

Fisher Healthcare Sure-Vue Kits



Contents

Women's Health | Bacterial | Fecal Occult Blood | Serology | Virology | Parasitology

Women's Health

Human Chorionic Gonadotropin (hCG) Fisher Healthcare™ Sure-Vue™ STAT Serum/Urine hCG Test Kit



Visual, one-step test for the qualitative determination of human chorionic gonadotropin (hCG) in serum or urine; detects pregnancy as early as first day of missed menses.

- For professional in vitro diagnostic use only
- Urine results in three minutes; serum results in five minutes
- 10/20 mIU/mL for serum and urine respectively

Quantity	CLIA Complexity	Cat. No.	510K Number
30 Tests	Waived for Urine,	23-900-530	K062361
50 Tests	Moderate for Serum	23-900-531	K062361

Human Chorionic Gonadotropin (hCG) Fisher Healthcare™ Sure-Vue™ Serum/ Urine hCG Test Kit



One-step test for the qualitative detection of hCG in serum or urine to aid in early detection of pregnancy.

- For professional in vitro diagnostic use only
- Urine results in three minutes; serum results in five minutes
- 25 mIU/mL for serum and urine

Quantity	CLIA Complexity	Cat. No.	510K Number
30 Tests	Waived for Urine,	23-900-528	K993065
50 Tests	Moderate for Serum	23-900-529	K993065

Human Chorionic Gonadotropin (hCG) Fisher Healthcare™ Sure-Vue™ Urine hCG Test Kit



Visual, one-step test for the qualitative determination of human chorionic gonadotropin (hCG) in urine to aid in early detection of pregnancy.

- For professional in vitro diagnostic use only
- Results in three minutes

Description	CLIA Complexity	Quantity	Cat. No.	510K Number
Urine hCG Dipstick Test	Waived	25 Tests	23-900-527	K993203
Urine hCG Test Kit	Waived	30 Tests	23-900-526	K993317



Rapid Plasma Reagin (RPR)
**Fisher Healthcare™ Sure-Vue™
 Signature RPR Test Kit**

Detects the presence of antibodies in serum; used to screen for syphilis.

- For in vitro diagnostic use

Description	CLIA Complexity	Quantity	Cat. No.	510K Number
RPR Test Kit	Moderate	100 Tests	23-038-009	K851504
		500 Tests	23-038-010	K851504
RPR Test Kit, 30 Well	Moderate	5,000 Tests	23-038-020	K851504
RPR Test Kit, 10 Well	Moderate	5,000 Tests	23-038-021	K851504
RPR Antigen Suspension		1 x 9 mL	23-038-011	K851504
RPR Controls		3 x 1.5 mL	23-038-012	K851504
RPR Titer Control		1 x 1.5 mL	23-029-966	K851504
Dispensing Pipets		500/Pack	23-038-015	
Disposable RPR Slides		25/Pack	23-038-014	K851504
		50/Pack	23-038-013	K851504

Bacterial



Group A *Streptococcus*
**Fisher Healthcare™ Sure-Vue™
 Signature Strep A Test Kit**

Rapid, lateral flow test with 100% specificity.

- Sample type: throat swab
- Test time: five minutes

Description	CLIA Complexity	Quantity	Cat. No.	510K Number
Signature Strep A Test Kit	Waived	50 Tests	23-200-276	K992658



Group A Streptococcus

Fisher Healthcare™ Sure-Vue™ Lateral Flow Strep A Test Kit

One-step lateral-flow immunoassay for the qualitative detection of Group A Strep from throat swabs; used as an aid in the diagnosis of Group A Streptococcal infections.

- For in vitro diagnostic use only
- Results in five minutes

Description	CLIA Complexity	Quantity	Cat. No.	510K Number
Lateral Flow Strep A Test Kit	Waived and Moderate	27 Tests	23-900-532	K010582



Staphylococcus aureus

Fisher Healthcare™ Sure-Vue™ Staph ID Test Kit

Latex agglutination slide test for the qualitative detection of *Staphylococcus aureus* from primary cultures. Latex reagent responds to clumping factor and/or protein A to produce visible red agglutination.

- For in vitro diagnostic use

Description	CLIA Complexity	Quantity	Cat. No.
Staph ID Test Kit	Moderate	150 Tests	23-038-056
		300 Tests	23-046-870



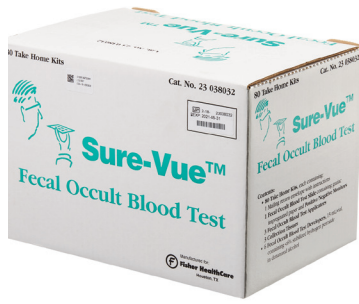
Staphylococcus aureus

Fisher Healthcare™ Sure-Vue™ Color Latex Staph ID Test Kit

Latex agglutination slide test for the qualitative detection of *Staphylococcus aureus* from primary cultures; produces visible red agglutination when results are positive.

- For in vitro diagnostic use
- Results within 30 seconds

Description	CLIA Complexity	Quantity	Cat. No.
Color Latex Staph ID Test Kit	Moderate	150 Tests	23-046-500
		300 Tests	23-046-501



Fecal Occult Blood Test (FOBT)

Fisher Healthcare™ Sure-Vue™
Fecal Occult Blood Test System

For the detection of fecal occult blood. Traditional guaiac format for routine screening; extra-sensitive format for more stringent testing.

- For screening purposes only

Description	Includes	Quantity	Cat. No.	510K Number
Traditional Guaiac Test (CLIA-Waived)				
FOBT Single Slide Tests	<ul style="list-style-type: none"> • 100 Test Slides with On-Slide Monitors • 100 Applicator Sticks • 2 x 15 mL Bottles of Developer 	100/Pack	23-038031	K911075
	<ul style="list-style-type: none"> • 1,000 Test Slides with On-Slide Monitors • 1,000 Applicator Sticks • 20 x 15 mL Bottles of Developer 	1,000/Pack	23-038040	K911075
FOBT Take-Home Kits	<p>Each Kit Contains:</p> <ul style="list-style-type: none"> • Test Instructions • Triple Test Slide with Monitors • Collection Tissues and Applicator Stick • Mailing Envelope • 6 x 15 mL Bottles of Developer 	80/Pack	23-038032	K911075
FOBT Developer	15 mL Bottles	20/Pack	23-038033	
Extra-Sensitive Test (CLIA-Waived)				
Extra-Sensitive FOBT Single Slide Tests	<ul style="list-style-type: none"> • 100 Extra-Sensitive Test Slides • 100 Applicator Sticks • 2 x 15 mL Bottles of Extra-Sensitive Developer 	100/Pack	23-038035	
Extra-Sensitive FOBT Take-Home Kits	<p>Each Kit Contains:</p> <ul style="list-style-type: none"> • Test Instructions • Triple Test Slide with Monitors • Collection Tissues and Applicator Stick • Mailing Envelope • 6 x 15 mL Bottles of Extra-Sensitive Developer 	80/Pack	23-038036	
Extra-Sensitive FOBT Developer	15 mL Bottles	20/Pack	23-038037	



Immunochemical Fecal Occult Blood (iFOB)

Fisher Healthcare™ Sure-Vue™ Signature Immunochemical Fecal Occult Blood Test

Immunochemical device for the rapid qualitative determination of fecal occult blood. Used to help detect gastrointestinal (GI) bleeding from disorders including diverticulitis, colitis, polyps, and colorectal cancer.

- Accurate, sensitive, and specific to the lower GI tract
- Results available in under 10 minutes

Description	CLIA Complexity	Quantity	Cat. No.	510K Number
iFOB Test Kits: Include Sample Collection Tubes and Test Cassettes	Waived	30 Tests	23048001	K041202
		50 Tests	23048002	K041202
iFOB Take-Home Kit Includes: <ul style="list-style-type: none"> • Patient Instructions • Collection Papers (2) • Specimen Pouch with Absorbent Pad • Mailing Envelope 	Waived	1 Kit	23048005	K041202
iFOBT Test Kit: Includes 50 Sample Collection Tubes, 50 Mailing Envelopes, 30 Test Cassettes, Package Insert	Waived	30 Tests	23048000	K041202
iFOB Test Cassettes Only		50/Pack	23048003	K041202
iFOB Sample Collection Tubes Only		50/Pack	23048004	K041202
iFOB Control Set: Includes Positive and Negative Controls		1 Set	23048006	K041202

Serology



C-Reactive Protein (CRP)

Fisher Healthcare™ Sure-Vue™ CRP Latex Test Kit

Qualitative and semi-quantitative test for the determination of serum CRP, an indicator of acute infection and illness. Features a suspension of latex particles coated with the IgG fraction of an anti-human CRP-specific serum.

- Test results in two minutes
- For in vitro diagnostic use

Description	CLIA Complexity	Quantity	Cat. No.	510K Number
CRP Latex Test Kit	Moderate	50 Tests	23038099	K910686
	Moderate	100 Tests	23038100	K910686



Mononucleosis

Fisher Healthcare™ Sure-Vue™ Signature Mono Test Kit

For the qualitative detection of infectious mononucleosis heterophilic antibodies in serum, plasma, or whole blood.

- Test time: five minutes

Description	CLIA Complexity	Quantity	Cat. No.	510K Number
Signature Mono Test Kit Includes: <ul style="list-style-type: none"> • Capillary Tubes, Transfer Pipets, Test Tubes • Workstation and Test Sticks • Reagents and Controls • Package Insert 	Waived for Whole Blood; Moderate for Serum/Plasma	25 Tests	23-200-275	K972231



Mononucleosis

Fisher Healthcare™ Sure-Vue™ Color Mono Test Kit

Color-enhanced slide test designed for the detection of infectious mononucleosis heterophile antibodies in serum or plasma.

- For in vitro diagnostic use
- Test results in two minutes

Quantity	CLIA Complexity	Cat. No.	510K Number
25 Tests	Moderate	23-038-176	K821386
50 Tests	Moderate	23-038-101	K821386
100 Tests	Moderate	23-038-102	K821386



Mononucleosis

Fisher Healthcare™ Sure-Vue™ Latex Mono Test Kit

Latex agglutination slide test designed for the qualitative and semi-quantitative detection of infectious mononucleosis heterophile antibodies in serum and plasma.

- For in vitro diagnostic use
- Test results in three minutes

Quantity	CLIA Complexity	Cat. No.	510K Number
50 Tests	Moderate	23-038-173	K821386
150 Tests	Moderate	23-038-174	K821386
1,000 Tests	Moderate	23-038-175	K821386



Rheumatoid Factor (RF)

Fisher Healthcare™ Sure-Vue™ RF Rapid Latex Test Kit

Latex agglutination test for the qualitative and semi-quantitative determination of rheumatoid factor in serum.

- For in vitro diagnostic use

Description	CLIA Complexity	Quantity	Cat. No.	510K Number
RF Rapid Latex Test Kit	Moderate	25 Tests	23-038177	K821319
		50 Tests	23-038178	K821319
		100 Tests	23-038179	K821319
		500 Tests	23-038180	K821319
Disposable Slides	Moderate	108/Pack	23-038181	
		25/Pack	23-038182	



Antistreptolysin-O (ASO)

Fisher Healthcare™ Sure-Vue™ ASO Test Kit

For the qualitative and semi-quantitative detection of Antistreptolysin-O (ASO) antibodies in human serum.

- Increased sensitivity for testing pediatric patients
- Two-minute latex agglutination slide test
- For in vitro diagnostic use

CLIA Complexity	Quantity	Cat. No.	510K Number
Moderate	50 Tests	23-038-105	K853857
Moderate	100 Tests	23-038-106	K853857
Moderate	500 Tests	23-038-107	K853857



Adenovirus

Fisher Healthcare™ Sure-Vue™ Adeno Test Kit

Rapid, membrane-based immunogold assay for the qualitative detection of adenovirus and its antigens. Aids in the diagnosis of conjunctivitis, respiratory illnesses, and gastroenteritis caused by adenovirus.

- Simple two-step procedure
- Results in 15 minutes

Description	CLIA Complexity	Quantity	Cat. No.
Test Kit	Moderate	20 Tests	SA067020
Adeno Control Set	Moderate	2 Vials	SA067022

Influenza A & B

Fisherbrand™ Sure-Vue™ Signature Test Influenza A&B Kit



Delivers rapid detection of influenza type A and B nucleoprotein antigens directly from nasal and nasopharyngeal swab specimens from patients.

- Accurate results reduce inappropriate use of antibiotics
- Provides results in as little as 10 minutes

Description	CLIA Complexity	Quantity	Cat. No.	510K Number
Influenza A & B Test Kit	Waived	25 Tests	23-200-279	K192719

Respiratory Syncytial Virus (RSV)

Fisher Healthcare™ Sure-Vue™ RSV Test Kit



Procedure to detect RSV antibodies in samples that are bloody or mucoid.

- Specimen types: nasopharyngeal washes, aspirates, and swabs
- Results in 15 minutes

Description	CLIA Complexity	Quantity	Cat. No.	510K Number
RSV Test Kit	Waived and Moderate	30 Tests	SA041130	K022845



Respiratory Syncytial Virus (RSV)

Fisher Healthcare™ Sure-Vue™ Controls for RSV Test Kit

Use with the Sure-Vue RSV Test Kit for results in five minutes.

Description	Quantity	Cat. No.	510K Number
RSV Controls, Positive and Negative	2 x 1 mL	SA041101	K022845

Rotavirus

Fisher Healthcare™ Sure-Vue™ Rota Test Kit



Rapid membrane-based immunogold assay for the qualitative detection of rotavirus antigen in human fecal specimens; aids in the diagnosis of acute gastroenteritis caused by rotavirus infection.

- For in vitro diagnostic use only
- Preliminary results in 30 seconds; final results in 15 minutes

Description	CLIA Complexity	Quantity	Cat. No.	510K Number
Rotavirus Test Kit	Moderate	25 Tests	SA069111	K990842
Rotavirus Control Set: Includes Positive and Negative Controls	Moderate	2 x 1 mL	SA069101	K990842

Rubella

Fisher Healthcare™ Sure-Vue™ Signature Rubella Latex Test Kit



Rapid latex agglutination test for the qualitative and semi-quantitative detection of both IgG and IgM anti-rubella virus antibodies in serum.

- For in vitro diagnostic use

Description	CLIA Complexity	Quantity	Cat. No.
Signature Rubella Latex Test Kit	Moderate	100 Tests	23-038-155
		500 Tests	23-038-156
		100 Tests	23-038-155
		500 Tests	23-038-156

Rubella

Fisher Healthcare™ Sure-Vue™ Rubella Latex Test Kit



Latex agglutination slide test for the qualitative and semi-quantitative determination of rubella virus antibodies in serum. The reagent is a suspension of latex particles coated with soluble rubella virus antigen from disrupted virus.

- For in vitro diagnostic use
- Test results in eight minutes

Description	CLIA Complexity	Quantity	Cat. No.
Rubella Latex Test Kit	Moderate	30 Tests	23-038-183
		100 Tests	23-038-184
		500 Tests	23-038-185



Cryptosporidium/Giardia
**Fisher Healthcare™ Sure-Vue™
 Signature Crypto/GI Test Kit**

Provides fast, accurate results for the two most common intestinal parasitic infections with one test that detects and differentiates between *Cryptosporidium* and *Giardia*.

- Improves turnaround times
- Test results in approximately 10 minutes

Kit Includes	CLIA Complexity	Quantity	Cat. No.	510K Number
30 Test Cards, Sample Treatment Buffer, Reagent A, Reagent B, Specimen Dilution Tubes, Pipets, Package Insert	Moderate	30 Tests	23-200-277	K983399

Disease State	Adenovirus	Antistreptolysin-O (ASO)	C-Reactive Protein (CRP)	<i>Cryptosporidium/ Giardia</i>
Sure-Vue Kit	Sure-Vue Adeno Test Kit	Sure-Vue ASO Test Kit	Sure-Vue CRP Latex Test Kit	Sure-Vue Signature Crypto/GI Test Kit
Catalog Number	SA067020	23-038-105 23-038-106 23-038-107	23038099 23038100	23-200-277
Test Method	Membrane-Based Immunoassay (Cassette)	Latex Slide Agglutination	Latex Slide Agglutination	Qualitative Immunochromatographic Assay
Specimen	Eye Swabs, Nasal and Nasopharyngeal Secretions, Fecal Samples, and Cell Culture Supernatant	Serum	Serum	Stool or Stool Specimen in SAF, 10% Formalin, MIF, Cary-Blair, C&S, or Stuart's Transport Media
Results	Qualitative	Qualitative or Semi-Quantitative	Qualitative or Semi-Quantitative	Qualitative
CLIA Complexity	Moderate	Moderate	Moderate	Moderate
Controls	Internal Procedural Control Only	Includes Positive and Negative Controls	Includes Positive and Negative Controls	External Controls Sold Separately (23200278)
Sensitivity	96.80%	200 IU	6 mg/L	Crypto – 97.3%/Giardia – 100%
Specificity	94.10%	>95%	NA	Crypto – 100%/Giardia – 100%
Time to Result	15 Minutes	2 Minutes	2 Minutes	10 Minutes

Disease State	Fecal Occult Blood	Immunochemical Fecal Occult Blood	Human Chorionic Gonadotropin (hCG)	
Sure-Vue Kit	Sure-Vue Fecal Occult Blood Test System	Sure-Vue Signature Immunochemical Fecal Occult Blood Test	Sure-Vue STAT Serum/Urine hCG Test Kit	Sure-Vue Serum/Urine hCG Test Kit
Catalog Number	23-038-031 23-038-032 23-038-035 23-038-036 23-038-040	23-048-000 23-048-001 23-048-002 23-048-005	23-900-530 23-900-531	23-900-528 23-900-529
Test Method	Guaiaac (Paper Slide)	Immunochemical (iFOB)	Rapid Chromatographic Immunoassay (Cassette)	Rapid Chromatographic Immunoassay (Cassette)
Specimen	Stool	Stool	Urine or Serum	Urine or Serum
Results	Qualitative	Qualitative	Qualitative	Qualitative
CLIA Complexity	Waived	Waived	Waived (Urine) or Moderate (Serum)	Waived (Urine) or Moderate (Serum)
Controls	Each Slide Includes Positive and Negative Monitors	Internal Quality Control Included within Each Test; External QC Available for Purchase	Not Included	Not Included
Sensitivity	0.3 mg% Hemoglobin; 0.2 mg% Hemoglobin (Extra Sensitive)	>87% (Detects hHB as Low as 50 ng/mL)	>99%	>99%
Specificity	Specificity: 0.5% vs. 1.2% False Positives as Compared to Guaiaac; 0.9% vs. 1.2% False Positives as Compared to Guaiaac (Extra Sensitive)	>96% (Highly Specific for Human Hemoglobin)	>99%	>99%
Time to Result	30 Seconds	Less Than 10 Minutes	3 Minutes (Urine); 5 Minutes (Serum)	3 Minutes (Urine); 5 Minutes (Serum)

Disease State	Rheumatoid Factor (RF)	Rotavirus	Rapid Plasma Reagin (RPR)	Respiratory Syncytial Virus (RSV)
Sure-Vue Kit	Sure-Vue RF Rapid Latex Test Kit	Sure-Vue Rota Test Kit	Sure-Vue RPR Test Kit	Sure-Vue RSV Test Kit
Catalog Number	23-038-177 23-038-178 23-038-179 23-038-180	SA069111	23-038-009 23-038-010 23-038-021 23-029-966	SA041130
Test Method	Latex Slide Agglutination	Membrane-Based Immunoassay (Cassette)	Nontreponemal Slide Flocculation (Carbon)	Membrane-Based Immunoassay (Cassette)
Specimen	Serum	Stool	Serum	Nasopharyngeal Aspirate, Swab, or Wash
Results	Qualitative and Semi-Quantitative	Qualitative	Qualitative and Semi-Quantitative	Qualitative
CLIA Complexity	Moderate	Moderate	Moderate	Waived and Moderate
Controls	Includes Positive and Negative Controls	Includes Internal Procedural Controls Only	Includes Non-Reactive, Reactive, and Weakly-Reactive Controls	Procedural Controls Only
Sensitivity	8 IU/mL	>98%	Same as VDRL	97%
Specificity	>95%	>98%	NA	98%
Time to Result	2 Minutes	15 Minutes	8 Minutes	15 Minutes

Disease State	Rubella		<i>Staphylococcus aureus</i>	
	Sure-Vue Signature Rubella Latex Test	Sure-Vue Rubella Latex Test Kit	Sure-Vue SELECT Staph ID Test Kit	Sure-Vue Color Staph ID Latex Test Kit
Sure-Vue Kit	Sure-Vue Signature Rubella Latex Test	Sure-Vue Rubella Latex Test Kit	Sure-Vue SELECT Staph ID Test Kit	Sure-Vue Color Staph ID Latex Test Kit
Catalog Number	23038155 23038156	23-038-183 23-038-184 23-038-185	23-038-056 23-046-870	23-046-500 23-046-501
Test Method	Latex Slide Agglutination	Latex Slide Agglutination	Latex Slide Agglutination	Color-Enhanced Latex Slide Agglutination
Specimen	Serum	Serum	Colonies from Culture Plate (Incubated Overnight)	Colonies from Culture Plate (Incubated Overnight)
Results	Qualitative and Semi-Quantitative	Qualitative and Semi-Quantitative	Qualitative	Qualitative
CLIA Complexity	Moderate	Moderate	Moderate	Moderate
Controls	High Positive, Low Positive, and Negative Controls Included	Includes Low Positive, High Positive, and Negative Controls	Not Included	Includes Positive, Negative, and Latex Controls
Sensitivity	10 to 20 IU/mL	1 to 2 IU (Non-Dilution); 10 to 20 IU (Dilution)	99%	99%
Specificity	>99%	>99%	92%	100%
Time to Result	8 Minutes	8 Minutes	Up to 20 Seconds	Up to 30 Seconds

Disease State	<i>Group A Streptococcus</i>	
Sure-Vue Kit	Sure-Vue Signature Strep A Test Kit	Sure-Vue Strep A Lateral Flow Test Kit
Catalog Number	23-200-276	23-900-532
Test Method	Color Chromatographic Immunoassay (Dipstick)	Chromatographic Immunoassay (Dipstick)
Specimen	Throat Swab	Throat Swab
Results	Qualitative	Qualitative
CLIA Complexity	Waived	Waived and Moderate
Controls	Includes Positive and Negative Controls	Includes Internal Procedural Controls Only
Sensitivity	95.70%	97%
Specificity	100%	95%
Time to Result	7 Minutes	6 Minutes

The information provided is for informational purposes only. There are no warranties, promises, or representations of any kind, expressed or implied, as to the nature, standard, or accuracy of the information being provided. This information does not purport to provide legal or certified coding advice. Policies regarding appropriate coding and payment levels can vary greatly from payer to payer and change over time, therefore it is the individual provider's responsibility to determine appropriate coding, charges, and claims for a particular service as required under federal and state law. It is strongly recommended that providers contact their contracted payers to determine appropriate coding and charge or payment levels prior to submitting claims. As of November 11, 2019, these products meet FDA reclassification requirements. Policies regarding reclassification can vary and change over time, therefore it is the individual provider's responsibility to perform due diligence and make an individual determination regarding a product's classification.

Find it at fisherhealthcare.com

Distributed by Fisher Healthcare. Contact us today:

In the United States

Order online: fisherhealthcare.com

Call customer service: 1-800-640-0640

