Revive Genetics Diagnostics Laboratory

CLIA: 10D2337214

Carrier Panel
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 Suite107, Palmetto Bay, FL 33157	Lab Director Uzma Farooq, MD	Phone Number 786-250-3419

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Test Selection

Select	Panel	Genes	Brief Description
	Express Gene™ Carrier Detection Core Panel	20 genes	Focused panel of common, high-yield carrier conditions appropriate for broad routine screening.
	Express Gene™ Carrier Detection Standard Panel	61 genes	Adds clinically established recessive and X-linked conditions commonly included in commercial carrier screening.
	Express Gene™ Carrier Detection Expanded Panel	175 genes	Broader pan-ethnic carrier screening with additional severe childhood-onset conditions.
	Express Gene™ Carrier Detection Comprehensive Panel	277 genes	Large carrier panel for broader reproductive risk assessment when expanded testing is desired.
	Express Gene™ Consanguinity / Extended Recessive Panel	924 genes	Extensive recessive-risk panel intended for couples with consanguinity, strong family history, or complex reproductive risk.
	Express Gene™ Carrier Detection Custom Panel	Variable	Gene selected based on known familial variants or provider-directed clinical indication. Gene/Condition names _____
	Express Gene™ Fragile X Syndrome by TP-PCR.	1 gene	Analysis of FMR1 CGG repeat expansion for Fragile X carrier status.
	Express Gene™ Spinal Muscular Atrophy (SMA) by MLPA	1 gene	SMN1/SMN2 copy number analysis for SMA carrier status.

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 Diagnostics. 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.

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Consent for Carrier Screening Genetic Testing: Your physician has ordered **Carrier Screening Genetic Testing** to determine whether you are a **carrier of one or more inherited genetic conditions**. Carrier screening is typically performed before or during pregnancy to assess the **risk of passing on autosomal recessive or X-linked disorders** to your child. This test is a **screening test**, which means that **positive (carrier) results do not mean you or your child will develop the condition**, but they may indicate an increased reproductive risk. In most cases, **carriers are healthy and have no symptoms** of the condition. If both partners are carriers of the same autosomal recessive condition, there is a **25% chance with each pregnancy** that the child may be affected. For X-linked conditions, female carriers may pass the condition to sons with up to **50% probability**. The carrier panel includes some (NOT ALL) **inherited conditions**, such as, **Cystic Fibrosis, Spinal Muscular Atrophy, Sickle Cell Anemia, Tay-Sachs Disease, a**nd Only known previously reported pathogenic mutation will be reported. Carrier panel gene list is available on our website. Therefore, the test cannot rule out defect/s on remaining genes/conditions. The assumption for carrier panel is that healthy individuals are tested for recessive disease carrier status. Therefore, dominant disorders, (autosomal or X-linked), de-novo mutations, di-genic disorders, and chromosomal abnormalities are not covered by Carrier Panel test. Please be aware of the following key points: **This test does not diagnose disease** in you or your fetus; it only identifies carrier status of mother or biological father. **A negative result does not eliminate all genetic risk**. Some mutations may not be detectable with current technology, there are Denovo mutations that happen in fetus and there are novel (new) mutations that are not previously reported. These types of mutations are not covered by Carrier detection tests. **Residual risk remains** even with negative results, particularly for rare variants or genes not included in the panel. **Follow-up testing may be recommended** for your partner if you are identified as a carrier. Genetic counseling is recommended to discuss results and implications for family planning.

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: _____