One Test for a Clean Bill of Gynecological Health

Bella One PAP®

genetic molecular cervical test

Boost effectiveness of patient testing

Awareness about the link between HPV and cervical cancer has grown exponentially – leading to earlier detection and prevention. The CDC estimates that up to 93 percent of cervical cancers can be prevented. And yet, 33 percent of the 12,000 women who are diagnosed annually will die.

The Bella One PAP is a FDA-approved test to screen for presence of human papillomavirus (HPV) DNA along with genotyping for high risk strains of HPV. The molecular panel also screens for presence of sexually transmitted infections and bacterial vaginosis pathogens that pose a threat to women's health. Often symptom-less, these gynecological conditions can cause irreversible damage to women's reproductive system and overall health making it all the more important for sexually active women to be tested regularly.

Provide your patients with a streamlined screening experience by administering one simple test that encompasses a molecular PAP smear and or co-testing while accounting for a range of other harmful conditions.

Early screening is crucial to survival, with cervical cancer screenings if we can identify the HPV virus DNA responsible for precancerous and cancerous cervical lesions, we can change the course of the disease. Survival rates can jump from near hopelessness to a happy ending with little interruption. Patients need to be screened as per ASCCP-ACOG guidelines and or as clinically indicated.

Why Bella One PAP?

The Bella One PAP screens for presence of Human Papilloma Virus (HPV) DNA as well as precancerous cells to determine whether a woman is at high-risk for developing cervical precancerous or cancerous conditions. – in addition Bella One Pap is design to test for a host of other infectious gynecological conditions.

One Simple Test

Unlike regular PAP smears, Bella One PAP is the comprehensive test that provides an overall assessment of gynecological health.

Early Detection

The Bella One PAP detects cell abnormalities and high-risk strains of HPV that increase the odds of developing cervical cancer – enabling more targeted monitoring in at-risk patients.

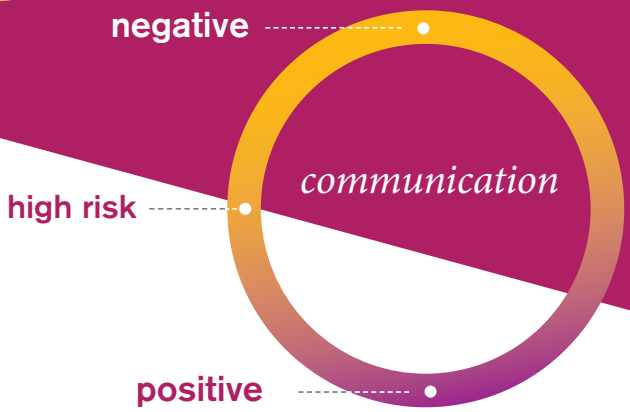
Prevent Permanent Damage

Because many women present few symptoms – or none at all – certain STI's like gonorrhea, trichomonas, and chlamydia can go unnoticed for too long, creating complications that could last a lifetime.

pcgmolecular
preventive care innovation

755 Mount Vernon Rd, Suite 270 Atlanta, GA 30328 **404.301.4460** www.pcgmolecular.com

value for your practice



educating patients

We recommend that women be given the Bella One PAP in lieu of the traditional pap. We strive to be a partner with you in this effort and will provide you all the necessary tools to create value for your patients and your practice, such as:

- *A* patient education flyer *that explains the importance of the screen and what to expect via results.*
- *A* consent form *for the patient to sign so refusals can be placed in their file.*
- *A* negative letter *if patients results are negative PCG Molecular will send your patient a letter via email on your behalf within 5 business days.*

What is the procedure like?

The patient experience is similar and or less invasive than the traditional pap smear collection. The collection tool is slightly different, resembling more of a brush that reaches both the vagina and the uterine cervix and still gently lifts cells as it did before. To self collect this cervical specimen, instructions are provided for the patient and or medical provider that explains step by step the collection procedure.

helping you communicate lab results

for negative results

PCG Molecular will send your patients a letter via email on your behalf within 5 business days if patient results are negative.

for "watch" or high risk results

Being placed on a watch is no reason for patients to panic. It doesn't mean they have cervical cancer or that they will ever get them. All it means is that we need to watch their cases more closely. We will send you a report and give you a sample letter to send to your pa-tients that communicates the results and what next steps to follow.

for positive results

You will receive a detailed report for those patients that test positive for precancerous or cancerous cells, or sexually transmitted infections. These patients may require additional tests, along with a personal call. We can advise you of next steps and referrals if you need them.

pcgmolecular
preventive care innovation

755 Mount Vernon Rd, Suite 270 Atlanta, GA 30328 **404.301.4460** www.pcgmolecular.com

pcgpathology

755 Mount Vernon Hwy
Atlanta, Georgia 30328
404.301.4460
www.pcgmolecular.com

CLIA #11D2124751

Bella One PAP® GYN CYTOLOGY REPORT

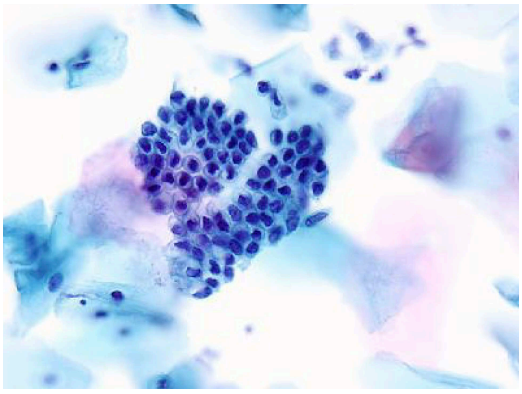
PATIENT INFORMATION	PHYSICIAN INFORMATION:	CASE INFORMATION:
Smith, Johana	**Joe Johnson, MD, FACOG**	**CASE:** GYN-22-1000
Sex: F	Medical Company	**REQ:** 000000
PID: 000000	123 Georgia Street, Suite 000	**DATE COLLECTED:** 00/00/00
DOB: 00/00/0000	Atlanta, GA 30328	**RECIEVED DATE:** 00/00/00
		REPORT DATE: 00/00/00

NEGATIVE RESULTS for Intraepithelial Lesion or Malignancy
NEGATIVE RESULTS for HPV

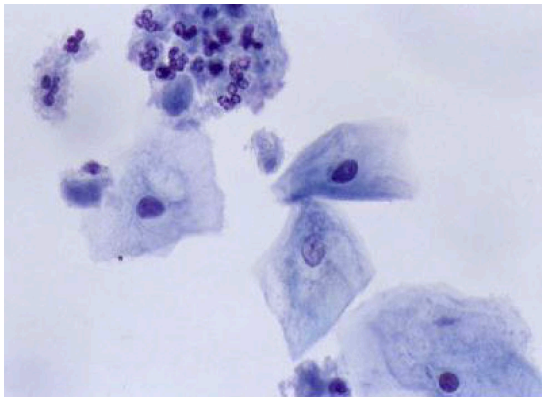
SPECIMEN ADEQUACY: Satisfactory for Evaluation

Specimen Source: Cervix-ThinPrep Pap **Clinical History:** Routine Screening **Date of Last Menstrual Period:** 10/28/22

Micro-Photogropahs



Endocervical cells



Ectocervical squamous cells

Recommendation: Follow ASCCP Cervical Cancer Screening Guidelines.

References:

2019 ASCCP Risk-Based Management Consensus Guidelines for Abnormal Cervical Cancer Screening Tests and Cancer Precursors Rebecca B. Perkins, MD, MSc,1 Richard S. Guido, MD,2 Philip E. Castle, PhD,3 David Chelmow, MD,4 Mark H. Einstein, MD, MS,5 Francisco Garcia, MD, MPH,6 Warner K. Huh, MD,7 Jane J. Kim, PhD, MSc,8 Anna-Barbara Moscicki, MD,9 Ritu Nayar, MD,10 Mona Saraiya, MD, MPH,11 George F. Sawaya, MD,12 Nicolas Wentzensen, MD, PhD, MS,13 and Mark Schiffman, MD, MPH14 for the 2019 ASCCP Risk-Based Management Consensus Guidelines Committee Key Words: cervical cytology, HPV testing, management of abnormal cervical cancer screening tests, guidelines (J Low Genit Tract Dis 2020;24: 102–131)

Pathologist Electronic Signature
Armando Moncada Jr. M.D. FCAP

pcgmolecular
preventive care innovation

755 Mount Vernon Hwy
Atlanta, Georgia 30328
404.301.4460
www.pcgmolecular.com

CLIA #11D2124751

Bella One PAP® STI & BACTERIAL VAGINOSIS PANEL REPORT

PATIENT INFORMATION	PHYSICIAN INFORMATION:	CASE INFORMATION:
Smith, Johana	Joe Johnson, MD, FACOG	CASE: BOP-22-1000
Sex: F	Medical Company	REQ: 000000
PID: 000000	123 Georgia Street, Suite 000	DATE COLLECTED: 00/00/00
DOB: 00/00/0000	Atlanta, GA 30328	RECIEVED DATE: 00/00/00
		REPORT DATE: 00/00/00

100% Sensitivity, **99.9%** Specificity **Specimen Source:** Cervical vaginal **Methodology** Polymerase Chain Reaction (Real-Time PCR)

NEGATIVE RESULTS

STI Molecular Panel

Chlamydia trachomatis- **not detected**
Trichomonas vaginalis- **not detected**
Neisseria gonorrhoeae- **not detected**
Mycoplasma genitalium- **not detected**
Mycoplasma hominis- **not detected**
Ureaplasma urealyticum - **not detected**
Ureaplasma parvum- **not detected**
Herpes simplex virus- **not detected**
type 1 & 2 (HSV1 + HSV2)

BV Molecular Panel

Gardnerella vaginalis- **not detected**
Prevotella bivia- **not detected**
Atopobium vaginae- **not detected**
Mobiluncus curtisii- **not detected**
Bacteroides fragilis- **not detected**
Megasphaera Type 1- **not detected**
Pan–Lactobacillus - **not detected**
Bacterial vaginosis- **not detected**
associated bacteria 2

Interpretation:

A negative test result for these panels means that STI and bacterial vaginosis pathogens were not present in the specimen above the limit of detection. This patient's cervical vaginal specimen is negative for all pathogens.

Recommendation:

Follow up as clinically indicated.

Pathologist Electronic Signature
Armando Moncada Jr. M.D. FCAP