

Certificate of Analysis

Description

| | | | |
|---------------------|--|--------------------|-------------|
| Product Name | MiSeqDx® Cystic Fibrosis 139 Variant Assay (2 Run) | Catalog No. | DX-102-1004 |
| Part Number | 15036580 | Lot No. | A117887 |

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.

| | | | |
|--------------------|----------|-------------------|---------|
| Part Number | 15036580 | Lot Number | A117887 |
|--------------------|----------|-------------------|---------|

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 | BELINDA DO | Signature |  | Date | 16-FEB-2020 |
|------------|------------|-----------|--|------|-------------|