CLINICAL PATHOLOGY LABORATORIES
A Sonic Healthcare Company

Patient History and Consent for Non-Invasive Prenatal (NIP) and Maternal Serum Testing

Select the appropriate test(s) below.

Please submit this history form with completed CPL requisition including patient demographics and billing information.

Patient Information		Client Information	
PATIENT NAME (LAST, FIRST)	DATE OF BIRTH (MM/DD/YYYY)	REQUESTING PHYSICIAN	CLIENT ACCOUNT NUMBER

Prenatal Screening and Carrier Testing

❑ **2616 First Trimester Screen**[+@>] ***(Note: Sonogram Info Required Below)*** (GA: 10w 3d – 13w 6d)	❑ **5624 IntegratedScreen**[SM @ >] ***(Note: Sonogram Info Required Below)*** Sample 1 (GA: 10w 3d – 13w 6d) Sample 2 (GA: 15w 0d – 21w 6d)	**Harmony Tests (GA ≥ 10w)**[+>] Note: Prior Authorization required for Texas Medicaid ❑ 2399 Harmony™ Test (singleton or twin only) ❑ 2394 Harmony™ Test with Fetal Sex (singletons only) ❑ 2395 Harmony™ Test with Monosomy X (singletons only) ❑ 2396 Harmony™ Test with Sex Chromosome Aneuploidy (singletons only) ❑ 2397 Harmony™ Test with Fetal Sex and Sex Chromosome Aneuploidy (singletons only) ❑ 2398 Harmony™ Test with Fetal Sex and Monosomy X (singleton only)
❑ **5375 Quad Screen** [@>] (GA: 14w 0d – 21w 6d)	❑ **4087 SerumIntegratedScreen**[SM @ >] Sample 1 (GA, 10w 3d – 13w 6d) Sample 2 (GA, 15w 0d – 21w 6d)	**Maternal Genetic Carrier Screening** ❑ 5225 Fragile X Screen with Reflex [+*] ❑ 4118 Cystic Fibrosis, 39 mutations [+] ❑ 3124 Cystic Fibrosis 139 [+] ❑ 5457 Spinal Muscular Atrophy (SMA) [+] ❑ 5220 Ashkenazi Carrier Panel [+@>]
❑ **2617 Maternal AFP for NTD** [@] (GA: 14w 0d – 21w 6d)	**SequentialScreen**[TM @ >] ***(Note: Sonogram Info Required Below)*** ❑ 5780 Sample 1 (GA, 10w 3d – 13w 6d) ❑ 4059 Sample 2 (GA, 15w 0d – 21w 6d)	**Additional Maternal Testing and Screening** ❑ 2720 Hemoglobin Electrophoresis (Thalassemia and Hemoglobinopathy Carrier Testing) ❑ Other Testing: _____

Pregnancy Information Used In Risk Calculations

Testing: ❑ Initial ❑ Repeat **Maternal Height:** _____ft. _____in. **Weight**: _____ lbs.

Family History of Neural Tube Defect: ❑ Yes ❑ No **Family History of Down Syndrome**: ❑ Yes ❑ No

Pre-existing Insulin Dependent DM: ❑ Yes ❑ No **Current Smoker**: ❑ Yes ❑ No

Maternal Race (please check): ❑ Caucasian ❑ Hispanic ❑ African American ❑ Asian ❑ Other _____

Number of Fetuses: _____ **If twins**: ❑ Dichorionic ❑ Monochorionic

Donor Egg: ❑ Yes ❑ No **Donor DOB if applicable**: _____

Gestational Age: Determined by:

❑ **Sonogram**: Date of Sonogram: _____ GA at Sonogram: _____ weeks _____ days

Or ❑ **LMP**: _____ (mm/dd/yy)

Date Performed: _____ **Location**: _____

NT: Singleton _____ mm **If Twins**: Twin A _____ mm Twin B _____ mm

CRL: Singleton _____ mm Twin A _____ mm Twin B _____ mm

Sonographer: _____ **FMF/NTQR#**: _____ **State**: _____

Nasal Bones: ❑ Present ❑ Absent

Other clinical information:

Patient Acknowledgement and Consent	Physician Acknowledgement and Consent
My signature on this form indicates that I have read, or had read to me, the Patient Informed Consent for Non-Invasive Prenatal Screening on the back of this form, and I understand it. Furthermore I choose to ❑ **Opt In** ❑ **Opt Out** to anonymized laboratory development and validation studies.	I attest that this patient has been informed about the details for the test and its capabilities and limitations, and has given consent for this test.
Patient Name:_____	Physician Name:_____
Patient Signature: _____ Date: _____	Physician Signature: _____ Date: _____

Please direct all inquiries to Clinical Pathology Laboratories Customer Service 800-633-4757 or 512-873-1600

Symbols: [@] Medicare Limited Coverage [+] Not Covered by Medicare [>] More than on CPT code will be billed *Reflex testing if indicated at additional charge

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Patient Informed Consent for NIP Testing

The Harmony Prenatal Test is a laboratory-developed test that analyzes fetal cell-free DNA (cfDNA) in maternal blood to aid in the risk determination of fetal trisomy 21, trisomy 18, and trisomy 13. The term "trisomy" refers to a chromosomal condition that occurs when there are three (3) copies of the specific chromosome instead of the expected two (2).

- **Trisomy 21** is due to an extra copy of chromosome 21. Trisomy 21 causes Down syndrome. Infants born with Down syndrome may have mild to moderate intellectual disabilities, a heart defect or other medical conditions. It is estimated that Down syndrome is present in 1 out of every 740 newborns.
- **Trisomy 18** is due to an extra copy of chromosome 18. Trisomy 18 causes Edward syndrome and is associated with a high rate of miscarriage. Infants born with Edward syndrome may have various medical conditions and a shortened lifespan. It is estimated that Edward syndrome is present in approximately 1 out of every 5,000 newborns.
- **Trisomy 13** is due to an extra copy of chromosome 13. Trisomy 13 causes Patau syndrome and is associated with a high rate of miscarriage. Infants born with Patau syndrome may have severe congenital heart defects and other medical conditions. Survival beyond the first year is rare. It is estimated that Patau syndrome is present in approximately 1 out of every 16,000 newborns.

Eligible patients are of at least 10 weeks gestational age with a singleton or twin pregnancy resulting from natural conception or in vitro fertilization (IVF). Patients who are pregnant with more than two fetuses are not eligible for the Harmony Prenatal Test. The test is not intended nor validated for diagnosis, detection of mosaicism, partial trisomy, or translocations. Clinical studies demonstrate high accuracy for fetal trisomy detection, but not all trisomy fetuses will be detected. Some trisomy fetuses may have “LOW RISK” results. Some euploid (not trisomic) fetuses may have "HIGH RISK" results. Results should be considered in the context of other clinical criteria. It is recommended that a HIGH RISK result or other evidence of a chromosomal abnormality be confirmed through fetal karyotype analysis by an invasive procedure (usually, amniocentesis). It is recommended that results be communicated in a setting designated by your healthcare provider that includes appropriate counseling.

The Harmony Prenatal Test with Y analysis is a laboratory developed test that aids in the risk determination of fetal trisomy 21, trisomy 18, and trisomy 13, and evaluates Y chromosome sequences, providing information on fetal sex and Y chromosome aneuploidy. Eligible patients are of at least 10 weeks gestational age with a singleton pregnancy resulting from natural conception or IVF. Patients who are pregnant with more than one fetus are not eligible for the Harmony Prenatal Test with Y analysis. The test is not intended nor validated for diagnosis, detection of mosaicism, partial aneuploidy, or translocations. Results should be considered in the context of other clinical criteria. It is recommended that results be communicated in a setting designated by your healthcare provider that includes appropriate counseling.

The Harmony Prenatal Test with X and Y analysis is a laboratory developed test that aids in the risk determination of fetal trisomy 21, trisomy 18, and trisomy 13 and evaluates X and Y chromosome sequences, providing information on fetal sex and sex chromosome aneuploidy. Eligible patients are of at least 10 weeks gestational age with a singleton pregnancy resulting from natural conception or IVF. Patients who are pregnant with more than one fetus are not eligible for the Harmony Prenatal Test with X and Y analysis. The test is not intended nor validated for diagnosis, detection of mosaicism, partial trisomy, or translocations. Results should be considered in the context of other clinical criteria. It is recommended that results be communicated in a setting designated by your healthcare provider that includes appropriate counseling.

No additional clinical testing will be performed on my blood sample other than those authorized by my healthcare provider. Ariosa Diagnostics, Inc. will disclose the test results only to the healthcare provider listed on the front of this form, or to his/her agent, unless otherwise authorized by me or as required by laws, regulations, or judicial order.
Unless you check the opt-out box on the front page, you acknowledge and agree that after the completion of your selected test(s), the remaining unused portion of your sample may be anonymized and stored for longer than 60 days for use in internal laboratory validation, process development, and/or quality control studies at Ariosa. In addition, your results may be included in a confidential data registry to validate the performance of Ariosa’s tests and to assist Ariosa with improving its services to patients. In all cases, your samples and results will be stored, used, and destroyed in compliance with applicable US laws, rules, and regulations.

It is standard of care for physicians to obtain informed consent for genetic testing.
This form is designed to address the requirements of New York State Civil Rights Law Section 79-1 and Massachusetts General Law Part I Title XVI Chapter 111, Section 70G