



*A test your patients can trust. A company you know and trust.*

**informaSeq<sup>®</sup> Prenatal Test** – an advanced, non-invasive, prenatal screening for T21, T18, and T13 chromosomal aneuploidies using next generation technology.

# informaSeq® Prenatal Test

*P*rovide your patients with a precise, non-invasive test that can assess risk for multiple fetal chromosomal aneuploidies from a single blood draw. Safe and accurate, informaSeq can be administered as early as 10 weeks, giving you and your patients the information you both need.



**informaSeq can be ordered with a number of different options.**

*The basic informaSeq test screens for:*

- T21 (Down syndrome)
- T18 (Edwards syndrome)
- T13 (Patau syndrome)

*Optional testing detects:*

- Monosomy X (MX; Turner syndrome)
- XXX (Triple X)
- XXY (Klinefelter syndrome)
- XYY (Jacobs syndrome)
- Fetal gender (XX or XY) – aids in stratifying the risk for X-linked disorders such as hemophilia

## Choose the informaSeq test that best meets the needs of your patients and your practice.

Test #	CPT Codes	informaSeq Prenatal Test	Test Description
550746	81420	informaSeq	Provides risk assessment for the most common autosomal trisomies.
550757	81420	informaSeq with Y analysis	Provides risk assessment for the most common autosomal trisomies, and also provides fetal gender, but not sex chromosome aneuploidies.
550716	81420	informaSeq with XY analysis	Provides risk assessment for the most common autosomal trisomies, sex chromosome aneuploidies, and also provides fetal gender. This test is only available for singleton pregnancies.

**Please note:** This test does not assess risk for mosaicism, partial trisomies, or translocations. Sex chromosome aneuploidy options may only be ordered for singleton pregnancies.

### *Specimen Requirements*

#### Whole Blood

- Use only the black and tan capped blood collection tube from the informaSeq kit
- One Streck tube, minimum 7 mL
- Store samples at room temperature and transport at ambient temperature in the informaSeq kit

#### Turnaround Time

- 5-7 business days upon sample receipt

# Answers Your Patients Can Trust

When you recommend prenatal testing for your patients, you can do so with confidence in our company, our laboratory, and the test. informaSeq's high detection rates (sensitivity) and low false-positive rates (specificity) for common chromosomal and sex aneuploidies provide reliable answers you and your patients can trust.

## Predictive values in the most common chromosomal aneuploidies<sup>1</sup>

	Positive Predictive Value	Negative Predictive Value
Trisomy 21	96.8%	99.9%
Trisomies combined	92.0%	99.9%

## Test performance in the most common chromosomal aneuploidies<sup>1</sup>

	Sensitivity	Specificity
21	99.1%	99.9%
18	98.3%	99.9%
13	98.2%	99.9%

## Test performance in the most common sex chromosomes<sup>2</sup>

	Sensitivity	Specificity
MX	95.0%	99.0%
XX	97.6%	99.2%
XY	99.1%	98.9%
XXX XXY XYY	These are more rare aneuploidies with limited data, precluding performance calculations.	

Sex chromosome mosaicism cannot be distinguished by this method (the occurrence of which is <0.3%).

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*Reliable* results support  
informed decision making.

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# From a Company You Know and Trust

*Clear, interpretable result report*

<b>Clinical Information</b>		
<b>Fetal Number:</b> 1	<b>Gestational Age at Collection:</b> 11.3 weeks	
<b>Indication for Testing:</b> Not Provided.		
<b>Screen Result:</b> <b>No Aneuploidy Detected</b>		<b>Fetal Fraction (%): 13.5%</b>
<b>Chromosome</b>	<b>Result</b>	<b>Interpretation</b>
Chromosome 21	No Aneuploidy Detected	Consistent with diploid chromosome 21
Chromosome 18	No Aneuploidy Detected	Consistent with diploid chromosome 18
Chromosome 13	No Aneuploidy Detected	Consistent with diploid chromosome 13
<b>Comments:</b> Correlation of these results with clinical findings is recommended. For definitive diagnostic testing, consider CVS or amniocentesis		

*Identifiable results:*

- Screen result highlighted for easy identification
- Results and interpretation clearly defined in the table
- Fetal fraction provided for client information and convenience

*Test results:*

- No aneuploidy detected
- Aneuploidy suspected
- Aneuploidy detected

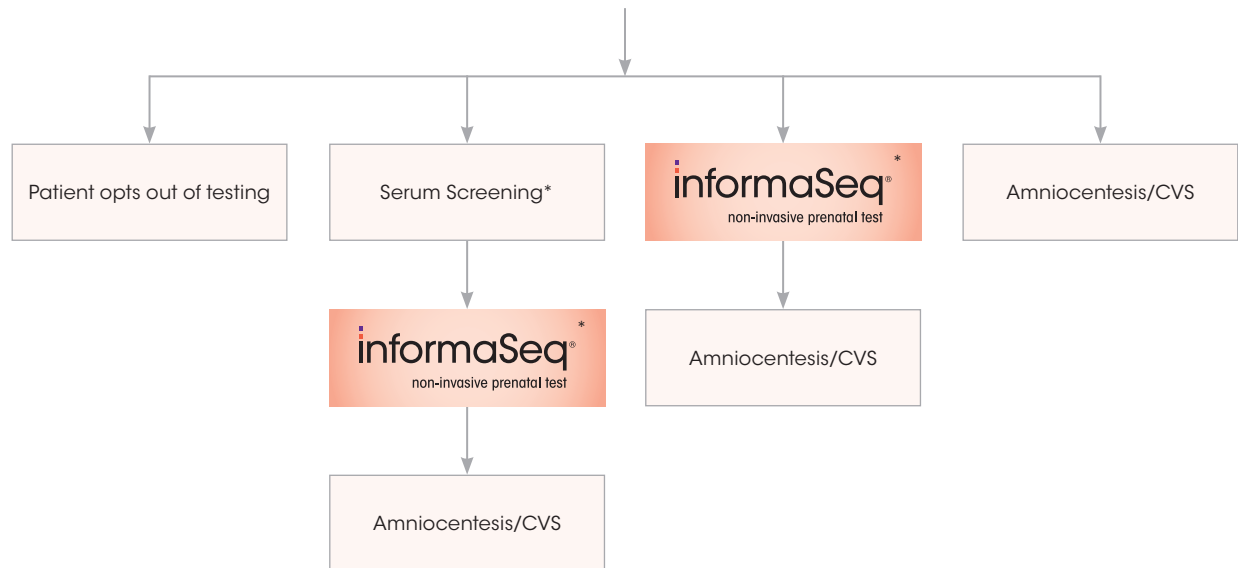
## REFERENCES

1. Bhatt, S et al. Clinical Laboratory Experience with Noninvasive Prenatal Testing: Update on Clinically Relevant Metrics. ISPD 2014 poster.
2. Verinata Health, Inc. (2012) analytical validation of the verifi® Prenatal Test: Enhanced Test Performance For Detecting Trisomies 21, 18, 13 and the Option for Classification of Sex Chromosome Status. Redwood City, CA.
3. ACOG Practice Bulletin 77. Screening for fetal chromosomal abnormalities. *Obstet Gynecol* 2007; 109:217-227.
4. ACOG Committee Opinion No. 640. Cell-free DNA Screening for Fetal Aneuploidy. *Obstet Gynecol* 2015; 126:e31-7.

# Complete Laboratory Services to Simplify Your Workflow

It is critical that your laboratory have the capability to provide the necessary follow-up testing and/or counseling your patients may require. Integrated Genetics offers a full complement of reproductive genetic screening and diagnostic options.

## *Patient Options for Trisomies 21, 18, and 13*



\*Screening tests – a diagnostic test should be recommended for a patient found at increased risk of aneuploidy by serum screening or who has a positive cell-free DNA test result.<sup>3,4</sup>

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*Whether* you test in the first trimester, second trimester, or both, trust Integrated Genetics to offer you the **Right Test at the Right Time** for your serum screening needs.

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Help patients get answers and support for complex questions with a trusted partner in genetic testing and counseling.

### *Access to Expert Genetic Counseling*

Our trusted genetic counseling services are now available remotely to patients with positive informaSeq Prenatal Test results through the *Telegenetic Counseling to You* program. Available to patients by telephone or tele-video, the *Telegenetic Counseling to You* program includes:

- An explanation of informaSeq results to patients
- An evaluation of other genetic risks to the pregnancy or intended pregnancy based on family history (as provided by the patient to the genetic counselor)
- A review of appropriate follow-up testing options, if applicable, based on the results of the patient's genetic risk assessment performed by the genetic counselor
- A genetic counseling report for the referring physician, summarizing the genetic risks identified and testing options discussed during the counseling session

Patients with positive informaSeq Prenatal Test results referred by their physicians for genetic counseling can call **855-GC-CALLS (855-422-2557)** to schedule an appointment.

### *Affordable Payment Options for Your Patients*

#### **Insurance**

Integrated Genetics is contracted with over 400 healthcare plans, helping patients maximize their benefits

#### **Patient-specific programs**

Integrated Genetics offers payment plans, special payment plans for financial hardship, and indigent requests from a physician or clinical facility

#### **Medicare/Medicaid**

Integrated Genetics accepts both Medicare and Medicaid and will bill these programs on the patient's behalf

Please call us toll-free at **800-845-6167** for any billing questions. We are available between the hours of 8:00 AM and 5:00 PM, Monday through Friday.

## From a Company You Know and Trust

### informaSeq®, an advanced and accurate non-invasive prenatal test

- Accurate prenatal testing directed by board-certified molecular geneticists **as early as 10 weeks gestational age**
- Testing performed via deep sequencing, which increases detection, even in samples with a lower fraction of fetal DNA fragments

### Genetic counseling, to give your patients vital information

- The largest national commercial genetic counseling team with unparalleled services
- Convenient telegenetic counseling services providing access for more patients
- Call **855-GC-CALLS (855-422-2557)** to learn more about our exceptional services

### Integrated Genetics, an experienced partner

- Over 25 years of genetic testing expertise
- A comprehensive menu of screening and diagnostic tests focused on women's reproductive health
- Extensive managed care contracts, helping patients maximize their benefits
- Nationwide network of patient service centers, allowing for convenient access to sample collection

**When you order  
informaSeq testing,  
you're choosing  
a trusted partner.**

**Integrated Genetics** – a leading provider of reproductive genetic testing services, driven by its commitment to physicians and patients. Learn more by visiting [www.integratedgenetics.com](http://www.integratedgenetics.com) or calling Integrated Genetics Client Services at **800-848-4436**.

**informaSeq®**  
non-invasive prenatal test

**Integrated  
GENETICS**  
.....  
LabCorp Specialty Testing Group

informaSeq® Prenatal Test is Powered by Illumina® sequencing technology.

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