illumina®

Certificate of Analysis

Description

Product Name	MiSeqDx® Cystic Fibrosis 139 Variant Assay (20 Run)	**Catalog No.**	DX-102-1003
Part Number	15036577	**Lot No.**	A118725

Test Conditions

Kitted reagents were tested by performing a MiSeqDx® Cystic Fibrosis 139 Variant Assay run 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).

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

Coriell Sample ID	Mutations (Common Name)*
NA07381	F508del, 3849+10kbC>T
NA07857	M1101K (HOM)
NA11290	621+1G>T, A455E
NA12785	R347P, G551D
NA18668	CFTR dele2,3, F508del
NA18802	Y122X, R1158X
NA20836	3905insT
NA18803	F508del, 2183AA>G

* All mutations are heterozygous unless indicated otherwise.

illumina®

Part Number	15036577	Lot Number	A118725

Test Results

Run 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	Donna Mae Cruz	Date	06 AUG 2017