Client: Example Client ABC123
123 Test Drive
Salt Lake City, UT 84108
UNITED STATES

Physician: Doctor, Example

Patient: Patient, Example

DOB	12/31/1752
Sex:	Female
Patient Identifiers:	01234567890ABCD, 012345
Visit Number (FIN):	01234567890ABCD
Collection Date:	01/01/2017 12:34

Non-Invasive Prenatal Aneuploidy Screen by cell-free DNA Sequencing

ARUP test code 3003043

Multiple Gestation	No
Gestational Age at Draw	10 wks or over
Report Fetal Sex	Yes
Fetal Fraction	10.1 %
EER Non-Invasive Prenatal NGS Aneu	See Note Authorized individuals can access the ARUP Enhanced Report using the following link: [redacted]
Trisomy 21	Low Risk
Trisomy 18	**High Risk** *
Trisomy 13	Low Risk
Sex Chromosome Trisomies and Monosomy X	Low Risk
Fetus Sex	Female
Result Summary	High Risk This pregnancy is classified as HIGH RISK for trisomy 18 (Edwards syndrome) by this screen. This result should be confirmed by a diagnostic test. The chance that a pregnancy classified as high risk will have the screened condition (the positive predictive value, or PPV) is affected by the pre-test risk for the screened condition. For women with no additional risk factors, 23-33% of pregnancies classified as high risk by NIPT are found to have trisomy 18. For women with a high pre-test risk, 67-84% of pregnancies classified as high risk by NIPT are found to have trisomy 18. Online calculators are available to determine patient-specific PPV based on clinical context. This is a screening test and is NOT diagnostic for the condition(s) listed in this report. Both false positive and false negative results may occur. Appropriate clinical follow-up such as genetic counseling, comprehensive ultrasound, and

H=High, L=Low, *=Abnormal, C=Critical

confirmatory diagnostic testing should be undertaken as recommended by the patient's healthcare provider. Irrevocable action such as pregnancy termination should not be taken based on the results of this screening test.

Health care providers with questions may contact an ARUP genetic counselor at (800) 242-2787 ext. 2141.

This result has been reviewed and approved by [redacted]

INTERPRETIVE INFORMATION: Non-Invasive Prenatal Aneuploidy Screen by cell-free DNA Sequencing
CHARACTERISTICS: This assay is a screening test that interrogates chromosomal abnormalities (i.e., aneuploidies) using cell free DNA (cfDNA) extracted from the blood plasma of any singleton pregnancy. Patient risk for trisomy 13, trisomy 18, trisomy 21, and sex chromosome aneuploidies is reported. Fetal fraction, in conjunction with other data quality metrics, must be met in order for each sample to yield a result. The assay is intended for use as a screen only and is not equivalent to prenatal genetic diagnostic testing.

METHODOLOGY: Next Generation Sequencing (NGS) (aka Massively Parallel Sequencing (MPS)) of fetal and maternal cfDNA present in the plasma.

ANALYTICAL VALIDATION ACCURACY: The analytical sensitivity was calculated using positive percent agreement compared to established methods to detect fetal aneuploidy. For samples with greater than 5 percent observed fetal fraction, the positive percent agreements (PPA) are as follows: T13 greater than 99.9 percent, T18 greater than 99.9 percent, and T21 is 96.1 percent. The combined PPA for all aneuploidies is 97.5 percent. For samples with less than or equal to 5 percent observed fetal fraction, the positive percent agreements (PPA) are as follows: T13 is 66.7 percent, T18 is 60 percent, and T21 is 87.5 percent. The combined PPA for all aneuploidies is 72.3 percent. The specificity, as calculated as negative percent agreement, is 99.5 percent across all observed fetal fraction values.

CLINICAL PERFORMANCE: Information on clinical performance for this assay can be found in the following reference: Borth H. Analysis of cell-free DNA in a consecutive series of 13,607 routine cases for the detection of fetal chromosomal aneuploidies in a single center in Germany. Arch Gynecol Obstet. 2021;303(6):1407-1414.

LIMITATIONS: This is a screening test and should not be considered in isolation from other clinical findings and diagnostic test results. High risk results must be confirmed by diagnostic testing (amniocentesis, CVS, or postnatal testing) before any clinical decisions are made based on the screening test result. The current iteration of this assay is limited to reporting the following on singleton pregnancies: fetal sex, fetal fraction, risk level for trisomy 13, 18, 21, and risk level for sex chromosome aneuploidies XO, XXX, XXY, and XYY. This assay is not meant to detect deletions or duplications within a chromosome, polyploidy, maternal abnormalities, balanced chromosome rearrangements, or chromosomal aneuploidies not listed above. Results may be confounded by the following: recent maternal blood transfusion, organ transplant, surgery, immunotherapy, malignancy, maternal mosaicism, placental mosaicism, fetal demise, disappearing twin, fetal partial aneuploidy, and/or fetal mosaicism. Samples with observed fetal fraction less than 5.0 percent have lower sensitivity to detect fetal aneuploidy, and the accuracy of the fetal fraction estimate is significantly lower. Fetal demise/miscarriage is not assessed.

This test was developed and its performance characteristics

determined by ARUP Laboratories. It has not been cleared or approved by the US Food and Drug Administration. This test was performed in a CLIA certified laboratory and is intended for clinical purposes.

Counseling and informed consent are recommended for genetic testing. Consent forms are available online.

VERIFIED/REPORTED DATES

Procedure	Accession	Collected	Received	Verified/Reported
Multiple Gestation	22-143-101012	5/23/2022 8:40:00 AM	5/23/2022 8:45:08 AM	5/23/2022 8:57:00 AM
Gestational Age at Draw	22-143-101012	5/23/2022 8:40:00 AM	5/23/2022 8:45:08 AM	5/23/2022 8:57:00 AM
Report Fetal Sex	22-143-101012	5/23/2022 8:40:00 AM	5/23/2022 8:45:08 AM	5/23/2022 8:57:00 AM
Fetal Fraction	22-143-101012	5/23/2022 8:40:00 AM	5/23/2022 8:45:08 AM	5/23/2022 12:20:00 PM
EER Non-Invasive Prenatal NGS Aneu	22-143-101012	5/23/2022 8:40:00 AM	5/23/2022 8:45:08 AM	5/23/2022 12:21:00 PM
Trisomy 21	22-143-101012	5/23/2022 8:40:00 AM	5/23/2022 8:45:08 AM	5/23/2022 12:20:00 PM
Trisomy 18	22-143-101012	5/23/2022 8:40:00 AM	5/23/2022 8:45:08 AM	5/23/2022 12:20:00 PM
Trisomy 13	22-143-101012	5/23/2022 8:40:00 AM	5/23/2022 8:45:08 AM	5/23/2022 12:20:00 PM
Sex Chromosome Trisomies and Monosomy X	22-143-101012	5/23/2022 8:40:00 AM	5/23/2022 8:45:08 AM	5/23/2022 12:20:00 PM
Fetus Sex	22-143-101012	5/23/2022 8:40:00 AM	5/23/2022 8:45:08 AM	5/23/2022 12:20:00 PM
Result Summary	22-143-101012	5/23/2022 8:40:00 AM	5/23/2022 8:45:08 AM	5/23/2022 12:20:00 PM

END OF CHART

H=High, L=Low, *=Abnormal, C=Critical