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English

*e*BDS

REF **400-03E**

eBDS SAMPLE SET

Bacteria Detection System for Testing of Platelet Products and Leucocyte-Reduced Red Cells.

For In-Vitro Diagnostic Use.

NOT FOR TRANSFUSION.

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*e*BDS SAMPLE SET

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For *In-Vitro* Diagnostic Use

NOT FOR TRANSFUSION

(Re-order No: 400-03E)

INTENDED USE

The *e*BDS Sample Set is intended for use with the *e*BDS Oxygen Analyser in qualitative procedures for the recovery and detection of aerobic and facultative anaerobic microorganisms (bacteria) for quality control testing of apheresis and whole blood derived platelet products in plasma or platelet additive solution (PAS), and leucocyte-reduced red cell components.

Sterile fluid pathway. Sterilised by gamma irradiation.

SUMMARY AND EXPLANATION

The *e*BDS Sample Set is used to determine if normally sterile leucocyte-reduced and non leucocyte-reduced platelets and leucocyte-reduced red cells contain bacteria. Measurement of bacteria in platelet products when performed, has generally involved classical microbiological methods. The use of markers for bacterial growth, such as pH and glucose concentration, has been investigated but suffered from lack of sensitivity and specificity[1,2,3,4]. The *e*BDS Sample Set makes use of oxygen concentration as a marker for bacterial growth. When used with a sterile connection device, the *e*BDS Sample Set provides a functionally closed system for sampling and requires no additional reagents. The system requires the use of the *e*BDS Oxygen Analyser to measure the percentage of oxygen in the sample pouch, after a 35 °C incubation of the blood component sample in the sample pouch.

TEST PRINCIPLE

The method of detection is based upon the measurement of the oxygen content of the air within the sample pouch as a marker for bacteria. The *e*BDS system uses the *e*BDS Oxygen Analyser to measure the percentage of oxygen in the headspace gas of the sample pouch. If bacteria are present in the blood component sample collected, an increasing amount of oxygen is consumed through the metabolic activity and proliferation of the bacteria in the sample during incubation, resulting in a measurable decrease in oxygen content of the sample as well as the air within the sample pouch.

REAGENTS

Two tablets, each containing 1.75 mg sodium polyanethol sulphonate (SPS), trypticase soy broth, calcium chloride and manufacturing processing agents, are contained within the sample pouch. There are no reconstitution, mixing, or dilution steps.

STORAGE CONDITIONS

Do not store above 40°C. Do not freeze. Do not use if packaging is damaged or end protector is loose or displaced. Do not use if there is evidence of damage to the *e*BDS Sample Set or if the pouch does not contain two tablets. Do not use after the expiration date. Contents of unit pack must be used within 14 days of opening.

PRECAUTION

For *In-Vitro* Diagnostic Use.
NOT FOR TRANSFUSION.

INSTRUCTIONS FOR USE

Materials required but not supplied:
35°C Incubator with a flatbed platelet agitator
Sterile connection device and wafers
Tube sealer
Tubing stripper
Clamp or haemostat

Specimen Collection and Preparation

Note: When sampling platelets in PAS or red cell components, ensure Data and *e*BDS Oxygen Analyser have been configured appropriately.

1. For optimal bacteria detection of platelet products, sample 24 hours or longer after collection.

   For optimal bacteria detection of red cell components, sample 24 hours or longer after collection.

   Sampling earlier than the periods specified above may not permit very slow growing organisms time to proliferate to levels sufficient to be detected.
2. At the desired time following collection, remove blood component from storage area and prepare sample as described below.
3. Clamp the tubing of the Sample Set below the check valve.
4. Platelet components: Gently mix platelet product and strip tubing of platelet bag.

   Red cell components: Mix end over end ten times, and strip tubing to be sterile connected to *e*BDS Sample Set.

   Ensure the tubing is filled completely with a well-mixed representative sample.
5. Sterile connect blood component pack to *e*BDS Sample Set following manufacturer's instructions. To ensure maximum length of Sample Set tubing is connected to the blood component pack, place the plug of the sample set tubing at the end of the groove within the sterile connection device.
6. If required, affix a label containing the Unit Number to the tab of the sample pouch.
7. Gently mix the blood component pack.
8. Suspend or hold the blood component pack above the sample pouch ensuring the fill lines are horizontal (Note: sample port should be facing downwards).
9. Open clamp and allow fluid to flow until the fluid level reaches at or between the two lines located on sample pouch. (The pouch is considered "underfilled" if the liquid level is below the first line, and "overfilled" if liquid level is over the second line.) Overfill of the sample pouch can result in a false positive. Underfill can result in a false negative.
10. Clamp tubing.
11. Seal tubing on both sides of the check valve*. Note: 10-15 cm of tubing should remain on the blood component. Note: If testing platelets in PAS or red cell components, enter donation ID, product code and *e*BDS pouch lot number into Data.
12. Detach check valve from sample pouch and blood component pack and discard check valve*. Note: Blood component in tubing may be recovered by stripping contents back into the blood component pack.
13. Place sample pouch on horizontal platelet agitator inside a 35 °C incubator, see table below for appropriate hold and incubation intervals. Orient the sample pouch so that agitation is along the long axis of the sample pouch. Ensure that printed label is uppermost.
14. Return blood component bag to storage.
15. Measure the percentage of oxygen in the headspace of the sample pouch within the specified 35 °C incubation period (see table below).

Component	Minimum Pre-*e*BDS Sampling Hold Period/Condition for Optimal Sensitivity	*e*BDS Pouch Incubation Time at 35ºC
Platelets in Plasma	24 hrs at 22 ºC±2 ºC	18-30 hrs
Platelets in PAS	24 hrs at 22 ºC±2 ºC	24-48 hrs
Red Cells	24 hrs at 4 ºC±2 ºC	48-72 hrs

Assay Procedure (using *e*BDS Oxygen Analyser)

16. Confirm *e*BDS Oxygen Analyser is ready to measure sample.
17. Use the Sampling Stand to orient sample site in the vertical position. Insert probe of the oxygen analyser through the sampling site septum and protective membrane into the headspace air of the sample pouch.

    Notes:
    - Do not hold/squeeze body of sample pouch when inserting probe, pressure may activate alarm on oxygen analyser.
    - Do not insert probe into liquid in the sample pouch.
    - Do not use alcohol to cleanse sampling site. Alcohol may interfere with the oxygen analysis.
18. Measure percentage of oxygen by aspirating the headspace air of the sample pouch per the analyser's operating instructions. (See "Sample Test Procedure" in the *e*BDS Oxygen Analyser User's Guide.)
19. If "Pass" is displayed, the test did not detect bacterial contamination and indicates the sample is NEGATIVE at the time of oxygen measurement. Document result and discard *e*BDS sample pouch*.
20. A flashing "FAIL" indicates that the percentage of oxygen is less than the acceptable limit.
21. If a flashing "FAIL" is indicated, it is likely that the sample is contaminated with bacteria, and it is recommended that the blood component unit is discarded after culturing to confirm result*.
22. If an alert message is displayed, follow the instructions indicated on the *e*BDS Oxygen Analyser's display to enable a re-test. Only one re-test of the percentage of oxygen in a given *e*BDS Sample Set can be done. If a re-test is desired, return to step 16.
23. If an additional test of the blood component unit is desired, attach a new *e*BDS Sample Set and proceed from Step 2 above.

INTERPRETATION OF RESULTS

Positive or negative results are determined by the *e*BDS Oxygen Analyser's software. Positive results indicating potential bacterial contamination are displayed as "FAIL". Negative results are displayed as "Pass". Should an error message be displayed and not resolved, or if for any reason there is a question about the ability to obtain a proper "Pass" or "Fail" indication for a given blood component, the test should be considered invalid.

EXPECTED VALUES

It is expected that >99% of all products tested will have no bacteria present, and in that case the oxygen concentration will be acceptable with "Pass" displayed at the time of the oxygen measurement. Those units with oxygen concentrations below the acceptable threshold will give a positive result with "FAIL" displayed.

PERFORMANCE CHARACTERISTICS

When used with the *e*BDS Oxygen Analyser, the *e*BDS Sample Set permits the recovery and detection of aerobic and facultative anaerobic bacteria from platelets and leucocyte-reduced red cell components.

Platelets

Evaluations of the *e*BDS Sample Set involved testing of leucocyte-reduced and non leucocyte-reduced platelet units inoculated with one of ten bacteria reported to have caused 98% of the fatalities due to bacteria contaminated platelet concentrates (PC) in the period from 1976 to 1988[5]. In summary, these studies have shown that 100% detection was achieved with testing of 280 leucocyte-reduced platelet units contaminated with a low bioburden of bacteria and with sampling for the *e*BDS after 24 hours storage. These studies have also shown that 100% detection was achieved with testing of 189 non leucocyte-reduced platelet units contaminated with a low bioburden of bacteria and with sampling for the *e*BDS Sample Set after 24 hours storage.

Briefly, the evaluation studies were performed as follows: Leucocyte-reduced apheresis or whole blood derived random donor PC were inoculated with a target dose of 1-15 CFU/mL of each of ten microorganisms known to be associated with platelet transfusion-transmitted infection (see Table 1 below). Immediately after mixing, a sample was taken to determine bacteria level in the PC (Table 1). After 24 hours storage of the inoculated PC, another sample was taken to determine the 24-hour growth levels (Table 1), and an aliquot was taken into the *e*BDS sample pouch which was then incubated for 24 hours at 35 ºC with agitation on a horizontal shaker. Four test sites participated in the study with two sites testing apheresis platelets and two sites testing whole blood derived platelets. Each site conducted at least five replicate studies on each of the ten organisms. For PAS, a further three test sites conducted studies on apheresis and buffy coat derived platelets stored in PAS.

Non leucocyte-reduced whole blood derived PC were inoculated with a target dose of 1-15 CFU/mL of each of ten microorganisms known to be associated with platelet transfusion-transmitted infection (see Table 1). After 24 hours storage of the inoculated PC, a sample was taken to determine the 24 hour growth levels (Table 1), and an aliquot was taken into the *e*BDS Sample Pouch which was then incubated for 24-30 hours at 35 ºC with agitation on a horizontal shaker. Three test sites participated in the study with two sites testing with CP2D and one site testing with CPD. Each site conducted at least five replicate studies on each of the ten organisms.

Additionally, aliquots were also taken into the *e*BDS Sample Pouch for both leucocyte-reduced and non leucocyte-reduced PC at 24 hours post inoculation and then incubated for 18 hours at 35 ºC with agitation on a horizontal shaker (Table 2). In summary, these studies have shown that 99.2% and 96% detection was achieved with testing of 247 leucocyte-reduced and 198 non leucocyte-reduced platelet units (respectively), contaminated with a low bioburden of bacteria and with sampling for the *e*BDS after 24 hours storage followed by an 18 hour pouch incubation.

Furthermore, in five replicate studies of all ten organisms, samples were also taken for 30-hour incubation in addition to 24-hour incubation at 35 ºC before testing for percent oxygen. Finally, a total of 226 non-inoculated standard PC (24 apheresis and 202 random donor platelets) were also sampled and tested with the *e*BDS.

As shown by Tables 1 and 2, the *e*BDS permitted detection of aerobic and facultative anaerobic bacteria from platelet products having bacteria levels of 1-15 CFU/mL and more. In 914 contaminated platelet product units in plasma evaluated with the *e*BDS, there were ten failures in detection (Table 2 with 18 hour incubation). Two leucocyte-reduced units were inoculated with *Enterobacter cloacae* and sampled at Time 24 with 18 hours incubation while eight non leucocyte-reduced units (four units were inoculated with *Staphylococcus epidermidis*, two units were inoculated with *Klebsiella pneumoniae*, one unit was inoculated with *Pseudomonas aeruginosa*, and one unit was inoculated with *Serratia marcescens*) were sampled at Time 24 with 18 hours incubation.

However, in each of these ten cases detection was obtained with sampling of the units at Time 24 with 24 hours incubation (Table 1). Thus, 100% detection was obtained with sampling both apheresis and whole blood derived platelets at 24 hours after inoculation followed by 24 hours incubation for all samples tested. Similarly, 100% detection was obtained after 30 hours incubation. Finally, none of the 372 non-inoculated control units tested positive with the *e*BDS.

Red Cells

Evaluations of the *e*BDS Sample Set involved individual testing of leucocyte-reduced red cell units inoculated with one of the twelve bacteria reported to have caused 88% of the fatalities due to bacteria contaminated red cell components in the period from 1976 to 1998[6].

Briefly, the evaluation studies were performed as follows: Leucoreduced red cell components in CPD/SAGM or CP2D/AS-3 were inoculated with a target dose of 1-15 CFU/mL of each of twelve microorganisms known to be associated with red cell transfusion-transmitted infection (see Table 3 below). Immediately after mixing, a sample was taken to determine bacteria level in the red cell unit (Table 3). After 24 hour storage of the red cell unit, another sample was taken to determine the 24 hour growth levels (Table 4), and an aliquot was taken into the *e*BDS sample pouch, which was then incubated for 48 hours at 35 °C with agitation on a horizontal shaker. Samples were also taken at 7 days, 21 days, and 35 days (for red cell components in CPD/SAGM) or 42 days (for red cell components in CP2D/AS-3) to determine growth levels (Table 5, 6, and 7, respectively). Three test sites participated in the study. Each site conducted at least five replicate studies on each of the twelve organisms. A total of 633 non-inoculated standard red cell units were also sampled and tested with the *e*BDS. As shown by Tables 3 to 7, the *e*BDS permitted detection of aerobic and facultative anaerobic bacteria from leucoreduced red cell components having target bacteria levels of 1-15 CFU/mL or more. 100% detection was obtained with sampling at 0 hrs, 24 hrs, 7 days, 21 days, and 35 or 42 days after inoculation followed by 48 hours incubation for all samples tested. None of the 633 non-inoculated control units tested positive with the *e*BDS.

PRECAUTIONS AND LIMITATIONS OF PROCEDURE

1. The *e*BDS Sample Set is designed to detect bacteria contamination in platelets and leucocyte-reduced red cell components. Users need to be aware that certain bacteria grow very slowly[7], and if the initial contamination level with such bacteria is very low, the aliquot taken for *e*BDS testing may not contain any bacteria. In these cases the bacteria will not be detected, and a negative result ("Pass") will be indicated. Longer hold times of the blood components prior to sampling are likely to enhance the ability to detect these slow growing organisms.
2. Tests of the *e*BDS Sample Set were performed using CP2D and ACD-A platelet products. PAS studies were performed using 20-30% CPD plasma and 70-80% PASII (T-Sol). Red cell studies were performed using standard CPD/SAGM or CP2D/AS-3 components.
3. This device was tested with the bacteria listed below. Bacteria that do not grow to sufficient levels in the blood component or in the sample pouch, or that do not utilize sufficient oxygen to be determined to be positive will not be detected.
4. Failure to maintain agitation during incubation may result in a false negative.
5. Sensitivity and specificity figures are derived from in-house and field trials using random donor and apheresis derived platelet concentrates, purposefully contaminated with low levels of bacteria (target dose of 1-15 CFU/mL) and either sampled immediately and/or stored for 24 hours and sampled into the *e*BDS Sample Set, and then tested for percentage of oxygen after 24 to 30 hours incubation at 35 ºC. Similar studies were performed with red cell components stored for 24 hours and sampled into the *e*BDS Sample Set and then tested for percentage of oxygen after 48-72 hours incubation at 35 ºC. Extended hold times prior to sampling may increase sensitivity. Variation in these statistics may be observed under conditions of actual use. **NOTE:** Failure to dissolve tablets in fluid may result in a false positive.
6. A negative result ("Pass") should not be interpreted that the blood component being tested is sterile. A negative result could be due to variables experienced within the process, such as improper sample collection for the *e*BDS system, or lack of microorganisms in the aliquot collected into the sample pouch.
7. Overfill of the sample pouch can result in a false positive. Underfill can result in a false negative. [The sample pouch is considered "overfilled" when the pouch is filled with liquid at a level which is higher than the second witness mark (line). The sample pouch is considered "underfilled" when the pouch is filled with liquid at a level which is lower than the first witness mark.]
8. Non-leucoreduced red cells or platelets with unusually high platelet counts ($>3.0 \times 10^9$ per mL) may result in false positives.
9. Alcohol may interfere with the oxygen analysis, and should not be used to cleanse the sampling site prior to inserting the probe of the oxygen analyzer.
10. Use sterile tubing welder in accordance with the manufacturer's instructions for use; only tubing which is compatible with sterile tubing welders can be used to maintain a closed system. The dimensions and composition of the *e*BDS Sample Set tubing meets the requirements for use with sterile tubing welders and should only be used in conjunction with products known to be compatible.

* During processing, always observe the following precautions:

1. Sealing should be done in a manner that avoids fluid splatter.
2. Always dispose of blood-contaminated products in a manner consistent with established BIOHAZARD safety procedures.

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PLATELET DATA

*Table 1 shows bacteria levels in the platelet products at the time of inoculation and after 24 hour storage at which time samples were taken into e*BDS *Sample Set for 24 to 30 hours of incubation, with the resulting detection frequency (Plasma includes results for leucocyte-reduced and non leucocyte-reduced platelet products)*

Table 1

	Inoculation bacteria level Median (range) CFU/mL Plasma	Inoculation bacteria level Median (range) CFU/mL PAS	**Bacteria level at sampling time after 24 hrs storage (Sample Time = 24 hrs, 24-30 hour incubation)**								**Detection with Sampling at 24 Hours**	
			≤ 5 CFU/mL Plasma	≤ 5 CFU/mL PAS	**6-15 CFU/mL Plasma**	6-15 CFU/mL PAS	**16-50 CFU/mL Plasma**	16-50 CFU/mL PAS	**>51 CFU/mL Plasma**	>51 CFU/mL PAS	**Cases Detected of Cases Sampled Plasma**	Cases Detected of Cases Sampled PAS
S. epidermidis ATCC#49134	**7 (2-52)**	4 (1-10)	**7**	15	**19**	7	**16**	2	**3**	2	**45 of 45**	26 of 26
S. agalactiae ATCC#12927	**5 (2-20)**	10 (1-17)	**3**	6	**11**	2	**17**	8	**14**	10	**45 of 45**	26 of 26
S. aureus ATCC#27217	**8 (2-51)**	8 (3-25)				2	**8**		**39**	24	**47 of 47**	26 of 26
P. aeruginosa ATCC#27853	**9 (1-15)**	8 (3-17)		1	**1**	1	**8**		**32**	24	**41 of 41**	26 of 26
S. choleraesuis ATCC#8326	**8 (1-55)**	10 (2-34)	**11**		**2**	3	**8**	7	**17**	9	**38 of 38**	19 of 19
E. coli ATCC#25922	**6 (2-15)**	6 (1-20)	**5**		**2**				**37**	20	**44 of 44**	20 of 20
E. cloacae ATCC#29005	**8 (2-13)**	13 (5-32)	**14**		**5**	1	**11**		**16**	19	**46 of 46**	20 of 20
B. cereus ATCC#7064	**13 (3-27)**	3 (1-7)	**5**		**3**		**2**		**41**	20	**51 of 51**	20 of 20
K. pneumoniae ATCC#8045	**5 (1-17)**	5 (1-14)	**21**		**11**	1	**4**	2	**14**	17	**50 of 50**	20 of 20
S. marcescens ATCC#43862	**9 (1-16)**	9 (1-18)	**7**		**1**		**3**		**51**	20	**62 of 62**	20 of 20
TOTAL:			**73**	22	**55**	17	**77**	19	**264**	165	**469 of 469 (100%)**	223 of 223 (100%)

*Table 2 shows bacteria level in the platelet products after 24 hour storage at which time samples were taken into e*BDS *Sample Set for 18 hour incubation, with the resulting detection frequency (results for leucocyte-reduced and non leucocyte-reduced platelet products).*

Table 2

	Bacteria level at sampling time after 24 hrs storage (Sample Time = 24 hrs, 18 hour incubation)				**Detection with Sampling at 24 hours**
	≤ 5 CFU/mL Plasma	**6 - 15 CFU/mL Plasma**	**16 - 50 CFU/mL Plasma**	**> 51 CFU/mL Plasma**	**Cases Detected of Cases Sampled Plasma**
S. epidermidis ATCC#49134	**15**	**12**	**10**	**7**	**44 of 48**
S. agalactiae ATCC#12927	**16**	**4**	**12**	**6**	**38 of 38**
S. aureus ATCC#27217	**3**	**2**	**6**	**28**	**39 of 39**
P. aeruginosa ATCC#27853			**3**	**35**	**38 of 39**
S. choleraesuis ATCC#8326	**10**	**7**	**16**	**5**	**38 of 38**
E. coli ATCC#25922	**8**	**2**		**28**	**38 of 38**
E. cloacae ATCC#29005	**16**	**5**	**14**	**8**	**43 of 45**
B. cereus ATCC#7064	**5**	**4**		**35**	**44 of 44**
K. pneumoniae ATCC#8045	**16**	**8**	**6**	**7**	**37 of 39**
S. marcescens ATCC#43862	**7**	**1**	**3**	**49**	**60 of 61**
TOTAL:	**96**	**45**	**70**	**208**	**419 of 429 (97.7%)**

RED CELL COMPONENT DATA

Table 3 shows bacteria levels of the leucoreduced red cell components and detection with sampling from units performed immediately after inoculation (Sample Time = 0 hrs).

Table 3

Bacteria level in whole blood derived leucoreduced red cell components at sampling time immediately after inoculation and mixing (Sample Time = 0 hrs)

Detection with sampling at 0 hrs

Bacteria	No. detected at various CFU/mL levels				Total Cases of Detection
	< 5 CFU/mL	6-15 CFU/mL	16-50 CFU/mL	> 51 CFU/mL	
K. pneumoniae ATCC#8045		4	11	3	18 of 18
S. liquefaciens ATCC#35551	8	6	1		15 of 15
P. aeruginosa ATCC#278530		10	5	3	18 of 18
P. putida ATCC#492819128		3		3	6 of 6
P. fluorescens ATCC#17569	8	5	2	3	18 of 18
E. amnigenes ATCC#33731	5	3	2		10 of 10
E. coli ATCC#25922		11	4		15 of 15
Y. enterocolitica ATCC#27729	9	7	3	3	22 of 22
B. cereus ATCC#7064		3	7	3	13 of 13
L. monocytogenes ATCC#19115			10		10 of 10
S. aureus ATCC#27217	1	8	1		10 of 10
S. epidermidis ATCC#49134	2	8		3	13 of 13
TOTAL:	33	68	46	21	168 of 168 (100%)

Table 4 shows bacteria level in the leucoreduced red cell components and detection after 24 hour storage at which time samples were taken into the eBDS *Sample Set (Sample Time = 24 hrs), and the resulting detection frequency.*

Table 4

Bacteria level in whole blood derived leucoreduced red cell components at sampling time after 24 hours storage (Sample Time = 24 hrs)

Detection with sampling at 24 hrs

Bacteria	No. detected at various CFU/mL levels				Total Cases of Detection
	< 5 CFU/mL	6-15 CFU/mL	16-50 CFU/mL	> 51 CFU/mL	
K. pneumoniae	2	4	9	3	18 of 18
S. liquefaciens	9	5	1		15 of 15
P. aeruginosa	1	9	6	2	18 of 18
P. putida	1	2		3	6 of 6
P. fluorescens	2	7	2	3	14 of 14
E. amnigenes	6	1	2		9 of 9
E. coli		8	7		15 of 15
Y. enterocolitica	9	1	2	5	17 of 17
B. cereus		4	3	5	12 of 12
L. monocytogenes	3	1	6		10 of 10
S. aureus		9	1		10 of 10
S. epidermidis	4	5	1	3	13 of 13
TOTAL:	37	56	40	24	157 of 157 (100%)

RED CELL COMPONENT DATA continued

Table 5 shows bacteria levels in the leucoreduced red cell components and detection after 7 days of storage at which time samples were taken into the eBDS Sample Set (Sample Time = 7 days), and the resulting detection frequency.

Table 5

Bacteria level in whole blood derived leucoreduced red cell components at sampling time after 7 days of storage (Sample Time = 7 days)

Detection with sampling at 7 Days

Bacteria	No. detected at various CFU/mL levels				Total Cases of Detection
	< 5 CFU/mL	6-15 CFU/mL	16-50 CFU/mL	> 51 CFU/mL	
K. pneumoniae	12				12 of 12
S. liquefaciens				15	15 of 15
P. aeruginosa		6	8	3	17 of 17
P. putida	2			3	5 of 5
P. fluorescens				18	18 of 18
E. amnigenes	1	1	1	7	10 of 10
E. coli	11	4			15 of 15
Y. enterocolitica	3	1	1	12	17 of 17
B. cereus	4	4	3		11 of 11
L. monocytogenes	1	4		5	10 of 10
S. aureus	5	4	1		10 of 10
S. epidermidis	4	3	2	4	13 of 13
TOTAL:	43	27	16	67	153 of 153 (100%)

Table 6 shows bacteria level in the leucoreduced red cell components and detection after 21 days of storage at which time samples were taken into the eBDS Sample Set (Sample Time = 21 days), and the resulting detection frequency.

Table 6

Bacteria level in whole blood derived leucoreduced red cell components at sampling time after 21 days of storage (Sample Time = 21 days)

Detection with sampling at 21 Days

Bacteria	No. detected at various CFU/mL levels				Total Cases of Detection
	< 5 CFU/mL	6-15 CFU/mL	16-50 CFU/mL	> 51 CFU/mL	
K. pneumoniae	1	1			2 of 2
S. liquefaciens				15	15 of 15
P. aeruginosa	4	7	6	1	18 of 18
P. putida	3		2	1	6 of 6
P. fluorescens				18	18 of 18
E. amnigenes				10	10 of 10
E. coli	9				9 of 9
Y. enterocolitica	2			15	17 of 17
B. cereus	4				4 of 4
L. monocytogenes	3	1		6	10 of 10
S. aureus	6	4			10 of 10
S. epidermidis	7		2	1	10 of 10
TOTAL:	39	13	10	67	129 of 129 (100%)

RED CELL COMPONENT DATA continued

Table 7 shows bacteria levels in the leucoreduced red cell components and detection after 35 days of storage (CPD/SAG-M) or 42 days of storage (CP2D/AS-3), at which time samples were taken into the eBDS *Sample Set (Sample Time = 35 or 42 days), and the resulting detection frequency.*

Table 7

Bacteria level in whole blood derived leucoreduced red cell components at sampling time after 35 days of storage (CPD/SAG-M) or 42 days storage (CP2D/AS-3) (Sample Time = 35 or 42 days)

Detection with sampling at 35 or 42 Days

	No. detected at various CFU/mL levels				
Bacteria	**< 5 CFU/mL**	**6-15 CFU/mL**	**16-50 CFU/mL**	**> 51 CFU/mL**	**Total Cases of Detection**
K. pneumoniae					**0 of 0**
S. liquefaciens				10	**10 of 10**
P. aeruginosa	10	3	3	2	**18 of 18**
P. putida	2		2	1	**5 of 5**
P. fluorescens				13	**13 of 13**
E. amnigenes				10	**10 of 10**
E. coli	4				**4 of 4**
Y. enterocolitica				12	**12 of 12**
B. cereus	2				**2 of 2**
L. monocytogenes	1		2	7	**10 of 10**
S. aureus	9				**9 of 9**
S. epidermidis	8		3		**11 of 11**
TOTAL:	**36**	**3**	**10**	**55**	**104 of 104 (100%)**

The current revision of the Instructions For Use (IFU) for this product is:
Leaflet Part Number: 147400036Z AA
Date of Last Update: August 2016
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