

## Gynecologic Cytology and Molecular Specimen Collection Information

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## ThinPrep® Age-Based Pap Testing w/Imaging

TEST	
<b>Gynecologic Pap Test (ThinPrep®) w/Imaging</b>	
<b>Test Description:</b>	Cytologic screening for cervical cancer, precancerous lesions, atypical cells, and other cytologic abnormalities defined by the Bethesda System.
<b>Order Number:</b>	24250
<b>Performance Lab Name:</b>	South Bend Medical Foundation
<b>CPT Code:</b>	88175
<b>Also Known As:</b>	Cervical Cancer Screening, Pap Smear

SPECIMEN REQUIREMENTS	
<b>Specimen:</b>	Gynecological Pap sample collected in <b>ThinPrep® specimen vial</b>
<b>Specimen Requirements:</b>	<p>With each specimen, please submit a completed requisition along with pertinent clinical information, e.g., last menstrual period (LMP), hormonal status (postmenopausal, pregnant, postpartum), hormone therapy (including birth control pills, treatment for endocrine responsive malignancy, estrogen creams), use of intrauterine device (IUD), and whether the patient is at high risk for cervical cancer.</p> <p>Following is a list of risk factors:</p> <ul style="list-style-type: none"> <li>• Previous gynecological history of dysplasia or cancer</li> <li>• HPV infection</li> <li>• HIV infection</li> <li>• Multiple sexual partners</li> <li>• Grossly visible lesion</li> <li>• Early age of sexual intercourse</li> <li>• DES exposure</li> <li>• Smoker</li> <li>• Abnormal vaginal bleeding</li> <li>• Prior abnormal Pap smear or history of malignancy</li> </ul> <div style="border: 1px solid black; padding: 5px; margin-top: 10px;"> <p><b>Note:</b> Per CLIA criteria, Pap tests will be referred for pathologist review if laboratory suspects:</p> <ul style="list-style-type: none"> <li>• Reactive or reparative cellular changes</li> <li>• Atypical squamous or glandular cells of undetermined significance</li> <li>• Cells in premalignant or malignant category</li> </ul> </div>
<b>Specimen Collection:</b>	ThinPrep® specimens, please refer to <a href="#">instructions</a> in Collection of Pap Specimens <b>Using ThinPrep® Vial. Endocervical Brush/Spatula &amp; Broom</b> <a href="#">instructions</a> .
<b>Storage/Transport:</b>	Store specimens at room temperature (15° to 30° C) until transported, DO NOT FREEZE.
<b>Rejection Criteria:</b>	<a href="#">Click here</a> for Specimen Rejection Criteria. <i>Do not deposit cervical mucus plug into the ThinPrep® vial with the cervical sample. Lubricant use may result in an unsatisfactory specimen.</i>
<b>Turnaround Time:</b>	2-3 Days

TEST	
<b>Gynecologic Pap Test w/Imaging, reflex HR HPV if ASCUS</b>	
<b>Test Description:</b>	Refer to technical test information <a href="#">here</a> .
<b>Order Number:</b>	24251
<b>Performance Lab Name:</b>	South Bend Medical Foundation
<b>CPT Code:</b>	88175, add 87624 if ASCUS
<b>Also Known As:</b>	Age based Cervical Cancer Screening, Pap Smear

SPECIMEN REQUIREMENTS	
<b>Specimen:</b>	Gynecological Pap sample collected in <b>ThinPrep® specimen vial</b>
<b>Specimen Requirements:</b>	<p>With each specimen, please submit a completed requisition along with pertinent clinical information, e.g., last menstrual period (LMP), hormonal status (postmenopausal, pregnant, postpartum), hormone therapy (including birth control pills, treatment for endocrine responsive malignancy, estrogen creams), use of intrauterine device (IUD), and whether the patient is at high risk for cervical cancer.</p> <p>Following is a list of risk factors:</p> <ul style="list-style-type: none"> <li>• Previous gynecological history of dysplasia or cancer</li> <li>• HPV infection</li> <li>• HIV infection</li> <li>• Multiple sexual partners</li> <li>• Grossly visible lesion</li> <li>• Early age of sexual intercourse</li> <li>• DES exposure</li> <li>• Smoker</li> <li>• Abnormal vaginal bleeding</li> <li>• Prior abnormal Pap smear or history of malignancy</li> </ul>
	<p><b>Note:</b> Per CLIA criteria, Pap tests will be referred for pathologist review if laboratory suspects:</p> <ul style="list-style-type: none"> <li>• Reactive or reparative cellular changes</li> <li>• Atypical squamous or glandular cells of undetermined significance</li> <li>• Cells in premalignant or malignant category</li> </ul>
<b>Specimen Collection:</b>	ThinPrep® specimens, please refer to <a href="#">instructions</a> in Collection of Pap Specimens <b>Using ThinPrep® Vial. Endocervical Brush/Spatula &amp; Broom</b> <a href="#">instructions</a> .
<b>Storage/Transport:</b>	Store specimens at room temperature (15° to 30° C) until transported, DO NOT FREEZE.
<b>Rejection Criteria:</b>	<a href="#">Click here</a> for Specimen Rejection Criteria. <i>Do not deposit cervical mucus plug into the ThinPrep® vial with the cervical sample. Lubricant use may result in an unsatisfactory specimen.</i>
<b>Turnaround Time:</b>	2-3 Days

TEST	
<b>Gynecologic Pap w/Imaging &amp; HR HPV Co-Test</b>	
<b>Test Description:</b>	Refer to technical test information <a href="#">here</a> .
<b>Order Number:</b>	24254
<b>Performance Lab Name:</b>	South Bend Medical Foundation
<b>CPT Code:</b>	88175, 87624
<b>Also Known As:</b>	Aged-based Cervical Cancer Screening Co-Test, Pap Smear, Co-Test

SPECIMEN REQUIREMENTS	
<b>Specimen:</b>	Gynecological Pap sample collected in <b>ThinPrep® specimen vial</b>
<b>Specimen Requirements:</b>	<p>With each specimen, please submit a completed requisition along with pertinent clinical information, e.g., last menstrual period (LMP), hormonal status (postmenopausal, pregnant, postpartum), hormone therapy (including birth control pills, treatment for endocrine responsive malignancy, estrogen creams), use of intrauterine device (IUD), and whether the patient is at high risk for cervical cancer.</p> <p>Following is a list of risk factors:</p> <ul style="list-style-type: none"> <li>• Previous gynecological history of dysplasia or cancer</li> <li>• HPV infection</li> <li>• HIV infection</li> <li>• Multiple sexual partners</li> <li>• Grossly visible lesion</li> <li>• Early age of sexual intercourse</li> <li>• DES exposure</li> <li>• Smoker</li> <li>• Abnormal vaginal bleeding</li> <li>• Prior abnormal Pap smear or history of malignancy</li> </ul> <div style="border: 1px solid black; padding: 5px; margin-top: 10px;"> <p><b>Note:</b> Per CLIA criteria, Pap tests will be referred for pathologist review if laboratory suspects:</p> <ul style="list-style-type: none"> <li>• Reactive or reparative cellular changes</li> <li>• Atypical squamous or glandular cells of undetermined significance</li> <li>• Cells in premalignant or malignant category</li> </ul> </div>
<b>Specimen Collection:</b>	ThinPrep® specimens, please refer to <a href="#">instructions</a> in Collection of Pap Specimens Using <b>ThinPrep® Vial. Endocervical Brush/Spatula &amp; Broom</b> <a href="#">instructions</a> .
<b>Storage/Transport:</b>	Store specimens at room temperature (15° to 30° C) until transported, DO NOT FREEZE.
<b>Rejection Criteria:</b>	<a href="#">Click here</a> for Specimen Rejection Criteria. <i>Do not deposit cervical mucus plug into the ThinPrep® vial with the cervical sample. Lubricant use may result in an unsatisfactory specimen.</i>
<b>Turnaround Time:</b>	2-3 Days

**TEST**
**Requested Add-on High Risk HPV (mRNA) (within 30 days of Pap)**

<b>Test Description:</b>	Refer to technical test information <a href="#">here</a> . (CT/NG) <a href="#">here</a> .
<b>Order Number:</b>	24256
<b>Performance Lab Name:</b>	South Bend Medical Foundation
<b>CPT Code:</b>	87624
<b>Also Known As:</b>	Cervical Cancer Screening Human Papillomavirus

**SPECIMEN REQUIREMENTS**

<b>Specimen:</b>	Gynecological Pap sample collected in <b>ThinPrep® specimen vial</b>
<b>Specimen Requirements:</b>	<p>With each specimen, please submit a completed requisition along with pertinent clinical information, e.g., last menstrual period (LMP), hormonal status (postmenopausal, pregnant, postpartum), hormone therapy (including birth control pills, treatment for endocrine responsive malignancy, estrogen creams), use of intrauterine device (IUD), and whether the patient is at high risk for cervical cancer.</p> <p>Following is a list of risk factors:</p> <ul style="list-style-type: none"> <li>• Previous gynecological history of dysplasia or cancer</li> <li>• HPV infection</li> <li>• HIV infection</li> <li>• Multiple sexual partners</li> <li>• Grossly visible lesion</li> <li>• Early age of sexual intercourse</li> <li>• DES exposure</li> <li>• Smoker</li> <li>• Abnormal vaginal bleeding</li> <li>• Prior abnormal Pap smear or history of malignancy</li> </ul>
	<p><b>Note:</b> Per CLIA criteria, Pap tests will be referred for pathologist review if laboratory suspects:</p> <ul style="list-style-type: none"> <li>• Reactive or reparative cellular changes</li> <li>• Atypical squamous or glandular cells of undetermined significance</li> <li>• Cells in premalignant or malignant category</li> </ul>
<b>Specimen Collection:</b>	ThinPrep® specimens, please refer to <a href="#">instructions</a> in Collection of Pap Specimens <b>Using ThinPrep® Vial. Endocervical Brush/Spatula &amp; Broom</b> <a href="#">instructions</a> .
<b>Storage/Transport:</b>	Store specimens at room temperature (15° to 30° C) until transported, DO NOT FREEZE.
<b>Rejection Criteria:</b>	<a href="#">Click here</a> for Specimen Rejection Criteria. <i>Do not deposit cervical mucus plug into the ThinPrep® vial with the cervical sample. Lubricant use may result in an unsatisfactory specimen.</i>
<b>Turnaround Time:</b>	2-3 Days

**TEST**
**Gynecologic Pap Test w/Imaging, reflex HR HPV if ASCUS, w/Reflex to HPV Genotyping 16 18/45**

<b>Test Description:</b>	Refer to technical test information <a href="#">here</a> . (CT/NG) <a href="#">here</a> .
<b>Order Number:</b>	24252
<b>Performance Lab Name:</b>	South Bend Medical Foundation
<b>CPT Code:</b>	88175, add 87624 if ASCUS
<b>Also Known As:</b>	Cervical Cancer Screening plus Co-Test if ASCUS plus Genotyping if ASCUS

**SPECIMEN REQUIREMENTS**

<b>Specimen:</b>	Gynecological Pap sample collected in <b>ThinPrep® specimen vial</b>	
<b>Specimen Requirements:</b>	<p>With each specimen, please submit a completed requisition along with pertinent clinical information, e.g., last menstrual period (LMP), hormonal status (postmenopausal, pregnant, postpartum), hormone therapy (including birth control pills, treatment for endocrine responsive malignancy, estrogen creams), use of intrauterine device (IUD), and whether the patient is at high risk for cervical cancer.</p> <p>Following is a list of risk factors:</p> <ul style="list-style-type: none"> <li>• Previous gynecological history of dysplasia or cancer</li> <li>• HPV infection</li> <li>• HIV infection</li> <li>• Multiple sexual partners</li> <li>• Grossly visible lesion</li> <li>• Early age of sexual intercourse</li> <li>• DES exposure</li> <li>• Smoker</li> <li>• Abnormal vaginal bleeding</li> <li>• Prior abnormal Pap smear or history of malignancy</li> </ul>	
<b>Note:</b>	<p>Per CLIA criteria, Pap tests will be referred for pathologist review if laboratory suspects:</p> <ul style="list-style-type: none"> <li>• Reactive or reparative cellular changes</li> <li>• Atypical squamous or glandular cells of undetermined significance</li> <li>• Cells in premalignant or malignant category</li> </ul>	
<b>Specimen Collection:</b>	ThinPrep® specimens, please refer to <a href="#">instructions</a> in Collection of Pap Specimens Using <b>ThinPrep® Vial. Endocervical Brush/Spatula &amp; Broom</b> <a href="#">instructions</a> .	
<b>Storage/Transport:</b>	Store specimens at room temperature (15° to 30° C) until transported, DO NOT FREEZE.	
<b>Rejection Criteria:</b>	<p><a href="#">Click here</a> for Specimen Rejection Criteria. <i>Do not deposit cervical mucus plug into the ThinPrep® vial with the cervical sample. Lubricant use may result in an unsatisfactory specimen.</i></p>	
<b>Turnaround Time:</b>	2-3 Days	

TEST	
<b>Requested Add-on Genotyping 16 18/45 w/HPV HR Positive (within 30 days)</b>	
<b>Test Description:</b>	Refer to technical test information <a href="#">here</a> . (CT/NG) <a href="#">here</a> & (TV) <a href="#">here</a> .
<b>Order Number:</b>	24255
<b>Performance Lab Name:</b>	South Bend Medical Foundation
<b>CPT Code:</b>	87625
<b>Also Known As:</b>	Cervical Cancer Screening plus Chlamydia/Gonococcus/Trichomonas vaginalis

SPECIMEN REQUIREMENTS	
<b>Specimen:</b>	Gynecological Pap sample collected in <b>ThinPrep® specimen vial</b>
<b>Specimen Requirements:</b>	<p>With each specimen, please submit a completed requisition along with pertinent clinical information, e.g., last menstrual period (LMP), hormonal status (postmenopausal, pregnant, postpartum), hormone therapy (including birth control pills, treatment for endocrine responsive malignancy, estrogen creams), use of intrauterine device (IUD), and whether the patient is at high risk for cervical cancer.</p> <p>Following is a list of risk factors:</p> <ul style="list-style-type: none"> <li>• Previous gynecological history of dysplasia or cancer</li> <li>• HPV infection</li> <li>• HIV infection</li> <li>• Multiple sexual partners</li> <li>• Grossly visible lesion</li> <li>• Early age of sexual intercourse</li> <li>• DES exposure</li> <li>• Smoker</li> <li>• Abnormal vaginal bleeding</li> <li>• Prior abnormal Pap smear or history of malignancy</li> </ul> <div style="border: 1px solid black; padding: 5px; margin-top: 10px;"> <p><b>Note:</b> Per CLIA criteria, Pap tests will be referred for pathologist review if laboratory suspects:</p> <ul style="list-style-type: none"> <li>• Reactive or reparative cellular changes</li> <li>• Atypical squamous or glandular cells of undetermined significance</li> <li>• Cells in premalignant or malignant category</li> </ul> </div>
<b>Specimen Collection:</b>	ThinPrep® specimens, please refer to <a href="#">instructions</a> in Collection of Pap Specimens <b>Using ThinPrep® Vial. Endocervical Brush/Spatula &amp; Broom</b> <a href="#">instructions</a> .
<b>Storage/Transport:</b>	Store specimens at room temperature (15° to 30° C) until transported, DO NOT FREEZE.
<b>Rejection Criteria:</b>	<a href="#">Click here</a> for Specimen Rejection Criteria. <i>Do not deposit cervical mucus plug into the ThinPrep® vial with the cervical sample. Lubricant use may result in an unsatisfactory specimen.</i>
<b>Turnaround Time:</b>	2-3 Days

## ThinPrep® Age-Based Pap Tests w/Imaging & Aptima® High Risk (HR) HPV (mRNA) w/Reflex to Genotyping

TEST	
<b>Gynecologic Pap Test w/Imaging &amp; Aptima® High Risk HPV (mRNA) Co-Test, w/reflex to Genotyping 16 18/45</b>	
<b>Test Description:</b>	Refer to technical test information <a href="#">here</a> .
<b>Order Number:</b>	24253
<b>Performance Lab Name:</b>	South Bend Medical Foundation
<b>CPT Code:</b>	88175, 87624, add 87625 if ASCUS
<b>Also Known As:</b>	Cervical Cancer Screening Co-Test, Co-Test with Genotyping

SPECIMEN REQUIREMENTS	
<b>Specimen:</b>	Gynecological Pap sample collected in <b>ThinPrep® specimen vial</b>
<b>Specimen Requirements:</b>	<p>With each specimen, please submit a completed requisition along with pertinent clinical information, e.g., last menstrual period (LMP), hormonal status (postmenopausal, pregnant, postpartum), hormone therapy (including birth control pills, treatment for endocrine responsive malignancy, estrogen creams), use of intrauterine device (IUD), and whether the patient is at high risk for cervical cancer.</p> <p>Following is a list of risk factors:</p> <ul style="list-style-type: none"> <li>• Previous gynecological history of dysplasia or cancer</li> <li>• HPV infection</li> <li>• HIV infection</li> <li>• Multiple sexual partners</li> <li>• Grossly visible lesion</li> <li>• Early age of sexual intercourse</li> <li>• DES exposure</li> <li>• Smoker</li> <li>• Abnormal vaginal bleeding</li> <li>• Prior abnormal Pap smear or history of malignancy</li> </ul> <div style="border: 1px solid black; padding: 5px; margin-top: 10px;"> <p><b>Note:</b> Per CLIA criteria, Pap tests will be referred for pathologist review if laboratory suspects:</p> <ul style="list-style-type: none"> <li>• Reactive or reparative cellular changes</li> <li>• Atypical squamous or glandular cells of undetermined significance</li> <li>• Cells in premalignant or malignant category</li> </ul> </div>
<b>Specimen Collection:</b>	ThinPrep® specimens, please refer to <a href="#">instructions</a> in Collection of Pap Specimens Using <b>ThinPrep® Vial. Endocervical Brush/Spatula &amp; Broom</b> <a href="#">instructions</a> .
<b>Storage/Transport:</b>	Store specimens at room temperature (15° to 30° C) until transported, DO NOT FREEZE.
<b>Rejection Criteria:</b>	<a href="#">Click here</a> for Specimen Rejection Criteria. <i>Do not deposit cervical mucus plug into the ThinPrep® vial with the cervical sample. Lubricant use may result in an unsatisfactory specimen.</i>
<b>Turnaround Time:</b>	2-3 Days

## Molecular Testing

TEST	
<b>Chlamydia trachomatis and Neisseria gonorrhoeae, (CT/NG)</b>	
<b>Test Description:</b>	Detection of Chlamydia trachomatis and Neisseria Gonorrhoeae by FDA approved Aptima COMBO 2® (Hologic) nucleic acid amplification method (NAAT). Refer to technical test information (CT/NG) <a href="#">here</a> .
<b>Order Number:</b>	36370
<b>Performance Lab Name:</b>	South Bend Medical Foundation
<b>CPT Code:</b>	87491, 87591
<b>Also Known As:</b>	CT/NG

SPECIMEN REQUIREMENTS	
<b>Specimen:</b>	Gynecological Pap sample, Urine sample
<b>Specimen Requirements:</b>	<p>Submit only one (1) of the following specimens:</p> <ul style="list-style-type: none"> <li>ThinPrep® Pap specimen</li> <li>Endocervical swab using APTIMA® Unisex Swab Collection Kit</li> <li>Vaginal swab using APTIMA® Multitest Swab Specimen Kit</li> <li>using the APTIMA® Urine Specimen Collection Kit</li> </ul>
<b>Specimen Collection:</b>	<ul style="list-style-type: none"> <li>ThinPrep® specimens – please refer to <a href="#">instructions</a> in Collection of Pap Specimens using ThinPrep®. Collect material for a routine Pap specimen; it is important that cervical mucus be removed.</li> <li>Endocervical swab specimens – please refer to instructions in Collection of Endocervical Swab Specimens using the Aptima® <a href="#">Unisex Swab Specimen Collection Kit</a>.</li> <li>Vaginal swab specimens – please refer to instructions in Collection of <a href="#">Vaginal Swab Specimens</a> using the Aptima® Multitest Swab Collection Kit.</li> <li>Urine specimens – please refer to instructions in Collection of <a href="#">Urine Specimens</a> using the Aptima® Urine Specimen Collection Kit.</li> </ul>
<b>Storage/Transport:</b>	Store specimens at room temperature (15° to 30° C) until transported, DO NOT FREEZE.
<b>Rejection Criteria:</b>	<ul style="list-style-type: none"> <li>APTIMA® swab vial specimens submitted without a swab will be rejected.</li> <li>APTIMA® urine vials must be filled with urine to the level designated on the tube (between the black lines). Over- or under-filled tubes will be rejected.</li> </ul> <a href="#">Click here</a> for Specimen Rejection Criteria
<b>Turnaround Time:</b>	2-3 Days
<b>Methodology:</b>	Transcription-mediated amplification (TMA)
<b>Limitations:</b>	Test results may be affected by improper/inadequate specimen collection. If excess mucus is not removed prior to specimen collection, sampling of columnar epithelial cells lining the endocervix is not ensured, which could cause a false negative test result.

**TEST**
**Candida vaginosis & Trichomonas vaginalis (CV/TV)**

<b>Test Description:</b>	Trichomonas vaginalis and Candida vaginosis testing by molecular methods. Refer to technical test information (CV/TV) <a href="#">here</a> .
<b>Order Number:</b>	36371
<b>Performance Lab Name:</b>	South Bend Medical Foundation
<b>CPT Code:</b>	87481, 87661
<b>Also Known As:</b>	Candida vaginosis & Trichomonas vaginalis

**SPECIMEN REQUIREMENTS**

<b>Specimen:</b>	Gynecological Pap sample
<b>Specimen Requirements:</b>	Submit only one (1) of the following specimens: <ul style="list-style-type: none"> <li>• Vaginal swab using APTIMA® Multitest Swab Specimen Kit</li> </ul>
<b>Specimen Collection:</b>	<ul style="list-style-type: none"> <li>• Vaginal swab specimens – please refer to instructions in Collection of <a href="#">Vaginal Swab Specimens</a> using the Aptima® Multitest Swab Collection Kit.</li> </ul>
<b>Storage/Transport:</b>	Store specimens at room temperature (15° to 30° C) until transported, DO NOT FREEZE.
<b>Rejection Criteria:</b>	APTIMA® swab vial specimens submitted without a swab will be rejected. <a href="#">Click here</a> for Specimen Rejection Criteria.
<b>Turnaround Time:</b>	2-3 Days

**TEST**
**Herpes Simplex Virus (HSV 1 & 2)**

<b>Test Description:</b>	Detection and differentiation of Herpes simplex virus types 1 and 2. Refer to technical test information (HSV 1&2) <a href="#">here</a> .
<b>Order Number:</b>	36374
<b>Performance Lab Name:</b>	South Bend Medical Foundation
<b>CPT Code:</b>	87529 x2
<b>Also Known As:</b>	Herpes Simplex Virus (HSV 1 & 2)

**SPECIMEN REQUIREMENTS**

<b>Specimen:</b>	Lesion Swab Sample
<b>Specimen Requirements:</b>	Submit only one (1) of the following specimens: <ul style="list-style-type: none"> <li>• Lesion swab using APTIMA® Multitest Swab Specimen Kit</li> </ul>
<b>Specimen Collection:</b>	<ul style="list-style-type: none"> <li>• Swab specimen – <a href="#">swab the lesion</a> using sufficient pressure to ensure good contact of the swab with the lesion. Gently rotate the swab. Remove the cap from the specimen transport tube and immediately place the swab into the tube. Carefully break the shaft against the side of the tube at the scoreline, then discard the top portion of the swab shaft. Tightly recap the tube.</li> </ul>
<b>Storage/Transport:</b>	Swab specimens are stable if stored at 2-30°C for 60 days. <i>However, liquid-based cytology specimens are stable if stored at 2-30°C for 30 days.</i>
<b>Rejection Criteria:</b>	APTIMA® swab vial specimens submitted without a swab will be rejected. <a href="#">Click here</a> for Specimen Rejection Criteria.
<b>Turnaround Time:</b>	2-3 Days
<b>Methodology:</b>	Transcription-mediated Amplification (TMA)
<b>Limitations:</b>	<ul style="list-style-type: none"> <li>• Test results may be affected by improper/inadequate specimen collection.</li> <li>• A negative result indicates that HSV-1 and -2 DNA are not present at detectable quantities. It does not indicate that an individual has never been exposed to HSV-1 and/or 2 and does not exclude the possibility of latent infection.</li> </ul>

**TEST**
**Bacterial vaginosis (BV)**

<b>Test Description:</b>	Refer to technical test information (BV) <a href="#">here</a> .
<b>Order Number:</b>	36372
<b>Performance Lab Name:</b>	South Bend Medical Foundation
<b>CPT Code:</b>	81513
<b>Also Known As:</b>	Gardnerella vaginalis; Lactobacillus; Atopobium

**SPECIMEN REQUIREMENTS**

<b>Specimen:</b>	Gynecological Pap sample
<b>Specimen Requirements:</b>	Submit only one (1) of the following specimens: <ul style="list-style-type: none"> <li>• Vaginal swab using APTIMA® Multitest Swab Specimen Kit</li> </ul>
<b>Specimen Collection:</b>	<ul style="list-style-type: none"> <li>• Vaginal swab specimens – please refer to instructions in Collection of <a href="#">Vaginal Swab Specimens</a> using the Aptima® Multitest Swab Collection Kit.</li> </ul>
<b>Storage/Transport:</b>	Store specimens at room temperature (15° to 30° C) until transported, DO NOT FREEZE.
<b>Rejection Criteria:</b>	APTIMA® swab vial specimens submitted without a swab will be rejected. <a href="#">Click here</a> for Specimen Rejection Criteria.
<b>Turnaround Time:</b>	2-3 Days
<b>Methodology:</b>	Transcription-mediated Amplification (TMA)
<b>Limitations:</b>	Test results may be affected by improper/inadequate specimen collection.

**TEST**
**Trichomonas vaginalis (TV)**

<b>Test Description:</b>	Detection of Trichomonas vaginalis by the FDA-approved APTIMA® Trichomonas vaginalis Assay (Hologic) Refer to technical test information (TV) <a href="#">here</a> .
<b>Order Number:</b>	36041
<b>Performance Lab Name:</b>	South Bend Medical Foundation
<b>CPT Code:</b>	87661
<b>Also Known As:</b>	Trichomonas vaginalis

**SPECIMEN REQUIREMENTS**

<b>Specimen:</b>	Gynecological Pap sample, Urine sample
<b>Specimen Requirements:</b>	<p>Submit only one (1) of the following specimens:</p> <ul style="list-style-type: none"> <li>ThinPrep® Pap specimen</li> <li>Endocervical swab using APTIMA® Unisex Swab Collection Kit</li> <li>Vaginal swab using APTIMA® Multitest Swab Specimen Kit</li> <li>Urine using the APTIMA® Urine Specimen Collection Kit</li> </ul>
<b>Specimen Collection:</b>	<ul style="list-style-type: none"> <li>ThinPrep® specimens – please refer to <a href="#">instructions</a> in Collection of Pap Specimens using ThinPrep®. Collect material as for a routine Pap specimen; it is important that cervical mucus be removed.</li> <li>Endocervical swab specimens – please refer to instructions in Collection of Endocervical Swab Specimens using the Aptima® <a href="#">Unisex Swab Specimen Collection Kit</a>.</li> <li>Vaginal swab specimens – please refer to instructions in Collection of <a href="#">Vaginal Swab Specimens</a> using the Aptima® Multitest Swab Collection Kit.</li> <li>Urine specimens – please refer to instructions in Collection of <a href="#">Urine Specimens</a> using the Aptima® Urine Specimen Collection Kit.</li> </ul>
<b>Storage/Transport:</b>	Store specimens at room temperature (15° to 30° C) until transported, DO NOT FREEZE.
<b>Rejection Criteria:</b>	<ul style="list-style-type: none"> <li>APTIMA® swab vial specimens submitted without a swab will be rejected.</li> <li>APTIMA® urine vials must be filled with urine to the level designated on the tube (between the black lines). Over- or under-filled tubes will be rejected.</li> </ul> <p><a href="#">Click here</a> for Specimen Rejection Criteria</p>
<b>Turnaround Time:</b>	2-3 Days
<b>Methodology:</b>	Transcription-mediated amplification (TMA)
<b>Limitations:</b>	<ul style="list-style-type: none"> <li>Test results may be affected by improper/ inadequate specimen collection.</li> <li>If excess mucus is not removed prior to specimen collection, sampling of columnar epithelial cells lining the endocervix is not ensured, which could cause a false negative test result.</li> </ul>

**TEST**
**Mycoplasma genitalium (M.gen)**

<b>Test Description:</b>	Detection of Mycoplasma genitalium by the FDA-approved APTIMA (Hologic). Refer to technical test information (M. gen) <a href="#">here</a> .
<b>Order Number:</b>	36373
<b>Performance Lab Name:</b>	South Bend Medical Foundation
<b>CPT Code:</b>	87563
<b>Also Known As:</b>	M. gen

**SPECIMEN REQUIREMENTS**

<b>Specimen:</b>	Gynecological Pap sample, Urine sample
<b>Specimen Requirements:</b>	<p>Submit only one (1) of the following specimens:</p> <ul style="list-style-type: none"> <li>• Endocervical swab using APTIMA® Unisex Swab Collection Kit</li> <li>• Vaginal swab using APTIMA® Multitest Swab Specimen Kit</li> <li>• Urine using the APTIMA® Urine Specimen Collection Kit</li> </ul>
<b>Specimen Collection:</b>	<ul style="list-style-type: none"> <li>• Endocervical swab specimens – please refer to <a href="#">instructions</a> in Collection of Endocervical Swab Specimens using the Aptima® <a href="#">Unisex Swab Specimen Collection Kit</a>.</li> <li>• Vaginal swab specimens – please refer to instructions in Collection of <a href="#">Vaginal Swab Specimens</a> using the Aptima® Multitest Swab Collection Kit.</li> <li>• Urine specimens – please refer to instructions in Collection of <a href="#">Urine Specimens</a> using the Aptima® Urine Specimen Collection Kit.</li> </ul>
<b>Storage/Transport:</b>	Store specimens at room temperature (15° to 30° C) until transported, DO NOT FREEZE.
<b>Rejection Criteria:</b>	<ul style="list-style-type: none"> <li>• APTIMA® swab vial specimens submitted without a swab will be rejected.</li> <li>• APTIMA® urine vials must be filled with urine to the level designated on the tube (between the black lines). Over- or under-filled tubes will be rejected.</li> </ul> <p><a href="#">Click here</a> for Specimen Rejection Criteria.</p>
<b>Turnaround Time:</b>	2-3 Days
<b>Methodology:</b>	Transcription-mediated amplification (TMA)
<b>Limitations:</b>	<ul style="list-style-type: none"> <li>• Test results may be affected by improper/ inadequate specimen collection.</li> <li>• If excess mucus is not removed prior to specimen collection, sampling of columnar epithelial cells lining the endocervix is not ensured, which could cause a false negative test result.</li> </ul>

## Molecular Panels

<b>PANEL</b>	
<b>Chlamydia trachomatis/Neisseria Gonorrhoeae/Trichomonas vaginalis (CT/NG/TV)</b>	
<b>Test Description:</b>	STI Screening Panel- Chlamydia trachomatis/Neisseria Gonorrhoeae, Trichomonas vaginalis Refer to technical test information (CT/NG) <a href="#">here</a> & (TV) <a href="#">here</a> .
<b>Order Number:</b>	35374
<b>Performance Lab Name:</b>	South Bend Medical Foundation
<b>CPT Code:</b>	87491, 87591, 87661
<b>Also Known As:</b>	Sexually Transmitted Infections Panel

<b>SPECIMEN REQUIREMENTS</b>	
<b>Specimen:</b>	Gynecological Pap sample, Urine sample
<b>Specimen Requirements:</b>	<p>Submit only one (1) of the following specimens:</p> <ul style="list-style-type: none"> <li>• ThinPrep® Pap specimen</li> <li>• Endocervical swab using APTIMA® Unisex Swab Collection Kit</li> <li>• Vaginal swab using APTIMA® Multitest Swab Specimen Kit</li> <li>• Urine using the APTIMA® Urine Specimen Collection Kit</li> </ul>
<b>Specimen Collection:</b>	<ul style="list-style-type: none"> <li>• ThinPrep® specimens – please refer to <a href="#">instructions</a> in Collection of Pap Specimens using ThinPrep®. Collect material for a routine Pap specimen; it is important that cervical mucus be removed.</li> <li>• Endocervical swab specimens – please refer to <a href="#">instructions</a> in Collection of Endocervical Swab Specimens using the Aptima® <a href="#">Unisex Swab Specimen Collection Kit</a>.</li> <li>• Vaginal swab specimens – please refer to instructions in Collection of <a href="#">Vaginal Swab Specimens</a> using the Aptima® Multitest Swab Collection Kit.</li> <li>• Urine specimens – please refer to instructions in Collection of <a href="#">Urine Specimens</a> using the Aptima® Urine Specimen Collection Kit.</li> </ul>
<b>Storage/Transport:</b>	Store specimens at room temperature (15° to 30° C) until transported, DO NOT FREEZE.
<b>Rejection Criteria:</b>	<ul style="list-style-type: none"> <li>• APTIMA® swab vial specimens submitted without a swab will be rejected.</li> <li>• APTIMA® urine vials must be filled with urine to the level designated on the tube (between the black lines). Over- or under-filled tubes will be rejected.</li> </ul> <p><a href="#">Click here</a> for Specimen Rejection Criteria.</p>
<b>Turnaround Time:</b>	2-3 Days
<b>Methodology:</b>	Transcription-mediated amplification (TMA)
<b>Limitations:</b>	<ul style="list-style-type: none"> <li>• Test results may be affected by improper/ inadequate specimen collection.</li> <li>• If excess mucus is not removed prior to specimen collection, sampling of columnar epithelial cells lining the endocervix is not ensured, which could cause a false negative test result.</li> </ul>