

Certificate of Analysis

Description

| | | | | | |
|---------------------|------------------------------------|------------------------|-------------|-------------------|---------|
| Product Name | VeriSeq™ NIPT Sample Prep Kit (96) | | | | |
| Part Number | 15066802 | Expiration Date | 12-DEC-2020 | Lot Number | A147702 |

1. Sample Preparation QC

Test Conditions

The VeriSeq NIPT Sample Prep Kit (96) lot was tested using a half-batch plate of prequalified pooled maternal plasma samples and non-template controls (NTC). 23 pooled fetal male plasma samples, 23 pooled fetal female samples and 2 non-template control samples were prepared using the VeriSeq NIPT Workflow. Prepared libraries were sequenced on a NextSeq 2x36 pair-end run. Sequencing output was analyzed using the VeriSeq NIPT Assay Software. Results are listed below under "Test Results".

In addition to the metrics listed below, all batch samples have achieved a "pass" for all QC metrics assessed by the VeriSeq NIPT Assay Software.

Test Results

| VeriSeq NIPT Run Metric | Specification | UOM | Result |
|---|---|---------|--------|
| NTC NES ^a | < 100k | N/A | Pass |
| Total NES/Total Clusters (NES Recovery Ratio) | > -0.0012942 * CD ^b + 0.85024 | N/A | Pass |
| Fetal Fraction Estimate ^c | 7.2% to 11.6% | Percent | Pass |

¹ Non-Excluded Sites

^b CD is cluster density in K/mm²

^c Fetal Fraction Estimate specification is set according to the known fetal fraction of the prequalified pooled plasma

Certification

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

| | | | |
|-------------------|----------------|--------------|---------------|
| Print Name | DONNA MAE CRUZ | Title | QC ANALYST II |
| Signature | | Date | 24-OCT-2019 |