DIALAB Produktion und Vertrieb von chemisch-technischen Produkten und Laborinstrumenten Gesellschaft m.b.H.
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CMV IgG

(en) English

REF
V00004

Content

1 Microwell plate: 96 wells (12 x 8-well antigen coated strips, individual breakaway)
-1x 12 mL Enzyme Conjugate
-1x 50 mL Wash Buffer
-1x 12 mL Specimen Diluent
-1x 8 mL Substrate Solution A
-1x 8 mL Substrate Solution B
-1x 8 mL Stop Solution
-4x 1 mL Calibrators
-3 Plate sealers
-1 Package Insert
-1 Certificate of Analysis

For professional in vitro diagnostic use only.

INTENDED USE

Enzyme Linked Immunosorbent Assay for the qualitative and quantitative determination of IgG Antibodies to Cytomegalovirus (CMV) in human serum or plasma. It is intended as an aid in the diagnosis of possible CMV infection.

DIAGNOSTIC SIGNIFICANCE

Cytomegalovirus (CMV) is a member of the Herpes virus family which includes Herpes Simplex virus (HSV) type 1 and 2, Varicella Zoster virus (VZV) and Epstein-Barr virus (EBV). It is a ubiquitous human pathogen transmitted through saliva, sexual contact, perinatally, organ transplantation or blood transfusion. In majority of the cases, the infection remains asymptomatic. However, CMV infection can cause serious illness in newborns and immunosuppressed individuals such as patients with AIDS, HIV, cancer or patients that received organ transplants.[1] During immunosuppressive therapy, a reactivation of the latent virus or primary infection occurs frequently. For most newborns, CMV infections can be acquired before birth, during birth and later in life. The infection may cause severe congenital abnormalities such as microcephaly, motor disability, and mental retardation.[2, 3, 4] Therefore, determining primary maternal infections and distinguishing primary from latent infection is of great importance. The presence of IgM antibodies indicates the presence of primary infection, while presence of IgG antibodies indicates immune status of patients. The DIALAB CMV IgG ELISA is an immunoassay for the qualitative and quantitative detection of the presence of IgG antibodies to CMV in serum or plasma specimen. The test utilizes purified CMV antigens to selectively detect antibodies to CMV in serum or plasma.

TEST PRINCIPLE

The DIALAB CMV IgG ELISA is a solid phase enzyme immunoassay based on indirect principle for the qualitative and quantitative detection of IgG antibodies to CMV in human serum or plasma. The microwell plate is coated with CMV antigens. During testing, the specimen diluent and the specimens are added to the antigen coated microwell plate and then incubated. If the specimens contain IgG antibodies to CMV, it will bind to the antigens coated on the microwell plate to form immobilized antigen-CMV IgG antibody complexes. If the specimens do not contain IgG antibodies to CMV, the complexes will not be formed. After initial incubation, the microwell plate is washed to remove unbound materials. The enzyme-conjugated anti-human IgG antibodies are added to the microwell plate and then incubated. The enzyme-conjugated anti-human IgG antibodies will bind to the immobilized antigen-CMV IgG antibody complexes present. After the second incubation, the microwell plate is washed to remove unbound materials. Substrate Solution A and Substrate Solution B are added and then incubated to produce a blue color indicating the amount of CMV IgG antibodies present in the specimens. Sulfuric acid solution is added to the microwell plate to stop the reaction producing a color change from blue to yellow. The color intensity, which corresponds to the amount of CMV IgG antibodies present in the specimens, is measured with a microplate reader at 450/630-700 nm or 450 nm.

REAGENT COMPOSITION

- **Microwell plate:** strips coated with purified CMV antigens
- **Enzyme Conjugate:** Anti-human IgG antibody bound to peroxidase; Preservative: 0.1 % ProClin™ 300
- **Wash Buffer:** 25x conc., Tris-HCl buffer containing 0.1 % Tween 20; Preservative: 0.1 % ProClin™ 300
- **Specimen Diluent:** Tris buffer, Preservative: 0.1 % ProClin™ 300
- **Substrate Solution A:** Citrate-phosphate buffer containing hydrogen peroxide; Preservative: 0.1 % ProClin™ 300

- **Substrate Solution B:** Buffer containing tetramethylbenzidine (TMB); Preservative: 0.1 % ProClin™ 300
- **Stop Solution:** 0.5 M Sulfuric acid
- **Calibrators:** Buffer containing the following amounts of CMV IgG antibodies; Preservative: 0.1 % ProClin™ 300
  1) Calibrator A - 0 IU/mL (contains BSA) 2) Calibrator B - 15 IU/mL
  3) Calibrator C - 60 IU/mL 4) Calibrator D - 150 IU/mL

MATERIAL REQUIRED BUT NOT PROVIDED

- Freshly distilled or deionized water
- Sodium hypochlorite solution for decontamination
- Absorbent paper or paper towel
- Water bath or incubator capable of maintaining 37°C ± 2°C
- Calibrated automatic or manual microwell plate washer capable of aspirating and dispensing 350 µL/well
- Disposable gloves
- Calibrated micropipettes with disposable tips capable of dispensing 5, 50 and 100 µL
- Graduated cylinders for wash buffer dilution
- Vortex mixer for specimen mixing (optional)
- Timer
- Disposable reagent reservoirs
- Calibrated microplate reader capable of reading at 450 nm with a 630-700 nm reference filter, or reading at 450 nm without a reference filter
- Automated processor (optional)

REAGENT PREPARATION

Wash Buffer:
Prepare Working Wash Buffer by diluting the Concentrated Wash Buffer 1:25. Pour the contents of the bottle in a graduated cylinder and fill it with freshly distilled or deionized water to 1250 mL. It is stable for 2 weeks at 15-30°C. Note: If crystals are present in the concentrated Wash Buffer, warm it up at 37°C until all crystals dissolve.

Allow reagents and specimens to reach room temperature (15-30°C) prior to testing. The procedure must be strictly followed. Assay must proceed to completion within time limits. Arrange the calibrators so that well A1 is the Blank well. From well A1, arrange the calibrators in a horizontal or vertical configuration. The procedure below assigns specific wells arranged in a vertical configuration. Configuration may depend on software.

STORAGE AND STABILITY

- Unopened test kits should be stored at 2-8°C upon receipt. All reagents are stable through the expiration date printed on the box if stored between 2-8°C. Once opened, all reagents are stable for up to 3 months after the first opening date if stored between 2-8°C. Return reagents to 2-8°C immediately after use.
- Allow the sealed pouch to reach room temperature before opening the pouch and removing the required number of strips to prevent condensation of the microwell plate. The remaining unused strips should be stored in the original resealable pouch at 2-8°C and can be used within 3 months of the opening date. Return the remaining unused strips and supplied desiccant to the original resealable pouch, firmly press the seal closure to seal the pouch completely and immediately store at 2-8°C.
- Concentrated Wash Buffer may be stored at room temperature to avoid crystallization. If crystals are present, warm up the solution at 37°C. Working Wash Buffer is stable for 2 weeks at room temperature.
- Do not expose reagents especially the Substrate Solution to strong light or hypochlorite fumes during storage or incubation steps.
- Do not store Stop Solution in a shallow dish or return it the original bottle after use.

WARNINGS AND PRECAUTIONS

Calibrators A-D, Enzyme Conjugate, Sample Diluent, Substrate Solution A, Substrate Solution B and Wash Buffer contain 0.1 % ProClin™ 300 as a preservative, which is classified as below:

Warning

H317:	May cause an allergic skin reaction.
P261:	Avoid breathing dust/fume/gas/vapours/spray.
P272:	Contaminated work clothing should not be allowed out of the workplace.
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.
P362+P364:	Take off contaminated clothing and wash it before reuse.

P501: Dispose of contents and container in accordance to local, regional, national and international regulations.

- For professional in vitro diagnostic use only. Do not use after expiration date.
- Do not mix reagents from other kits with different lot numbers.
- Avoid cross contamination between reagents to ensure valid test results.
- Follow the wash procedure to ensure optimum assay performance.
- Use Plate Sealer to cover microwell plate during incubation to minimize evaporation.
- Use a new pipet tip for each specimen assayed.
- Ensure that the bottom of the plate is clean and dry and that no bubbles are present on the surface of the liquid before reading the plate. Do not allow wells to dry out during the assay procedure.
- Do not touch the bottom of the wells with pipette tips. Do not touch the bottom of the microwell plate with fingertips.
- Do not allow sodium hypochlorite fumes from chlorine bleach or other sources to contact the microwell plate during the assay as the color reaction may be inhibited.
- All equipment should be used with care, calibrated regularly and maintained following the equipment manufacturer's instructions.
- Some components of this kit contain human blood derivatives, which were found to be non-reactive for the HIV-1/HIV-2/HIV-O, and HCV antibodies, as well as HBsAg. No known test method can offer complete assurance that products derived from human blood will not transmit infectious agents. Therefore, all blood derivatives should be considered potentially infectious. It is recommended that these reagents and human specimens be handled using established good laboratory working practices.
- Wear disposable gloves and other protective clothing such as laboratory coats and eye protection while handling kit reagents and specimens. Wash hands thoroughly when finished.
- ProClin 300™ is included as a preservative in the Enzyme Conjugate, Concentrated Wash Buffer, Specimen Diluent, Substrate Solution and Calibrators. Avoid any contact with skin or eyes.
- Do not eat, drink or smoke in the area where the specimens or kits are handled. Do not mouth pipette.
- Avoid any contact of the Substrate Solution A, Substrate Solution B, and Stop Solution with skin or mucosa. The Stop Solution contains 0.5 M sulfuric acid which is a strong acid. If spills occur, wipe immediately with large amounts of water. If the acid contacts the skin or eyes, flush with large amounts of water and seek medical attention.
- Non-disposable apparatus should be sterilized after use. The preferred method is to autoclave for one hour at 121°C. Disposables should be autoclaved or incinerated. Do not autoclave materials containing sodium hypochlorite.
- Handle and dispose all specimens and materials used to perform the test as if they contained infectious agents. Observe established precautions against microbiological hazards throughout all the procedures and follow the standard procedures for proper disposal of specimens.
- Observe Good Laboratory Practices when handling chemicals and potentially infectious material. Discard all contaminated material, specimens and reagents of human origin after proper decontamination and by following local, state and federal regulations.
- Neutralized acids and other liquids should be decontaminated by adding sufficient volume of sodium hypochlorite to obtain a final concentration of at least 1.0%. A 30 minute exposure to a 1.0% sodium hypochlorite may be necessary to ensure effective decontamination.

SPECIMEN COLLECTION AND STORAGE

- The DIALAB CMV IgG ELISA can be performed using only human serum or plasma collected from venipuncture whole blood.
- EDTA, sodium heparin, and ACD collection tubes may be used to collect venipuncture whole blood and plasma specimens. The preservative sodium azide inactivates horseradish peroxide and may lead to erroneous results.
- Separate serum or plasma from blood as soon as possible to avoid hemolysis. Grossly hemolytic, lipidic or turbid samples should not be used. Specimen with extensive particulate should be clarified by centrifugation prior to use. Do not use specimes with fibrin particles or contaminated with microbial growth.
- Serum and plasma specimens may be stored at 2-8°C for up to 7 days prior to assaying. For long term storage, specimens should be kept frozen below -20°C.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
- If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.

TEST PROCEDURE

1. Leave A1 as Blank well.
2. Add 100 µL of Calibrator A in wells B1 and C1. (Yellow Reagent)
   Add 100 µL of Calibrator B in wells D1 and E1. (Blue Reagent)

Add 100 µL of Calibrator C in wells F1 and G1. (Blue Reagent)
Add 100 µL of Calibrator D in wells H1 and A2. (Blue Reagent)

3. Add 100 µL of Specimen Diluent to assigned wells starting at B2. The color of Specimen Diluent is green.
   Add 5 µL of specimen to wells starting at B2. Then a color change from green to blue will occur to verify that the specimen has been added.
   Remove unused strips from the microwell plate, and store in the original resealable pouch at 2-8°C.
4. Mix gently by swirling the microwell plate on a flat bench for 30 seconds.
   Cover the microwell plate with the Plate Sealer and incubate in a water bath or an incubator at 37°C ± 2°C for 30 minutes ± 2 minutes.
5. Remove the Plate Sealer.
   Wash each well 5 times with 350 µL of Working Wash Buffer per well, then remove the liquid.
   Turn the microwell plate upside down on absorbent tissue for a few seconds. Ensure that all wells have been completely washed and dried.
   Note: Improper washing may cause false positive results.
6. Add 100 µL of Enzyme Conjugate to each well except for the Blank well. The color of Enzyme Conjugate is red.
7. Cover the microplate plate with the Plate Sealer and incubate in a water bath or an incubator at 37°C ± 2°C for 30 minutes ± 2 minutes.
8. Repeat Step 5.
9. Add 50 µL of Substrate Solution A to each well. (Clear Reagent)
   Add 50 µL of Substrate Solution B to each well. (Clear Reagent)
   Then a blue color should develop in wells containing positive specimens.
10. Mix gently then cover microwell plate with Plate Sealer and incubate in a water bath or incubator at 37°C ± 2°C for 10 minutes ± 1 minute.
11. Remove the Plate Sealer.
    Add 50 µL of Stop Solution to each well. (Clear Reagent)
    Then a yellow color should develop in wells containing Positive specimens.
12. Read at 450/630-700 nm in 30 minutes.
    Note: Microwell plate can also be read at 450 nm, but it is strongly recommended to read it at 450/630-700 nm for better results.

Assay Scheme:

REAGENTS	A1 BLANK	CALIBRATORS	SAMPLE
Calibrators	-	100 µL	-
Sample Diluent	-	-	100 µL
Sample	-	-	5 µL
Cover strips with Plate Sealer.			
Incubate 30 min. at +37°C.			
Peel out the Plate Sealer and aspirate the reaction solution from all wells.			
Wash 5 times with 350 µL of diluted Wash Buffer, carefully aspirating off the remaining liquid.			
Enzyme Conjugate	-	100 µL	100 µL
Cover strips with Plate Sealer.			
Incubate 30 min. at +37°C.			
Peel out the Plate Sealer and aspirate the reaction solution from all wells.			
Wash 5 times with 350 µL of diluted Wash Buffer, carefully aspirating off the remaining liquid.			
Substrate Solution A	50 µL	50 µL	50 µL
Substrate Solution B	50 µL	50 µL	50 µL
Cover strips with a new Plate Sealer.			
Incubate 10 min. at +37°C., protected from light.			
Stop Solution	50 µL	50 µL	50 µL
Read the absorbance of each well against A1 blanking-well at 450 nm and 630-700 nm in 30 min.			

Note for automated processing:
Automatic ELISA microplate processors may be used to perform the assay after validating the results to ensure they are equivalent to those obtained using the manual method for the same specimens. Incubation times may vary depending on the processors used but do not program less incubation times than the procedure listed above. When automatic ELISA microplate processors are used, periodic validation is recommended to ensure proper results.

INTERPRETATION OF RESULTS

Qualitative
Calculate the Index Value to obtain qualitative specimen results.

1. If the test is valid, obtain Cut-Off Value by subtracting the Blank Absorbance from the Mean Absorbance of Calibrator B. See an example of Cut-Off Value calculation below.

Item	Absorbance
Blank Absorbance: Well A1	0.009
Cut-Off Value: Mean Absorbance of Calibrator B – Blank Absorbance	0.261 - 0.009 = 0.252

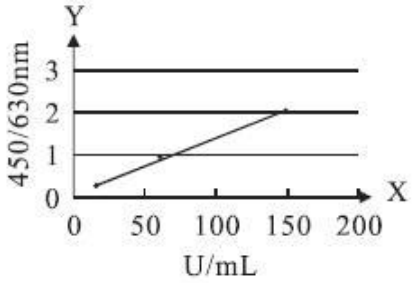
2. Calculate the Index Value by dividing the Specimen Absorbance by the Cut-Off Value, then read the results by referring to the Interpretation of Results table below.

Item	Absorbance
Specimen: Well B2	0.836
Cut-Off Value	0.252
Index Value: Specimen/Cut-Off Value	0.836/0.252 = 3.317

Quantitative

Draw the calibration curve and obtain quantitative specimen results.

1. Subtract the Blank Absorbance from the Mean Absorbance of each Calibrator, then plot them on the Y-axis against their concentration in U/mL on the X-axis on a linear graph paper and draw the calibration curve. Draw the best fitted line through data points to obtain a standard curve. Refer to an example of the calibration curve at right.
   Note: Do not use the calibration curve at right to make any calculation. A calibration curve must be performed for each run.
2. Obtain quantitative specimen results from their absorbance by using the calibration curve.
   Note: Specimens that have an absorbance above Calibrator D should be pre-diluted using Specimen Diluent and retested. The concentration must be multiplied with the dilution factor. Automated reading and calculation may be performed using linear regression on suitable computer programs



Results	Qualitative	Quantitative
	Index Value	Concentration
Negative	< 0.9	< 13.5 U/mL
Positive	> 1.1	≥ 16.5 U/mL
Equivocal*	≥ 0.9 and ≤ 1.1	13.5 - 16.5 U/mL

***Note:** For Equivocal results, the specimens should be re-tested in duplicate and calculate the average value to make judgement. Specimens that are repeatedly Equivocal after re-test, should be tested using an alternate method. If the results remain Equivocal, collect a new specimen in two weeks. If the new specimen is positive, the specimen is presumed to be positive.

QUALITIY CONTROL AND CALIBRATION

1. Calculate the Mean Absorbance of Calibrators A-D by referring to the table below.

Example of Calibrator B Calculation

Item	Absorbance
Calibrator B: Well D1	0.268
Calibrator B: Well E1	0.254
Total Absorbance of Calibrator B	0.268 + 0.254 = 0.522
Mean Absorbance of Calibrator B	0.522/2 = 0.261

2. Check the validation requirements below to determine if the test results are valid.

Item	Validation Requirements
Blank Well	Blank Absorbance should be < 0.050 if read at 450/630-700 nm Note: It should be < 0.100 if read at 450 nm
Calibrator A	Mean Absorbance after subtraction of Blank Absorbance should be < 0.150
Calibrator B	Mean Absorbance after subtraction of Blank Absorbance should be > 0.150
Calibrator C	Mean Absorbance after subtraction of Blank Absorbance should be > Calibrator B and < Calibrator D
Calibrator D	Mean Absorbance after subtraction of Blank Absorbance should be > 1.200

Note: The test results are considered invalid if the above validation requirements are not met. Repeat the test or contact your local distributor.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

The DIALAB CMV IgG ELISA has correctly identified specimens of a mixed titer performance panel and has been compared to a leading commercial CMV IgG ELISA using clinical specimens. The results show that the clinical sensitivity of the DIALAB CMV IgG ELISA is 98.0%, and the clinical specificity is 98.3%.

CMV IgG ELISA vs. Other ELISA

Method		Other ELISA		Total Results
CMV IgG ELISA	**Results**	Positive	Negative	
	Positive	100	1	101
	Negative	2	58	60
Total Results		102	59	161

Clinical Sensitivity: 98.0% (93.1-99.8%)*
Clinical Specificity: 98.3% (90.9-100.0%)*
Overall Agreement: 98.1% (94.7-99.6%)*
*95% Confidence Interval

Reproducability

Intra-Assay: Within-run precision has been determined by using 15 replicates of three specimens: a low positive, a medium positive, and a high positive.

Inter-Assay: Between-run precision has been determined by 3 independent assays on the same three specimens: a low positive, a medium positive, and a high positive. Three different lots of the DIALAB CMV IgG ELISA have been tested using these specimens over a 5-day period.

Specimen	Intra-Assay			Inter-Assay		
	Mean Absorbance / Cut-Off	Standard Deviation	Coefficient of Variation (%)	Mean Absorbance / Cut-Off	Standard Deviation	Coefficient of Variation (%)
1	1.752	0.128	7.306	1.838	0.120	6.529
2	4.431	0.349	7.876	4.439	0.290	6.533
3	9.041	0.723	7.997	9.017	0.774	8.584

Interferences

Interferences are not observed up to a concentration of 1 mg/mL Acetaminophen, 0.2 mg/mL Gentistic Acid, 0.1 mg/mL Ascorbic Acid, 0.1 mg/mL Acetosalisilyc Acid, 0.1 mg/mL Caffeine, 0.6 mg/mL Oxalic Acid, 2 mg/mL Bilirubin, 2 mg/mL Hemoglobin, 1 % Methanol and 1% Ethanol. Rheumatoid factors do not interfere with the test.

Cross-Reactivity

Cross-reactivity is not observed in Syphilis, HBsAg, HIV, HCV, HSV IgG, Toxoplasma IgG and Rubella IgG positive specimens.

TRACEABILITY

A human serum sample demonstrating high levels of anti-CMV IgG activity was defined as containing 150 units of CMV IgG antibody per mL (U/mL). The calibrators for the DIALAB CMV IgG ELISA are manufactured by dilution and are referenced to this standard.

EXPECTED VALUES

Samples with measured CMV IgG antibody concentrations smaller than 13.5 U/mL are considered to be negative while samples ≥ 16.5 U/mL are positive to CMV IgG antibodies. If the measured antibody concentration is between 13.5 and 16.5 U/mL further testing is necessary.

LIMITATIONS

- The DIALAB CMV IgG ELISA is used for the detection of IgG antibodies to CMV in human serum or plasma. Diagnosis of an infectious disease should not be established based on a single test result. Further testing, including confirmatory testing, should be performed before a specimen is considered positive. A negative test result does not exclude the possibility of exposure. Specimens containing precipitate may give inconsistent test results.
- As with all diagnostic tests, all results must be interpreted together with other clinical information the physician.

- As with other sensitive immunoassays, there is the possibility that the positive result cannot be repeated due to inadequate washing from the initial test. The results may be affected due to procedural or instrument error.

WASTE MANAGEMENT

Reagents must be disposed of in accordance with local regulations.

LITERATURE

1. Hodinka, RL, and Friedman, HM. Human Cytomegalovirus. In: Manual of Clinical Microbiology 6th Edition (1995) 884-894.
2. Hanshaw, JB, Scheiner, AP, Moxley, AW, Gaev, L, Abel, V, and Scheiner, B. School Failure and Deafness after “Silent” Congenital Cytomegalovirus Infection. N. Engl. J. Med.(1976) 295:468-470.
3. Reynolds, DW, Stagno, S, Stubbs, KG, Dabte, AJ, Livingston, NM, Saxon, SS, Alford, CA. Inapparent Congenital Cytomegalovurus. N. Engl. J. Med. (1974) 790:291-296.
4. Stern, H. Cytomegalovirus Vaccine: Justification and Problems. In: Waterson AP (ed.) Recent Advances in Clinical Virology (1977) 117-134.

USED SYMBOLS

Symbol	Description
Cont.	Content
CE 0123	
IVD	
2°C 8°C	

EU Safety Data Sheet

According to Regulation (EU) No. 1907/2006 (REACH) and Regulation (EU) No. 2015/830
Date of issue/revision: May 8th, 2019

CMV IgG

1. Identification of the substance/preparation and of the company/undertaking

1.1 Identification of the substance or preparation

CMV IgG

The reagent is part of the following catalogue numbers:

V00004
V00004V
V00004LV

1.2 Relevant identified uses of the substance or mixture and uses advised against

General use: Laboratory reagent for in-vitro diagnostics in human samples

1.3 Details of the supplier of the safety data sheet

Company name:	DIALAB - Produktion und Vertrieb von chemisch – technischen Produkten und Laborinstrumenten Gesellschaft m.b.H
Street:	Hondastrasse, Objekt M55, IZ-NOE Sued
Postal code, city, state:	A-2351 Wiener Neudorf, Austria
World Wide Web:	www.dialab.at
E-mail:	office@dialab.at
Telephone:	+43 (0)2236 660910-0
Telefax:	+43 (0)2236 660910-30
Dept. Responsible for information:	+43 (0)2236 660910-0

1.4. Emergency telephone number

Vienna General Hospital, Toxication Centre, phone: +43-(0)1-4064343

2. Hazards identification

2.1 Classification of the substance or mixture:

Classification according to Directive 1272/2008/EC:

Calibrator A Calibrator B Calibrator C Calibrator D Enzyme Conjugate Sample Diluent Substrate Solution A Substrate Solution B Wash Buffer	Skin Sens. Cat 1; H317

2.2 Label elements:

Labelling (1272/2008/EC):

Calibrator A Calibrator B Calibrator C Calibrator D Enzyme Conjugate Sample Diluent Substrate Solution A Substrate Solution B Wash Buffer	 Warning H317 P261 P272 P280 P302+P352 P333+P313 P362+P364 P501

2.3 Other hazards:

PBT assessment: No data available.

vPnB assessment: No data available

3. Composition / information on ingredients

3.1 Substances

Not applicable

3.2 Mixtures

Positive Control, Cut-Off Calibrator, Negative Control, Enzyme Conjugate, Sample Diluent, Substrate Solution A, Substrate Solution B, Wash Buffer				
Ingredient	*EC No*	*CAS No*	*Conc (w/v)*	*Reg 1272/2008*
5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-2H-isothiazol-3-one, (3:1), the effective ingredient in ProClin™ 300	247-500-7 220-239-6	55965-84-9	≥0.003 - <0.005%	Acute Tox. 3 H301 Acute Tox. 3 H311 Skin Corr. 1B H314 Skin Sens. 1 H317 Acute Tox. 3 H331 Aquatic Acute 1 H400 Aquatic Chronic 1 H410

** The information above is for 2-methyl-2H-isothiazol-3-one. It has only ≥0.003 - <0.005% concentration in the product, therefore only H317 is applicable.*

3.3 Other information

This product does not contain substances to be mentioned according to EU regulation 1272/2008.

4. First aid measures

4.1 Description of first aid measures

General advice: When in doubt or if symptoms are observed, get medical advice. Show this safety data sheet to the doctor in attendance.

After inhalation: Move to fresh air. Generally, this aqueous product is not a significant inhalation hazard in the kit volumes and concentrations present. If breathing is irregular or if respiratory arrest occurs, call emergency medical assistance immediately.

After skin contact: IMMEDIATELY remove contaminated clothing. Wash with plenty of soap and water. If more severe symptoms develop, call a physician.

After eye contact: Rinse immediately with plenty of water for at least 15 minutes. Ensure adequate flushing by separating the eyelids with fingers while flushing with water. Immediate medical attention is required.

After swallowing: Do NOT induce vomiting. Wash out mouth thoroughly with water. IMMEDIATELY see a physician. Never give anything by mouth to an unconscious person.

4.2 Most important symptoms and effects, both acute and delayed

Symptoms/effects after skin contact: May cause an allergic skin reaction.

Symptoms/effects after skin contact: Liquid splashes in eye may cause irritation.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

5. Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media: Use extinguishing media appropriate for surrounding fire.

Unsuitable extinguishing media: No data available

5.2 Special hazards arising from the substance or mixture

Combustion generates toxic fumes of the following: Nitrogen oxides (NOx) sulfur oxides.

5.3 Advice for firefighters

Firefighting procedures: Cool containers/tanks with water spray. Minimize exposure. Do not breathe fumes. Contain run-off.

Special protective equipment for firefighters: Wear self-contained breathing apparatus and protective suit.

6. Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Avoid direct contact with skin, eyes, mucous membranes. Wear appropriate lab personal protective equipment, including gloves, lab coat and eye/face protection. If a hazardous material comes in contact with the skin during clean-up operations, IMMEDIATELY remove all contaminated clothing and wash exposed skin areas with soap and water.

6.2 Environmental precautions

Do not allow material to contaminate ground water system. Prevent product from entering drains. If necessary, inform the competent authorities.

6.3 Methods and material for containment and cleaning up

WARNING: Keep spills and clean-up residuals out of municipal sewers and open bodies of water. Adsorb the spill with spill pillows or inert solids such as clay or vermiculite and transfer contaminated materials to suitable containers for disposal.
Decontaminate biohazard source material spills, which should always be treated as potentially infectious, deactivate spill area with freshly prepared solution of 5% sodium biocarbonate and 5% sodium hypochlorite in water. Apply solution to the spill area at a ratio of 10 volumes deactivation solution per estimated volume of residual spill to deactivate any residual active ingredient. Let stand for 30 minutes. Flush the spill area with copious amounts of water to chemical sewer (if in accordance with local procedures, permits and regulations). Do not add deactivation solution to the waist pail to deactivate the adsorbed material.
Neutralize acidic spills with the appropriate acid neutralization/adsorbent product.

6.4 Reference to other section

For disposal, see section 13.

7. Handling and storage

7.1 Precautions for safe handling

This test kit may cause an allergic skin reaction. This test kit should be handled only by qualified personnel trained in laboratory procedures and who are familiar with their potential hazards. Do not handle material near food, feed or drinking water. Refer to section 8 for personal protection.

7.2 Conditions for safe storage, including any incompatibilities

Do not store this material near food, feed or drinking water.
Store test kits in 2-8°C refrigerators designated and labeled to contain human blood products.

7.3 Specific end use(s)

Refer to other sections, if applicable, have been provided in the previous sub-sections.
Refer to the product package insert for additional product information.

8. Exposure controls/personal protection

The information below is for 2-methyl-2H-isothiazol-3-one. It has only ≥0.003 - <0.005% concentration in the product.

8.1 Control parameters

5-Chloro-2-mehtyl-4-isothiazolin-3-one and 2-Methyl-2H-isothiazol-3-one (3:1 mixture), the effective ingredient in ProClin^{300}					
CAS-No: 55965-84-9					
Country	**Limit value – 8 h**		**Limit value – short term**		**Legal basis**
	ppm	**mg/m^3**	**ppm**	**mg/m^3**	
Austria		0.05			from GESTIS Database
Germany (DFG)		0.2 (1)		0.4 (1) (2)	
Switzerland		0.2 (1)		0.4 (1)	
	Remarks				
Germany (DFG)	(1) Inhalable fraction (2) 15 minutes average value				
Switzerland	(1) inhalable fraction				

8.2 Exposure controls

Appropriate engineering controls

Handle in accordance with good industrial hygiene and safety practice.
Wash hands before breaks and at the end of workday.

Personal protective equipment

Respiratory protection:	Do not breathe mist/vapours/spray. In case of fire, wear self-contaminated breathing apparatus.
Hand protection:	Wear non-permeable rubber, neoprene, latex or nitrile disposable gloves. Change gloves when they become contaminated. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash hands thoroughly after removing gloves.
Eye/face protection:	Wear safety glasses or goggles when a splash hazard exists.
Skin protection:	Wear non-permeable rubber, neoprene, latex or nitrile disposable gloves. Change gloves when they become contaminated. Wash hands thoroughly after removing gloves.
Body protection:	Wear long laboratory coat. The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

Environmental exposure controls

No data available.

9. Physical and chemical properties

9.1 Information on basic physical and chemical properties:

Below mentioned data applies to the buffer solution:

Physical state:	Variable, generally aqueous liquids, except for the microwell plate.
Colour:	Variable.
Odour:	No special odour.
Odour threshold:	No data available.
pH value:	Variable, most of the components are between pH 2 and 8.
Boiling point:	No data available.
Melting point:	No data available.
Decomposition point:	No data available.
Flash point:	No data available.
Auto-ignition temperature:	No data available.
Oxidising properties:	No data available.
Explosive properties:	No data available.
Flammability:	No data available.
Lower flammability or explosive limits:	No data available.
Upper flammability or explosive limits:	No data available.
Vapour pressure:	No data available.
Vapour density:	No data available.
Evaporation rate:	No data available.
Relative density:	No data available.
Solubility:	No data available.
Partition coefficient:	No data available.
Viscosity:	No data available.
Other information:	No data available.

9.2 Other information

No data available

10. Stability and reactivity

10.1 Reactivity

No data available.

10.2 Chemical stability

No data available.

10.3 Possibility of hazardous reactions

Stable under recommended storage conditions. Product will not undergo polymerization.

10.4 Conditions to avoid

Keep away from open flames, hot surfaces and sources of ignition.

10.5 Incompatible materials

Avoid contact with the following: Oxidizing agents, amines, reducing agents, mercaptans.

10.6 Hazardous decomposition products

Nitrogen oxides (NOx), Sulphur oxides, hydrogen chloride.

11. Toxicological information

The information below is for ProClin 300:

11.1 Information on toxicological effects

Acute oral toxicity:	Rat, LD50: 457 – 472 mg/kg
Acute dermal toxicity:	Rat, LD50: >1008 mg/kg Rat, LD50: 660 mg/kg
Acute inhalation toxicity:	Rat, LC50: 1.21 – 2.36 mg/L/4hr
Skin irritation:	Corrosive to skin from a concentration of 0.75% a.i. After dermal exposure, it induces irreversible skin reaction in rabbits.
Eye irritation;	No data available.
Respiratory or skin sensitization:	After dermal exposure, it induces skin sensitization effects in animals (guinea pigs and mice) and humans.
Germ cell mutagenicity:	No data available.
Reproduction toxicity:	No data available.
Carcinogenicity:	No data available.
STOT-single exposure:	No data available.
STOT-repeated exposure:	No data available.
Aspiration hazard:	No data available.

11.2 Further information

No data available.

12. Ecological information

12.1 Toxicity

Very toxic to aquatic life.
Very toxic to aquatic life with long-lasting effects.

12.2 Persistence and degradability

No data available.

12.3 Bioaccumulative potential

No data available.

12.4 Mobility in soil

No data available.

12.5 Results of PBT and vPvB assessment

This product contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Other adverse effects

No data available.

12.7 Other information

No data available.

13. Disposal considerations

13. 1 Waste treatment methods

Product

Disposal of hazardous and/or laboratory wastes, product or packaging must be conducted in accordance with all applicable local, regional, national and international regulations.
Potentially infectious material must be appropriately decontaminated or disposed of as infectious material, check your applicable ordinances accordingly.

Contaminated packaging:

Disposal should be in accordance with local, state or national legislations. Contaminated packaging must be disposed of in the same manner as the product.

14. Transport information

14.1 UN number

This product is not regulated for transport.

14.2 UN proper shipping name

This product is not regulated for transport.

14.3 Transport hazard class(es)

This product is not regulated for transport.

14.4 Packing group

This product is not regulated for transport.

14.5 Environmental hazards

No data available.

14.6 Special precautions for user

Not necessary.

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

No data available.

15. Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

EU regulations: This product is not classified according to EU regulations 1272/2008.

15.2 Chemical Safety Assessment

No data available.

16. Other information

Reason of Change: Addition of P261, general revision.

List of H-and P-phrases:

H301	Toxic if swallowed.
H311	Toxic in contact with skin.
H314	Causes severe skin burns and eye damage.
H317	May cause an allergic skin reaction.
H331	Toxic if inhaled.
P261	Avoid breathing dust/fumes/gas/mist/vapours/spray.
P272	Contaminated work clothing should not be allowed out of the workplace.
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.
P362+P364	Take off contaminated clothing and wash it before reuse.
P501	Dispose of contents and container in accordance to local, regional, national and international regulations.

Group that issues data sheet
Contact person: see section 1, department responsible for information.

Dialab GmbH provides the information in this data sheet in good faith, declaring it is up-to-date at time of revision. However, this document is intended only as a guide for professional use, according to the intended purposes of the product. It does not represent a guarantee for the properties of the product described in terms of the legal warranty regulations.
The product is for in vitro diagnostic use only by trained personnel.

Version: **3**
Revision date: **May 8th, 2019**