Introduction
When working with biopharmaceuticals, it is essential to evaluate the final therapeutic material to ensure that it is free of contaminating substances, such as residual DNA from the host cell. Quantitative data is needed to ensure a high-quality, safe therapeutic product. The presence of residual host cell DNA in the final product is of concern due to its potential oncogenic properties.

Host cell DNA should be detected using a sensitive analytical technique that yields quantitative data. DNA extraction is a primary concern, as the gDNA must be recovered from complex samples and diverse sample matrices with a consistently high recovery, reproducibility, and robustness. Use of a specially formulated conditioning buffer to equalize samples allows for a standardized processing independent of the nature of the sample matrix. The QIAexpress® CERTAL Residual DNA Kit and CERTAL Vero Detection Kit provide automated solutions for purification of residual host cell DNA and viral nucleic acids from bioprocess purification buffer, cell culture supernatant samples, and vaccine preparations using the QIAexpress SP.

Subsequent quantification of host cell DNA and viral nucleic acids using the CERTAL CHO Detection Kit and CERTAL Vero Detection Kit on the QIAxpress AS and RotorGene® Q enables evaluation of the quality and safety of biologic medicinal products.

Flexible and fully automated purification procedure delivers high precision, down to trace amounts
QIAexpress CERTAL Kits combine the speed and efficiency of silica-based purification with the convenient handling of single-use cartridges. The Certal CHO Detection Kit and the Certal Vero Detection Kit on the QIAxpress SP, deliver high precision from experiment to experiment and also allow purification of even low (trace) amounts of residual host cell DNA.

High recovery rate, independent of sample matrix
QIAxpress CERTAL Kits purely residual host cell DNA equally well from a broad spectrum of sample matrices. We formulated a unique conditioning buffer to optimize the recovery rate of residual gDNA, independent of the sample matrix or process buffers with significantly different pH, salt, or protein concentrations. There is no need for extensive pretreatment of different sample types, making final product release testing more straightforward.

Small-scale antibody purification process and analysis of residual DNA clearance
The development process for the production of a biologic therapeutic (e.g., a monoclonal antibody) in cell lines includes the need to prove the absence of host cell contaminants (e.g., genomic DNA) and adventitious agents (e.g., residual DNA clearance), Small-scale antibody purification process and analysis of residual host cell DNA.

The DNA clearance steps in the process were chosen to be Protein A and AIX followed by 0.1 M glycine, pH 3.2, Buffer C. An in-house, 96-well filtration plate also contained a 5 ng/mL of CHO DNA.

Conclusions
Flexible and fully automated purification on the QIAexpress enables the user to purify as little as 1 pg residual host cell gDNA from a broad variety of bioprocess samples with recoveries of 80–100%.

Optimized protocols and reagents as part of streamlined workflow ensure consistent, reliable, high-quality results.

Excellent reproducibility in combination with low limit of quantification.

Complete kits and proven protocols support user requirements.

The applications presented here are for research use only. Not for use in diagnostic procedures.