Analytical performance verification of 3222-002B Vanadis Core Reagent Cartridge II.

The 3222-002B Vanadis Core™ Reagent Cartridge II has undergone extensive analytical performance verification to ensure compliance with all relevant requirements. This technical note provides supplementary details about the verification activities and serves as a complement to the information presented in the Instructions for Use (IFU).

The performance verification activities included, but were not limited to, the following assessments:

- Cross-reactivity
- Cut-off determination
- Interference testing
- Measuring range
- Precision
- Sample dilution
- Stability of samples, kits and components

Precision studies

The precision evaluation was divided into two parts, with the combined results presented in the IFU. Due to the limited availability of clinical samples with Sex Chromosomal Aneuploidy (SCA), genomic DNA was used for verification. The affected sample types included in the studies were Trisomy 21 (T21), Trisomy 18 (T18), Trisomy 13 (T13) and the SCA types X0, XXX, XXY and XYY. These samples were processed using the Vanadis Core and Vanadis View™ instruments.

1. Repeatability study

- Conducted over four runs
- Utilized a single reagent lot and one set of instruments

2. Reproducibility study

- Conducted over ten runs
- Included three reagent lots and three instrument sets

The results of the repeatability and reproducibility studies have been summarized in the following tables.

Table 1: Classification results from the repeatability study of the Vanadis Core Reagent Cartridge II, using one lot of reagents and one set of instruments. One unaffected sample failed Quality Assessment and is excluded from the table.

Classification result	Sample type				
	T21	T18	T13	SCA	Unaffected
Increased risk for T21	40	0	0	0	0
Increased risk for T18	0	40	0	0	0
Increased risk for T13	0	0	39	0	0
Increased risk for SCA	0	0	0	35	2
Low risk	0	0	1	5	173
Total	40	40	40	40	175
Percent concordant	100.0%	100.0%	97.5%	87.5%	98.9%

Table 2: Classification results from the repeatability study of the Vanadis Core Reagent Cartridge II divided by SCA sample type. The results were generated using one lot of reagents and one set of instruments.

Classification result	Sample type			
	X0	XXX	XXY	XYY
Increased risk for SCA	10	8	9	8
Low risk	0	2	1	2
Total	10	10	10	10
Percent concordant	100.0%	80.0%	90.0%	80.0%

Table 3: Classification results from the reproducibility study of the Vanadis Core Reagent Cartridge II, using three lots of reagents and three sets of instruments. One unaffected sample and one SCA sample failed Quality Assessment and are excluded from the table.

Classification result	Sample type				
	T21	T18	T13	SCA	Unaffected
Increased risk for T21	100	0	0	0	1
Increased risk for T18	0	100	0	0	0
Increased risk for T13	0	0	100	0	1
Increased risk for SCA	0	0	0	96	6
Low risk	0	0	0	2	425
Total	100	100	100	98	433
Percent concordant	100.0%	100.0%	100.0%	98.0%	98.2%

Table 4: Classification results from the reproducibility study of the Vanadis Core Reagent Cartridge II divided by SCA sample type. The results were generated using three lots of reagents and three sets of instruments. One X0 sample failed Quality Assessment and is excluded from the table.

Classification result	Sample type			
	X0	XXX	XXY	XYY
Increased risk for SCA	23	23	24	26
Low risk	2	0	0	0
Total	25	23	24	26
Percent concordant	92.0%	100.0%	100.0%	100.0%