Datasheet for ABIN997000

Syphilis IgM Antibody ELISA Kit

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Overview

Quantity:	96 tests
Target:	Syphilis IgM Antibody
Reactivity:	Treponema pallidum
Method Type:	Sandwich ELISA
Application:	ELISA

Product Details

Purpose:	Syphilis TPA-Treponema pallidum IgM ELISA kit provides materials for the qualitative and semi quantitative determination of IgM-class antibodies to Treponema pallidum in serum.
Analytical Method:	Qualitative and Semi-Quantitative
Detection Method:	Colorimetric
Specificity:	95 %
Material not included:	1. A microtiter plate calibrated reader (450/620nm ±10 nm) DAR 800. 2. Calibrated variable precision micropipettes. 3. Incubator 37 °C. 4. Manual or automatic equipment for rinsing wells 5. Vortex tube mixer 6. Deionized or (freshly) distilled water 7. Timer 8. Absorbent paper

Target Details

Target:	Syphilis IgM Antibody
Target Type:	Antibody

Application Details

Comment:	Quality Control: I M M 1. It is recommended to use control samples according to state and federal regulations. The use of control samples is advised to assure the day to day validity of results. Use controls at both normal and pathological levels. 2. It is also recommended to make use of national or international Quality Assessment programs in order to ensure the accuracy of the results. 3. If the results of the assay do not fit to the established acceptable ranges of control materials patient results should be considered invalid. 4. In this case, please check the following technical areas: Pipetting and timing devices, photometer, expiration dates of reagents, storage and incubation conditions, aspiration and washing methods. 5. After checking the above mentioned items without finding any error contact your distributor or DAI directly. Limitations of procedure: 1. Bacterial contamination or repeated freeze-thaw cycles of the specimen may affect the absorbance values. In immunocompromised patients and newborns serological data only have restricted value.
Sample Volume:	10 µL
Assay Time:	1 - 2 h
Plate:	Pre-coated
Reagent Preparation:	Reagent Preparation ce Allow all reagents and required number of strips to reach room temperature prior to use. Wash Solution Dilute Wash Solution 1+19 (e. g. 10 mL + 190 mL) with fresh and germ free redistilled 7. water. This diluted wash solution has a pH value of 7.2 ± 0. 2. Consumption: approx. 5 mL per determination. Crystals in the solution disappear by warming up to 37 °C in a water bath. Be sure that the crystals are completely dissolved before use. The diluted Wash Solution is stable for 4 weeks at 2 °C to 8 °C.

Application Details

Sample Preparation:	Specimen: Serum can be used in this assay. Do not use haemolytic, icteric or lipaemic specimens. Serum: Collect blood by venipuncture, allow to clot, and separate serum by centrifugation at room temperature. Do not centrifuge before complete clotting has occurred. Patients receiving anticoagulant therapy may require increased clotting time. Specimen Storage Specimens should be capped and may be stored for up to 5 days at 2 °C to 8 °C prior to assaying. Specimens held for a longer time should be frozen only once at -20 °C prior to assay. Thawed samples should be inverted several times prior to testing. Specimen Dilution Prior to assaying each patient specimen is first to be diluted with Sample Diluent. For the absorption of rheumatoid factor these prediluted samples then have to be incubated with IgG-RF-Sorbent. 1. Dilute each patient specimen 1+50 with Sample Diluent, e.g. 10 µL of specimen + 0.5 mL of Sample Diluent. Mix well. 2. Mix well the IgG-RF-Sorbent before use. 3. Dilute this prediluted sample 1+1 with IgG-RF-Sorbent e. g. 60 µL prediluted sample + 60 µL IgG-RF-Sorbent. Mix well. 4. Let stand for at least 15 minutes at room temperature or overnight at 2 °C - 8 °C and mix well again. 5. Take 100 µL of these pre-treated samples for the ELISA. Please note: Controls are ready for use and must not be diluted!
Assay Procedure:	Prior to commencing the assay, dilute Wash Solution, prepare patient samples as described below and establish carefully the distribution and identification plan supplied in the kit for all specimens and controls. 1. Select the required number of microtiter strips or wells and insert them into the holder. Please allocate at least: 1 well (e.g. A1) for the substrate blank, 1 well (e.g. B1) for the Neg. Control, 2 wells (e.g. C1+D1) for the Cut-off Control and 1 well (e.g. E1) for the Pos. Control. It is left to the user to determine controls and patient samples in duplicate. 2. Dispense 100 µepsilon of Neg. Control into well B1 100 µepsilon of Cut-off Control into wells C1 and D1 100 µepsilon of Pos. Control into well E1 and 100 µepsilon of each pre-treated sample with new disposable tips into appropriate wells. Leave well A1 for substrate blank! 3. Cover wells with foil supplied in the kit. Incubate for 60 minutes at 37 °C. 4. Briskly shake out the contents of the wells. Rinse the wells 5 times with diluted Wash Solution (300 µL per well). Strike the wells sharply on absorbent paper to remove residual droplets. Important note: The sensitivity and precision of this assay is markedly influenced by the correct performance of

	the washing procedure! Dispense 100 µL Enzyme Conjugate into each well, except A1. Cover wells with foil. Incubate for 30 minutes at room temperature. Do not expose to direct sun light! Briskly shake out the contents of the wells. Rinse the wells 5 times with diluted Wash Solution (300 mL per well). Strike the wells sharply on absorbent paper to remove residual droplets. Add 100 mL of Substrate Solution into all wells. Incubate for exactly 15 minutes at room temperature in the dark. Stop the enzymatic reaction by adding 100 µ epsilon of Stop Solution to each well. Any blue color developed during the incubation turns into yellow. Note: Highly positive patient samples can cause dark precipitates of the chromogen! Read the optical density at 450/620 nm with a microtiter plate reader within 30 minutes after adding the Stop Solution. Measurement Adjust the ELISA microplate or microstrip reader to zero using the substrate blank in well A1 . If - due to technical reasons - the ELISA reader cannot be adjusted to zero using the substrate blank in well A1, subtract the absorbance value of well A1 from all other absorbance values measured in order to obtain reliable results! Measure the absorbance of all wells at 450 nm and record the absorbance values for each control and patient sample in the distribution and identification plan. Dual wavelength reading using 620 nm as reference wavelength is recommended. Where applicable calculate the mean absorbance values of all duplicates.
Calculation of Results:	Validation of the Test Run The test run may be considered valid provided the following criteria are met: Substrate blank in A1: Absorbance value lower than 0.100 Neg. Control in B1: Absorbance value lower than 0.200 Cut-off Control in C1/D1 : Absorbance value between 0.350 - 0.800 Pos. Control in E1: Absorbance value between 0.650-3.000 Calculations Mean absorbance value of Cut-off Control [CO] Calculate the mean absorbance value of the two (2) Cut-off Control determinations (e.g. in C1/D1). Example: (0.44 + 0.46): 2 = 0.45 = CO Interpretation > Negative: Patient (mean) absorbance values more than 10 % below CO (Mean OD patient < 09 x CO) > Positive: Patient (mean) absorbance values more than 10 % above CO (Mean OD patient > 11 x CO) > Equivocal: Patient (mean) absorbance values from 10 % above to 10 % below CO repeat test 2 - 4 weeks later - with new patient samples Results in DAI Units [DU] Patient (mean) absorbance value x 10 = [DAI Units = DU] (0.9 x CO < Mean OD patient - 11 x CO) Results in the second test again in the grey zone ^ NEGATIVE CO Example: 1.580 x 10 = 35 du 0.45 Interpretation of Results Cut-off value: 10 DU Grey zone: 9 - 11 DU Negative: < 9 DU Positive: > 11 DU Diagnostic Specificity The diagnostic specificity is defined as the probability of the assay of scoring negative in the absence of the specific analyte. It is 95 %.
Restrictions:	For Research Use only

Handling

Storage:	4 °C
Expiry Date:	12-14 months