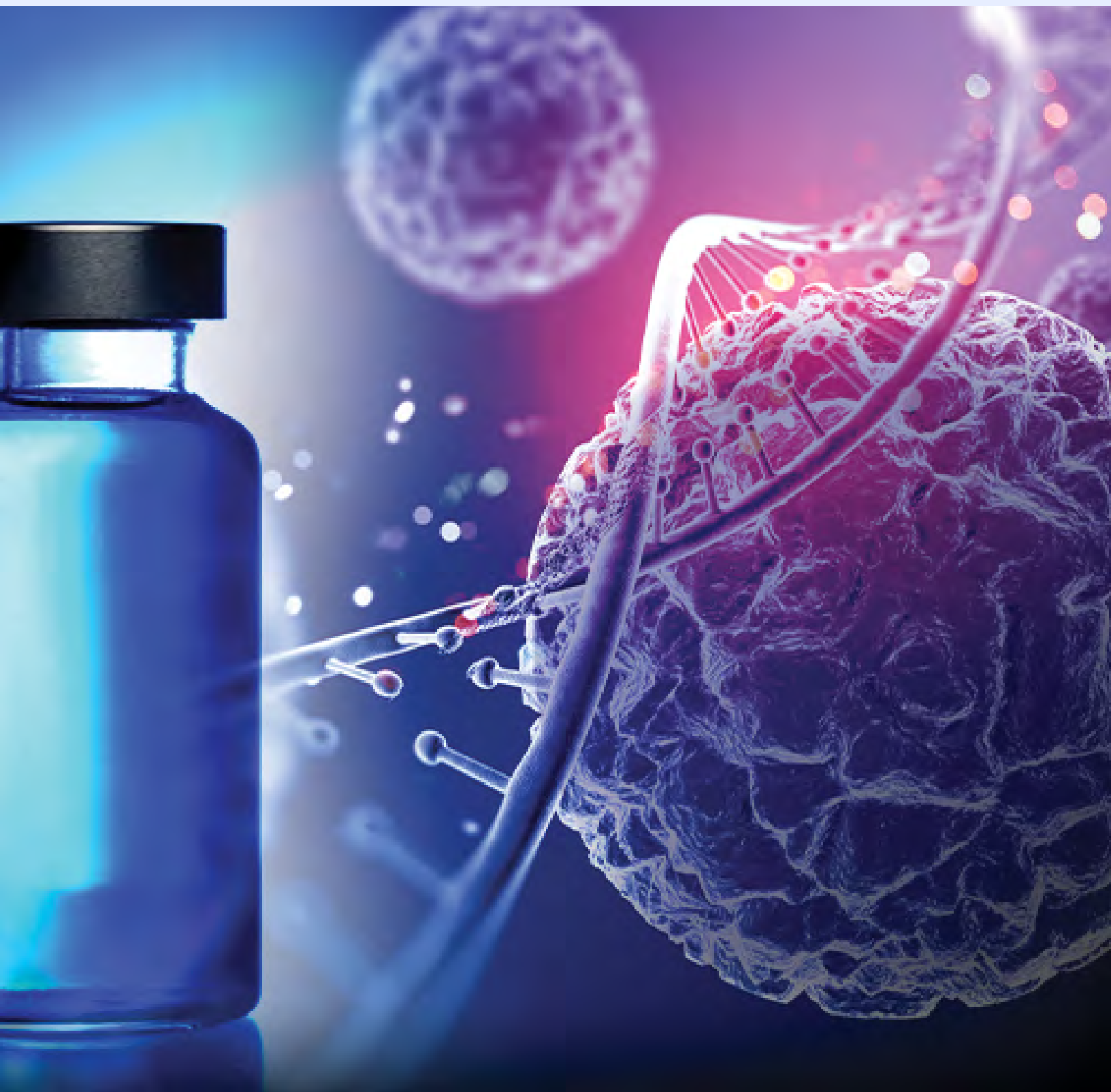




EndonucleaseGTP™ ELISA Kit

Impurity analysis for safer gene therapy and vaccine biologics



EndonucleaseGTP™ ELISA Kit

The Cygnus Technologies EndonucleaseGTP ELISA Kit

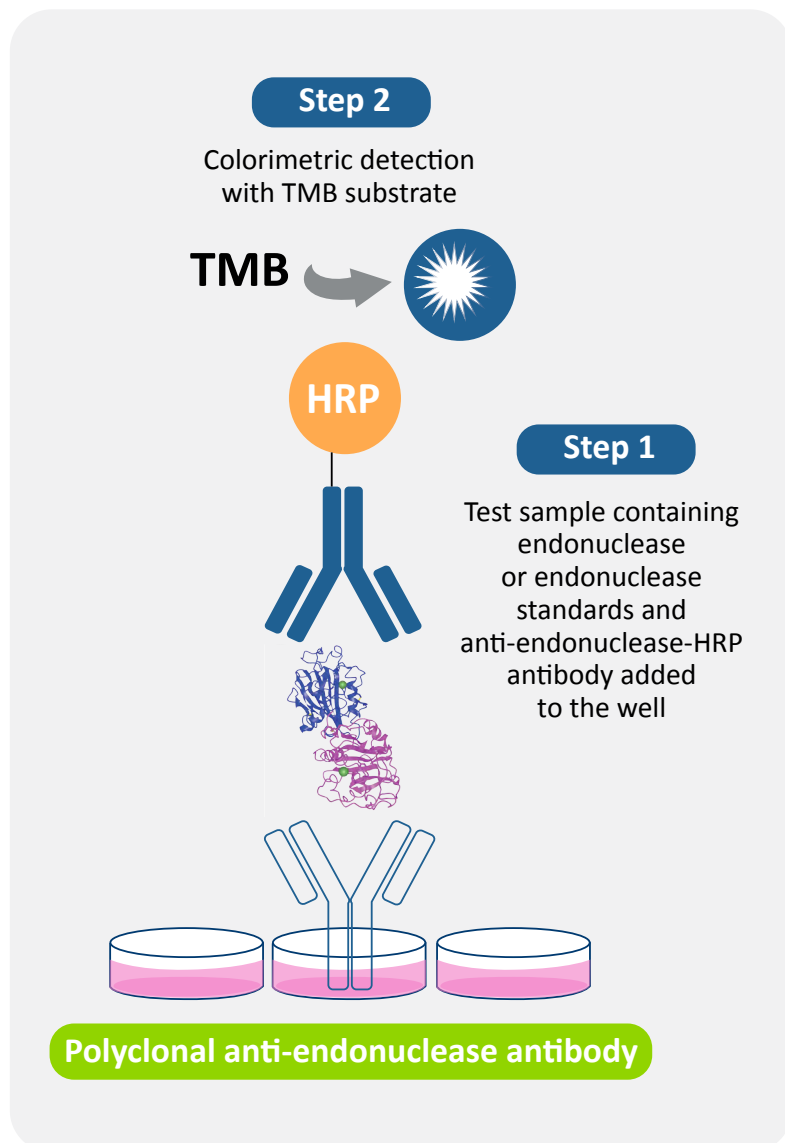
is a sensitive and specific assay for the detection and quantification of residual endonuclease impurity in recombinant viral vector and vaccine preparations.

Expression of recombinant viral vectors and vaccines in mammalian cell culture is a cost-effective method for producing commercial quantities of gene therapy and vaccine biologics. The processes used to manufacture and purify these products, however, often use an endonuclease to remove endogenous host cell DNA and RNA, as well as unincorporated plasmid DNA from viral vector production. During purification, the endonuclease contamination must be reduced to the lowest levels practical.

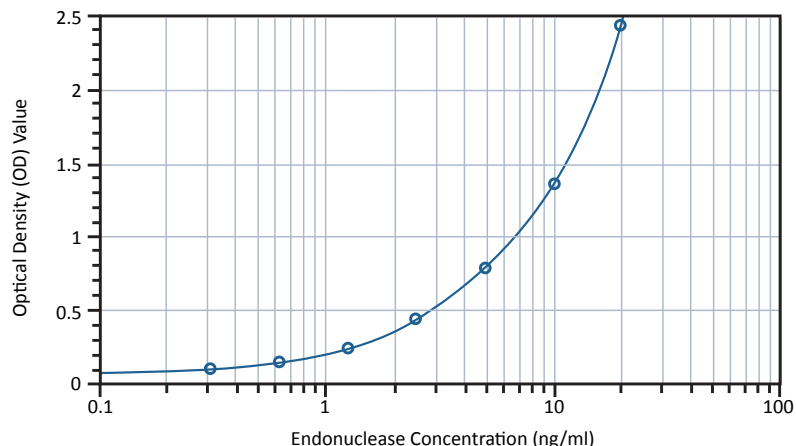
The EndonucleaseGTP ELISA Kit is based on an antibody generated and affinity-purified against a genetically engineered endonuclease from *Serratia marcescens*. With a detection limit of ~0.06 ng/ml, it is a sensitive and specific method for residual endonuclease detection in purification process development, process control, routine quality control and product release testing. The kit uses a simple protocol in which samples containing endonuclease are reacted simultaneously with an HRP-labeled anti-endonuclease detection antibody in microtiter strips coated with affinity-purified capture anti-endonuclease antibody. The EndonucleaseGTP ELISA Kit contains all ready-to-use components needed to evaluate the presence of endonuclease impurities in 96 samples, including a set of calibrated endonuclease standards.

- The most sensitive endonuclease ELISA kit: LOD ~0.06 ng/ml; LLOQ ~0.31 ng/ml
- Qualified for inter- and intra-assay precision, sensitivity, accuracy, and Hook capacity
- Simultaneous protocol with results in <2 hours
- Seamless transfer from purification process development to QC testing and to lot release testing
- Suitable for the detection and quantification of Benzonase Nuclease and DENARASE

EndonucleaseGTP ELISA Kit



EndonucleaseGTP ELISA Standard Curve



Typical standard curve from an assay run using a 4-parameter fit method

Intra- and Inter-Assay Variability

Intra-assay			Inter-assay		
# of tests	Target (ng/mL)	%CV	# of tests	Target (ng/mL)	%CV
20	0.75	5.1	20	0.75	2.9
20	3	3.6	20	3	2.1
20	12	3.6	20	12	4.3

Assay precision as determined by intra- and inter-assay variability

Technical Specifications and User Protocol: EndonucleaseGTP ELISA Kit vs Competitor M Endonuclease ELISA Kit

	Cygnus Technologies EndonucleaseGTP ELISA Kit	Competitor M Endonuclease ELISA Kit
Technical Specifications		
LOD LOQ	0.06 ng/ml 0.31 ng/ml	0.2 ng/ml Not available
Assay Range	0.31 – 20 ng/ml	Not available
Precision, %CV	Intra-assay 3.6–5.1; Inter-assay 2.9 - 4.3	Not available
Accuracy, % recovery	92 – 103	Not available
Protocol		
Assay Preparation	All reagents, including ready-to-use endonuclease standards, detection antibody, wash buffer	Endonuclease standards, detection antibody and wash buffer preparation required
Standard Preparation Time	None	Make standard dilutions ~15 min
Format	Simultaneous	Sequential
Detection System	Anti-endonuclease:HRP + TMB	Anti-endonuclease:HRP + TMB
Number of Wash Steps	1	2
Total time to result	1 hr 35 min (includes 1 x 5 min wash)	4 hr (includes standards, detection antibody and wash buffer prep time and 2 x 5 min washes)

Ordering Information

Product	Catalog No.
EndonucleaseGTP™ ELISA Kit	F960



Process-Related Impurity Analysis for Cell and Gene Therapy and Vaccine Product Manufacturing

Cygnus Technologies offers industry-leading host cell protein (HCP) ELISA kits for virtually all expression systems used for viral vector and vaccine production, ELISA kits to detect cell culture media components such as BSA, HSA, Transferrin and Insulin, as well as residual host cell DNA extraction and detection kits.

HCP ELISA Kits	Catalog No.	Process Impurity Kits	Catalog No.	Host Cell DNA Extraction and Detection	Catalog No.
HEK 239 HCP ELISA Kit	F650R	Bovine Serum Albumin (BSA) ELISA Kit	F030	Host Cell DNA Extraction Kits	D100T, D100W
BHK HCP ELISA Kit	F510	Human Serum Albumin (HSA) ELISA Kit	F055	Human Host Cell DNA Detection Kits	D160T, D160W
HeLa HCP ELISA Kit	F810	Human Transferrin ELISA Kit	F035N		
SF9 HCP ELISA Kit	F840	Ultra-sensitive Insulin ELISA Kit	F280		
Vero HCP ELISA Kit	F500				
MDCK HCP ELISA Kit	F800				
A549 HCP ELISA Kit	F230				
MRC5 HCP ELISA Kit	F300				
PER.C6 HCP ELISA Kit	F530				
CAP HCP ELISA Kit	F820				

Interested in Qualifying a Cygnus HCP ELISA Kit for Your Specific Process?

Contact our technical experts to discuss comprehensive qualification of Cygnus generic HCP ELISA assays with state-of-the-art orthogonal methods: AAE and Mass Spectrometry. As the pioneer and leader in biopharmaceutical impurity analysis, major biopharmaceutical companies worldwide have trusted their results from our assays for over 20 years. Cygnus assay qualification services meet the expectations of regulators around the world.

To start your project, contact techsupport@cygnustechnologies.com

Trust Your Assays. Trust Your Results.

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