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Certificate of Analysis

Description

Product Name	MiSeqDx® Cystic Fibrosis Clinical Sequencing Assay Kit	Catalog No.	DX-102-1001
Part Number	15036620	Lot No.	A100525

Test Conditions

Kitted reagents were tested by performing a MiSeqDx® Cystic Fibrosis Clinical Sequencing Assay run using a set of eight samples, seven Coriell cell line derived genomic DNA samples (http://ccr.coriell.org/) and one "No Template Control" (NTC). Samples 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).

***Note**: Flow cells are serialized and release tested separately via a hybridization assay.*

Coriell Sample ID	Variations - Genomic Coordinate (chr7,hg19)/ (Genotype Result)	Coriell Sample ID	Variations - Genomic Coordinate (chr7,hg19)/ (Genotype Result)
	117199533 (A/A)	NA12785	117180324 (G/C)
NA07381	117199644 (ATCT/A)		117199533 (G/A)
	117232223 (C/T)		117227860 (G/A)
	117235055 (T/G)		117235055 (T/G)
	117280015 (C/T)		117306991 (C/T)
	117307108 (G/A)		117307108 (G/A)
	117188661 ((TG)10(T)7/(TG)10(T)9)		117188661 ((TG)11(T)7/(TG)10(T)7)
NA07857	117199533 (G/A)	NA18668	117199533 (G/A)
	117199709 (G/A)		117199644 (ATCT/A)
	117235055 (T/G)		117138366 (Het Deletion)
	117251797 (A/A)		117188661 ((TG)11(T)7/(TG)10(T)9)
	117188661 ((TG)11(T)7/(TG)10(T)7)	NA18802	117149147 (G/A)
NA11290	117171169 (G/T)		117171045 (T/A)
	117188849 (C/A)		117175347 (G/T)
	117199533 (A/A)		117199533 (G/A)
	117188661 ((TG)10(T)9/(TG)10(T)9)		117235055 (T/G)
NA20836	117282541 (C/CT)		117267579 (C/T)
	117188661 ((TG)11(T)7/(TG)11(T)7)		117188661 ((TG)11(T)7/(TG)10(T)7)

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Test Results

Metric	Specification	Result
Call Rate[1]	≥ 99%	Pass
Accuracy[2]	All genotypes correctly called	Pass

[1] Call Rate for a given sample, is the number of positions/regions with genotype calls as a percentage of the number of positions/regions sequenced.
[2] Accuracy for a given sample, is the percent agreement with a reference method (Sanger bi-directional sequencing, and PCR assay for large deletions), calculated for those base positions that receive a base call.

Certification

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

Quality Review

Print Name	DONNA MAE CRUZ	Signature		Date	24 AUG 2013