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Gynecologic Cytology and Molecular Specimen Collection Information

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ThinPrep® Age-Based Pap Testing w/Imaging

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

SPECIMEN REQUIREMENTS	
Specimen:	Gynecological Pap sample collected in **ThinPrep® specimen vial**
Specimen Requirements:	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. Following is a list of risk factors: • Previous gynecological history of dysplasia or cancer • HPV infection • HIV infection • Multiple sexual partners • Grossly visible lesion • Early age of sexual intercourse • DES exposure • Smoker • Abnormal vaginal bleeding • Prior abnormal Pap smear or history of malignancy **Note**: Per CLIA criteria, Pap tests will be referred for pathologist review if laboratory suspects: • Reactive or reparative cellular changes • Atypical squamous or glandular cells of undetermined significance • Cells in premalignant or malignant category
Specimen Collection:	ThinPrep® specimens, please refer to instructions in Collection of Pap Specimens **Using ThinPrep® Vial. Endocervical Brush/Spatula & Broom** instructions.
Storage/Transport:	Store specimens at room temperature (15° to 30° C) until transported, DO NOT FREEZE.
Rejection Criteria:	Click here for Specimen Rejection Criteria. *Do not deposit cervical mucus plug into the ThinPrep® vial with the cervical sample. Lubricant use may result in an unsatisfactory specimen.*
Turnaround Time:	2-3 Days

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TEST	
Gynecologic Pap Test w/Imaging, reflex HR HPV if ASCUS (ages 21 and over)	
Test Description:	Refer to technical test information here.
Order Number:	24251
Performance Lab Name:	South Bend Medical Foundation
CPT Code:	88175, add 87624 if ASCUS
Also Known As:	Age based Cervical Cancer Screening, Pap Smear

SPECIMEN REQUIREMENTS	
Specimen:	Gynecological Pap sample collected in **ThinPrep® specimen vial**
Specimen Requirements:	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. Following is a list of risk factors: • Previous gynecological history of dysplasia or cancer • HPV infection • HIV infection • Multiple sexual partners • Grossly visible lesion • Early age of sexual intercourse • DES exposure • Smoker • Abnormal vaginal bleeding • Prior abnormal Pap smear or history of malignancy **Note**: Per CLIA criteria, Pap tests will be referred for pathologist review if laboratory suspects: • Reactive or reparative cellular changes • Atypical squamous or glandular cells of undetermined significance • Cells in premalignant or malignant category
Specimen Collection:	ThinPrep® specimens, please refer to instructions in Collection of Pap Specimens **Using ThinPrep® Vial. Endocervical Brush/Spatula & Broom** instructions.
Storage/Transport:	Store specimens at room temperature (15° to 30° C) until transported, DO NOT FREEZE.
Rejection Criteria:	Click here for Specimen Rejection Criteria. *Do not deposit cervical mucus plug into the ThinPrep® vial with the cervical sample. Lubricant use may result in an unsatisfactory specimen.*
Turnaround Time:	2-3 Days

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TEST	
Gynecologic Pap w/Imaging & HR HPV Co-Test (ages 30-65)	
Test Description:	Refer to technical test information here.
Order Number:	24254
Performance Lab Name:	South Bend Medical Foundation
CPT Code:	88175, 87624
Also Known As:	Aged-based Cervical Cancer Screening Co-Test, Pap Smear, Co-Test

SPECIMEN REQUIREMENTS	
Specimen:	Gynecological Pap sample collected in **ThinPrep® specimen vial**
Specimen Requirements:	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. Following is a list of risk factors: • Previous gynecological history of dysplasia or cancer • HPV infection • HIV infection • Multiple sexual partners • Grossly visible lesion • Early age of sexual intercourse • DES exposure • Smoker • Abnormal vaginal bleeding • Prior abnormal Pap smear or history of malignancy **Note**: Per CLIA criteria, Pap tests will be referred for pathologist review if laboratory suspects: • Reactive or reparative cellular changes • Atypical squamous or glandular cells of undetermined significance • Cells in premalignant or malignant category
Specimen Collection:	ThinPrep® specimens, please refer to instructions in Collection of Pap Specimens Using **ThinPrep® Vial. Endocervical Brush/Spatula & Broom** instructions.
Storage/Transport:	Store specimens at room temperature (15° to 30° C) until transported, DO NOT FREEZE.
Rejection Criteria:	Click here for Specimen Rejection Criteria. *Do not deposit cervical mucus plug into the ThinPrep® vial with the cervical sample. Lubricant use may result in an unsatisfactory specimen.*
Turnaround Time:	2-3 Days

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TEST	
Gynecologic Pap Test w/Imaging, reflex HR HPV if ASCUS, CT/NG	
Test Description:	Refer to technical test information here. (CT/NG) here.
Order Number:	24252
Performance Lab Name:	South Bend Medical Foundation
CPT Code:	88175, 87491, 87591, add 87624 if ASCUS
Also Known As:	Cervical Cancer Screening plus Chlamydia/Gonococcus

SPECIMEN REQUIREMENTS	
Specimen:	Gynecological Pap sample collected in **ThinPrep® specimen vial**
Specimen Requirements:	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. Following is a list of risk factors: • Previous gynecological history of dysplasia or cancer • HPV infection • HIV infection • Multiple sexual partners • Grossly visible lesion • Early age of sexual intercourse • DES exposure • Smoker • Abnormal vaginal bleeding • Prior abnormal Pap smear or history of malignancy **Note**: Per CLIA criteria, Pap tests will be referred for pathologist review if laboratory suspects: • Reactive or reparative cellular changes • Atypical squamous or glandular cells of undetermined significance • Cells in premalignant or malignant category
Specimen Collection:	ThinPrep® specimens, please refer to instructions in Collection of Pap Specimens Using **ThinPrep® Vial. Endocervical Brush/Spatula & Broom** instructions.
Storage/Transport:	Store specimens at room temperature (15° to 30° C) until transported, DO NOT FREEZE.
Rejection Criteria:	Click here for Specimen Rejection Criteria. *Do not deposit cervical mucus plug into the ThinPrep® vial with the cervical sample. Lubricant use may result in an unsatisfactory specimen.*
Turnaround Time:	2-3 Days

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TEST	
Gynecologic Pap Test w/Imaging, reflex HR HPV if ASCUS, CT/NG/TV	
Test Description:	Refer to technical test information here. (CT/NG) here & (TV) here.
Order Number:	24255
Performance Lab Name:	South Bend Medical Foundation
CPT Code:	88175, 87491, 87591, 87661, add 87624 if ASCUS
Also Known As:	Cervical Cancer Screening plus Chlamydia/Gonococcus/Trichomonas vaginalis

SPECIMEN REQUIREMENTS	
Specimen:	Gynecological Pap sample collected in **ThinPrep® specimen vial**
Specimen Requirements:	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. Following is a list of risk factors: • Previous gynecological history of dysplasia or cancer • HPV infection • HIV infection • Multiple sexual partners • Grossly visible lesion • Early age of sexual intercourse • DES exposure • Smoker • Abnormal vaginal bleeding • Prior abnormal Pap smear or history of malignancy **Note**: Per CLIA criteria, Pap tests will be referred for pathologist review if laboratory suspects: • Reactive or reparative cellular changes • Atypical squamous or glandular cells of undetermined significance • Cells in premalignant or malignant category
Specimen Collection:	ThinPrep® specimens, please refer to instructions in Collection of Pap Specimens **Using ThinPrep® Vial. Endocervical Brush/Spatula & Broom** instructions.
Storage/Transport:	Store specimens at room temperature (15° to 30° C) until transported, DO NOT FREEZE.
Rejection Criteria:	Click here for Specimen Rejection Criteria. *Do not deposit cervical mucus plug into the ThinPrep® vial with the cervical sample. Lubricant use may result in an unsatisfactory specimen.*
Turnaround Time:	2-3 Days

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

TEST	
Gynecologic Pap Test w/Imaging & Aptima® High Risk HPV (mRNA) Co-Test, w/reflex to Genotyping 16 18/45 (Ages 30-65)	
Test Description:	Refer to technical test information here.
Order Number:	24253
Performance Lab Name:	South Bend Medical Foundation
CPT Code:	88175, 87624, add 87625 if ASCUS
Also Known As:	Cervical Cancer Screening Co-Test, Co-Test with Genotyping

SPECIMEN REQUIREMENTS	
Specimen:	Gynecological Pap sample collected in **ThinPrep® specimen vial**
Specimen Requirements:	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. Following is a list of risk factors: • Previous gynecological history of dysplasia or cancer • HPV infection • HIV infection • Multiple sexual partners • Grossly visible lesion • Early age of sexual intercourse • DES exposure • Smoker • Abnormal vaginal bleeding • Prior abnormal Pap smear or history of malignancy **Note**: Per CLIA criteria, Pap tests will be referred for pathologist review if laboratory suspects: • Reactive or reparative cellular changes • Atypical squamous or glandular cells of undetermined significance • Cells in premalignant or malignant category
Specimen Collection:	ThinPrep® specimens, please refer to instructions in Collection of Pap Specimens **Using ThinPrep® Vial. Endocervical Brush/Spatula & Broom** instructions.
Storage/Transport:	Store specimens at room temperature (15° to 30° C) until transported, DO NOT FREEZE.
Rejection Criteria:	Click here for Specimen Rejection Criteria. *Do not deposit cervical mucus plug into the ThinPrep® vial with the cervical sample. Lubricant use may result in an unsatisfactory specimen.*
Turnaround Time:	2-3 Days

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TEST	
Gynecologic Pap Test w/Imaging & Aptima® High Risk HPV (mRNA) Co-Test, w/reflex to HPV Genotyping 16 18/45, CT/NG	
Test Description:	Refer to technical test information here. (CT/NG) here.
Order Number:	24256
Performance Lab Name:	South Bend Medical Foundation
CPT Code:	88175, 87491, 87591, 87624 if ASCUS, add 87625 if ASCUS
Also Known As:	Cervical Cancer Screening Co-Test with Genotyping if ASCUS plus Chlamydia/Gonococcus

SPECIMEN REQUIREMENTS	
Specimen:	Gynecological Pap sample collected in **ThinPrep® specimen vial**
Specimen Requirements:	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. Following is a list of risk factors: • Previous gynecological history of dysplasia or cancer • HPV infection • HIV infection • Multiple sexual partners • Grossly visible lesion • Early age of sexual intercourse • DES exposure • Smoker • Abnormal vaginal bleeding • Prior abnormal Pap smear or history of malignancy **Note**: Per CLIA criteria, Pap tests will be referred for pathologist review if laboratory suspects: • Reactive or reparative cellular changes • Atypical squamous or glandular cells of undetermined significance • Cells in premalignant or malignant category
Specimen Collection:	ThinPrep® specimens, please refer to instructions in Collection of Pap Specimens **Using ThinPrep® Vial. Endocervical Brush/Spatula & Broom** instructions.
Storage/Transport:	Store specimens at room temperature (15° to 30° C) until transported, DO NOT FREEZE.
Rejection Criteria:	Click here for Specimen Rejection Criteria. *Do not deposit cervical mucus plug into the ThinPrep® vial with the cervical sample. Lubricant use may result in an unsatisfactory specimen.*
Turnaround Time:	2-3 Days

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TEST	
Gynecologic Pap Test w/Imaging & Aptima® High Risk HPV (mRNA) Co-Test, w/reflex to HPV Genotyping 16 18/45, CT/NG/TV	
Test Description:	Refer to technical test information here. (CT/NG) here & (TV) here.
Order Number:	24257
Performance Lab Name:	South Bend Medical Foundation
CPT Code:	88175, 87491, 87591, 87661, 87624 if ASCUS, add 87625 if ASCUS
Also Known As:	Cervical Cancer Screening Co-Test with Genotyping if ASCUS plus Chlamydia/Gonococcus/Trichomonas vaginalis

SPECIMEN REQUIREMENTS	
Specimen:	Gynecological Pap sample collected in **ThinPrep® specimen vial**
Specimen Requirements:	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. Following is a list of risk factors: • Previous gynecological history of dysplasia or cancer • HPV infection • HIV infection • Multiple sexual partners • Grossly visible lesion • Early age of sexual intercourse • DES exposure • Smoker • Abnormal vaginal bleeding • Prior abnormal Pap smear or history of malignancy **Note**: Per CLIA criteria, Pap tests will be referred for pathologist review if laboratory suspects: • Reactive or reparative cellular changes • Atypical squamous or glandular cells of undetermined significance • Cells in premalignant or malignant category
Specimen Collection:	ThinPrep® specimens, please refer to instructions in Collection of Pap Specimens **Using ThinPrep® Vial. Endocervical Brush/Spatula & Broom** instructions.
Storage/Transport:	Store specimens at room temperature (15° to 30° C) until transported, DO NOT FREEZE.
Rejection Criteria:	Click here for Specimen Rejection Criteria. *Do not deposit cervical mucus plug into the ThinPrep® vial with the cervical sample. Lubricant use may result in an unsatisfactory specimen.*
Turnaround Time:	2-3 Days

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TEST	
High Risk HPV, reflex to Genotyping 16 18/45	
Test Description:	Refer to technical test information here. Detection of High-Risk HPV by the FDA-approved APTIMA® HPV (Hologic) nucleic acid amplification method. Reflex testing (if HPV positive) detects and differentiates the HPV genotypes 16 and 18/45.
Order Number:	24258
Performance Lab Name:	South Bend Medical Foundation
CPT Code:	87625
Also Known As:	HPV Genotype 16 18/45

SPECIMEN REQUIREMENTS	
Specimen:	Gynecological Pap sample collected in **ThinPrep® specimen vial**
Specimen Requirements:	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. Following is a list of risk factors: • Previous gynecological history of dysplasia or cancer • HPV infection • HIV infection • Multiple sexual partners • Grossly visible lesion • Early age of sexual intercourse • DES exposure • Smoker • Abnormal vaginal bleeding • Prior abnormal Pap smear or history of malignancy **Note**: Per CLIA criteria, Pap tests will be referred for pathologist review if laboratory suspects: • Reactive or reparative cellular changes • Atypical squamous or glandular cells of undetermined significance • Cells in premalignant or malignant category
Specimen Collection:	ThinPrep® specimens, please refer to instructions in Collection of Pap Specimens **Using ThinPrep® Vial. Endocervical Brush/Spatula & Broom** instructions.
Storage/Transport:	Store specimens at room temperature (15° to 30° C) until transported, DO NOT FREEZE.
Rejection Criteria:	Click here for Specimen Rejection Criteria. *Do not deposit cervical mucus plug into the ThinPrep® vial with the cervical sample. Lubricant use may result in an unsatisfactory specimen.*
Turnaround Time:	2-3 Days
Methodology:	Transcription-mediated amplification (TMA)

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Molecular Testing

TEST	
Chlamydia trachomatis and Neisseria gonorrhoeae, (CT/NG)	
Test Description:	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) here.
Order Number:	36370
Performance Lab Name:	South Bend Medical Foundation
CPT Code:	87491, 87591
Also Known As:	CT/NG

SPECIMEN REQUIREMENTS	
Specimen:	Gynecological Pap sample, Urine sample
Specimen Requirements:	Submit only one (1) of the following specimens: • ThinPrep® Pap specimen • Endocervical swab using APTIMA® Unisex Swab Collection Kit • Vaginal swab using APTIMA® Multitest Swab Specimen Kit • using the APTIMA® Urine Specimen Collection Kit
Specimen Collection:	• ThinPrep® specimens – please refer to instructions in Collection of Pap Specimens using ThinPrep®. Collect material for a routine Pap specimen; it is important that cervical mucus be removed. • Endocervical swab specimens – please refer to instructions in Collection of Endocervical Swab Specimens using the Aptima® Unisex Swab Specimen Collection Kit. • Vaginal swab specimens – please refer to instructions in Collection of Vaginal Swab Specimens using the Aptima® Multitest Swab Collection Kit. • Urine specimens – please refer to instructions in Collection of Urine Specimens using the Aptima® Urine Specimen Collection Kit.
Storage/Transport:	Store specimens at room temperature (15° to 30° C) until transported, DO NOT FREEZE.
Rejection Criteria:	• APTIMA® swab vial specimens submitted without a swab will be rejected. • 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. Click here for Specimen Rejection Criteria
Turnaround Time:	2-3 Days
Methodology:	Transcription-mediated amplification (TMA)
Limitations:	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.

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

SPECIMEN REQUIREMENTS	
Specimen:	Gynecological Pap sample
Specimen Requirements:	Submit only one (1) of the following specimens: • Vaginal swab using APTIMA® Multitest Swab Specimen Kit
Specimen Collection:	• Vaginal swab specimens – please refer to instructions in Collection of Vaginal Swab Specimens using the Aptima® Multitest Swab Collection Kit.
Storage/Transport:	Store specimens at room temperature (15° to 30° C) until transported, DO NOT FREEZE.
Rejection Criteria:	APTIMA® swab vial specimens submitted without a swab will be rejected. Click here for Specimen Rejection Criteria.
Turnaround Time:	2-3 Days

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

SPECIMEN REQUIREMENTS	
Specimen:	Lesion Swab Sample
Specimen Requirements:	Submit only one (1) of the following specimens: • Lesion swab using APTIMA® Multitest Swab Specimen Kit
Specimen Collection:	• Swab specimen – swab the lesion 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.
Storage/Transport:	Swab specimens are stable if stored at 2-30°C for 60 days. *However*, liquid-based cytology specimens are stable if stored at 2-30°C for 30 days.
Rejection Criteria:	APTIMA® swab vial specimens submitted without a swab will be rejected. Click here for Specimen Rejection Criteria.
Turnaround Time:	2-3 Days
Methodology:	Transcription-mediated Amplification (TMA)
Limitations:	• Test results may be affected by improper/inadequate specimen collection. • 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.

TEST	
Bacterial vaginosis (BV)	
Test Description:	Refer to technical test information (BV) here.
Order Number:	36372
Performance Lab Name:	South Bend Medical Foundation
CPT Code:	81513
Also Known As:	Gardnerella vaginalis; Lactobacillus; Atopobium

SPECIMEN REQUIREMENTS	
Specimen:	Gynecological Pap sample
Specimen Requirements:	Submit only one (1) of the following specimens: • Vaginal swab using APTIMA® Multitest Swab Specimen Kit
Specimen Collection:	• Vaginal swab specimens – please refer to instructions in Collection of Vaginal Swab Specimens using the Aptima® Multitest Swab Collection Kit.
Storage/Transport:	Store specimens at room temperature (15° to 30° C) until transported, DO NOT FREEZE.
Rejection Criteria:	APTIMA® swab vial specimens submitted without a swab will be rejected. Click here for Specimen Rejection Criteria.
Turnaround Time:	2-3 Days
Methodology:	Transcription-mediated Amplification (TMA)
Limitations:	Test results may be affected by improper/inadequate specimen collection.

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

SPECIMEN REQUIREMENTS	
Specimen:	Gynecological Pap sample, Urine sample
Specimen Requirements:	Submit only one (1) of the following specimens: • ThinPrep® Pap specimen • Endocervical swab using APTIMA® Unisex Swab Collection Kit • Vaginal swab using APTIMA® Multitest Swab Specimen Kit • Urine using the APTIMA® Urine Specimen Collection Kit
Specimen Collection:	• ThinPrep® specimens – please refer to instructions in Collection of Pap Specimens using ThinPrep®. Collect material as for a routine Pap specimen; it is important that cervical mucus be removed. • Endocervical swab specimens – please refer to instructions in Collection of Endocervical Swab Specimens using the Aptima® Unisex Swab Specimen Collection Kit. • Vaginal swab specimens – please refer to instructions in Collection of Vaginal Swab Specimens using the Aptima® Multitest Swab Collection Kit. • Urine specimens – please refer to instructions in Collection of Urine Specimens using the Aptima® Urine Specimen Collection Kit.
Storage/Transport:	Store specimens at room temperature (15° to 30° C) until transported, DO NOT FREEZE.
Rejection Criteria:	• APTIMA® swab vial specimens submitted without a swab will be rejected. • 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. Click here for Specimen Rejection Criteria
Turnaround Time:	2-3 Days
Methodology:	Transcription-mediated amplification (TMA)
Limitations:	• 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.

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

SPECIMEN REQUIREMENTS	
Specimen:	Gynecological Pap sample, Urine sample
Specimen Requirements:	Submit only one (1) of the following specimens: • Endocervical swab using APTIMA® Unisex Swab Collection Kit • Vaginal swab using APTIMA® Multitest Swab Specimen Kit • Urine using the APTIMA® Urine Specimen Collection Kit
Specimen Collection:	• Endocervical swab specimens – please refer to instructions in Collection of Endocervical Swab Specimens using the Aptima® Unisex Swab Specimen Collection Kit. • Vaginal swab specimens – please refer to instructions in Collection of Vaginal Swab Specimens using the Aptima® Multitest Swab Collection Kit. • Urine specimens – please refer to instructions in Collection of Urine Specimens using the Aptima® Urine Specimen Collection Kit.
Storage/Transport:	Store specimens at room temperature (15° to 30° C) until transported, DO NOT FREEZE.
Rejection Criteria:	• APTIMA® swab vial specimens submitted without a swab will be rejected. • 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. Click here for Specimen Rejection Criteria.
Turnaround Time:	2-3 Days
Methodology:	Transcription-mediated amplification (TMA)
Limitations:	• 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.

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Molecular Panels

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

SPECIMEN REQUIREMENTS	
Specimen:	Gynecological Pap sample, Urine sample
Specimen Requirements:	Submit only one (1) of the following specimens: • ThinPrep® Pap specimen • Endocervical swab using APTIMA® Unisex Swab Collection Kit • Vaginal swab using APTIMA® Multitest Swab Specimen Kit • Urine using the APTIMA® Urine Specimen Collection Kit
Specimen Collection:	• ThinPrep® specimens – please refer to instructions in Collection of Pap Specimens using ThinPrep®. Collect material for a routine Pap specimen; it is important that cervical mucus be removed. • Endocervical swab specimens – please refer to instructions in Collection of Endocervical Swab Specimens using the Aptima® Unisex Swab Specimen Collection Kit. • Vaginal swab specimens – please refer to instructions in Collection of Vaginal Swab Specimens using the Aptima® Multitest Swab Collection Kit. • Urine specimens – please refer to instructions in Collection of Urine Specimens using the Aptima® Urine Specimen Collection Kit.
Storage/Transport:	Store specimens at room temperature (15° to 30° C) until transported, DO NOT FREEZE.
Rejection Criteria:	• APTIMA® swab vial specimens submitted without a swab will be rejected. • 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. Click here for Specimen Rejection Criteria.
Turnaround Time:	2-3 Days
Methodology:	Transcription-mediated amplification (TMA)
Limitations:	• 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.

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PANEL	
Vaginitis	
Test Description:	Bacterial vaginosis/Candida vaginosis, Trichomonas vaginalis (BV) Refer to technical test information (BV) here & (CV/TV) here.
Order Number:	35124
Performance Lab Name:	South Bend Medical Foundation
CPT Code:	81513, 87481, 87661
Also Known As:	Vaginitis Panel

SPECIMEN REQUIREMENTS	
Specimen:	Gynecological Pap sample
Specimen Requirements:	Submit only one (1) of the following specimens: • Vaginal swab using APTIMA® Multitest Swab Specimen Kit
Specimen Collection:	• Vaginal swab specimens – please refer to instructions in Collection of Vaginal Swab Specimens using the Aptima® Multitest Swab Collection Kit.
Storage/Transport:	Store specimens at room temperature (15° to 30° C) until transported, DO NOT FREEZE.
Rejection Criteria:	• APTIMA® swab vial specimens submitted without a swab will be rejected. Click here for Specimen Rejection Criteria.
Turnaround Time:	2-3 Days
Limitations:	Refer to specific test limitations.

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PANEL	
Vaginitis+	
Test Description:	Bacterial vaginosis, Candida vaginosis/Trichomonas vaginalis, Chlamydia trachomatis/Neisseria gonorrhoeae and testing by molecular methods. Refer to technical test information (BV) here, (CV/TV) here &(CT/NG) here.
Order Number:	35125
Performance Lab Name:	South Bend Medical Foundation
CPT Code:	81513, 87481, 87661, 87491, 87591
Also Known As:	

SPECIMEN REQUIREMENTS	
Specimen:	Gynecological Pap sample
Specimen Requirements:	Submit only one (1) of the following specimens: • Vaginal swab using APTIMA® Multitest Swab Specimen Kit
Specimen Collection:	• Vaginal swab specimens – please refer to instructions in Collection of Vaginal Swab Specimens using the Aptima® Multitest Swab Collection Kit.
Storage/Transport:	Store specimens at room temperature (15° to 30° C) until transported, DO NOT FREEZE.
Rejection Criteria:	• APTIMA® swab vial specimens submitted without a swab will be rejected. Click here for Specimen Rejection Criteria.
Turnaround Time:	2-3 Days
Limitations:	Refer to specific test limitations.

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PANEL	
Vaginitis+ with M. gen	
Test Description:	STI Screening Panel- Bacterial vaginosis, Candida vaginosis/Trichomonas vaginitis, Chlamydia trachomatis/Neisseria Gonorrhoeae with mycoplasma genitalium. Refer to technical test information (BV) here, (CV/TV) here, (CT/NG) here & (M. gen) here.
Order Number:	35126
Performance Lab Name:	South Bend Medical Foundation
CPT Code:	81513, 87591, 87481, 87661, 87563
Also Known As:	Sexually Transmitted Infections Panel

SPECIMEN REQUIREMENTS	
Specimen:	Gynecological Pap sample
Specimen Requirements:	Submit one (1) of the following specimens: • Vaginal swab using APTIMA® Multitest Swab Specimen Kit
Specimen Collection:	• Vaginal swab specimens – please refer to instructions in Collection of Vaginal Swab Specimens using the Aptima® Multitest Swab Collection Kit.
Storage/Transport:	Store specimens at room temperature (15° to 30° C) until transported, DO NOT FREEZE.
Rejection Criteria:	• APTIMA® swab vial specimens submitted without a swab will be rejected. Click here for Specimen Rejection Criteria.
Turnaround Time:	2-3 Days
Methodology:	Transcription-mediated amplification (TMA)
Limitations:	• 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.

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PANEL	
Cervicitis/Urethritis	
Test Description:	Extended STI Screening Panel- Chlamydia trachomatis/Neisseria Gonorrhoeae, Trichomonas vaginalis, mycoplasma genitalium. Refer to technical test information (CT/NG) here, (TV) here, & (M. gen) here.
Order Number:	35123
Performance Lab Name:	South Bend Medical Foundation
CPT Code:	87491, 87591, 87661, 87563
Also Known As:	Extended Sexually Transmitted Infections Panel

SPECIMEN REQUIREMENTS	
Specimen:	Gynecological Pap sample, Urine sample
Specimen Requirements:	Submit only one (1) of the following specimens: • Endocervical swab using APTIMA® Unisex Swab Collection Kit • Vaginal swab using APTIMA® Multitest Swab Specimen Kit • Urine using the APTIMA® Urine Specimen Collection Kit
Specimen Collection:	• Endocervical swab specimens – please refer to instructions in Collection of Endocervical Swab Specimens using the Aptima® Unisex Swab Specimen Collection Kit. • Vaginal swab specimens – please refer to instructions in Collection of Vaginal Swab Specimens using the Aptima® Multitest Swab Collection Kit. • Urine specimens – please refer to instructions in Collection of Urine Specimens using the Aptima® Urine Specimen Collection Kit.
Storage/Transport:	Store specimens at room temperature (15° to 30° C) until transported, DO NOT FREEZE.
Rejection Criteria:	• APTIMA® swab vial specimens submitted without a swab will be rejected. • 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. Click here for Specimen Rejection Criteria.
Turnaround Time:	2-3 Days
Limitations:	• Test results may be affected by improper/ inadequate specimen collection.