Certificate of Analysis

Description

Product Name	TruSight Cystic Fibrosis Library Prep	**Catalog Number**	20036925
Part Number	20036925	**Lot Number**	A161231

Test Conditions

Kitted reagents were tested by performing the Cystic Fibrosis 139-Variant Assay and Cystic Fibrosis Clinical Sequencing Assay using a set of eight Coriell cell line derived genomic DNA samples (http://ccr.coriell.org/). Multiple replicates (at least 3) of each of the eight unique samples and "No Template Controls" (NTCs) were sequenced using a 2 x 150 cycle paired-end run configuration. The sample set provides representation of different types of sequence variations which could be present in CFTR gene in clinical samples (single nucleotide variations, small insertions/deletions, compound insertion/deletions, insertion/deletions in homopolymeric regions, large deletions).

Coriell Sample ID	*Cystic Fibrosis 139-Variant* Mutations (Common Name)*	*Cystic Fibrosis Clinical Sequencing* Genomic Coordinate (chr7,hg19)/ (Genotype Result)
NA07381	F508del, 3849+10kbC>T	117199533 (A/A) 117199644 (ATCT/A) 117232223 (C/T) 117235055 (T/G) 117280015 (C/T) 117307108 (G/A) 117188661 ((TG)10(T)7/(TG)10(T)9)
NA07857	M1101K (HOM)	117199533 (G/A) 117199709 (G/A) 117235055 (T/G) 117251797 (A/A) 117188661 ((TG)11(T)7/(TG)10(T)7)
NA11290	621+1G>T, A455E	117171169 (G/T) 117188849 (C/A) 117199533 (A/A) 117188661 ((TG)10(T)9/(TG)10(T)9)
NA12785	R347P, G551D	117180324 (G/C) 117199533 (G/A) 117227860 (G/A) 117235055 (T/G) 117306991 (C/T) 117307108 (G/A) 117188661 ((TG)11(T)7/(TG)10(T)7)
NA18668	CFTR dele2,3, F508del	117199533 (G/A) 117199644 (ATCT/A) 117138366 (Het Deletion) 117188661 ((TG)11(T)7/(TG)10(T)9)
NA18802	Y122X, R1158X	117149147 (G/A) 117171045 (T/A) 117175347 (G/T) 117199533 (G/A)

Coriell Sample ID	*Cystic Fibrosis 139-Variant* Mutations (Common Name)*	*Cystic Fibrosis Clinical Sequencing* Genomic Coordinate (chr7,hg19)/ (Genotype Result)
		117235055 (T/G) 117267579 (C/T) 117188661 ((TG)11(T)7/(TG)10(T)7)
NA20836	3905insT	117282541 (C/CT) 117188661 ((TG)11(T)7/(TG)11(T)7)
NA18803	F508del, 2183AA>G	117199533 (A/A) 117199644 (ATCT/A) 117232271 (AAA/AG) 117188661 ((TG)10(T)7/(TG)10(T)9)

* All mutations are heterozygous unless indicated otherwise

Test Results

Metric	Specification	Result
	Cumulative	Cumulative
CF 139 Accuracy	All genotypes correctly called	All genotypes correctly called
CF Clinical Accuracy	All genotypes correctly called	All genotypes correctly called
CF 139 Call Rate	≥ 99%	100%
CF Clinical Call Rate	≥ 99%	100%

Certification

This document certifies that the product(s) described above meet quality specifications.

Quality Review

Print Name	BELINDA DO	Signature		Date	16-OCT-2020