

Document: K362DIE

Instruction version: 008

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Cat.# K362D Dry milk antigen EIA

Format version 008

SUMMARY**PRINCIPLE OF THE TEST**

This test is based on two-site sandwich enzyme immunoassay principle. Tested specimen is placed into the microwells coated by the antibody to Dry milk antigen. Antigen from the specimen bind coated antibody on the microwell surface. Unbound material is removed by washing procedure. Second antibodies directed towards Dry milk antigen, and labelled with peroxidase, are then added into the microwells. After subsequent washing procedure, the remaining enzymatic activity bound to the microwell surface is detected and quantified by addition of chromogen-substrate mixture, stop solution and photometry at 450 nm. Optical density in the microwell is directly related to the quantity of antigen in the specimen.

KIT CONTENTS

	Code	Description	Qty	Units	Colour code
1	P362D	anti-Dry milk antigen EIA strips, 8x12 wells	1	pcs	
2	N003	Plate sealing tape	2	pcs	
3	SP362DZ	Sample preparation buffer, 2 ml	1	pcs	colourless
4	C362DZ	Calibrators, 1 ml*	1	pcs	yellow
5	S008Z	Washing solution concentrate 21x, 22 ml	1	pcs	colourless
6	T362DZ	Conjugate, 11 ml	1	pcs	red
7	R055Z	Substrate solution, 11 ml	1	pcs	colourless
8	R050Z	Stop solution, 11 ml	1	pcs	colourless
9	K362DI	Instruction Dry milk antigen EIA	1	pcs	
10	K362DQ	QC data sheet Dry milk antigen EIA	1	pcs	
*	The set contains 6 calibrators: 0; 1; 5; 15; 25; 50 % Dry milk antigen				

materials required but not provided

- Distilled or deionized water;

NECESSARY EQUIPMENT

Microplate photometer with 450 nm wavelength and OD measuring range 0-3.0.

Dry thermostat for 37°C

HANDLING NOTES

1. INFECTION HAZARD: There are no available test methods that can absolutely assure that Hepatitis B and C viruses, HIV-1/2, or other infectious agents are not present in the reagents of this kit. All human blood products, including patient samples, should be considered potentially infectious. Handling and disposal of this material should comply with the rules defined by appropriate local biohazard safety guidelines.
2. Avoid contact with 5% H₂SO₄. It may cause skin irritation and burns.
3. Do not use reagents after expiration date.
4. Do not mix or use components from kits with different lot numbers.
5. Replace caps on reagents immediately. Do not swap caps.
6. Do not pipette reagents by mouth.

STORAGE CONDITIONS AND STABILITY

1. Store the whole kit at 2 to 8°C upon receipt until the expiration date.
2. After opening the pouch keep unused microtiter wells TIGHTLY SEALED BY ADHESIVE TAPE (INCLUDED) to minimize exposure to moisture.

DISPOSAL OF THE KIT

Kit components should be considered as potentially infectious material and discarded according to appropriate local biohazard safety guidelines.

SPECIMEN COLLECTION AND STORAGE

1. This kit is intended for use with serum or plasma (ACD- or heparinized). Grossly hemolytic, lipemic, or turbid samples should be avoided.
2. Specimens may be stored for up to 48 hours at 2-8°C before testing. For a longer storage, the specimens should be frozen at -20°C or lower. Repeated freezing/thawing should be avoided.

ASSAY PROCEDURE**Reagent Preparation**

1. All reagents (including the desired number of unsealed microstrips) should be allowed to reach room temperature (18 to 25°C) before use.

2. All reagents should be mixed by gentle inversion or vortexing prior to use. Do not allow foam formation.
3. Prepare working wash solution: dilute wash solution concentrate (S008Z) 1:21 in distilled water – e.g., 1 ml concentrate + 20 ml distilled water. *Stability after dilution:* 5 days at 18-25°C or 30 days at 2-8°C.
4. It is recommended to spin down shortly the tubes containing calibrators on a low speed centrifuge.

Procedural Note:

It is recommended that pipetting of all calibrators and samples should be completed within 3 minutes.

Sample preparation:

1	Dispense 1 ml of liquid milk sample into the test tube
2	Add 20 µl of Sample preparation buffer (SP362DZ), mix well and wait 5 minutes
3	Centrifuge samples at 10 000 g during 5 minutes. Use supernatant in analysis without dilution

Comments:

For testing Dry milk samples for falsification first prepare 10% (w/ v) solution in water.

Test flowchart

1	Put the desired number of microstrips into the frame; allocate two wells for each unknown sample and 12 wells for the calibrators. DO NOT REMOVE ADHESIVE SEALING TAPE FROM UNUSED STRIPS.
2	Dispense 100 µl of calibrator or unknown sample into the wells
3	Incubate 30 minutes at 37°C.
4	Prepare washing solution by 21x dilution of washing solution concentrate (code S008Z) by distilled water. Diluted washing solution is stable for 2 weeks at +2-8°C. Wash strips 3 times
5	Dispense 100 µl of Conjugate into the wells.
6	Incubate 30 minutes at 37°C
7	Wash the strips 5 times.
8	Dispense 100 µl of substrate into the wells
9	Incubate 10 minutes at 20-25°C
10	Dispense 100 µl of stop solution into the wells.
	Measure OD (optical density) at 450 nm.
	Set photometer blank on first calibrator
*	Apply point-by-point method for data reduction.

See the example of calibration curve in Quality Control insert.

Quality control

Control sample(s) should fit into the ranges shown in QC insert (see attached).