Performance of VACUETTE® ACD-A 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 VACUETTE® ACD-A evacuated blood collection tube is used to preserve red blood cells.

VACUETTE® ACD-A tubes are made of PET (polyethylene terephthalate). The yellow caps are produced from PE (polyethylene). The rubber component is composed of Bromine Butyl Caoutchouc. The sterile tube is available with a liquid additive of Citric acid, Trisodium Citrate and Dextrose.

The citrate prevents the clotting of the blood specimen and Dextrose maintains the cell metabolism for test analyses. In the ACD-A formulation there is less dilution than in the ACD-B formulation, thus making relatively greater amounts of dextrose available for metabolizing red blood cells and thus preserving them better.

Blood collected in VACUETTE® ACD-A preserves red blood cells for approx. 21 days at 1-6°C [2].

Study Objective:

Part 1:

The study was carried out in cooperation with an external laboratory in Linz, Austria, to demonstrate the functionality of VACUETTE® ACD-A tubes in blood collection at initial time point and after 3 days of cell preservation in comparison to the VACUTAINER® ACD-A tubes. VACUETTE® ACD-A 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® ACD-A tubes was repeated after 21 days comparing the results of initial time point to the results after 21 days to demonstrate stability of over time. The testing profile was limited to Blood grouping 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	VACUETTE® ACD-A 9 ml, (Item No.: 455055)
B	VACUTAINER® ACD-A 8.5 ml, glass, (Item No.: 366645)

Blood was collected from in total 40 apparently healthy male and female donors. Informed consent was given by each participant. The study was approved by the EC upper Austria. The

specimens from twenty subjects were used for part 1 and those from the other 20 subjects were tested in 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, and testing was done immediately after removing the samples from the refrigerator and samples were not adapted to room temperature.

All samples 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® ACD-A tubes (Sample A) and BD Vacutainer® ACD-A tubes (Sample B) was demonstrated in this study (see results in table 1 below). The time between blood sampling and measurement at the laboratory was between 4 to 10 hours.

Summary Part 1 after 72h:

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

The results in the tables (table 1 and table 2) below confirm the stability of the results on the third day compared to the initial results as well as the equivalence of the results of Sample A and Sample B.

Summary Part 2 after 21 days:

The samples for the initial measurement at the laboratory were measured 3-8h after blood collection.

Performance testing (table 3 and table 4) after 21 days (tubes were stored in a refrigerator at 4°C) of the VACUETTE® ACD-A tubes was done in the same way as initial testing. The results confirm stability of blood group and Rhesus factor testing after 21 days.

Conclusion:

Substantially equivalent performance has been demonstrated between VACUETTE® ACD-A tubes in comparison to BD Vacutainer® ACD-A tubes at initial time point and after 3 days. The equivalent performance of the VACUETTE® ACD-A tubes was also shown in view of the tested parameters (limited profile) after 21 days relative to the initial results demonstrating stability over time.

References:

[1] GBO Instructions for Use 980200 Rev. 22

[2] GBO CI_D_ACD/CPDA_Rev00

Results in detail part 1: Initial testing (20 subjects part 1) (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 positive	CcD_ee	negative	negative	**1B**	A positive	CcD_ee	negative	negative
2A	A positive	CCD_ee	negative	negative	**2B**	A positive	CCD_ee	negative	negative
3A	A negative	ccddee	negative	negative	**3B**	A negative	ccddee	negative	negative
4A	0 positive	ccD_Ee	negative	negative	**4B**	0 positive	ccD_Ee	negative	negative
5A	A positive	ccD_Ee	negative	negative	**5B**	A positive	ccD_Ee	negative	negative
6A	0 negative	ccddEe	negative	negative	**6B**	0 negative	ccddEe	negative	negative
7A	B positive	CCD_ee	negative	negative	**7B**	B positive	CCD_ee	negative	negative
8A	B negative	ccddee	negative	negative	**8B**	B negative	ccddee	negative	negative
9A	A positive	ccD_Ee	negative	negative	**9B**	A positive	ccD_Ee	negative	negative
10A	A positive	CCD_ee	negative	negative	**10B**	A positive	CCD_ee	negative	negative
11A	A positive	CcD_ee	negative	negative	**11B**	A positive	CcD_ee	negative	negative
12A	A positive	CCD_ee	negative	negative	**12B**	A positive	CCD_ee	negative	negative
13A	AB positive	CcD_ee	negative	negative	**13B**	AB positive	CcD_ee	negative	negative
14A	A positive	CCD_ee	negative	negative	**14B**	A positive	CCD_ee	negative	negative
15A	0 positive	ccD_Ee	negative	negative	**15B**	0 positive	ccD_Ee	negative	negative
16A	0 positive	CcD_Ee	negative	negative	**16B**	0 positive	CcD_Ee	negative	negative
17A	A positive	CcD_ee	negative	negative	**17B**	A positive	CcD_ee	negative	negative
18A	0 positive	ccD_EE	negative	negative	**18B**	0 positive	ccD_EE	negative	negative
19A	0 positive	CcD_ee	negative	negative	**19B**	0 positive	CcD_ee	negative	negative
20A	0 positive	CcD_Ee	negative	negative	**20B**	0 positive	CcD_Ee	negative	negative

Results in detail part 1: Testing after 3 days (20 subjects part 1) (Table 2) – Samples A and B

Analysis after 3 days									
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 positive	CcD_ee	negative	negative	**1B**	A positive	CcD_ee	negative	negative
2A	A positive	CCD_ee	negative	negative	**2B**	A positive	CCD_ee	negative	negative
3A	A negative	ccddee	negative	negative	**3B**	A negative	ccddee	negative	negative
4A	0 positive	ccD_Ee	negative	negative	**4B**	0 positive	ccD_Ee	negative	negative
5A	A positive	ccD_Ee	negative	negative	**5B**	A positive	ccD_Ee	negative	negative
6A	0 negative	ccddEe	negative	negative	**6B**	0 negativ	ccddEe	negative	negative
7A	B positive	CCD_ee	negative	negative	**7B**	B positive	CCD_ee	negative	negative
8A	B negative	ccddee	negative	negative	**8B**	B negative	ccddee	negative	negative
9A	A positive	ccD_Ee	negative	negative	**9B**	A positive	ccD_Ee	negative	negative
10A	A positive	CCD_ee	negative	negative	**10B**	A positive	CCD_ee	negative	negative
11A	A positive	CcD_ee	negative	negative	**11B**	A positive	CcD_ee	negative	negative
12A	A positive	CCD_ee	negative	negative	**12B**	A positive	CCD_ee	negative	negative
13A	AB positive	CcD_ee	negative	negative	**13B**	AB positive	CcD_ee	negative	negative
14A	A positive	CCD_ee	negative	negative	**14B**	A positive	CCD_ee	negative	negative
15A	0 positive	ccD_Ee	negative	negative	**15B**	0 positive	ccD_Ee	negative	negative
16A	0 positive	CcD_Ee	negative	negative	**16B**	0 positive	CcD_Ee	negative	negative
17A	A positive	CcD_ee	negative	negative	**17B**	A positive	CcD_ee	negative	negative
18A	0 positive	ccD_EE	negative	negative	**18B**	0 positive	ccD_EE	negative	negative
19A	0 positive	CcD_ee	negative	negative	**19B**	0 positive	CcD_ee	negative	negative
20A	0 positive	CcD_Ee	negative	negative	**20B**	0 positive	CcD_Ee	negative	negative

Performance testing part 2 after 21 days (20 subjects part 2) – comparison of initial results with results after 21 days – Sample A

Initial testing results (Table 3):

N	blood group and rhesus
1A	A positive
2A	A positive
3A	B positive
4A	B positive
5A	A positive
6A	0 positive
7A	AB positive
8A	0 positive
9A	0 negative
10A	A positive
11A	0 negative
12A	0 positive
13A	0 negative
14A	B positive
15A	A positive
16A	0 positive
17A	A positive
18A	B negative
19A	A positive
20A	0 positive

Results after 21 days (Table 4)

N	blood group and rhesus
1A	A positive
2A	A positive
3A	B positive
4A	B positive
5A	A positive
6A	0 positive
7A	AB positive
8A	0 positive
9A	0 negative
10A	A positive
11A	0 negative
12A	0 positive
13A	0 negative
14A	B positive
15A	A positive
16A	0 positive
17A	A positive
18A	B negative
19A	A positive
20A	0 positive