New Leaders In Fertility & Endocrinology , LLC (www.FertilityLeaders.com)

PATIENT AUTHORIZATION for USE or DISCLOSURE of PROTECTED HEALTH INFORMATION (PHI)

Name of Individual Patient (or Personal Representative) who is authorizing the Release of Records:
(Please complete the following information)

Name: _____ Date of Birth: ____/____/____
Address: _____ Phone:(_____) _____

I hereby voluntarily authorize the disclose and use of my Protected Health Information*:

(Check the specific tests, reports that are needed)

☐ All Fertility-related Testing ☐ Hysterosalpingogram (HSG) ☐ Semen Analysis (male)
☐ Genetic Screening/Test Reports ☐ Surgical Report(s) Date(s): _____ ☐ Pathology Reports
☐ Infectious Disease Screening Tests ☐ Other (Describe specifically): _____

***Note: If these records contain any information about HIV/AIDS status, cancer diagnosis, drug/alcohol abuse or sexually transmitted disease, you are hereby authorizing disclosure of this information.**

I authorize the Custodian of Records at _____
Phone: _____ Fax: _____ **to send my records to** (check one box)**:**

☐ New Leaders In Fertility & Endocrinology
4400 Bayou Blvd, Suite 36 Pensacola FL 32503
Phone: 850-857-3733
Main Fax: 850-857-0670 or Tallahassee: 850-857-0670

☐ (Other) Name: _____
Address: _____
Phone: (____)_____
Fax: (____)_____

The information may be used and/or disclosed for each of the following purposes:

☐ For use in my Health Care ☐ For Employment Purposes ☐ For Payment/Insurance
☐ Patient's personal request ☐ Other:_____

This Authorization shall expire no later than one (1) year from the date of signature.

I understand that I may revoke the authorization at anytime by giving written notice to the Privacy Officer. However, I understand that I may not revoke this authorization for any actions taken before receipt of my written notice to revoke this authorization. In addition, I understand that if I am giving this authorization as a condition of obtaining insurance coverage, and I revoke this authorization, the insurance company has the right to contest my claims under the insurance policy.

I understand that under most circumstances a health care provider may not condition treatment, payment, enrollment, or eligibility for benefits on my signing this authorization. However, I understand that signing an authorization that permits the use and/or disclosure of my Protected Health Information for research purposes may be a condition on my treatment if I am undergoing research-related treatment. Also, I may be required to sign an authorization if my treatment is provided solely for the purpose of creating Protected Health Information for disclosure to a third party. And under some circumstances, a health plan may condition my enrollment in a health plan or my eligibility for benefits on my providing an authorization permitting the health plan to make enrollment and eligibility determinations.

I have had the chance to read and think about the content of this authorization form and I agree with all statements made in this authorization. I understand that, by signing this form, I am confirming my authorization for use and/or disclosure of Protected Health Information described in this form with the people and/or organizations named in this form.

_____ _____ _____
Patient's or Representative's Signature Printed Name Date

Patients have a right to a copy of this form after it is signed. A copy will be retained in the Medical Record.

New Leaders In Fertility & Endocrinology, LLC (aka NewLIFE)

NOTICE OF PRIVACY PRACTICES

EFFECTIVE DATE 4/14/2003

Revised: 1/1/2014

THIS NOTICE DESCRIBES HOW MEDICAL INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESS TO THIS INFORMATION. PLEASE REVIEW IT CAREFULLY.

If you have any questions about this Notice please contact our Privacy Officer: Stephanie LaFountaine

This notice describes how we may use and disclose your protected health information to carry out treatment, payment or health care operations and for other purposes that are permitted or required by law. It also describes your rights to access and control your protected health information. "Protected health information" or PHI is information about you, including demographic information, that may identify you and that relates to your past, present or future physical or mental health or condition and related health care services.

We are required to abide by the terms of this Notice of Privacy Practices. We may change the terms of our notice, at any time. The new notice will be effective for all protected health information that we maintain at that time. Upon your request, we will provide you with any revised Notice of Privacy Practices. You may request a revised version by accessing our website, or calling the office and requesting that a revised copy be sent to you in the mail or asking for one at the time of your next appointment.

1. USES AND DISCLOSURES OF PROTECTED HEALTH INFORMATION

Your protected health information may be used/disclosed by your physician, our office staff and others outside of our office who are involved in your care and treatment for the purpose of providing health care services to you. Your protected health information may also be used and disclosed to pay your health care bills and to support the operation of your the practice.

Following are examples of the types of uses and disclosures of your protected health information that we are permitted to make. These examples are not meant to be exhaustive, but to describe the types of uses and disclosures that may be made by our office.

Treatment: We may use and disclose your protected health information to provide, coordinate, or manage your health care and any related services. This includes the coordination or management of your health care with another provider. We may also disclose protected health information to other physicians who may be treating you. For example, your protected health information may be provided to a physician to whom you have been referred to ensure that the physician has the necessary information to diagnose or treat you. In addition, we may disclose your protected health information from time-to-time to another physician or health care provider (*e.g.*, a specialist or laboratory) who, at the request of your physician, becomes involved in your care by providing assistance with your health care diagnosis or treatment to your physician.

Payment: Your protected health information may be used and disclosed to obtain payment for your health care services provided by us or by another provider. This may include certain activities that your health insurance plan may undertake before it approves or pays for the health care services we recommend for you such as: making a determination of eligibility or coverage for insurance benefits, reviewing services provided to you for medical necessity, and undertaking utilization review activities.

Health Care Operations: We may use or disclose, your protected health information to support the business activities of the practice. These activities include, but are not limited to, quality assessment activities, employee review activities, training of medical students, licensing, fundraising activities, and conducting or arranging for other business activities.

We may share your protected health information with third party "business associates" that perform various activities (for example, billing, accounting or transcription services) for our practice. Whenever an arrangement between our office and a business associate involves the use or disclosure of your protected health information, we will have a written contract that contains terms that will protect the privacy of your protected health information.

We may use or disclose your protected health information, as necessary, to provide you with information about treatment alternatives or other health-related benefits and services that may be of interest to you. You may contact our Privacy Officer to request that these materials not be sent to you.

Other Permitted and Required Uses and Disclosures That May Be Made Without Your Authorization or Opportunity to Agree or Object

We may use or disclose your protected health information in the following situations without your authorization or providing you the opportunity to agree or object. These situations include:

Required By Law: We may use or disclose your protected health information to the extent that the use or disclosure is required by law. The use or disclosure will be made in compliance with the law and will be limited to the relevant requirements of the law. You will be notified, if required by law, of any such uses or disclosures.

Public Health: We may disclose your protected health information for public health activities and purposes to a public health authority that is permitted by law to collect or receive the information. For example, a disclosure may be made for the purpose of preventing or controlling disease, injury or disability.

Communicable Diseases: We may disclose your protected health information, if authorized by law, to a person who may have been exposed to a communicable disease or may otherwise be at risk of contracting or spreading the disease or condition.

Health Oversight: We may disclose protected health information to a health oversight agency for activities authorized by law, such as audits, investigations, and inspections. Oversight agencies seeking this information include government agencies that oversee the health care system, government benefit programs, other government regulatory programs and civil rights laws.

Food and Drug Administration: We may disclose your protected health information to a person or company required by the Food and Drug Administration for the purpose of quality, safety, or

effectiveness of FDA-regulated products or activities including, to report adverse events, product defects or problems, biologic product deviations, to track products; to enable product recalls; to make repairs or replacements, or to conduct post marketing surveillance, as required.

Legal Proceedings: We may disclose protected health information in the course of any judicial or administrative proceeding, in response to an order of a court or administrative tribunal (to the extent such disclosure is expressly authorized), or in certain conditions in response to a subpoena, discovery request or other lawful process.

Law Enforcement: We may also disclose protected health information, so long as applicable legal requirements are met, for law enforcement purposes. These law enforcement purposes include (1) legal processes and otherwise required by law, (2) limited information requests for identification and location purposes, (3) pertaining to victims of a crime, (4) suspicion that death has occurred as a result of criminal conduct, (5) in the event that a crime occurs on the premises of our practice, and (6) medical emergency (not on our practice's premises) and it is likely that a crime has occurred.

Research: We may disclose your protected health information to researchers when their research has been approved by an institutional review board that has reviewed the research proposal and established protocols to ensure the privacy of your protected health information.

Military Activity and National Security: When the appropriate conditions apply, we may use or disclose protected health information of individuals who are Armed Forces personnel (1) for activities deemed necessary by appropriate military command authorities; (2) for the purpose of a determination by the Department of Veterans Affairs of your eligibility for benefits, or (3) to foreign military authority if you are a member of that foreign military services. We may also disclose your protected health information to authorized federal officials for conducting national security and intelligence activities, including for the provision of protective services to the President or others legally authorized.

Uses and Disclosures of Protected Health Information Based upon Your Written Authorization

Other uses and disclosures of your protected health information will be made only with your written authorization, unless otherwise permitted or required by law as described below. You may revoke this authorization in writing at any time. If you revoke your authorization, we will no longer use or disclose your protected health information for the reasons covered by your written authorization. Please understand that we are unable to take back any disclosures already made with your authorization.

Other Permitted and Required Uses and Disclosures That Require Providing You the Opportunity to Agree or Object

We may use and disclose your protected health information in the following instances. You have the opportunity to agree or object to the use or disclosure of all or part of your protected health information. If you are not present or able to agree or object to the use or disclosure of the protected health information, then your physician may, using professional judgement, determine whether the disclosure is in your best interest.

Others Involved in Your Health Care or Payment for your Care: In our fertility practice, medical information will be shared between the male and female partners. Unless you object, we may disclose to a member of your family, a relative, a close friend or any other person you identify, your protected health information that directly relates to that person's involvement in your health care. If you are

unable to agree or object to such a disclosure, we may disclose such information as necessary if we determine that it is in your best interest, based on our professional judgment. We may use or disclose protected health information to notify or assist in notifying a family member, personal representative or any other person that is responsible for your care of your location, general condition or death. Finally, we may use or disclose your protected health information to an authorized public or private entity to assist in disaster relief efforts and to coordinate uses and disclosures to family or other individuals involved in your health care.

2. YOUR RIGHTS

Following is a statement of your rights with respect to your protected health information and a brief description of how you may exercise these rights.

You have the right to inspect and copy your protected health information. This means you may inspect and obtain a copy of protected health information about you for so long as we maintain the protected health information. You may obtain your medical record that contains medical and and any other records that the practice uses for making decisions about you. As permitted by federal or state law, we may charge you a reasonable fee for the effort to make a copy of your records. Alternatives to a printed record may include electronic/digital formats.

Under federal law, however, you may not inspect or copy the following records: psychotherapy notes; information compiled in reasonable anticipation of, or use in, a civil, criminal, or administrative action or proceeding; and laboratory results that are subject to law that prohibits access to protected health information. Depending on the circumstances, a decision to deny access may be reviewable. In some circumstances, you may have a right to have this decision reviewed. Please contact our Privacy Officer if you have questions about access to your medical record.

You have the right to request a restriction of your protected health information. This means you may ask us not to use or disclose a part of your protected health information for the purposes of treatment, payment or health care operations. You may also request that any part of your protected health information not be disclosed to family members or friends who may be involved in your care or for notification purposes as described in this Notice of Privacy Practices. Your request must state the specific restriction requested and to whom you want the restriction to apply.

Your physician is not required to agree to a restriction that you may request. If your physician does agree to the requested restriction, we may not use or disclose your protected health information in violation of that restriction unless it is needed to provide emergency treatment. With this in mind, please discuss any restriction you wish to request with your physician. Requests for restrictions of the uses and disclosures of protected health information should be submitted in writing to NewLIFE's Privacy Officer.

(Acknowledgment of receipt is requested separately)

New Leaders In Fertility & Endocrinology
New Patient Appointment Reservation & Cancellation Policy

Staff members at New LIFE are committed to our patients and we continue to accept new patients. As the only board-certified fertility specialist in the area, a missed appointment is a missed opportunity and delay for another patient.

Therefore, we require a check or credit card to hold your appointment time. If for any reason you are unable to keep your appointment, please call at least one business day in advance to allow us to schedule another patient. A $100.00 fee will be applied otherwise and will need to be cleared before another appointment is made.

To achieve a productive first visit, communication and records are essential. If for whatever reason, the office is unable to contact you in the days preceding your appointment (at least 24 hours before), the right is reserved to cancel your appointment and insert another patient. In such cases, the office will attempt to provide a voice message or email notification.

Thank you for your attention to and consideration of this courtesy extended to all of our patients.

Please designate/complete one of the appointment reservation methods below and return this form with your other materials

☐ I have attached a personal check in the amount of $100.00 to be deposited. It will be voided, returned or refunded upon compliance with this appointment policy

☐ I authorize a charge of $100.00 to my credit card (information below),

Credit Card: MasterCard ☐ Visa ☐

Credit Card Number: _____ Expiration: _____

Name of Cardholder: _____ 3digit Security Code: _____

Cardholder Billing Address: _____

Credit Card Authorizing Signature: _____

Cancellation Policy Acknowledgement: if I fail to make my scheduled appointment and fail to notify the office at least 24 hours (one full business day) in advance. I authorize payment as indicated above.

Patient's Signature: _____ Date: _____

New Leaders in Fertility and Endocrinology, LLC - New Patient Authorizations

Print Female Patient's Name:_____ Date of Birth: _____

Print Male Partner's Name (if applicable):_____ Date of Birth: _____

Acknowledgement of Receipt of Notice of Privacy Practices for Offices

By signing below, I/we acknowledge that I/we have received and read a copy of this office's Notice of Privacy Practices and hereby give my/our consent and permission to all previously outlined uses/releases of Protected Health Information.

_____ _____

Female Signature Date Male's Signature (if applicable) Date

Authorization to Receive Medical Care

The undersigned hereby make the following Acknowledgments and Agreements regarding the medical testing and treatment to be provided to me/us as patient(s).

1. I/We recognize that a condition exists that may need medical care and do hereby voluntarily consent to such medical care, encompassing diagnostic procedures and medical treatment as is deemed necessary. I understand that this medical care may include tests, examinations and medical treatments and procedures.
2. I/We am aware that the practice of medicine and surgery and the administration of medical care are not exact, and I acknowledge that no guarantees have been made to me as a result of diagnostic procedures, surgical procedures, medical procedures, treatments, examinations or care.
3. I/We certify that I/we understand the contents of this form.
4. Release of medical information: I/We acknowledge the records concerning me and/or my spouse as patient(s) are the property of the office of New Leaders in Fertility and Endocrinology, LLC (NewLIFE) and are maintained for the use and benefit of NewLIFE and its medical staff in providing care and treatment. I hereby authorize NewLIFE to disclose all or any part of my patient record to any person or corporation which is or may be liable under contract to NewLIFE or to me or a family member of mine for all or part of NewLIFE's charges, including but not limited to: hospital or medical service companies, Worker's Compensation carriers, welfare agencies, or my employer, provided such release of information shall be in accordance with the state and federal laws and regulations.
5. Assignment of Insurance: I/We hereby authorize payment of all insurance benefits related to care provided by NewLIFE, for this period of medical treatment, hospitalization, Emergency Room treatment or outpatient services to be made directly to NewLIFE.
6. Financial Agreements: For and in consideration of services rendered, I/We agree to pay NewLIFE for all charges not covered by insurance payments as statements are rendered. For specific services that are not covered or that NewLIFE believes will be denied or has experienced denied coverage, I/we may be asked to make a deposit for such services in advance, pending evaluation of claims. Further, should it become necessary to enforce collection of any unpaid balance for medical services or treatment rendered, each of the undersigned agrees to pay all collections and legal expenses incurred, or in litigation, including trial and appellate review, and in arbitration, bankruptcy, or other administrative or judicial proceedings.

_____ _____ _____ _____

Female's Signature: Date Male's Signature (if applicable) Date

Patient Consent to Fertility Testing and Basic Treatments

(These topics are presented and explained in detail in the General Fertility – Patient Information Booklet)

Hysterosalpingography (HSG or "dye test") is a diagnostic test to determine if the fallopian tubes are open, providing sperm with access to eggs. Pictures are made with X-rays after injection of "dye" or with ultrasound after injection of salt water (saline). Uterine cramping is common during this short, but important test. Infection may occur in less than 1% of patients but rare serious cases may require hospitalization and intravenous antibiotics. There are no simple alternatives to obtain this important information, but outpatient laparoscopic surgery will often provide addition information.

Hysteroscopy is an office procedure to view the inside of the uterus for defects or abnormalities that may interfere with implantation or normal pregnancy. Salt water is used to fill the uterus and a thin flexible tube is passed through the cervix while an image is displayed on a video display. There may be some mild cramping during the procedure and although rare, infection and perforation of the uterus are possible complications.

Ovulation induction is performed with oral medications such as clomiphene citrate, letrozole, and anastrozole (Clomid®, Femara®, Arimidex®) and/or injections such as Human Menopausal Gonadotropins or synthetically prepared FSH hormone (hMG, Gonal F®, Follistim®). Ovulation induction may require blood testing and/or vaginal ultrasound to monitor the response.

Fertility injections may be used to stimulate more than one egg per cycle and require daily injections for an average of 10 days. Your response must be monitored by blood hormone levels and ovarian ultrasounds, which may show the number and size of developing follicles (containing eggs). These tests of your response will be performed repeatedly while taking such medications. When the eggs are ready to ovulate (mature), a different injection, human chorionic gonadotropin (hCG) may be prescribed for you to trigger the release of your egg(s). If pregnancy is suggested by a missed period and confirmed by blood tests, ultrasound may be employed to confirm the location of the pregnancy.

Possible Risks and Discomforts:
This therapy is associated with possible risks from drawing blood samples, ovarian examination by ultrasound, fertility medications/injections. Cycles may be cancelled for hyperstimulation or the opposite, absence of an adequate response.

Risks of Drawing Blood Samples

a) Discomfort, bruising (blood in adjacent tissue) and bleeding from the puncture site occur with moderate frequency, are usually not serious and have no long-term effect. These discomforts may be treated by applying direct pressure / moist heat.
b) Infection may occur following puncture of the skin by the needle. The chance that this will occur is very low and no serious harm will result. Treatment is with antibiotics and moist heat.

Complications and Risks of Fertility Injections and hCG Trigger Injections

a) Injury from injection: You, your partner or another individual may be trained to give injections. There is some risk that damage may occur from the needle in the skin or muscle. Deep injections may cause nerve injury and subsequent pain and numbness. There is no treatment and symptoms from the injury may go away without treatment.
b) Allergic reactions: These are rare but usually consist of skin rashes, dizziness or pain at the injection site. Symptoms may be treated with an antihistamine or other medications.
c) Emotional changes: Moodiness, anxiety and irritation are possible but are often related to the stress of treatment rather than the medications. When experienced, these are usually tolerable and require no treatment.
d) Ovarian Hyperstimulation (OHSS): If over-responsive to fertility injections, ovaries may become too large, may bleed, twist or rupture. Fluid may collect in your abdomen and/or lungs and your blood may become over concentrated resulting in kidney damage or blood clots if not treated. Severe ovarian hyperstimulation is rare (<1%) for patients closely monitored, but polycystic ovary syndrome and other factors may raise the chances. Hyperstimulation is often treated with intravenous fluid therapy, removal of abdominal fluid and avoidance of pelvic exams and intercourse. It may require hospitalization. OHSS is best avoided by withholding the hCG injection and avoiding pregnancy with an excessive ovarian response.
e) Multiple pregnancies / multiple births: Because medications may stimulate more than one egg, pregnancy with two or more babies occurs in 7-8% with oral medications and up to 25% of pregnancies with injections compared to 1% in the general population. This cannot be reliably predicted or prevented by contemporary monitoring but multiple gestation brings a higher chance of miscarriage, infant birth defects, pregnancy induced hypertension (toxemia), hemorrhage, premature delivery and handicaps due to low birth weight along with other maternal complications. In addition, care for multiple, premature babies is very expensive and physically and emotionally demanding. Options to avoid this, cycle cancellation and interventions such as selective reduction and others, are presented in detail in Patient Educational Booklets.
f) Miscarriage & Ectopic (tubal) Pregnancies: Pregnancy after fertility injections is associated with chance of miscarriage at 15-25% but is similar to the chance seen in women of similar age but conceiving spontaneously. While a tubal pregnancy (ectopic) may occur in 1-2% of spontaneous pregnancies, these treatments may carry a slightly higher risk of 1-3%. Tubal pregnancy is likely to require surgery or medicines. A combination of tubal and intrauterine pregnancies ("heterotopic") requires surgical treatment.
g) Ovarian Cancer: Risk of ovarian cancer appears partly related to the number of times a woman ovulates and carries a pregnancy. Being infertile alone increases the chance of ovarian cancer, while pregnancy and birth control pill use decrease risk. Controversial reports of a possible link between fertility drugs and ovarian cancer have been published, but the American Society for Reproductive Medicine recommends that continued use of these medications is reasonable as pregnancy and breastfeeding reduce cancer risks. (for additional information, read ASRM statements)

Intrauterine Insemination (IUI) is a procedure for placement of sperm inside the uterus. If IUI has been recommended in place of sexual intercourse, the sexually intimate, male partner will be asked to provide a semen sample to the office when the female appears to be near ovulation. Semen is prepared to separate sperm from seminal fluid and concentrate the most motile sperm.

Risks of Intrauterine Insemination (IUI)

a) Uterine cramping occurs occasionally during and after IUI but is usually mild and treatment is usually not required.
b) Infection. Bacteria in the semen or in the vagina may be passed into the uterus. The chance of infection is believed to be very small but may require antibiotics. A rare severe infection may require hospitalization and intravenous antibiotics.

INFORMED CONSENT: I/we hereby consent to diagnostic testing and basic therapeutic procedures based on the above risks. I/we have received the Patient Information Booklet provided by NewLIFE. Specifically, I/we am/are informed of the risks of ovarian hyperstimulation and multiple births and hereby confirm understanding of the need to carefully follow recommended dosages and agree to continue to return for evaluation and care while receiving these self-administered medications. I/we hereby acknowledge the potential risks and side effects of these medications and treatments, and that I/we recognize my/our right to refuse any therapy. I/we hereby provide fully informed consent.

_____ _____ _____ _____
Female's Signature: Date Male's Signature (if applicable) Date

Name & Signature of NewLIFE Employee as Witness_____Date _____

GoodStart Genetics

Good Start Assist

OUR PROMISE TO YOU…NO BILLING SURPRISES

Prepare for tomorrow with the answers you need today.

We believe every patient should have access to highly accurate genetic testing.

With that in mind, we offer **Good Start Assist**. Patients can proceed with genetic testing knowing that Good Start Genetics is committed to working with each patient to find payment solutions to accommodate their needs.

We encourage patients to call us for all billing questions and to discuss payment solutions.

Toll-free: 1-877-246-9203
Confidential Email: solutions@gsgenetics.com

Genetic testing is important.

Genetic testing provides important information about your reproductive risks and is part of routine care in most OBGYN and IVF offices. It is recommended by professional medical societies and leading advocacy groups.

THE GOOD START ASSIST BILLING PROCESS:

STEP 1 Your physician will collect a blood or saliva sample and send it to Good Start Genetics for genetic testing.

STEP 2 After our lab receives your sample and testing is complete, we will submit a claim to your insurance company.

STEP 3 Once your insurance company processes the claim, they will send you an Explanation of Benefits (EOB). The EOB will explain what insurance paid towards your genetic testing, and what portion, if any, is your responsibility. *Please note: the EOB is not a bill; it is for informational purposes only.*

If it is determined that your responsibility will be under $100:

We will send you a bill. You may contact Client Solutions to help find a payment solution that works for you.

If it is determined that your responsibility will be over $100:

We will contact you **prior to sending a bill** to review our Good Start Assist payment solutions.

We will contact patients with an out-of-pocket cost over $100 to discuss payment solutions.

DON'T WANT TO WAIT? Contact us directly to discuss your options.

GOOD START ASSIST PAYMENT SOLUTIONS

- Flexible payment options (billed over time with no interest or fees)
- Financial assistance for patients who qualify

More information for you. Better options for your family.

Your insurance company may send a payment check directly to you. If this occurs, please endorse the check to **Good Start Genetics** and send the check along with the EOB to:

Good Start Genetics
P. O. Box 416658
Boston, MA 02241-6658

GeneVu
Carrier Screening

Questions? Contact Client Solutions toll-free at 1-877-246-9203 or solutions@gsgenetics.com.

Good Start Genetics, Inc. developed GeneVu™ and EmbryVu™ and performs the tests in its CLIA certified and CAP accredited laboratory. These tests were developed and their performance characteristics determined by Good Start Genetics®. They have not been cleared or approved by the U.S. Food and Drug Administration. However, the laboratory is regulated under the Clinical Laboratory Improvement Amendments (CLIA) as qualified to perform high complexity clinical testing and the tests have been analytically validated in accordance with CLIA standards.

GSG-ASSIST rev1