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SERODIA®-TP·PA
(For In Vitro Diagnostic Use)

Passive Particle Agglutination Test for Detection of antibodies to Treponema Pallidum
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1. **PRINCIPLE OF THE PROCEDURE**

SERODIA-TP·PA kit is manufactured using gelatin particle carriers sensitized with purified pathogenic Treponema Pallidum (Nichols Strain). The test is based on the principle that sensitized particles are agglutinated by the presence of antibodies to Treponema Pallidum in human serum/plasma.

2. **INTENDED USE**

SERODIA-TP·PA is an in vitro Passive Particle Agglutination Assay for the detection of antibodies to Treponema Pallidum in Serum or plasma specimens.

3. **FEATURES**

SERODIA-TP·PA offers following features:

(1) Simple test procedure: The test does not require special equipment and the procedure utilizes standard "U" shaped microtray, it is suitable for the testing of small number of specimens as well as mass screening.

(2) Short reaction time: The procedure allows for visual interpretations to be made after a two-hour incubation.

(3) High specificity: The kit uses artificial particles, specifically developed by Fujirebio Inc. as carriers. These particles can minimize the nonspecific agglutination usually observed with use of other carriers.

4. **KIT COMPONENTS**

The kit contains sufficient reagents to perform 100, 220, 550, and 600 qualitative tests. Each kit contains the following reagents and accessories:
<table>
<thead>
<tr>
<th>Reagents</th>
<th>Reconstituting Solution</th>
<th>Sample Diluent</th>
<th>Sensitized Particles</th>
<th>Unsensitized Particles</th>
<th>Positive Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>Screening: 100 (20×5)</td>
<td>8 mL × 1 vial</td>
<td>29 mL × 1 vial</td>
<td>0.6 mL* × 5 vials</td>
<td>0.6 mL* × 5 vials</td>
<td>0.5 mL × 1 vial</td>
</tr>
<tr>
<td>Screening: 220 (55×4)</td>
<td>18 mL × 1 vial</td>
<td>60 mL × 1 bottle</td>
<td>1.5 mL* × 4 vials</td>
<td>1.5 mL* × 4 vials</td>
<td>0.5 mL × 1 vial</td>
</tr>
<tr>
<td>Screening: 550 (110×5)</td>
<td>18 mL × 2 vials</td>
<td>60 mL × 2 bottles</td>
<td>3.0 mL* × 5 vials</td>
<td>3.0 mL* × 5 vials</td>
<td>0.5 mL × 1 vial</td>
</tr>
<tr>
<td>Screening: 600 (300×2)</td>
<td>18 mL × 2 vials</td>
<td>60 mL × 2 bottles</td>
<td>8.0 mL* × 2 vials</td>
<td>8.0 mL* × 2 vials</td>
<td>0.5 mL × 1 vial</td>
</tr>
</tbody>
</table>

* After Reconstitution

A) Reconstituting Solution (Liquid)
Use for reconstitution of Sensitized Particles and Unsensitized Particles. This reagent contains 0.06% (w/v) of sodium azide per vial as a preservative.

B) Sample Diluent (Liquid)
Use for dilution of Specimens. This reagent contains 0.10% (w/v) of sodium azide per vial as a preservative.

C) Sensitized Particles (Lyophilized)
Lyophilized preparation of gelatin particles coated with Treponema Pallidum. Reconstituted by adding prescribed quantity of Reconstituting Solution. The reconstituted solution contains 0.08% (w/v) of sodium azide per vial as a preservative.

D) Unsensitized Particles (Lyophilized)
Lyophilized preparation of tanned gelatin particles. Reconstituted by adding prescribed quantity of Reconstituting Solution. The reconstituted solution contains 0.08% (w/v) of sodium azide per vial as a preservative.
E) Positive Control (Liquid)

This control is prepared from rabbit serum containing antibodies to T. Pallidum. The control should show a titer of 1:320 (final dilution) when tested according to the procedure described in Table 2. This reagent contains 0.10% (w/v) of sodium azide as a preservative.

Accessories: Droppers (25 μL): 2 droppers (20 × 5, 55 × 4, 110 × 5)
4 droppers (300 × 2)

The droppers are designed for the sole purpose of dispensing the reconstituted Sensitized and Unsensitized particles.

5. MATERIALS REQUIRED BUT NOT PROVIDED

Prepare the following laboratory equipment before testing:

(1) Fastec-U microplate
(2) Diluters 25 μL (0.025 mL)
(3) Calibrated pipette droppers 25 μL (0.025 mL)
(4) Pipettes Micropipette and Volumetric pipettes
(5) Droppers
(6) Plate Mixer (automatic vibratory shaker)*
(7) Plate Viewer
(8) Tips

*Do not use rotator

6. PREPARATION

(1) Preparation of specimens:
Erythrocytes of other visible components present in the serum or plasma samples should be removed by centrifugation prior to testing in order to prevent interference with test results. Serum inactivation has no affect on test result. Do not inactivate plasma.

(2) Reconstitution of lyophilized particles:
Reconstitute Sensitized and Unsensitized Particles with
prescribed quantity of Reconstituting Solution, respectively, at room temperature (15-30°C) 30 minutes prior to use. In order to obtain suitable test results, make sure to mix the Sensitized and Unsensitized Particles thoroughly before testing.

(3) After adding Sensitized and Unsensitized Particles into the microplate wells, mix the contents of the wells THOROUGHLY.

(4) During the incubation, cover the microplate and keep free from vibration.

(5) The positive control should be processed at least once on the day of testing or when a batch of specimen are run.

7. TEST PROCEDURE

The test procedure is as follows:

(1) QUALITATIVE TEST (see Table 1 for further details)

1) Place 4 drops (100 μL) of Sample Diluent in well #1, and 1 drop (25 μL) in wells #2 through #4 using calibrated pipette dropper.

2) Add 25 μL of specimen to well #1 using micropipette.

3) Fill the micropipette or a diluter with 25 μL of the diluted solution well #1 and mix well. Transfer 25 μL of the mixture of specimen and Sample Diluent into well #2. Then mix well and repeat this procedure again with wells #2, #3, and #4 to obtain serial doubling dilutions.

4) Place 1 drop (25 μL) of Unsensitized Particles in well #3, 1 drop (25 μL) of Sensitized Particles in well #4 using droppers supplied in the kit.

5) Mix the contents of the wells thoroughly (for approximately 30 seconds) using a plate mixer (automatic vibratory shaker). DO NOT USE ROTATOR. Then cover the plate and let it stand at room temperature (15-30°C) for 2 hours before reading. The incubation can be extended to overnight without any perceptible difference in patterns.
Table 1. QUALITATIVE TEST PROCEDURES (SUMMARY)

<table>
<thead>
<tr>
<th>WELL NO.</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample Diluent (μL)</td>
<td>100</td>
<td>25</td>
<td>25</td>
<td>25</td>
</tr>
<tr>
<td>Test Specimen (μL)</td>
<td>25</td>
<td>25</td>
<td>25</td>
<td>25</td>
</tr>
<tr>
<td>Test Specimen Dilution</td>
<td>1:5</td>
<td>1:10</td>
<td>1:20</td>
<td>1:40</td>
</tr>
<tr>
<td>Unsensitized Particles (μL)</td>
<td>25</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sensitized Particles (μL)</td>
<td></td>
<td>25</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Final Dilution</td>
<td></td>
<td>1:40</td>
<td>1:80</td>
<td></td>
</tr>
</tbody>
</table>

Mix the content using a plate mixer, cover the plate and incubate for 2 hours

It is recommended that specimens showing positive reactions and/or indeterminate in the Qualitative Assay be confirmed in the Quantitative Assay for accurate interpretation.

(2) QUANTITATIVE TEST (see Table 2 for further details)

1) Place 4 drops (100 μL) of Sample Diluent in well #1 and drop 1 drop (25 μL) in wells #2 through #12.

2) Add 25 μL of specimen to well #1, using micropipette.

3) Fill the micropipette or a diluter with 25 μL of the diluted solution well #1 and mix well. Transfer 25 μL of the mixture of specimen and Sample Diluent into well #2. Then mix well and repeat this procedure again to well #12 to obtain serial doubting dilutions.

4) Place 1 drop (25 μL) of Unsensitized Particles in well #3, 1 drop (25 μL) of Sensitized Particles in wells #4 through #12 using droppers supplied in the kit.

5) Mix the contents of the wells thoroughly (for approximately
30 seconds) using plate mixer (automatic vibratory shaker). DO NOT USE ROTATOR. Then cover the plate and let it stand at room temperature (15-30°C) for 2 hours before reading. The incubation can be extended to overnight without any perceptible difference in patterns.

(3) CONTROL TESTS
1) Confirm that each specimen reacts negatively (at the final dilution titer of 1:40) with Unsensitized Particles.

2) Confirm that the Sample Diluent reacts negatively with both Sensitized and Unsensitized Particles for each test run (reagents control).

3) Confirm that the titer of the Positive Control is 1:320 (at the final dilution) for the Sensitized Particles for each test kit (see Table 2).

Table 2. QUANTITATIVE AND POSITIVE CONTROL TEST PROCEDURES (SUMMARY)

<table>
<thead>
<tr>
<th>Well No.</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>12</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample Diluent (μL)</td>
<td>100</td>
<td>25</td>
<td>25</td>
<td>25</td>
<td>25</td>
<td>25</td>
<td>25</td>
</tr>
<tr>
<td>Test Specimen or Positive Control (μL)</td>
<td>25</td>
<td>25</td>
<td>25</td>
<td>25</td>
<td>25</td>
<td>25</td>
<td>(discard)</td>
</tr>
<tr>
<td>Test Specimen Dilution</td>
<td>1:5</td>
<td>1:10</td>
<td>1:20</td>
<td>1:40</td>
<td>1:80</td>
<td>1:160</td>
<td>1:10,240</td>
</tr>
<tr>
<td>Unsensitized Particles (μL)</td>
<td>25</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sensitized Particles (μL)</td>
<td>25</td>
<td>25</td>
<td>25</td>
<td>25</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Final Dilution</td>
<td>1:40</td>
<td>1:80</td>
<td>1:160</td>
<td>1:320</td>
<td>1:20,480</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Mix the content using a plate mixer, cover the plate and incubate for 2 hours

Interpretation
8. **INTERPRETATION OF RESULTS**

Place the microplate gently on a plate viewer, compare the agglutination patterns with those of the reagents control and interpret according to the criteria shown in Table 3.

<table>
<thead>
<tr>
<th>Settling Patterns of Particles</th>
<th>Reading</th>
</tr>
</thead>
<tbody>
<tr>
<td>Particles concentrated in the shape of a button in the center of the well with a smooth round outer margin</td>
<td>(−)</td>
</tr>
<tr>
<td>Particles concentrated in the shape of a compact ring with a smooth round outer margin</td>
<td>(±)</td>
</tr>
<tr>
<td>Definite large ring with a rough multiform outer margin and peripheral agglutination</td>
<td>(+)</td>
</tr>
<tr>
<td>Agglutinated particles spread out covering the bottom of the well uniformly</td>
<td>(++)</td>
</tr>
</tbody>
</table>

*Specimens which show an indeterminate result (±) should be retested following the Table 1 Test Procedure and test results shall be interpreted according to the criteria in Table 3. A repeated ± should be confirmed by other methods for accurate interpretation.

9. **CRITERIA FOR INTERPRETATION**

Positive
A specimen showing (−) with Unsensitized Particles (1:40 final dilution) but demonstrating (+) with Sensitized Particles (1:80 final dilution or more) is interpreted as POSITIVE. In quantitative tests, the antibody titer is determined as the final dilution giving a (+) pattern.

Negative
Regardless of the reading of the reaction pattern with Unsensitized Particles, a specimen showing (−) with Sensitized Particles (1:80 final dilution) is interpreted as NEGATIVE.
Indeterminate
A specimen which showing (−) with Unsensitized Particles (1:40 final dilution) and demonstrating (±) with Sensitized Particles (1:80 final dilution) is interpreted as INDETERMINATE.

*For specimens showing positive or indeterminate results with SERODIA-TP·PA test, the results should be confirmed by testing with other methods and retesting on another day using a specimen freshly collected. A comprehensive assessment of the patient's condition should comprise the careful analysis of the patient's clinical symptoms and interpretation of results of available tests for the disease.

10. ABSORPTION PROCEDURE
If a specimen causes agglutination with both Unsensitized and Sensitized Particles or shows indeterminate, it should be retested after the following absorption procedure.

1) Place 0.95 mL of reconstituted Unsensitized Particles in a small test tube.

2) Add 50 μL of specimen into the tube and mix thoroughly. Then, incubate at room temperature (15-30°C) for 20 minutes or more (mix one or twice during incubation).

3) Centrifuge for 5 minutes at 2,000 rpm. Take the supernatant (absorbed 1:20 diluted specimen) carefully, then place 50 μL in well #3 of the microplate.

4) Place 1 drop (25 μL) of Sample Diluent in wells #4 through #12. Using a diluter or a micropipette, prepare serial doubling dilutions from wells #3 through #12.

5) Place 1 drop (25 μL) of Unsensitized Particles in well #3, 1 drop (25 μL) of Sensitized Particles in wells #4 through #12 using droppers supplied in the kit.

6) Mix the contents of the wells thoroughly (for approximately 30
seconds) using a plate mixer (automatic vibratory Shaker). **DO NOT USE ROTATOR.** Then cover the plate and let it stand at room temperature (15-30°C) for 2 hours before reading. The incubation can be extended to overnight without any perceptible difference in patterns.

11. PERFORMANCE CHARACTERISTICS

1) **Specificity**
   When 496 SERODIA-TP non-reactive samples were tested by SERODIA-TP·PA, all samples were negative. The specificity was 100% (95% confidence limits: 98.04-100%).

2) **Sensitivity**
   When 391 SERODIA-TP reactive samples were tested by SERODIA-TP·PA, all samples were positive. The sensitivity was 100% sensitivity (95% confidence limits: 98.04-100%).

3) **Reproducibility**
   When 3 in-house reference samples (final dilution 1:160 or more) were tested 5 consecutive times respectively according to the test procedure, all results were found to be within ±1 doubling dilution.

4) **Positive Primary and Secondary Samples**
   100 Venereal Disease Research Laboratory (VDRL) and Rapid Plasma Reagin (RPR) reactive Syphilis sera, obtained from patients medically diagnosed with primary and secondary stage disease, were used for the evaluation of the SERODIA-TP·PA. Half of the patients were on penicillin therapy at the time the blood sample was drawn. This panel consisted of specimens from 27 treated-primary infection, 23 untreated primary infection, 24 treated-secondary stage, and 26 untreated-secondary stage patients. All specimens were positive by SERODIA-TP·PA. Incubating-stage syphilis samples were not specifically identified and tested in these studies.
5) Influence by Biological substances
The following biological substances were investigated in respect to their influence on the test result. They were added to make below-mentioned concentrations in the in-house reference samples, which consist of 3 Positive specimens and 3 Negative specimens.
As all results are found to be within $\pm 1$ doubling dilution, specimens are acceptable for testing if they do not exceed any of the concentration written in Table 4.

Table 4. INFLUENCE BY BIOLOGICAL SUBSTANCES

<table>
<thead>
<tr>
<th>Biological substances &amp; concentrations</th>
<th>No.1</th>
<th>No.2</th>
<th>No.3</th>
<th>No.4</th>
<th>No.5</th>
<th>No.6</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bilirubin (mg/dL)</td>
<td>Not added</td>
<td>1:160</td>
<td>1:640</td>
<td>1:2560</td>
<td>$&lt;1:80$</td>
<td>$&lt;1:80$</td>
</tr>
<tr>
<td></td>
<td>6.45</td>
<td>1:160</td>
<td>1:640</td>
<td>1:2560</td>
<td>$&lt;1:80$</td>
<td>$&lt;1:80$</td>
</tr>
<tr>
<td></td>
<td>12.9</td>
<td>1:160</td>
<td>1:640</td>
<td>1:2560</td>
<td>$&lt;1:80$</td>
<td>$&lt;1:80$</td>
</tr>
<tr>
<td></td>
<td>21.5</td>
<td>1:160</td>
<td>1:640</td>
<td>1:2560</td>
<td>$&lt;1:80$</td>
<td>$&lt;1:80$</td>
</tr>
<tr>
<td>Free Bilirubin (mg/dL)</td>
<td>Not added</td>
<td>1:160</td>
<td>1:640</td>
<td>1:5120</td>
<td>$&lt;1:80$</td>
<td>$&lt;1:80$</td>
</tr>
<tr>
<td></td>
<td>5.25</td>
<td>1:160</td>
<td>1:640</td>
<td>1:2560</td>
<td>$&lt;1:80$</td>
<td>$&lt;1:80$</td>
</tr>
<tr>
<td></td>
<td>10.5</td>
<td>1:160</td>
<td>1:640</td>
<td>1:2560</td>
<td>$&lt;1:80$</td>
<td>$&lt;1:80$</td>
</tr>
<tr>
<td></td>
<td>17.5</td>
<td>1:160</td>
<td>1:640</td>
<td>1:5120</td>
<td>$&lt;1:80$</td>
<td>$&lt;1:80$</td>
</tr>
<tr>
<td>Hemolytic Hemoglobin (mg/dL)</td>
<td>Not added</td>
<td>1:160</td>
<td>1:640</td>
<td>1:2560</td>
<td>$&lt;1:80$</td>
<td>$&lt;1:80$</td>
</tr>
<tr>
<td></td>
<td>168</td>
<td>1:160</td>
<td>1:640</td>
<td>1:2560</td>
<td>$&lt;1:80$</td>
<td>$&lt;1:80$</td>
</tr>
<tr>
<td></td>
<td>336</td>
<td>1:160</td>
<td>1:640</td>
<td>1:2560</td>
<td>$&lt;1:80$</td>
<td>$&lt;1:80$</td>
</tr>
<tr>
<td></td>
<td>560</td>
<td>1:160</td>
<td>1:640</td>
<td>1:2560</td>
<td>$&lt;1:80$</td>
<td>$&lt;1:80$</td>
</tr>
<tr>
<td>Chylomicron (Turbidity)</td>
<td>Not added</td>
<td>1:160</td>
<td>1:640</td>
<td>1:2560</td>
<td>$&lt;1:80$</td>
<td>$&lt;1:80$</td>
</tr>
<tr>
<td></td>
<td>700</td>
<td>1:160</td>
<td>1:640</td>
<td>1:2560</td>
<td>$&lt;1:80$</td>
<td>$&lt;1:80$</td>
</tr>
<tr>
<td></td>
<td>1400</td>
<td>1:160</td>
<td>1:640</td>
<td>1:2560</td>
<td>$&lt;1:80$</td>
<td>$&lt;1:80$</td>
</tr>
<tr>
<td></td>
<td>2300</td>
<td>1:160</td>
<td>1:640</td>
<td>1:2560</td>
<td>$&lt;1:80$</td>
<td>$&lt;1:80$</td>
</tr>
</tbody>
</table>

6) Potential Cross Reactors
To evaluate the potential cross reactors, 174 samples confirmed
positive for each respective disease condition, were assayed by the SERODIA-TP·PA and SeraTek MHA-TP Assay, which is a hemagglutination test kit. The total number of disease categories and reactive result is listed in Table 5. SERODIA-TP·PA showed no difference in results as compared to SeraTek MHA-TP Assay, in the samples evaluated. SERODIA-TP·PA reactive patients were also reactive with the SeraTek MHA-TP Assay, but further evaluation by the Fluorescent Treponema Pallidum absorption (FTA-ABS) was not performed.

Table 5. POTENTIAL CROSS REACTORS

<table>
<thead>
<tr>
<th>Category</th>
<th>Number Tested</th>
<th>SERODIA-TP·PA Number Reactive</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drug Users</td>
<td>10</td>
<td>1</td>
</tr>
<tr>
<td>Toxo (IgM &amp; IgG)</td>
<td>21</td>
<td>2</td>
</tr>
<tr>
<td>SLE</td>
<td>23</td>
<td>0</td>
</tr>
<tr>
<td>HIV</td>
<td>81</td>
<td>19</td>
</tr>
<tr>
<td>H.pylori</td>
<td>10</td>
<td>1</td>
</tr>
<tr>
<td>Arthritis</td>
<td>19</td>
<td>1</td>
</tr>
<tr>
<td>Lyme Disease</td>
<td>10</td>
<td>0</td>
</tr>
</tbody>
</table>

12. CORRELATION RESULTS
The results of the correlation test performed SERODIA-TP using 391 samples are shown in Table 6. The measured values were within ±1 doubling dilution of the control value in the specification, with 100% consistency. As a result of the linear regression analysis, an excellent correlation (correlation coefficient \( r = 0.964 \), regression formula \( y = 1.009x + 0.296 \)) was observed.
13. PRECAUTIONS

1) When a specimen shows reactive or indeterminate in the Qualitative Assay, the specimen should be retested in the Quantitative Assay. A repeated reactive or indeterminate specimen should be confirmed by other methods (FTA-ABS).

2) This kit is designed for the sole purpose of detecting Treponema Pallidum antibodies in serum/plasma specimens. It does not, however, detect TP directly. The test results should not be used in isolation but used in conjunction with the patient's clinical symptoms, clinical history, and any other available data to produce an overall clinical diagnosis.

3) At the early stage of infection, in case of extremely low concentration of the antibodies, it is recognized that presently available methods (including this kit) for detection of antibodies to TP are not sensitive enough to detect existing antibodies. Therefore, in case infection is suspected, even if test results are negative, specimens should be retested and interpreted in conjunction with the results of other test methods and also
with patient's clinical symptoms, clinical history and any other available data to produce an overall clinical diagnosis.

4) Note that some specimens with very high antibody titer may exhibit the prozoning phenomenon at lower dilutions.

5) When patients specimen injected blood derivatives/preparations including immunoglobulin is interpreted, positive reaction might be observed.

6) Specimens are potentially infected by HBV, HIV, HCV, or other hazardous microorganisms and should be handled carefully. All used accessories and equipments (e.g. pipettes and tubes), waste solutions, tips, etc., should be decontaminated with sodium hypochlorite solution {1,000 ppm (0.1%) available chlorine by soaking for at least 1 hour}, glutaraldehyde solution (for more than 1 hour with 2.0% solution), autoclaving (at 121°C for more than 1 hour), or incineration.

7) Sodium azide is contained as preservative. Sodium azide has been reported to form explosive lead and copper azides in laboratory plumbing. To prevent azide build-up, flush with large volumes of wafer if solutions containing azide are disposed of in the sink.

8) Quality assurance is given for each production lot. Do not use the reagents in combination with the kit of other production lots.

9) The kit is designed for use with the "U" shaped FASTEC microplate.

10) When using any instruments or device with SERODIA-TP·PA, follow the instructions given with the instrument/device.

11) Should the reagent come into contact with the eyes or mouth, rinse thoroughly with water and seek medical attention or treatment if necessary.

12) When disposing of reagents or vessels, separate them according to medical or industrial waste regulations.
13) Ideally, lyophilized reagents contained in the kit should be used within the same day of reconstitution. However, under proper storage conditions at 2-10°C, they will remain stable for 7 days after reconstitution. In such a case, perform a Control Test to confirm their quality before use. Reconstituted Sensitized and Unsensitized particles should be sealed with sealing film to prevent contamination from any foreign bodies during storage.

14. STORAGE
Always store reagents at 2-10°C when not in use. Do not freeze.

15. SHELF LIFE
Shelf life is indicated by the expiration date printed on the test package or the reagent labels.

16. REFERENCES


Authorised Representative: FUJIREBIO EUROPE B.V.

Takkebijsters 69c 4817 BL Breda, The Netherlands
TEL:31-76-571-0440

Manufacturer: FUJIREBIO INC.

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