HEALGEN®







US Product Catalog

2025

About Us

Better health for all is the driving force behind Healgen®.

For over 18 years, our dedicated team of researchers, product innovators, and scientific leaders worked side-by-side with our partners, healthcare providers and organizations, to address the most urgent health needs. This collaborative spirit is the bedrock of our committment to breaking down barriers and creating opportunities for better health across communities, large and small.

Today we are proud of our global presence - an extensive network of more than 150 partners and service centers across four continents - and a proven track record of positively impacting over 2 billion lives across more than 140 nations.

As you explore our latest US product catalog, we invite you to discover new opportunities to serve your patients and communities - together with Healgen®.

The catalog features a comprehensive range of trusted medical devices and essential healthcare products. Each product is engineered for reliability, ease of use, and broad accessibility, ensuring seamless integration into various healthcare settings and ultimately contributing to better patient outcomes.

As we look to the future, our purpose remains unwavering: to be the bedrock of better health, today and for generations to come.

Healgen® - The Genesis of Better Health

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Infectious Disease
RESPIRATORY





Healgen® Rapid Check® COVID-19/Flu A&B Antigen Test [OTC]



Healgen® Rapid Check® COVID-19/Flu A&B Antigen Test Pro [POC]



Healgen® Rapid COVID-19 Antigen Test [POC]



Rapid Check® RSV Antigen Test Cassette [POC]

Rapid Strep A Antigen Test [POC]

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Healgen® Rapid Check® Covid-19/Flu A&B Antigen Test

For At-Home Use

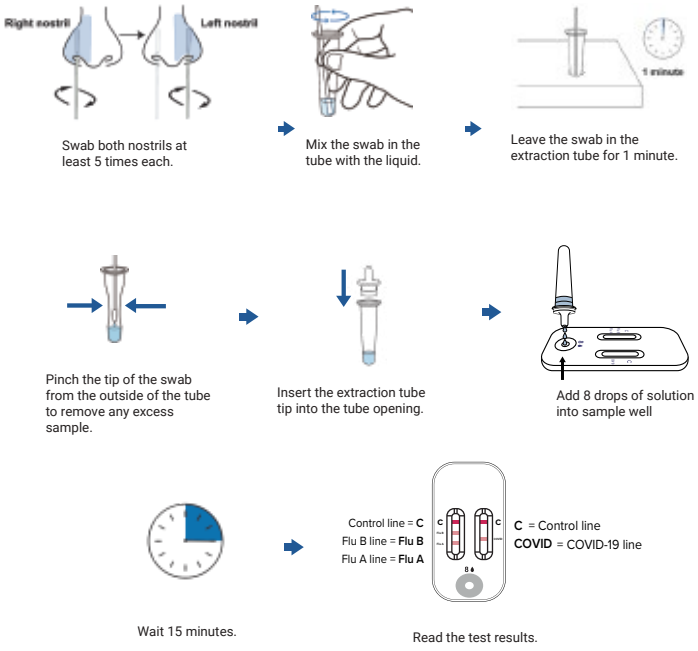
For the qualitative detection and differentiation of influenza A, and influenza B nucleoprotein antigens and SARS-CoV-2 nucleocapsid antigen directly in anterior nasal swab samples from individuals with signs and symptoms of respiratory tract infection. Symptoms of respiratory infections due to SARS-CoV-2 and influenza can be similar. This test is for non-prescription home use by individuals aged 14 years or older testing themselves, or adults testing individuals aged 2 years or older.

KEY FEATURES & BENEFITS

- 15 Minute Rapid Detection
- 24 Months Shelf Life
- Simple and Effective Testing
- External Quality Controls Available
- Excellent Test Performance (Comparator method RT-PCR)

Test	Positive Percent Agreement (PPA)	Negative Percent Agreement (NPA)
SARS-CoV-2	92.0%	99.0%
Flu A	92.5%	99.9%
Flu B	90.5%	99.9%

TEST PROCEDURE



Please note: These visuals are not a substitute for the official testing instructions. Always consult the Instructions for Use for complete and accurate procedures.

Product	REF/ Catalog #	Quantity
Healgen® Rapid Check® COVID-19/Flu A&B Antigen Test	GCFC-525SKa-HX x= kit size	1/2/4/5/6/10 tests/kit

Healgen® Rapid Check® Covid-19/Flu A&B Antigen Test Pro

For Professional Use



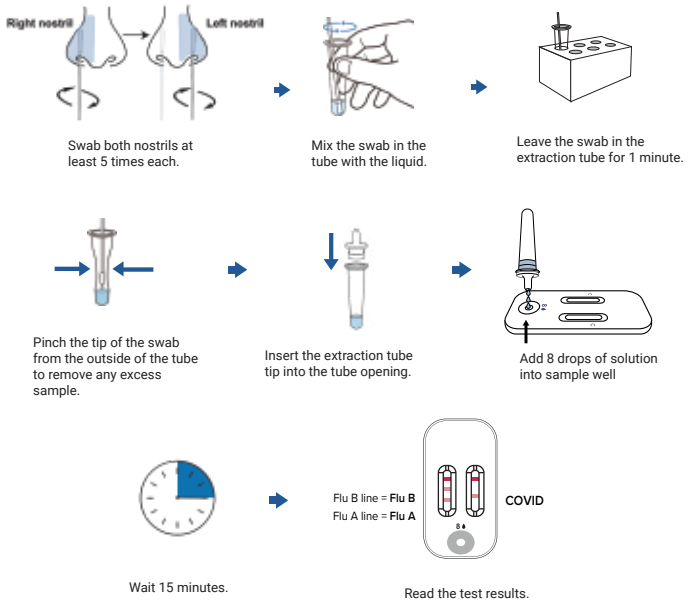
For the qualitative detection and differentiation of influenza A, and influenza B nucleoprotein antigens and SARS-CoV-2 nucleocapsid antigen directly from anterior nasal swab specimens of individuals with signs and symptoms of respiratory tract infection consistent with COVID-19 within the first five (5) days of symptom onset when tested at least twice over three days with at least 48 hours between tests. Clinical signs and symptoms of respiratory viral infection due to SARS-CoV-2 and Influenza can be similar.

KEY FEATURES & BENEFITS

- **15 Minute Rapid Detection**
- **24 Months Shelf Life**
- **Simple and Effective Testing**
- **External Quality Controls Available**
- **Excellent Test Performance** (Comparator method RT-PCR)

Test	Positive Percent Agreement (PPA)	Negative Percent Agreement (NPA)
SARS-CoV-2	92.0%	99.0%
Flu A	92.5%	99.9%
Flu B	90.5%	99.9%

TEST PROCEDURE



Please note: These visuals are not a substitute for the official testing instructions. Always consult the Instructions for Use for complete and accurate procedures.

Product	REF/ Catalog #	Quantity
Healgen® Rapid Check® COVID-19/Flu A&B Antigen Test Pro	GCFC-525SKa-10T	10 tests/kit
	GCFC-525SKa-25T	25 tests/kit
External Controls: Healgen® Rapid Check® COVID-19/Flu A&B Ag Antigen Test Pro	GCFC-PN2	1 set (1 negative and 1 positive control swab)
	GCFC-PN20	10 sets (10 negative and 10 positive control swabs)
	GCFC-PN40	20 sets (20 negative and 20 positive control swabs)



Healgen® Rapid COVID-19 Antigen Test

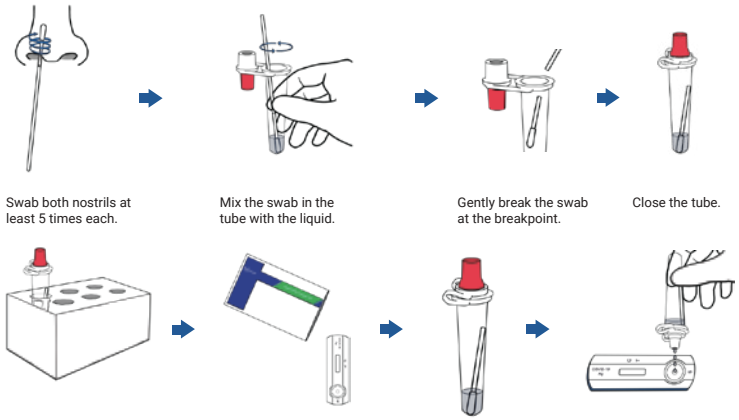
For Prescription Use | CLIA-Waived

For the rapid, qualitative detection of nucleocapsid protein antigen, IgG/IgM antibodies, neutralizing antibody from SARS-CoV-2 in human Whole blood, serum, plasma, nasopharyngeal swab, nasal swab and oral fluid specimens with signs and simptoms of respiratory tract infection consistent with COVID-19 within the first six (6) days of symptom onset. There are no age restrictions for testing.

KEY FEATURES & BENEFITS

- 15 Minute Rapid Detection
- 24 Months Shelf Life
- Simple and Effective Testing
- External Quality Controls Available

TEST PROCEDURE



Please note: These visuals are not a substitute for the official testing instructions. Always consult the Instructions for Use for complete and accurate procedures.

LoD ($TCID_{50}$/mL)	Positive Percent Agreement (PPA)	Negative Percent Agreement (NPA)
5.75 x 10^3	85.4%	99.7%

Product	REF/ Catalog #	Quantity
Healgen® Rapid COVID-19 Antigen Test	GCCOV-502a-NA	20 tests/kit
External Controls: Healgen® Rapid COVID-19 Antigen Test	GCCOV(Ag)-PN10	5 each negative and positive control swabs
	GCCOV(Ag)-PN20	10 each negative and positive control swabs

Healgen® Rapid Check®
RSV Antigen Test Cassette

For Prescription Use | CLIA-Waived



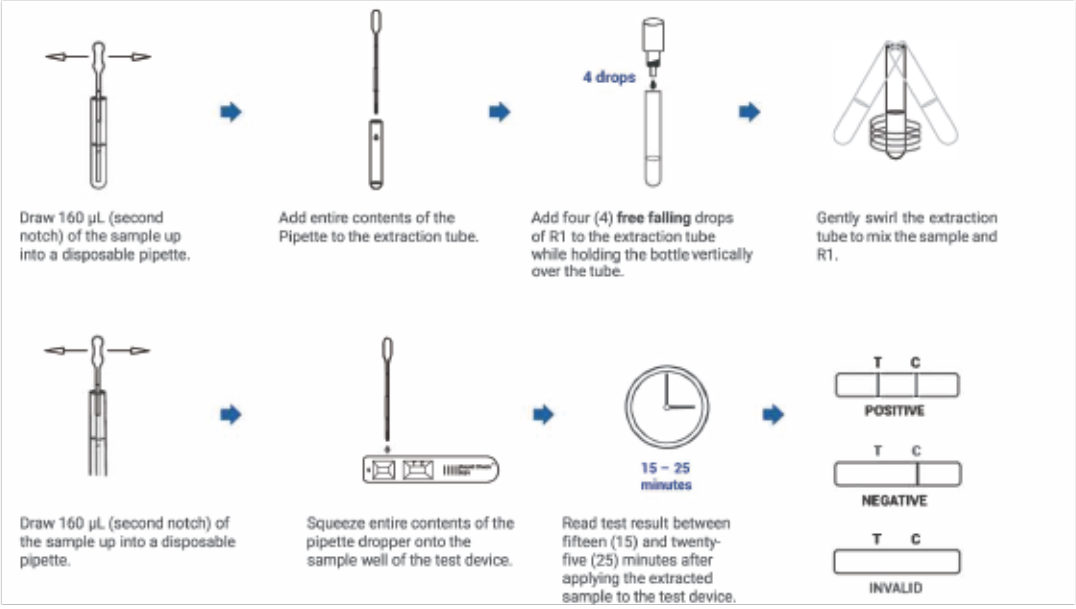
For the rapid qualitative detection of Respiratory Syncytial Virus (RSV) antigen (viral fusion protein) in human nasal/nasopharyngeal swab, nasal/nasopharyngeal aspirate specimens in children less than 6 years and adults over the age of 60.

Positive Percent Agreement (PPA)	Negative Percent Agreement (NPA)
93.9%	97.7%

KEY FEATURES & BENEFITS

- **15 Minute Rapid Detection**
- **24 Months Shelf Life**
- **Clinical Data Age of Patients ranged from 2 days to 100 years old**
- **Quality Controls Included**
- **Excellent Test Performance** (Compared to Tissue Culture, EIA and Direct Fluorescent Antibody)

TEST PROCEDURE



Please note: These visuals are not a substitute for the official testing instructions. Always consult the Instructions for Use for complete and accurate procedures.

Product	REF/ Catalog #	Quantity
Healgen® Rapid Check® RSV Antigen Test Cassette	GCRSV-502b-PBS	20 tests/kit



Healgen® Rapid Strep A Antigen Test

For Prescription Use | CLIA-Waived

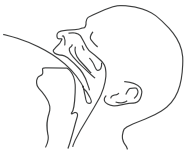
For the rapid qualitative detection of Streptococcus pyogenes (Group A β-hemolytic Streptococcus, Strep A) antigen from throat swab specimens of symptomatic patients to aid in the diagnosis of Group A Streptococcus bacterial infection.

KEY FEATURES & BENEFITS

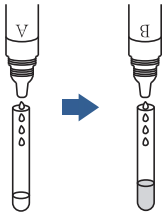
- **5 Minute Rapid Detection**
- **24 Months Shelf Life**
- **Quality Controls Included**
- **Excellent Test Performance** (Compared to Culture)

Positive Percent Agreement (PPA)	Negative Percent Agreement (NPA)
96.5%	99.5%

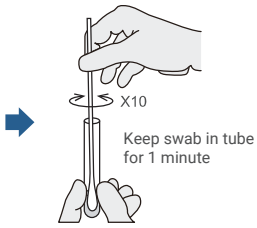
TEST PROCEDURE



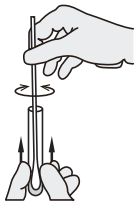
Collect throat swab sample with sterile swab.



Add 4 drops of Reagent A and Reagent B to extraction tube. Swirl the tube to mix solution.



Place swab into the tube and agitate for 10 times, then wait 1 minute



Press swab against the tube side, withdraw the swab to squeeze out liquid inside the swab. Discard the swab.



Remove test strip from pouch. Insert test strip into the extraction tube and start the timer.



5 minutes

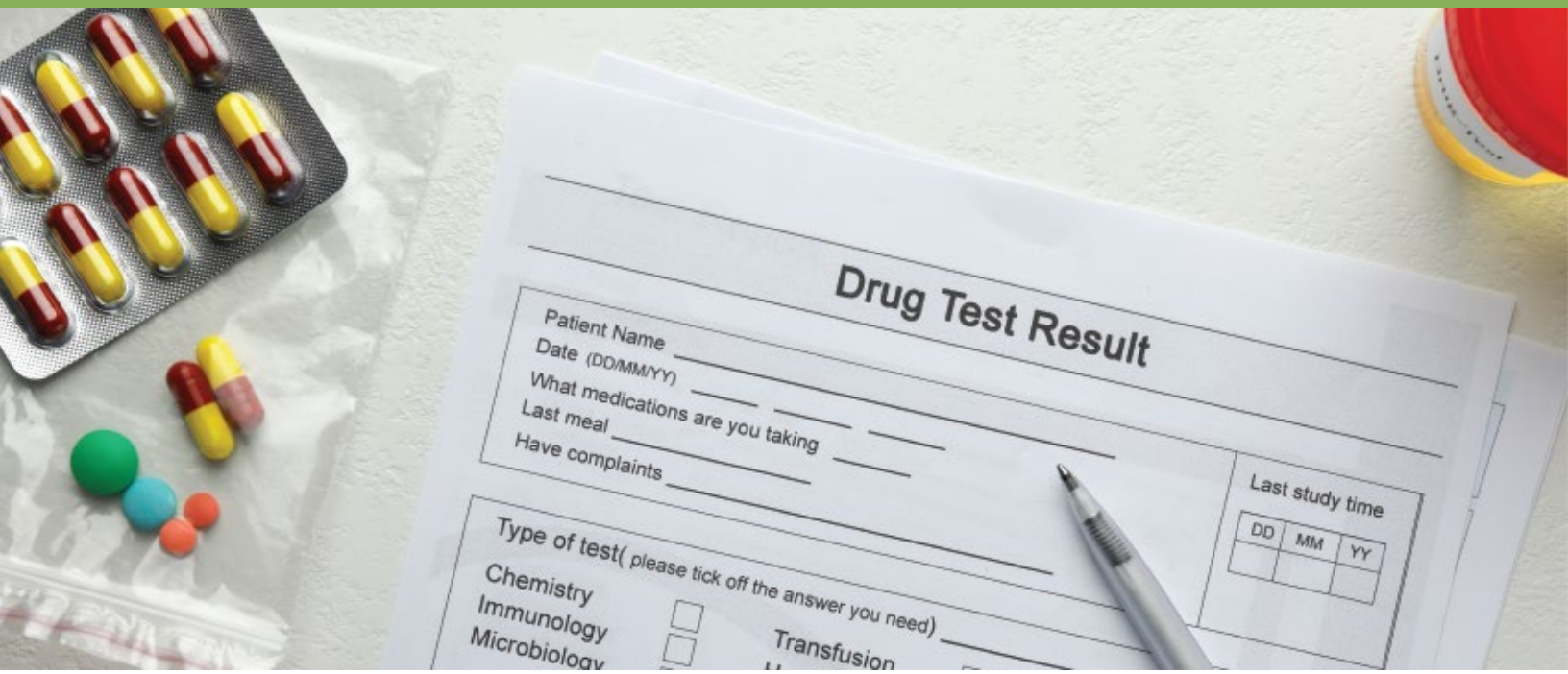
Wait for the colored line(s) to appear. Read the result at 5 minutes. Do not read the result after 10 minutes.

Please note: These visuals are not a substitute for the official testing instructions. Always consult the Instructions for Use for complete and accurate procedures.

Product	REF/ Catalog #	Quantity
Healgen® Rapid Strep A Antigen Test	GCSTR-501Ca	25 tests/kit

Toxicology

USE IN MULTIPLE TESTING SCENARIOS



AVAILABLE FORMATS

Urine Drug Tests						
	Dip Card	**Cassette**	**Strip**	**Cups**		
Oral Fluid Drug Tests						
	Oral Fluid Device L			**Oral Fluid Device E**		
Harm Reduction						
	Strip			**Cassette**		

For information regarding available configuration details please contact your sales representative.

Urine Drug Tests

		Intended Use			
Drug Item	Cutoff (ng/mL)	Forensic (FUO)	Employment & Insurance (EUO)	Over-the-Counter (OTC)	Prescription (Rx)
6-MAM	10	X	X	X	
ALC	>0.04% BAC	X			
AMP	250/300	X	X		
AMP	500/1000	X	X	X	X
BAR	200	X	X		
BAR	300	X	X	X	X
BUP	5/10	X	X	X	
BZO	150/200	X	X		
BZO	300	X	X	X	X
COC	100/150/300	X	X	X	X
COT	200	X			
EDDP	100	X	X		
EDDP	300	X	X	X	X
ETG	300/500	X			
FEN	1/5	X	X	X	
FEN	10/20/50/100/200/300	X	X		
GABA	1000/2000	X			
HCD	10	X	X		
HMO	300	X	X		
K2	25/50	X			
K3	10	X			
KET	100/1000	X			
KRA	250/300	X			
LSD	10/20	X	X		
MDMA	150/250/300	X	X		
MDMA	500	X	X	X	X
MDPV	1000	X			
MET	250/300	X	X		
MET	500/1000	X	X	X	X
MOP	150	X	X		
MOP	300	X	X	X	X
MQL	300	X	X		
MTD	50	X	X	X	
MTD	200	X	X		
MTD	300	X	X	X	X
OPI	2000	X	X	X	X
OXY	100	X	X	X	X
PCP	25	X	X	X	X
PPX	300	X	X	X	X
TCA	1000	X	X	X	X
THC	15/18/20/25/40	X	X		
THC	50	X	X	X	X
TRA	100	X		X	
TRA	200	X			

Oral Fluid Drug Tests

		Intended Use			
Drug Item	**Cutoff (ng/mL)**	**Forensic (FUO)**	**Employment & Insurance (EUO)**	**Over-the-Counter (OTC)**	**Prescription (Rx)**
6-MAM	5/10/15	X	X		
ALC	>0.2%BAC	X			
AMP	50	X	X		
BAR	50/300	X	X		
BUP	5/10	X	X		
BZO	10/50	X	X		
COC	20/50	X	X		
COT	30	X		X	X
COT	50	X			
EDDP	20	X	X		
FEN	10	X	X		
K2	5/25	X			
KET	50/100	X			
LSD	10/25	X	X		
MDMA	50	X	X		
MDPV	10/100	X			
MET	50	X	X		
MOP	15	X	X		
MQL	100/150	X	X		
MTD	30/75	X	X		
OPI	40	X	X		
OXY	20/50	X	X		
PCP	10	X	X		
PPX	50	X	X		
TCA	100	X	X		
THC	12/25	X	X		
THC	40	X	X		X
TRA	50	X			



Harm Reduction: Fentanyl/Xylazine Residue Test

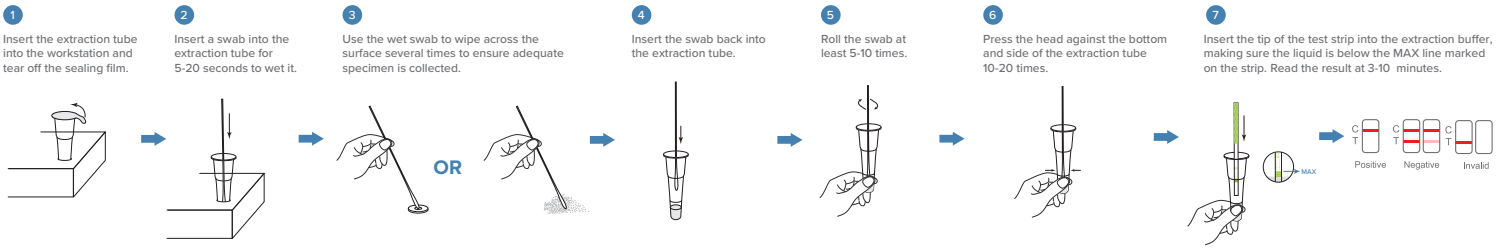


For the rapid, qualitative detection of Fentanyl and Xylazine or the single detection or Fentanyl or Xylazine residue on surfaces, including the outer surface of pills.

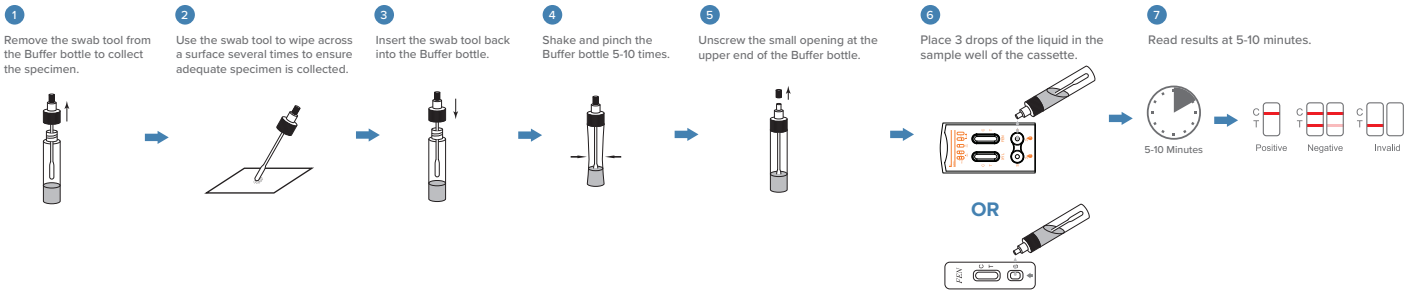
KEY FEATURES & BENEFITS

- Simple Collection and Testing Procedure
- Easy Visual Interpretation
- Strip Test Time to Results: 3-10 minutes
- Cassette Test Time to Results: 5-10 minutes
- 24 Months Shelf Life

STRIP TEST PROCEDURE



CASSETTE TEST PROCEDURE



Please note: These visuals are not a substitute for the official testing instructions. Always consult the Instructions for Use for complete and accurate procedures.

Product	REF/Catalog #	Format	Cutoff (ng/mL)	Kit Size
Fentanyl Residue Test Kit	GBFEN-1001a	Strip	5	20 Tests/Kit
Fentanyl Residue Test Kit	GBFEN-1002a	Cassette		
Xylazine Residue Test Kit	GBXYL-1001a	Strip	50	
Xylazine Residue Test Kit	GBXYL-1002a	Cassette		
Fentanyl/Xylazine Residue Test Kit	GBDOA-1025-001	Cassette	5/50	

Fertility & Women's Health





hCG Pregnancy Tests



LH Ovulation Rapid Tests



FSH Menopause Tests



UTI Test Strip



Vaginal pH Rapid Test



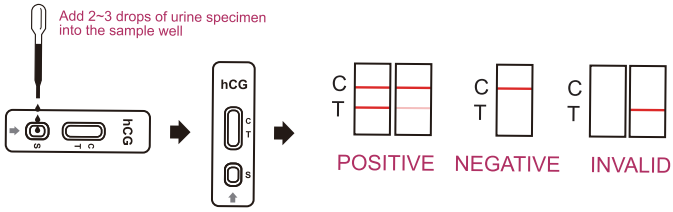
hCG Pregnancy Test

For the qualitative detection of human chorionic gonadotropin (hCG) in urine to aid in the early detection of pregnancy

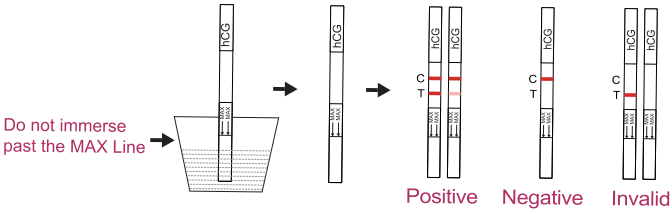
KEY FEATURES & BENEFITS

- Rapid Visual Results Within 3 Minutes
- Accuracy Greater Than 99%*
- Detects Pregnancy 6 Days Sooner Than the Date of the Expected Period*
- 24 Months Shelf Life

CASSETTE TEST PROCEDURE



STRIP TEST PROCEDURE





Please note: These visuals are not a substitute for the official testing instructions. Always consult the Instructions for Use for complete and accurate procedures.

REF/ Catalog #	Quantity	Cutoff	Format	Rx/OTC
GAHCG-101a-50, 100	50/100 tests/kit	25 mIU/mL	Strip	Rx
GAHCG-101a-H5, 10	5/10 tests/kit			OTC
GAHCG-102a	25 tests/kit		Cassette	Rx
GAHCG-102a-H1,2	1/2 tests/kit			OTC
GAHCG-103a-H1,2	1/2 tests/kit			OTC
GAHCG-103m-H1,2*	1/2 tests/kit	10 mIU/mL	Midstream	OTC

Rx = For Prescription Use Only OTC = For Over-the-Counter Use

LH Ovulation Rapid Test

For the qualitative detection of luteinizing hormone (LH) in urine to aid in the detection of ovulation



KEY FEATURES & BENEFITS

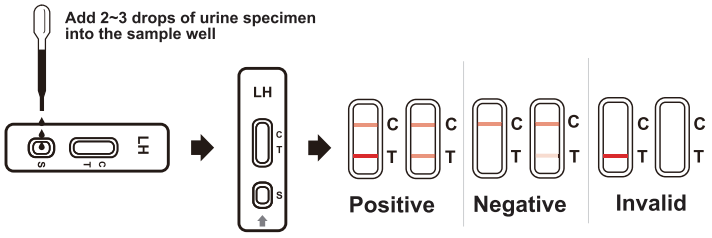
- Rapid Visual Results in 10 Minutes
- Accuracy Greater Than 99%*
- Positive Result Indicates Ovulation Should Begin Within the Next 24-36 Hours
- 24 Months Shelf Life



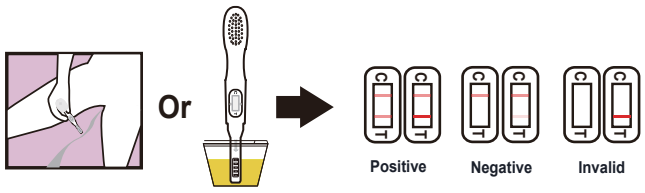
REF/ Catalog #	Quantity	Cutoff	Format
GALH-101a	100 Tests/Kit	25 mIU/mL	Strip
GALH-101d		30 mIU/mL	
GALH-101b		40 mIU/mL	
GALH-102a	25 Tests/Kit	25 mIU/mL	Cassette
GALH-102d		30 mIU/mL	
GALH-102b		40 mIU/mL	
GALH-103a	1/5 Test(s)/Kit	25 mIU/mL	Midstream
GALH-103d		30 mIU/mL	
GALH-103b		40 mIU/mL	

* The claim is not reviewed by the FDA

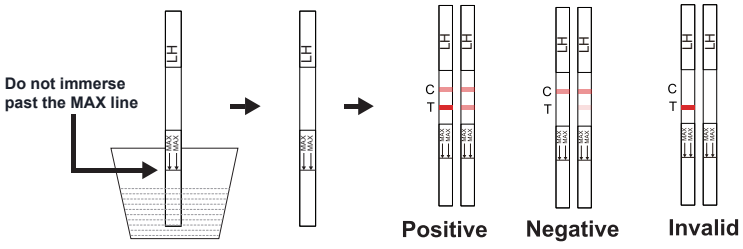
CASSETTE TEST PROCEDURE



MIDSTREAM TEST PROCEDURE



STRIP TEST PROCEDURE



Please note: These visuals are not a substitute for the official testing instructions. Always consult the Instructions for Use for complete and accurate procedures.



FSH Menopause Test

For the qualitative detection of Follicle Stimulating Hormone (FSH) level in urine to evaluate the onset of menopause in women

KEY FEATURES & BENEFITS

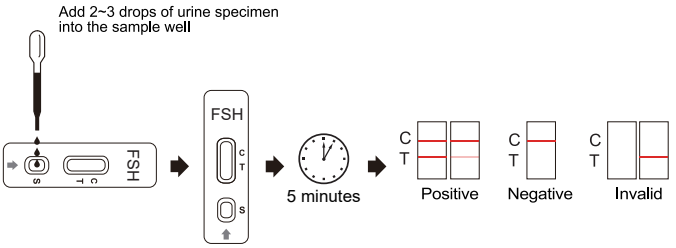
- Rapid Visual Results Within 5 Minutes
- Accuracy Greater Than 99%*
- Serial Testing: 2 Tests 1 Week Apart
- 24 Months Shelf Life



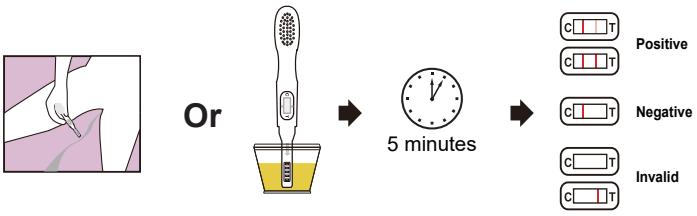
REF/ Catalog #	Quantity	Cutoff	Format
GAFSH-101a	100 Tests/Kit	25 mIU/mL	Strip
GAFSH-102a	25 Tests/Kit		Cassette
GAFSH-103a	1 Test/Kit		Midstream

* The claim is not reviewed by the FDA

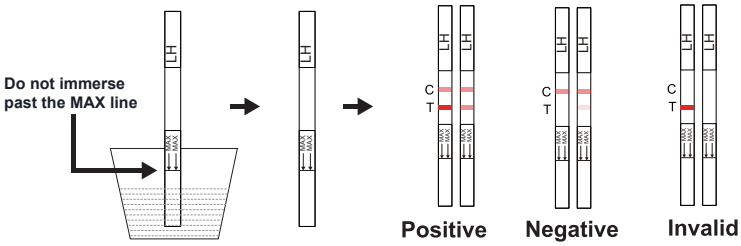
CASSETTE TEST PROCEDURE



MIDSTREAM TEST PROCEDURE



STRIP TEST PROCEDURE



Please note: These visuals are not a substitute for the official testing instructions. Always consult the Instructions for Use for complete and accurate procedures.

UTI Test Strip

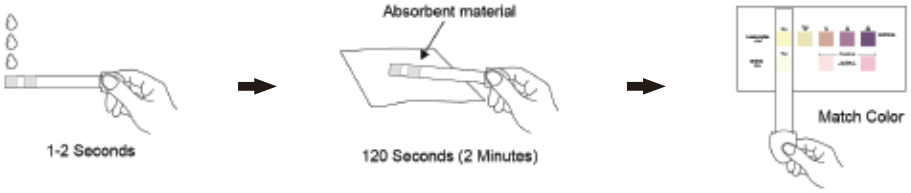
For the qualitative detection of leukocytes (white blood cells) and nitrite in urine as an aid in the screening of a Urinary Tract Infection (UTI)



KEY FEATURES & BENEFITS

- Rapid Visual Results In 2 Minutes
- Accuracy Greater Than 99%
- 24 Months Shelf Life

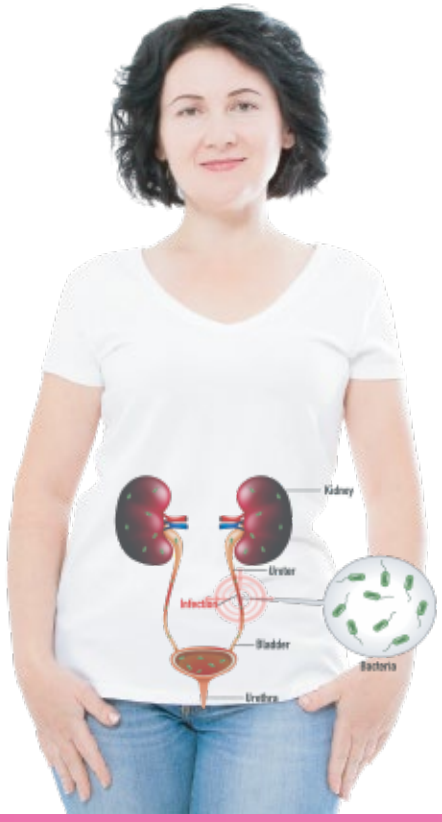
STRIP TEST PROCEDURE



Please note: These visuals are not a substitute for the official testing instructions. Always consult the Instructions for Use for complete and accurate procedures.

Sensitivity & Detection Time		
Parameter	**Sensitivity**	**Read Time**
Nitrite (mg/dL)	0.05	2 minutes
Leukocytes (cells/µL)	15	2 minutes

REF/Catalog #	Quantity
UTI-2T-H1	1 Test
UTI-2T-H3	3 Tests
UTI-2T-H6	6 Tests



Vaginal pH Rapid Test



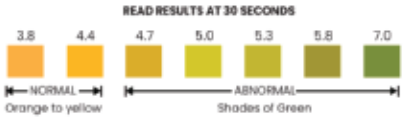
For the qualitative detection of pH in female vaginal swab specimens to aid in the diagnosis of bacterial vaginosis.

KEY FEATURES & BENEFITS

- Rapid Visual Results In Under 2 Minutes
- Accuracy Greater Than 99%
- pH Range 3.8 - 7.0
- 24 Months Shelf Life

STRIP TEST PROCEDURE





CASSETTE TEST PROCEDURE



Please note: These visuals are not a substitute for the official testing instructions. Always consult the Instructions for Use for complete and accurate procedures.

REF/Catalog #	Quantity	Format	Rx/OTC
VPH-501a	25 Tests/Kit	Strip	Rx
VPH-501a-H2,5	2/5 Tests/Kit		OTC
VPH-502a	25 Cassettes/Kit	Cassette	Rx
VPH-502a-H1,2	1/2 Cassettes/Kit		OTC

Rx = For Prescription Use Only OTC = For Over-the-Counter Use



Oncology





Fecal Ocult Blood Rapid Test Cassette



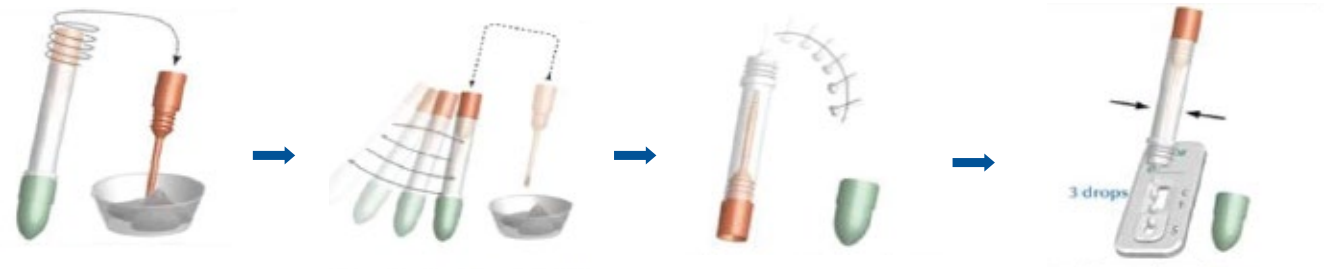
Fecal Ocult Blood Rapid Test Cassette

For the qualitative detection of low levels of fecal occult blood in feces

KEY FEATURES & BENEFITS

- Rapid Visual Results In 5 Minutes
- Can Detect As Low As 50 ng/mL of Hemoglobin or 5 µg Hemoglobin/g in feces
- No Diet Restriction Required Before Testing
- 24 Months Shelf Life

CASSETTE TEST PROCEDURE



Insert the stick into the stool specimen at 6 different sites before inserting the applicator back into the tube.

Shake the tube for 5 seconds.

Holding the tube upright, carefully break of the tip of collection device.

Squeeeze three drops of the stool sample solution into the sample well of the cassette. Read the test results within 5-10 minutes.

Please note: These visuals are not a substitute for the official testing instructions. Always consult the Instructions for Use for complete and accurate procedures.

Product	REF/Catalog#	Format	Specimen	Quantity
FOB Rapid Test: 50 ng/mL	GEFOD-601b	Strip	Feces	25 tests/kit
FOB Rapid Test: 50 ng/mL	GEFOB-602b	Cassette	Feces	20 tests/kit

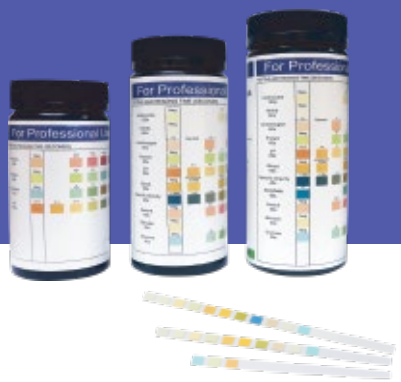
Biochemistry
URINALYSIS





Healgen® Urine Reagent Strips (URS)

Healgen® Urine Reagent Strips (URS)



The Healgen® Series Urine Reagent Strips (URS) and Urine Analyzers are in vitro test systems intended for qualitative and semi-quantitative analysis of the parameter listed in the following table.

The Healgen® Series Urine Reagent Strips (URS) and Urine Analyzers are intended for use to detect conditions indicating possible diabetes, metabolic abnormalities, liver diseases, kidney function, and urinary tract infections.

Test results can be used along with other diagnostic information to rule out certain disease states and to determine if microscopic analysis is needed.

REF/Catalog #	URS-4T	URS-10T	URS-11T
Parameters	**4 Parameters**	**10 Parameters**	**11 Parameters**
Protein	X	X	X
Ketone	X	X	X
Glucose	X	X	X
pH	X	X	X
Blood		X	X
Leukocytes		X	X
Nitrite		X	X
Bilirubin		X	X
Urobilinogen		X	X
Specific Gravity		X	X
Ascorbic Acid			X

The Healgen® 10 and 11 strips can be read visually and instrumentally with the Healgen 500 and 800 Analyzers. The Healgen® 4 reagent strip can be read visually only.

The shelf life of unopened urine reagent strip canisters is 24 months. Once opened, the remaining strips have a shelf life of 3 months. This 3-month period applies if the canister is properly sealed and stored under optimal conditions.



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