

AMS 2000 Trading Impex SRL Verification and Validation Program

This training program contains verification and validation phases. Each phase must be reviewed and approved by appointed personnel in order to move forward to the next phase. At the completion and approval of the validation phase, AMS 2000 Trading Impex SRL is approved by Natera to use the Panorama™ name for Non-Invasive Prenatal Testing (NIPT).



Phase 1: Verification Procedures

This phase is intended to evaluate analytical results for crucial steps of the procedure. Steps are listed in the recommended order of execution.

Procedure**Purpose****(1) Library Preparation**

- (a) Using samples provided by Natera, execute library prep with 15 ng input; post-Ampure measure library quantity using BioAnalyzer/LabChip® (recommended) or Quant-iT™ Broad Range kit.

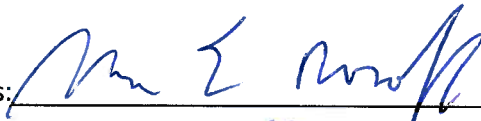
Verifies yield of library preparation and Ampure cleanup. Natera will provide samples; results will be compared to matched controls.

- (b) Repeat (1a) on two additional days with multiple operators if possible.

Demonstrates reproducibility.

Results Verified by Natera:

Associate Director of Applications:



Marc L. Rosoff

Date: 6/1/17

(2) cfDNA Extraction

- (a) Extract cfDNA from plasma. Quantitate cfDNA using Quant-iT™ High Sensitivity Assay Kit, or Qubit® dsDNA HS Assay Kit.

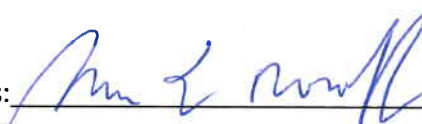
Verifies yield of the extraction procedure. Natera will provide samples; results will be compared to matched controls.

- (b) Repeat (2a) on two additional days with multiple operators if possible.

Demonstrates reproducibility.

Results Verified by Natera:

Associate Director of Applications:



Marc L. Rosoff

Date: 6/1/17



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Procedure

(3) Sequencing and sample data upload

- (a) Upload and process Natera provided sequencing run data and manifests.

- (b) With sequencing ready pools and sample data provided by Natera, format data for upload and sequence samples per protocol. Submit data.

Purpose

Verifies operability of the sequencing API. Natera will review results.

Verifies proper encapsulation of data to Constellation and confirms laboratory sequencing procedure. Samples and data provided by Natera, results will be compared to matched samples.

Results Verified by Natera:

Associate Director, Software Applications:

Date:

6/2/2017

(4) Multiplex PCR through sequencing

- (a) Using library and corresponding parent DNA material provided by Natera, execute the protocol from the multiplex PCR procedure through pooling and sequencing.

- (b) Repeat (4a) on two additional days with multiple operators.

Verifies PCR proper sequencing data characteristics, quality control metrics, and proper pooling and dilution for sequencing. Natera will provide samples; results will be compared to matched controls.

Demonstrates reproducibility.

Results Verified by Natera:

Associate Director of Applications:

Marc L. Rosoff

Date:

6/2/17



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Phase 2: Validation Procedures

This phase is intended to ensure that the partner can run Panorama from beginning to end. Results for these steps should be communicated to Natera. By passing this validation, the partner is approved by Natera to use the Panorama™ name for Non-Invasive Prenatal Testing (NIPT).

Part I

On each of 3 days, execute complete protocol on 8 pregnancy blood samples (24 total). Samples will be provided by Partner's Lab.

Purpose

Validates end-to-end execution of protocol.

Results Verified by Natera:

Associate Director of Applications: [Signature] Date: 6/2/17

Associate Director, Software Applications: [Signature] Date: 6/2/2017

Part II

Using library and corresponding parent DNA material provided by Natera, execute protocol from multiplex PCR through sequencing.

Purpose

Demonstrate non-inferiority of critical metrics (CFE) and equivalent clinical result

Results Verified by Natera:

Associate Director of Applications: [Signature] Date: 6/2/17

Associate Director, Software Applications: [Signature] Date: 6/2/2017

Director, Statistical Research & Development: [Signature] Date: 6/2/2017

Certification of Completion:

AMS 2000 Trading Impex SRL completed all verification and validation procedures:

Associate Director of Applications: *Am E. Noroff* Date: 6/2/17

CEO, AMS 2000 Trading Impex SRL: _____ Date: _____