Sarstedt S-Monovette® CPDA

Verification of blood group serological tests after adaptation of the S-Monovette® CPDA to DIN EN ISO 6710:2017-12

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Abstract

The S-Monovette® CPDA was adapted to DIN EN ISO 6710:2017-12 with regard to the mixing ratio of preparation to blood. To verify the blood stabilizing property, the most important immunohematological examinations (determination of blood group, antibody screening test, cross-match, direct Coombs test) were checked using the column agglutination method as an example. In the immunohematological tests described here, identical results were obtained compared to the predecessor S-Monovette® CPDA.

Introduction

Immunohematological examinations are important routine examinations in the field of transfusion medicine.[1] The determination of the blood group in the AB0, Rhesus and Kell systems, the test for irregular blood group antibodies (antibody search test) as well as serological compatibility tests (cross-matches) are the most frequently requested parameters.

Different prepared blood samples can be used as test material.[2] One preparation that preserves the blood sample for a period of up to 35 days is the CPDA preparation (sodium citrate, sodium phosphate, dextrose, adenine).[3] For this reason, the S-Monovette® CPDA is also used as a pilot tube for a blood unit.

The S-Monovette® CPDA has been adapted to DIN EN ISO 6710:2017-12 with regard to the mixing ratio of preparation volume and blood volume (1 part preparation volume + 6 parts blood volume)[4]. This means a small change in the presented volume of the CPDA solution and thus also in the nominal volume. The composition of the CPDA solution according to DIN EN ISO 6710:2017-12 remains the same.

The aim of this work is to verify the determination of immunohematological parameters from the new S-Monovette® CPDA. For this purpose, comparative studies were carried out between the new S-Monovette® CPDA and the predecessor S-Monovette® CPDA using the column agglutination method as an example.

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Material & Methods

Due to the adaptation of the S-Monovette® CPDA to DIN EN ISO 6710:2017-12, the mixing ratio of preparation / blood volume changes from 1 + 7 in the predecessor S-Monovette® to 1 + 6 in the adapted S-Monovette®. This changes the nominal volumes as follows:

Art.-No. 01.1610.001: from previously 8,5 mL to 8,8 mL

Art.-No. 01.1938.001: from previously 5,6 mL to 5,7 mL

In this study, verification is exemplified using the 8.5 mL or 8.8 mL S-Monovette® CPDA, as it represents the market standard in Germany. After blood collection into 8.5 mL or 8.8 mL S-Monovettes CPDA, samples were inverted five times and then shipped to an external laboratory for analysis. After sufficient sedimentation of the erythrocytes, the samples were used the next day for analysis of the following parameters:

- Blood grouping (AB0) including Kell and Rhesus formula
- Antibody screening test
- polyspecific Direct Coombs Test
- serological compatibility sample (cross-match) of the erythrocytes of the CPDA sample with the plasma of test recipients

After 35 days of storage of the samples at 2 - 6 °C, the analyses were performed again, with the exception of the Direct Coombs Test. The Direct Coombs Test was repeated after 10 days of storage.

The analyses were all carried out using the column agglutination method. In this method, antigen and antibodies, i.e. patient erythrocytes and antisera or patient serum and test cells, react with each other in a plastic column.[5] After a incubation time, the column is centrifuged, leaving agglutinates on the column material, while non-agglutinated cells pass the column material and accumulate at the bottom of the column. In this study, the Vision Max device from Ortho Clinical Diagnostics GmbH was used.

Results

The results are given in semi-quantitative form from 0 (negative) to ++++ (very strong positive). In the following, the results of 10 donors are given as an extract from the verification, in each case on the first day and on the 35th day after blood collection. In each case, the results from the predecessor S-Monovette® CPDA ("P") are compared with the results from the new S-Monovette® CPDA ("N") adapted to DIN EN ISO. Apart from minimal fluctuations in the reaction strength (+++ vs. ++++), all resulting results are identical throughout.

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Tab. 1: Blood group determinations of 10 donors (1 - 10), each from predecessor S-Monovettes CPDA (P) and new S-Monovettes CPDA (N), on the first day after blood collection; reaction strengths from 0 (negative) to ++++ (very strong positive).

	Results with antisera					Test erythrocytes results				Rhesus formula with antisera clone-1						Rhesus formula with antisera clone-2						
ID-No.	Anti-A	Anti-B	Anti-D Reagent 1	Anti-D Reagent 2	Control	A1-Cells	B-Cells	0-Cells	Anti-K	Anti-C	Anti-E	Anti-c	Anti-e	Anti-K	Control	Anti-C	Anti-E	Anti-c	Anti-e	Anti-K	Control	Blood group result
1P	0	0	++++	++++	0	+++	++++	0	0	++++	0	0	++++	0	0	++++	0	0	++++	0	0	0 RhD-positiv CCD.ee Kell negativ
1N	0	0	++++	++++	0	++++	++++	0	0	++++	0	0	++++	0	0	++++	0	0	++++	0	0	0 RhD-positiv CCD.ee Kell negativ
2P	++++	0	0	0	0	0	+++	0	++++	0	0	++++	++++	++++	0	0	0	++++	++++	+++	0	A RhD-negativ ccddee Kell positiv
2N	++++	0	0	0	0	0	+++	0	++++	0	0	++++	++++	++++	0	0	0	++++	++++	+++	0	A RhD-negativ ccddee Kell positiv
3P	0	0	0	0	0	++++	+++	0	++++	0	0	++++	++++	+++	0	0	0	++++	++++	+++	0	0 RhD-negativ ccddee Kell positiv
3N	0	0	0	0	0	+++	++++	0	++++	0	0	++++	++++	++++	0	0	0	++++	++++	+++	0	0 RhD-negativ ccddee Kell positiv
4P	++++	0	++++	++++	0	0	+++	0	0	++++	0	0	++++	0	0	++++	0	0	++++	0	0	A RhD-positiv CCD.ee Kell negativ
4N	++++	0	++++	++++	0	0	+++	0	0	++++	0	0	++++	0	0	++++	0	0	++++	0	0	A RhD-positiv CCD.ee Kell negativ
5P	0	0	++++	++++	0	+++	+++	0	0	++++	0	0	++++	0	0	++++	0	0	++++	0	0	0 RhD-positiv CCD.ee Kell negativ
5N	0	0	++++	++++	0	+++	+++	0	0	++++	0	0	++++	0	0	++++	0	0	++++	0	0	0 RhD-positiv CCD.ee Kell negativ
6P	0	0	++++	++++	0	++++	++++	0	0	0	++++	++++	++++	0	0	0	++++	++++	++++	0	0	0 RhD-positiv ccD.Ee Kell negativ
6N	0	0	++++	++++	0	+++	++++	0	0	0	++++	++++	++++	0	0	0	++++	++++	++++	0	0	0 RhD-positiv ccD.Ee Kell negativ
7P	++++	0	0	0	0	0	+++	0	0	0	0	++++	++++	0	0	0	0	++++	++++	0	0	A RhD-negativ ccddee Kell negativ
7N	++++	0	0	0	0	0	+++	0	0	0	0	++++	++++	0	0	0	0	++++	++++	0	0	A RhD-negativ ccddee Kell negativ
8P	0	++++	++++	++++	0	+++	0	0	0	++++	0	++++	++++	0	0	++++	0	++++	++++	0	0	B RhD-positiv CcD.ee Kell negativ
8N	0	++++	++++	++++	0	+++	0	0	0	++++	0	++++	++++	0	0	++++	0	++++	++++	0	0	B RhD-positiv CcD.ee Kell negativ
9P	++++	0	++++	++++	0	0	++++	0	0	++++	0	++++	++++	0	0	++++	0	++++	++++	0	0	A RhD-positiv CcD.ee Kell negativ
9N	++++	0	++++	++++	0	0	++++	0	0	++++	0	++++	++++	0	0	++++	0	++++	++++	0	0	A RhD-positiv CcD.ee Kell negativ
10P	0	0	0	0	0	++++	+++	0	+++	0	0	++++	++++	+++	0	0	0	++++	++++	+++	0	0 RhD-negativ ccddee Kell positiv
10N	0	0	0	0	0	++++	++++	0	+++	0	0	++++	++++	+++	0	0	0	++++	++++	+++	0	0 RhD-negativ ccddee Kell positiv

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Tab. 2: Blood group determinations of 10 donors (1 - 10), each from predecessor S-Monovettes CPDA (P) and new S-Monovettes CPDA (N), on day 35 after blood collection; reaction strengths from 0 (negative) to ++++ (very strong positive).

	Results with antisera					Test erythrocytes results				Rhesus formula with antisera clone-1						Rhesus formula with antisera clone-2						
ID-No.	Anti-A	Anti-B	Anti-D Reagent 1	Anti-D Reagent 2	Control	A1-Cells	B-Cells	0-Cells	Anti-K	Anti-C	Anti-E	Anti-c	Anti-e	Anti-K	Control	Anti-C	Anti-E	Anti-c	Anti-e	Anti-K	Control	Blood group result
1P	0	0	++++	++++	0	++++	++++	0	0	++++	0	0	++++	0	0	++++	0	0	++++	0	0	0 RhD-positiv CCD.ee Kell negativ
1N	0	0	++++	++++	0	++++	+++	0	0	++++	0	0	++++	0	0	++++	0	0	++++	0	0	0 RhD-positiv CCD.ee Kell negativ
2P	++++	0	0	0	0	0	+++	0	++++	0	0	++++	++++	++++	0	0	0	++++	++++	+++	0	A RhD-negativ ccddee Kell positiv
2N	++++	0	0	0	0	0	+++	0	++++	0	0	++++	++++	++++	0	0	0	++++	++++	++++	0	A RhD-negativ ccddee Kell positiv
3P	0	0	0	0	0	+++	++++	0	++++	0	0	++++	++++	+++	0	0	0	++++	++++	+++	0	0 RhD-negativ ccddee Kell positiv
3N	0	0	0	0	0	+++	++++	0	+++	0	0	++++	++++	++++	0	0	0	++++	++++	+++	0	0 RhD-negativ ccddee Kell positiv
4P	++++	0	++++	++++	0	0	+++	0	0	++++	0	0	++++	0	0	++++	0	0	++++	0	0	A RhD-positiv CCD.ee Kell negativ
4N	++++	0	++++	++++	0	0	+++	0	0	++++	0	0	++++	0	0	++++	0	0	++++	0	0	A RhD-positiv CCD.ee Kell negativ
5P	0	0	++++	++++	0	+++	+++	0	0	++++	0	0	++++	0	0	++++	0	0	++++	0	0	0 RhD-positiv CCD.ee Kell negativ
5N	0	0	++++	++++	0	+++	+++	0	0	++++	0	0	++++	0	0	++++	0	0	++++	0	0	0 RhD-positiv CCD.ee Kell negativ
6P	0	0	++++	++++	0	+++	++++	0	0	0	++++	++++	++++	0	0	0	++++	++++	++++	0	0	0 RhD-positiv ccD.Ee Kell negativ
6N	0	0	++++	++++	0	+++	+++	0	0	0	++++	++++	++++	0	0	0	++++	++++	++++	0	0	0 RhD-positiv ccD.Ee Kell negativ
7P	++++	0	0	0	0	0	+++	0	0	0	0	++++	++++	0	0	0	0	++++	++++	0	0	A RhD-negativ ccddee Kell negativ
7N	++++	0	0	0	0	0	+++	0	0	0	0	++++	++++	0	0	0	0	++++	++++	0	0	A RhD-negativ ccddee Kell negativ
8P	0	++++	++++	++++	0	+++	0	0	0	++++	0	++++	++++	0	0	++++	0	++++	++++	0	0	B RhD-positiv CcD.ee Kell negativ
8N	0	++++	++++	++++	0	+++	0	0	0	++++	0	++++	++++	0	0	++++	0	++++	++++	0	0	B Rh D-positiv CcD.ee Kell negativ
9P	++++	0	++++	++++	0	0	++++	0	0	++++	0	++++	++++	0	0	++++	0	++++	++++	0	0	A RhD-positiv CcD.ee Kell negativ
9N	++++	0	++++	++++	0	0	++++	0	0	++++	0	++++	++++	0	0	++++	0	++++	++++	0	0	A RhD-positiv CcD.ee Kell negativ
10P	0	0	0	0	0	++++	++++	0	++++	0	0	++++	++++	+++	0	0	0	++++	++++	+++	0	0 RhD-negativ ccddee Kell positiv
10N	0	0	0	0	0	++++	++++	0	++++	0	0	++++	++++	+++	0	0	0	++++	++++	+++	0	0 RhD-negativ ccddee Kell positiv

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Tab. 3: Direct Coombs test, antibody screening test and serological compatibility test (cross-match) of 10 donors (1 - 10), each from predecessor S-Monovettes CPDA (P) and new S-Monovettes CPDA (N), on the first day after blood collection; reaction strengths from 0 (negative) to ++++ (very strong positive) (* CMP = compatible)

	Direct Coombs test		Antibody screening test with tester erythrocytes			Antibody screening test	Crossmatch
ID-No.	Reactivity	Result	Cells-1	Cells-2	Cells-3	Result	Result*
1P	0	negativ	0	0	0	negativ	CMP
1N	0	negativ	0	0	0	negativ	CMP
2P	0	negativ	0	0	0	negativ	CMP
2N	0	negativ	0	0	0	negativ	CMP
3P	0	negativ	++++	+++	0	positiv	CMP
3N	0	negativ	++++	+++	0	positiv	CMP
4P	0	negativ	0	0	0	negativ	CMP
4N	0	negativ	0	0	0	negativ	CMP
5P	0	negativ	0	0	0	negativ	CMP
5N	0	negativ	0	0	0	negativ	CMP
6P	0	negativ	0	0	0	negativ	CMP
6N	0	negativ	0	0	0	negativ	CMP
7P	0	negativ	0	0	0	negativ	CMP
7N	0	negativ	0	0	0	negativ	CMP
8P	0	negativ	0	0	0	negativ	CMP
8N	0	negativ	0	0	0	negativ	CMP
9P	0	negativ	0	0	0	negativ	CMP
9N	0	negativ	0	0	0	negativ	CMP
10P	0	negativ	+++	+++	0	positiv	CMP
10N	0	negativ	+++	+++	0	positiv	CMP

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Tab. 4: Antibody screening test and serological compatibility sample (cross-match) of 10 donors (1 - 10), each from predecessor S-Monovettes CPDA (P) and new S-Monovettes CPDA (N), on day 35 after blood collection; reaction strengths from 0 (negative) to ++++ (very strong positive) (* CMP = compatible).

	Antibody screening test with tester erythrocytes			Antibody screening test	Crossmatch
ID-No.	Cells-1	Cells-2	Cells-3	Result	Result*
1P	0	0	0	negativ	CMP
1N	0	0	0	negativ	CMP
2P	0	0	0	negativ	CMP
2N	0	0	0	negativ	CMP
3P	+++	+++	0	positiv	CMP
3N	+++	+++	0	positiv	CMP
4P	0	0	0	negativ	CMP
4N	0	0	0	negativ	CMP
5P	0	0	0	negativ	CMP
5N	0	0	0	negativ	CMP
6P	0	0	0	negativ	CMP
6N	0	0	0	negativ	CMP
7P	0	0	0	negativ	CMP
7N	0	0	0	negativ	CMP
8P	0	0	0	negativ	CMP
8N	0	0	0	negativ	CMP
9P	0	0	0	negativ	CMP
9N	0	0	0	negativ	CMP
10P	+++	+++	0	positiv	CMP
10N	+++	+++	0	positiv	CMP

Tab. 5: Direct Coombs test of 5 donors (6 - 10), each from predecessor S-Monovettes CPDA (P) and new S-Monovettes CPDA (N), on day 10 after blood collection; reaction strengths from 0 (negative) to ++++ (very strong positive).

	Direct Coombs test	
ID-No.	Reactivity	Result Day 10
6P	0	negativ
6N	0	negativ
7P	0	negativ
7N	0	negativ
8P	0	negativ
8N	0	negativ
9P	0	negativ
9N	0	negativ
10P	0	negativ
10N	0	negativ

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Discussion

The predecessor S-Monovette® CPDA has always been a suitable Monovette® for immunohematological tests. The ingredients of the preparation are able to stabilize the blood samples for 35 days for the above-mentioned examinations. Consequently, it has also proven itself as a pilot tube for blood preservation, as CPDA is also used as a stabilizer in blood preserves.[6; 7]

The adaptation of the S-Monovette® CPDA to DIN EN ISO 6710:2017-12 required minor changes to the predecessor S-Monovette® CPDA, mainly concerning the mixing ratio and the nominal volume. In the present study, the most important immune-hematological tests, including serological compatibility testing (red cells from the S-Monovette® CPDA with plasma from test recipients) from the predecessor S-Monovette® CPDA and new S-Monovette® CPDA were compared. The investigations were carried out both on the first day after blood collection and after 35 days of storage at 2 - 6 °C using the column agglutination method (DCT after 10 days of storage). Apart from individual minimal differences in the reaction strengths (+++ or ++++), the results were always completely identical. These minimal variations are presumably caused by random variations during sample preparation, further processing, materials used, or sample age.

Conclusion

This study has shown that the S-Monovette® CPDA adapted to DIN EN ISO 6710:2017-12 provides equivalent results for the immuno-hematological parameters tested here as the previously accepted S-Monovette® CPDA. Thus, the conformity of the S-Monovette® CPDA with the (EU) 2017/746 (IVDR) was confirmed in parallel.[8] The tests were performed on sedimented blood samples using column agglutination procedures. Other methods, devices and analyses were not tested and must be checked by the user.

Disclosure

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