AccuDiag™ Measles IgG ELISA Kit

REF 1408-P1

IVD See External Label 2-8°C 96 Tests

Measles IgG ELISA	
Principle	Indirect ELISA
Detection	Quantitative
Sample	10 µL serum/plasma
Incubation Time	75 minutes
Sensitivity	99.3%
Specificity	91.0%
Shelf Life	12 Months from the manufacturing date

PRODUCT FEATURES

- Very easy to use with little training
- Highly specific and consistent Assay
- Provides accurate results quickly
- Reading of results both visually and as absorbance data

INTENDED USE

The Diagnostic Automation, Inc. ELISA, Measles IgG Enzyme-Linked Immunosorbent Assay (ELISA) is intended for the detection and quantitative determination of IgG antibodies to Measles (Rubeola) virus in human sera. Individual serum specimens may be used for the determination of immune status. Paired sera, acute and convalescent, may be used to demonstrate seroconversion or a significant rise in antibody as an aid in the diagnosis of recent or current infection. **For *in vitro* diagnostic use. High Complexity test.**

SIGNIFICANCE AND SUMMARY

Since the introduction of a measles virus vaccine, the U.S. has mounted an effective immunization program which has essentially eliminated measles as a major childhood disease. However, as a result of vaccine failure or the failure to be vaccinated, a recent and persistent shift in the susceptible population towards young adults has been recorded.[1] In the case of measles, severity of illness and mortality rates are highest among adults.[2] Thus, serology has become increasingly important as a tool for determining the immune status of the young adult population entering college or the military. In addition, the linkage between measles infection and premature delivery or spontaneous abortion supports screening pregnant mothers for susceptibility.[3]

Although measles has been recognized as a disease for over two thousand years, a description of its epidemiology first appeared in a paper by Panum in 1849. In his study of an epidemic in the Faroe Islands, Panum observed that measles had an incubation period of two weeks and was contagious but that lifelong immunity followed primary infection.[4] Over 100 years later, in 1963, the first live measles vaccine was licensed in the United States. Vaccine development was made possible by Enders and Peebles' discovery, in 1954, that the virus could be successfully grown in an in vitro cell culture system.[5] The success of the vaccine program is evident by the precipitous drop in the annual incidence.

Classified as a paramyxovirus, measles produces a highly contagious respiratory infection. The disease is spread during the prodromal phase through direct contact with respiratory secretions in the form of droplets.[3] Ironically, because of the low incidence of measles, younger physicians often diagnose the illness late in infection after the patient has exposed others. This has resulted in small isolated miniepidemics among the susceptible population.

Several diseases in addition to Measles have been associated but not causally linked to measles virus. This list includes subacute sclerosing panencephalitis (SSPE),[6] systemic lupus erythematosus (SLE)[7] and multiple sclerosis (MS).[8] Patients with SSPE, a chronic degenerative neurologic disease, have documented high levels of antibody to measles virus. However, for SLE and MS there is less pronounced but statistically significant elevation in antibody levels. The significance or role of measles virus infection in these disease states is unknown at the present time.

Since the presence of circulating IgG antibody to measles virus is indicative of previous infection or vaccination, screening the young adult population about to enter college or the military, pregnant women, and other individuals at risk, for seropositivity, is a valuable tool for determining their immune status.

The Diagnostic Automation, Inc. Measles IgG ELISA kit provides all the necessary reagents for the rapid determination and quantitation of IgG antibody to measles virus in human sera.

The sensitivity, specificity, and reproducibility of enzyme-linked immunoassays is comparable to other serological tests for antibody, such as immunofluorescence, complement fixation, hemagglutination and radioimmunoassay.[13,14,15]

ASSAY PRINCIPLE

Enzyme-Linked Immunosorbent Assays (ELISA) rely on the ability of biological materials (i.e., antigens) to adsorb to plastic surfaces such as polystyrene (solid phase). When antigens bound to the solid phase are brought into contact with a patient's serum, antigen specific antibody, if present, will bind to the antigen on the solid phase forming antigen- antibody complexes. Excess antibody is removed by washing. This is followed by the addition of goat anti-human IgG conjugated with horseradish peroxidase which then binds to the antibody-antigen complexes. The excess conjugate is removed by washing,

followed by the addition of Chromogen/Substrate, tetramethylbenzidine (TMB). If specific antibody to the antigen is present in the patient's serum, a blue color develops. When the enzymatic reaction is stopped with 1N H_2SO_4, the contents of the wells turn yellow. The color, which is indicative of the concentration of antibody in the serum, can be read on a suitable spectrophotometer or ELISA microwell plate reader.[9,10,11,12]

SPECIMEN COLLECTION & PREPARATION

1. Handle all blood and serum as if capable of transmitting infectious agents.
2. Optimal performance of the DAI ELISA kit depends upon the use of fresh serum samples (clear, non-hemolyzed, nonlipemic, non-icteric). A minimum volume of 50 µL is recommended, in case repeat testing is required. Specimens should be collected aseptically by venipuncture.[17] Early separation from the clot prevents hemolysis of serum.
3. Store serum between 2 and 8°C if testing will take place within two days. If specimens are to be kept for longer periods, store at -20°C or colder. Do not use a frost-free freezer because it may allow the specimens to go through freeze-thaw cycles and degrade antibody. Samples that are improperly stored or are subjected to multiple freeze-thaw cycles may yield erroneous results.
4. If paired sera are to be collected, acute samples should be collected as soon as possible after the onset of symptoms. The second sample should be collected 14 to 21 days after the acute specimen was collected. Both samples must be run in duplicate on the same plate to test for a significant rise. If the first specimen is obtained late during the course of the infection, a significant rise may not be detectable.
5. The NCCLS provides recommendations for storing blood specimens (Approved Standard Procedures for the Handling and Processing of Blood Specimens, H18-A. 1990).[17]

REAGENTS

Each kit contains the following components in sufficient quantities to perform the number of tests indicated on the package label.

Materials provided with the kit

1. **Measles virus antigen (inactivated) coated microassay plate**: 96 wells, configured in twelve 1x8 strips stored in a foil pouch with desiccant. (96T: one plate)
2. **Serum Diluent Type I:** Ready to use, contains Proclin® (0.1%) as a preservative. (96T: one bottle, 30 mL each)
3. **Calibrator:** Human serum or defibrinated plasma. Sodium azide (< 0.1%) and pen/strep (0.01%) added as preservatives, with kit specific factor printed on vial label. The Calibrator is used to calibrate the assay to account for day-to-day fluctuations in temperature and other testing conditions. (96T: one vial, 0.4mL) *
4. **Positive Control:** Human serum or defibrinated plasma. Sodium azide (< 0.1%) and pen/strep (0.01%) added as preservatives, with established range printed on vial label. The Positive Control is utilized to control the positive range of the assay. (96T: one vial, 0.4 mL)*
5. **Negative Control:** Human serum or defibrinated plasma. Sodium azide (< 0.1%) and pen/strep (0.01%) added as preservatives, with established range printed on vial label. The Negative Control is utilized to control the negative range of the assay (96T: one vial, 0.4 mL)*
6. **Horseradish-peroxidase (HRP) Conjugate:** Ready to use. Goat anti-human IgG, containing Proclin (0.1%) and gentamicin as preservatives. (96T: one bottle, 16 mL)
7. **Chromogen/Substrate Solution Type I:** Tetramethylbenzidine (TMB), ready to use. The reagent should remain closed when not in use. If allowed to evaporate, a precipitate may form in the reagent wells. (96T: one bottle, 15 mL)
8. **Wash Buffer Type I (20X concentrate):** Dilute 1 part concentrate + 19 parts deionized or distilled water. Contains TBS, Tween-20 and Proclin® (0.1%) as a preservative. (96T: one bottle, 50 mL)
9. **Stop Solution:** Ready to use, contains a 1N H_2SO_4 solution. (96T: one bottle, 15 mL)

**Note: serum vials may contain excess volume.*

Materials required but not provided

1. Wash bottle, automated or semi-automated microwell plate washing system.
2. Micropipettes, including multichannel, capable of accurately delivering 10-200 µLvolumes (less than 3% CV).
3. One liter graduated cylinder.
4. Paper towels.
5. Test tube for serum dilution.
6. Reagent reservoirs for multichannel pipettes.
7. Pipette tips.
8. Distilled or deionized water (dH_2O), CAP (College of American Pathology) Type 1 or equivalent.[19, 20]
9. Timer capable of measuring to an accuracy of +/- 1 second (0 – 60minutes).
10. Disposal basins and 0.5% sodium hypochlorite (50 mL bleach in 950mL dH_2O).
11. Single or dual wavelength microplate reader with 450 nm filter. If dual wavelength is used, set the reference filter to 600-650 nm. Read the Operator's Manual or contact the instrument manufacturer to establish linearity performance specifications of the reader.

Note: Use only clean, dry glassware.

REAGENT PREPARATION

1. All reagents must be removed from refrigeration and allowed to come to room temperature before use (21° to 25°C). Return all reagents to refrigerator promptly after use.
2. All samples and controls should be vortexed before use.
3. Dilute 50 mL of the 20X Wash Buffer Type I to 1 L with distilled and/or deionized H_2O Mix well.

ASSAY PROCEDURE

Note: To evaluate paired sera, both serum samples must be tested in duplicate and run in the same plate. It is recommended that the serum pairs be run in adjacent wells.

1. Place the desired number of strips into a microwell frame. Allow four (4) Control/Calibrator determinations (one Negative Control, two Calibrators and one Positive Control) per run. A reagent blank (RB) should be run on each assay. Check software and reader requirements for the correct Control/Calibrator configuration. Return unused strips to the sealable bag with desiccant, seal and immediately refrigerate.

Example Configuration:

Plate Location	Sample Description	Plate Location	Sample Description
1A	RB	2A	Patient # 4
1B	NC	2B	Patient # 5
1C	Cal	2C	Patient # 6
1D	Cal	2D	Patient # 7

Plate Location	Sample Description	Plate Location	Sample Description
1E	PC	2E	Patient # 8 (Acute 1)
1F	Patient # 1	2F	Patient # 9 (Acute 2)
1G	Patient # 2	2G	Patient # 10 (Convalescent 1)
1H	Patient # 3	2H	Patient # 11 (Convalescent 2)

RB = Reagent Blank - well without serum addition run with all reagents. Utilized to blank reader.

NC = Negative Control

Cal = Calibrator

PC = Positive Control

2. Dilute test sera, Calibrator and Control sera 1:21 (e.g., 10 µL + 200 µL) in Serum Diluent. Mix well. (For manual dilutions it is suggested to dispense the Serum Diluent into the test tube first and then add the patient serum.)
3. To individual wells add 100 µL of diluted patient sera, Calibrator and Controls. Add 100 µL of Serum Diluent to the reagent blank well. Check software and reader requirements for the correct reagent blank well configuration.
4. Incubate each well at room temperature (21° to 25° C) for **25 minutes +/- 5 minutes**.
5. Aspirate or shake out liquid from all wells. Using semi-automated or automated washing equipment add 250-300 µL of diluted Wash Buffer to each well. Aspirate or shake out to remove all liquid. Repeat the wash procedure two times (for a total of three washes) for manual or semi-automated equipment or four times (for a total of five washes) for automated equipment. After the final wash, blot the plate on paper toweling to remove all liquid from the wells.

IMPORTANT NOTE: Regarding steps 5 and 8 - Insufficient or excessive washing will result in assay variation and will affect validity of results. Therefore, for best results the use of semiautomated or automated equipment set to deliver a volume to completely fill each well (250-300 µL) is recommended. A total of five (5) washes may be necessary with automated equipment. Complete removal of the Wash Buffer after the last wash is critical for the accurate performance of the test. Also, visually ensure that no bubbles are remaining in the wells.

6. Add 100 µL Conjugate to each well, including the reagent blank well. Avoid bubbles upon addition as they may yield erroneous results.
7. Incubate each well at room temperature (21 to 25°C) for **25 minutes +/- 5 minutes**.
8. Repeat wash as described in Step 5.
9. Add 100 µL Chromogen/Substrate solution (TMB) to each well, including reagent blank well, maintaining a constant rate of addition across the plate.
10. Incubate each well at room temperature (21 to 25°C) for **10-15 minutes**.
11. Stop reaction by addition of 100 µL of Stop Solution (1N H_2SO_4) following the same order of Chromogen/Substrate addition, including reagent blank well. Tap the plate gently along the outsides to mix contents of the wells. The plate may be held up to one (1) hour after addition of the Stop Solution before reading.
12. The developed color should be read on an ELISA plate reader equipped with a 450 nm filter. If dual wavelength is used, set the reference filter to 600-650 nm. The instrument should be blanked on air. The reagent blank must be less than 0.150 Absorbance at 450 nm. If the reagent blank is > 0.150, the run must be repeated. Blank the reader on the reagent blank well and then continue to read the entire plate. Dispose of used plates after readings have been obtained.

RESULTS

CALCULATIONS

1. **Mean Calibrator O.D. (Optical Density)** - Calculate the mean O.D. value from the two Calibrator determinations.
2. **Correction Factor** - To account for day-to-day fluctuations in assay activity due to room temperature and timing, a Correction Factor is determined by Diagnostic Automation Inc. for each lot of kits. The Correction Factor is printed on the Calibrator vial.
3. **Cutoff Calibrator Value** - The Cutoff Calibrator Value for each assay is determined by multiplying the Correction Factor by the mean Calibrator O.D. determined in Step 1.
4. **ISR Value** - Calculate an Immune Status Ratio (ISR) for each specimen by dividing the specimen O.D. Value by the Cutoff Calibrator Value determined in Step 3.

Example:

O.D's obtained for Calibrator	=0.38,0.42
Mean O.D. for Calibrator	=0.40
Correction factor	=0.50
Cutoff Calibrator Value	=0.50 x 0.40 = 0.20
O.D. obtained for patient sera	=0.60
ISR Value	=0.60/0.20 = 3.00

ANALYSIS

1. The patients' ISR (Immune Status Ratio) values are interpreted as follows:

ISR Value	Results	Interpretation
≤ 0.90	Negative	No detectable IgG antibody to Measles by the ELISA test. Such individuals are presumed to be uninfected with Measles and to be susceptible to primary infection.
0.91-1.09	Equivocal	Samples should be retested. See number (2) below.
≥ 1.10	Positive	Indicates presence of detectable IgG antibody to Measles by the ELISA test. Indicative of current or previous infection. The individual may be at risk of transmitting Measles infection, but is not necessarily currently contagious.

2. Samples that remain equivocal after repeat testing should be retested on an alternate method, e.g. immunofluorescence assay (IFA). If results remain equivocal upon further testing, an additional sample should be taken. (See Limitation No. 3)
3. In the evaluation of paired sera, if the acute specimen is negative and the convalescent specimen is positive, a seroconversion has taken place. This indicates a significant change in antibody level and the patient is undergoing a primary infection.
4. To evaluate paired sera for a significant change in antibody level or seroconversion, both samples must be tested in duplicate in the same assay. The mean ISR of both samples (acute and convalescent) must be greater than 1.00 to evaluate the paired sera for significant rise in antibody level.
5. Additional Quality Control for Paired Sera: (See NOTE under Assay Procedure). As a check for acceptable reproducibility of both the acute sera (tested in duplicate) and the convalescent sera (tested in duplicate), the following criteria must be met for valid results:

$$\frac{\text{Acute 1 ISR}}{\text{Acute 2 ISR}} = 0.8 \text{ to } 1.2 \qquad \frac{\text{Convalescent 1 ISR}}{\text{Convalescent 2 ISR}} = 0.8 \text{ to } 1.2$$

6. Compare the ISR of the pairs by calculating as follows:

$$\frac{\text{Mean ISR (second sample)} - \text{Mean ISR (first sample)}}{\text{Mean ISR (first sample)}} \times 100 = \text{RISE IN ISR LEVEL}$$

% Rise in ISR	Interpretation
< 30.0%	No significant change in antibody level. No evidence of recent infection. If active disease is still suspected, a third sample should be collected and tested in the same assay as the first sample to look for a significant rise in antibody level.
≥ 30.0%	Statistically significant change in antibody level detected. This identifies those persons who are presumed to be experiencing recent or current episodes of measles infection (reactivation, reinfection or a primary infection where the acute specimen was obtained too late to demonstrate seroconversion).

Note: When evaluating paired sera, it should be determined if samples with high absorbance values are within linearity specifications of the spectrophotometer. Read the Operator's Manual or contact the instrument's manufacturer to obtain the established linearity specifications of your spectrophotometer.

QUALITY CONTROL

For the assay to be considered valid the following conditions must be met:

1. Calibrator and Controls must be run with each test run.
2. Reagent blank (when read against air blank) must be <0.150 Absorbance (A) at 450 nm.
3. Negative Control must be < 0.250 A at 450 nm (when read against reagent blank).
4. Each Calibrator must be ≥0.250 A at 450 nm (when read against reagent blank).
5. Positive Control must be ≥0.500 A at 450 nm (when read against reagent blank).
6. The ISR (Immune Status Ratio) Values for the Positive and Negative Controls should be in their respective ranges printed on the vials. If the Control values are not within their respective ranges, the test should be considered invalid and should be repeated.
7. Additional Controls may be tested according to guidelines or requirements of local, state, and/or federal regulations or accrediting organizations.
8. Refer to NCCLS C24-A for guidance on appropriate Quality Control practices.[18]
9. If above criteria are not met on repeat testing, contact Diagnostic Automation, Inc. Technical Services.

PERFORMANCE CHARACTERISTICS

SENSITIVITY AND SPECIFICITY

172 random samples were tested on the Diagnostic Automation, Inc. Measles IgG ELISA and another commercially available Measles IgG ELISA. There was complete agreement on 143 samples. There were 27 discrepant samples which were tested on a commercially available Measles IgG IFA. Twenty samples were positive by the DAI ELISA and negative by the other commercial ELISA. Two of the remaining seven discrepants were resolved in favor of the DAI Measles IgG ELISA. Two samples were resolved in favor of the other commercial ELISA and three samples remained unresolved. When tested by IFA, 19 were positive and 1 was negative. Therefore 21 out of 27 discrepants were resolved in favor of the DAI Measles IgG ELISA. This data indicates a sensitivity of 99.3% and a specificity of 91.0%.

INTRA-ASSAY PRECISION

Table 1 presents the results of five (5) samples individually pipetted in groups of twenty (20) in a single assay.

Table 1: Intra-Assay Precision for Measles IgG

	n	Mean ISR	Std Dev	% CV
Serum 1	20	2.62	0.100	4.6%
Serum 2	20	0.39	0.069	17.9%
Serum 3	20	0.43	0.020	4.7%
Serum 4	20	2.40	0.120	5.0%
Serum 5	20	2.13	0.080	3.8%

INTER-ASSAY PRECISION

The same master lot of the Diagnostic Automation, Inc. Measles IgG ELISA was evaluated on three (3) different days using five (5) samples individually pipetted in groups of five (5). The data are summarized in Table 2:

Table 2: Inter-Assay Precision for Measles IgG

	Day 1	Day 2	Day 3	n	Mean ISR	Std Dev	% CV
Serum 1	2.80	2.79	3.03	3	2.89	0.149	5.2%
Serum 2	0.45	0.46	0.60	3	0.51	0.077	15.2%
Serum 3	0.41	0.47	0.39	3	0.42	0.044	10.4%
Serum 4	2.49	2.26	2.47	3	2.41	0.140	5.8%
Serum 5	2.13	2.23	2.23	3	2.20	0.100	4.6%

INTER-LOT PRECISION

Table 3 presents a summary of the lot to lot precision data determined by replicate testing of five (5) samples individually pipetted in groups of five (5) using three (3) different lots of reagents.

Table 3: Inter-Lot Precision for Measles IgG

	Lot 1	Lot 2	Lot 3	n	Mean ISR	Std Dev	% CV
Serum 1	2.66	2.74	2.74	3	2.72	0.100	3.7%
Serum 2	0.46	0.52	0.60	3	0.53	0.136	25.7%
Serum 3	0.32	0.40	0.41	3	0.38	0.042	11.1%
Serum 4	1.76	2.07	2.16	3	2.00	0.187	9.4%
Serum 5	1.55	2.09	2.11	3	1.92	0.274	14.3%

EVALUATION OF PAIRED SERUM SAMPLES

Paired serum samples (acute and convalescent) were collected from 21 individuals. These paired samples were assayed with the Diagnostic Automation, Inc. Measles IgG ELISA, and compared with results obtained with a comparable Measles ELISA and a Measles IFA. Fifteen samples demonstrated a significant rise in antibody level (> 30%). Of these, 7 individuals seroconverted from a negative acute sample to a positive convalescent sample. The remaining 9 samples were positive or equivocal on acute samples and positive on convalescent samples. Four pairs were positive by the DAI Measles IgG ELISA but did not show a significant rise in ISR. Two of these sample pairs did have a four-fold rise in IFA titer and one sample pair did not. The remaining paired samples did not show a significant rise by the other ELISA test method.

LIMITATIONS OF THE ASSAY

1. The user of this kit is advised to carefully read and understand the package insert. Strict adherence to the protocol is necessary to obtain reliable test results. In particular, correct sample and reagent pipetting, along with careful washing and timing of the incubation steps are essential for accurate results.
2. This kit is designed to measure IgG antibody in patient samples. Positive results in neonates must be interpreted with caution, since maternal IgG is transferred passively from the mother to the fetus before birth. IgM assays are generally more useful indicators of infection in children below 6 months of age.
3. Samples collected very early in the course of an infection may not have detectable levels of IgG. In such cases, it is recommended that an IgM assay be performed, or a second serum sample be obtained 14 to 21 days later to be tested in parallel with the original sample to determine seroconversion.
4. The results of ELISA performed on serum from patients with immunosuppression or recent blood transfusion must be interpreted with caution. The presence of IgG antibody against a particular virus or organism may not assure protection from that disease.
5. The values obtained from this assay are intended to be an aid to diagnosis only. Each physician must interpret the results in light of the patient's history, physical findings and other diagnostic procedures.

STORAGE CONDITIONS

1. Store unopened kit between 2 and 8°C. The test kit may be used throughout the expiration date of the kit. Refer to the package label for the expiration date.
2. Unopened microassay plates must be stored between 2 and 8°C. Unused strips must be immediately resealed in a sealable bag with desiccant and returned to storage between 2 and 8°C.
3. Store HRP Conjugate between 2 and 8°C.
4. Store the Calibrator, Positive and Negative Controls between 2 and 8°C.
5. Store Serum Diluent Type I and 20X Wash Buffer Type I between 2 and 8° C.
6. Store the Chromogen/Substrate Solution Type I between 2 and 8°C. The reagent should remain closed when not in use. If allowed to evaporate, a precipitate may form in the reagent wells.
7. Store 1X (diluted) Wash Buffer Type I at room temperature (21 to 25°C) for up to 5 days, or up to 1 week between 2 and 8°C.

Note: If constant storage temperature is maintained, reagents and substrate will be stable for the dating period of the kit. Refer to package label for expiration date. Precautions were taken in the manufacture of this product to protect the reagents from contamination and bacteriostatic agents have been added to the liquid reagents. Care should be exercised to protect the reagents in this kit from contamination.

PRECAUTIONS

1. For *in vitro* diagnostic use.
2. The human serum components used in the preparation of the Controls and Calibrator in this kit have been tested by an FDA approved method for the presence of antibodies to human immunodeficiency virus 1 & 2 (HIV 1&2), hepatitis C (HCV) as well as hepatitis B surface antigen and found negative. Because no test method can offer complete assurance that HIV, HCV, hepatitis B virus, or other infectious agents are absent, specimens and human-based reagents should be handled as if capable of transmitting infectious agents.
3. The Centers for Disease Control & Prevention and the National Institutes of Health recommend that potentially infectious agents be handled at the Biosafety Level 2.[16]
4. The components in this kit have been quality control tested as a Master Lot unit. Do not mix components from different lot numbers except Chromogen/Substrate Solution Type I, Stop Solution, Wash Buffer Type I, and Serum Diluent Type I. Do not mix with components from other manufacturers.
5. Do not use reagents beyond the stated expiration date marked on the package label.
6. All reagents must be at room temperature (21 to 25 °C) before running assay. Remove only the volume of reagents that is needed. Do not pour reagents back into vials as reagent contamination may occur.
7. Before opening Control and Calibrator vials, tap firmly on the benchtop to ensure that all liquid is at the bottom of the vial.
8. Use only distilled or deionized water and clean glassware.
9. Do not let wells dry during assay; add reagents immediately after completing wash steps.
10. Avoid cross-contamination of reagents. Wash hands before and after handling reagents. Cross-contamination of reagents and/or samples could cause erroneous results.
11. If washing steps are performed manually, wells are to be washed three times. Up to five wash cycles may be necessary if a washing manifold or automated equipment is used.
12. Sodium azide inhibits Conjugate activity. Clean pipette tips must be used for the Conjugate addition so that sodium azide is not carried over from other reagents.
13. It has been reported that sodium azide may react with lead and copper in plumbing to form explosive compounds. When disposing, flush drains with water to minimize build-up of metal azide compounds.
14. Never pipette by mouth or allow reagents or patient sample to come into contact with skin. Reagents containing proclin, sodium azide, and TMB may be irritating. Avoid contact with skin and eyes. In case of contact, flush with plenty of water.
15. If a sodium hypochlorite (bleach) solution is being used as a disinfectant, do not expose to work area during actual test procedure because of potential interference with enzyme activity.
16. Avoid contact of Stop Solution (1N sulfuric acid) with skin or eyes. If contact occurs, immediately flush area with water.
17. Caution: Liquid waste at acid pH must be neutralized prior to adding sodium hypochlorite (bleach) solution to avoid formation of poisonous gas. Recommend disposing of reacted, stopped plates in biohazard bags. See Precaution 3.
18. The concentrations of anti-Measles in a given specimen determined with assays from different manufacturers can vary due to differences in assay methods and reagent specificity. Never pipette by mouth or allow reagents or patient sample to come into contact with skin. Reagents containing proclin, sodium azide, and TMB may be irritating. Avoid contact with skin and eyes. In case of contact, flush with plenty of water.

The safety data sheet is available upon request.

WARNING

Serum Diluent, Conjugate, and Wash Buffer contain 0.1% ProClin 300®, a biocidal preservative that may cause sensitization by skin contact; prolonged or repeated exposure may cause allergic reaction in certain sensitive individuals.

H317: May cause an allergic skin reaction.
P280: Wear protective gloves / protective clothing / eye protection / face protection.
P302 + P352: IF ON SKIN: Wash with plenty of soap and water.
P333 + P313: If skin irritation or rash occurs: Get medical advice/ attention.
P501: Dispose of contents and container in accordance to local, regional, national and international regulations.
WARNING
Serum Diluent and Controls contain <0.1% sodium azide.
H302: Harmful if swallowed.
P264: Wash thoroughly with plenty of soap and water after handling.
P270: Do not eat, drink, or smoke when using this product.
P301+P312: IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.
P330: If swallowed, rinse mouth.
P501: Dispose of contents/container to in accordance to local, regional, national and international regulations.

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MANUFACTURER AND BRAND DETAILS

ISO 13485:2016

bsi ISO 13485 Quality Management for Medical Devices CERTIFIED

Diagnostic Automation/Cortez Diagnostics, Inc.
21250 Califa Street, Suite 102 and 116,
Woodland Hills, California 91367 USA

Date Adopted	**2023-11**
Brand Name	**AccuDiag™**
REF 1408-P1	**AccuDiag™ - Measles IgG ELISA**
EC REP	**CEpartner4U, Esdoornlaan 13, 3951 DB Maarn, The Netherlands** www.cepartner4u.eu
Revision Date: 2015-03-31	