revivegenetics.us

Revive Genetics Diagnostics Laboratory

CLIA: 10D2337214

Non-Invasive Prenatal Screening (NIPS)

Requisition & Consent Form

Patient Information

Last Name	First Name	DOB	Sex	MRN

Address	City	State	Zip	Phone Number

Email	Gestational Age (W+D)	Name of Baby's Father	Father's DOB

Ethnicity ☐ African American ☐ Ashkenazi Jewish ☐ East Asian ☐ Hispanic ☐ Middle Eastern ☐ White ☐ Other

Insurance/Billing Information

Insurance Name	Member ID	Group ID

Primary Name	Primary DOB	Relationship
		☐ Self ☐ Spouse ☐ Child

Ordering Provider/ Facility

Provider Name	NPI	Facility Name	Email

Address	City	State	Zip	Phone Number

Specimen Information

Specimen Type		

Collector Name	Collection Date/ Time	Collection Site
		☐ Office ☐ Lab ☐ Home ☐ Other

Confirmation of Medical Necessity for Genetic Testing:

I certify that I am a licensed healthcare provider (or authorized representative/genetic counselor) ordering non-invasive prenatal screening (NIPS/NIPT) and/or carrier screening. I confirm that the patient has been informed of the purpose, scope, limitations, and potential risks of this testing, has had the opportunity to ask questions and seek genetic counseling, and has provided informed consent, which is on file. I attest that this testing is medically necessary and will be used in the clinical management of the patient. I further confirm that the patient authorizes Revive Genetics Laboratory to release relevant information to third-party payors for reimbursement purposes, to receive direct payment for services rendered, and, where applicable, to act as the patient's designated representative for insurance appeals. I acknowledge that the patient understands and accepts financial responsibility for any amounts not covered by insurance, including payments made directly to the patient.

Medical Professional Signature _____DATE_____

Print Name: _____

Website www.revivegenetics.us Email info@revivegenetics.us	Address 9000 SW 152nd St Suite 107, Palmetto Bay, FL 33157	Lab Director Uzma Farooq, MD	Phone Number 786-250-3419

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Test Selection

Select	Panel	Chromosomes	Brief Description
	Express Gene™ Non-Invasive Prenatal **Basic** Screening (NIPS/NIPT)	13, 18, 21, Gender (X,Y)	Screens for Down syndrome (Trisomy 21), Edwards syndrome (Trisomy 18), Patau syndrome (Trisomy 13), and fetal sex (X/Y).
	Express Gene™ Non-Invasive Prenatal **Complete** Screening (NIPS/NIPT)	13,18,21, Gender (X,Y), 15, 22	Screens for Down syndrome (Trisomy 21), Edwards syndrome (Trisomy 18), Patau syndrome (Trisomy 13), Trisomy 15, Trisomy 22, and fetal sex (X/Y).
	Express Gene™ Non-Invasive Prenatal **Comprehensive** Screening (NIPS/NIPT)	Aneuploidies of all chromosomes (1-22, X, Y)	Screens for aneuploidies of all chromosomes (1–22, X, and Y), including Down syndrome, Edwards syndrome, Patau syndrome, sex chromosome abnormalities, and other rare whole-chromosome aneuploidies.

Indications for Testing (Check All That Apply)

☐ Routine Screening ☐ Assisted Pregnancies (IVF/IUI) ☐ Recurrent Abortion

List Relevant History and Ultrasound Findings

Pregnancy: ☐ Singleton ☐ Twin ☐ Triplet | Is current pregnancy high risk: ☐ Yes ☐ No | Mother's Weight:_____ kg/lb

Indicate if any of the following conditions exist:

☐ Embryo-donor Pregnancy ☐ History of Transfusion ☐ Organ Transplant Recipient ☐ Other Significant Co-morbidity

Method notes: NIPT/NIPS is performed using genome-wide NGS to assess chromosomal copy number changes, reporting validated aneuploidies and select sub-chromosomal abnormalities; this is a screening test and not diagnostic. Carrier screening is performed using WGS with targeted analysis of selected genes, reporting SNVs, indels, and splice-site variants, with CNVs and repeat expansions reported only for validated loci; not all variant types or regions are detected. **For further details, please visit www.revivegenetics.us**

Informed Consent:

Consent to Testing and Use of Results: I confirm that the submitted specimen belongs to the identified patient and is voluntarily provided for analysis by Revive Genetics Laboratory. I authorize the laboratory and my healthcare provider to analyze my clinical and genetic information, release results to the ordering provider, and share necessary information with my insurance carrier for billing and reimbursement purposes.

Consent for NIPT/NIPS Screening: NIPT/NIPS is a non-invasive screening test, not diagnostic, used to assess risk for chromosomal abnormalities (e.g., Trisomy 21, 18, 13, and selected sex chromosome aneuploidies). Positive results must be confirmed by diagnostic testing (e.g., amniocentesis). NIPS is non-invasive with no risk to fetus. The test is designed to investigate structural chromosomal abnormalities, such as Trisomy, and Monosomies. The test does not detect single gene disorders or all chromosomal abnormalities, may have false positives/negatives, and performance varies by condition and pregnancy type (e.g., singleton vs. multiple gestation). Fetal sex determination is optional and may have reduced accuracy, particularly in multiple pregnancies. The test cannot identify any mutation or variation at the nucleotide level. Therefore, diseases such as cystic fibrosis, or any other **inherited mendelian disorders CANNOT be identified using this test**. NIPS can be performed from 10 weeks of gestation. The Revive Genetics NIPS test is predicting structural chromosomal abnormalities related to chromosome 13, 18, 21 with 99% sensitivity on singleton and twin pregnancies. The NIPT test sensitivity for Sex chromosome aneuploidies (i.e. Turner syndrome) is 93% and test is accurate only for singleton pregnancies. Specificity of NIPT test is evaluated at 95% and al positive aneuploidy cases MUST be confirmed using Amniocentesis. Since false positive is evaluated at 5%, the NIPT test can only be regarded as screening test. **Gender prediction is NOT the purpose of NIPS test,** and the **accuracy of gender prediction is 90%** in singleton pregnancies, and it cannot predict gender in twin / multiple pregnancies.

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By signing this consent form, you acknowledge that:
You understand the purpose, benefits, and limitations of carrier and NIPT screening.
You understand that **results may have reproductive and emotional implications** for you and your family.
You understand that your results will be reviewed by your ordering physician and may be disclosed to you and, with your permission, your reproductive partner.
You consent to undergoing this genetic test and agree to be contacted with the results.

Additionally, there is a limitation on NGS sequencing methodology, that certain variation might not being captured or identified with this method. Results from this test(s) are treated with complete confidentiality and reports rendered only to the patient and his/her physician. No tests other than those authorized will be performed and patient samples will be saved for 60 days and then destroyed after testing. I have read this consent or have had it read to me. I have been given a copy of this form. I have been given the chance to ask questions before I sign this form. I have been told that I can ask other questions at any time. I want to have this NIPS and or Carrier Detection genetic test done.

Consent / Insurance Release: By signing this form, I hereby authorize Revive Genetics Laboratory to submit the medical information regarding this testing to my designated insurance carrier for reimbursement if necessary. I also authorize benefits to be payable to Revive Genetics Laboratory. I understand that I am responsible for any amounts not paid by insurance for reasons but not limited to non-covered and non-authorized services. I permit a copy of this authorization to be used in place of the original.

Patient or parent/guardian Signature _____DATE_____

Print Name: _____

Consent use of sample or data for research: To improve genetic testing results and solve unexplored genetic diseases, I understand and agree that my leftover specimen, genetic data, and/or clinical information may be used anonymously for research, education, and other business purposes. I hereby authorize Revive Genetics Laboratory to contact me in future regarding disease symptoms, recently discovered genes, mutations or to follow up on disease outcomes. To “opt in” for sample retention, you can sign below, without affecting processing of your tests.

Patient or parent/guardian Signature _____DATE_____

Print Name: _____

Medical Professional Signature _____DATE_____

Print Name: _____