Diagnostic Automation / Cortez Diagnostics, Inc.
IMMUNO DIAGNOSTICS

AccuDiag™ Chikungunya IgM ELISA Kit

REF 8113-25

Test	Chikungunya IgM ELISA
Method	Enzyme Linked Immunosorbent Assay
Principle	Competitive Immunoassay
Detection Range	Qualitative
Sample	4 µL
Specificity	100 %
Sensitivity	100 %
Total Time	~ 100 min
Shelf Life	12 Months from the manufacturing date

INTENDED USE

The Diagnostic Automation, Inc. Chikungunya IgM ELISA is designed for the qualitative detection of IgM antibodies present in human serum targeting chikungunya virus E2/E1 proteins. This test is not intended to screen blood or blood components.

SUMMARY AND EXPLANATION

Chikungunya virus (CHIKV) is a mosquito-borne alphavirus first isolated during an epidemic in Tanzania in 1953 [1] [2]. Acute symptoms of the disease are easily confused with dengue fever, and include sudden onset of high fever and polyarthralgia. The arthralgia can be debilitating and may last for periods of months or even years after the initial infection [3] [4]. As chikungunya may co-circulate with other diseases spread by *Aedes spp.* mosquitoes (e.g., dengue and yellow fever), it may be difficult to quickly and accurately diagnose the disease. CHIKV has re-emerged in recent years in a number of countries, causing outbreaks in Kenya, India, Italy and the Americas, resulting in significant healthcare consequences. Outbreaks on island populations (Lamu, Union of the Comoros) have resulted in epidemics that have infected greater than 50% of the population [3].

The DAI Chikungunya IgM ELISA is an enzyme linked sandwich-type immunoassay for the detection of human IgM antibodies targeting the CHIKV E2/E1 envelope glycoproteins. Polystyrene microtiter wells are pre-coated with capture antibodies for human IgM. Positive Control, Cut-Off Control, Negative Control and unknown test samples are diluted into a sample dilution buffer and then added to the ELISA plate. After incubation and washing, a subsequent ready-to-use CHIKV Antigen [5] [6] is added to each well. After a subsequent incubation and wash step, an HRP conjugated monoclonal antibody specific for CHIKV E2/E1 complex [7] is added to each well. After washing, wells are incubated with a tetramethylbenzidine (TMB) substrate. An acidic Stop Solution is then added and the degree of enzymatic turnover is determined by the absorbance (optical density) measurement at 450 nanometers. If human IgM antibodies targeting the CHIKV envelope glycoproteins are present, a complex is formed consisting of the IgM, antigen, and conjugate. If IgM antibodies targeting the CHIKV envelope glycoproteins are not present, then the complex of the antigen and conjugate are washed away.

SPECIMEN COLLECTION AND PREPARATION

- Human serum must be used with this assay. Reagents have not been optimized, or tested with whole blood or plasma so these blood forms cannot be tested directly.
- Remove serum from the clot of red blood cells as soon as possible to avoid hemolysis.
- Testing should be performed as soon as possible after collection. Do not leave sera at room temperature for prolonged periods.
- Serum should be used and the usual precautions for venipuncture should be observed. The samples may be stored at 2-8ºC for up to 7 days or frozen at -20ºC or lower for up to 30 days. To maintain long-term longevity of the serum, store at -70ºC. Avoid repeated freezing and thawing of samples.
- Frozen samples should be thawed to room temperature and mixed thoroughly by gentle swirling or inversion prior to use. Always quick-spin before use.
- If sera are to be shipped, they should be packed in compliance with Federal Regulations covering transportation of infectious agents.
- Do not use sera if any indication of growth is observed.

MATERIALS AND COMPONENTS

Materials provided with the test kits

The DAI Chikungunya IgM ELISA contains sufficient reagents for one plate of 96 wells (12 x 8 strips) for human IgM targeting CHIKV. This is sufficient for testing a maximum of 90 unknown samples for human IgM, with controls included in duplicate.

Warning: Do not use any reagents where damage to the packaging has occurred.

1. **Coated Microtiter Test Strips for IgM (1 plate containing 12, 1x8 strips for human IgM):** ELISA plate strip holder with 96 (12x8 strips) coated polystyrene microtiter wells. Store at 2-8°C until expiry.
2. **Chikungunya IgM Negative Control (1x50µL):** The negative control will aid in verifying the validity of the kit. Store at 2-8°C until expiry. Centrifuge briefly prior to use to sediment any precipitate.
3. **Chikungunya IgM Positive Control (1x50µL):** The positive control will aid in verifying the validity of the kit. Store at 2-8°C until expiry. Centrifuge briefly prior to use to sediment any precipitate.
4. **Chikungunya IgM Cut-Off Control (1x50µL):** The cut-off control will aid in verifying the validity of the kit and establishing the threshold for reactive samples. Store at 2-8°C until expiry. Centrifuge briefly prior to use to sediment any precipitate.
5. **Sample Dilution Buffer for Chikungunya (2x25mL):** This solution is used for diluting all serum samples and controls prior to testing in the ELISA. Store at 2-8°C until expiry.
6. **Chikungunya Antigen (1x9mL):** This vial contains ready-to-use chikungunya antigen that comprises the chikungunya envelope glycoproteins.
7. **Conjugate Diluent for Chikungunya (1x9mL):** This solution is used for adding the enzyme conjugate to the ELISA assay. Do not use without first adding the 100X Conjugate, as described in the ***Preparation of Reagents*** section. Store at 2-8°C until expiry.

8. **100X Conjugate for Chikungunya (1x150µL):** This contains horseradish peroxidase-labeled monoclonal antibody targeting chikungunya virus. Mix well prior to use. The 100X Conjugate is added to the Conjugate Diluent before use. Store the undiluted 100X conjugate at 2-8ºC until expiry.
9. **10X Wash Buffer (1x120mL):** One bottle of 10x concentrated Wash Buffer to be used as directed in Test Procedure. Store at 2-8ºC until expiry.
10. **Liquid TMB Substrate (1x12mL):** To be used as directed in Test Procedure. Store at 2-8ºC until expiry.
    Note: This substrate is light-sensitive and should be stored in the original bottle.
11. **Stop Solution (1x9mL):** To be used to terminate the reaction as directed in Test Procedure. Store at 2-8ºC until expiry.
    Caution: This is a strong acid, wear protective gloves, mask and safety glasses. Dispose of all materials according to safety rules and regulations.

Materials required but not provided

1. ELISA Spectrophotometer capable of absorbance measurement at 450 nm
2. Biological or High-Grade Water
3. Vacuum Pump
4. Automatic Plate Washer
5. 37ºC Incubator without humidification or CO2
6. 1-10 µL Single-Channel Pipettors, 50-200 µL Single-and Multi-Channel Pipettors
7. Polypropylene tubes or 96 well dilution plates
8. Parafilm or similar plate cover
9. Timer
10. Vortex

ASSAY PROCEDURE

Bring all kit reagents and specimens to room temperature (~25ºC) before use. Thoroughly mix the reagents and samples before use by gentle inversion.

CAUTION: THIS KIT HAS NOT BEEN OPTIMIZED BY DAI FOR USE WITH ANY PARTICULAR AUTOMATED ELISA PROCESSING SYSTEM. USE WITH AN AUTOMATED ELISA PROCESSING SYSTEM WILL REQUIRE PROPER VALIDATION TO ENSURE RESULTS ARE EQUIVALENT TO THE EXPECTATIONS DESCRIBED IN THIS PACKAGE INSERT. MODIFICATIONS TO THE PROTOCOL OF THESE SYSTEMS AND/OR DIFFERENT VOLUMES OF REAGENTS MAY BE REQUIRED.

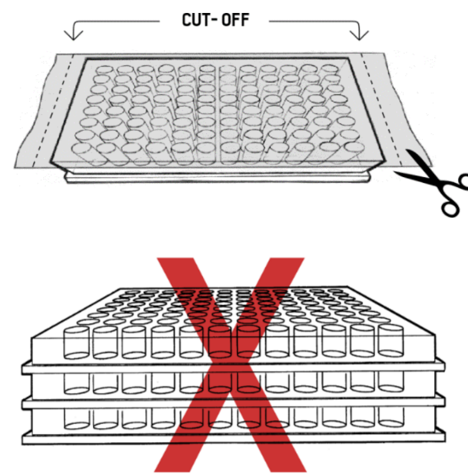
Preparation of Reagents:

- Preparation of 1X Wash Buffer
  Dilute the 10X Wash Buffer to 1X using Biological or High-Grade Water. To prepare a 1X wash buffer solution, mix 120 mL 10X wash buffer with 1080 mL distilled (or deionized water). Mix thoroughly to ensure that any precipitate is dissolved and that the solution is uniform. Once diluted to 1X, the solution can be stored at room temperature for up to 6 months. Check for contamination prior to use. Discard if contamination is suspected.
- Microtitration Wells
  Select the corresponding strips depending upon the number of samples to test. Evaluate the plate to ensure the strips are flat and properly aligned to the plate. The remaining unused wells should be repackaged and sealed immediately with the supplied desiccant and stored at 2-8°C until ready to use or expiration.
- Preparation of the Chikungunya Ready To Use Enzyme Conjugate
  Add 90 µL of 100X Conjugate for Chikungunya directly to the 9 mL bottle of Conjugate Diluent for Chikungunya (1 part: 100 parts). Mix by inverting solution several times. For smaller volumes, aliquot the required volume of sample diluent into a separate, clean polypropylene test tube and add the appropriate volume of 100X Conjugate for Chikungunya to the diluent in the test tube. Prepare only the required amount needed for a given test run.

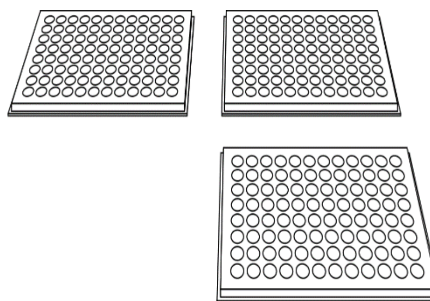
ASSAY PROCEDURE

1. Positive, Cut-Off and Negative Controls should be assayed in duplicate (and run each time the assay is performed on every plate). Unknown serum samples may be assayed in singlet. However, it is recommended to run samples in duplicate until the operator is familiar with the assay.
2. Dilute the Controls and unknown serum samples in the Sample Dilution Buffer for Chikungunya. Samples should be diluted 1/100 into a clean dilution plate well or separate clean polypropylene test tube. For example, dilute 4 µL of sample into 396 µL of Sample Dilution Buffer. Mix well by pipetting up and down several times.
3. Add 50 µL of the 1/100 diluted Controls and unknown serum samples to the appropriate ELISA plate wells.
4. Cover the plate with parafilm, as shown below.

Note: *This is to ensure even temperature distribution in all wells from bottom and sides; any extra parafilm can be cut off once the top is sealed to block evaporation.*



CORRECT METHOD



Note: Do not stack plates on top of each other. They should be spread out as a single layer. This is very important for even temperature distribution. Do not use CO_2 or other gases. Do not place plates in contact with any wet substances such as wet paper towels etc.

5. Incubate at 37°C for 30 minutes (± 1 minutes) in an incubator. The incubator should be properly calibrated and verified to maintain 37°C ± 2°C using an external, reference thermometer.
6. After the incubation, wash the plate 6 times with an automatic plate washer using 1x Wash buffer. Use 300 µL per well in each wash cycle.
7. Add 50 µL of the Chikungunya Antigen to each ELISA plate well. Return any remaining Chikungunya Antigen to the proper storage conditions (-20°C to -80°C).
8. Cover the plate with parafilm.
9. Incubate at 37°C for 30 minutes (± 1 minutes) in an incubator.
10. During the incubation, prepare a fresh volume of Ready To Use Enzyme Conjugate as described in the Preparation of Reagents section (e.g., add 90 µL of 100X Conjugate for Chikungunya directly to the 9 mL bottle of Conjugate Diluent for Chikungunya, 1 part: 100 parts). Prepare only the minimum amount of Ready To Use Enzyme Conjugate necessary for the assay run.
11. After the incubation, wash the plate 6 times with an automatic plate washer using 1x Wash buffer. Use 300 µL per well in each wash cycle.
12. Add 50 µL of the Ready To Use Enzyme Conjugate to each ELISA plate well.
13. Cover the plate with parafilm.
14. Incubate at 37°C for 30 minutes (± 1 minute) in an incubator.
15. After the incubation, wash the plate 6 times with an automatic plate washer using 1x Wash buffer. Use 300 µL per well in each wash cycle.
16. Apply 75 µL of Liquid TMB substrate into all wells using a multi-channel pipetter. ***Note:*** *The Liquid TMB is light-sensitive. Avoid exposure to unnecessary light sources.*
17. Incubate the plate in the dark, at room temperature for 10 minutes (± 30 seconds).
18. Add 50 µL of Stop Solution into all wells using a multi-channel pipetter and let the plate stand, uncovered at room temperature for 1 minute.
19. Read the optical density value at 450nm (OD_{450}) with a Microplate reader. DO NOT SUBTRACT OR NORMALIZE ANY BLANK VALUES OR WELLS.
20. Analyze the data as shown in the Quality Control section and Interpretation of Results section.

Procedure Summary

Dilute Controls and Samples 1/100 into the Sample Dilution Buffer (4uL:396uL). Controls should be assayed in duplicate.

Add 50uL of diluted Controls and Samples to the appropriate ELISA plate wells.

Cover with parafilm, incubate 30 minutes, 37°C.

Wash plate 6x. Add 50 µL of the Chikungunya Antigen to each ELISA plate well. Make sure to return the antigen to -20°C to -80°C storage

Cover with parafilm, incubate 30 minutes, 37°C.

Prepare a fresh volume of Ready To Use Enzyme Conjugate (e.g., add 90 µL of 100X Conjugate for Chikungunya directly to the 9 mL bottle of Conjugate Diluent for Chikungunya). Prepare only the minimum volume necessary for the assay run.

Wash plate 6x. Add 50 µL of Ready To Use Enzyme Conjugate to each ELISA plate well.

Cover with parafilm, incubate 30 minutes, 37°C.

Wash plate 6x. Add 75 µL of TMB to all wells. Avoid exposure to light. Incubate 10 minutes at room temperature.

Add 50 µL of Stop solution to each well. Measure the OD_{450} (do NOT subtract background or reference wavelengths).

QUALITY CONTROL

Each kit contains positive, cut-off and negative control sera. Positive, cut-off and negative controls must be run on each plate tested. Acceptable optical density (OD) values for these controls are found on the specification table below. The negative and positive controls are intended to monitor for substantial reagent failure. The test is invalid and must be repeated if either of the controls do not meet the specifications. The cut-off control is provided to establish a threshold above which a samples is considered reactive. Quality Control (QC) procedures must be performed in conformance with local, state, and/or federal regulations or accreditation requirements and the user's own laboratory's standard QC procedures. It is recommended that the user refer to CLSI C24-A and 42 CFR 493.1256 for guidance on appropriate QC practices. The results below are given strictly for guidance purposes only. Analysis is applicable when using RAW spectrophotometric readings only and where automatic subtraction of water or reagent blanks is not employed.

Calculate the mean (average) value of Chikungunya IgM Negative Control.

Example 1: Mean Negative Control

	OD_{450}
Replicate 1	0.084
Replicate 2	0.094
Sum	0.178

Mean OD_{450} = 0.178 ÷ 2 = 0.089

Calculate the mean (average) value of Chikungunya IgM Positive Control.

Example 2: Mean Positive Control

	OD_{450}
Replicate 1	1.540
Replicate 2	1.378
Sum	2.918

Mean OD_{450} = 2.918 ÷ 2 = 1.459

Calculate the mean (average) value of Chikungunya IgM Cut-off Control.

Example 3: Mean Cut-Off Control

	OD_{450}
Replicate 1	0.182
Replicate 2	0.194
Sum	0.376

Mean OD_{450} = 0.376 ÷ 2 = 0.188
Cut-Off Control Value = 0.188

Calculation of the Chikungunya IgM Discrimination Capacity: The Discrimination Capacity ($R_{PC/NC}$) for the ELISA is defined as the ratio of the Positive Control to the Negative Control.

Example 4: Discrimination Capacity ($R_{PC/NC}$)

	OD_{450}
Mean Positive OD_{450}	1.459
Mean Negative OD_{450}	0.089
Ratio	16.39

$R_{PC/NC}$ = 1.459 ÷ 0.089 = 16.39

Quality Control Requirements: The following criteria must be fulfilled for the Diagnostic Automation, Inc. Chikungunya IgM ELISA in order for the assay run to be considered valid.

Quality Control Requirements

	Requirement
Mean Negative OD_{450}	≤ 0.200
Mean Positive OD_{450}	≥ 0.500
Mean Cut-Off OD_{450}	> Mean Neg. Control OD_{450}
$R_{PC/NC}$	≥ 5.00

Calculation of the Chikungunya IgM Immune Status Ratio (ISR) Value: Calculate the Immune Status Ratio (ISR) for each sample in the assay. The ISR value for each sample is defined as the ratio of the test sample OD_{450} to the mean Cut-Off Control value.

Example 5: ISR Value

	OD_{450}
Mean Test Sample OD_{450}	0.876
Cut-Off Control Value	0.188

ISR = 0.876 ÷ 0.188 = 4.66

PERFORMANCE CHARACTERISTICS

Sensitivity and specificity studies:

A retrospective study utilized archived samples from individuals displaying signs and symptoms of chikungunya infection. Samples were tested in both DAI Chikungunya IgM ELISA and IFA in a lab in eastern United States. The two false negatives were weakly positive by IFA.

		IFA		
		Positive	Negative	Total
DAI Chikungunya IgM ELISA	Positive	20	0	20
	Negative	2	2	4
	Total	22	2	24
Positive % agreement: 90.9% [95% CI: 72.2-97.5%]*				
Negative % agreement: 100% [95% CI: 34.2-100%]*				

*Wilson score method for calculating 95% confidence intervals

Reproducibility study:
The reproducibility study was run at Diagnostic Automation, Inc. 3 different individuals ran tests on 5 different days each. Operators tested the same panel of samples in triplicate using the same lot of Diagnostic Automation, Inc. Chikungunya IgM ELISA. All assays were performed according to the kit insert. The panel consisted of four clinical serum specimens diluted in an analyte-negative matrix, and included a positive specimen, two weak positive specimens, and a negative specimen. The serum dilutions selected also ensured that the analyte concentration in the specimens represented a clinically relevant range. The total precision %CV (from "total" standard deviation from triplicate results) for the raw OD and ISR values is shown in the table below. The Diagnostic Automation,Inc. Chikungunya IgM ELISA's total precision %CV (from "total" standard deviation from triplicate results) for the raw OD values varied from 21-31%, depending upon the sample. The ISR total precision %CV varied from 10-13%, depending upon the sample. This variability measurement inherently included noise due to operator-to-operator variation.

	%CV$_{Total}$ – OD450	**%CV**$_{Total}$ - ISR
Positive Control	21.419	13.092
Negative Control	23.152	12.810
Cut-off Control	30.446	0.000
panel #1	27.073	10.078
panel #2	28.631	12.850
panel #3	26.682	11.372
panel #4	30.142	12.320

Cross-reactivity study:
Sera that tested positive for other potentially cross-reactive pathogens were evaluated with the Diagnostic Automation, Inc. Chikungunya IgM ELISA in order to determine cross-reactivity.

Disease	Number of samples	Number of positives	% Specificity [95% Confidence Interval]*
Epstein-Barr Virus	3	0	100% [43.9-100%]
Anti-nuclear antibody	3	0	100% [43.9-100%]
Rheumatoid factor	3	0	100% [43.9-100%]
Herpes simplex virus	3	0	100% [43.9-100%]
Human immunodeficiency virus	3	0	100% [43.9-100%]
Hepatitis C virus	3	0	100% [43.9-100%]
West Nile virus	6	0	100% [61.0-100%]
La Crosse encephalitis virus	3	0	100% [43.9-100%]
Eastern equine encephalitis virus	3	3	0% [0-56.1%]

Interference study:
Four potentially interfering substances commonly occurring in serum were tested for their effect on the CHIK$_{jj}$ DAI IgM ELISA test. In addition to the kit's positive, negative and cut-off controls, a panel of four simulated clinical specimens were tested, ranging in strength from negative to weakly positive to strongly positive. The five potentially interfering substances were Bilirubin (0.2 mg/mL), Cholesterol (5 mg/mL), Triglycerides (30 mg/mL), Hemoglobin (160 mg/mL). There were no statistically significant effects of any of the substances at the concentrations tested. All of the substances were tested at concentrations above normal physiological levels.

RESULTS

FOR ACCURATE RESULTS DO NOT SUBTRACT "BLANK" WELL VALUES OR REFERENCE WAVELENGTHS

Samples with ISR values ≥ 1.0 are considered "Reactive" and samples with ISR values < 1.0 are considered "Non-Reactive". Any samples in the range of 0.90 < ISR Value < 1.10, should be considered retested and the sample evaluated in duplicate to verify the sample status.

ISR Value	Interpretation
< 1.0	"Non-Reactive". Sample is considered to not have IgM antibodies specific for chikungunya
≥ 1.0	"Reactive". Sample is considered to have IgM antibodies specific for chikungunya present
0.9 - 1.10	Repeat test sample in duplicate to verify results

LIMITATIONS OF PROCEDURE

1. Not for sale or distribution in the United States of America.
2. Serological cross-reactivity with other alphavirus samples must be considered. Certain sera (e.g., rheumatoid factors, hemolyzed samples, HAMA-positive, etc.) may give false positive results. Therefore, any positive sera must be confirmed with other tests.
3. Do not use samples withg high cholesterol levels (> 300 mg/dL) or high triglyceride levels (> 3000 mg/dL).
4. Do not use hemolyzed (bloody) serum samples as this may affect OD values.

PRECAUTIONS

1. Not for sale or distribution in the United States of America.
2. All human source materials used in the preparation of controls have tested negative for antibodies to HIV 1&2, Hepatitis C and Hepatitis B surface antigen. However, no test method can ensure 100% efficiency or sensitivity. Therefore, all human controls and antigen should be handled as potentially infectious material. The Centers for Disease Control and Prevention and the National Institutes of Health recommend that potentially infectious agents be handled at the Biosafety Level 2.

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3. A thorough understanding of this package insert is necessary for successful use of the product. Reliable results will only be obtained by using precise laboratory techniques and accurately following the package insert.
4. Do not mix various lots of any kit component within an individual assay.
5. Do not use any component beyond the expiration date shown on its label.
6. Avoid exposure of the reagents to excessive heat or direct sunlight during storage and incubation.
7. Some reagents may form a slight precipitate, mix gently before use.
8. Incomplete washing will adversely affect the outcome and assay precision.
9. To minimize potential assay drift due to variation in the substrate incubation time, care should be taken to add the stopping solution into the wells in the same order and speed used to add the TMB solution.
10. Avoid microbial contamination of reagents.
11. Avoid contamination of the TMB Substrate Solution with the Enzyme Conjugate-HRP.
12. Wear protective clothing, eye protection and disposable gloves while performing the assay. Wash hands thoroughly afterwards.
13. Use a clean disposable pipette tip for each reagent, Standard, Control or specimen.
14. Cover working area with disposable absorbent paper.

WARNING: POTENTIALLY BIOHAZARDOUS MATERIAL
This kit may contain reagents made with human serum or plasma. The serum or plasma used has been heat-inactivated unless otherwise stated. Handle all sera and kits used as if they contain infectious agents. Observe established precautions against microbiological hazards while performing all procedures and follow the standard procedures for proper disposal of specimens.

CHEMICAL HAZARD:
Material Safety Data Sheets (MSDS) are available for all components of this kit. Review all appropriate MSDS before performing this assay. Avoid all contact between hands and eyes or mucous membranes during testing. If contact does occur, consult the applicable MSDS for appropriate treatment.

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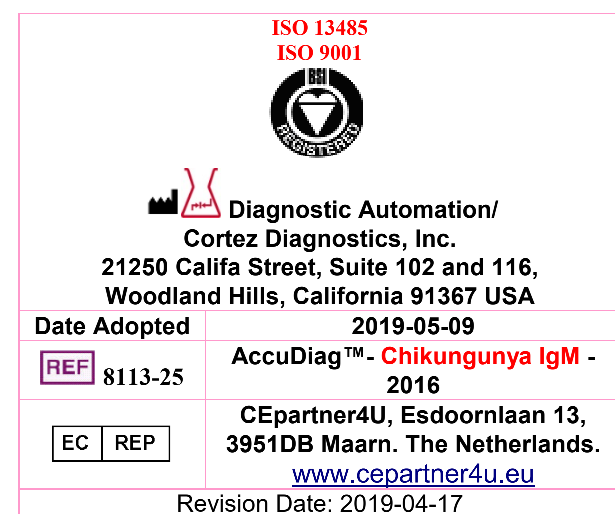

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