KRISHGEN PUDGALA
PARTNER FOR PRECISION DIAGNOSTICS

Measles Virus Antibody IgM GENLISA® ELISA

REF : KBD956

Ver 2.0

IVD

Enzyme Immunoassay for the Qualitative Determination of Measles Virus Antibody IgM in human serum and plasma

IVD	**For In-vitro Diagnostic Use**	**REF**	**Catalog Number**
	**Store At**	**LOT**	**Batch Code**
	**Manufactured By**		**Biological Risk**
	**Expiry Date**		**Consult Operating Instructions**

For *In-vitro Diagnostic Use only. Purchase does not include or carry the right to resell or transfer this product either as a stand-alone product or as a component of another product. Any use of this product other than the permitted use without the express written authorization of KRISHGEN Pudgala LLP is strictly prohibited.*

REF KBD956 Σ 96 tests

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Introduction:

Measles is a highly contagious acute viral disease caused by the measles virus, a member of the genus Morbillivirus of the family Paramyxoviridae. It is transmitted through respiratory droplets and is characterised by high fever, cough, coryza, conjunctivitis, and a characteristic maculopapular rash. Measles infection can lead to serious complications such as pneumonia, encephalitis, diarrhoea, and, in severe cases, death, particularly in young children and immunocompromised individuals. Laboratory confirmation is essential for early diagnosis and surveillance. Measles-specific IgM antibodies are detectable in serum within a few days after the onset of rash and indicate recent or acute infection. Detection of Measles IgM is therefore a reliable and widely used method for the laboratory diagnosis of primary measles infection and for epidemiological monitoring and outbreak control.

Intended Use:

The Measles Virus Antibody IgM GENLISA® ELISA kit is used as an analytical tool for Qualitative determination of Measles Virus Antibody IgM in serum, plasma and other biological samples.

Principle:

The method employs Indirect ELISA technique. Antigen specific to Measles virus is pre-coated onto microwells. Samples and standards are pipetted into microwells and Measles Virus Antibody IgM present in the sample are bound by the antigen. Anti-IgM conjugated to HRP is added and incubated to form a complex. After washing microwells in order to remove any non-specific binding, the substrate solution (TMB) is added to microwells and color develops proportionally to the amount of Measles Virus Antibody IgM in the sample. Color development is then stopped by addition of stop solution. Absorbance is measured at 450 nm.

Materials Provided:

1. Measles Virus Antigen Coated Microtiter Plate (12 x 8 wells) – 1 no
2. Predilution Plate (12 x 8 wells) – 1 no.
3. Positive Control – 0.5 ml
4. Negative Control – 0.5 ml
5. Sample Prediluent – 20 ml
6. Sample diluent – 12 ml
7. Anti-IgM:HRP Conjugate Solution – 12 ml
8. (20X) Wash Buffer – 50 ml
9. TMB Substrate – 12 ml
10. Stop Solution – 12 ml
11. Instruction Manual

Materials to be provided by the End-User:

1. Microtiter Plate Reader able to measure absorbance at 450 nm.
2. Adjustable pipettes and multichannel pipette to measure volumes ranging from 10 ul to 1000 ul.
3. Deionized (DI) water.
4. Wash bottle or automated microplate washer.
5. Graph paper or software for data analysis.
6. Timer.
7. Absorbent Paper.

Handling/Storage:

1. Kit should be stored at 2-8°C upon receipt and when it is not in use.
2. Keep un-used wells in their sealed bag with desiccants.
3. Do not use expired date reagents.
4. Do not freeze.
5. Protect from light and moisture.

Health Hazard Warnings:

1. Reagents that contain preservatives may be harmful if ingested, inhaled or absorbed through the skin. Refer to the MSDS online for details.
2. To reduce the likelihood of blood-borne transmission of infectious agents, handle all serum and/or plasma in accordance with NCCLS regulations.

Specimen Collection and Handling:

Serum- Coagulate at room temperature for 10-20 minutes; centrifuge for 20-min at 2000-3000 rpm. Remove the supernatant. If precipitation appears, re-centrifuge.
Plasma- Use EDTA or citrate plasma as an anticoagulant, mix for 10-20 minutes; centrifuge for 15-min at 2000-3000 rpm. Remove the supernatant carefully. If precipitation appears, re-centrifuge.

Reagent Preparation:

Predilute the Patient samples and control 1:10 with sample prediluent. Dispense 90 ul of sample prediluent in the E.P. tubes and add 10 ul of samples and controls, Mix them.

Test Procedure:

1. All reagents should be allowed to reach room temperature before use.
2. Add 9**0 ul Sample Diluent** into each well.
3. Add **10 ul** of **Prediluted controls and samples** to respective wells.
4. Cover the plate with a sealer and incubate for 30 minutes at 37°C.
5. Aspirate and wash plate 4 times with diluted Wash Buffer and blot residual buffer by firmly tapping plate upside down on absorbent paper. Wipe of any liquid from the bottom outside of the microtiter wells as any residue can interfere in the reading step.
6. Add **100 ul** of **Anti-IgM:HRP Conjugate solution** to each well.
7. Cover the plate with a sealer and incubate for 30 minutes at 37°C.
8. Aspirate and wash as per step no. 5 above.
9. Add **100 ul** of **TMB Substrate** into each well.
10. Do not cover the plate with the sealer and incubate it in the dark for 15 minutes at 18-25°C.
11. Add 100 ul of Stop Solution to all wells. The wells should turn from blue to yellow in color.
12. Read the absorbance at 450 nm with a microplate within 10-15 minutes after addition of Stop solution.

Validation of the test:

The test run may be considered valid provided the following criteria are met:

Positive Control	OD ≥ 1.200
Negative Control	OD ≤ 0.150
Negative Control	Nc x 0.5 ≤ Ncn ≤ Nc x 2.0, Ncn – each n-value of negative control (Nc1, Nc2, Nc3)

If one of the negative control absorbance does not match the above criteria, this value should be discarded and a mean value should be calculated using the other two values. If more than one negative control absorbance does not meet the criteria, the test is invalid and must be repeated.

Calculation of Results:

Calculate the mean absorbance value for 3 negative controls (Nc), Cut off value (CO) and $Ratio_{sample}$:

Nc = (Nc1 + Nc2 + Nc3) / 3;

CO = Nc + 0.3;

$Ratio_{sample} = OD_{sample}/CO$,

Interpretation of Results:

$Ratio_{sample}$ >1.1	Positive
0.8 ≤ $Ratio_{sample}$ ≤ 1.1	Doubtful
$Ratio_{sample}$ < 0.8	Negative

If the result is doubtful, repeat the test. If it remains doubtful, collect a new serum sample.

Performance Characteristics:

Specificity and Sensitivity
Sensitivity of the test kit Measles Antibody IgM was evaluated using 82 sera which contain IgM antibodies to Measles. The sera were characterized in the CE-marked test kits for the determination of IgM antibodies to Measles. In the test kit Measles Antibody IgM among IgM positive sera 22 samples (26.8%) were identified as positive (5).
In the study of 92 negative for antibodies to Measles sera, specificity rate was above 97.8%.

Precision

Intra-Assay precision:
Coefficient of variation (CV) was calculated by measuring 2 samples with various specific antibody levels in 32-replicate determinations using 1 lot of the test kit.

Serum No	OD_{mean}	$Ratio_{mean}$	CV%
227	1.198	3.82	5.7
1162	2.406	7.66	4.7

Inter-Assay precision:
Coefficient of variation (CV) was calculated by measuring 2 samples with various specific antibody levels in 4 ELISA performances during 4 days, in 8-replicate determinations.

Serum No	OD_{mean}	$Ratio_{mean}$	CV%
227	1.195	3.74	6.0
1162	2.463	7.72	5.3

Safety Precautions:

- **This kit is For In-vitro Diagnostic Use only**. Follow the working instructions carefully.
- The expiration dates stated on the kit are to be observed. The same relates to the stability stated for reagents.
- Do not use or mix reagents from different lots.
- Do not use reagents from other manufacturers.
- Avoid time shift during pipetting of reagents.

- All reagents should be kept in the original shipping container.
- Some of the reagents contain small amount of sodium azide (< 0.1 % w/w) as preservative. They must not be swallowed or allowed to come into contact with skin or mucosa.
- Source materials maybe derived from human body fluids or organs used in the preparation of this kit were tested and found negative for HBsAg and HIV as well as for HCV antibodies. However, no known test guarantees the absence of such viral agents. Therefore, handle all components and all patient samples as if potentially hazardous.
- Since the kit contains potentially hazardous materials, the following precautions should be observed.
- Do not smoke, eat or drink while handling kit material.
- Always use protective gloves.
- Never pipette material by mouth.
- Wipe up spills promptly, washing the affected surface thoroughly with a decontaminant.
- In any case GLP should be applied with all general and individual regulations to the use of this kit.

LIMITED WARRANTY

Krishgen Pudgala LLP does not warrant against damages or defects arising in shipping or handling, or out of accident or improper or abnormal use of the product; against defects in products or components not manufactured by Krishgen Pudgala LLP, or against damages resulting from such non-Krishgen Pudgala LLP made products or components. Krishgen Pudgala LLP passes on to customer the warranty it received (if any) from the maker thereof of such non-Krishgen made products or components. This warranty also does not apply to product to which changes or modifications have been made or attempted by persons other than pursuant to written authorization by Krishgen Pudgala LLP.

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Regulatory Status:

CE Marked	Europe
FDA registered	USA
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