Laboratory Name:	
Laboratory Address:	
Date of this packet:	
Insert Revision:	05-27-2014

Fisher Scientific Sure-Vue® *H. pylori* Test
Laboratory Procedure

This procedure is intended to provide a ready outline reference for performance of the assay. These abbreviated directions for use are not intended to replace the complete package insert. **Any modifications to this document are the sole responsibility of the Facility.**

A rapid test for the qualitative detection of IgG antibodies to *Helicobacter pylori* (*H. pylori*) in whole blood, serum and plasma.

For professional *in vitro* diagnostic use only.

CLIA Category: **Whole Blood - Waived**
Serum/ Plasma - Moderately Complex

1. Intended Use

The **Sure-Vue® *H. pylori* Test (Whole Blood/Serum/Plasma)** is a rapid chromatographic immunoassay for the qualitative detection of IgG antibodies to *Helicobacter pylori* in whole blood, serum or plasma to aid in the diagnosis of *H. pylori* infection in adults 18 years of age and older.

2. Summary

H. pylori is a small, spiral-shaped bacterium that lives in the surface of the stomach and duodenum. It is implicated in the etiology of a variety of gastrointestinal diseases, including duodenal and gastric ulcer, non-ulcer dyspepsia and active and chronic gastritis.[1,2]

Both invasive and non-invasive methods are used to diagnose *H. pylori* infection in patients with symptoms of gastrointestinal disease. Sample-dependent and costly invasive diagnostic methods include gastric or duodenal biopsy followed by urease testing (presumptive), culture, and/or histologic staining.[3] Non-invasive techniques include the urea breath test, which requires expensive laboratory equipment and moderate radiation exposure, and serological methods.[4,5]

Individuals infected with *H. pylori* develop serum IgG antibodies which correlate strongly with histologically confirmed *H. pylori* infection.[6,7,8] The **Sure-Vue® *H. pylori* Test (Whole Blood/Serum/Plasma)** is a simple test that utilizes a combination of *H. pylori* antigen coated particles and anti-human IgG to qualitatively and selectively detect *H. pylori* IgG antibodies in whole blood, serum or plasma in just minutes.

3. Test Principle

The **Sure-Vue® *H. pylori* Test (Whole Blood/Serum/Plasma)** is a qualitative membrane strip based immunoassay for the detection of *H. pylori* IgG antibodies in whole blood, serum or plasma. In this test procedure, anti-human IgG is immobilized in the test line region of the device. The sample reacts

with *H. pylori* antigen-coated particles that have been applied to the label pad. This mixture migrates chromatographically along the length of the test strip and interacts with the immobilized anti-human IgG. If the sample contains *H. pylori* IgG antibodies, a colored line will appear in the test line region indicating a positive result. If the sample does not contain *H. pylori* IgG antibodies, a colored line will not appear in this region indicating a negative result. To serve as a procedural control, a colored line will always appear at the control line region, indicating that proper volume of sample has been added and membrane wicking has occurred.

4. Specimen Collection/Treatment

The **Sure-Vue® *H. pylori* Test (Whole Blood/Serum/Plasma)** can be performed using whole blood (from venipuncture or fingerstick), serum or plasma.

A. Specimen:	**Acceptable specimen types:** • Whole blood from venipuncture (Waived) • Whole blood from fingerstick (Waived) • Serum (Moderately Complex) • Plasma (Moderately Complex)
B. Specimen Collection:	**To collect Venipuncture Whole Blood samples:** Collect anti-coagulated blood sample (sodium or lithium heparin, potassium or sodium EDTA, sodium oxalate, sodium citrate) following standard laboratory procedures. **To collect Fingerstick Whole Blood samples:** • Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry. • Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger. • Puncture the skin with a sterile lancet. Wipe away the first sign of blood. • Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site. • Touch the end of the capillary tube to the blood until filled to the line; avoid air bubbles. • Place the bulb onto the top end of the capillary tube. • Squeeze the bulb to dispense the whole blood. **For serum or plasma samples:** Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed samples.
C. Specimen Storage:	**Testing should ideally be performed immediately after the samples have been collected.** Do not leave the samples at room temperature for prolonged periods. Whole blood collected by venipuncture should be stored at 2-8ºC if the test is to be run within 2 days of collection. Whole blood collected by fingerstick should be tested immediately. Do not freeze whole blood samples. Serum or plasma samples may be stored at 2-8ºC for up to 3 days. For long term storage, samples should be kept below -20ºC. Bring samples to room temperature prior to testing. Frozen samples must be completely thawed and mixed well prior to testing. Samples should not be frozen and thawed repeatedly. If samples are to be shipped, they should be packed in compliance with

	federal regulations covering the transportation of etiologic agents.
D. Handling Precautions:	Patient samples, controls, and test devices should be handled as though they could transmit disease. Observe established precautions against microbial hazards.

5. Reagents and Equipment

The test device contains H. pylori antigen-coated particles and anti-human IgG coated membrane.

A. Materials Provided

- Test devices with disposable sample droppers
- Disposable heparinized capillary tubes and dispensing bulbs
- Positive control (Diluted human plasma containing *H. pylori-specific IgG, 0.09% sodium azide*
- Negative control (Diluted human plasma, 0.09% sodium azide)
- Sample Buffer
- Procedure card
- Package inserts

B. Materials Required But Not Provided

- Sample collection container (for venipuncture whole blood)
- Lancet (for fingerstick whole blood only)
- Centrifuge (for serum and plasma only)
- Timer

6. Storage and Stability

The kit can be stored at room temperature or refrigerated (2-30ºC). The test device is stable through the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

7. Quality Control

Internal Quality Control

Internal procedural controls are included in the test. A red line appearing in the control region (C) is an internal positive procedural control. It confirms sufficient sample volume and correct procedural technique. A clear background is an internal negative background control. If the test is working properly, the background in the result area should be white to light pink and not interfere with the ability to read the test result.

External Quality Control

It is recommended that a positive and negative external control be run every 30 tests, and as deemed necessary by your internal laboratory procedures. External positive and negative controls are supplied in the kit. If controls do not perform as expected, assay results are invalid.

Procedure for External Quality Control Testing

Using the positive or negative external controls in place of a patient sample, add 2 drops of positive or negative control solution to the sample well of a new test device, then add 1 drop of Sample Buffer. Start the timer. Continue with Step 3 in the Directions For Use section (Test Procedure section).

8. Precautions

1. For professional *in vitro* diagnostic use only. Do not use after expiration date.

2. Do not eat, drink or smoke in the area where the specimen samples and kits are handled.

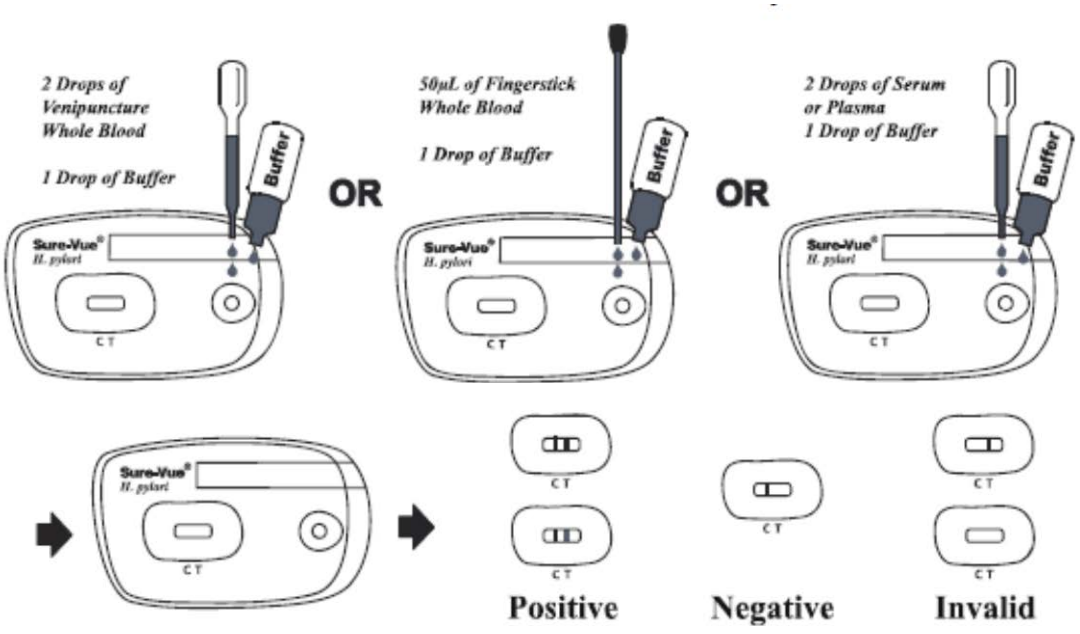
3. The positive and negative controls contain human plasma. Handle controls and all specimen samples as if they contain infectious agents. Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of specimen samples.
4. The positive and negative controls contain sodium azide as a preservative.
5. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimen samples are assayed.
6. Humidity and temperature can adversely affect results.

9. Test Procedure

Allow the test device, sample, buffer and controls to reach room temperature (15-30ºC) before testing.

1. Remove the test device from the foil pouch and use it as soon as possible. For best results, perform the test immediately after opening the foil pouch.
2. Place the test device on a clean and level surface.
   - For **Whole Blood (Venipuncture)** samples: Hold the dropper upright and add **2 drops of whole blood** (about 50 µl) to the sample well of the test device. Then add **1 drop of Sample Buffer** to the sample well. Start the timer.
   - For **Whole Blood (Fingerstick)** samples: Add **one capillary tube of blood** (about 50 µl) to the sample well of the test device. Then add **1 drop of Sample Buffer** to the sample well. Start the timer.
   - For **Serum or Plasma** samples: Hold the dropper upright and add **2 drops of serum or plasma** (about 50 µl) to the sample well of the test device. Then add **1 drop of Sample Buffer** to the sample well. Start the timer. Avoid trapping air bubbles in the sample well. See the illustration below.
3. Wait for the red line(s) to appear. The result should be read at 10 minutes. The background should be clear before the result is read.

Note: Low levels of *H. pylori* IgG specific antibodies might result in a weak line in the test region (T) after a long period of time. Do not read the result after 15 minutes.



10. Interpretation of Test Results

(Please refer to the illustration)

POSITIVE*: Two distinct red lines appear. One line should be in the control region (C) and another line should be in the test region (T). A positive result means that *H. pylori* IgG specific antibodies were detected in the sample.
***NOTE:** The shade of the red color in the test line region (T) will vary based on the amount of *H. pylori* IgG specific antibodies in the sample. Any shade of red in the test region (T) should be considered positive.

NEGATIVE: One red line appears in the control region (C). No apparent red or pink line appears in the test region (T). A negative result means that *H. pylori* IgG specific antibodies were not found in the sample or are below the detection limit of the test.

INVALID: No line appears in the control region (C). If this occurs, read the directions again and repeat the test with a new test device. If the result is still invalid, stop using the test kit and call 1-866-216-0094 for Technical Assistance.

11. Limitations

1. The **Sure-Vue® *H. pylori* Test (Whole Blood/Serum/Plasma)** should be used only to evaluate patients with clinical signs and symptoms suggestive of gastrointestinal disease and is not intended for use with asymptomatic patients.
2. The **Sure-Vue® *H. pylori* Test (Whole Blood/Serum/Plasma)** is for *in vitro* diagnostic use only. The test should be used for the detection of *H. pylori* IgG antibodies in whole blood, serum or plasma samples only. Neither the quantitative value nor the rate of increase in *H. pylori* antibody concentration can be determined by this qualitative test.
3. The **Sure-Vue® *H. pylori* Test (Whole Blood/Serum/Plasma)** will only indicate the presence of *H. pylori* IgG antibodies in the sample and should not be used as the sole criteria for the diagnosis of *H. pylori* infection.
4. Grossly hemolysed samples will yield invalid results. Strictly follow the Package Insert instructions to obtain accurate results.
5. A positive result does not allow one to distinguish between active infection and colonization by *H. pylori*.
6. A positive result only indicates the presence of IgG antibody to *H. pylori* and does not necessarily indicate that gastrointestinal disease is present.
7. A negative result indicates that IgG antibody *to H. pylori* is not present or is below the detection limit of the test.
8. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
9. Literature references have suggested cross reactivity of IgG antibody with a closely related organism, *Borrelia burgdorferi*. Performance of this assay has not been evaluated with this organism. Therefore, the specificity of this test device is not known if this organism is encountered.
10. This assay has not been established for patients under 18 years of age.

12. Expected Values

H. pylori infection is present worldwide and has been shown to correlate with age, ethnic background, family size, and socioeconomic class.[9] In the United States, the incidence of infection may increase 1-2% annually.[10] Eighty to 100% of individuals with signs and symptoms of other gastrointestinal conditions such as duodenal ulcers are reported to be positive for *H. pylori* infection.[11]

13. Performance Characteristics

Clinical Sensitivity, Specificity and Accuracy

Using two independent sites, a total of 484 clinical samples were obtained from a population of symptomatic individuals who presented for endoscopic examination for the detection of *H. pylori* infection. Culture and/or histology of biopsy specimens served as the reference method for the study done in Site A while histology and/or rapid urease test of the biopsy specimens served as the reference method for the study done in Site B. Whole blood (venous and fingerstick), serum and plasma were also collected for the detection of *H. pylori* specific IgG antibody by the **Sure-Vue® *H. pylori* Test**.

Of the 321 fresh clinical samples collected in Site A, 136 were considered biopsy positive and 185 clinical specimens were considered biopsy negative. Biopsy "positive" was defined as either or both culture and histology are positive and biopsy "negative" was defined as both culture and histology are negative. The results for each sample matrix are summarized below.

Serum

		Culture/Histology +	Culture/Histology –
Sure-Vue®	+	121	21
***H. pylori* Test**	–	15	164

Sensitivity = 121/136 = 89% (82% - 94%)*
Specificity = 164/185 = 89% (83% - 93%)*
Accuracy = 285/321 = 89% (84% - 92%)*

Plasma

		Culture/Histology +	Culture/Histology –
Sure-Vue®	+	120	21
***H. pylori* Test**	–	16	164

Sensitivity = 120/136 = 88% (81% - 93%)*
Specificity = 164/185 = 89% (83% - 93%)*
Accuracy = 284/321 = 88% (84% - 92%)*

Fingerstick

		Culture/Histology +	Culture/Histology –
Sure-Vue®	+	54	12
***H. pylori* Test**	–	8	76

Sensitivity = 54/62 = 87% (76% - 94%)*
Specificity = 76/88 = 86% (77% - 93%)*

Venous Whole Blood

Culture/Histology

		+	–
Sure-Vue®	+	119	22
H. pylori **Test**	–	17	163

Sensitivity = 119/136 = 88% (81% - 93%)*
Specificity = 163/185 = 88% (83% - 92%)*
Accuracy = 282/321 = 88% (84% - 91%)*

*****Denotes 95% Confidence Interval

Of the 163 archived clinical serum samples collected and tested in site B, 71 were deemed biopsy positive and 92 were deemed biopsy negative. Biopsy “positive” was defined as either or both histology and rapid urease test are positive and biopsy “negative” was defined as both histology and rapid urease test are negative.

Histology/Rapid Urease Test

		+	–
Sure-Vue®	+	52	16
H. pylori **Test**	–	19	76

Sensitivity = 52/71 = 73% (61% - 83%)*
Specificity = 76/92 = 83% (73% - 90%)*
Accuracy = 128/163.=78% (71% - 84%)*

*Denotes 95% Confidence Interval

Similarly, the matching archived plasma samples were also tested yielding a sensitivity of 65% (52-76)*, a specificity of 89% (81-95)* and an accuracy of 78% (71-84)*. Using Fisher HealthCare’s exact test, a statistical comparison was made between the results obtained with the archived serum and plasma samples. The resultant P value is 1.0, indicating that there is no significant difference between the results obtained from the two sample matrices tested.

The discrepant samples were checked with a commercially available EIA to confirm the presence of *H. pylori* specific IgG antibody in the samples. Of the 35 discrepant samples, 3 were equivocal, 14 out of 16 positive samples were shown to have *H. pylori* specific IgG antibody, and 10 out of the 19 negative samples did not contain the *H. pylori* specific IgG antibody.

In addition, the above archived clinical samples were tested with two commercially available rapid diagnostic test kits, sample volume permitting. One hundred sixty-two (162) plasma specimens were used to compare the **Sure-Vue® *H. pylori* Test** to Comparator A, while 163 serum specimens were used to compare the product to Comparator B. The correlation between the **Sure-Vue® *H. pylori* Test** and the comparator rapid diagnostic test kits are summarized below.

Comparator A

+	–

Sure-Vue®	+	54	2
***H. pylori* Test**	–	15	91

Positive Agreement = 54/69 = 78% (67% - 87%)*
Negative Agreement = 91/93 = 98% (92% - 100%)*
Overall Agreement = 145/162 = 90% (84% - 94%)*

Comparator B

		+	–
Sure-Vue®	+	67	1
***H. pylori* Test**	–	1	94

Positive Agreement = 67/68 = 98% (92% - 100%)*
Negative Agreement = 94/95 = 99% (94% - 100%)*
Overall Agreement = 161/163 = 99% (96% - 100%)*

*Denotes 95% Confidence Interval

POL Studies

Three physicians' offices were used to conduct an evaluation of the **Sure-Vue® *H. pylori* Test (Whole Blood/Serum/Plasma)**. Personnel with various educational backgrounds performed the testing. Each physician's office tested a randomly coded panel of samples consisting of negative (20), low positive (20) and medium positive (20) for three days. The results obtained had a >99% correlation with the expected results.

Cross-Reactivity

Sera containing known amounts of IgG antibodies to *H. pylori* have been tested with *C. jejuni, C. fetus, C. coli, P. aeruginosa* and *E. coli*. No cross-reactivity was observed, indicating that the **Sure-Vue® *H. pylori* Test (Whole Blood/Serum/Plasma)** has a high degree of specificity for human serum IgG antibodies to *H. pylori*.

Interference Studies

No interference with the **Sure-Vue® *H. pylori* Test (Whole Blood/Serum/Plasma)** results was observed in samples containing high levels of hemoglobin (up to 1000mg/dL), bilirubin (up to 1000mg/dL), human serum albumin (up to 2000mg/mL). The test results were also unaffected when the hematocrit was altered ranging from 20% to 67%. 600mg/dL triglyceride concentration sample did not interfere with test performance.

Reproducibility Studies

Three lots were used to perform reproducibility studies of the **Sure-Vue® *H. pylori* Test (Whole Blood/Serum/Plasma)**. Three sample matrices (serum, plasma and whole blood) were tested with replicates of ten tests each using four levels for each sample matrix (negative, low positive, medium positive and high positive). The results demonstrated that the **Sure-Vue® *H. pylori* Test (Whole Blood/Serum/Plasma)** has relatively high levels of precision when tested within run, between runs and between days.

14. References

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bacterial colonization and gastritis. Amer. J. Gastroenterology. 82(4):292-96; 1987.

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9. Lotfeld, R.J.L.F., E. Slobberingh, J.P. Van Spreeuwel, J.A. Flendrig, & J.W. Arends. 1991. The prevalence of anti-*Helicobacter (Campylobacter) pylori* antibodies in patients and healthy blood donors. J. Med. Microbiol. 32:105-109.
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11. Perez-Perez G, Dworkin, B, Chodos, J, Blaser, M. 1988. *Campylobacter pylori* antibodies in humans. Annals of Internal Med. 109:11-17.

For Technical Assistance: 1-866-216-0094
To Order:

Phone: 1-800-640-0640
Fax: 1-800-290-0290
www.fisherhealthcare.com

Test Procedure Approval and Review Sheet

Prepared By:	
Date:	
Supervisor Review:	
Date:	
Laboratory Director or Designee Approval:	
Implementation Date:	
Supersedes Procedure Dated:	
Date Procedure Retired:	

Laboratory Director or Designee	Date Reviewed	Laboratory Director or Designee	Date Reviewed

Fisher Scientific Sure-Vue® *H. pylori* Test Verification Form

Account Name: _____

Address: _____

_____

Telephone: _____

Fisher Scientific Sure-Vue® *H. pylori* Test Lot #/Exp: _____

Date: _____

Supervisor Signature: _____

Record the results from reference samples below.

Record the Sample #, the **Fisher Scientific Sure-Vue® *H. pylori* Test (Whole Blood/Serum/Plasma)** results, Tester's Initials, and any comments. After the **Fisher Scientific Sure-Vue® *H. pylori* Test (Whole Blood/Serum/Plasma)** results have been recorded (positive or negative) then record the Expected Results (positive or negative).

Sample #	Expected Results	**Fisher Scientific Sure-Vue® *H. pylori* Test** Result	Tester's Initials	Comments

Fisher Scientific Sure-Vue® *H. pylori* Test Verification Form (Continued)

Sample #	Expected Results	**Fisher Scientific Sure-Vue® *H. pylori* Test** Result	Tester's Initials	Comments

Review: _____ Date: _____

Laboratory Director Review and Approval for Clinical Use: _____

Date: _____

Fisher Scientific Sure-Vue® *H. pylori* Test External Quality Control

There are two options for complying with CLIA's daily QC requirements for non-waived test systems under Section 493.1256 of the regulations:

- *Run two levels of external controls daily before patient testing OR*
- *Laboratories may develop and implement an IQCP for each non-waived test system.*

Alere IQCP Support Documents may be found at http://www.alere.com/IQCP. *The following listed conditions are also required as a minimum requirement:*

External QC testing is recommended:

- To be run every 30 tests, and as deemed necessary by your internal laboratory procedures
- Additional tests including External Controls should be performed to meet the requirements of local, state, and/or federal regulations and/or accrediting organizations

Date	**Fisher Scientific Sure-Vue® *H. pylori* Test** Lot/Exp	Positive Ctrl Lot/Exp	Negative Ctrl Lot/Exp	Positive Control Result	Negative Control Result	Tester's Initials	Comments

Reviewed by: _____ Date: _____

Fisher Scientific Sure-Vue® *H. pylori* Test Internal Controls and Patient Record

Lot Number _____ **Exp. Date** _____

External controls are recommended to be run every 30 tests, as deemed necessary by your internal laboratory procedures, and federal, state, and local guidelines should be followed.

Record the Date, Patient's Name, Patient Test Result, Internal Control Results and the Tester's initials.
Positive Internal Control = A red line appearing in the control region (C) is an internal positive procedural control.
Negative Internal Control = A clear background - The background in the result area should be white to light pink and not interfere with the ability to read the test result.

Date	Patient Name	Patient ID Number	Patient Results	Are the Internal Control Results Invalid or Valid?		Internal Control Results		Comments	Tester's Initials
				Invalid	**Valid**	**+**	**-**		

Reviewed By: _____ Date: _____

Fisher Scientific Sure-Vue® *H. pylori* Test Lot to Lot Comparisons

Name of Facility: _____

External Quality Controls are required to test a new lot of reagents.

- Run every 30 tests, and as deemed necessary by your internal laboratory procedures
- When required by local, state, and/or federal regulations, accrediting groups, or your lab's Quality Control procedures

	CURRENT Fisher Scientific Sure-Vue® *H. pylori* Test In-Use Kit					**NEW Fisher Scientific Sure-Vue® *H. pylori* Test Kit**					
Date	**Fisher Scientific Sure-Vue® *H. pylori* Test** Kit Lot/Exp	Positive Control Lot/Exp	Negative Control Lot/Exp	Positive Control Result	Negative Control Result	**Fisher Scientific Sure-Vue® *H. pylori* Test** Kit Lot/Exp	Positive Control Lot/Exp	Negative Control Lot/Exp	Positive Control Result	Negative Control Result	Tech's Initials

Reviewed by: _____ Date: _____

Quality Assessment Review Form and Checklist

These forms are used for periodical review of the patient testing process. These should be filed with the quality assessment records.

Quality Assessment Activity	**Comments**	**Date**	**Initials**
Patient Test Management: Evaluate criteria for specimen submission, handling, and rejection; test results requisitions and reporting, accuracy and reliability of reports.			
Quality Control: Assess calibration and control data, reference range verification, errors in reporting results, corrective actions taken with appropriate documentation records.			
Proficiency Testing: Review the effectiveness of corrective actions taken for unsatisfactory performance or failures.			
Comparison of Test Results: Review at least semi-annually comparative results for multiple methods, instruments, or site correlations when more than one procedure exists.			
Relationship of Patient Test Information to Test Results*:* Evaluate patient test reports for accuracy of patient information, test results, and normal ranges. Identify and evaluate results inconsistent with Patient's age, sex, diagnosis, and other test parameters.			
Personnel: Evaluate the effectiveness of policies and procedures for assuring employees competence of testing and reporting test results.			
Communications: Evaluate documented problems and corrective actions that occur between the laboratory and the authorized individual who orders or receives the test result.			
Complaint Investigation: Evaluate documented complaints and corrective actions.			
Quality Assessment Reviews with Staff: Document discussion with Staff regarding identified problems and corrective actions during the QA review.			

Corrective Action Form

Problem/Error	**Corrective Action**

Technologist: _____ Date: _____

Supervisor: _____ Date: _____

Laboratory Director: _____ Date: _____

TEMPERATURE LOG

Equipment: _____

Name of Facility: _____

To be recorded at the beginning of each workday. Temperature Range: _____

Date	°C	Initials	Adjustments	Date	°C	Initials	Adjustments

Tips for Successful Proficiency Testing (PT) Performance

- Strictly follow the PT provider's storage or handling requirement ***before testing PT specimens***.
- Analyze PT specimens ***within the time frame*** provided by the PT provider.
- Contact the PT provider ***promptly*** when specimens are received damaged. You may be able to receive a replacement immediately.
- Avoid clerical error when filling out PT answer sheets. Be sure to ***enter the correct result next to the correct analyte*** on the answer form.
- Remember to identify the instrument or method you are using to perform your PT so you are ***graded among your peer group***.
- Make copies of all answer forms ***before submitting them*** to your PT provider.
- Please contact Technical Support at 877-441-7440 or Lateral.Flow.Support@alere.com for further information on proficiency provider.

Certification of Training

This is to verify that personnel responsible for running the **Fisher Scientific Sure-Vue® *H. pylori* Test (Whole Blood/Serum/Plasma)** at _____ have been thoroughly in-serviced on the test and the test procedure. This has included:

- **Review of the package insert**
- **Demonstration of the product assay**
- **Successful performance of the Fisher Scientific Sure-Vue® *H. pylori* Test (Whole Blood/Serum/ Plasma) and interpretation of results**

Names of the personnel who have been trained with the **Fisher Scientific Sure-Vue® *H. pylori* Test (Whole Blood/Serum/Plasma)** and are responsible for reporting patient results:

PRINT NAME	SIGNATURE	DATE

Signature of Laboratory Director(s) responsible for personnel and testing:

_____ _____
Signature Date

_____ _____
Signature Date

_____ _____
Trainer Date

Testing Personnel Training Assessment

Test Method: Fisher Scientific Sure-Vue® *H. pylori* Test

Procedure	Satisfactory	Unsatisfactory	Not Applicable	Comments / Corrective Actions
Observation of Test Performance:				
Patient Sample Preparation (if applicable)				
Specimen Handling/Processing				
Testing				
Recording/Reporting Results				
Assessment of Test Performance Using Known Samples				
Review of Records:				
Patient/Quality Control Log Sheet Records				
Proficiency Testing Records				
Assessment of Problem Solving Skills				

(Attach all supporting documents)

Evaluator:_____ Date: _____

Employee:_____

Fisher Scientific Sure-Vue® *H. pylori* Test Quiz

Name:_____

Date: _____ **Score:**_____

Circle T (True) or F (False) for each Question:

1.	The **Fisher Scientific Sure-Vue® *H. pylori* Test (Whole Blood/Serum/Plasma)** must remain in the sealed pouch until use.	T	F
2.	The **Fisher Scientific Sure-Vue® *H. pylori* Test (Whole Blood/Serum/Plasma)** kit can be stored at room temperature or refrigerated.	T	F
3.	Serum or plasma samples may be stored at 2-8ºC for up to 5 days.	T	F
4.	Separate serum or plasma from blood as soon as possible to avoid hemolysis.	T	F
5.	When using the test device to perform a CLIA Moderate Complexity test, the sample types are whole blood from venipuncture or fingerstick.	T	F
6.	If a red line appears in the control region (C) and no line appears in the test region (T), this indicates a negative result.	T	F
7.	Following the Directions for use (or Test Procedure section), first, add one drop of Sample Buffer to the sample well. Then, add the sample (either 2 drops of serum or plasma, 2 drops of venipuncture whole blood, or 50 µl of fingerstick whole blood).	T	F
8.	All samples should be brought to room temperature prior to testing.	T	F
9.	For external quality control testing, in place of a patient sample, add 2 drops of positive or negative control solution to the sample well, then add 1 drop of Sample Buffer.	T	F
10.	Read test results at 5 minutes.	T	F

Fisher Scientific Sure-Vue® *H. pylori* Test Quiz Answer Key

	Answer Key	Explanation
1.	T	The **Fisher Scientific Sure-Vue® *H. pylori* Test (Whole Blood/Serum/Plasma)** must remain in the sealed pouch until use. Remove the test device from the foil pouch and use it as soon as possible.
2.	T	The **Fisher Scientific Sure-Vue® *H. pylori* Test (Whole Blood/Serum/Plasma)** kit can be stored at 2-30ºC, room temperature or refrigerated. Do not freeze. Allow the test device, sample, buffer and controls to reach room temperature (15-30ºC) before testing.
3.	F	Serum or plasma samples may be stored at 2-8ºC for up to 3 days. For long term storage, samples should be kept below -20ºC.
4.	T	Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed samples.
5.	F	The acceptable sample types for the **Fisher Scientific Sure-Vue® *H. pylori* Test (Whole Blood/Serum/Plasma)** are whole blood, serum, or plasma. However, the moderate complexity test applies to serum or plasma samples only. (The waived test sample types are whole blood from venipuncture or fingerstick.)
6.	T	If a red line appears in the control region (C), and no apparent red or pink line appears in the test region (T), this indicates a negative result.
7.	F	First, add the sample, (2 drops of serum or plasma, 2 drops of venipuncture whole blood, or 50 µL of fingerstick whole blood), to the sample well of the test device. Then, add 1 drop of Sample Buffer to the sample well.
8.	T	Bring samples to room temperature prior to testing.
9.	T	To perform the procedure for external quality control testing, the positive or negative external controls are used in place of a patient sample. Two drops of either positive or negative control solution is added to the sample well of a new test device, then 1 drop of Sample Buffer is added.
10.	F	The result should be read at 10 minutes. The background should be clear before the result is read. (Do not read the result after 15 minutes.)