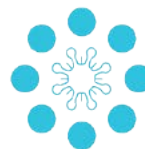


12/23/2024

CLIENT SERVICES MANUAL



SPECTRUM
SIMPLY TEST®

Powered by:

Alimetrix

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ALIMETRIX SCOPE OF PATIENT SERVICES

LABORATORY INFORMATION

800 Hudson Way
Huntsville, AL 35806

CLIA Number: 01D2113023

CAP Number: 9450297

HOURS OF OPERATION

Client Services

8am-5:30pm CST Monday – Friday

Laboratory Hours of Operation

8am-5:30pm CST Monday – Friday

CONTACT INFORMATION

Client Services

877-SIMPLY-25 (877-467-5925)

Laboratory Services

844-4-GENOME (844-443-6663)

Fax

256.327.0981

Email

Client Services:

info@simplytest.com

Lab Services:

labmanager@simplytestresults.com

Kit and supply requests

info@simplytest.com

DIAGNOSTIC SERVICES AND TURN-AROUND TIMES

SimplySTI

Two (2) business days from receipt of sample

SimplyHPV

Two (2) business days from receipt of sample

SimplyPERIO

Two (2) business days from receipt of sample

SimplyHORMONE

Two (2) business days from receipt of sample



ALIMETRIX COMPANY MISSION

ABOUT ALIMETRIX

Alimetrix was founded upon the desire to provide clinicians with relevant and actionable data, as quickly as possible, using the most relevant technological platform. We've assembled a highly sophisticated repertoire of technologies, each of which is most suitable to the specific demands of our assay targets. Previously, as assay development partners for clients the world over, we had the opportunity to witness both the strengths and weaknesses of many different assay design philosophies. We have seen firsthand the successes and shortcomings of many different platforms. At Alimetrix our mission is to take that knowledge and use it to provide diagnostic assays that deliver relevant, actionable information, with best-in-class accuracy, all in a timely fashion. Our goal is to empower clinicians with the highest quality diagnostic information, enabling them to positively affect the patient's recovery.

OUR MISSION

To alleviate suffering through informed disease insight and the development of state-of-the-art diagnostic tools.

OUR GOAL

To always deliver clinically actionable information that will positively affect the patient's outcome.

LABORATORY LEADERSHIP

Joel Peek, Ph.D.

CEO, President, and Founder of Alimetrix, Inc.

Mark McQuain, M.Sc., Ph.D.

Chief Technical Officer

Jonas Boateng, M.Sc., Ph.D.

Chief Operating Officer

Carol Quinter M.Sc., Ph.D.

Laboratory Director of Clinical Services

Richard Spera MD, FACP

Medical Director

Jennifer Serrett, B.Sc.

Director of Clinical Process Improvement

TEST MENU

SimplySTI®

SimplyHPV®

SimplyHORMONE®

SimplyPERIO®

PATIENT PREPARATION

- Read all the instructions for collecting and shipping specimen before beginning the collection process.
- Specimen collection protocols in this manual are those that are recommended for each of the panels that Alimetrix offers. Substitution of collection kit components or specimen types must be preapproved by Alimetrix before the specimen is submitted for testing.
- Follow the specimen collection procedure.
- Prevent specimen rejection:
 - Make sure the top is seated properly and screwed tightly on the tube to prevent leaks in transport.
 - Label the specimen transfer tube with two identifiers. Preferred identifiers are the patient's first and last name and date of birth along with the barcode label. The name, date of birth and barcode must match the name, date of birth, and barcode on the requisition.
Unlabeled specimens will not be tested.
- Complete all required fields on the requisition (if needed). Writing must be legible.
- Package and ship the specimen and requisition according to shipping instructions.

SPECIMEN CONTAINER AND VOLUME REQUIREMENTS

- Spectrum BIOMAX® SDNA-RUO Collection Device collection tube containing 0.75 mL of cV3 stabilizing buffer and 1 mL of patient saliva or urine sample
- Spectrum BIOMAX® SDNA-1000 Collection Device collection tube containing 1.5 mL of cV3 stabilizing buffer and 2 mL patient saliva or urine sample
- 903 Five Spot Blood Card (DBS) with four or more spots filled with at least 60% of blood
- Vacutainer® serum separation tube (SST) containing venous blood centrifuged to separate out serum
- The collection tube and/or DBS card are properly placed into biohazard shipping bag and then placed into USPS shipping box
- Collection tube shows no signs of damage, crack, or leakage, and volumes are accurate
 - 1.75 mL for BIOMAX® SDNA-RUO Collection Device collection
 - 3.5 mL for BIOMAX® SDNA-1000 Collection Device collection
- Specimen remains in collection tube and cap is securely applied

SPECIMEN LABELING REQUIREMENTS

- Barcode label must be applied to collection tube
- There must be two patient identifiers (name and DOB) on collection tube
- The 2 patient identifiers on collection tube must exactly match 2 identifiers on patient demographics form

Clients will be contacted as soon as possible if any issues need to be resolved.

WHAT IS STI?

Infections are transmitted from human to human through sexual contact when a body fluid containing a sexually transmitted pathogen is deposited on a susceptible body site.

CLINICAL PRESENTATIONS	MOST COMMON STI PATHOGENS
Pain when urinating	Gonorrhoeae (GC)
Abdominal and/or pelvic pain (pelvic inflammatory disease)	Chlamydia (CT)
Vaginal or penile discharge	Trichomonas (Trich)
Painful and non-painful sores	Herpes 1 and 2 (HSV 1, 2)
Rectal pain	Mycoplasma genitalium (MG)
Sore throat	Syphilis (<i>T. pallidum</i>)
Infertility	Human Papilloma Virus (HPV)
Pregnancy complications such as failure to thrive	Human Immunodeficiency Virus (HIV)
Pelvic inflammatory disease	Hepatitis viruses (HBV, HCV)

BURDEN IN THE US [1]

1.6 million cases of Chlamydia (6% increase from 2015)
677,769 cases of Gonorrhea (45% increase from 2016)
133,945 cases of Syphilis (52% increase from 2016)
2,148 cases of Congenital Syphilis (235% increase from 2016)

WHY TEST?

- Clinical presentation of STIs is very similar to other infections such as UTIs and vaginitis.
- Testing is the only way to know if an STI pathogen is responsible for the clinical presentation.
- Testing is the only way to know the best treatment plan for the clinical presentation.
- STIs are asymptomatic in at least 50% of infected individuals.
- Asymptomatic individuals can transmit the infection to their sexual partners and babies.
- Left untreated, the infection can spread from the infected site systemically.
- The systemic spread of STIs is associated with an increase in morbidity and in some cases fatality.

WHY CHOOSE SimplySTI?

Simply STI is an innovative multiplex PCR and serology-based platform which provides fast, highly sensitive, specific, and accurate detection of 12 major pathogens associated with STIs.

- The CDC recommends the use of nucleic acid technology for detection of STIs.[2]
- The complexity of the STI ecological pool presents a significant challenge to culture-based technology (CBT) due to the lack of sensitivity and specificity compared to nucleic acid technology.
- Multiplex nucleic acid technology provides improved sensitivity and specificity over CBT (n=1855) [3]
 - 100% specificity
 - 18% detection rate compared to 3% for CBT
 - Detection of additional 27 coinfections by PCR vs CBT
- Simply STI has the most comprehensive test menu compared to most competitors.
- Wide selection of sample types ensures you are using the appropriate sample for the right diagnosis.

SimplySTI can rapidly identify co-infections

The failure to demonstrate all organisms infecting a given patient may result in incomplete therapy which may result in poor outcomes including sustained communicability, extension of infection beyond the genital tract, and transmission to an unborn or newborn child.

SimplySTI includes *Trichomonas vaginalis*

The burden of *Trichomonas vaginalis* and the substantial evidence linking it to adverse health outcomes, including pelvic inflammatory disease, adverse pregnancy outcomes and increased susceptibility to HIV, speaks to the appropriateness of its inclusion in routine screening [4,5].

SimplySTI includes both HSV-1 and HSV-2

Many individuals infected with HSV are asymptomatic or have very mild symptoms that go unnoticed or are mistaken for another skin condition [6]. The preferred HSV tests for patients with active genital ulcers are detection of HSV DNA by nucleic acid amplification tests (NAATs) such as polymerase chain reaction (PCR) or isolation by viral culture [6].

SimplySTI includes Syphilis

In 2016, a total of 27,814 cases of primary and secondary syphilis were reported in the United States, yielding a rate of 8.7 cases per 100,000 population. There was a 17.6% increase from 2015 to 2016 [7].

WHO TO TEST?

- Patients exhibiting clinical presentations (symptomatic patients)
- Asymptomatic patients (see CDC guidelines) [8]
- Patients with substance use disorder.

SELECT THE RIGHT SPECIMEN TYPE TO TEST

MALES

First void urine
Saliva*
Capillary blood (DBS Card)

FEMALE

First void urine
Saliva*
Capillary blood (DBS Card)

*Obtain an adequate history of sexual practices to determine if saliva is appropriate.

Specimen Type	Chlamydia		Gonorrhea		Trichomonas	
	Sensitivity	Specificity	Sensitivity	Specificity	Sensitivity	Specificity
Vaginal Swab†	96.6%	96.8%	96%	99.2%	100%	99%
Vaginal Swab**	98.4%	96.8%	100%	99.5%		
Endocervical Swab	94.2%	97.6%	99.2%	98.7%	100%	99.4%
Urine (female)	94.7%	98.9%	91.3%	99.3%	95.2%	98.9%
Urine (male)	97.9%	98.5%	98.5%	99.6%		
Urethral (male)	95.9%	97.5%	99.1%	97.8%		
ThinPrep	96.7%	99.2%	92.3%	99.8%		

†Clinician collected

**Patient collected

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1. <https://www.cdc.gov/std/statistics/2020/default.htm>
2. <https://www.cdc.gov/std/treatment-guidelines/screening-recommendations.htm>
3. Comprehensive Screening for Sexually Transmitted Pathogens. Medlab Management. Sept-Oct. 2014. Vol 3 #5
4. CDC Treatment Guidelines: <https://www.cdc.gov/std/tg2015/default.htm>
5. Krupp, Karl, and Purnima Madhivanan. "Antibiotic Resistance in Prevalent Bacterial and Protozoan Sexually Transmitted Infections." *Indian Journal of Sexually Transmitted Diseases* 36.1 (2015): 3–8. PMC. Web. 15 May 2018.
6. Centers for Disease Control and Prevention. Sexually Transmitted Diseases Treatment Guidelines, 2015. *MMWR Morb Mortal Wkly Rep Recomm Rep*, 2015. 64(RR-3): 27-32.
7. <https://www.cdc.gov/std/stats16/Syphilis.htm>
8. <https://www.cdc.gov/std/laboratory/2014labrec/2014-lab-rec.pdf>

SimplySTI: Premium

12 Pathogen Genital Detection Panel

Neisseria Gonorrhoeae (NG)
Chlamydia Trachomatis (CT)
Trichomonas Vaginalis (TV)
Mycoplasma Genitalium (Mgen)
Ureaplasma Urealyticum (UU)
Treponema Pallidum (Syphilis)
Herpes Simplex Virus 1 (HSV-1)
Herpes Simplex Virus 2 (HSV-2)
HIV 1 & 2
Hepatitis B Virus (HBV)
Hepatitis C Virus (HCV)
Monkeypox Virus (MPXV)

SimplySTI: Premium Plus

12 Pathogen Genital Detection Panel

Neisseria Gonorrhoeae (NG)
Chlamydia Trachomatis (CT)
Trichomonas Vaginalis (TV)
Mycoplasma Genitalium (Mgen)
Ureaplasma Urealyticum (UU)
Treponema Pallidum (Syphilis)
Herpes Simplex Virus 1 (HSV-1)
Herpes Simplex Virus 2 (HSV-2)
HIV 1 & 2
Hepatitis B Virus (HBV)
Hepatitis C Virus (HCV)
Monkeypox Virus (MPXV)

9 Pathogen Oral Detection Panel

Neisseria Gonorrhoeae (NG)
Chlamydia Trachomatis (CT)
Trichomonas Vaginalis (TV)
Mycoplasma Genitalium (Mgen)
Ureaplasma Urealyticum (UU)
Treponema Pallidum (Syphilis)
Herpes Simplex Virus 1 (HSV-1)
Herpes Simplex Virus 2 (HSV-2)
Monkeypox Virus (MPXV)

SimplySTI: Complete

9 Pathogen Genital Detection Panel

Neisseria Gonorrhoeae (NG)
Chlamydia Trachomatis (CT)
Trichomonas Vaginalis (TV)
Mycoplasma Genitalium (Mgen)
Ureaplasma Urealyticum (UU)
Treponema Pallidum (Syphilis)
Herpes Simplex Virus 1 (HSV-1)
Herpes Simplex Virus 2 (HSV-2)
Monkeypox Virus (MPXV)

SimplySTI: Complete Plus

9 Pathogen Genital Detection Panel

Neisseria Gonorrhoeae (NG)
Chlamydia Trachomatis (CT)
Trichomonas Vaginalis (TV)
Mycoplasma Genitalium (Mgen)
Ureaplasma Urealyticum (UU)
Treponema Pallidum (Syphilis)
Herpes Simplex Virus 1 (HSV-1)
Herpes Simplex Virus 2 (HSV-2)
Monkeypox Virus (MPXV)

9 Pathogen Oral Detection Panel

Neisseria Gonorrhoeae (NG)
Chlamydia Trachomatis (CT)
Trichomonas Vaginalis (TV)
Mycoplasma Genitalium (Mgen)
Ureaplasma Urealyticum (UU)
Treponema Pallidum (Syphilis)
Herpes Simplex Virus 1 (HSV-1)
Herpes Simplex Virus 2 (HSV-2)
Monkeypox Virus (MPXV)

SimplySTI: Oral

9 Pathogen Oral Detection Panel

Neisseria Gonorrhoeae (NG)

Chlamydia Trachomatis (CT)

Trichomonas Vaginalis (TV)

Mycoplasma Genitalium (Mgen)

Ureaplasma Urealyticum (UU)

Treponema Pallidum (Syphilis)

Herpes Simplex Virus 1 (HSV-1)

Herpes Simplex Virus 2 (HSV-2)

Monkeypox Virus (MPXV)

IMPORTANT ALIMETRIX™ DOES NOT ACCEPT SPECIMENS FOR SEXUALLY TRANSMITTED PATHOGENS IN THE FOLLOWING CONDITIONS:

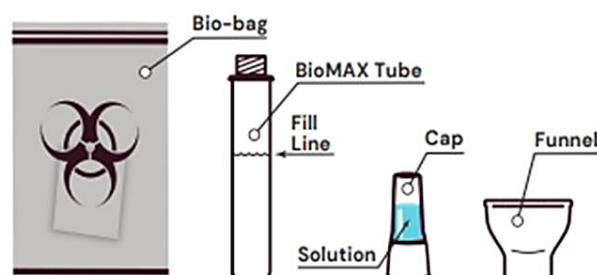
- WHEN FORENSIC USE IS TO BE CONSIDERED AND CHAIN OF EVIDENCE MUST BE MAINTAINED
 - PATIENT IS UNDER 15 YEARS OF AGE
-

1 Saliva Collection Start Here

Read all instructions before starting collection.

Wash your hands before touching collection device to prevent possible contamination.

Do NOT eat, drink, smoke, brush teeth, or chew gum for 30 minutes before giving your saliva sample.



SAFETY & WARNING INFORMATION

- No one under 18 years of age unless directed by a physician.
- Do not use if any kit component is damaged, expired, or missing.
- Do not substitute any of the kit components provided with alternatives.
- Cap may be considered a choking hazard. Keep out of reach of children.
- Wash with water if solution comes in contact with eyes or skin.
- Securely attach tube cap and do not remove.
- Do not allow blue solution to come in contact with bleach.
- Do not use in any test platform or laboratory processes containing sodium hypochlorite as a hazardous chemical reaction could occur.
- **DO NOT INGEST LIQUID.**
- All patient specimens must be handled as containing potential biohazards.
- Individual state laws regarding reportable organisms will be followed.
- You are **STRONGLY** advised to discuss your test results with your health care provider to obtain proper treatment for any positive results.
- **Not for forensic use.**

2

Fill the tube with saliva to the black wavy line. Fill the tube until your saliva (not including bubbles) is at or just above the wavy line. **DO NOT OVERFILL.**

3

Replace the funnel with the fluid cap. Remove the funnel from the tube. Screw on the enclosed cap **TIGHTLY** to release the solution that will stabilize your saliva.

4

Firmly screw cap down to release solution and seal tube. You will know it works when the blue solution from the cap is released into the tube. Do not remove cap once solution is released.

5

Shake the tube for at least five seconds. This will ensure your sample mixes thoroughly with the stabilizing solution.

SENDING SAMPLES TO THE LAB FOR TESTING

1. Remove SimplySTI sleeve from test box to reveal the prepaid shipping label on the outside of the box.
2. After collection, place specimen sample inside bio-bag and seal.
3. Place bio-bag with sample into shipping box and seal box closed.
4. Hand package directly to USPS mailman or drop package off at any USPS Post Office, drop box, or ship center.

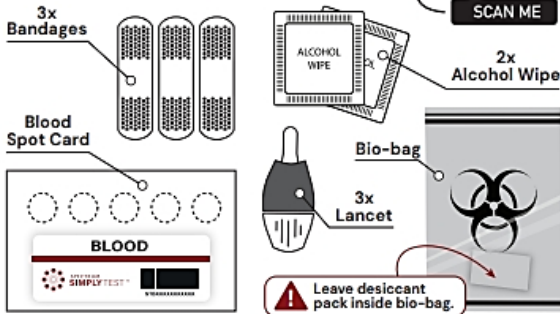


simplytest.com

GENITAL DETECTION PANEL INSTRUCTIONS

1 Blood Collection Start Here

Prepare your test area before you start your collection. Open your blood spot card to reveal collection circles and open bandages for easy access.



Drink water and make sure you are well hydrated. Right before collection, wash & leave your hands under warm, running water for 2-minutes.



Hang arm by side at hip level & shake hands for 15 seconds. With hand by side, massage index or middle finger towards the nail at least 10 times.



Sanitize the selected finger with the provided alcohol wipe. Allow finger to completely dry.



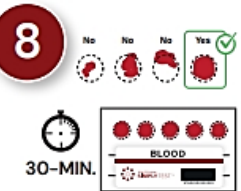
Remove the lancet cap by twisting it off. Support the SIDE of your selected finger against a solid surface.



Position the tip of the lancet on the INSIDE, SIDE (not center) of the finger & press down until you hear a click to activate the needle.



Dangle finger above collection card & lightly squeeze the finger base to get the best blood flow. Blood droplet may contact card, but DO NOT touch card with finger.



Use additional lancets as needed to completely fill ALL FIVE circles. Before closing card's attached cover, lay sample card open to dry for at least 30 MINUTES.



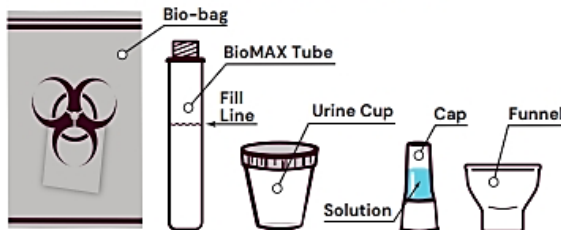
Wipe away blood with provided alcohol wipe. Place bandage on finger to stop bleeding. Place closed blood sample collection card in the biohazard bag and seal closed.

1 Urine Collection Start Here

Read all instructions before starting collection.

Wash your hands before touching urine cup to prevent sample contamination.

First morning urine is preferred. If first morning urine isn't possible, patient should not urinate for at least one hour prior to collection. Female patients should not cleanse the labial area prior to providing specimen.



Fill urine cup only half full with first catch urine (initial urine stream, not midstream). Collecting larger volumes of urine may result in dilution, reducing test sensitivity.



Use the BIOMAX collection tube and provided pipette to transfer urine from cup into the tube.



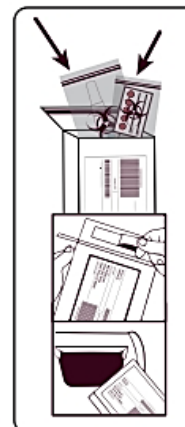
Using pipette, transfer urine from cup to the tube until fill line is reached. DO NOT overfill tube.



Remove the attached funnel and screw the enclosed cap TIGHTLY to release solution into the tube. Do not remove cap once solution is released. Shake the tube for at least 5 seconds.

SENDING SAMPLES TO THE LAB FOR TESTING

1. Remove SimplySTI sleeve from test box to reveal the prepaid shipping label on the outside of the box.
2. After collection, place specimen sample inside bio-bag and seal.
3. Place bio-bag with sample into shipping box and seal box closed.
4. Hand package directly to USPS mailman or drop package off at any USPS Post Office, drop box, or ship center.



simplytest.com



800 Hudson Way, Huntsville, AL 35806
P: 844-443-6663 | F: 256-327-0981
Testing Performed By Alimetric - CLIA #: 01D2113023
Medical Director: Dr. Richard V. Spera MD, FACP

simplytest.com |

FINAL REPORT

COMPLETE PLUS

Sample Type: Urine & Saliva

Reported: 03/20/2023 14:31

PATIENT INFO	(1) URINE SAMPLE	(2) SALIVA SAMPLE	ORDERING PROVIDER
DOB: 09/20/1980 (40 yrs) Gender: Female ID#: 951750 Location: Test Site A	Specimen#: 5555550005 Accession#: 777000-12345 Collected: 03/15/2023 Received: 03/20/2023 09:57	Specimen#: 5555550005 Accession#: 777000-12345 Collected: 03/15/2023 Received: 03/20/2023 09:57	Glenn Close MD 8977 Lone Peak Parkway Draper, UT 84020 800-555-5555

Negative	Positive	Attn.	URINE TARGETS	GENITAL
	✓	!	NG Neisseria gonorrhoeae	
	✓	!	CT Chlamydia trachomatis	
✓			TV Trichomonas vaginalis	
✓			Mgen Mycoplasma genitalium	
✓			HSV1 Herpes Simplex Virus 1	
✓			HSV2 Herpes Simplex Virus 2	
✓			UU Ureaplasma urealyticum	
✓			TP Treponema pallidum*	
✓			MPXV Monkeypox virus	

Negative	Positive	Attn.	SALIVA TARGETS	ORAL
	✓	!	NG Neisseria gonorrhoeae	
	✓	!	CT Chlamydia trachomatis	
✓			TV Trichomonas vaginalis	
✓			Mgen Mycoplasma genitalium	
✓			HSV1 Herpes Simplex Virus 1	
✓			HSV2 Herpes Simplex Virus 2	
✓			UU Ureaplasma urealyticum	
✓			TP Treponema pallidum*	
✓			MPXV Monkeypox virus	

The expected normal test result for all target pathogens reported in this panel is "Negative".

Oropharyngeal infection with *T. vaginalis*, *M. genitalium*, or *U. urealyticum* is rare but not unreported. Positive results need to be carefully considered in light of the patient's complete clinical picture, especially when immunocompromised.

* A lesion swab is preferred for detection of active *T. pallidum* (syphilis) and a blood specimen for detection of asymptomatic syphilis. A lesion swab or respiratory secretions are preferred for detection of Mpox (monkeypox). While periodically detected in urine, there is limited data on the efficacy of urine as a specimen source for these pathogens.

PATIENT PREPARATION

- Read all the instructions for collecting and shipping specimen before beginning the collection process.
- Specimen collection protocols in this manual are those that are recommended for each of the panels that Alimetrix offers. Substitution of collection kit components or specimen types must be preapproved by Alimetrix before the specimen is submitted for testing.
- Follow the specimen collection procedure.
- Prevent specimen rejection:
 - Label the specimen transport container with two identifiers. Preferred identifiers are the patient's first and last name and date of birth along with the barcode label. The name, date of birth and barcode must match the name, date of birth, and barcode on the requisition.
Unlabeled specimens will not be tested.
- Complete all required fields on the requisition (if needed). Writing must be legible.
- Package and ship the specimen and requisition according to shipping instructions.

SPECIMEN CONTAINER AND VOLUME REQUIREMENTS

- Evalyn® Brush collection device
- Collection brush has been properly re-capped, labeled, and placed into biohazard shipping bag
- Biohazard bag containing brush is placed into foam bag for transport
- Specimen submitted on collection brush with cap securely applied

SPECIMEN LABELING REQUIREMENTS

- Barcode label must be applied to collection brush
- There must be two patient identifiers (name and DOB) on barcode label
- The 2 patient identifiers on collection brush must exactly match 2 identifiers on patient demographics form

Clients will be contacted as soon as possible if any issues need to be resolved.

IMPORTANT ALIMETRIX™ DOES NOT ACCEPT SPECIMENS FOR SEXUALLY TRANSMITTED PATHOGENS IN THE FOLLOWING CONDITIONS

- WHEN FORENSIC USE IS TO BE CONSIDERED AND CHAIN OF EVIDENCE MUST BE MAINTAINED
 - PATIENT IS UNDER 15 YEARS OF AGE
-

WHAT IS HPV?

Human papillomaviruses (HPVs) are small double-stranded DNA viruses which are intraepithelial pathogens infecting cutaneous and mucosal surfaces. HPV can be categorized into high-risk and low-risk types based on their association with the development of certain cancers. High-risk HPV (hrHPV) can persist in the body for an extended period and, in some cases, lead to the formation of precancerous lesions that may progress to cancer if left untreated. Identification of persistence through screening is important when defining patient risk for HPV associated malignancies.

HPV TYPES	CLINICAL PRESENTATIONS
HPV 6, HPV 11 (low risk)	Benign lesions of the skin (warts), mucous membrane of the genital and anal areas (warts) or extragenital (papillomas of the mouth) or of the respiratory (recurrent respiratory papillomatosis)
HPV 16, HPV 18, HPV 45, HPV 31, HPV 33 (aggressive high-risk)	Development of precancerous lesions and cancers of various organs especially cervical cancer.

BURDEN IN THE US

CDC estimates that about 80 million people are currently infected with HPV in the United States and about 14 million people in the US get a new HPV infection every year.[1]

According to the American Cancer Society's 2023 statistics, an estimated 13,960 new cases of cervical cancer are expected, with roughly 4,310 deaths from the disease.

WHY TEST?

According to the American Cancer Society Journal (ACSJ), cervical cancer is the fourth most frequently diagnosed cancer and the fourth leading cause of cancer death in women. An estimated 604,000 women were diagnosed with cervical cancer worldwide and about 342,000 women died from the disease in 2020. In addition, cervical cancer is the most diagnosed cancer in 23 countries.[2]

Cervical cancer was the first cancer in females to be identified as being caused almost exclusively by a virus. Twelve HPV types (hrHPV) have been identified as tumor causing and classified as group 1 carcinogens. Persistent infection with these hrHPV types is a risk factor for the development of cancer of the cervix, vulva, and vagina.

Identifying those with persistent infection and contributing cofactors before the onset of dysplasia is key to reducing the incidence of HPV related cancer.

WHY CHOOSE SimplyHPV?

WHO recommends using HPV DNA molecular detection as the primary screening test using samples taken by a health-care provider or self-collected, rather than VIA or cytology in screening and treatment approaches among both the general population of women and women living with HIV.[3]

SimplyHPV is a molecular test that detects the presence of 14 sexually transmitted high-risk HPV types from self-collected vaginal and cervical specimens.

- Early detection of high-risk HPV can lead to improved management and possible prevention of cancer.
- SimplyHPV is more accurate and specific than standalone Pap tests, so the testing interval is longer.
- SimplyHPV was validated using a self-collection device for privacy and better comfort.

WHO TO TEST?

GUIDELINES	AMERICAN CANCER SOCIETY (2020)	US PREVENTIVE SERVICES TASK FORCE (2018)
Age 21-24	No screening	Pap test every 3 years
Age 25-29	HPV test every 5 years (preferred) HPV/Pap co-test every 5 years Pap test every 3 years	Pap test every 3 years
Age 30-65	HPV test every 5 years (preferred) HPV/Pap co-test every 5 years Pap test every 3 years	HPV test every 5 years HPV/Pap co-test every 5 years Pap tests every 3 years
Age 65 and older	No screening if a series of prior tests were normal	No screening if a series of prior tests were normal and not at high risk for cervical cancer

REFERENCES

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SimplyHPV® PANEL TARGETS

High-Risk HPV Types Detected

HPV-16, HPV-18, HPV-31, HPV-33, HPV-35, HPV-39, HPV-45, HPV-51, HPV-52, HPV-56, HPV-58, HPV-59, HPV-66, and HPV-68

evalyn®brush

Simple, safe and reliable

These instructions apply to the usage of the Evalyn®Brush.

The Evalyn®Brush

The Evalyn®Brush is a sterile device that allows you to carry out tests yourself at home. Using the Evalyn®Brush, you can retrieve vaginal cell material simply and painlessly. This cell material is then analysed in a professional laboratory.

Important notes

- Do not use if the packaging of the Evalyn®Brush is damaged or if the expiry date has passed.
- Do not use during menstruation.
- Do not use during pregnancy or for three months following pregnancy.
- Do not use any other vaginal products for at least two days before using the Evalyn®Brush. Vaginal contraceptives, condoms and water-based lubricants can be used as normal.
- For single use only.
- Re-use can result in infection and/or incorrect diagnosis.



1. Wash your hands before usage.



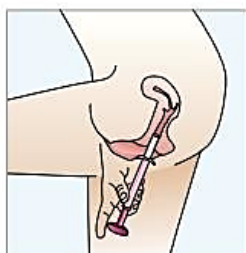
2. Remove the Evalyn®Brush from the packaging. Do not throw the packaging away, as it is necessary for sending the Evalyn®Brush to the laboratory after usage.



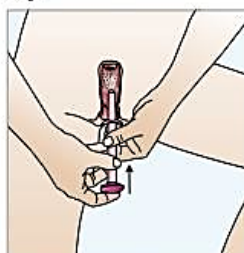
3. Press the sides of the pink cap with your thumb and index finger to remove the pink cap from the Evalyn®Brush. Ensure that you do not touch the white fibres of the Evalyn®Brush with your hands!



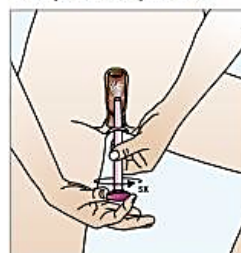
4. Obtain the sample whilst in a standing position. Assume a comfortable stance (e.g. as if you were about to insert a tampon).



5. Spread your labia with one hand, and with the other, insert the Evalyn®Brush into your vagina until the wings touch your labia.



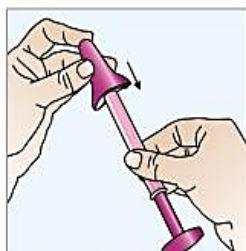
6. Hold the transparent casing with one hand, and with your other hand, push the pink plunger in the direction of the transparent casing. You will hear and feel a click when the brush is in the right position with the pink plunger directly against the casing.



7. Turn the pink plunger five rotations in the same direction. After each rotation, you will hear a click. This helps you count the rotations. After turning the plunger five times, carefully remove the Evalyn®Brush.



8. Hold the transparent casing with one hand, and with your other hand, pull on the pink plunger until the white brush disappears into the casing. When doing so, do not touch the top part of the Evalyn®Brush above the wings.



9. Hold the transparent end to ensure the white brush does not extend again. Place the pink cap back on the Evalyn®Brush using your thumb and index finger. You will hear a click when it is properly in place.



10. Put the Evalyn®Brush back inside the packaging.



11. Place the packaging containing the Evalyn®Brush into the plastic bag provided and seal it.



12. Use the return envelope to send the plastic bag containing the Evalyn®Brush together with other required information.

SimplyHPV® SAMPLE LABORATORY REPORT



800 Hudson Way, Huntsville, AL 35806
P: 844-443-6663 | F: 256-327-0981
Testing Performed By Alimetrix - CLIA #: 01D2113023
Medical Director: Dr. Richard V. Spera MD, FACP

simplytest.com |

FINAL REPORT

HPV

Sample Type: Urine
Reported: 03/20/2023 14:31
All values are reported in genomic copies/mL

PATIENT INFO

DOB: 09/20/1980 (40 yrs)
Gender: Female
ID#: 951750
Location: Test Site A

SAMPLE INFO

Specimen#: 5555550005
Accession#: 777000-12345
Collected: 03/15/2023
Received: 03/20/2023 09:57

ORDERING PROVIDER

Glenn Close MD
8977 Lone Peak Parkway
Draper, UT 84020
800-555-5555

Negative	Positive	Attn.	URINE-STI Targets
	✓	!	16 HPV 16
✓			18 HPV 18
✓			OHR Other High Risk HPV*

*A lesion swab is preferred for detection of active *T. pallidum* (syphilis). There is limited data on the usefulness of detecting syphilis in urine. For detection of asymptomatic (no symptom) syphilis, consider our **SimplyTest for Syphilis** test.

EXPECTED RESULTS for all target pathogens in this report are "Negative".

* Other High Risk HPV indicates testing for HPV- 13, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68.



COMMENTS + ACTIONABLE CLINICAL INSIGHTS

! HPV 16

A test-of-cure – follow-up testing to be sure the infection was treated successfully – is not needed for genital and rectal infections; however, if a person's symptoms continue for more than a few days after receiving treatment, he or she should return to a health care provider to be reevaluated. A test-of-cure is needed 7-14 days after treatment for people who are treated for a throat infection. Because re-infection is common, men and women with gonorrhea should be retested three months after treatment of the initial infection, regardless of whether they believe that their sex partners were successfully treated.

This test was developed and its performance characteristics determined by Alimetrix Corporation. The test is a molecular multiplex assay verified for use in the diagnosis and management of sexually transmitted infections. Alimetrix Corporation is a CAP accredited, Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, certified high-complexity laboratory. CLIA recognizes and supports the use of laboratory developed tests for diagnosis and management of diseases in human subjects.

PATIENT PREPARATION

- Read all the instructions for collecting and shipping specimen before beginning the collection process.
 - Specimen collection protocols in this manual are those that are recommended for each of the panels that Alimetrix offers. Substitution of collection kit components or specimen types must be preapproved by Alimetrix before the specimen is submitted for testing.
 - Follow the specimen collection procedure.
 - Prevent specimen rejection:
 - Make sure the top is seated properly and screwed tightly on the tube to prevent leaks in transport.
 - Label the specimen transfer tube with two identifiers. Preferred identifiers are the patient's first and last name and date of birth along with the barcode label. The name, date of birth and barcode must match the name, date of birth, and barcode on the requisition.
- Unlabeled specimens will not be tested.**
- Complete all required fields on the requisition (if needed). Writing must be legible.
 - Package and ship the specimen and requisition according to shipping instructions.

SPECIMEN CONTAINER AND VOLUME REQUIREMENTS

- Spectrum BIOMAX® SDNA-RUO Collection Device collection tube containing 0.75 mL of cV3 stabilizing buffer and 1 mL of patient saliva sample
- Spectrum BIOMAX® SDNA-1000 Collection Device collection tube containing 1.5 mL of cV3 stabilizing buffer and 2 mL patient saliva sample
- The collection tube is properly placed into biohazard shipping bag and then placed into USPS shipping box
- Collection tube shows no signs of damage, crack, or leakage, and volumes are accurate
 - 1.75 mL for BIOMAX® SDNA-RUO Collection Device collection
 - 3.5 mL for BIOMAX® SDNA-1000 Collection Device collection
- Specimen remains in collection tube and cap is securely applied

PROPER SPECIMEN LABELING

- Barcode label must be applied to collection tube
- There must be 2 patient identifiers (name and DOB) on barcode label
- The 2 patient identifiers on collection tube must exactly match 2 identifiers on patient demographics form

Clients will be contacted as soon as possible if any issues need to be resolved.

WHAT IS GUM DISEASE?

Gum disease (aka periodontal disease) is a polymicrobial biofilm infection. This inflammatory disease has two stages: gingivitis and periodontitis. Gingivitis is a mild form of periodontal disease characterized by inflammation of the gums. It can be reversed if detected early and treated. Periodontitis is the chronic form and cannot be reversed. Triggered by pathogenic bacteria (periodontopathogens), it leads to the damage of soft tissue and bone supporting the teeth. These periodontopathogens have been categorized into five bacterial clusters. [1]

COMPLEX	BACTERIAL CLUSTER	CHARACTERISTICS
Red	<i>Treponema denticola</i> , <i>Porphyromonas gingivalis</i> , <i>Tannerella forsythia</i>	Exhibit a very strong relationship with pocket depth and bleeding on probing. Appears later during biofilm development and are often found with orange complex members.
Orange	<i>Fusobacterium nucleatum</i> , <i>Prevotella intermedia</i> , <i>Peptostreptococcus micros</i> , <i>Eubacterium nodatum</i> , <i>Campylobacter rectus</i> , <i>Campylobacter showae</i> , <i>Streptococcus constellatus</i> , <i>Campylobacter gracilis</i>	These bacteria can bind to other bacteria and are considered as “linking” organisms that bridge commensal colonies, which are generally periodontal pathogens. Their presence is required for the aggressive propagation of red complex bacteria in the oral cavity. [2]
Yellow	<i>Streptococcus sanguinis</i> , <i>Streptococcus oralis</i> , <i>Streptococcus mitis</i> , <i>Streptococcus gordonii</i> , <i>Streptococcus intermedius</i>	Initial colonizers in the formation of microbial biofilm complexes in subgingival plaque. They are mostly <i>Streptococci</i> .
Green	<i>Capnocytophaga</i> , <i>Campylobacter concisus</i> , <i>Eikenella corrodens</i>	Considered early colonizers, the green complex bacteria are less pathogenic but contribute to the overall microbial ecosystem and influence disease progression. [3]
Purple	<i>Veillonella parvula</i> , <i>Actinomyces odontolyticus</i> , <i>Aggregatibacter actinomycetemcomitans</i> , <i>Selenomonas noxia</i> , <i>Actinomyces naeslundii</i>	Early colonizers of the tooth surface and part of the normal oral microbiome. They precede colonization of orange and red complexes. Unlike the other members in this group, <i>A. actinomycetemcomitans</i> is associated with aggressive periodontitis. [4]

BURDEN IN THE US

90% of the population has some form of gum disease. [5] In some it may be easy to spot, however, in the vast majority these dangerous and damaging periodontal pathogens can't be identified by a perio probe or a visual exam. Testing delivers evidence and identifies the causative bacterial burden using DNA analysis.

WHY TEST?

Gum disease is the most undiagnosed & untreated disease with the highest impact on bodily systems & functions. Gone unchecked, periodopathogens and their toxins can easily move through the bloodstream with far reaching and catastrophic effects on organs like the heart, arteries and central nervous system. [5]

Testing drives more patients into the necessary periodontal therapy they need with a commitment to better home care regimens.

WHY CHOOSE SimplyPERIO?

SimplyPERIO® is a molecular assay for the quantitative detection of various bacterial, viral, and fungal agents causing periodontal disease or oral microbiome dysbiosis.

SimplyPERIO can identify early tooth decay

An overgrowth of *Streptococcus mutans* coinciding with low amounts of *Streptococcus sanguinis* can cause an imbalance in the dental biofilm resulting in cavities and tooth decay. [6]

SimplyPERIO includes *Candida*

Periodontal disease and tooth loss are more prevalent in adults with an oral microbiome containing abundantly high levels of *Candida*. *Candida* can also associate with other oral bacteria and form antibiotic resistant mixed biofilms. [7]

SimplyPERIO includes herpesviruses HSV-1 and HSV-2

The presence of a herpesvirus in adults with periodontal disease can lead to co-infections contributing to the breakdown of tooth-supportive tissues. [8]

SimplyPERIO includes high-risk oral bacteria

Aggregatibacter actinomycetemcomitans, *Porphyromonas gingivalis*, *Tannerella forsythia*, *Treponema denticola*, and *Fusobacterium nucleatum* are the main agents that cause aggressive periodontitis and/or chronic periodontal disease. They are also associated with adverse cardiovascular effects in adults 30 years of age and older. [9]

WHO TO TEST?

- Test everyone!
- Patients with bleeding (Gingivitis) while charting or cleaning and those with mild, moderate, or severe periodontitis.
- Those patients with unexplained inflammatory biomarkers such as hsCRP.
- All patients pre and post restorative care procedures (braces, extraction, root canals, implants).
- Those currently pregnant or actively pursuing pregnancy.
- Patients at current risk of any systemic health disease.

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1. Socransky SS, Haffajee AD, Cugini MA, Smith C, Kent RL. Microbial complexes in subgingival plaque. *J Clin Periodontol* 1998; 25:13444.
2. Tadjoeidin FM, Masulili SLC, Rizal MI, Kusdhany LS, Turana Y, Ismail RI, Bachtar BM. The Red and Orange Complex Subgingival Microbiome of Cognitive Impairment and Cognitively Normal Elderly with Periodontitis. *Geriatrics (Basel)*. 2022 Jan 4;7(1):12. Doi: 10.3390/geriatrics7010012.
3. Albu, Ștefan-Dimitrie & Suci, Ioana & Albu, Cristina-Crenguta & Dragomirescu, Anca-Oana & Ionescu, Ecaterina. (2024). Impact of Malocclusions on Periodontopathogenic Bacterial Load and Progression of Periodontal Disease: A Quantitative Analysis. *Microorganisms*. 12. 1553. 10.3390/microorganisms12081553.
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8. Banks, Jonathan M., Kristelle J. Capistrano, Daniela A. Brandini, Filza Zaidi, Pari Thakkar, Rani Rahat, Joel Schwartz, and Afsar R. Naqvi. 2024. "Herpesviruses and SARS-CoV-2: Viral Association with Oral Inflammatory Diseases" *Pathogens* 13, no. 1: 58. <https://doi.org/10.3390/pathogens13010058>
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PURPLE COMPLEX

Aggregatibacter actinomycetemcomitans (Aa)

RED COMPLEX

Porphyromonas gingivalis (Pg)

Tannerella forsythia (Tf)

Treponema denticola (Td)

ORANGE COMPLEX

Prevotella intermedia (Pi)

Campylobacter rectus (Cr)

Fusobacterium nucleatum (Fn)

Fusobacterium nucleatum subsp. animalis (Fa)

GREEN COMPLEX

Eikenella corrodens (Ec)

CARIES RISK

Streptococcus mutans (Sm)

Streptococcus sanguinis (Ss)

YEAST

Candida albicans (Ca)

PERI-IMPLANTITIS RISK

Pseudomonas aeruginosa (Pa)

SimplyPERIO® SPECIMEN COLLECTION INSTRUCTIONS



SIMPLYPERIO®

- Check to ensure everything is provided to complete sample collection
- Please read the entire instructions or watch video before beginning sample collection



1 This SimplyPERIO test only uses the instructions found on this purple card. Remove the Saliva Collection Tube with funnel from the blister pack & set aside for use in step 4.



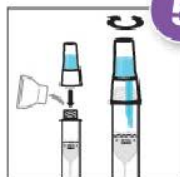
2 Open the Clear Saline Tube with the Clear Saline Rinse (sterile salt water) rinse. Tip the tube up to get it in your mouth.
DO NOT SWALLOW



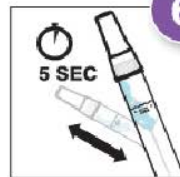
3 Swish around your mouth for at least 15 seconds. Try to stimulate the gums while you are swishing.



4 Spit saline solution with saliva into collection tube using the funnel. Continue to spit into device until reaching the fill line.
(Warnings & safety information can be found inside Device IFU if needed.)



5 Remove the funnel from tube. Screw cap filled with blue solution onto tube and tighten. Once fully tightened, the solution will release and flow into tube mixing with saliva.



6 Tilt the tube back and forth to mix saliva with the preservation solution. Place saliva sample inside bio-bag and seal closed.

(Continue to step 7 on back of this card.)

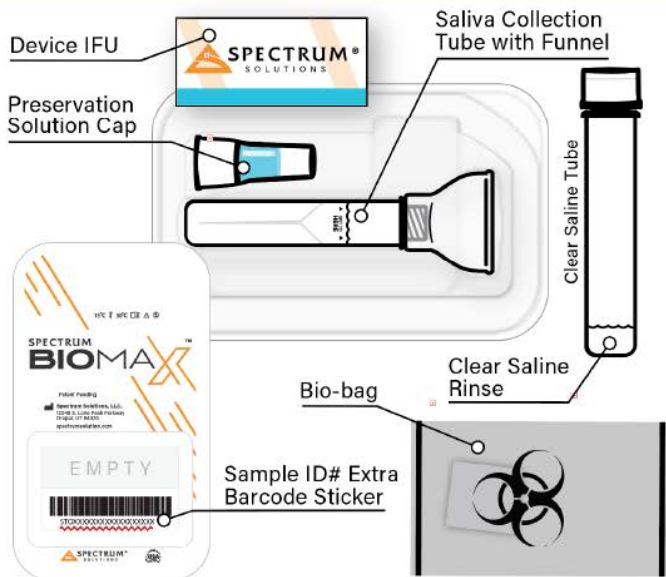


SIMPLYPERIO®

Scan to view video instructions online

simplytest.com

WATCH NOW



SENDING SAMPLES TO THE LAB FOR TESTING

- 7 Remove SimplyPERIO sleeve from box to reveal the prepaid shipping label.
- 8 Place bio-bag with sample into box and seal box closed.
- 9 Hand package directly to USPS postman or drop package at Post Office, drop box, or ship center.





FINAL REPORT

PERIODONTAL PREMIUM
Sample Type: Saliva
Reported: 2024-10-10T16:09

800 Hudson Way, Huntsville, AL 35806
P: 844-443-6663 | F: 256-327-0981
Testing Performed By Alimetrix - CLIA #: 01D2113023
Medical Director: Dr. Richard V. Spera MD, FACP
simplytest.com |

PATIENT INFO	SAMPLE INFO	ORDERING PROVIDER
	Specimen#: FR952048425719 Collected: 2024-10-03T17:10 Received: 2024-10-08T13:40	

	Low	Medium	High	NON-VIRAL TARGETS
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All displayed values are in genomic copies x1000/mL except Fusobacterium nucleatum which is in genomic copies x10,000/mL.



PERI-IMPLANTITIS RISK



*The presence of Streptococcus Sanguinis is associated with healthy plaque biofilm.
Reference bar ranges have been normalized for clarity. ND = Not Detected UML = Upper Measuring Limit (>9999).

POSITIVE	NEGATIVE	ATTENTION	VIRAL TARGETS
			HERPES SIMPLEX VIRUS 1 (HSV-1)
			HERPES SIMPLEX VIRUS 2 (HSV-2)
		!	CYTOMEGALOVIRUS
			EPSTEIN BARR VIRUS

SimplyHORMONE® SPECIMEN COLLECTION ELEMENTS

PATIENT PREPARATION

- Read all the instructions for collecting and shipping specimen before beginning the collection process.
- Specimen collection protocols in this manual are those that are recommended for each of the panels that Alimetrix offers. Substitution of collection kit components or specimen types must be preapproved by Alimetrix before the specimen is submitted for testing.
- Follow the specimen collection procedure.
- Prevent specimen rejection:
 - Make sure the top is seated properly and screwed tightly on the tube to prevent leaks in transport.
 - Label the specimen transfer tube with two identifiers. Preferred identifiers are the patient's first and last name and date of birth along with the barcode label. The name, date of birth, date of collection, time of collection, and barcode must match the name, date of birth, date of collection, time of collection, and barcode on the requisition.

Unlabeled specimens will not be tested.

- Complete all required fields on the requisition (if needed). Writing must be legible.
- Package and ship the specimen and requisition according to shipping instructions.

SPECIMEN CONTAINER AND VOLUME REQUIREMENTS

- Spectrum BIOMAX® SMD-RUO Collection Device collection tube contains 1 mL of SMD protein stabilizing buffer and 2 mL of patient saliva
- Collection tube is properly placed into biohazard shipping bag and then placed into USPS shipping box
- Collection tube shows no signs of damage, crack, or leakage, and volumes are accurate
 - 3 mL for BIOMAX® SMD-RUO Collection Device collection
- Specimen remains in collection tube and cap is securely applied

PROPER SPECIMEN LABELING

- Barcode label must be applied to collection tube
- There must be 2 patient identifiers (name and DOB) on barcode label
- The 2 patient identifiers on collection tube must exactly match 2 identifiers on patient demographics form
- Collection date and time must be provided with sample shipment and match patient demographics form

Clients will be contacted as soon as possible if any issues need to be resolved.

UNDERSTANDING HORMONES FOR HEALTH & WELLNESS

Hormones are released directly into the bloodstream by a complex and interactive network called the endocrine system. The foundation of hormonal balance relies on four key organs the thyroid, adrenal, ovaries and testes. These cornerstone organs work together, as well as individually, to secrete cortisol, testosterone, progesterone, estradiol, and Dehydroepiandrosterone (DHEA). These hormones not only influence our overall health and wellness, but their levels also influence and impact each other.

HORMONE	DESCRIPTION
Cortisol	Known as the stress hormone, cortisol influences the body's response to stress and helps regulate metabolism.
Testosterone	Crucial for both men and women, testosterone contributes to muscle mass, bone density, sex drive, and overall vitality.
Estrogen	Impacts metabolism, menstrual cycles, pregnancy, mood, bone health, and sexual wellness.
Progesterone	Plays a vital role in the female reproductive cycle preparing the uterine lining, supporting the early stages of gestation, and plays secondary role in balancing other hormones and in metabolism. Progesterone increases the levels of estrogen in males. Levels fluctuate with the menstrual cycle and pregnancy
DHEA	Serves as a precursor to male and female hormones, influencing overall hormonal balance. DHEA is the building block of other hormones. DHEA imbalance is associated with adrenal hyperplasia and adrenal tumors. Symptoms of dysfunction of the adrenals include unexplained weight loss; nausea and vomiting; dizziness; craving for salt

WHY TEST?

A hormone imbalance can occur when one or more of the cornerstone organs start secreting more or less of a given hormone. Understanding and maintaining the proper balance of cortisol, testosterone, progesterone, estrogen, and DHEA plays an integral role for individuals looking to maintain an overall normal healthy state of wellbeing and for those seeking to optimize performance and functionality. Hormone levels are influenced by many factors, including stress, lifestyle choices, aging, medical conditions, medications, and hormonal therapies.

Free hormones in saliva, which are not bound to carrier proteins, are believed to reflect the biologically active fraction of hormones available to impact the body. Salivary hormone testing offers a non-invasive and convenient method for: 1) assessing free hormone levels, 2) allowing evaluation of hormone patterns over time, 3) studying stress responses, 4) monitoring hormone replacement therapy, and 5) investigating hormone-related health outcomes.

SYMPTOMS ASSOCIATED WITH HORMONAL IMBALANCE IN MALES

HORMONE	HIGH LEVELS	LOW LEVELS
Cortisol	weight gain and rounding of the face; acne; easy bruising; muscle weakness; severe fatigue; brain fog; irritability; headache	anxiety; Fatigue, particularly in the morning; depression; lack of ability to cope with stress; food cravings; increased susceptibility to infection
Testosterone	aggressive behavior; excess body hair; acne; headaches; high blood pressure; high sex drive	reduced sex drive; erectile dysfunction; loss of body hair; lean muscle wasting; fatigue; depression; weight gain
Progesterone	depression, fatigue, heart disease; decreased sperm count	depression; mood swings; anxiety; low sex drive; erectile dysfunction
Estrogen	sperm levels, motility and quality are affected; erectile dysfunction; weight gain; depression; fatigue; breast enlargement	depression; mood swings; anxiety; low sex drive; erectile dysfunction
DHEA	excessive hair growth; hair loss; aggressive behaviors; irritability; trouble sleeping; acne	depression; sexual dysfunction; heart disease; obesity; osteoporosis

SYMPTOMS ASSOCIATED WITH HORMONAL IMBALANCE IN FEMALES

HORMONE	HIGH LEVELS	LOW LEVELS
Cortisol	weight gain and rounding of the face; acne; easy bruising; muscle weakness; severe fatigue; brain fog; irritability; headache	anxiety; fatigue, particularly in the morning; depression; lack of ability to cope with stress; food cravings; increased susceptibility to infection
Testosterone	excessive facial and body hair; acne; mood swings; small breasts; loss of sex drive; infertility; obesity	fatigue; loss of strength and muscle tone; Irregular menstrual cycle; depression; loss of body hair; reduced sex drive
Progesterone	anxiety; bloating; depression; reduced sex drive; weight loss or gain; breast tenderness and swelling	Irregular menstrual cycle; spotting; headaches; infertility
Estrogen	polyps; fibroids; endometriosis; ovarian, breast and uterine cancer; heart disease; dementia; insulin resistance	brain fog; mood swings; hot flashes; night sweats; irregular or no periods; osteoporosis; tender breasts; weight gain
DHEA	excessive hair growth; hair loss; aggressive behaviors; irritability; trouble sleeping; acne	depression; sexual dysfunction; heart disease; obesity; osteoporosis

WHY CHOOSE SimplyHORMONE®?

SimplyHORMONE® is a competitive enzyme immunoassay (EIA) for the measurement of free-active hormones in saliva which impact the four key organs of the endocrine system.

Most hormones in the body are in the blood where they are bound by proteins. In this state, they are inactive and don't impact the cells. Only unbound or free hormones can affect the body. For example, less than 2% of testosterone and 10% of cortisol is free in the body at any moment. The FDA has approved saliva tests for the measurement of free steroidal hormones equivalent to serum-based tests. SimplyHORMONE uses FDA-modified non-invasive salivary based assays to measure free active levels of cortisol, estradiol, DHEA, progesterone, and testosterone. [1,2,3,4]

WHO TO TEST?

- Patients exhibiting symptoms indicative of high or low hormone levels.
- Patients on hormone replacement therapy who are looking to monitor their hormone levels.
- Patients with fertility issues.
- Patients looking to monitor their hormonal health.

REFERENCES

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4. Establishment registration and device listing. [access data.fda.gov](https://www.accessdata.fda.gov):
https://www.accessdata.fda.gov/cdrh_docs/reviews/K062534.pdf
https://www.accessdata.fda.gov/cdrh_docs/reviews/K043175.pdf
https://www.accessdata.fda.gov/cdrh_docs/reviews/K041349.pdf
https://www.accessdata.fda.gov/cdrh_docs/reviews/K033786.pdf

SimplyHORMONE Complete Check

- Cortisol
- DHEA
- Estradiol
- Progesterone
- Testosterone

SimplyHORMONE Testosterone

- Testosterone

SimplyHORMONE Cortisol


- Cortisol

SimplyHORMONE Cortisol 24

- Cortisol x3

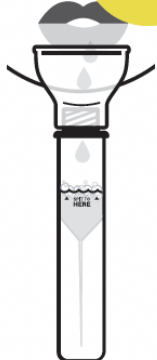
SimplyHORMONE® SPECIMEN COLLECTION INSTRUCTIONS

SimplyHORMONE® CORTISOL 24 (Cover page of collection instructions)



1 Follow sample collection instructions located inside device package.

No food, drink, gum chewing or brushing teeth 30 minutes prior to providing the specimen.




2

FIRST COLLECTION
Collect saliva into device before 10:00 A.M. while fasting.


SECOND COLLECTION
Collect additional saliva sample into a second device between 4 P.M. – 8 P.M.

THIRD COLLECTION
Collect final saliva sample into a third device between 10 P.M. – 12 A.M.




3 Write patient's full name and date of birth on tube. This step is required. Failure to provide both may result in sample rejection.

4 Record collection date and time in portal. **This is an important step as test results are based off date and time of collection.**



WATCH NOW




SIMPLY HORMONE®

- Samples may keep at room temperature until shipping.
- See back of card for sample shipping instructions.

2023187v3.0 REF 2023186 12/27/2024


CORTISOL 24



1

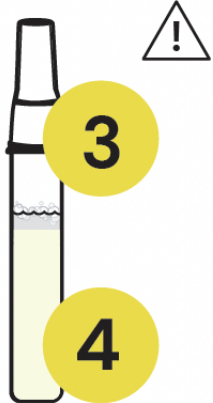
Follow sample collection instructions located inside device package.

No food, drink, gum chewing or brushing teeth 30 minutes prior to providing the specimen.



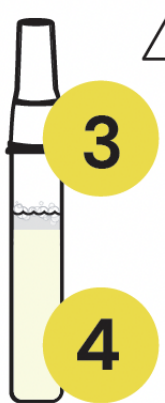
2

SAMPLE COLLECTION:
Collect saliva into device before 10:00 A.M. while fasting.




3

Write patient's full name and date of birth on tube.
This step is required. Failure to provide both may result in sample rejection.



4

Record collection date and time in portal. **This is an important step as test results are based off date and time of collection.**



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TESTOSTERONE

2023174v4.0 REF 2023159 12/27/2024

- If monitoring testosterone therapy one morning test is sufficient.
- If establishing initial screening value two tests should be done on two consecutive mornings.
- Speak to your physician about which collection option is right for you.
- Samples may keep at room temperature until shipping.
- See back of card for sample shipping instructions.





1

Follow sample collection instructions located inside device package.

No food, drink, gum chewing or brushing teeth 30 minutes prior to providing the specimen.



2

SAMPLE COLLECTION:

- Collect before 10:00 A.M. while fasting.
- If menstruating, collect saliva between day three and day seven of cycle.
- Postmenopausal patients may collect on any day.



3

Write patient's full name and date of birth on tube.

This step is required. Failure to provide both may result in sample rejection.

4

Record collection date and time in portal. This is an important step as test results are based off date and time of collection.



SIMPLY
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2023421v2.0 REF 2023423 12/27/2024

- Samples may keep at room temperature until shipping.
- See back of card for sample shipping instructions.
- Simply Hormone tests for Estradiol, DHEA, Progesterone, Testosterone, & Cortisol.

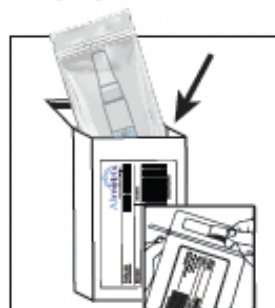
 **WATCH NOW**



simplytest.com

SENDING SAMPLES TO THE LAB FOR TESTING

- 4** Remove SimplyTest® sleeve from box to reveal the prepaid shipping label.
- 5** Place bio-bag with bio-sample into box and seal box closed.
- 6** Hand package directly to USPS postman or drop package at post office, drop box, or ship center.



KIT CONTENTS

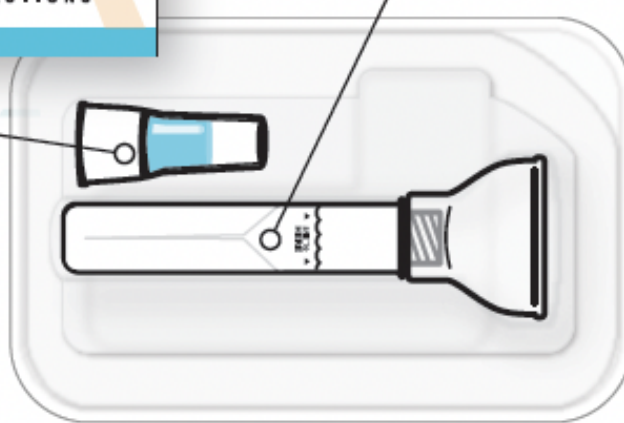
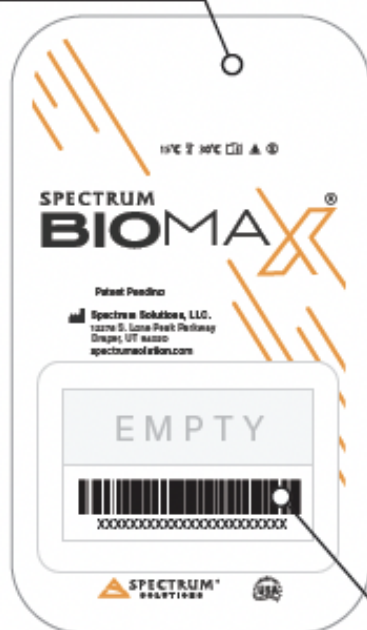
Device Instructions



Saliva Collection Tube with Funnel

Preservation Solution Cap

Tray Lid



Device Barcode Sticker



Bio-Bag

SimplyHORMONE® SAMPLE LABORATORY REPORT



800 Hudson Way, Huntsville, AL 35806
P: 844-443-6663 | F: 256-327-0981
Testing Performed By Alimetrix - CLIA #: 01D2113023
Medical Director: Dr. Richard V. Spera MD, FACP

simplytest.com |

FINAL REPORT

COMPLETE MALE

Sample Type: Saliva
Reported: 03/20/2023 14:31

PATIENT INFO

DOB: 09/20/1980 (60 yrs)
Gender: Male
ID#: 951750
Location: Test Site A

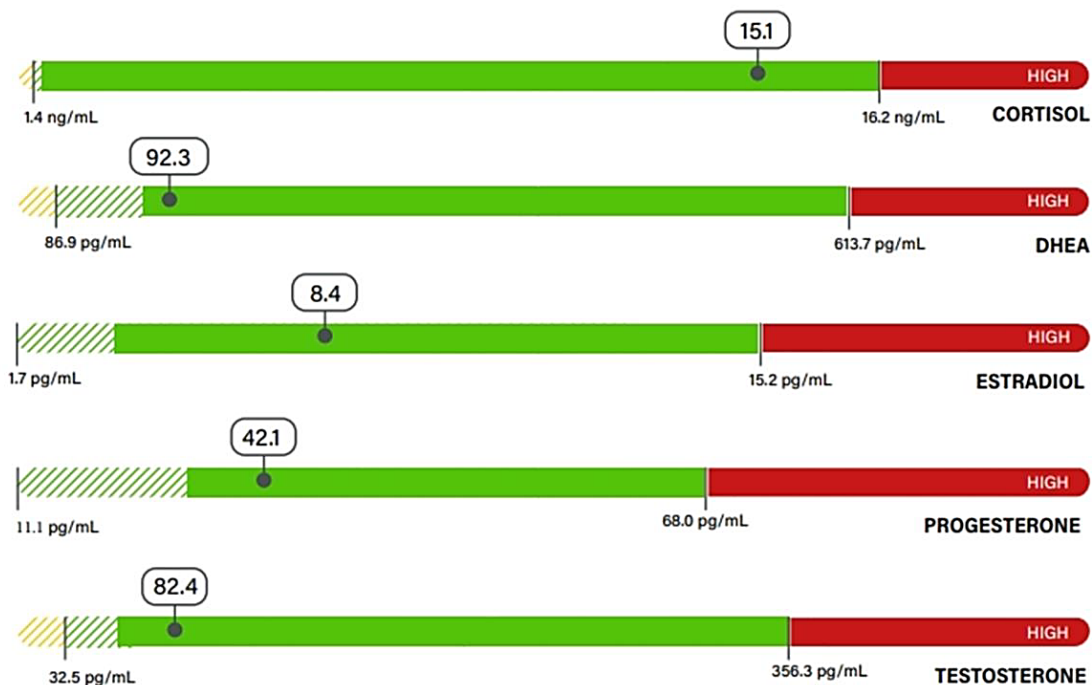
SAMPLE INFO

Specimen#: 5555550005
Accession#: 777000-12345
Collected [1]: 03/16/2023 05:45
Received: 03/20/2023 09:57

ORDERING PROVIDER

Glenn Close MD
8977 Lone Peak Parkway
Draper, UT 84020
800-555-5555

Cortisol levels reported in ng/mL (1 ng/mL = 0.1 ug/dL). All other hormone levels reported in pg/mL (1 pg/mL = 0.1 ng/dL).



Your hormone levels are shown in the bubbles above the bars. Normal/expected range for each test is shown in green. Levels reported below the quantitation limit (shown in striped regions) should be interpreted with caution. Yellow striped regions are below normal range.



COMMENTS + ACTIONABLE CLINICAL INSIGHTS

[Lab supervisor/manager comment field]

SimplyHormone Complete Male is an enzyme-linked immunosorbent assay (ELISA) for the measurement of free active Cortisol, Testosterone, DHEA, Estradiol, and Progesterone in male saliva. This test was developed and its performance characteristics determined by Alimetrix Corporation. Alimetrix Corporation is a CAP accredited, Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, certified high-complexity laboratory. CLIA recognizes and supports the use of laboratory developed tests for diagnosis and management of diseases in human subjects.