to 24 samples in triplicate, as compared to 3 samples in triplicate using a manual method.

To help ensure performance that meets or exceeds regulatory compliance, the resDNASEQ dPCR kit has been internally validated on the Applied Biosystems™ QuantStudio™ Absolute Q™ Digital PCR System. Data analysis is streamlined using the QuantStudio Absolute Q dPCR Software, which includes accurate quantitation and security, audit, and e-signature (SAE) capabilities to help enable 21 CFR Part 11 compliance.



**Figure 3. An integrated workflow solution to support process development and a good manufacturing practice (GMP) environment.**



### Powerfully simple digital PCR

The Applied Biosystems™ QuantStudio™ Absolute Q™ Digital PCR System offers an easy-to-use workflow, delivering results from DNA samples in <3 hours with minimal hands-on time. Moreover, there is no steep learning curve, as the workflow is nearly identical to that for real-time PCR.

- **Simple**—streamlined workflow integrates all dPCR steps into a single instrument
- **Fast**—the QuantStudio Absolute Q system requires only one hands-on step that takes <5 minutes to complete with minimal technical skill

## Ordering information

Product	Quantity	Cat. No.
resDNASEQ dPCR CHO DNA Kit	100 reactions	A59366
<b>Sample preparation and automation</b>		
PrepSEQ Residual DNA Sample Preparation Kit	100 reactions	4413686
Pharma KingFisher Apex 96 Deep-Well Magnetic Particle Processor	1 instrument	A57715
<b>System</b>		
QuantStudio Absolute Q Digital PCR System	1 instrument	A52864
Absolute Q DNA Digital PCR Master Mix (5X)	200 reactions	A52490
<b>Service</b>		
QuantStudio Absolute Q IQ/OQ Service	1 service	A53878
QuantStudio Absolute Q CSV Service 1 service A55623	1 service	A55623
Pharma KingFisher Apex IQ/OQ Service	1 service	A31532

 Learn more at [thermofisher.com/resdnaseq](https://thermofisher.com/resdnaseq)

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