INTENDED USE

The Diagnostic Automation, Inc. Myeloperoxidase (MPO) Test System is intended for the qualitative and semi-quantitative detection of IgG-class antibody to myeloperoxidase in human serum. The Test System is intended to be used as an aid in the diagnosis of various autoimmune vasculitic disorders characterized by elevated levels of anti-neutrophil cytoplasmic antibodies (ANCA). MPO-ANCA may be associated with autoimmune disorders such as Wegener’s granulomatosis, ICGN, MPA and PRS. This test is for In Vitro diagnostic use.

SUMMARY AND EXPLANATION

Anti-neutrophil cytoplasmic antibody (ANCA). Since this initial discovery, scientists have associated ANCA with a number of Systemic Vasculitides (SV). Scientists now recognize ANCA to include two primary specificities: C-ANCA directed against Proenzyme-3 (PR-3), and P-ANCA directed against Myeloperoxidase (MPO). Testing for both P-ANCA and C-ANCA is highly recommended in the laboratory workup of patients who present with clinical features suggestive of SV. The clinical syndromes most frequently associated with ANCA are as follows:

Wegener’s granulomatosis
Polyarteritis
"Overlap" Vasculitis
Idiopathic Crescentic Glomerulonephritis (ICGN)
Kawasaki Disease

Although the initial identification of C-ANCA and P-ANCA was based on the indirect immunofluorescence procedures, further identification and purification of PR-3 and MPO has resulted in the development of enzyme immunoassays (ELISA) for both PR-3 and MPO.

TEST PRINCIPLE

The Diagnostic Automation Myeloperoxidase (MPO) ELISA test system is designed to detect IgG class antibodies to MPO in human sera. Wells of plastic microwell strips are sensitized by passive adsorption with MPO antigen. The test procedure involves three incubation steps:

1. Test sera (properly diluted) are incubated in antigen coated microwells. Any antigen specific antibody in the sample will bind to the immobilized antigen. The plate is washed to remove unbound antibody and other serum components.
2. Peroxidase Conjugated goat anti-human IgG (Fc chain specific) is added to the wells and the plate is incubated. The Conjugate will react with IgG antibody immobilized on the solid phase in step 1. The wells are washed to remove unreacted Conjugate.
3. The microwells containing immobilized peroxidase Conjugate are incubated with peroxidase Substrate Solution. Hydrolysis of the Substrate by peroxidase produces a color change. After a period of time the reaction is stopped and the color intensity of the solution is measured photometrically. The color intensity of the solution depends upon the antibody concentration in the original test sample.

SPECIMEN COLLECTION AND PREPARATION

1. It is recommended that specimen collection be carried out in accordance with CLSI document M29: Protection of Laboratory Workers from Infectious Disease (Current Edition).
2. No known test method can offer complete assurance that human blood samples will not transmit infection. Therefore, all blood derivatives should be considered potentially infectious.
3. Only freshly drawn and properly refrigerated sera obtained by approved aseptic venipuncture procedures should be used in this assay. No anticoagulants or preservatives should be added. Avoid using hemolyzed, lipemic, or bacterially contaminated sera.
4. Store sample at room temperature for no longer than 8 hours. If testing is not performed within 8 hours, sera may be stored between 2-8°C for no longer than 48 hours. If delay in testing is anticipated, store test sera at ~20°C or lower. Avoid multiple freeze/thaw cycles that may cause loss of antibody activity and give erroneous results. It is the responsibility of the individual laboratory to use all available references and/or its own studies to determine stability criteria for its laboratory.

MATERIALS AND COMPONENTS

Each Test System contains the following components in sufficient quantities to perform the number of tests indicated on packaging label.

NOTE: The following components contain Sodium Azide as a preservative at a concentration of < 0.1% w/v: Controls, Calibrators and Sample Diluent.

Materials provided with the test kits

Reactive Reagents
1. Plate: 96 wells configured in twelve, 1x8- well, strips coated with inactivated Myeloperoxidase antigen. The strips are packaged in a strip holder and sealed in an envelope with desiccant.
2. Conjugate: Conjugated (horseradish peroxidase) goat anti-human IgG (Fc chain specific). One, 15 mL, white- capped bottle. Ready to use.
3. Positive Control (Human Serum): One, 0.35 mL, red- capped, vial.
4. Calibrator (Human Serum): One, 0.5 mL, blue- capped vial.
5. Negative Control (Human Serum): One, 0.35 mL, green- capped vial.
6. Sample Diluent: One, 30 mL, green- capped, bottle containing Tween-20, bovine serum albumin and phosphate-buffered-saline, (pH 7.2 ± 0.2). Ready to use. Note: The Diluent will change color when combined with serum.
Materials required but not provided
1. ELISA microwell reader capable of reading at a wavelength of 450nm.
2. Pipettes capable of accurately delivering 10 to 200µL.
3. Multichannel pipette capable of accurately delivering 50-200µL.
4. Reagent reservoirs for multichannel pipettes.
5. Wash bottle or microwell washing system.
6. Distilled or deionized water.
7. Pipettes capable of accurately delivering 50µL.
8. Disposable pipette tips.
10. Laboratory timer to monitor incubation steps.
11. Disposal basin and disinfectant. (Example: 10% household bleach - 0.5% sodium hypochlorite.)

ASSAY PROCEDURE

1. Remove the individual component from storage and allow them to warm to room temperature (20-25°C.)
2. Determine the number of microwells needed. Allow six Control/Calibrator determinations (one Reagent Blank, one Negative Control, three Calibrators and one Positive Control) per run. Run a Reagent Blank on each assay. Check software and reader requirements for the correct Controls/Calibrator configurations. Return unused strips to the resealable pouch with desiccant, seal, and return to storage between 2°C and 8°C.

<table>
<thead>
<tr>
<th>EXAMPLE PLATE SET-UP</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
</tr>
<tr>
<td>A</td>
</tr>
<tr>
<td>B</td>
</tr>
<tr>
<td>C</td>
</tr>
<tr>
<td>D</td>
</tr>
<tr>
<td>E</td>
</tr>
<tr>
<td>F</td>
</tr>
<tr>
<td>G</td>
</tr>
<tr>
<td>H</td>
</tr>
</tbody>
</table>

3. Prepare a 1:21 dilution (e.g.: 10µL of serum + 200µL of Sample Diluent) of the Negative Control, Calibrator, Positive Control, and each patient serum. The sample diluent will undergo a color change confirming that the specimen has been combined with the diluent.
4. To individual wells, add 100µL of each diluted control, calibrator and patient specimen. Ensure that the samples are properly mixed. Use a different pipette tip for each sample.
5. Add 100µL of Sample Diluent to well A1 as a reagent blank. Check software and reader requirements for the correct reagent blank well configuration.
6. Incubate the plate at room temperature (20-25°C) for 25 ± 5 minutes.
7. Wash the microwell strips 5 times.

Test System also contains:

a. Component Label containing lot specific information inside the Test System box.
b. Package Insert providing instructions for use.

A. Manual Wash Procedure:
   a. Vigorously shake out the liquid from the wells.
   b. Fill each microwell with Wash Buffer. Make sure no air bubbles are trapped in the wells.
   c. Repeat steps a. and b. for a total of 5 washes.
   d. Shake out the wash solution from all the wells. Invert the plate over a paper towel and tap firmly to remove any residual wash solution from the wells. Visually inspect the plate to ensure that no residual wash solution remains. Collect wash solution in a disposable basin and treat with disinfectant at the end of the day’s run.

B. Automated Wash Procedure:
   If using an automated microwell wash system, set the dispensing volume to 300-350µL/well. Set the wash cycle for 5 washes with no delay between washes. If necessary, the microwell plate may be removed from the washer, inverted over a paper towel and tapped firmly to remove any residual wash solution from the microwells.

8. Add 100µL of the Conjugate to each well, including reagent blank well, at the same rate and in the same order as the specimens.
9. Incubate the plate at room temperature (20-25°C) for 25 ± 5 minutes.
10. Wash the microwells by following the procedure as described in step 7.
11. Add 100µL of TMB to each well, including reagent blank well, at the same rate and in the same order as the specimens.
12. Incubate the plate at room temperature (20-25°C) for 10 to 15 minutes.
13. Stop the reaction by adding 50µL of Stop Solution to each well, including reagent blank well, at the same rate and in the same order as the TMB. Positive samples will turn from blue to yellow. After adding the Stop Solution, tap the plate several times to ensure that the samples are thoroughly mixed.
14. Set the microwell reader to read at a wavelength of 450nm and measure the optical density (OD) of each well against the reagent blank. The plate should be read within 30 minutes after the addition of the Stop Solution.

ABBREVIATED TEST PROCEDURE

1. Dilute Serum 1:21.
2. Add diluted sample to microwell - 100µL/well. Incubate 25 ± 5 minutes.
3. Wash.
4. Add Conjugate - 100µL/well. Incubate 25 ± 5 minutes.
5. Wash.
6. Add TMB - 100µL/well. Incubate 10 - 15 minutes.
7. Add Stop Solution - 50µL/well. Mix.
8. READ within 30 minutes.

RESULTS

The Calibrator within this Test System has been assigned both a Correction Factor for the generation of Index Values and a Calibrator Value for the generation of Unit Values. Based upon testing of normal and disease-state specimens, a maximum normal Unit Value has been determined by the manufacturer and correlated to the Calibrator.

1. Calculations:
   A. Correction Factor
      The manufacturer determined a Cutoff OD Value for positive samples and correlated it to the Calibrator. The Correction Factor (CF) allows for the determination of the Cutoff Value for positive samples. It will also correct for slight day-to-day variations in test results. The Correction Factor is determined for each lot of components and is printed on the Component Label located in the Test System box.
   B. Cutoff OD Value
      To obtain the cutoff OD value, multiply the CF by the mean OD of the Calibrator determined above. (CF x mean OD of Calibrator = cutoff OD value)
C. **Index Values or OD Ratios**

Calculate the Index Value or OD Ratio for each specimen by dividing its OD value by the cutoff OD from step 2.

**Example:**

<table>
<thead>
<tr>
<th>Mean OD of Calibrator</th>
<th>Correction Factor (CF)</th>
<th>Cut off OD</th>
<th>Unknown Specimen OD</th>
<th>Specimen Index Value or OD Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.793</td>
<td>0.25</td>
<td>0.793 x 0.25 = 0.198</td>
<td>0.432</td>
<td>0.432 / 0.198 = 2.18</td>
</tr>
</tbody>
</table>

D. **Conversion of Optical Density to AAU/mL:** The conversion of OD to Unit Value (AAU/mL) can be represented by the following equation:

Test Specimen AAU/mL = \((A \times B) / C\)  

Where: AAU/mL = Unknown Unit Value to be determined;  
A = OD of the test specimen in question;  
B = Unit Value of the Positive Calibrator (AAU/mL)  
C = The mean OD of the Calibrator.

**Example:**

<table>
<thead>
<tr>
<th>Test Specimen OD = 0.946</th>
<th>Test Specimen AAU/mL = ((0.946 \times 155)/0.435)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calibrator OD = 0.435</td>
<td>Test Specimen = (337) AAU/mL</td>
</tr>
<tr>
<td>Calibrator Unit Value = (155) AAU/mL</td>
<td></td>
</tr>
</tbody>
</table>

2. **Interpretations:**

Index Values or OD ratios are interpreted as follows:

<table>
<thead>
<tr>
<th>Unit Values</th>
<th>Index Value or OD Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>Negative Specimens</td>
<td>&lt;150 AAU/mL ≤ 0.90</td>
</tr>
<tr>
<td>Equivocal Specimens</td>
<td>150 to 180 AAU/mL 0.91 to 1.09</td>
</tr>
<tr>
<td>Positive Specimens</td>
<td>&gt;180 AAU/mL ≥ 1.10</td>
</tr>
</tbody>
</table>

Retest specimens with OD Ratio Values in the equivocal range (0.91 – 0.99) in duplicate. Report any two of the three results which agree. Evaluate repeatedly equivocal specimens using an alternate serological method and/or re-evaluate by drawing another sample one to three weeks later.

**QUALITY CONTROL**

1. Each time the assay is run the Calibrator must be run in triplicate. A reagent Blank, Negative Control, and Positive Control must also be included in each assay.

2. Calculate the mean of the three Calibrator wells. If any of the three values differ by more than 15% from the mean, discard that value and calculate the mean using the remaining two wells.

3. The mean OD value for the Calibrator and the OD values for the Positive and Negative Controls should fall within the following ranges:

<table>
<thead>
<tr>
<th>OD Range</th>
<th>Negative Control</th>
<th>Calibrator</th>
<th>Positive Calibrator</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>≤0.250</td>
<td>≥0.300</td>
<td>≥0.500</td>
</tr>
</tbody>
</table>

a. The OD of the Negative Control divided by the mean OD of the Calibrator should be ≤ 0.9.

b. The OD of the Positive Control divided by the mean OD of the Calibrator should be ≥ 1.25.

c. If the above conditions are not met the test should be considered invalid and should be repeated.

4. The Positive Control and Negative Control are intended to monitor for substantial reagent failure and will not ensure precision at the assay cut-off.

5. Additional controls may be tested according to guidelines or requirements of local, state, and/or federal regulations or accrediting organizations.

6. Refer to CLSI document C24: Statistical Quality Control for Quantitative Measurements Procedures, for guidance on appropriate QC practices.

**PERFORMANCE CHARACTERISTICS**

A. **Comparative Study**

Performance of an in-house comparative study demonstrated the equivalence of the DAI ELISA MPO Test System to another commercially available ELISA. Performance was evaluated using 316 samples; 196 disease-state samples, 113 samples which were sent to a reference laboratory in the Northeastern United States for routine ANCA serology, and 7 samples which were previously tested and found to be reactive for ANCA. A summary of the clinical samples appears in Table 1 below. Summarized results of the investigation appear in Table below:

<table>
<thead>
<tr>
<th>Table 1</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>AGE</th>
<th>n</th>
<th>Male</th>
<th>Female</th>
<th>High</th>
<th>Low</th>
<th>Mean</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>45</td>
<td>18</td>
<td>27</td>
<td>82</td>
<td>34</td>
<td>54.7</td>
<td></td>
<td></td>
</tr>
<tr>
<td>41</td>
<td>21</td>
<td>20</td>
<td>100</td>
<td>22</td>
<td>63.2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>41</td>
<td>16</td>
<td>25</td>
<td>87</td>
<td>20</td>
<td>63.1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>39</td>
<td>17</td>
<td>22</td>
<td>94</td>
<td>11</td>
<td>60.8</td>
<td></td>
<td></td>
</tr>
<tr>
<td>30</td>
<td>15</td>
<td>15</td>
<td>78</td>
<td>3</td>
<td>43.4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>Information Not Available</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>113</td>
<td>Information Not Available</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

B. **Reproducibility**

Six samples were tested to assess reproducibility; three positive, one near the cut off zone, and two negative. Each sample was tested once a day, in replicates of eight for three days resulting in 24 data points. The intra-assay and inter-assay precision was calculated from the resulting data. The results of the tests are presented in Table below.

| Table 2 |

<table>
<thead>
<tr>
<th>DAI ELISA MPO Test System</th>
<th>Positive</th>
<th>Negative</th>
<th>Equivocal*</th>
<th>Totals</th>
</tr>
</thead>
<tbody>
<tr>
<td>Commercial ELISA Test System</td>
<td>+</td>
<td>93</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>-</td>
<td>2</td>
<td>195</td>
<td>4</td>
<td>201</td>
</tr>
<tr>
<td>Equivocal*</td>
<td>6</td>
<td>12</td>
<td>1</td>
<td>19</td>
</tr>
<tr>
<td>Totals</td>
<td>101</td>
<td>329</td>
<td>6</td>
<td>316</td>
</tr>
</tbody>
</table>

**Relative Sensitivity = 93 / 95 = 97.9%  
95% Confidence Interval** **95.0 to 100%**

Relative Specificity = 195 / 197 = 98.9% - 95% Confidence Interval 97.6 to 99.9%

Relative Agreement = 288 / 292 = 98.6% - 95% Confidence Interval 97.3 to 99.9%

Equivocal specimens were excluded from all calculations.

**95% confidence intervals calculated using the exact method**

C. **Cross Reactivity**

A study was performed to evaluate the assay for potential cross reactivity to other autoantibodies. Eight specimens, which were positive for antibodies to nuclear antigens (ANA) on HEp-2 cells were tested. The results showed that two of the specimens demonstrated a homogeneous pattern, two demonstrated a nucleolar pattern, and six demonstrated a pattern characteristic of ANCA.
pattern, two demonstrated a centromere pattern, and two demonstrated a speckled pattern. For the summary of the results of this study, see Table below. The results of this investigation indicate that cross reactivity with other antinuclear antibodies is unlikely.

### Table 4. Results of the Cross Reactivity Investigation

<table>
<thead>
<tr>
<th>Sample No.</th>
<th>Pattern</th>
<th>Endpoint Titer</th>
<th>Optical Density</th>
<th>AAU/mL</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Homogeneous</td>
<td>1:1280</td>
<td>0.02</td>
<td>36</td>
</tr>
<tr>
<td>2</td>
<td>Homogeneous</td>
<td>1:640</td>
<td>0.01</td>
<td>15</td>
</tr>
<tr>
<td>3</td>
<td>Speckled</td>
<td>1:2560</td>
<td>0.02</td>
<td>30</td>
</tr>
<tr>
<td>4</td>
<td>Nucleolar</td>
<td>1:1280</td>
<td>0.01</td>
<td>25</td>
</tr>
<tr>
<td>5</td>
<td>Centromere</td>
<td>1:1280</td>
<td>0.02</td>
<td>28</td>
</tr>
<tr>
<td>6</td>
<td>Centromere</td>
<td>1:1280</td>
<td>0.01</td>
<td>10</td>
</tr>
<tr>
<td>7</td>
<td>Speckled</td>
<td>1:5120</td>
<td>0.02</td>
<td>30</td>
</tr>
<tr>
<td>8</td>
<td>Nucleolar</td>
<td>1:10240</td>
<td>0.00</td>
<td>5</td>
</tr>
</tbody>
</table>

### LIMITATIONS OF PROCEDURE

1. A diagnosis should not be made on the basis of anti-MPO ELISA results alone. The results for anti-MPO should be interpreted in conjunction with the clinical evaluation and the results of other diagnostic procedures.
2. The performance characteristics of this device have not been established for lipemic, hemolyzed and icteric specimens; therefore, these specimens should not be tested with this assay.
3. The results of this assay are not diagnostic proof of the presence or absence of disease. Immunosuppressive therapy should not be started based on a positive result.

### EXPECTED VALUES

Diagnostic Automation, Inc. evaluated 90 normal donor sera from Southwestern United States for Myeloperoxidase autoantibodies. Of the 90 tested, no samples were positive. In another study using 113 specimens, which were sent to a reference laboratory in Northeastern United States, eight (8/113 = 7.1%) were positive for anti-Myeloperoxidase IgG. Taken together, these studies demonstrate that the incidence of IgG antibody to Myeloperoxidase is relatively rare.

### PRECAUTIONS

1. For In Vitro Diagnostic Use
2. Follow normal precautions exercised in handling laboratory reagents. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. Wear suitable protective clothing, gloves, and eye/face protection. Do not breathe vapor. Dispose of waste observing all local, state, and federal laws.
3. The wells of the Slide do not contain viable organisms. However, consider the Slide potentially bio-hazardous materials and handle accordingly.
4. The Controls are potentially bio-hazardous materials. Source materials from which these products were derived were found negative for HIV-1 antigen, HBsAg and for antibodies against HCV and HIV by approved test methods. However, since no test method can offer complete assurance that infectious agents are absent, these products should be handled at the Bio-safety Level 2 as recommended for any potentially infectious human serum or blood specimen in the Centers for Disease Control/National Institutes of Health manual “ Biosafety in Microbiological and Biomedical Laboratories”: current edition; and OSHA’s Standard for Bloodborne Pathogens.
5. Adherence to the specified time and temperature of incubations is essential for accurate results. All reagents must be allowed to reach room temperature (20 - 25°C) before starting the assay. Return unused reagents to refrigerated temperature immediately after use.
6. Improper washing could cause false positive or false negative results. Be sure to minimize the amount of any residual wash solution; (e.g., by blotting

or aspiration) before adding Conjugate or Substrate. Do not allow the wells to dry out between incubations.
7. The Sample Diluent, Controls, Conjugate and Wash Buffer contain Sodium Azide at a concentration of < 0.1% (w/v). Sodium Azide has been reported to form lead or copper azides in laboratory plumbing which may cause explosions on hammering. To prevent, rinse sink thoroughly with water after disposing of solution containing Sodium Azide.
8. The Stop Solution is TOXIC if inhaled, has contact with skin or if swallowed. It can cause burns. In case of accident or ill feelings, seek medical advice immediately.
9. The TMB Solution is HARMFUL. It is irritating to eyes, respiratory system and skin.
10. The Wash Buffer concentrate is an IRRITANT. It is irritating to eyes, respiratory system and skin.
11. Wipe the bottom of the plate free of residual liquid and/or fingerprints that can alter optical density (OD) readings.
12. Dilution or adulteration of these reagents may generate erroneous results.
13. Do not use reagents from other sources or manufacturers.
14. TMB Solution should be colorless, very pale yellow, very pale green, or very pale blue when used. Contamination of the TMB with conjugate or other oxidants will cause the solution to change color prematurely. Do not use the TMB if it is noticeably blue in color.
15. Never pipette by mouth. Avoid contact of reagents and patient specimens with skin and mucous membranes.
16. Avoid microbial contamination of reagents. Incorrect results may occur.
17. Cross contamination of reagents and/or samples could cause erroneous results.
18. Reusable glassware must be washed and thoroughly rinsed free of all detergents.
19. Avoid splashing or generation of aerosols.
20. Do not expose reagents to strong light during storage or incubation.
21. Allowing the microwell strips and holder to equilibrate to room temperature prior to opening the protective envelope will protect the wells from condensation.
22. Collect the wash solution in a disposal basin. Treat the waste solution with disinfectant (i.e.: 10% household bleach - 0.5% Sodium Hypochlorite). Avoid exposure of reagents to bleach fumes.
23. Caution: Liquid waste at acid pH should be neutralized before adding to bleach solution.
24. Do not use ELISA plate if the indicator strip on the desiccant pouch has turned from blue to pink.
25. Do not allow the conjugate to come in contact with containers or instruments that may have previously contained a solution utilizing sodium azide as a preservative. Residual amounts of sodium azide may destroy the conjugate’s enzymatic activity.
26. Do not expose any of the reactive reagents to bleach-containing solutions or to any strong odors from bleach-containing solutions. Trace amounts of bleach (sodium hypochlorite) may destroy the biological activity of many of the reactive reagents within this kit.

### STORAGE

<table>
<thead>
<tr>
<th>Temperature</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>2-8°C</td>
<td>Coated: Microwell Strips Immediately reseal extra strips with desiccant and return to proper storage. After opening – strips are stable for 60 days, as long as the indicator strips on the desiccant pouch remains blue.</td>
</tr>
<tr>
<td>2-8°C</td>
<td>Conjugate – DO NOT FREEZE</td>
</tr>
<tr>
<td>2-8°C</td>
<td>Unopened Test System, Calibrator, Positive Control, Negative Control, TMB, Sample Diluent</td>
</tr>
<tr>
<td>2-25°C</td>
<td>Stop Solution: 2 - 25°C Wash Buffer (1X): 20-25°C for up to 7 days, 2-8°C for 30 days. Wash Buffer (10X): 2-25°C</td>
</tr>
<tr>
<td>2-25°C</td>
<td>Wash Buffer (10X): 2-25°C</td>
</tr>
</tbody>
</table>
REFERENCES