

Certificate of Analysis

Description

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|--------------|--|-------------|-------------|
| Product Name | MiSeqDx® Cystic Fibrosis Clinical Sequencing Assay Kit | Catalog No. | DX-102-1001 |
| Part Number | 15036620 | Lot No. | A100522 |

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) |
|-------------------|--|-------------------|--|
| NA07381 | 117199533 (A/A) | NA12785 | 117180324 (G/C) |
| | 117199644 (ATCT/A) | | 117199533 (G/A) |
| | 117232223 (C/T) | | 117227860 (G/A) |
| | 117235055 (T/G) | | 117235055 (T/G) |
| | 117280015 (C/T) | | 117306991 (C/T) |
| NA07857 | 117307108 (G/A) | NA18668 | 117307108 (G/A) |
| | 117188661 ((TG)10(T)7/(TG)10(T)9) | | 117188661 ((TG)11(T)7/(TG)10(T)7) |
| | 117199533 (G/A) | | 117199533 (G/A) |
| | 117199709 (G/A) | | 117199644 (ATCT/A) |
| | 117235055 (T/G) | | 117138366 (Het Deletion) |
| NA11290 | 117251797 (A/A) | NA18802 | 117188661 ((TG)11(T)7/(TG)10(T)9) |
| | 117188661 ((TG)11(T)7/(TG)10(T)7) | | 117149147 (G/A) |
| | 117171169 (G/T) | | 117171045 (T/A) |
| | 117188849 (C/A) | | 117175347 (G/T) |
| | 117199533 (A/A) | | 117199533 (G/A) |
| NA20836 | 117188661 ((TG)10(T)9/(TG)10(T)9) | | 117235055 (T/G) |
| | 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 | 20 APR 2018 |
|------------|----------------|-----------|--|------|-------------|