Pepsinogen I ELISA Assay Kit

Catalog Number:
PP131-K01 (1 x 96 wells)

For Research Use Only. Not for use in diagnostic procedures.

v. 2.0 (08.27.15)
INTENDED USE
The Eagle Biosciences Human Pepsinogen I ELISA Assay Kit (enzyme-linked immunoassay kit) is intended for the quantitative determination of human pepsinogen I levels in serum. The Eagle Biosciences Human Pepsinogen I ELISA Assay Kit is for research use only and not to be used in diagnostic procedures.

INTRODUCTION
Pepsinogen consists of a single polypeptide chain of 375 amino acids with an average molecular weight of 42 kDa. Pepsinogen I is synthesized at gastric chief cells and mucous neck cells, while pepsinogen II is produced not only by gastric chief cells, mucous neck cells, but also by clear mucous cells of antrum, etc. The clinical applications of measuring pepsinogen I and pepsinogen II are of useful aid in diagnosing severe atrophic gastritis and stomach cancer. It was suggested that the measurement of serum pepsinogens served as a “serological biopsy” for predicting the presence of atrophic gastritis or superficial gastritis.

Atrophic Gastritis: It was found that a serum pepsinogen I level failed to less than 20 ng/ml was highly specific for severe atrophic gastritis. It is also observed that serum pepsinogen I levels fell with increasing severity of mucosal damage in atrophic gastritis. The diagnostic sensitivity and specificity of serum pepsinogen I level for advanced atrophic corpus gastritis are about 92% and 90% respectively. On the other hand, the decrease in serum pepsinogen I levels in patients with pernicious anemia and atrophic gastritis was found to be associated with normal or raised pepsinogen II levels. Therefore, a pepsinogen I/pepsinogen II ratio is significantly lower than those with superficial gastritis or normal remnant mucosa.

Stomach Cancer: Low serum pepsinogen I levels were found in patients with gastric cancer, with a threefold higher incidence. Other studies have concluded that low serum pepsinogen I levels may identify persons at increased risk for intestinal types of stomach cancer.

Duodenal Ulcer: A low serum pepsinogen I level can exclude a diagnosis of duodenal ulcer. Although a high pepsinogen I level has less clinical useful for establishing the diagnosis of a duodenal ulcer, the combination of hypergastrinemia and a highly elevated serum pepsinogen I strongly suggests the possibility of the Zollinger-Ellison syndrome.

PRINCIPLE OF THE ASSAY
The Eagle Biosciences Human Pepsinogen I ELISA Assay Kit is designed, developed and produced for the quantitative measurement of human pepsinogen I level in serum sample. The assay utilizes the two-site “sandwich” technique with two selected monoclonal antibodies that bind to different epitopes of human pepsinogen I without any cross-reaction to human pepsinogen II.

Assay standards, controls and patient serum samples containing human pepsinogen I is added directly to microtiter wells of microplate that was coated with a streptavidin. Simultaneously, a biotinylated antibody and a horseradish peroxidase conjugated antibody are added to each well. After the first incubation period, on the wall of microtiter well captures the biotinylated antibody as well as an immuno complex in the form of “streptavidin – biotin-antibody – pepsinogen I–HRP-antibody”. Unbound proteins as well as unbound HRP conjugated antibody in each microtiter well are removed in the subsequent washing step. The well is incubated with a substrate solution in a timed reaction and then measured in a spectrophotometric microplate reader. The enzymatic activity of the tracer antibody bound to the pepsinogen I on the wall of
the microtiter well is directly proportional to the amount of pepsinogen I in the sample. A
standard curve is generated by plotting the absorbance versus the respective human
pepsinogen I concentration for each standard on Point-to-Point, CubicSpline or 4-Parameter
plot. The concentration of human pepsinogen I in test samples is determined directly from this
standard curve.

REAGENTS: Preparation and Storage
This test kit must be stored at 2 – 8°C upon receipt. For the expiration date of the kit refer to the
label on the kit box. All components are stable until the expiration date. Allow all reagents to
come to room temperature prior to use. Reagents from different kit lot numbers should not be
combined or interchanged.

1. Streptavidin Coated Microplate
   One microplate with 12 x eight strips (96 wells total) coated with streptavidin. The plate
   is framed and sealed in a foil Ziploc bag with a desiccant. This reagent should be stored
   at 2 – 8°C and is stable until the expiration date on the Pepsinogen I ELISA Assay Kit box.

2. Pepsinogen I Tracer Antibody
   One vial contains 0.6 mL concentrated horseradish peroxidase (HRP) conjugated anti-
   human pepsinogen I tracer antibody in a stabilized protein matrix. This reagent must be
diluted with Tracer Antibody Diluent before use. This reagent should be stored at 2 – 8°C
   and is stable until the expiration date on the Pepsinogen I ELISA Assay Kit box.

3. Pepsinogen I Capture Antibody
   One vial contains 0.6 mL concentrated biotinylated anti-human pepsinogen I capture
   antibody in a stabilized protein matrix. This reagent must be diluted with Tracer Antibody
   Diluent before use. This reagent should be stored at 2 – 8°C and is stable until the
   expiration date on the Pepsinogen I ELISA Assay Kit box.

4. Tracer Antibody Diluent
   One vial contains 12 mL ready to use buffer. It should be only used for tracer antibody
dilution according to the assay procedures. This reagent should be stored at 2 – 8°C and
   is stable until the expiration date on the Pepsinogen I ELISA Assay Kit box.

5. ELISA Wash Concentrate
   One bottle contains 30 mL of 30 fold concentrate. Before use the contents must be
diluted with 870 mL of distilled water and mix well. Upon dilution this yields a working
wash solution containing a surfactant in phosphate buffered saline with a non-azide
preservative. The diluted solution should be stored at room temperature and is stable
until the expiration date on the Pepsinogen I ELISA Assay Kit box.

6. ELISA HRP Substrate
   One bottle contains 12 mL of tetramethylbenzidine (TMB) with hydrogen peroxide. This
   reagent should be stored at 2 – 8°C and is stable until the expiration date on the
   Pepsinogen I ELISA Assay Kit box.

7. ELISA STOP SOLUTION
One bottle contains 12 mL of 0.5 M sulfuric acid. This reagent should be stored at 2 – 8°C or room temperature and is stable until the expiration date on the Pepsinogen I ELISA Assay Kit box.

8. Pepsinogen I Standards
Six vials each contain lyophilized human pepsinogen I in a bovine serum albumin based matrix with a non-azide preservative. Refer to vial for exact concentration for each standard. All the standards should be reconstituted with DI-water and stored at -20°C or below after the first use with up to 3 freeze cycles.

9. Pepsinogen I Controls
Two vials each contain lyophilized human pepsinogen I in a bovine serum albumin based matrix with a non-azide preservative. Refer to vials for exact concentration range for each control. Both controls should be reconstituted with DI-water and store at -20°C or below after the first use with up to 3 freeze cycles.

SAFETY PRECAUTIONS
The Human Pepsinogen I ELISA Assay Kit reagents must be used in a professional laboratory environment and is for Research Use Only and is not to be used in diagnostic procedures. Only source material from which reagents of bovine serum was derived in the contiguous 48 United States. It was obtained only from donor health animals maintained under veterinary supervision and found free of contagious diseases. Wear gloves while performing this assay and handle these reagents as if they were potentially infectious. Avoid contact with reagents containing TMB, hydrogen peroxide, or sulfuric acid. TMB may cause irritation to skin and mucous membranes and cause an allergic skin reaction. TMB is a suspected carcinogen. Sulfuric acid may cause severe irritation on contact with skin. Do not get in eyes, on skin, or on clothing. Do not ingest or inhale fumes. On contact, flush with copious amounts of water for at least 15 minutes. Use Good Laboratory Practices.

MATERIALS REQUIRED BUT NOT PROVIDED
- Precision single channel pipettes capable of delivering 15 µL, 50 µL, 100 µL, and 1000 µL etc.
- Repeating dispenser suitable for delivering 100 µL.
- Disposable pipette tips suitable for above volume dispensing.
- Disposable 12 x 75 mm or 13 x 100 glass or plastic tubes.
- Disposable plastic 1000 mL bottle with caps.
- Aluminum foil.
- Deionized water.
- Plastic microtiter well cover or polyethylene film.
- ELISA multichannel wash bottle or automatic (semi-automatic) washing system.
- Spectrophotometric microplate reader capable of reading absorbance at 450nm.

SPECIMEN COLLECTION
Only 50 µL of human serum is required for human pepsinogen I measurement in duplicate. No special preparation of individual is necessary prior to specimen collection. However, it is recommend drawing a 10 hour fasting serum sample for the test. Whole blood should be collected and must be allowed to clot for minimum 30 minutes at room temperature before the serum is separated by centrifugation (850 – 1500xg for 10 minutes). The serum should be separated from the clot within three hours of blood collection and transferred to a clean test
tube. Serum samples should be stored at –20°C or below until measurement. Avoid repeated more than three times freezing and thawing of specimen.

**Reagent Preparation**

1. Prior to use allow all reagents to come to room temperature. Reagents from different kit lot numbers should not be combined or interchanged.
2. ELISA Wash Concentrate must be diluted to working solution prior use. Please see REAGENTS section for details.
3. Reconstitute all assay standards and controls by adding 1.0 mL of demineralized water to the vial of standard level 1 and 0.5 mL demineralized water to the vials of standard level 2 - 6 and control 1 & 2. Allow the standards and controls to sit undisturbed for 10 minutes, and then mix well by gentle vortexing. One must make sure that all solid is dissolved completely prior to use. These reconstituted standards and controls must be stored at -10°C or below. Do not exceed 3 freeze-thaw cycles.
4. Place a sufficient number of streptavidin coated microwell strips in a holder to run human pepsinogen I standards, controls and unknown samples in duplicate.
5. **Test Configuration**

<table>
<thead>
<tr>
<th>ROW</th>
<th>STRIP 1</th>
<th>STRIP 2</th>
<th>STRIP 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>STD 1</td>
<td>STD 5</td>
<td>SAMPLE 1</td>
</tr>
<tr>
<td>B</td>
<td>STD 1</td>
<td>STD 5</td>
<td>SAMPLE 1</td>
</tr>
<tr>
<td>C</td>
<td>STD 2</td>
<td>STD 6</td>
<td>SAMPLE 2</td>
</tr>
<tr>
<td>D</td>
<td>STD 2</td>
<td>STD 6</td>
<td>SAMPLE 2</td>
</tr>
<tr>
<td>E</td>
<td>STD 3</td>
<td>C 1</td>
<td>SAMPLE 3</td>
</tr>
<tr>
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<td>STD 3</td>
<td>C 1</td>
<td>SAMPLE 3</td>
</tr>
<tr>
<td>G</td>
<td>STD 4</td>
<td>C 2</td>
<td></td>
</tr>
<tr>
<td>H</td>
<td>STD 4</td>
<td>C 2</td>
<td></td>
</tr>
</tbody>
</table>

6. Prepare working Tracer Antibody and Capture Antibody mixture by 1:21 fold dilution of the Pepsinogen I Tracer Antibody and the Pepsinogen I Capture Antibody with the Tracer Antibody Diluent. For each strip, it is required to mix 1 mL of Tracer Antibody Diluent with the addition of 50 µL of Tracer Antibody and 50 µL Capture Antibody in a clean test tube or vial. Following is a table that outlines the relationship of strips used and antibody mix prepared.

<table>
<thead>
<tr>
<th>Strip no.</th>
<th>Tracer Antibody Diluent</th>
<th>Tracer Antibody</th>
<th>Capture Antibody</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1 mL</td>
<td>50 µL</td>
<td>50 µL</td>
</tr>
<tr>
<td>2</td>
<td>2 mL</td>
<td>100 µL</td>
<td>100 µL</td>
</tr>
<tr>
<td>3</td>
<td>3 mL</td>
<td>150 µL</td>
<td>150 µL</td>
</tr>
<tr>
<td>4</td>
<td>4 mL</td>
<td>200 µL</td>
<td>200 µL</td>
</tr>
<tr>
<td>5</td>
<td>5 mL</td>
<td>250 µL</td>
<td>250 µL</td>
</tr>
<tr>
<td>6</td>
<td>6 mL</td>
<td>300 µL</td>
<td>300 µL</td>
</tr>
<tr>
<td>7</td>
<td>7 mL</td>
<td>350 µL</td>
<td>350 µL</td>
</tr>
<tr>
<td>8</td>
<td>8 mL</td>
<td>400 µL</td>
<td>400 µL</td>
</tr>
<tr>
<td>9</td>
<td>9 mL</td>
<td>450 µL</td>
<td>450 µL</td>
</tr>
<tr>
<td>10</td>
<td>10 mL</td>
<td>500 µL</td>
<td>500 µL</td>
</tr>
<tr>
<td>11</td>
<td>11 mL</td>
<td>550 µL</td>
<td>550 µL</td>
</tr>
<tr>
<td>12</td>
<td>12 mL</td>
<td>600 µL</td>
<td>600 µL</td>
</tr>
</tbody>
</table>

**Note:** this antibody mix should be freshly prepared right before running the assay.
**Manual Assay Procedure**

1. Add 25 µL of standards, controls and patient serum samples into the designated microwell.
2. Add 100 µL of above antibody mixture to each well.
3. Mix gently and cover the plate with one plate sealer and also with aluminum foil to avoid exposure to light.
4. Incubate plate at room temperature for 1 hour.
5. Remove the aluminum foil and plate sealer. Aspirate the contents of each well. Wash each well 5 times by dispensing 350 µL of working wash solution into each well and then completely aspirating the contents. Alternatively, an automated microplate washer can be used.
6. Add 100 µL of ELISA HRP Substrate into each of the wells.
7. Cover the plate with one new plate sealer and also with aluminum foil to avoid exposure to light.
8. Incubate plate at room temperature for 20 minutes (This incubation period may be reduced to 8 – 15 min if a lower OD reading is demanded to fit to the plate readers specification).
9. Remove the aluminum foil and plate sealer. Add 100 µL of ELISA Stop Solution into each of the wells. Mix gently.
10. Read the absorbance at 450 nm within 10 minutes in a microplate reader.

**Assay Procedure on Automated ELISA System**

1. Add 25 µL of standards, controls and patient serum samples into the designated microwell.
2. Add 100 µL of above antibody mixture to each well.
3. Incubate plate with initial shaking for 1 minutes and further incubation at 37°C for 45 minutes.
4. Wash each well 5 times by dispensing 350 µL of working wash solution into each well and then completely aspirating the contents.
5. Add 100 µL of ELISA HRP Substrate into each of the wells.
6. Incubate plate at 37°C for 15 minutes.
7. Add 100 µL of ELISA Stop Solution into each of the wells. Mix gently.
8. Read the absorbance at 450 nm

**Note:** The above automated ELISA procedure has been performed on DS2 system. A satisfactory patient sample correlation was observed between the manual and automated assay procedures ($r = 0.943, \text{ slope } = 1.0958$). One may adjust the procedure according to different automated ELISA system used in each laboratory.

**PROCEDURAL NOTES**

1. It is recommended that all standards, controls and unknown samples be assayed in duplicate. The average absorbance reading of each duplicate should be used for data reduction and the calculation of results.
2. Keep light sensitive reagents in the original bottles and avoid unnecessary exposure to the light.
3. Store any unused antibody coated strips in the foil Ziploc bag with desiccant to protect from moisture.
4. Careful technique and use of properly calibrated pipetting devices are necessary to ensure reproducibility of the test.
5. Incubation times or temperatures other than those stated in this insert may affect the results.
6. Avoid air bubbles in the microwell as this could result in lower binding efficiency and higher CV% of duplicate reading.
7. All reagents should be mix gently and thoroughly prior use. Avoid foaming.

**INTERPRETATION OF RESULTS**

1. Calculate the average absorbance for each pair of duplicate test results.
2. Subtract the average absorbance of the STD 1 (0 ng/mL) from the average absorbance of all other readings to obtain corrected absorbance.
3. The standard curve is generated by the corrected absorbance of all standard levels on the ordinate against the standard concentration on the abscissa using point-to-point or log-log paper. Appropriate computer assisted data reduction programs may also be used for the calculation of results.
4. It is recommended to use following curve fits: (1) Point-to-Point, or (2) 4-Parameter or (3) CubicSpline.

The human pepsinogen I concentrations for the controls and patient samples are read directly from the standard curve using their respective corrected absorbance. If log-log graphic paper or computer assisted data reduction program utilizing logarithmic transformation are used, sample having corrected absorbance between the second standard and the next highest standard should be calculated by the formula:

\[
\text{Value of unknown} = \frac{\text{Corrected Absorbance (unknown)}}{\text{Corrected Absorbance (2nd STD)}} \times \text{Value of the 2nd STD}
\]
EXAMPLE DATA AND STANDARD CURVE
A typical absorbance data and the resulting standard curve from Human Pepsinogen I ELISA Assay Kit are represented. This curve should not be used in lieu of standard curve run with each assay.

<table>
<thead>
<tr>
<th>Well I.D.</th>
<th>OD 450/650 nm Absorbance</th>
<th>Results ng/mL</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Readings</td>
<td>Average</td>
</tr>
<tr>
<td>0 ng/mL</td>
<td>0.053</td>
<td>0.050</td>
</tr>
<tr>
<td>3 ng/mL</td>
<td>0.119</td>
<td>0.118</td>
</tr>
<tr>
<td>10 ng/mL</td>
<td>0.262</td>
<td>0.246</td>
</tr>
<tr>
<td>30 ng/mL</td>
<td>0.616</td>
<td>0.622</td>
</tr>
<tr>
<td>90 ng/mL</td>
<td>1.565</td>
<td>1.387</td>
</tr>
<tr>
<td>300 ng/mL</td>
<td>2.766</td>
<td>2.604</td>
</tr>
<tr>
<td>Control 1</td>
<td>0.373</td>
<td>0.363</td>
</tr>
<tr>
<td>Control 2</td>
<td>1.692</td>
<td>1.587</td>
</tr>
</tbody>
</table>
EXPECTED VALUES
Seventy-three normal adult sera were measured with this Human Pepsinogen I ELISA assay Kit. The expected normal range is listed in the following table with different percentile cut-off and the median level of this group of population is 62.8 ng/mL.

<table>
<thead>
<tr>
<th>Percentile Cut-off</th>
<th>Normal Range (ng/mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>95%</td>
<td>25 – 200</td>
</tr>
<tr>
<td>90%</td>
<td>30 – 150</td>
</tr>
<tr>
<td>85%</td>
<td>40 – 120</td>
</tr>
<tr>
<td>80%</td>
<td>40 – 100</td>
</tr>
</tbody>
</table>

It is highly recommend that each laboratory should establish their own normal range for pepsinogen I based on local populations.

Subjects with atrophic gastritis, as well as subjects with stomach cancer would have a pepsinogen I level below 20 ng/mL.

LIMITATION OF THE PROCEDURE
1. Since there is no Gold Standard concentration available for human pepsinogen I measurement, the values of assay standards were established by diluting a highly purified human pepsinogen I in a protein matrix.
2. For unknown sample value read directly from the assay is greater than 300 ng/mL, it is recommend to measure a further diluted sample for more accurate measurement.
3. If there is not a microplate reader in your laboratory being able to read beyond 2.0 at OD 450 nm, one can adjust the computer program for an assay without the standard level 6 from the standard set.
4. Bacterial or fungal contamination of serum specimens or reagents, or cross contamination between reagents may cause erroneous results.
5. Water deionized with polyester resins may inactive the horseradish peroxidase enzyme.

QUALITY CONTROL
To assure the validity of the results each assay should include adequate controls with known pepsinogen I levels. We recommends that all assays include the laboratory’s own human serum based pepsinogen I controls in addition to those provided with this kits.
PERFORMANCE CHARACTERISTICS

Sensitivity
The sensitivity of this Human Pepsinogen I ELISA Assay Kit is 0.1 ng/mL as determined by measuring zero standard 16 times in the same assay and calculating the detection limit at 3 standard deviation above the pepsinogen I zero standard. Whereas the assay analytical sensitivity is approximately 0.5 ng/mL.

Specificity
This assay measures human pepsinogen I without any cross-reaction to human pepsinogen II.

Linearity
Two human serum samples were diluted with assay buffer and assayed. The results in the value of ng/mL are as follows:

<table>
<thead>
<tr>
<th>#</th>
<th>DILUTION</th>
<th>OBSERVED VALUE</th>
<th>EXPECTED VALUE</th>
<th>RECOVERY %</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Neat</td>
<td>31.90</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>1:2</td>
<td>16.21</td>
<td>15.95</td>
<td>102</td>
</tr>
<tr>
<td></td>
<td>1:4</td>
<td>7.95</td>
<td>7.78</td>
<td>102</td>
</tr>
<tr>
<td></td>
<td>1:8</td>
<td>3.73</td>
<td>3.99</td>
<td>93</td>
</tr>
<tr>
<td></td>
<td>1:16</td>
<td>2.11</td>
<td>1.99</td>
<td>106</td>
</tr>
<tr>
<td>2</td>
<td>Neat</td>
<td>252.00</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>1:2</td>
<td>125.27</td>
<td>126.00</td>
<td>99</td>
</tr>
<tr>
<td></td>
<td>1:4</td>
<td>64.12</td>
<td>63.00</td>
<td>102</td>
</tr>
<tr>
<td></td>
<td>1:8</td>
<td>31.25</td>
<td>31.50</td>
<td>99</td>
</tr>
<tr>
<td></td>
<td>1:16</td>
<td>16.92</td>
<td>15.75</td>
<td>107</td>
</tr>
</tbody>
</table>

Precision
The intra-assay precision is validated by measuring two samples in a single assay with 20-replicate determinations.

<table>
<thead>
<tr>
<th>Mean Pepsinogen I Value (ng/mL)</th>
<th>CV (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>18.2</td>
<td>5.3</td>
</tr>
<tr>
<td>121.1</td>
<td>4.8</td>
</tr>
</tbody>
</table>

The inter-assay precision is validated by measuring two control samples in duplicate in 12 individual assays.

<table>
<thead>
<tr>
<th>Mean Pepsinogen I Value (ng/mL)</th>
<th>CV (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>17.5</td>
<td>6.9</td>
</tr>
<tr>
<td>123.7</td>
<td>5.7</td>
</tr>
</tbody>
</table>
**Recovery**

Two patient samples were spiked with various amounts of human pepsinogen I and assayed. The results in the value of ng/mL are as follows:

<table>
<thead>
<tr>
<th></th>
<th>Orig. Value</th>
<th>Amount Spiked</th>
<th>Observed Value</th>
<th>Expected Value</th>
<th>Recovery %</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>18.6</td>
<td>10</td>
<td>12.6</td>
<td>14.3</td>
<td>88</td>
</tr>
<tr>
<td></td>
<td></td>
<td>30</td>
<td>25.1</td>
<td>24.3</td>
<td>103</td>
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<tr>
<td></td>
<td></td>
<td>90</td>
<td>56.2</td>
<td>54.3</td>
<td>103</td>
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<tr>
<td>2</td>
<td>121.1</td>
<td>10</td>
<td>61.3</td>
<td>65.6</td>
<td>93</td>
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<tr>
<td></td>
<td></td>
<td>30</td>
<td>70.9</td>
<td>75.6</td>
<td>94</td>
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<tr>
<td></td>
<td></td>
<td>90</td>
<td>104.7</td>
<td>105.6</td>
<td>99</td>
</tr>
</tbody>
</table>

**“Hook” Effect**

It was determined that this pepsinogen I ELISA did not show any high dose “hook” effect up to 10,000 ng/mL of pepsinogen I.

**REFERENCES**

11. Shumakov AR, Fedorov SN, Kalinovskii VP, Khanson KP.
Warranty Information

Eagle Biosciences, Inc. warrants its Product(s) to operate or perform substantially in conformance with its specifications, as set forth in the accompanying package insert. This warranty is expressly limited to the refund of the price of any defective Product or the replacement of any defective Product with new Product. This warranty applies only when the Buyer gives written notice to the Eagle Biosciences within the expiration period of the Product(s) by the Buyer. In addition, Eagle Biosciences has no obligation to replace Product(s) as result of a) Buyer negligence, fault, or misuse, b) improper use, c) improper storage and handling, d) intentional damage, or e) event of force majeure, acts of God, or accident.

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For further information about this kit, its application or the procedures in this kit, please contact the Technical Service Team at Eagle Biosciences, Inc. at info@eaglebio.com or at 866-411-8023.