



SYPHILIS Ab ELISA KIT

Syphilis Ab ELISA KIT is an in-vitro diagnostic qualitative immunoassay for the detection of antibodies to *Treponema pallidum* in human serum or plasma. The kit is basically intended to be used for screening purpose by healthcare professionals only.

-  Solid phase enzyme linked immunosorbent assay using “Double Antigen Sandwich” technique
-  Specificity : 100% Sensitivity: 100%
-  Sample type: Human Serum or Plasma
-  Pack Size: 96 wells
-  Micro-Plate format: Breakaway 12 x 8 wells suitable for any workload
-  Assay run time: 120 minutes
-  Ready to use positive and negative controls

Methodology

Antibodies to *Treponema pallidum* present in Serum / Plasma bind to the coated recombinant treponemal antigens and forms antigen-antibody-antigen enzyme sandwich complex against the addition of Enzyme Conjugate. The absorbance of enzyme activity is determined by measuring the developed colour at 450 nm / 620 nm wavelength against addition of substrate solution.

TEST PROCEDURE

Add 50 µL sample diluent in each well																																								
Add 50 µL N.C from A1 to C1, 50 µL of P.C from D1 to E1 and 50 µL sample from F1 to G1																																								
Cover the plate and incubate at 37°C for 60 mins																																								
Preparation of working wash solution: (1ml wash conc +19 ml distilled water)	<table border="1"> <tr> <td>No. of strip</td> <td>1</td><td>2</td><td>3</td><td>4</td><td>5</td><td>6</td><td>7</td><td>8</td><td>9</td><td>10</td><td>11</td><td>12</td> </tr> <tr> <td>20x Washing Solution</td> <td>1</td><td>2</td><td>3</td><td>4</td><td>5</td><td>6</td><td>7</td><td>8</td><td>9</td><td>10</td><td>11</td><td>12</td> </tr> <tr> <td>Distilled water</td> <td>19</td><td>38</td><td>57</td><td>76</td><td>95</td><td>114</td><td>133</td><td>152</td><td>171</td><td>190</td><td>209</td><td>228</td> </tr> </table>	No. of strip	1	2	3	4	5	6	7	8	9	10	11	12	20x Washing Solution	1	2	3	4	5	6	7	8	9	10	11	12	Distilled water	19	38	57	76	95	114	133	152	171	190	209	228
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Preparation of working enzyme conjugate solution	<table border="1"> <tr> <td>No. of strip</td> <td>1</td><td>2</td><td>3</td><td>4</td><td>5</td><td>6</td><td>7</td><td>8</td><td>9</td><td>10</td><td>11</td><td>12</td> </tr> <tr> <td>Conjugate (1:100X) conc. µL</td> <td>10</td><td>20</td><td>30</td><td>40</td><td>50</td><td>60</td><td>70</td><td>80</td><td>90</td><td>100</td><td>110</td><td>120</td> </tr> <tr> <td>Conjugate Diluent (µL)</td> <td>990</td><td>1980</td><td>2970</td><td>3960</td><td>4950</td><td>5940</td><td>6930</td><td>7920</td><td>8910</td><td>9900</td><td>10890</td><td>11880</td> </tr> </table>	No. of strip	1	2	3	4	5	6	7	8	9	10	11	12	Conjugate (1:100X) conc. µL	10	20	30	40	50	60	70	80	90	100	110	120	Conjugate Diluent (µL)	990	1980	2970	3960	4950	5940	6930	7920	8910	9900	10890	11880
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Add 100 µL of working enzyme conjugate in each well																																								
Cover the plate and incubate at 37°C for 30 mins																																								
Wash (5 Cycles) with working wash solution																																								
Add 100 µL of substrate in each well																																								
Cover the plate and incubate at 37°C for 30 mins																																								
Add 50 µL of stop solution and read result 450 nm/620 nm																																								

Pre-Assay Preparation

1. Conjugate Solution (100 x Conc = 1µl+99 µl) 1:99 dilution
10 µl of Conc 100 X + 990 µl of Diluent

2. Washing Solution (20 x Conc = 1ml+19ml)

1:19 dilution (eg. 10ml of 10x wash solution to 190 ml distilled water)

ASSAY VALIDATION

Negative Control: The mean absorbance of the Negative Controls (NCx) should not be less than or equal to 0.200

Positive Control: The mean absorbance of the Positive Control (PCx) should be greater than or equal to 0.800. If the results are outside the above ranges or borderline, then the assay should be repeated

Result Interpretation

Cut-off value= Ncx + 0.200

For example

Negative Control 1 absorbance = 0.021

Negative Control 2 absorbance = 0.023

Negative Control 3 absorbance = 0.025

Ncx = (0.021+0.023+0.025)/3 = 0.023

Cut-off value= Ncx+0.200 = 0.023 + 0.200 = 0.223

Interpretation of the results

Samples with an absorbance less than the cut-off value are considered **Non-Reactive**

Samples with an absorbance equal to or greater than the cut-off value are considered **Reactive**

*Ref the kit insert provided along with the kit for procedure and detailed calculations

Performance Characteristics

1. Diagnostic Sensitivity:

Samples tested	No. of Samples tested	Results		Total (Sensitivity)
		Positive	Negative	
Positive	57	57	0	100%

2. Diagnostic Specificity:

Samples tested	No. of Samples tested	Results		Total (Specificity)
		Positive	Negative	
Negative	233	0	233	100%

ORDERING INFORMATION

Product Code	Product Name	Pack Size	Storage	Shelf Life
30201413	Syphilis Ab ELISA kit	96 Tests	2-8°C	15 Months

*Please note: Product specifications are subject to change without prior notice owing to product modifications, improvements / up-gradation.



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