BIOGENIX LABS
By M42

G42 Healthcare - Omics Center of Excellence (Biogenix Labs)
Masdar City - Abu Dhabi
Contact: +971 58 166 1261
Email: clinical.genomics@m42.ae

For scanning and accuracy, affix patient label within this outlined box.

Patient Name:

MRN No:

Only use black ball point pens to ensure scanning integrity.
No sharpies, highlighters, or red ink please.

Non-Invasive Prenatal Testing Consent Form

SECTION I: CONSENT FOR CLINICAL GENETIC TESTING	
Name of individual to be tested	
Emirate's ID	

SECTION II: PATIENT INFORMED CONSENT STATEMENT

- I consent to non-invasive prenatal testing and confirm that I have been informed about the purpose, scope and limitations of the test by my healthcare provider. I understand this is a screening test for selected abnormalities and the results would be reviewed by my healthcare provider. I have had the opportunity to ask questions and understand I can request further information.
- I confirm that I have read the Privacy Policy on the back page of this form.
- I consent to the processing of my personal data as outlined in the Privacy Policy.
- I confirm that the personal information I have provided is accurate and complete.

Retention of specimens.

- I consent to the long-term preservation and use of my leftover specimens to be stored at Biogenix Laboratory and de-identified test results in a secure cloud storage facility for future academic and commercial research purposes (some commercial partners may be based outside the UAE) all of which will have the necessary regulatory and ethical approvals, as stated in the Informed Consent. I understand that this unique de-identified dataset will be stored in a secure cloud in accordance with all applicable UAE laws and the relevant authorities' regulations. I understand I am free to withdraw at any time without giving a reason and without affecting my medical rights.
- I consent to the generation of genomic data from my leftover specimens.
- I consent to my data derived from my specimens to be linked with my other health data as contained in my personal medical records to create a unique consolidated de-identified dataset to be explored for research purposes.
- I understand that this unique de-identified dataset will be stored securely in the cloud, in compliance with all applicable UAE laws and regulations from relevant authorities.

SECTION III: PATIENT DECLARATION OF CONSENT

By signing this Informed Consent for clinical genetic testing, I acknowledge that I have read and understood the contents of this consent form, and that I have had the opportunity to ask and have had any additional questions answered by my primary care physician or genetics professional. With my signature below, I give my consent to clinical genetic testing (or consent on behalf of the patient for whom I am the legal guardian).

Name of Patient /Legal Guardian	Emirates ID of Signatory	Signature of Patient/Legal Guardian [with date]	Witness/Interpreter

SECTION IV: ORDERING CLINICIAN SIGN-OFF

I have explained genetic testing to the consenting party. I have addressed the limitations of the genetic testing that will be performed, based on current data-and literature. I confirm that the patient is capable of giving these consents (alternatively that consent was given by a legal guardian of the patient), that all questions of the patient have been answered, and the patient has had the necessary time to consider his/her decision to proceed with the test of the provided sample.

Name of Referring Clinician	Signature	Date	Witness/Interpreter

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Non-Invasive Prenatal Testing Consent Form

PURPOSE

NIPT is a non-invasive prenatal screening test that analyses circulating cell free DNA (cfDNA) from a maternal peripheral whole blood specimen. The genome wide screen test is indicated for use in pregnant women of at least 10 weeks gestation for the detection of fetal anomaly of chromosomes 21, 18, 13, X and Y along with partial duplications and deletions of at least 7 Mb for all autosomes. Sex chromosome aneuploidy cannot be reported for twin samples, only presence or absence of Y chromosome will be reported (if fetal sex is requested).

ELIGIBILITY CRITERIA

Patients should be at least 10 weeks pregnant to undergo the test. It is recommended to perform the test before 24 weeks of gestation to allow sufficient time for any necessary follow-up diagnoses or procedures.

NOT ELIGIBLE for NIPT:

- Couples with a known chromosomal abnormality
- Pregnancy with triplets or more fetuses
- Presence of malignant tumors
- History of transplant surgery or stem cell therapy
- Allogeneic blood transfusion received within the past year
- Human serum albumin therapy or exogenous DNA immunotherapy received within the last four weeks
- Fetal ultrasound indicating a structural abnormality
- Vanishing twin syndrome, unless the developmental arrest occurred within the first eight weeks of pregnancy and more than eight weeks prior to the test date

Patients with the following conditions are at high risk for maternal genetic abnormalities, which may lead to inaccurate test results. Please assess any genetic abnormalities before proceeding with the test. The decision to undergo testing should be made by the patient and/or their healthcare provider, following local medical and bioethics guidelines, laws, and regulations. By signing this form, you acknowledge that you are aware of and accept the associated risks:

- Patients who have undergone Assisted Reproductive Technology (ART)
- Patients with a history of abnormal pregnancies or a family history of genetic diseases or abnormalities
- Previous screening results indicating fetal abnormalities
- Pregnancy involving twins or vanishing twins

TEST LIMITATIONS

NIPT is a screening test, not a diagnostic test, and does not replace prenatal diagnostic procedures like CVS or amniocentesis. Results are informational only. High-risk results should prompt genetic counselling and possible invasive testing, while low-risk results do not guarantee an unaffected pregnancy or rule out other chromosomal abnormalities.

Inaccurate results may occur due to:

· Courier or shipping delays
· Laboratory errors
· Biological factors (e.g., insufficient fetal fraction, sample contamination, mosaicism)
· Recent maternal blood transfusions or organ transplants
· Unrecognized twin or vanishing pregnancies

Approximately 1-2% of pregnancies may have confined placental mosaicism, where the placenta may have chromosomal abnormalities while the fetus does not. The assay is not designed to detect polyploidy, balanced chromosome rearrangements, or open neural tube defects. Test results should be interpreted by a qualified professional and cannot be the sole basis for diagnosis or management decisions.

NIPT is validated for singleton pregnancies and monochorionic twins; dichorionic twins are excluded from options involving sex chromosome aneuploidies and microdeletions due to ambiguity. Fetal gender can only indicate the presence or absence of a Y chromosome.

False negatives and positives are possible. Negative results do not eliminate the risk of other conditions, making follow-up ultrasounds essential. Positive results require confirmation through invasive testing and may reflect chromosomal changes in the placenta or mother rather than the fetus.

Disclaimer: This test has been validated by Biogenix Clinical Laboratory and is intended for clinical use, not for investigational or research purposes. It cannot detect abnormalities related to chromosomal polyploidy, translocations, inversions, uniparental disomy (UPD), monogenic or polygenic diseases, imprinting disorders, or fetal chimeric chromosomal abnormalities.

RESULTS

Test reports will be available within 7-10 days after the laboratory receives the sample. Due to the complexity and implications of the results, reports will be sent only to the undersigned healthcare provider. Patients are encouraged to contact their healthcare provider for results and interpretation. High-risk results should be followed up with confirmatory diagnostic tests.

In some cases, samples may fail quality control, or the initial analysis may not yield a conclusive result. If this occurs, resampling or reanalysis may be necessary. This will be offered at no additional cost, but it may delay the report. Your healthcare provider will notify you if this happens.

CONFIDENTIALITY STATEMENT

Your information and test results will be kept confidential, and all data will remain anonymous during analysis. Only your healthcare provider will receive your test results, unless required or authorized by applicable law.

To process your test, we require clinical information about your pregnancy, including any ultrasound, screening, or diagnostic tests performed. This clinical information may also be used for auditing, quality assurance, and research purposes. Biogenix Laboratory complies with all relevant UAE laws and regulations.

The sample and completed information—including your first name, last name, address, date of birth, medical conditions, symptoms, and other relevant medical information—will be sent to Biogenix Laboratory, located in Abu Dhabi, United Arab Emirates.

USE OF LEFTOVER SPECIMENS AND INFORMATION

Your de-identified specimens and genetic information may be used for academic and commercial health research, scientific purposes, technological development, and clinical research. Your participation will help researchers understand diseases and develop new prevention and treatment methods, ultimately enhancing future care.

With regulatory approval, your sample and related data will be linked to your existing clinical information to create a unique de-identified dataset. This dataset may be shared with research partners for the exploration of disease prevention, treatment responses, and healthcare technologies, all in compliance with applicable UAE laws.

Researchers will analyse this de-identified data to identify patterns and insights about disease development. This analysis may involve researchers, scientists, healthcare professionals, and authorized third parties, including some based outside the UAE.

All personal data will be de-identified to protect your identity. Identifiable information such as your name, Emirates ID number, and contact details will not be included. Your sample and data will be assigned a unique identification code and stored in accordance with UAE regulations.

RIGHT OF REVOCATION

Your participation is voluntary. You may withdraw your sample and discontinue your participation in the research at any time without penalty and without needing to provide a reason. If you revoke your participation, your sample and data will be destroyed. However, if your de-identified sample and data have already been shared or included in research analysis, it may not be possible to remove them from previously conducted research.

You have the right not to be informed of test results (the right not to know), to halt testing at any time before receiving results, and to request the destruction of all test materials and results collected up to that point.

Your withdrawal will not affect your medical care or legal rights. To request the destruction of your sample or deletion of personal data, please contact clinical.genomics@m42.ae. If you have any questions about your rights as a research subject, or if you have concerns or complaints, please reach out to the same email address.

Test Performance: The information below is based on a study conducted by the manufacturer. The performance metrics for detecting trisomies 21, 18, and 13 are derived from outcomes in 2,307 singleton and twin pregnancies.

References:

- Bianchi D et al. N Engl J Med. 2014;370(9):799-808.
- Grati, et al. Genet Med. 2014;16: 620–624.
- ACOG Practice Bulletin No. 163. Obstet Gynecol. 2016;127(5):e123-137.
- ACOG/SMFM Joint Committee Opinion No. 545, Dec 2012.

	Trisomy 21	Trisomy 18	Trisomy 13	Any Anomaly	Rare Autosomal Aneuploidy	Partial Deletions and Duplications
Sensitivity	> 99.9% (130/130)	> 99.9% (41/41)	> 99.9% (26/26)	95.5% (318/333)	96.4% (27/28)	74.1% (20/27)
2-sided 95% CI	97.1%, 100%	91.4%, 100%	87.1%, 100%	92.7%, 97.3%	82.3%, 99.4%	55.3%, 86.8%
Specificity	99.90% (1982/1984)	99.90% (1995/1997)	99.90% (2000/2002)	99.34% (1954/1967)	99.80% (2001/2005)	99.80% (2000/2004)
2-sided 95% CI	99.63%, 99.97%	99.64%, 99.97%	99.64%, 99.97%	98.87%, 99.61%	99.49%, 99.92%	99.49%, 99.92%

Estimates for Trisomy 21, 18, and 13 in Simulated Population of Twin Pregnancies:

	Trisomy 21	Trisomy 18	Trisomy 13
Sensitivity	96.4%	95.7%	93.6%
2-sided 95% CI	(86.4%, 98.9%)	(68.3%, 99.4%)	(64.1%, 98.9%)
Specificity	99.9%	> 99.9%	> 99.9%
2-sided 95% CI	(99.8%, > 99.9%)	(99.9%, > 99.9%)	(99.9%, > 99.9%)

Percent Concordance for Fetal Sex Classification:

	Cytogenetic Results			
Fetal Sex Classification	XO	XXX	XXY	XYY
Percent Concordant	90.5%	100%	100%	91.7%