illumina

Certificate of Analysis

Description

Product Name	VeriSeq™ NIPT Sample Prep Kit (48 Samples)				
Part Number	15066801	**Expiration Date**	31-JUL-2019	**Lot Number**	A116045

1. Sample Preparation QC

Test Conditions

The TG VeriSeq NIPT Sample Prep Kit (48 Samples) 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/mm^2
[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	Caitlin Knudsen	Title	Quality Control Associate I
Signature	Caitlin Knudsen	Date	31-JAN-2019