

## **AMS 2000 Trading Impex SRL Microdeletions Verification and Validation Program**

This training program consists of verification and validation phases for microdeletions. Each phase must be reviewed and approved by appointed personnel in order to move forward to the next phase. With the completion and approval of the validation phase, the partner is approved by Natera to use the Panorama® name for Non-Invasive Prenatal Testing (NIPT) for aneuploidy and microdeletion testing.



### 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**

(3) Sequencing and sample data upload

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

**Purpose**


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

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

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:

Director, Software Applications:

 Date: Sep 28, 2017

(4) Multiplex PCR through sequencing

- (a) Using cfDNA libraries provided by Natera, execute the protocol from the multiplex PCR procedure through pooling and sequencing.

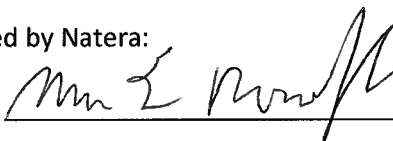
Verifies PCR proper sequencing data characteristics, quality control metrics, and proper pooling and dilution for sequencing. Natera will provide samples; results will be compared to matched controls.

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

Demonstrates reproducibility.

Results Verified by Natera:

Director, FAS:

 Date: 9/28/17

## 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).

### Procedure (Part I)

On each of 3 days, execute complete protocol on pregnancy blood samples (at least 10). Samples will be provided by Partner's Lab.

### Purpose

Validates end-to-end execution of protocol.

Results Verified by Natera:

Director, FAS:  Date: 9/28/17

Director, Software Applications:  Date: Sep 28, 2017

Director, Statistical Research & Development:  Date: 9/28/17

### Procedure (Part II)

Using cfDNA libraries provided by Natera, execute protocol from multiplex PCR through sequencing.

### Purpose

Demonstrate non-inferiority of critical metrics and equivalent clinical results.

Results Verified by Natera:

Director, FAS:  Date: 9/28/17

Director, Software Applications:  Date: Sep 28, 2017

Director, Statistical Research & Development:  Date: 9/28/17