For In Vitro Diagnostic Use

CLIA Complexity: High

Intended Use
The QUANTA Lite™ H. pylori IgA kit is an enzyme-linked immunosorbent assay (ELISA) for the qualitative detection of IgA antibodies to H. pylori (Helicobacter pylori) in human serum. This test is intended to aid in the diagnosis of H. pylori infection in adult patients 18 years or older with clinical signs and symptoms of gastrointestinal disease. The QUANTA Lite™ H. pylori IgA should be performed and interpreted in conjunction with the QUANTA Lite™ H. pylori IgG for the detection of IgG antibodies to H. pylori.

Summary and Explanation of the test
The causal relationship between H. pylori infection and peptic ulcer disease has become well established since it was first proposed in 1983. H. pylori infection is present in over 95% of patients with duodenal ulcers, 80% of patients with gastric ulcers, and is associated with gastric carcinoma and lymphoma. Eradication of H. pylori infection reduces ulcer recurrence. Treatment of H. pylori infection has been recommended for patients with duodenal or gastric ulcers and recently for functional dyspepsia. Diagnosis of H. pylori infection includes both invasive and noninvasive methods. Invasive tests include endoscopy for direct observation of the gastric antral mucosa and for obtaining biopsies for urease testing, histologic staining (Warthin-Starry), and culture. Culture is considered the "gold standard"; however, it is the least sensitive test (70-80% sensitivity). Histologic and urease testing have sensitivities and specificities over 90%. Primary disadvantages of invasive methods are risk and discomfort to the patient, high cost, and false negative results because of the patchy distribution of H. pylori in the stomach. Non-invasive tests include breath testing using 14C or 13C-labeled urea and serological tests. Breath testing is sensitive and specific, but is costly. Serology provides a low cost, sensitive, and specific alternative to invasive and/or costly procedures such as endoscopy and the 14C urea breath test.

In most cases, detection of IgG class antibodies to H. pylori provides accurate determination of H. pylori infection with sensitivities and specificities of over 90%. Approximately 2-7% of patients tested for both H. pylori IgG and IgA antibodies however, have been found to be H. pylori IgG negative, but H. pylori IgA positive. Measurement of only IgG antibodies can therefore miss some true cases of H. pylori infection and result in infected patients not receiving treatment or being subjected to much more expensive and often invasive testing procedures. In addition to detection of some patients who may be missed by IgG H. pylori assays, other studies supporting the clinical utility of measuring IgA H. pylori antibodies include: 1) findings that report high levels of IgA H. pylori antibodies together with low levels of serum pepsinogen I are risk factors for gastric cancer, 2) following treatment, IgA antibody values may decrease more rapidly than IgG values, 3) detection of IgA antibodies to H. pylori may aid in the diagnosis of symptomatic individuals with equivocal or low H. pylori IgG values, and 4) the ratio of IgA/IgG H. pylori antibody values may be related to the grade of H. pylori associated chronic gastritis.

Principles of the Procedure
Purified H. pylori antigen is bound to the wells of a polystyrene microwell plate under conditions that will preserve the antigen in its native state. Pre-diluted controls and diluted patient sera are added to separate wells, allowing any H. pylori antibodies present to bind to the immobilized antigen. Unbound sample is washed away and an enzyme labeled anti-human IgA conjugate is added to each well. A second incubation allows the enzyme labeled anti-human IgA to bind to any patient antibodies, which have become attached to the microwells. After washing away any unbound enzyme labeled anti-human IgA, the remaining enzyme activity is measured by adding a chromogenic substrate and measuring the intensity of the color that develops. The assay can be evaluated spectrophotometrically by measuring and comparing the color intensity that develops in the patient wells with the color in the control wells.

Reagents
1. Polystyrene microwell ELISA plate coated with a purified H. pylori antigen, (12-1 x 8 wells), with holder in foil package containing desiccants
2. ELISA Negative Control, 1 vial of buffer containing preservative and human serum with no human IgA antibodies to H. pylori, prediluted, 1.2mL
3. H. pylori IgA ELISA Low Positive, 1 vial of buffer containing preservative and human serum IgA antibodies to H. pylori, prediluted, 1.2mL
4. H. pylori IgA ELISA High Positive, 1 vial of buffer containing preservative and human serum IgA antibodies to H. pylori, prediluted, 1.2mL
5. HRP Sample Diluent, 1 vial — colored pink containing Tris-buffered saline, Tween 20, protein stabilizers and preservative, 50mL
6. HRP Wash Concentrate, 1 vial of 40x concentrate - colored red containing Tris-buffered saline and Tween 20, 25mL. Refer to the Methods Section for dilution instructions.
7. HRP IgA Conjugate, (goat), anti-human IgA, 1 vial — colorless containing buffer, protein stabilizers and preservative, 10mL
8. TMB Chromogen, 1 vial containing stabilizers, 10mL
9. HRP Stop Solution, 0.344M Sulfuric Acid, 1 vial — colorless, 10mL

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Warnings
1. WARNING: This product contains a chemical (0.02% chloramphenicol) in the sample diluent, controls, and conjugate known to the State of California to cause cancer.
2. All human source material used in the preparation of controls for this product has been tested and found negative for antibody to HIV, HBsAg, and HCV by FDA cleared methods. No test method however can offer complete assurance that HIV, HBsAg, HCV or other infectious agents are absent. Therefore, the H. pylori IgA ELISA Low Positive, H. pylori IgA ELISA High Positive and ELISA Negative Control should be handled in the same manner as potentially infectious material. 10
3. Sodium Azide is used as a preservative. Sodium Azide is a poison and may be toxic if ingested or absorbed through the skin or eyes. Sodium azide may react with lead or copper plumbing to form potentially explosive metal azides. Flush sinks, if used for reagent disposal, with large volumes of water to prevent azide build-up.
4. The HRP conjugate contains a dilute poisonous/corrosive chemical, which may be toxic if ingested in large amounts. To prevent possible chemical burns, avoid contact with skin and eyes.
5. TMB Chromogen contains an irritant, which may be harmful if inhaled, ingested or absorbed through the skin. To prevent injury, avoid inhalation, ingestion or contact with skin and eyes.
6. The HRP Stop Solution consists of a dilute sulfuric acid solution. Avoid exposure to bases, metals, or other compounds, which may react with acids. Sulfuric acid is a poison and corrosive, which may be toxic if ingested. To prevent chemical burns, avoid contact with skin and eyes.
7. Use appropriate personal protective equipment while working with the reagents provided.
8. Spilled reagents should be cleaned up immediately. Observe all federal, state and local environmental regulations when disposing of wastes.

Precautions
1. This product is for In Vitro Diagnostic Use.
2. Substitution of components other than those provided in this system may lead to inconsistent results.
3. Complete or inefficient washing and insufficient liquid removal from the ELISA well strips will cause poor precision and/or high background.
4. Adaptation of this assay for use with automated sample processors and other liquid handling devices, in whole or in part, may yield differences in test results from those obtained using the manual procedure. It is the responsibility of each laboratory to validate that their automated procedure yields test results within acceptable limits.
5. A variety of factors influence the assay performance. These include the starting temperature of the reagents, the ambient temperature, the accuracy and reproducibility of the pipetting technique, the thoroughness of washing and liquid removal from the wells of the ELISA strips, the photometer used to measure the results, and the length of the incubation times during the assay. Careful attention to consistency is required to obtain accurate and reproducible results.
6. Strict adherence to the protocol is recommended.
7. Incomplete resealing of the zip-lock pouch containing microwell strips and desiccants will result in antigen degradation and poor precision.
8. Unacceptably low absorbencies may be observed following two or more uses from a single bottle of HRP conjugate over a period of time. It is important to follow all recommended HRP conjugate handling procedures to prevent this occurrence.
9. Chemical contamination of the HRP conjugate can result from improper cleaning or rinsing of equipment or instruments. Residues from common laboratory chemicals such as formalin, bleach, ethanol, or detergent will cause degradation of the HRP conjugate over time. Thoroughly rinse all equipment or instruments after the use of chemical cleaners/disinfectants.

Storage Conditions
1. Store all the kit reagents at 2-8°C. Do not freeze. Reagents are stable until the expiration date when stored and handled as directed.
2. Unused antigen coated microwell strips should be resealed securely in the foil pouch containing desiccants and stored at 2-8°C.
3. Diluted wash buffer is stable for 1 week at 2-8°C.

Specimen Collection
This procedure should be performed with a serum specimen. Addition of azide or other preservatives to the test samples may adversely affect the results. Microbiially contaminated, heat-treated, or specimens containing visible particulate should not be used. Grossly hemolyzed or lipemic serum or specimens should be avoided.
Following collection, the serum should be separated from the clot. NCCLS Document H18-A recommends the following storage conditions for samples: 1) Store samples at room temperature no longer than 8 hours. 2) If the assay will not be completed within 8 hours, refrigerate the sample at 2-8°C. 3) If the assay will not be completed within 48 hrs, or for shipment of the sample, freeze at -20°C or lower. Frozen specimens must be mixed well after thawing and prior to testing.Repeatedly frozen and thawed specimens are not recommended.
Procedure

Materials provided

1. *H. pylori* IgA ELISA microwell plate, (12-1 x 8 wells), with holder
2. 1.2mL prediluted ELISA Negative Control
3. 1.2mL prediluted *H. pylori* IgA ELISA Low Positive
4. 1.2mL prediluted *H. pylori* IgA ELISA High Positive
5. 50mL HRP Sample Diluent
6. 25mL HRP Wash Concentrate, 40x concentrate
7. 10mL HRP IgA Conjugate, (goat), anti-human IgA
8. 10mL TMB Chromogen
9. 10mL HRP Stop Solution, 0.344M Sulfuric Acid

Additional Materials Required But Not Provided

- Micropipets to deliver 5, 100, 200-300, and 500µL
- Disposable micropipet tips
- Test tubes for patient sample dilutions, 4mL volume
- Distilled or deionized water
- 1L container for diluted HRP Wash Concentrate
- Microwell plate reader capable of measuring OD at 450nm (and 620nm for dual wavelength readings)

Method

Before you start

1. Bring all reagents and samples to room temperature (20-26°C) and mix well.
2. Dilute the HRP Wash Concentrate 1:40 by adding the contents of the HRP Wash Concentrate bottle to 975mL of distilled or deionized water. If the entire plate will not be run within this period, a smaller quantity can be prepared by adding 2.0mL of the concentrate to 78mL of distilled or deionized water for every 16 wells that will be used. The diluted buffer is stable for 1 week at 2-8°C.
3. Prepare a 1:101 dilution of each patient sample by adding 5µL of sample to 500µL of HRP Sample Diluent. Diluted samples must be used within 8 hours of preparation.
4. Determination of the presence or absence of *H. pylori* using arbitrary units requires two wells for each of the three controls and one or two wells for each patient sample. It is recommended that samples be run in duplicate.

Assay procedure

1. **ALL REAGENTS MUST BE BROUGHT TO ROOM TEMPERATURE (20-26°C) PRIOR TO BEGINNING THE ASSAY.** Place the required number of microwells/strips in the holder. Immediately return unused strips to the pouch containing desiccants and seal securely to minimize exposure to water vapor.
2. Add 100µL of the prediluted *H. pylori* IgA ELISA Low Positive, the *H. pylori* IgA ELISA High Positive, the ELISA Negative Control and the diluted patient samples to the wells. Cover the wells and incubate for 30 minutes at room temperature on a level surface. The incubation time begins after the last sample addition.
3. Wash step: Thoroughly aspirate the contents of each well. Add 200-300µL of the diluted HRP Wash buffer to all wells then aspirate. Repeat this sequence twice more for a total of three washes. Invert the plate and tap it on absorbent material to remove any residual fluid after the last wash. It is important to completely empty each well after each washing step. Maintain the same sequence for the aspiration as was used for the sample addition.
4. Add 100µL of the HRP IgA Conjugate to each well. Conjugate should be removed from the bottles using standard aseptic conditions and good laboratory techniques. Remove only the amount of conjugate from the bottle necessary for the assay. **TO AVOID POTENTIAL MICROBIAL AND/OR CHEMICAL CONTAMINATION, NEVER RETURN UNUSED CONJUGATE TO THE BOTTLE.** Incubate the wells for 30 minutes as in step 2.
5. Wash step: Repeat step 3.
6. Add 100µL of TMB Chromogen to each well and incubate in the dark for 30 minutes at room temperature.
7. Add 100µL of HRP Stop Solution to each well. Maintain the same sequence and timing of HRP Stop Solution addition as was used for the TMB Chromogen. Gently tap the plate with a finger to thoroughly mix the wells.
8. Read the absorbance (OD) of each well at 450nm within one hour of stopping the reaction. If bichromatic measurements are desired, 620nm can be used as a reference wavelength.
Quality Control

1. The *H. pylori* IgA ELISA Low Positive, the *H. pylori* IgA ELISA High Positive and the ELISA Negative Control should be run with every batch of samples to ensure that all reagents and procedures perform properly.

2. Note that since the *H. pylori* IgA ELISA Low Positive, the *H. pylori* IgA ELISA High Positive and the ELISA Negative Control are prediluted, they do not control for procedural methods associated with dilution of specimens.

3. Additional controls may be tested according to guidelines or requirements of local, state and/or federal regulations or accrediting organizations. Additional suitable control sera may be prepared by aliquoting pooled human serum specimens and storing at ≤ -20°C.

4. In order for the test results to be considered valid, all of the criteria listed below must be met. If any of these are not met, the test should be considered invalid and the assay repeated.
   
a. The absorbance of the prediluted *H. pylori* IgA ELISA High Positive must be greater than the absorbance of the prediluted *H. pylori* IgA ELISA Low Positive, which must be greater than the absorbance of the prediluted ELISA Negative Control.
   
b. The prediluted *H. pylori* IgA ELISA High Positive must have an absorbance greater than 1.0 while the prediluted ELISA Negative Control absorbance cannot be over 0.2.
   
c. The *H. pylori* IgA ELISA Low Positive absorbance must be more than twice the ELISA Negative Control or over 0.25.
   
d. The ELISA Negative Control and *H. pylori* IgA ELISA High Positive are intended to monitor for substantial reagent failure. The *H. pylori* IgA ELISA High Positive will not ensure precision at the assay cutoff.
   
e. The user should refer to NCCLS Document C24-A11 for additional guidance on appropriate QC practices.

Calculation of Results

The average OD for each set of duplicates is first determined. The reactivity for each sample can then be calculated by dividing the average OD of the sample by the average OD of the *H. pylori* IgA ELISA Low Positive found on the label.

\[
\text{Sample Value} = \frac{\text{Sample OD (units)}}{\text{H. pylori IgA ELISA Low Positive OD (units)}} \times \text{H. pylori IgA ELISA Low Positive (units)}
\]

Reactivity is related to the quantity of antibody present in a non-linear fashion. While increases and decreases in patient antibody concentrations will be reflected in a corresponding rise or fall in reactivity, the change is not proportional (i.e. a doubling of the antibody concentration will not double the reactivity). If a more accurate quantitation of patient antibody is required, serial dilutions of the patient sample should be run and the last dilution to measure positive in the assay should be reported as the patient's antibody titer.

Interpretation of Results

The ELISA assay is very sensitive to technique and is capable of detecting even small differences in patient populations. The values shown below are suggested values only. Each laboratory should establish its own normal range based upon its own techniques, controls, equipment and patient population according to their own established procedures.

Samples are interpreted as negative (negative for IgA antibody to *H. pylori*), equivocal, or positive (IgA antibody to *H. pylori* detected) according to the table below:

<table>
<thead>
<tr>
<th>Units</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Negative</td>
<td>0.0 - 20.0</td>
</tr>
<tr>
<td>Equivocal</td>
<td>20.1 - 24.9</td>
</tr>
<tr>
<td>Positive</td>
<td>≥ 25</td>
</tr>
</tbody>
</table>

Equivocal specimens should be retested before results are reported.

1. The QUANTA Lite™ *H. pylori* IgA ELISA assay should be performed and interpreted in conjunction with the QUANTA Lite™ *H. pylori* IgG ELISA assay for the detection of IgG antibodies to *H. pylori*. Some samples may be *H. pylori* IgA antibody negative and *H. pylori* antibody IgG positive, while others may be *H. pylori* IgA antibody positive and *H. pylori* IgG antibody negative. Adequate performance/interpretation data have not been established for *H. pylori* IgA antibody positive and *H. pylori* IgG antibody negative samples and additional follow-up may be warranted.

2. A positive result only indicates previous immunological exposure to *H. pylori*. It cannot distinguish an active from an inactive *H. pylori* infection. Active infection is assessed by culture of biopsy material, by 14C urea breath test, or by other urease detection methods.

3. A specimen with equivocal levels of *H. pylori* IgA cannot be assessed for antibody status. If the results remain equivocal after repeat testing, the result should be reported as equivocal and/or an additional sample should be taken.
4. A negative result indicates no IgA antibody to \( H. pylori \) or levels below the detection limit of the assay. Specimens taken too early during primary infection may not have detectable levels of IgA antibody. If a primary infection is suspected, another specimen should be taken in 4-6 weeks and tested concurrently in the same assay with the original specimen.

5. It is suggested that the results reported by the laboratory should include: “The following results were obtained with the INOVA QUANTA Lite™ \( H. pylori \) IgA ELISA kit. IgA values obtained with different manufacturers’ assay methods may not be used interchangeably. The magnitude of the reported IgA levels cannot be correlated to an endpoint titer.”

Limitations of the Procedure
1. The presence of immune complexes or other immunoglobulin aggregates in the patient sample may cause an increased level of non-specific binding and produce false positives in this assay.
2. This test is intended to aid in the diagnosis of \( H. pylori \) infection for individuals with symptoms suggestive of gastrointestinal disease and is not intended for use with asymptomatic patients.
3. This test may be used to complement but not to substitute for \( H. pylori \) IgG antibody screening. \( H. pylori \) IgA results on specimens should not be reported without corresponding \( H. pylori \) IgG results on the specimen.
4. A negative \( H. pylori \) IgA result does not rule out the presence of \( H. pylori \) since many individuals with past or present \( H. pylori \) infection may be negative for \( H. pylori \) IgA.
5. A negative \( H. pylori \) IgA antibody result does not rule out the presence of \( H. pylori \) because the concentration of antibody may be below the detection limit of the assay.
6. Negative results may be obtained if specimens are drawn too early in the infection, prior to the appearance of detectable antibodies. If \( H. pylori \) infection is suspected, new samples should be obtained 4-6 weeks later and tested in parallel with the first sample.
7. A positive test result does not allow one to distinguish between active infection and colonization by \( H. pylori \).
8. A positive test result only indicates the presence of antibody to \( H. pylori \) and does not necessarily indicate that gastrointestinal disease is present.
9. The assay performance characteristics have not been established for matrices other than serum.
10. This assay has not been established for patients under 18 years of age.
11. Literature references have suggested that antibodies to Pseudomonas species may cross react with \( H. pylori \). The performance of this assay with sera containing anti-pseudomonas antibodies has not been evaluated.
12. Results of this assay should be used in conjunction with clinical findings and other serological tests.

Expected Values
It has been estimated that approximately 50% of the world population is infected with \( H. pylori \). In developing countries 50% or more of the population is infected with \( H. pylori \) by 10 years of age, while in developed countries childhood infection is infrequent. Seroprevalence of \( H. pylori \) IgG antibodies increases at about 0.5 – 1.0% per year with increasing age (i.e. approximately 60% seroprevalence for the 60 year old age group). \(^3\),\(^7\),\(^13\),\(^14\) Infected individuals have also been shown produce IgA antibodies to \( H. pylori \). A small number (2-7%) of individuals have been found to be positive for \( H. pylori \) IgA antibodies and negative for \( H. pylori \) IgG antibodies \(^12\),\(^15\),\(^16\),\(^18\). The ability of the QUANTA Lite™ \( H. pylori \) IgA ELISA to detect \( H. pylori \) IgA antibodies was evaluated by comparison to a commercially available \( H. pylori \) IgA ELISA and by evaluation of clinically defined patient samples. Results of the commercially available \( H. pylori \) IgA ELISA were determined according to the manufacturer's direction insert.

Normal Range
A panel of 120 specimens collected from asymptomatic, healthy individuals (age range 17-75, median 35) were tested with the QUANTA Lite™ \( H. pylori \) IgA ELISA. Of the 120 specimens, 9% (11/120) were found to be \( H. pylori \) IgA positive. When specimens which were \( H. pylori \) IgG positive or equivocal were excluded, 2.8% (3/105) were positive for \( H. pylori \) IgA antibodies (and negative for \( H. pylori \) IgG antibodies). This results in a calculated specificity of 97.1% (102/105) [95%CI= 91.9-99.4].

Specific Performance Characteristics
The performance of the QUANTA Lite™ \( H. pylori \) IgA ELISA assay was compared to a predicate commercial \( H. pylori \) IgA ELISA. 145 samples submitted for \( H. pylori \) antibody testing, 8 EQAS (external quality assessment scheme), plus 100 samples from asymptomatic, healthy individuals were tested by both assays. Of the 253 samples, 130 were positive and 91 negative by both methods.

Table 1:

<table>
<thead>
<tr>
<th>Predicate ( H. pylori ) IgA ELISA</th>
<th>+</th>
<th>+/-</th>
<th>-</th>
</tr>
</thead>
<tbody>
<tr>
<td>QUANTA Lite™</td>
<td>130</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>( H. pylori ) IgA ELISA</td>
<td>9</td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>4</td>
<td>91</td>
</tr>
</tbody>
</table>

\% Agreement positive: 91.5% (130/142) \( H. pylori \) IgA ELISA
\% Agreement negative: 90.1% (91/101)
Study specimens
A total of 111 archived serum specimens collected from patients with *H. pylori* infection documented by a combination of UBT, CLO, histology and/or culture methods were tested by the Quanta lite *H. pylori* IgA ELISA kit.

Table 2: Reference Method

<table>
<thead>
<tr>
<th>Reference Method</th>
<th>Sensitivity (not excluding equiv.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>QUANTA Lite™ <em>H. pylori</em> IgA ELISA</td>
<td>90.1% (100/111), [95% CI =83.0%-94.9%]</td>
</tr>
</tbody>
</table>

Cross-reactivity Study
An adsorption study was performed to evaluate cross-reactivity of bacterial antigens with the INOVA QUANTA Lite™ *H. pylori* IgA ELISA. Briefly, sera with different levels of antibodies to *H. pylori* were adsorbed with either *H. pylori*, *C. jejuni*, *C. coli*, *C. fetus*, or *E. coli* antigens and samples of untreated and treated sera were tested in the *H. pylori* IgA assay. All *H. pylori* seropositive specimens remained seropositive when absorbed with antigens other than *H. pylori*. The mean percent inhibition was 82% using *H. pylori* antigen and 10% when antigens derived from other organisms were used. Cross-reactivity as a result of the presence of anti-nuclear (3 sera), rheumatoid factor (3 sera), beta-2 microglobulin (3 sera), or *B. burgdorferi* (11 sera) antibodies was also tested and shown not to affect the specificity of the INOVA QUANTA Lite™ *H. pylori* IgA ELISA.

Interference
To determine if the presence of high levels of bilirubin, hemoglobin, cholesterol, or triglycerides in serum specimens interferes with the QUANTA Lite™ *H. pylori* IgA ELISA, two studies were performed. In the first, 6 serum specimens (4 *H. pylori* positive and 2 negative) were tested with and without the addition of bilirubin (40x normal level) or hemoglobin (66x normal). A second study consisted of spiking a positive *H. pylori* sera with sera containing high levels of cholesterol (3), triglycerides (1), or bilirubin (2). Although high levels of bilirubin, hemoglobin, or cholesterol did not appear to interfere with the assay, high triglyceride levels (one specimen) did show some interference.

Reproducibility/Precision
Intra-assay performance was evaluated by testing 6 specimens, including a negative, equivocal, borderline positive, low positive, moderate positive, and high positive specimen 12 times. The results are summarized in Table 3.

Table 3: Intra-assay Performance for QUANTA Lite™ *H. pylori* IgA ELISA

<table>
<thead>
<tr>
<th>Sera 1</th>
<th>Sera 2</th>
<th>Sera 3</th>
<th>Sera 4</th>
<th>Sera 5</th>
<th>Sera 6</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean</td>
<td>52.8</td>
<td>57.0</td>
<td>40.84</td>
<td>15.9</td>
<td>7.00</td>
</tr>
<tr>
<td>S.D.</td>
<td>2.15</td>
<td>2.18</td>
<td>0.72</td>
<td>1.2</td>
<td>0.68</td>
</tr>
<tr>
<td>C.V.%</td>
<td>4.74</td>
<td>3.8</td>
<td>1.77</td>
<td>7.56</td>
<td>9.72</td>
</tr>
</tbody>
</table>

Inter-assay performance was evaluated by testing 13 specimens including negative, low positive, moderate and high positive samples a total of six times over three days. Two runs per day, one in the morning and one in the afternoon. The results are summarized in Table 4.

Table 4: Inter-assay Performance for QUANTA Lite™ *H. pylori* IgA ELISA

<table>
<thead>
<tr>
<th>Sera 1</th>
<th>Sera 2</th>
<th>Sera 3</th>
<th>Sera 4</th>
<th>Sera 5</th>
<th>Sera 6</th>
<th>Sera 7</th>
<th>Sera 8</th>
<th>Sera 9</th>
<th>Sera 10</th>
<th>Sera 11</th>
<th>Sera 12</th>
<th>Sera 13</th>
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</thead>
<tbody>
<tr>
<td>Mean</td>
<td>53.7</td>
<td>6.1</td>
<td>54.7</td>
<td>53</td>
<td>17.5</td>
<td>19.1</td>
<td>43.4</td>
<td>49.4</td>
<td>31.1</td>
<td>5.8</td>
<td>26.7</td>
<td>28.9</td>
</tr>
<tr>
<td>S.D.</td>
<td>1.25</td>
<td>0.25</td>
<td>3.8</td>
<td>3.94</td>
<td>1.65</td>
<td>0.87</td>
<td>1.46</td>
<td>1.97</td>
<td>1.53</td>
<td>0.35</td>
<td>1.38</td>
<td>2.48</td>
</tr>
<tr>
<td>C.V.%</td>
<td>2.3</td>
<td>4.1</td>
<td>6.9</td>
<td>7.4</td>
<td>9.5</td>
<td>4.6</td>
<td>3.4</td>
<td>4.0</td>
<td>4.9</td>
<td>6.0</td>
<td>5.2</td>
<td>8.6</td>
</tr>
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References


Manufactured By:
INOVA Diagnostics, Inc.
9900 Old Grove Road
San Diego, CA 92131
United States of America

Authorized Representative in the EU:
Medical Technology Promedt Consulting GmbH
Altenhofstrasse 80
D-66386 St. Ingbert, Germany
Tel.: +49-6894-581020
Fax.: +49-6894-581021
www.mt-procons.com

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