

Pall eBDS Bacteria Detection System
The Total Solution for Detecting Bacteria in Platelets



Description

SYSTEM COMPONENTS

- ▶ The **Pall eBDS Sample Set** provides a functionally closed system for sampling platelet product and requires no additional reagents.
- ▶ The **Pall eBDS Oxygen Analyzer with Attached Bar Code Scanner** allows automatic data entry and generates a data string for electronic capture. The Pall eBDS Oxygen Analyzer is a rapid read device that measures the oxygen content in the headspace air of the sample pouch, compares the level to a preprogrammed threshold value, and provides a clear, easily interpreted Pass/Fail result.
- ▶ The **Incubator/Agitator** creates an environment designed to amplify the growth of bacteria. The Pall eBDS Sample Set pouches are incubated at 35 °C, the standard temperature used in microbiology for culturing. Agitation increases gas exchange within the sample pouch and enhances growth of bacteria. Three models of Incubator/Agitator combinations are available to address capacities and workflow.

Pall eBDS Sample Set



Reorder code: 400-03

- ▶ **Pall Data** is a software package that captures the output from the Pall eBDS Oxygen Analyzer and allows information to be queried into a user-defined report.
- ▶ The **Oxygen Sampling Stand** is a device that holds the Pall eBDS Sample Set pouch upright and secure during oxygen measurement.

Indication: Quality control testing of both AcrodoseSM Platelets, and leukoreduced and non-leukoreduced apheresis and whole blood derived platelet products.

BLOOD COMPONENTS THAT CAN BE TESTED:

- ▶ Acrodose Platelets – ‘Transfusion-ready’, pooled, leukoreduced, ABO matched platelets.
- ▶ Individual non-leukoreduced and leukoreduced WB-derived platelets.
- ▶ Individual non-leukoreduced and leukoreduced single donor platelets.

Pall eBDS Equipment



Performance

THE TESTING PRINCIPLE BEHIND THE PALL eBDS – Percent Oxygen in Air, the Practical Approach

The Pall eBDS novel approach to detection measures the oxygen content of air within the Pall eBDS Sample Set pouch as a surrogate marker for bacteria. The Pall eBDS Oxygen Analyzer is used to measure the percent of oxygen in the headspace gas of the sample pouch. If bacteria are present in the platelet 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 plasma as well as the air within the sample pouch.

This advanced technology designed to support blood bank cGMPs, enhances sensitivity and specificity, and easily integrates into routine practice.

Additional Features & Benefits of the Pall eBDS System

- ▶ **Sampling**
 - Single use, closed system processing minimizes false positives.
 - Reduced operator manipulation through enhanced sampling port design.
 - Minimal platelet loss of 4 mL.

- ▶ **Testing**
 - Single point test provides “test of record” prior to transfusion.
 - Detection prior to the time of release or the time of transfusion.
 - Rapid read system provides Pass/Fail results in approximately 30 seconds



Platelet Bacteria Detection Systems

Specifications

CONDITIONS OF USE

- ▶ **Shelf life:**
 - 2 years in unopened package.
 - The set can be removed from its packaging stored up to the expiration of the product no compromise of product integrity. The contents of the unit pack must be used within 14 days of opening.
- ▶ **Storage conditions:** Room temperature; avoid excessive heat; protect from freezing.
- ▶ **Single use.**

PALL eBDS SAMPLE SET

- ▶ **Latex content:** This product is free of natural rubber latex.
- ▶ **Protected sampling site:**
 - Sample port allows access to the headspace air within the sample pouch.
 - Protected sampling site contains a hydrophobic membrane that repels fluid away from the sampling port.
 - Pre-slit injection site for easier insertion of the blunt probe of the Pall eBDS Oxygen Analyzer.
- ▶ **Bacteria growth enhancing tablets that contain:**
 - Trypticase Soy Broth (TSB), a nutrient that enhances bacterial growth.
 - Sodium Polyanethol Sulfonate (SPS) that inhibits natural bactericidal agents in plasma and causes platelets to aggregate, reducing their oxygen consumption.
- ▶ **Sample pouch:**
 - Fill lines provide a visual stop for sample collection.
 - Labeling tab provides an ISBT128 bar code with lot number, unique identifier for ultimate traceability, and an area to place unit identification on sample pouch.
- ▶ **Check valve:**
 - Prevents potential back flow of sample pouch contents to protect platelet product.
 - Slows flow into sample pouch to control filling.
- ▶ **Tubing:** All tubing is compatible with standard sterile tubing connection devices.
 - Provides the air for oxygen measurements in the sample pouch.
 - Can be used for platelet count samples or stripped back to reduce platelet volume loss (approximately 4 mL).
- ▶ **Plastic:**
 - The pouch and tubing are polyvinyl chloride (PVC) with di (2-ethylhexyl) phthalate (DEHP) plasticizer.

PALL eBDS OXYGEN ANALYZER

- ▶ **Test Cycle Reading Time:** Rapid throughput, approximately 30 seconds to obtain reading.
- ▶ **Data entry:** automatically generated for electronic capture.
- ▶ **Test Result Displays:** Simple Pass or Fail displays.
- ▶ **Software security:** Passcode entry required to access set up menus.
- ▶ **Preventive maintenance:** None required. The instrument is calibrated annually by the manufacturer.
- ▶ **Baseline confirmation:** Automatically done every hour to provide quality assurance.
- ▶ **Barcode scanning:**
 - Four Input Options: User ID, Lot Number, Product Code, Donation ID; any or all of these fields may be selected for use.
 - Barcode symbology recognition prevents incorrect barcode entry (ISBT128, Codabar, USS Codabar).
- ▶ **PC handshaking:** This feature verifies that a PC with data collection software remains connected to the Analyzer. An alarm will display if disconnected, thereby ensuring data will not be lost.
- ▶ **RS-232 ports:** Two ports for connection to a barcode scanner and computer.

PALL DATA 5

Pall Medical offers Pall Data, a software package that allows information produced by data-enabled hardware to be captured, stored in a database, and queried. The system consists of three modules – **Capture, Query, and Maintain.**

- ▶ **Workflow:** Input, monitor, and record the processing steps for bacteria detection using the Pall eBDS.
- ▶ **Capture:** Captures the data and stores it in the database. The information cannot be altered.
- ▶ **Query:** Allows the information in the database to be sorted, queried, and a user defined report to be generated.
- ▶ **Maintain:** Allows capture and query features to be customized to facilitate data review.

The software can support multiple analyzers through links to the computer's RS232 COM ports or a network card. The modules can be customized for viewing and a user-defined report can be created to assist with workflow and testing reconciliation. For further information on Pall Data, refer to the software instructions for use.

CLIA Classification for Pall eBDS is moderate complexity.

Ordering Information

Pall eBDS Sample Set –

Case quantity: 40 sets, bulk packaged (4 sets/plastic pouch; 10 pouches per case) *

* Four (4) probes and filters included in each case.

Reorder Code: 400-03

Pall eBDS Equipment – The following Equipment and service is provided at no additional cost as a part of the Pall eBDS 'turnkey' system:

- ▶ Pall eBDS Oxygen Analyzer
- ▶ Bar Code Scanner
- ▶ Incubator/Agitator: Three sizes are available.
- ▶ Pall Data
- ▶ Oxygen Sampling Stand