Performance of VACUETTE® CPDA Tubes

Background:

Blood Grouping Tubes are available with ACD (Acid Citrate Dextrose) solutions in two formulations (VACUETTE® ACD-A or VACUETTE® ACD-B) or with CPDA solution (Citrate Phosphate Dextrose Adenine). Blood Grouping Tubes are used for blood grouping tests or cell preservation [1].

The sterile tube is available with a liquid additive of citric acid, monobasic sodium phosphate, dextrose and adenine.

The citrate prevents the clotting of the blood specimen, phosphate buffers the pH value, and Dextrose maintains the cell metabolism for test analyses. The addition of adenine supports the maintenance of red cell ATP during storage [2].

VACUETTE® CPDA tubes are made of PET (polyethylene terephthalate). The yellow caps are produced from PE (polyethylene). The rubber component is composed of Bromine Butyl Caoutchouc.

Blood collected in VACUETTE® CPDA tubes may be stored for up to approx. 35 days at 1-6°C [3].

Study Objective:

Part 1:

The study was carried out in cooperation with an external laboratory in Linz, Austria, to demonstrate the functionality of VACUETTE® CPDA tubes in blood collection at initial time point of cell preservation in comparison to the VACUTAINER® ACD-A tubes. VACUETTE® CPDA tubes were tested in comparison to VACUTAINER® ACD-A tubes for the following parameters: Blood grouping, Rhesus factor, Antibody screening (3 screening cells by indirect Coombs, 3 screening cells in papain), direct Coombs test (short), and anti-C manual / anti-C automatic.

Part 2:

Performance testing for VACUETTE® CPDA tubes was repeated after 72h and 35 days in order to compare the results after 72h and 35 days to the initial time point. Testing after 35 days was limited to blood group testing and Rhesus factor as it is common practice to do testing at initial time point only for all other parameters.

Study design:

The following tube types were used in this study:

Sample ID	Description
A	VACUTAINER® ACD-A 8.5 ml, glass, (Item No.: 366645)
B	VACUETTE® CPDA 9 ml, (Item No.: 455056)

Blood was collected from in total 20 apparently healthy male and female donors. Informed consent was given by each participant. The study was approved by the EC upper Austria. The specimens of twenty subjects were used in part 1 and part 2.

Blood was drawn into one tube of each sample A and B by using a Blood Collection Set (#450085) and Tourniquet (#840050). A discard tube was used to ensure the same amount of blood in all tubes. The order of draw was randomized. The tubes were gently inverted according to the instruction for use.

Initial analysis was done on an ORTHO AutoVue® Innova Analyzer (serial no. 3143 and 3298). After 72h, the tubes were taken out of the refrigerator. Testing was done immediately after removing the samples from the refrigerator and samples were not adapted to room temperature.

All tubes were centrifuged at 2566g for 6 min.

The following tests were carried out:

- Blood grouping
- Rhesus factor
- Antibody test (3 screening cells by indirect Coombs, 3 screening cells in papain) – part 1 only
- direct Coombs test (short) – part 1 only
- anti-C manual / anti-C automatic – part 1 only

Summary Part 1 at initial time point:

For the initial analysis, the equivalent performance of VACUETTE® CPDA tubes (Sample B) and BD Vacutainer® ACD-A tubes (Sample A) was demonstrated in this study (see results in table 1 below). The time between blood sampling and measurement at the external laboratory in Linz was between 5.5 to 10 hours.

Summary Part 2 after 72h:

After 3 days (tubes were stored in a refrigerator at 4°C), all samples B were analyzed in the same way as at the initial time point.

The results in the tables 2 and 3 below (comparison initial and 72 h results) confirm the stability of the results on the third day compared to the initial results. The time between blood sampling and the measurement at the laboratory after 3 days was between 74 to 76 hours.

Summary Part 2 after 35 days:

Performance testing with a reduced profile (table 4) after 35 days (tubes were stored in a refrigerator at 4°C) of the VACUETTE® CPDA tubes (sample B only) was done in the same way as initial testing. The results confirm stability of blood group and Rhesus factor testing after 35 days.

Conclusion:

Substantially equivalent performance has been demonstrated between VACUETTE® CPDA tubes in comparison to BD Vacutainer® ACD-A tubes at initial time point. The equivalent performance of the VACUETTE® CPDA tubes was also shown in view of the tested parameters after 3 and 35 days (limited profile) relative to the initial results demonstrating stability over time.

References:

[1] GBO Instructions for Use 980200 Rev. 22
[2] C.C. Peck, G.L. Moore, R.B. Bolin, R.B. Dawson, Adenine Blood Preservation. CRC Critical Reviews in Clinical Laboratory Science Vol 13, 1981 p. 173-212
[3] GBO CI_D_ACD/CPDA_Rev00

Results in detail part 1: Initial testing (20 subjects) (Table 1) – Samples A and B

Initial analysis									
Sample ID	**blood group and rhesus**	**Phenotype**	**antibody test**	**direct coombs test**	**Sample ID**	**blood group and rhesus**	**phenotype**	**antibody test**	**direct coombs test**
1A	A negative	ccddee K-	negative	negative	**1B**	A negative	ccddee K-	negative	negative
2A	A negative	ccddee K-	negative	negative	**2B**	A negative	ccddee K-	negative	negative
3A	A positive	ccD_Ee K-	negative	negative	**3B**	A positive	ccD_Ee K-	negative	negative
4A	A positive	CCD_ee K-	negative	negative	**4B**	A positive	CCD_ee K-	negative	negative
5A	O negative	ccddee K-	negative	negative	**5B**	O negative	ccddee K-	negative	negative
6A	O positive	CcD_ee K-	negative	negative	**6B**	O positive	CcD_ee K-	negative	negative
7A	AB positive	CcD_ee K-	negative	negative	**7B**	AB positive	CcD_ee K-	negative	negative
8A	O positive	ccD_Ee K-	negative	negative	**8B**	O positive	ccD_Ee K-	negative	negative
9A	B positive	CCD_ee K-	negative	negative	**9B**	B positive	CCD_ee K-	negative	negative
10A	O positive	ccD_Ee K-	negative	negative	**10B**	O positive	ccD_Ee K-	negative	negative
11A	B negative	ccddee K+	negative	negative	**11B**	B negative	ccddee K+	negative	negative
12A	A positive	CcD_Ee K-	negative	negative	**12B**	A positive	CcD_Ee K-	negative	negative
13A	A positive	CcD_ee K+	negative	negative	**13B**	A positive	CcD_ee K+	negative	negative
14A	A positive	CcD_ee K-	negative	negative	**14B**	A positive	CcD_ee K-	negative	negative
15A	O positive	CcD_ee K-	negative	negative	**15B**	O positive	CcD_ee K-	negative	negative
16A	AB positive	CcD_ee K-	negative	negative	**16B**	AB positive	CcD_ee K-	negative	negative
17A	O positive	CcD_ee K-	negative	negative	**17B**	O positive	CcD_ee K-	negative	negative
18A	O positive	CcD_ee K-	negative	negative	**18B**	O positive	CcD_ee K-	negative	negative
19A	A positive	CcD_Ee K-	negative	negative	**19B**	A positive	CcD_Ee K-	negative	negative
20A	O positive	ccD_EE K-	negative	negative	**20B**	O positive	ccD_EE K-	negative	negative

Results in detail part 1: Performance testing after 3 days (20 subjects) (Table 2 and Table 3)

Sample B only – comparison of initial results to results after 3 days

Initial testing				
Sample ID	**blood group and rhesus**	**phenotype**	**antibody test**	**direct coombs test**
1B	A negative	ccddee K-	negative	negative
2B	A negative	ccddee K-	negative	negative
3B	A positive	ccD_Ee K-	negative	negative
4B	A positive	CCD_ee K-	negative	negative
5B	O negative	ccddee K-	negative	negative
6B	O positive	CcD_ee K-	negative	negative
7B	AB positive	CcD_ee K-	negative	negative
8B	O positive	ccD_Ee K-	negative	negative
9B	B positive	CCD_ee K-	negative	negative
10B	O positive	ccD_Ee K-	negative	negative
11B	B negative	ccddee K+	negative	negative
12B	A positive	CcD_Ee K-	negative	negative
13B	A positive	CcD_ee K+	negative	negative
14B	A positive	CcD_ee K-	negative	negative
15B	O positive	CcD_ee K-	negative	negative
16B	AB positive	CcD_ee K-	negative	negative
17B	O positive	CcD_ee K-	negative	negative
18B	O positive	CcD_ee K-	negative	negative
19B	A positive	CcD_Ee K-	negative	negative
20B	O positive	ccD_EE K-	negative	negative

Testing after 3 days				
Sample ID	**blood group and rhesus**	**Phenotype**	**antibody test**	**direct coombs test**
1B	A negative	ccddee K-	negative	negative
2B	A negative	ccddee K-	negative	negative
3B	A positive	ccD_Ee K-	negative	negative
4B	A positive	CCD_ee K-	negative	negative
5B	0 negative	ccddee K-	negative	negative
6B	0 positive	CcD_ee K-	negative	negative
7B	AB positive	CcD_ee K-	negative	negative
8B	0 positive	ccD_Ee K-	negative	negative
9B	B positive	CCD_ee K-	negative	negative
10B	0 positive	ccD_Ee K-	negative	negative
11B	B negative	ccddee K+	negative	negative
12B	A positive	CcD_Ee K-	negative	negative
13B	A positive	CcD_ee K+	negative	negative
14B	A positive	CcD_ee K-	negative	negative
15B	0 positive	CcD_ee K-	negative	negative
16B	AB positive	CcD_ee K-	negative	negative
17B	0 positive	CcD_ee K-	negative	negative
18B	0 positive	CcD_ee K-	negative	negative
19B	A positive	CcD_Ee K-	negative	negative
20B	0 positive	ccD_EE K-	negative	negative

Results in detail part 2 - Performance testing after 35 days (20 subjects) (Table 4)

Sample B only – comparison of initial results to results after 35 days (limited profile)

Initial testing		Testing after 35 days	
Sample ID	**blood group and rhesus**	**Sample ID**	**blood group and rhesus**
1B	A negative	**1B**	A negative
2B	A negative	**2B**	A negative
3B	A positive	**3B**	A positive
4B	A positive	**4B**	A positive
5B	O negative	**5B**	0 negative
6B	O positive	**6B**	0 positive
7B	AB positive	**7B**	AB positive
8B	O positive	**8B**	0 positive
9B	B positive	**9B**	B positive
10B	O positive	**10B**	0 positive
11B	B negative	**11B**	B negative
12B	A positive	**12B**	A positive
13B	A positive	**13B**	A positive
14B	A positive	**14B**	A positive
15B	O positive	**15B**	0 positive
16B	AB positive	**16B**	AB positive
17B	O positive	**17B**	0 positive
18B	O positive	**18B**	0 positive
19B	A positive	**19B**	A positive
20B	O positive	**20B**	0 positive