Validation Summary of

Residual CV-1 DNA Quantitation Kit

■ INTRODUCTION

This report summarizes assay performance of SHENTEK® Residual CV-1 DNA Quantitation Kit. This kit is manufactured by Huzhou Shenke Biotechnology Co., Ltd. The data of this summary is for reference use. To demonstrate that the kit is suitable for an intended purpose, appropriate validation or qualification study with actual biological sample should be considered.

Parameters that may be evaluated for method validation are linearity, range, quantitation limit (QL), precision, accuracy and robustness, etc..

The report may be appropriate for actual biological sample on a case-by-case basis, and the users could consider completing sample suitability test (including QL and specificity validation) or more to meet regulatory requirements.

■ MATERIALS & METHODS

1. SHENTEK® Residual CV-1 DNA Quantitation Kit, Product No. 1101115.
2. The production of the kit is compliant with the requirements of ISO13485, and the assay validation compliant with the pharmacopoeia requirement.

■ RESULTS

1. Linearity and range

The range of the kit is 3.00E-03-3.00E+02 pg/μL. R^2=0.99958, amplification efficiency is 96.5%. The CV of the highest and lowest concentration points is not more than 20%, and the relative bias is within ± 20%; CV of the remaining concentration points is not more than 15%, and the relative bias is within ± 15%.

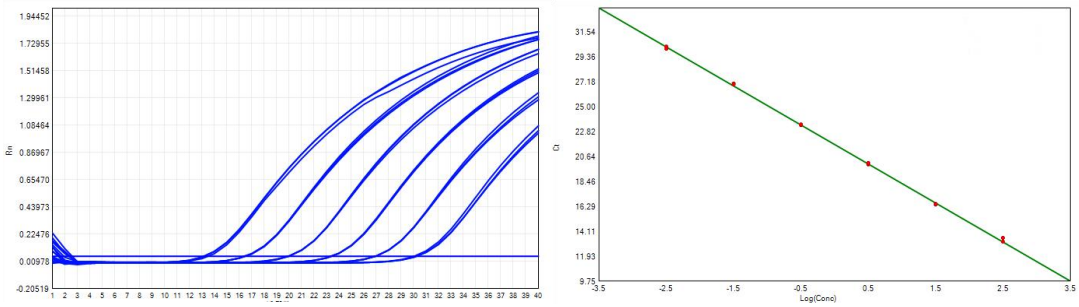

Fig1. Amplification graph and standard curve

2. Accuracy

The CV-1 DNA Control containing 3.00E-03 pg/μL was tested three times to analyze the sample recovery rate and CV value. The recovery rate was 112.7%, and the CV was 16.6%.

Table 1. Accuracy results

Theoretical Conc.(pg/μL)	3.00E-03
Ave. Value (pg/μL)	3.38E-03
CV (%)	16.6
Recovery (%)	112.7
Acceptance Criteria	The recovery is 50%-150%, CV≤20%.
Conclusion	Pass

3. Quantitation limit (QL)

The quantitation limit of the kit is 3.00E-03 pg/μL.

Table 2. Quantitation limit results

Theoretical Conc. (pg/μL)	3.00E-03
Ave. Value (pg/μL)	2.75E-03
CV (%)	11.50
Relative bias (%)	-8.4
Acceptance Criteria	CV≤20%, the relative bias is within ± 20%.
Conclusion	Pass

4. Precision

The sample was tested 10 times at a concentration of 3.00E-03 pg/μL to assess its repeatability. The CV value is 16.4%.

Table 3. Repeatability results

Theoretical Conc. (pg/μL)	3.00E-03
Ave. Value (pg/μL)	3.17E-03
CV (%)	16.4
Acceptance Criteria	CV≤20%.
Conclusion	Pass

5. Robustness

Two batches of kits were tested in 2 separate assays to assess batch-to-batch precision, and CV and relative bias met the acceptance criteria.

Table 4. Batch-to-batch precision results

Batch	1 n=10	2 n=10
Theoretical Conc. (pg/μL)	3.00E-03	
Ave. Value (pg/μL)	2.96E-03	
CV (%)	15.9	
Relative bias (%)	-1.4	
Acceptance Criteria	CV≤20%, the relative bias is within ± 20%.	
Conclusion	Pass	

■ CONCLUSION

Parameters concluding linearity, range, QL, accuracy, precision and robustness were all evaluated and met the requirements.

■ REFERENCES

[1] ICH Q2 (R2) Validation of Analytical Procedures

[2] USP <509> Residual DNA Testing

[3] USP <1225> Validation of Compendial Procedures

[4] ChP <9012> Bioanalytical Method Validation Guideline

[5] JP <G1-1-130> Validation of Analytical Procedures

Support & Contact

SHENTEK

Huzhou Shenke Biotechnology Co., Ltd.
www.shentekbio.com
Address: 8th Floor, 6B Building, No.1366 Hongfeng Road, Huzhou 313000, Zhejiang Province, China
E-mail: info@shentekbio.com
Phone: +1 (908) 822-3199 / (+86) 400-878-2189