AccuDiag™ CMV IgG ELISA KIT

REF 1201-2

IVD See external Label 8°C 2°C Σ 96 Tests

Test	CMV IgG
Method	Enzyme Linked Immunosorbent Assay
Principle	Sandwich Complex
Detection Range	Qualitative: Positive & Negative Control & Cut off
Sample	10µl serum
Total Time	~ 70 min
Shelf Life	12 Months from the manufacturing date
Specificity	93.9%
Sensitivity	96.4%

INTENDED USE

The CMV IgG ELISA test system is an enzyme-linked immunosorbent assay (ELISA) for the qualitative detection of IgG class antibodies to cytomegalovirus (CMV) in human serum. The test system is intended to be used to evaluate serologic evidence of previous or primary infection with CMV. This product is not FDA cleared (approved) for use in testing (i.e.,screening) blood or plasma donors. This test is intended for *in-vitro* diagnostic use only.

SUMMARY AND EXPLANATION

Cytomegalovirus (CMV) infections are widespread and usually asymptomatic; however, the virus may persist as a latent or chronic infection (1). The relatively frequent incidence and often severe disease in newborns and immunosuppressed individuals clearly establishes this agent as an important human pathogen (2-4). CMV infections can be classified as follows:

Congenital - Acquired before birth.
Perinatal - Acquired at birth
Postnatal - Acquired after birth

Of the newborn infants congenitally infected with CMV, 95% exhibit no clinically overt disease at birth (5). Of the remaining 5% of infected infants, clinical manifestations range from severe disease with jaundice, hepatosplenomegaly, thrombocytopenic purpura, cranial calcification, and growth retardation to pneumonitis, hydrocephaly or microcephaly and ocular defects (6). Infants with severe manifestations of congenital CMV infection may expire early after birth due to secondary complications; however, most survive with consequent neurological damage (2).

Health professionals must be guarded with the prognosis for congenitally infected infants who are asymptomatic at birth. Ten to 25% of infants may subsequently develop hearing loss (7). Five to 10% of infants may exhibit various degrees of mental retardation and central nervous system motor disorders (5). Surveys show the incidence of congenital CMV infection to be from 0.5 - 2.5%. Consequently, a careful documentation of the long-term effects of intrauterine infection is important (8).

Perinatally infected infants start excreting CMV 3 - 12 weeks after delivery, and with rare exception, remain asymptomatic (9). Acquisition of postnatal CMV infections can occur through close contact with individuals who are shedding the virus (2). CMV has been isolated from saliva, urine, breast milk, cervical secretions, and semen. Consequently, the transmission of the virus may occur through a variety of mechanisms (6 - 8). Sexual transmission of the virus appears to contribute to the acquisition of the virus by young adults (10). Although the acquisition age for CMV infection varies with socioeconomic conditions, only about 10 - 15% of children in the United States are seropositive. By age 35 however, about 50% of the population is seropositive (2 - 4).

The majority of individuals contracting postnatal CMV infections remain asymptomatic (2 - 4). A small percentage of individuals will develop a negative heterophile-antibody infectious mononucleosis syndrome. Characteristics of CMV mononucleosis include fever, lethargy, and atypical lymphocytosis; whereas, in Epstein-Barr virus induced infectious mononucleosis, pharyngitis, lymphadenopathy, and splenomegaly are the chief clinical features (11 - 12).

In immunocompromised patients, CMV infections happen frequently, often from reactivation of latent infection, and may be life-threatening (2 - 4). These patients include allograft recipients, cancer patients, and patients with acquired immunodeficiency syndrome (AIDS) (4, 13, and 15). Clinical manifestations of CMV disease in immunocompromised patients range from CMV mononucleosis to pneumonia, hepatitis, pericarditis, and encephalitis (4).

CMV infections may occur following blood transfusions, and the risk of infection increases with the number of donors and the volume of blood given (4). Seronegative recipients may contract primary infection via blood from a seropositive donor. In seropositive recipients, reactivated latent infection may occur. Most transfusion acquired CMV infections are either subclinical or characterized by CMV mononucleosis (2 - 4). However, in specific groups of patients, considerable morbidity and mortality can result from a transfusion-acquired primary CMV infection. These patients are immunocompromised and include premature infants, pregnant women, cancer patients, and transplant recipients (4 - 14). In these patients, transfusion acquired CMV infections can be prevented by giving only blood from seronegative donors to seronegative recipients (4 - 14).

Serologic procedures, which measure IgG antibodies to CMV, can aid in the diagnosis of CMV infection when testing paired acute and convalescent sera simultaneously and seroconversion, or a significant rise in titer, can be demonstrated (15). In addition, serologic procedures may aid in the prevention of transfusion acquired CMV infections by assessing the serologic status of donors and recipients (4 - 14).

Engvall and Perlman (19, 20) first described the ELISA (enzyme-linked immunosorbent assay) procedure. Since then, scientists have developed ELISA test systems for the detection of a wide variety of different antigens and antibodies, including antibodies to CMV (16, 17, and 21). They have also developed a number of serologic procedures other than ELISA to detect antibodies to CMV. These include complement fixation (16, 18), indirect immunofluorescence (18), indirect hemagglutination (18, 22), and latex agglutination (22). When compared to other serologic tests for detection of antibodies to CMV, ELISA may be a very specific, sensitive, and reliable method for detection of antibodies to CMV (16, 17, and 18).
The ELISA procedure allows for an objective determination of antibody status on a single dilution of the test specimen and is suitable for screening large numbers of patient samples.

TEST PRINCIPLE

The Diagnostic Automation Inc. CMV IgG ELISA test system is designed to detect IgG class antibodies to CMV in human sera. Wells of plastic microwell strips are

sensitized by passive adsorption with CMV antigen. The test procedure involves three incubation steps:

1. Test sera (properly diluted) are incubated in antigen coated microwells. Any antigen specific antibody in the sample will bind to the immobilized antigen. The plate is washed to remove unbound antibody and other serum components.
2. Peroxidase Conjugated goat anti-human IgG is added to the wells and the plate is incubated. The Conjugate will react with IgG antibody immobilized on the solid phase in step 1. The wells are washed to remove unreacted Conjugate.
3. The microwells containing immobilized peroxidase Conjugate are incubated with peroxidase Substrate Solution. Hydrolysis of the Substrate by peroxidase produces a color change. After a period of time the reaction is stopped and the color intensity of the solution is measured photometrically. The color intensity of the solution depends upon the antibody concentration in the original test sample.

SPECIMEN COLLECTION AND PREPARATION

1. It is recommended that specimen collection be carried out in accordance with CLSI document M29: Protection of Laboratory Workers from Infectious Disease.
2. No known test method can offer complete assurance that human blood samples will not transmit infection. Therefore, all blood derivatives should be considered potentially infectious.
3. Only freshly drawn and properly refrigerated sera obtained by approved aseptic venipuncture procedures should be used in this assay. No anticoagulants or preservatives should be added. Avoid using hemolyzed, lipemic, or bacterially contaminated sera.
4. Store sample at room temperature for no longer than 8 hours. If testing is not performed within 8 hours, sera may be stored between 2°C and 8°C for no longer than 5 days. If delay in testing is anticipated, store test sera at –20°C or lower. Avoid multiple freeze/thaw cycles that may cause loss of antibody activity and give erroneous results. It is the responsibility of the individual laboratory to use all available references and/or its own studies to determine stability criteria for its laboratory.

MATERIALS AND COMPONENTS

Materials provided with the test kits

Each kit contains the following components in sufficient quantities to perform the number of tests indicated on packaging label. **Note: The following components contain Sodium Azide as a preservative at a concentration of <0.1% (w/v): Controls, Calibrators and Sample Diluent.**

1. **Plate**. 96 wells configured in twelve 1x8-well strips coated with inactivated cytomegalovirus antigen (strain AD169.) The strips are packaged in a strip holder and sealed in an envelope with desiccant.
2. **Conjugate**. Conjugated (horseradish peroxidase) goat anti-human IgG (Fc chain specific). Ready to use. One, 15 mL vial with a white cap.
3. **Positive Control (Human Serum).** One, 0.35 mL vial with a red cap.
4. **Calibrator (Human Serum).** One, 0.5 mL vial with a blue cap.
5. **Negative Control (Human Serum).** One, 0.35 mL vial with a green cap.
6. **Sample Diluent.** One 30 mL bottle (green cap) containing Tween-20, bovine serum albumin and phosphate-buffered-saline, Ready to use. **NOTE: The Sample Diluent will change color in the presence of serum.**
7. **TMB:** One 15 mL amber bottle (amber cap) containing 3, 3', 5, 5'-tetramethylbenzidine (TMB). Ready to use.
8. **Stop solution:** One 15 mL bottle (red cap) containing 1M H_2SO_4, 0.7M HCl. Ready to use.
9. **Wash buffer concentrate (10X):** dilute 1 part concentrate + 9 parts deionized or distilled water. One 100 mL bottle (clear cap) containing a 10X concentrated phosphate-buffered-saline and Tween-20 solution (blue solution). **NOTE: 1X solution will have a pH of 7.2 ± 0.2.**

The following components are not kit lot number dependent and may be used interchangeably with the ELISA assays: TMB, Stop Solution, and Wash Buffer.

Note: Kit also contains:

1. Component list containing lot specific information is inside the kit box.
2. Package insert providing instructions for use.

Materials required but not provided

1. ELISA microwell reader capable of reading at a wavelength of 450nm.
2. Pipettes capable of accurately delivering 10 to 200µL.
3. Multichannel pipette capable of accurately delivering (50-200µL).
4. Reagent reservoirs for multichannel pipettes.
5. Wash bottle or microwell washing system.
6. Distilled or deionized water.
7. One liter graduated cylinder.
8. Serological pipettes.
9. Disposable pipette tips.
10. Paper towels.
11. Laboratory timer to monitor incubation steps.
12. Disposal basin and disinfectant. (example: 10% household bleach - 0.5% sodium hypochlorite.)

PRECAUTIONS

1. For *In Vitro* Diagnostic Use.
2. Normal precautions exercised in handling laboratory reagents should be followed. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. Wear suitable protective clothing, gloves, and eye/face protection. Do not breathe vapor. Dispose of waste observing all local, state, and federal laws.
3. The wells of the ELISA plate do not contain viable organisms. However, the strips should be considered **POTENTIALLY BIOHAZARDOUS MATERIALS** and handled accordingly.
4. The human serum controls are **POTENTIALLY BIOHAZARDOUS MATERIALS**. Source materials from which these products were derived were found negative for HIV-1 antigen, HBsAg and for antibodies against HCV and HIV by approved test methods. However, since no test method can offer complete assurance that infectious agents are absent, these products should be handled at the Biosafety Level 2 as recommended for any potentially infectious human serum or blood specimen in the Centers for Disease Control/National Institutes of Health manual "Biosafety in Microbiological and Biomedical Laboratories": current edition; and OSHA's Standard for Bloodborne Pathogens.
5. Adherence to the specified time and temperature of incubations is essential for accurate results. **All reagents must be allowed to reach room temperature (20-25°C) before starting the assay.** Return unused reagents to refrigerated temperature immediately after use.
6. Improper washing could cause false positive or false negative results. Be sure to minimize the amount of any residual wash solution; (e.g., by blotting or aspiration) before adding Conjugate or Substrate. Do not allow the wells to dry out between incubations.
7. The Sample Diluent, controls, wash buffer, and conjugate contain sodium azide at a concentration of <0.1% (w/v). Sodium azide has been reported to form lead or copper azides in laboratory plumbing which may cause explosions on hammering. To prevent, rinse sink thoroughly with water after disposing of solution containing sodium azide.
8. The Stop Solution is TOXIC. Causes burns. Toxic by inhalation, in contact with skin and if swallowed. In case of accident or if you feel unwell, seek medical advice immediately.
9. The TMB Solution is HARMFUL. Irritating to eyes, respiratory system and skin.
10. The Wash Buffer concentrate is an IRRITANT. Irritating to eyes, respiratory system and skin.
11. Wipe bottom of plate free of residual liquid and/or fingerprints that can alter optical density (OD) readings.
12. Dilution or adulteration of these reagents may generate erroneous results.
13. Reagents from other sources or manufacturers should not be used.
14. TMB Solution should be colorless, very pale yellow, very pale green, or very pale blue when used. Contamination of the TMB with conjugate or other

oxidants will cause the solution to change color prematurely. Do not use the TMB if it is noticeably blue in color.

15. Never pipette by mouth. Avoid contact of reagents and patient specimens with skin and mucous membranes.
16. Avoid microbial contamination of reagents. Incorrect results may occur.
17. Cross contamination of reagents and/or samples could cause erroneous results
18. Reusable glassware must be washed and thoroughly rinsed free of all detergents.
19. Avoid splashing or generation of aerosols.
20. Do not expose reagents to strong light during storage or incubation.
21. Allowing the microwell strips and holder to equilibrate to room temperature prior to opening the protective envelope will protect the wells from condensation.
22. Wash solution should be collected in a disposal basin. Treat the waste solution with 10% household bleach (0.5% sodium hypochlorite). Avoid exposure of reagents to bleach fumes.
23. Caution: Liquid waste at acid pH should be neutralized before adding to bleach solution.
24. Do not use ELISA plate if the indicator strip on the desiccant pouch has turned from blue to pink.
25. Do not allow the conjugate to come in contact with containers or instruments that may have previously contained a solution utilizing sodium azide as a preservative. Residual amounts of sodium azide may destroy the conjugate's enzymatic activity.
26. Do not expose any of the reactive reagents to bleach-containing solutions or to any strong odors from bleach-containing solutions. Trace amounts of bleach (sodium hypochlorite) may destroy the biological activity of many of the reactive reagents within this kit.

ASSAY PROCEDURE

1. Remove the individual components from storage and allow them to warm to room temperature (20-25°C).
2. Determine the number of microwells needed. Allow six Control/Calibrator determinations (one Blank, one Negative Control, three Calibrators and one Positive Control) per run. A Reagent Blank should be run on each assay. Check software and reader requirements for the correct Controls/Calibrator configurations. Return unused strips to the resealable pouch with desiccant, seal, and return to storage between 2° and 8°C.

EXAMPLE PLATE SET-UP

	1	2
A	Blank	Patient 3
B	Neg. Control	Patient 4
C	Calibrator	Etc.
D	Calibrator	
E	Calibrator	
F	Pos. Control	
G	Patient 1	
H	Patient 2	

3. Prepare a 1:21 dilution (e.g.: 10µL of serum + 200µL of Sample Diluent) of the Negative Control, Calibrator, Positive Control, and each patient serum. **NOTE: The Sample Diluent will undergo a color change confirming that the specimen has been combined with the diluent.**
4. To individual wells, add 100µL of each diluted control, calibrator and sample. Ensure that the samples are properly mixed. Use a different pipette tip for each sample.
5. Add 100µL of Sample Diluent to well A1 as a reagent blank. Check software and reader requirements for the correct reagent blank well configuration.
6. Incubate the plate at room temperature (20-25°C) for 25 ± 5 minutes.
7. Wash the microwell strips 5X.

A. Manual Wash Procedure:

a. Vigorously shake out the liquid from the wells.
b. Fill each microwell with Wash Buffer. Make sure no air bubbles are trapped in the wells.
c. Repeat steps a. and b. for a total of 5 washes.
d. Shake out the wash solution from all the wells. Invert the plate over a paper towel and tap firmly to remove any residual wash solution from the wells. Visually inspect the plate to ensure that no residual wash solution remains. Collect wash solution in a disposable basin and treat with disinfectant at the end of the day's run.

B. Automated Wash Procedure:

If using an automated microwell wash system, set the dispensing volume to 300-350µL/well. Set the wash cycle for 5 washes with no delay between washes. If necessary, the microwell plate may be removed from the washer, inverted over a paper towel and tapped firmly to remove any residual wash solution from the microwells.

8. Add 100µL of the Conjugate to each well, including reagent blank well, at the same rate and in the same order as the specimens were added.
9. Incubate the plate at room temperature (20-25°C) for 25 ± 5 minutes.
10. Wash the microwells by following the procedure as described in step 7.
11. Add 100µL of TMB to each well, including reagent blank well, at the same rate and in the same order as the specimens were added.
12. Incubate the plate at room temperature (20-25°C) for 10 to 15 minutes.
13. Stop the reaction by adding 50µL of Stop Solution to each well, including reagent blank well, at the same rate and in the same order as the TMB was added. Positive samples will turn from blue to yellow. After adding the Stop Solution, tap the plate several times to ensure that the samples are thoroughly mixed.
14. Set the microwell reader to read at a wavelength of 450nm and measure the optical density (OD) of each well against the reagent blank. The plate should be read within 30 minutes after the addition of the Stop Solution.

ABBREVIATED TEST PROCEDURE

1. Dilute Serum 1:21.
2. Add diluted sample to microwell - 100µL/well.
3. → *Incubate 25 ± 5 minutes.*
4. Wash.
5. Add Conjugate - 100µL/well.
6. → *Incubate 25 ± 5 minutes.*
7. Wash.
8. Add TMB - 100µL/well.
9. → *Incubate 10 - 15 minutes.*
10. Add Stop Solution - 50µL/well - Mix.
11. READ within 30 minutes.

RESULTS

A. Calculations:

1. *Correction Factor*

A cutoff OD value for positive samples has been determined by the manufacturer and correlated to the Calibrator. The correction factor (CF) will allow you to determine the cutoff value for positive samples and to correct for slight day-to-day variations in test results. The correction factor is determined for each lot of kit components and is printed on the Component List located in the kit box.

2. *Cutoff OD Value*

To obtain the cutoff OD value, multiply the CF by the mean OD of the Calibrator determined above.

(CF x *mean OD of Calibrator = cutoff OD value)*

3. *Index Values or OD Ratios*

Calculate the Index Value or OD Ratio for each specimen by dividing its OD value by the cutoff OD from step 2.

Example:			
	Mean OD of Calibrator	=	0.793
	Correction Factor (CF)	=	0.25
	Cut off OD	=	0.793 x 0.25 = 0.198
	Unknown Specimen OD	=	0.432
	Specimen Index Value or OD Ratio	=	0.432 / 0.198 = 2.18

B. Interpretations:

Index Values or OD ratios are interpreted as follows:

	Index Value or OD Ratio
Negative Specimens	≤ 0.90
Equivocal Specimens	0.91 to 1.09
Positive Specimens	≥ 1.10

1. An OD ratio ≤0.90 indicates no significant amount of IgG antibodies to CMV detected. A negative result indicates no current or previous infection with CMV. Presume that such individuals are susceptible to primary infection. However, specimens taken too early during a primary infection may not have detectable levels of IgG antibody. When health care professionals suspect a primary infection, take another specimen in eight to 14 days, and test concurrently in the same assay, with the original specimen, to look for seroconversion.
2. An OD ratio ≥ 1.10 is positive for IgG antibody to CMV. A positive value indicates a current or previous infection with CMV. Such individuals are presumed to be at risk of transmitting CMV infection but are not necessarily currently contagious.
3. Specimens with OD ratio values in the equivocal range (0.91 - 1.09) should be retested in duplicate. Report any two of the three results which agree. Evaluate repeatedly equivocal specimens using an alternate serological method and/or re-evaluate by drawing another sample one to three weeks later.
4. When testing to evaluate paired (acute and convalescent) sera, place both samples in the same assay. If the acute specimen is negative and the convalescent specimen is positive, seroconversion has taken place and that indicates a primary CMV infection.

PERFORMANCE CHARACTERISTICS

A. Comparative Study

The Diagnostics, Inc. CMV IgG ELISA test system was compared to a commercially available ELISA procedure. A total of 96 specimens from normal blood donors in the Northeastern United States were assayed by the two methods. These results are summarized below:

		Reference CMV IgG ELISA		
		Pos.	Neg.	Equivocal
Diagnostic Automation, Inc. CMV IgG ELISA	Pos.	54	2	2
	Neg.	2	31	2
	Equivocal	1	2	0

When compared to the other CMV IgG ELISA procedure, the CMV IgG ELISA showed a sensitivity of 96.4 % (54/56), a specific of 93.9 % (31/33), and an overall agreement of 95.3 % (85/89).

B. Reproducibility

Technicians tested four specimens to determine intra-assay and inter-assay variation: two strong positive specimens, a specimen near the cutoff zone, and a low negative specimen. On each of three days, a technician tested each specimen once a day, eight times each, resulting in 24 test points. A responsible party then calculated the mean OD ratio and coefficient of variation from the resulting data. A summary of the results of the experiment is below.

Inra-assay (n=8)							Inter-assay(n=3)	
	Run # 1		Run # 2		Run # 3			
Serum #	Mean Ratio	CV	Mean Ratio	CV	Mean Ratio	CV	Mean Ratio	CV
Serum # 1	4.62	8.9%	3.6	6.8%	4.01	6.3%	4.07	10.0%
Serum # 2	2.53	4.8%	2.46	7.0%	2.13	11.8%	2.37	7.4%
Serum # 3	1.13	10.8%	1.33	14.7%	1.17	6.6%	1.21	7.1%
Serum # 4	0.23	10.1%	0.35	16.1%	0.25	14.1%	0.27	18.9%

C. Cross Reactivity

A cross reactivity study tested ten serum samples, that were negative in the DAI ELISA CMV IgG Test System, using the indirect fluorescent antibody assay for the presence of IgG antibodies specific for Varicella-Zoster (VZ), Epstein-Barr Virus Viral Capsid Antigen (EBV-VCA) and Herpes Simplex Virus type 1 (HSV-1). All ten of the samples tested positive for EBV-VCA and HSV-1 IgG and two of the ten samples were positive for VZ IgG. These results indicate that the DAI ELISA CMV IgG Test System does not cross react with antibodies to other herpes viruses.

QUALITY CONTROL

1. Each time the assay is run the Calibrator must be run in triplicate. A reagent blank, Negative Control, and Positive Control must also be included in each assay.
2. Calculate the mean of the three Calibrator wells. If any of the three values differ by more than 15% from the mean, discard that value and calculate the mean using the remaining two wells.
3. The mean OD value for the Calibrator and the OD values for the Positive and Negative Controls should fall within the following ranges:

	OD Range
Negative Control	≤ 0.250
Calibrator	≥ 0.300
Positive Control	≥ 0.500

   a. The OD of the Negative Control divided by the mean OD of the Calibrator should be ≤ 0.9.
   b. The OD of the Positive Control divided by the mean OD of the Calibrator should be ≥ 1.25.
   c. If the above conditions are not met the test should be considered invalid and should be repeated.

4. The Positive Control and Negative Control are intended to monitor for substantial reagent failure and will not ensure precision at the assay cut-off.
5. Additional controls may be tested according to guidelines or requirements of local, state, and/or federal regulations or accrediting organizations.
6. Refer to CLSI document C24: Statistical Quality Control for Quantitative Measurements for guidance on appropriate QC practices.

LIMITATIONS OF PROCEDURE

1. The presence of IgG antibodies to CMV does not necessarily assure protection from future infection with CMV.
2. The antibody titer of a single serum specimen cannot be used to determine recent infection. Paired samples (acute and convalescent) should be collected and tested concurrently to demonstrate seroconversion.
3. Test results for demonstration of seroconversion should be interpreted in conjunction with the clinical evaluation and the results of other diagnostic procedures.

4. Specimens containing antibodies to nuclear antigens (as are found in patients with systemic lupus erythematosus) may give false positive results in the DAI CMV ELISA test.
5. Samples collected too early in the course of an infection may not have detectable levels of IgG. In such cases, a second sample may be collected after 2-7 weeks and tested concurrently with the original specimen to look for seroconversion.
6. A positive CMV IgG test in neonates should be interpreted with caution since passively acquired maternal antibody can persist for up to 6 months. A negative test for IgG antibody in the neonate may help exclude congenital infection. The most definitive diagnosis of active CMV infection requires viral isolation.
7. The results of this test are qualitative and should be considered as either positive or negative for the presence of CMV IgG antibodies.

EXPECTED VALUES

The incidence of CMV infection varies with age, geographic location, and socioeconomic status (2). In the United States, 10 to 30% of children are seropositive for CMV by the age of 10 years (2). By age 35, about 50% of the population is seropositive. The seropositive rate among homosexual men has been reported to be greater than 90% (15,17).

STORAGE

1. Store the unopened kit between 2° and 8°C.
2. Coated microwell strips: Store between 2° and 8°C. Extra strips should be immediately resealed with desiccant and returned to proper storage. Strips are stable for 60 days after the envelope has been opened and properly resealed and the indicator strip on the desiccant pouch remains blue.
3. Conjugate: Store between 2° and 8°C. DO NOT FREEZE.
4. Calibrator, Positive Control and Negative Control: Store between 2° and 8°C.
5. TMB: Store between 2° and 8°C.
6. Wash Buffer concentrate (10X): Store between 2° and 25°C. Diluted wash buffer (1X) is stable at room temperature (20° to 25° C) for up to 7 days or for 30 days between 2° and 8°C.
7. Sample Diluent: Store between 2° and 8°C.
8. Stop Solution: Store between 2° and 25°C.

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ISO 13485
ISO 9001

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