Prenatal Screen Sage™
Safe, accurate, genetic evaluation

NON-INVASIVE PRENATAL SCREENING TEST REPORT

Patient Details:			
Patient ID	patient_id	**Clinician Name**	physician
Patient Surname	surname	**Hospital/Clinic Name**	hospital_name
Patient Forename	forename	**Pregnancy Status: Singleton/Twin**	pregnancy_type
Date of Blood Draw	collection_date	**Report Generated:**	created_date
Patient Date of Birth	dob	**TIID**	specimen_id_2
Reporting facility	No.376-5, Fuxing Rd., Shulin Dist., New Taipei City 238, Taiwan (R.O.C.)		+886 2 26758068

I. Screening results

Chromosomes	Risk	Z score	Test Results	Reference interval
Chromosome 21			Low Risk	-6<Z score<2.8
Chromosome 18			Low Risk	-6<Z score<2.8
Chromosome 13			High Risk – Further Investigation Recommended	-6<Z score<2.8
Chromosome Y	-		Detected	NA
Fetal fraction				

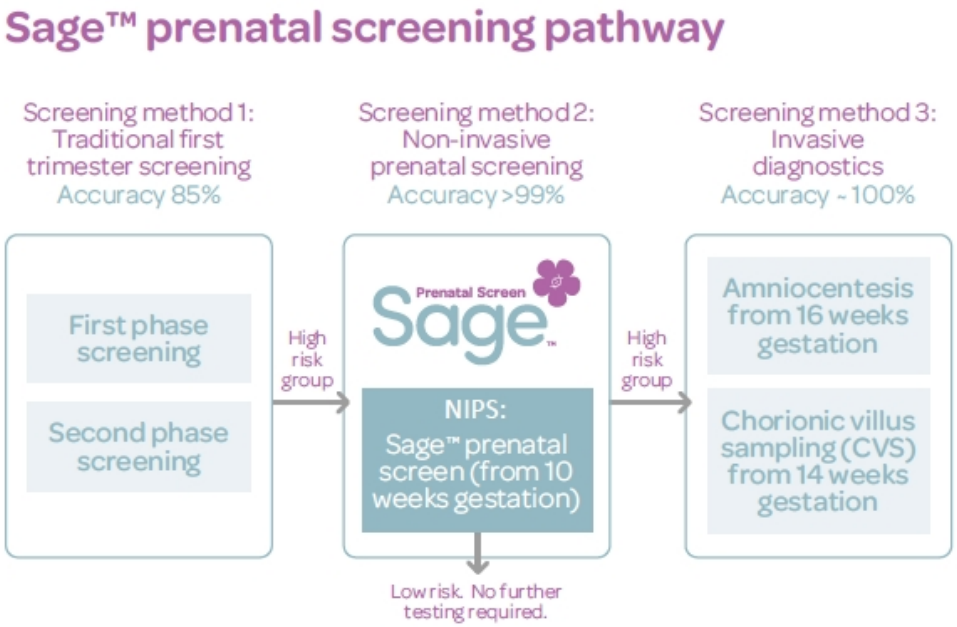
II. Supplementary information

- The NIPS test screens a maternal blood sample for chromosome aneuploidy in placental DNA using the following methodology:
  (1) Extraction of cell-free placental DNA from the maternal blood sample
  (2) High throughput sequencing of the extracted cell-free placental DNA
  (3) Calculation of molecular mass of placental DNA in all chromosomes
- The method is intended for use in pregnant women who are at least 10+0 weeks pregnant. The method is suitable for both singleton and twin pregnancies. The accuracy may be slightly lower in twin pregnancies due to multiple sources of fetal DNA.
- Based on the scope, the NIPS test can detect the following:
  (1) Chromosomes 13, 18 and 21
- The test is capable of genome-wide aneuploidy detection over the whole fetal genome and gives the results for chromosomes 13, 18 and 21. This test confers an accuracy of up to **99%** on the detection of fetal aneuploidy.

Results are indicated for screening, NOT diagnosis – (results should be reviewed and discussed with your healthcare provider)

Doctor | Laboratory Director | Bioinformatics Scientist

Pipeline version: XXXXXXXX



About Sage™ prenatal screen

The Sage™ prenatal screen is a new advanced non-invasive prenatal screening solution using the latest developments in DNA technology to detect placental DNA in maternal blood. Sage™ offers a menu-based chromosome analysis to estimate the risk of a fetus having Down's syndrome and other genetic disorders. Enabling pregnant women and their families fast, safe and reliable results and reducing the need for invasive tests and the associated risks, stress and anxiety. Sage™ is indicated for use in pregnant women who are at least 10 weeks pregnant. Chromosomal aneuploidy can then be detected using bioinformatics analyses, where the detection rate and sensitivity are over 99%.

Limitations

Sage™ is a screening test and all high-risk results should be confirmed through further investigation which may include tests such as amniocentesis or Chorionic Villus Sampling (CVS). Pregnant women with a high-risk result should be referred for genetic counseling and offered invasive prenatal diagnosis for confirmation of test results. Pregnant women with a negative test result do not ensure an unaffected pregnancy. While results of this testing are highly accurate, not all chromosomal abnormalities may be detected due to placental, maternal or fetal mosaicism, or other causes (micro-deletions, chromosome re-arrangements, translocations, inversions, unbalanced translocations, uniparental disomy). The test is not reportable for known multiple gestations, or if the gestational age is less than 10 weeks.

Test method

A simple maternal blood sample is taken from the pregnant mother from 10 weeks gestation without any risk to the fetus. Circulating cell-free placental DNA was purified from the plasma component of anti-coagulated 10mL of maternal whole blood. It was then converted into a genomic DNA library for Next Generation Sequencing and then determination of chromosomal aneuploidy.

References:

1. Obstet Gynecol 2012;119:890-901.
2. BMJ 2011;342:c7401.
3. Prenat Diagn 2012;32:c7401.
4. ACOG/SMFM Joint Committee Opinion No. 545, Dec 2012.