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CERTIFICATE OF ANALYSIS & LOT QC REPORT

Ready-to-Use Humanized Bivalent Fab Phage Display Library Kit (SKU: ADL-12)

Product Name:	Humanized Bivalent Fab Library Kit	Lot Number:	080226812
Catalog / SKU:	ADL-12	Mfg Date:	August 2, 2026
Format:	Fab (malE-Vk-Ck-gD tag : Still-VH-CH1-Hinge-GCN4)	Expiry Date:	August 2028 (-80°C)
Vector Architecture:	6277 bp (Amp ^R , pUC ori, f1 ori, lacI)	Master Scaffold:	BiFab-Humanized Framework

1. TITER & INFECTIOUS PHAGE DETERMINATION

Test Parameter	Specification	Measured Lot Result	Assay / Method	Status
Phage Titer	$\geq 3.0 \times 10^{12}$ pfu/ml	3.7×10^{12} pfu/ml	Plaque Formation Assay (<i>TG1 E. coli</i> overlayer)	PASS
Helper Phage Titer	2.0×10^{12} pfu/ml	2.0×10^{12} pfu/ml	M13KO7 Plaque Assay on K12 Host	PASS
TG1 Competency	$\geq 1.0 \times 10^8$ cfu/ μ g	2.5×10^8 cfu/ μ g	Transformation Efficiency with pUC19 Control	PASS

2. LIBRARY DIVERSITY CALCULATION & METHOD

Reported Functional Diversity: 3.4×10^{10} total unique transformants.

Calculation Methodology: Determined via extrapolation of total colony-forming units (cfu) across all transformation electroporations during library synthesis, scaled by the full-length in-frame clone ratio established by Next-Generation Sequencing (NGS).

3. LOT-SPECIFIC NGS SEQUENCING & READ DEPTH SUMMARY

NGS Quality Metric	Target Specification	Measured Lot Value
Sequencing Platform	Illumina Paired-End (2 × 300 bp)	Illumina NovaSeq 6000
Total Raw Read Depth	> 10,000,000 reads	14,850,200 reads
Filtered High-Quality Reads (Q ≥ 30)	> 85.0%	92.1%
Unique Full-Length Bivalent Fab Sequences	> 1,000,000 unique observed	1,658,410 unique sequences

4. SEQUENCE INTEGRITY & MUTATION RATES

Metric	Target Specification	Lot QC Result	Status
Insert-Positive Rate (Light & Heavy Chains)	> 90.0%	95.8%	PASS
In-Frame Ratio	> 85.0%	87.4%	PASS
Frameshift Rate	< 5.0%	2.5%	PASS
Premature Stop Codon Rate	< 5.0% (excl. Amber stop)	1.9%	PASS

* Note: Positions 2286–2288 and 3225–3227 contain engineered Amber stop codons (TAG) upstream of cP3 / anchor regions for conditional translation in suppressor TG1 vs non-suppressor host strains.

5. CLONE-ABUNDANCE & REDUNDANCY DISTRIBUTION

Gini Coefficient / Diversity Index: 0.23 (indicates high sequence balance across the pool, where 0 = perfect uniformity and 1 = extreme bias).

Top 100 Clones Contribution: Represents < **0.45%** of total NGS read count, confirming absence of clonal dominance.

Redundancy Profile: 92.8% of detected unique sequences were observed as singletons or doubletons at the sampled sequencing depth.

6. CONSTITUENT SUB-LIBRARY REPRESENTATION & PARATOPE DESIGN

Region / Domain	CDR Mutagenesis Profile & Design	Expected Share	NGS Observed Share
LCDR3 Library Domain	Trimer Phosphoramidite Mix across 9 positions (Y, S, G, A, F, W, H, P, V)	100.0%	99.2%
HCDR1 Domain	Binary Code (Tyr/Ser) at positions 30, 31, 32, 33	100.0%	98.9%
HCDR2 Domain	Binary Code (Tyr/Ser) at positions 55, 57, 59, 62, 64, 66	100.0%	98.7%
HCDR3 Library Domain	Trimer Phosphoramidite Mix across 13 positions (Fixed Anchors 105, 106, 114, 115)	100.0%	99.4%

7. KIT COMPONENTS & FORMULATIONS

Component	Quantity	Concentration	Storage Buffer
Humanized Bivalent Fab Library Phage	1.0 ml	3.7×10^{12} pfu/ml	1xPBS with 25% glycerol
M13KO7 Helper Phage	0.5 ml	2.0×10^{12} pfu/ml	1xPBS with 25% glycerol
Chemically Competent TG1 <i>E. coli</i>	0.5 ml	2.5×10^8 cfu/ml	2xYT with 25% glycerol
BiFab SEQF Primer (1.6 μ M)	0.2 ml	1.6 μ M	1xTE Buffer
BiFab SEQR Primer (1.6 μ M)	0.2 ml	1.6 μ M	1xTE Buffer

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Fusion BioLabs Analytical Services

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