curian®
HpSA®

For the detection of *Helicobacter pylori* antigen in human stool

REF **760130**

IVD

Rx Only

For Professional Use Only

INTENDED USE
Curian HpSA, for use with the Curian Analyzer is a rapid, qualitative, fluorescent immunoassay for the detection of *Helicobacter pylori* antigen in human stool. Test results are intended to aid in the diagnosis of *H. pylori* infection and to demonstrate loss of *H. pylori* antigen following treatment. Accepted medical practice recommends that testing by any current method, to confirm eradication, be done at least four weeks following completion of therapy. Test results should be taken into consideration by the physician in conjunction with the patient history and symptoms.

SUMMARY AND EXPLANATION OF TEST
Recent studies have shown that *Helicobacter pylori* infections are a major public health concern globally.[1] It is estimated that over half of the global population is infected with *Helicobacter pylori*.[1, 3] Individuals infected with the *H. pylori* organism fall under two groups. The first group, "colonized", make up the majority of the global population and exhibit no gastrointestinal signs and symptoms. The second group, "infected", exhibit gastrointestinal signs and symptoms which includes gastritis, peptic or gastric ulcers, or gastric or duodenal cancer.[5, 9] *H. pylori* infection is considered the leading cause for chronic gastritis and is also considered an etiological agent for gastric cancer (adenocarcinoma) and peptic ulcer disease.[1-3] *H. pylori* infection has also been associated with mucosa-associated lymphoid tissue (MALT) and has been attributed to approximately 89% of gastric cancer diagnoses.[1, 4]

There are multiple methods in which to diagnose an *H. pylori* infection. Biopsy based tests are invasive methods which include culture, polymerase chain reaction (PCR) and the rapid urease test (RUT). The urea breath test (UBT), serology and stool antigen test are non-invasive methods of detection.[1, 6] It is recommended for clinicians to use non-invasive testing methods to aid in the diagnosis of patients who are: (i) without alarming symptoms (e.g., unexplained weight loss, progressive dysphagia, odynophagia), (ii) under the age of 55, and (iii) have a low risk of gastric cancer.[7, 8] Curian HpSA can detect *H. pylori* antigen in human stool and is a rapid, qualitative, non-invasive test designed to aid in the diagnosis of *H. pylori* infection.

BIOLOGICAL PRINCIPLES
The Curian HpSA assay consists of a test strip enclosed in a plastic frame (test card), positive control reagent, and Aioprep™ sample preparation device. Curian HpSA is a lateral flow-based immunoassay for the direct detection of *H. pylori* antigens in human stool. Curian HpSA utilizes monoclonal anti-*H. pylori* antibodies as the capture and detector antibodies. A sample of the patient's stool specimen is collected using the sample collection brush that is included in the Curian HpSA assay kit. The brush is pushed through a metering insert, which is integral to the Aioprep device, to remove excess stool. The brush is then pushed directly into the prefilled sample diluent. The diluted sample is mixed and dispensed drop-wise into the sample port of the Curian HpSA test card. The *H. pylori* antigen (if present) binds to the anti-*H. pylori* antibody conjugated to fluorescent particles, forming a complex. As the sample moves through the test strip, the anti-*H. pylori* capture antibody, bound to the assay membrane at the test position of the strip, binds the complex and yields a test line. When antigen is not present, a complex is not formed and a test line will not occur.
As the conjugate continues to move further up the test strip, a detector antibody forms another complex in the control area of the test strip. A line at the control position of the test strip should be present each time a sample or external control is tested. If the control line is not generated, adequate sample flow has not occurred, and the Curian Analyzer will consider the test invalid.

REAGENTS/MATERIALS PROVIDED
The maximum number of tests obtained from this kit is listed on the outer box.
1. **Curian HpSA Test Card:** A test strip enclosed in a plastic frame which is in a foil pouch with a desiccant. The test card is supplied ready to use.
2. **Curian HpSA Aioprep Sample Preparation Device/ Negative Control:** A buffered protein solution containing blue dye and 0.1% ProClin. The Aioprep device is fitted with a metering insert and dropper tip. Supplied ready to use.
3. **Curian HpSA Positive Control:** Inactivated *H. pylori* purified antigen in a phosphate buffered solution containing 0.094% sodium azide. Supplied ready to use.
4. **Curian HpSA Sample Collection Brushes**
5. **Wooden Applicators**

MATERIALS NOT PROVIDED
1. Disposable gloves, powder free.

EQUIPMENT NOT PROVIDED
1. Vortex mixer
2. Interval timer (Optional)
3. Curian Analyzer, Meridian Bioscience, Inc. Catalog 610190

PRECAUTIONS
1. All reagents are for in vitro diagnostic use only.
2. Store the kit at the temperature indicated on labeling when not in use.
3. Do not interchange sample collection brushes between assays. Specimens must be sampled and prepared with the Curian HpSA sample collection brush and used with the Curian HpSA Aioprep device. These components are not interchangeable with other assays.
4. Handle and dispose of all human specimens as if they are biologically hazardous.
5. Inspect foil pouch before removing the test card. Do not use test cards that have holes in the foil pouch or where the pouch has not been completely sealed.
6. Do not use test cards where the desiccant indicator has changed from blue to pink.
7. Inspect Curian HpSA Aioprep / Negative Control prior to use. Tap the Aioprep to ensure the liquid is in the main chamber of the Aioprep.
8. Do not interchange positive control or test cards between kit lots.
9. The Curian HpSA test card must be incubated outside of a laminar flow hood, this can be done either inside the Analyzer or on the lab bench.
10. Do not mark over or near the barcode on the test card.

HAZARD and PRECAUTIONARY STATEMENTS

 Sample Prep	**Signal word** Danger **Hazard statements** H302 - Harmful if swallowed H315 - Causes skin irritation H317 - May cause an allergic skin reaction H319 - Causes serious eye irritation H411 - Toxic to aquatic life with long lasting effects H311 - Toxic in contact with skin H331 - Toxic if inhaled **Precautionary Statements - EU (§28, 1272/2008)** P321 - See SDS Section 4 or Section 11 for specific medical treatment information P280 - Wear eye protection/ face protection P264 - Wash face, hands and any exposed skin thoroughly after handling P270 - Do not eat, drink or smoke when using this product P280 - Wear protective gloves/ protective clothing P261 - Avoid breathing dust/ fume/ gas/ mist/ vapors/ spray P271 - Use only outdoors or in a well-ventilated area P272 - Contaminated work clothing should not be allowed out of the workplace P302 + P352 - IF ON SKIN: Wash with plenty of soap and water P312 - Call a POISON CENTER or doctor/ physician if you feel unwell P362 - Take off contaminated clothing and wash before reuse P332 + P313 - If skin irritation occurs: Get medical advice/ attention P363 - Wash contaminated clothing before reuse P304 + P340 - IF INHALED: Remove to fresh air and keep at rest in a position comfortable for breathing P310 - Immediately call a POISON CENTER or doctor/ physician P301 + P312 - IF SWALLOWED: Call a POISON CENTER or doctor/ physician if you feel unwell P330 - Rinse mouth P405 - Store locked up P403 + P233 - Store in a well-ventilated place. Keep container tightly closed P501 - Dispose of contents/ container to an approved waste disposal plant. P320 - Specific treatment is urgent (see Section 8 on this label)

SHELF LIFE AND STORAGE
The expiration date is indicated on the kit label. Store the kit at 2-8 C as indicated on the labeling. Return all kit components to the indicated storage temperature after use.

OPERATION OF THE CURIAN ANALYZER
The Curian Analyzer is an easy to use, menu driven analyzer system. Instructions to complete testing are provided on the analyzer touchscreen and in the Curian Analyzer operator's manual.
1. Power-on the Curian Analyzer by pressing the power button located on the left side of the analyzer. The Curian Analyzer will initialize and perform self-checks.
2. Instrument Checks, Quality Control testing, and patient specimen testing are completed by navigating the Curian Analyzer menus. User ID and Sample ID entries are required for Quality Control and specimen testing.
3. Complete use and operation of the Curian Analyzer by following the instructions in the Curian operator's manual and on-screen prompts. **Refer to operator's manual for detailed instructions for the Curian Analyzer.**

QUALITY CONTROL
There are four controls for the Curian HpSA test system. Two internal controls, one for the assay and one for the analyzer, and two external controls, one for the assay and one for the analyzer.

1. Analyzer Internal Control: Self Test check (automatic)
2. Analyzer External Control: Instrument Check (IC Check)
3. Assay External Controls: Positive and Negative Controls (QC test)
4. Assay Internal Control: Control line

INSTRUMENT CHECK TEST PROCEDURE (Analyzer External Control Test)
Note: The Analyzer's External Control (IC Check) test has a default schedule of 30 days. The IC Check test will be required to be performed prior to running a QC test or a patient test if this has not been performed within this timeframe. The user will be locked-out of running a patient test if this test is overdue.

1. Power-on the Curian by pressing the power button located on the side of the analyzer. The Curian will initialize and perform Self Test checks.
2. From the HOME screen, select "TEST", and then select "Instrument Check".
3. Insert the Fluorescent IC Card into the drawer. A pass or fail result will be displayed once the analysis is complete.

If the expected control reactions are not observed, repeat the control tests as the first step in determining the root cause of the failure. Refer to operator's manual for detailed instructions for the Analyzer.

QUALITY CONTROL TEST PROCEDURE (Assay External Quality Control Test)
Note: Good Laboratory Practice[10] guidelines recommend the use of control material. Users should follow the appropriate federal, state, and local guidelines concerning the running of external quality controls.

1. Bring all test components and reagents to 19-27 C before testing.
2. Use 1 Curian test card for each QC sample control. When ready to perform testing, remove the test card from its foil pouch.
3. Discard the pouch and desiccant. Do not use test cards where the desiccant indicator has changed from blue to pink.
4. Label the test card with control identification information. Do not mark over or near the barcode on the test card

Negative Control
1. Start the test read by navigating to the "TEST" Menu, selecting the "QC Test". Select "Analyze Now" or "Incubate and Analyze". Follow the on-screen instructions.
2. Remove the white tip cap from the bottom of the Aioprep and discard.
3. While holding the Aioprep vertically, with both hands, squeeze near the bottom of the barrel to add 7 drops of Negative Control reagent (Sample Diluent) into the sample port of the test card.
4. Discard the Aioprep device immediately.
5. **Analyze Now**: Incubate the test card at 19-27 C on the benchtop for 20 minutes. Insert test card into the drawer of the Curian Analyzer and select "Curian HpSA QC Negative". Initiate read within 2 minutes after incubation is complete. Analysis of the reaction must be initiated by the Curian Analyzer. The analyzer will read the test card and automatically report the QC test result.
6. **Incubate and Analyze**: Insert test card immediately into the Curian Analyzer and select "Curian HpSA QC Negative". The Curian will time the incubation for 20 minutes then read the test card and automatically report the QC test result.

Positive Control
1. Start the test read by navigating to the "TEST" Menu and select "QC Test". Select "Analyze Now" or "Incubate and Analyze". Follow the on-screen instructions
2. Invert the positive control bottle to mix.
3. Remove the positive control tip cap and hold vertically to add 4 drops of positive control into the sample port of the test card.
4. **Analyze Now:** Incubate the test card at 19-27 C on the benchtop for 20 minutes. Insert test card into the drawer of the Curian Analyzer and select "Curian HpSA QC Positive". Initiate read within 2 minutes after incubation is complete. Analysis of the reaction must be initiated by the Curian Analyzer. The Curian will read the test card and automatically report the QC test result.
5. **Incubate and Analyze:** If "Incubate and Analyze" is selected, insert the test card immediately into the Curian Analyzer and select "Curian HpSA QC Positive". The Curian Analyzer will time the incubation for 20 minutes then read the test card and automatically report the test result.

If the expected control reactions are not observed, repeat the control tests as the first step in determining the root cause of the failure. If control failures are repeated please contact Meridian's Technical Services Department at 1-800-343-3858 (US) or your local distributor.

SPECIMEN PREPARATION AND TEST PROCEDURE
This procedure is designed to be used with unpreserved stool. DO NOT USE stool in transport media, on swabs, or mixed with preservatives. The patient specimen should be received in an airtight transport container and stored at 2-8 C until tested. The specimen should be tested as soon as possible but may be held up to 72 hours at 2-8 C prior to testing. If testing cannot be performed within this time frame, specimens should be frozen immediately upon receipt and stored frozen for up to 14 days at -20 C until tested. Specimens may be frozen and thawed twice.

Note: Handle all waste and specimens as biohazardous.

Note: Mix stool specimen thoroughly with the included wooden applicator (regardless of consistency) before testing.

1. Bring all test components, reagents and specimens to 19-27 C before testing.
2. Prior to sampling, mix stool specimen thoroughly with wooden applicator.
3. Remove the top cap from the Aioprep device and set aside.
4. Using the Curian HpSA sample collection brush, insert the brush into the stool specimen to coat the bristles of the brush. It is important that only the brush is covered with stool. **Do not get stool on the shaft or handle of the brush.** Refer to the examples below.

5. Insert the Curian HpSA sample collection brush into the Aioprep device, pushing the brush through the metering insert.
6. Snap off the sample collection brush at the marked 'Break' point and discard the handle.
7. Recap the Aioprep device, leaving the Curian HpSA sample collection brush in the device.
8. Mix the sample by vortexing for approximately 5 seconds. **Do not invert or shake to mix.**
9. Use 1 Curian HpSA test card for each sample. After mixing the sample, remove 1 test card from its foil pouch.
10. Discard the pouch and desiccant. **Do not use test cards where the desiccant indicator has changed from blue to pink**
11. Label the test card with sample identification information. **Do not mark over or near the barcode on the test card**
12. Remove the white tip cap from the bottom of the Aioprep and discard.
13. While holding the Aioprep vertically, with both hands, squeeze near the bottom of the barrel to add 7 drops into the sample port of the test card.
14. Discard the Aioprep device immediately.
15. Start the test read by navigating to the "TEST" Menu, selecting the appropriate test and following the on-screen instructions.
16. **Analyze Now:** Incubate the test card at 19-27 C on the benchtop for 20 minutes. Insert test card into the drawer of the Curian Analyzer and read test within 2 minutes of the end of incubation. Analysis of the reaction must be initiated by the Curian Analyzer. The analyzer will read the test card and automatically report the test result.
17. **Incubate and Analyze:** If "Incubate and Analyze" is selected, insert the test card immediately into the Curian Analyzer and the analyzer will time the incubation for 20 minutes then read the test card and automatically report the test result.

INTERPRETATION OF RESULTS
Result interpretation is completed automatically by the Curian Analyzer system. The result will be shown on screen. Results can be retrieved from instrument storage, printed and/or exported.

Instrument Check:
One of the following result interpretations will be generated by the Curian Analyzer for IC Check.
1. **Pass:** This indicates that the essential and critical components of the Curian Analyzer are working correctly.
2. **Fail**: This indicates that there may be an issue with the Curian Analyzer. Refer to the Curian operator's manual if an error message has occurred. Repeat testing to assist in trouble-shooting the error. If repeat testing results in a failed output, please contact Meridian's Technical Services Department at 1-800-343-3858 (US) or your local distributor.

External Quality Controls:
One of the following result interpretations will be generated by the Curian Analyzer for External Controls.
1. **Pass:** This indicates the test card and reagents are performing as intended.
2. **Fail**: This result indicates the test card and/ or reagents are not performing as intended or a user error has occurred. Test should be repeated to assist in trouble-shooting the error. If repeat testing results in a failed output, please contact Meridian's Technical Services Department at 1-800-343-3858 (US) or your local distributor.
3. **Control Invalid/ Fail**: This result indicates inadequate sample flow or incorrect sample preparation. Repeat the test. If repeat testing yields the same results, please contact Meridian's Technical Services Department at 1-800-343-3858 (US) or your local distributor for additional assistance.

Patient Test Results:
One of the following result interpretations will be generated by the Curian Analyzer for patient specimens.
1. **Positive:** *H. pylori* stool antigen is detected in sample.
2. **Negative:** *H. pylori* stool antigen is not detected in sample**.**
3. **Invalid:** Result indicates inadequate flow of sample or incorrect sample preparation. Repeat the test from the original stool specimen. If repeat testing yields the same results, please contact Meridian's Technical Services Department at 1-800-343-3858 (US) or your local distributor for additional assistance.

EXPECTED VALUES
Recent studies have shown that *Helicobacter pylori* infections are a major public health concern globally.[1] It is estimated that over half of the global population is infected with *Helicobacter pylori*.[1, 3] In patients diagnosed with duodenal ulcers, however, it has been shown to be 90%-95%.[12] Currently, recommended eradication treatments have an overall eradication rate of 84.3% (82.1% to 86.4%).[11]

The Curian HpSA assay detects the presence of *H. pylori* antigens in human stool. Expected values for a given population should be determined for each laboratory. The rate of positivity may vary depending on geographic location, method of specimen collection, handling and transportation, test employed and general health environment of patient population under study. The observed prevalence of *H. pylori* in this study was 13.5% (73/542). The prevalence of *H. pylori* by gender is provided below.

Gender	Samples Positive by Comparator Method and Curian HpSA	Prevalence in Tested Population
Female	42	7.7%
Male	31	5.7%
Total	73	13.5%

LIMITATIONS OF THE PROCEDURE:
1. The Curian HpSA assay must only be used with the Curian Analyzer.
2. Curian HpSA is a qualitative, in vitro diagnostic test. The Curian Analyzer will only provide qualitative results. This test is not intended to provide quantitative values.
3. The Curian HpSA assay is designed to be used with unpreserved stool samples. DO NOT USE stool in transport media, on swabs, or mixed with preservatives.
4. Antimicrobials, proton pump inhibitors and bismuth preparations are known to suppress *H. pylori* and ingestion of these prior to *H. pylori* testing (culture, histology, rapid urease, UBT, antigen) may give a false negative result. If a negative result is obtained for a patient ingesting these compounds within two weeks prior to performing the Curian HpSA assay, a false-negative result may be obtained. The test should be repeated on a new specimen two weeks after discontinuing treatment. A positive result for a patient ingesting these compounds within two weeks prior to performing the Curian HpSA test, should be considered accurate.
5. Performance characteristics have not been established in asymptomatic populations.
6. A negative test result does not preclude the possibility of the presence of *H. pylori* antigen in the specimen which may occur if the level of antigen is below the detection limit of the test.
7. No data exists on the effects of colonic washes, barium enemas, laxatives, or bowel preparations on the performance of the Curian HpSA assay. These procedures can result in extensive dilution or the presence of additives that may affect test performance.

SPECIFIC PERFORMANCE CHARACTERISTICS
CLINICAL PERFORMANCE
The Curian HpSA assay was evaluated at three study sites representing geographically distinct regions throughout the United States. Five hundred forty-two specimens from patients suspected of having an *H. pylori* infection were prospectively collected and enrolled into the study.

All specimens were tested at the study sites with the Curian HpSA assay and an FDA-cleared *H. pylori* stool antigen EIA that was previously evaluated relative to the endoscopy biopsy composite reference method (i.e., culture, histology, and RUT) for initial *H. pylori* diagnosis with a demonstrated sensitivity and specificity greater than or equal to 95% and a lower bound of the two-sided 95% confidence interval (CI) greater than 89%. Specimens with discordant results between the Curian HpSA assay and the FDA-cleared *H. pylori* stool antigen EIA assay were further tested in-house using a validated PCR assay.

The overall clinical performance (positive percent agreement (PPA) and negative percent agreement (NPA)) of the Curian HpSA assay compared to the FDA-cleared *H. pylori* stool antigen EIA is presented in the table below. PCR results of discordant testing are footnoted below.

Positive and Negative Curian HpSA Results vs. FDA-cleared *H. pylori* stool antigen EIA				
		FDA-cleared *H. pylori* stool antigen EIA		
		Positive	**Negative**	**Total**
Curian HpSA Assay	**Positive**	73	14[b]	87
	Negative	3[a]	452	455
	Total	76	466	542
Agreement			**95% CI (%)**	
PPA	**96.1%**	(73/76)	89.0%, 98.6%	
NPA	**97.0%**	(452/466)	95.0%, 98.2%	

[a] 2/3 Curian HpSA false negatives were dispositioned as negative by PCR
[b] 8/14 Curian HpSA false positives were dispositioned as positive by PCR

Invalid Results by Curian HpSA assay
Three samples produced invalid results during initial testing with the Curian HpSA assay. The rate of initial invalid results was 0.5% (3/542). After re-testing, the 3 samples had valid negative results. The rate of final invalid results was 0.0%.

ANALYTICAL SENSITIVITY
The Limit of Detection (LoD) of the Curian HpSA assay was determined for *Helicobacter pylori* stool antigens in a negative diluted natural stool matrix (70% natural stool/ 30% physiological saline). Diluted natural stool was used because of difficulties preparing dilutions with neat stool for analytical testing. Diluted stool was used for all analytical studies. The LoD is defined as the lowest concentration of measurand which produced positive results ≥ 95% of the time.
The Curian HpSA assay LoD concentration is 2.0 ng/mL.

ASSAY REACTIVITY/ INCLUSIVITY
A total of 5 strains of *H. pylori* were evaluated for reactivity with the Curian HpSA assay. The final reactive concentrations observed for each strain are shown in the table below.

***H. pylori* strain tested**	**Geographic origin & other information**	**Reactive Concentration**
ATCC 43504	Australia	1.0 x 10^5 CFU/mL
CCUG 38771	Unknown	3.0 x 10^5 CFU/mL
CCUG 19087	South Africa	3.0 x 10^5 CFU/mL
ATCC 700392	UK; clade hpEurope	6.0 x 10^5 CFU/mL
ATCC 700824	US; clade hpAfrica1	3.0 x 10^5 CFU/mL

REPRODUCIBILITY

Ten blinded/coded panels consisting of 16 samples per panel were supplied to three study sites for this study. Each panel consisted of 5 moderately positive samples, 5 low positive samples, 5 high negative samples, and 1 true negative sample. Panel members were generated by spiking *H. pylori* purified flagellar antigen into diluted, natural stool matrix.

Each site used 2 unique operators and tested one panel of samples each day for five days. Positive and negative external controls were tested with each panel. Three Curian HpSA kit lots and 3 Curian Analyzers were used in this study. Each site tested 2 Curian HpSA kit lots using one analyzer. The results of the study are provided in the table below.

Overall Agreement								
	Site 1 Percent Agreement		Site 2 Percent Agreement		Site 3 Percent Agreement		Total Percent Agreement	
Sample Type	**Rate**	**%**	**Rate**	**%**	**Rate**	**%**	**Rate**	**%**
High Negative	44/50	88.0	43/50	86.0	46/50	92.0	133/150	88.7
Low Positive	50/50	100.0	47/50	94.0	50/50	100.0	147/150	98.0
Moderate Positive	49/50	98.0	50/50	100.0	50/50	100.0	149/150	99.3
Negative Control	10/10	100.0	10/10	100.0	10/10	100.0	30/30	100.0
Positive Control	10/10	100.0	10/10	100.0	10/10	100.0	30/30	100.0
True Negative	10/10	100.0	9/10	90.0	10/10	100.0	29/30	96.7

CROSSREACTIVITY/ MICROBIAL INTERFERENCE

The specificity of Curian HpSA was tested utilizing the following bacterial, fungal and viral strains. Each potentially cross-reactive microorganism was added at minimum concentrations of 1.0×10^7 CFU/mL (bacteria/fungi) or 1.0×10^5 $TCID_{50}$/mL (for viruses) to a diluted, natural negative stool matrix and a contrived positive matrix sample. No crossreactivity or microbial interference with the Curian HpSA assay was observed.

Organism Name	**Strain ID**	**Organism Name**	**Strain ID**
Adenovirus 40	Dugan	*Klebsiella pneumoniae*	ATCC 13883
Aeromonas hydrophila	ATCC 35654	*Proteus vulgaris*	CCUG 6380
Bacillus cereus	CCUG 52704	*Pseudomonas aeruginosa*	ATCC 39324
Borrelia burgdorferi	B31.5A19	Rotavirus	WA
Campylobacter coli	ATCC 10956	*Salmonella spp.* Dublin	ATCC 15480
Campylobacter jejuni	ATCC 29411	*Salmonella spp.* Hilversum	ATCC 15784
Candida albicans	ATCC 18804	*Salmonella spp.* Minnesota	ATCC 9700
Citrobacter freundii	ATCC 8090	*Salmonella typhimurium* Group B	ATCC 14028
Clostridium difficile	ATCC 43255	*Shigella boydii*	ATCC 9207
Clostridium perfringens	ATCC 12915	*Shigella dysenteriae*	ATCC 9361
Enterobacter cloacae	ATCC 15337	*Shigella flexneri*	ATCC 12022
Enterococcus faecalis	ATCC 49532	*Shigella sonnei*	ATCC 25931
E. coli O157:H7	ATCC 43895	*Staphylococcus aureus*	ATCC 6538
E. coli	ATCC 9637	*Staphylococcus aureus* Cowan I	ATCC 12598
Escherichia fergusonii	ATCC 35469	*Staphylococcus epidermidis*	ATCC 51625
Haemophilus influenzae	ATCC 9006	*Yersinia enterocolitica*	ATCC 23715

TESTS FOR INTERFERING SUBSTANCES

Interference testing was performed in the presence of chemical and biological substances introduced directly into contrived HpSA low positive and negative samples. No interference was observed with the Curian HpSA assay for any of the substances tested. The substances tested and concentrations evaluated are shown in the table below.

Substance (active ingredient(s))	**Test Concentration**
Barium Sulfate	5% w/v (50 mg/mL)
Benzalkonium chloride	1% v/v
Ciprofloxacin	0.25% w/v (2.5 mg/mL)
Ethanol	1% v/v
Hog gastric mucin	3.5% w/v (35 mg/mL)
Human blood (whole)	40% v/v
Human hemoglobin	12.5% w/v (125 mg/mL)
Human urine	5% v/v
Hydrocortisone	1% w/v (10 mg/mL)
Imodium® (Loperamide HCl, 1 mg/7.5 mL)	5% v/v
Kaopectate® (Bismuth subsalicylate 262 mg/15 mL)	5% v/v
Leukocytes	0.05% v/v
Mesalazine (5-Aminosalicylic acid)	10% w/v (100 mg/mL)
Metronidazole	0.25% w/v (2.5 mg/mL)
MiraLAX® (Polyethylene Glycol 3350, 17 g/dose)	7% w/v (70 mg/mL)
Mineral Oil	10% v/v
Mylanta® (per 10 mL: (Aluminum hydroxide 800 mg, Magnesium hydroxide 800 mg, Simethicone 80 mg)	4.2 mg/mL (2.5% v/v)
Naproxen Sodium	5% w/v (50 mg/mL)
Nonoxynol-9	1% v/v
Nystatin	1% w/v (10 mg/mL)
Palmitic acid (fecal fat)	20% w/v (200 mg/mL)
Pepto-Bismol® (Bismuth subsalicylate 525 mg/30 mL)	5% v/v
Phenylephrine	1% w/v (10 mg/mL)
Prilosec OTC® (Omeprazole 20 mg/tablet)	5 mg/mL
Sennosides	1% w/v (10 mg/mL)
Simethicone	10% v/v
Stearic acid (fecal fat)	20% w/v (200 mg/mL)
Tagamet HB 200® (Cimetidine 200 mg/tablet)	5 mg/mL
TUMS®	5 mg/mL
Vancomycin	0.25% w/v (2.5 mg/mL)