

ZOETIS DIAGNOSTICS

vetscan OptiCell

User Manual

2024



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The analyzer's protection will be impaired if used in a manner not specified by the manufacturer. Contact your Zoetis representative for details of warranty coverage, exclusionary defects, and warranty period. If any defects occur in the analyzer during active warranty period, Zoetis will repair or replace the defective parts free of charge. The analyzer's protection will be impaired if used in a manner not specified by the manufacturer. Contact your Zoetis representative for details of warranty coverage, exclusionary defects, and warranty period.



Caution: Animal blood is a potential source of zoonotic diseases. We recommend wearing personal protective equipment when handling animal blood or devices used for measuring animal blood. Be sure to follow local occupational health and safety regulations.

Read all instructions before using the Vetscan OptiCell™

The information in this manual is relevant to Vetscan OptiCell Model Number OptiCell 300.



EU Declaration of Conformity

Manufacturer

Zoetis, Inc. 333 Portage Street Kalamazoo, MI 49007, USA

The Directives covered by this Declaration

2014/35/EU Low Voltage Directive 2014/30/EU Electromagnetic Compliance Directive 2011/65/EU RoHS Directive including amendments

The current EU Declaration of Conformity is on file at Zoetis. The end-user license agreement and Zoetis privacy policy may be retrieved through the Vetscan Hub user interface.



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1. General Information

1.1 Introduction and intended use

Vetscan OptiCell is a fully automated point-of-care diagnostic hematology analyzer, featuring a combination of three technological innovations to provide consistent and accurate results: microfluidic Viscoelastic Focusing (VEF), Imaging-based AI algorithms, and a self-contained single-use cartridge system.

Innovative Artificial Intelligence (AI) driven cellular classification technology facilitates an automated complete blood count (CBC) analysis of 22 parameters using venous whole blood samples (K2/K3 EDTA anticoagulated) in validated species via a cartridge-based system.

√ White blood cell (WBC) count	✓ Red blood cell (RBC) count
✓ Neutrophil percentage	√ Hemoglobin (HGB)
✓ Neutrophil absolute count	√ Hematocrit (HCT)
√ Lymphocyte percentage	✓ Mean cell volume (MCV)
✓ Lymphocyte absolute count	✓ Mean corpuscular hemoglobin (MCH)
✓ Monocyte percentage	\checkmark Mean corpuscular hemoglobin concentration (MCHC)
✓ Monocyte absolute count	\checkmark Red blood cell distribution width (RDW)
✓ Eosinophil percentage	✓ Reticulocyte count
✓ Eosinophil absolute count	✓ Reticulocyte percentage
√ Basophil percentage	✓ Platelet count (PLT)
✓ Basophil absolute count	✓ Mean platelet volume (MPV)

Vetscan OptiCell provides highly accurate¹ automated hematological cellular analysis with a simplified sample preparation workflow, minimal analyzer maintenance, and no calibration requirement. The Vetscan OptiCell offers user guidance and sample alerts, via the Vetscan Hub™, when cellular morphological abnormalities or findings are detected. The Vetscan OptiCell analyzer and Vetscan OptiCell Hematology Cartridges are intended for veterinary and professional use only.

Reference: 1. Data on file. Study Report No. DHXMZ-US-24-235, 2024, Zoetis Inc.



If the Vetscan OptiCell is used in any way other than described in this manual, the analyzer may not operate as intended, may produce inaccurate or no results, and may pose a safety hazard.



2.1 Unpacking

When unpacking the analyzer, follow these guidelines:

- Remove Vetscan OptiCell from the shipping carton.
- Place the analyzer on a clean, level surface free of animal hair, dust, and other contaminants.
- Do not stack anything on top of Vetscan OptiCell analyzer.
- Do not place in direct sunlight, near an air-conditioner or heat source as this may increase the temperature outside of the specified range.

Check the components received with Vetscan OptiCell against the list and Figure 1 below to make sure all items required to set up the analyzer are included.

- A. Vetscan OptiCell Analyzer
- B. Power cable
- C. Power supply
- D. Ethernet cable
- E. Spare Fan Filter
- F. Quick Start Guide

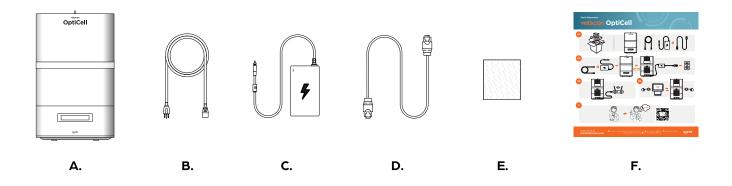


Figure 1: Vetscan OptiCell components

2.2 Installation Guidelines

Before setting up Vetscan OptiCell:

- Confirm room temperature is between 17 °C to 27 °C (63 °F to 81 °F). If the temperature increases outside the specified operating range the system will display a warning message on the Vetscan Hub.
- Confirm the room humidity is between 10% and 90% relative humidity, non-condensing.
- · Place the Vetscan OptiCell analyzer on a clean, flat, and stable surface not in direct sunlight.
- Do not stack anything on top of the Vetscan OptiCell analyzer.
- Ensure there is proper room ventilation and at least 10 cm (3.9 in) from the wall for access to the power connection and Ethernet port.



Connecting the Vetscan OptiCell:

- Attach the AC power cord (with electrical wall plug) to the power supply.
- Connect the Vetscan OptiCell to the power supply.
- Plug the AC power cord into a grounded electrical outlet powered directly from AC mains infrastructure.
- Power supply must be operated at an ambient temperature, not to exceed 40° C maximum operating temperature.
- Make sure all connections are secure.



To prevent power surges or power drain, do not plug the analyzer into the same circuit as a centrifuge or any other high-current device. If this is not possible, use an ancillary power conditioner or UPS.

- Connect one side of the supplied Ethernet cable to the Vetscan OptiCell analyzer.
- Connect the other side of the Ethernet cable to the same network as the Vetscan Hub (via a router, switch, or direct Ethernet port access)
- The network does not need to be connected to the internet to operate the Vetscan OptiCell. However, active internet connection is needed to send results to the Practice Information Management Software (PIMS) and get full access to online Vetscan Hub application features.

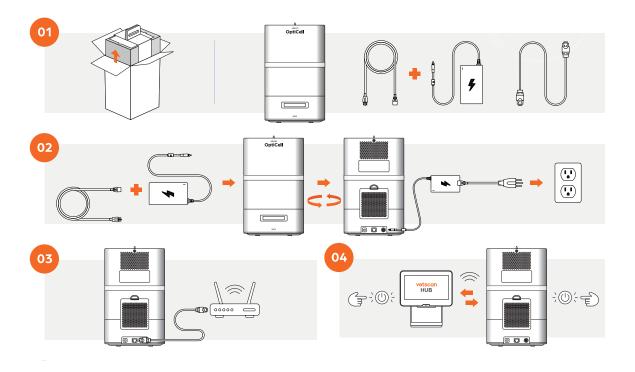


Figure 2: Vetscan OptiCell Quick Installation Guide

2.3 User Information and Precautions

Read the instructions in this User's Manual carefully before using the Vetscan OptiCell. Follow all instructions, warnings and precautions and keep the manual available for future reference. The Vetscan OptiCell analyzer and Vetscan OptiCell Hematology consumable tests (cartridges and blood samplers) are intended for veterinary use only.



If the Vetscan OptiCell is used in any way other than described in this manual, the analyzer may not operate as intended, may produce inaccurate or no results, and may pose a safety hazard.

- Always follow local regulations.
- Attempting to open or dismantle the analyzer may cause electric shock and will void the warranty.
- Do not place objects on top of the analyzer.
- Protect the analyzer from liquids including exposure to wet locations.
- Use only the power supply provided. Use of any other power supply may damage the analyzer, thus voiding the warranty. Usage of non-authorized power supplies may also be a safety hazard.
- The power supply must be connected to a main power outlet that is grounded.
- The Power Supply must be operated at an ambient that is limited to 40°C max and powered directly from AC mains infrastructure that provide 100-240VAC
- Ensure the power cord has a minimum rating of 10 A
- Never use a damaged power cord or power supply. Replace power cord if damaged.
- The analyzer and test kits are operational within ideal temperature range of 17-27 °C (63-81 °F), 10-90% RH, non-condensing.
- Never expose the Vetscan OptiCell to a heat source or to direct sunlight.
- When stored in a cold or warm area, let the analyzer acclimate to 17-27 °C (63-81 °F) in advance of powering on the analyzer.
- Do not place the analyzer near centrifuges due to vibration and/or electrical interferences.
- It is recommended to inspect Vetscan OptiCell analyzer for damage. If damaged, immediately contact Zoetis Diagnostic Technical Support. Contact information can be found at https://www.zoetis.com/customer-care.
- If the Vetscan OptiCell analyzer is accidentally dropped, immediately contact Zoetis Diagnostic Technical Support. Contact information can be found at https://www.zoetis.com/customer-care.
- Incompatible, used, or expired cartridges are not valid and will result in an error message.
- Before inserting the test, make sure that there are no foreign objects in the sample drawer. Vetscan OptiCell Hematology Cartridge should slide easily into the drawer with a gentle push, after the sample run has been initiated via Vetscan Hub.



2.4 Main Components

Front

- Anti-stack lid
- LED light band
- Sample door

Back

- Air inlet and outlet ventilation
- Power button
- Power input
- Fan filter
- LAN connector

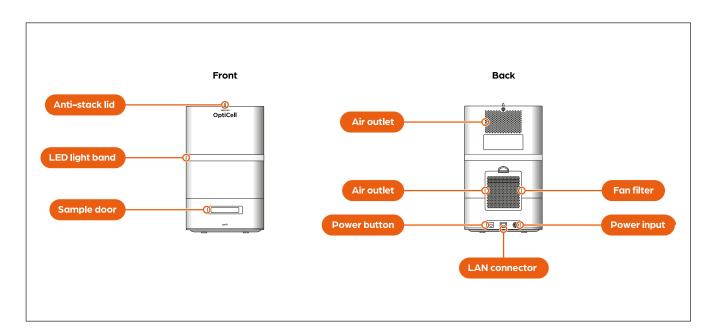


Figure 3: Vetscan OptiCell

2.4.1 Ventilation

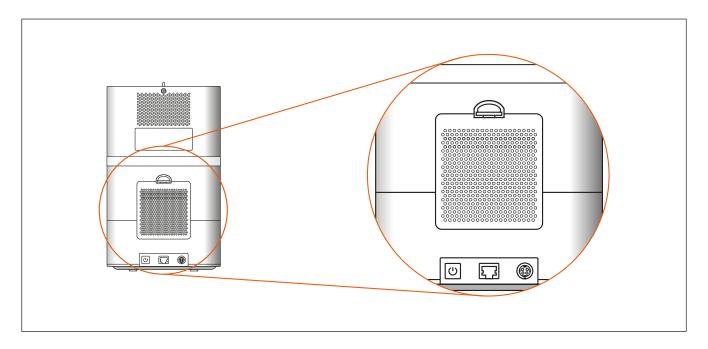


Figure 4: Vetscan OptiCell ventilation



The air inlet is located on the lower back panel of the analyzer and contains a removable fan filter. To remove the fan filter see the maintenance section.

Reader Status	Light Color
Start up/initializing/identify device	Breathing white
Idle	Steady white
Ready for operator to insert OptiCell Hematology Cartridge	Pulsing green
Analyzing	Steady green
Analysis complete	Steady white
Maintenance procedure (software update, quality control cartridge)	Steady blue
Low power mode	After 1 hour of inactivity, LED turns off (analyzer remains powered on and connected to Vetscan Hub).
Error	Breathing red. If error is not resolved after 5 minutes, the red LED will remain steady until addressed.

2.5 Power States

To power on, simply press the power button located on the lower back panel on Vetscan OptiCell. Vetscan OptiCell will initialize and connect with the Vetscan Hub ecosystem. The analyzer will automatically enter idle mode when not in use. The primary method for exiting idle mode of Vetscan OptiCell is through Vetscan Hub.

2.6 Additional Components (not included)

- Vetscan Hub
- A router

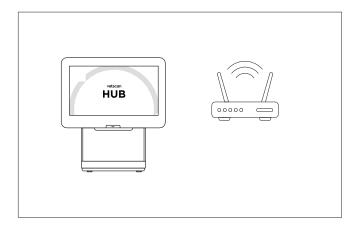


Figure 5: Vetscan Hub and router (not included).

2.6.1 Vetscan Hub

Vetscan OptiCell is controlled from a user interface hosted on Vetscan Hub (not included). Please refer to the Vetscan Hub User Manual: Operating System for information related to the operation of the Vetscan Hub. The Vetscan Hub and router (see Figure 5) are not part of Vetscan OptiCell packaging.

2.7 Basic Operating Instructions

2.7.1 Vetscan OptiCell Hematology Cartridge and Vetscan OptiCell Hematology Blood Samplers

Vetscan OptiCell introduces innovative technology using a combination of Al-powered machine vision (digital) imaging with flow cytometry that provides highly accurate and reliable complete blood cell count (CBC) results.¹ The blood sample and reagents are contained within the OptiCell Hematology Cartridge design, and flow through the reagent chambers where they react with test-specific reagents in preparation for analysis. During the analysis, blood cells are focused, aligned, and analyzed within the OptiCell Hematology Cartridge's proprietary design. Cell populations are differentiated by Al-powered machine learning algorithms which extract hundreds of cellular features, including cell size, morphology, and staining properties. Test results are presented via the Vetscan Hub display.

Combining the Vetscan OptiCell Hematology Cartridge and Vetscan OptiCell Hematology Blood Sampler together forms a self-contained, disposable, consumable unit used for the collection and preparation of a single blood sample for an automated complete blood count hematology analysis.

Figure 6 depicts an overview of Vetscan OptiCell Hematology Cartridges and Vetscan OptiCell Hematology Blood Samplers. Vetscan OptiCell hematology testing requires one OptiCell Hematology Cartridge and one OptiCell Hematology Blood Sampler per test. The blood sample is added into the OptiCell Hematology Blood Sampler capillary tubes, prior to inserting in the OptiCell Hematology Cartridge.

Reference: 1. Data on file. Study Report No. DHXMZ-US-24-235, 2024, Zoetis Inc.

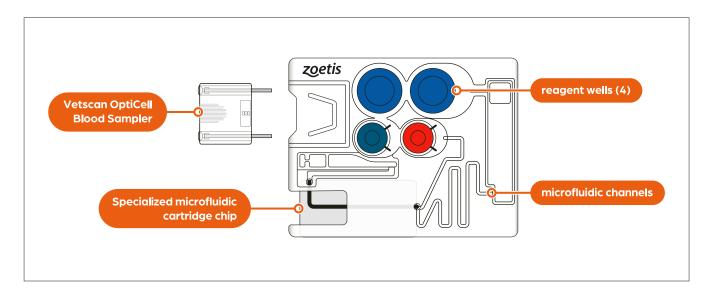


Figure 6: Generic view of Vetscan OptiCell Hematology Cartridge and Blood Sampler



2.7.2 Running a Sample

Testing workflow begins with placing a test order via Practice Information Management Software (PIMS) or directly through the Vetscan Hub screen. To order a new test, enter in patient-specific data and select Hematology – OptiCell.

Once the test order is submitted, select the pending order under the test menu and press 'start test'. The LED light band will begin to pulse green when OptiCell analyzer is ready to accept the OptiCell Hematology Cartridge and begin the analysis.

*Note - The sample door remains locked until the LED light band switches to pulsing green.

Next, follow the on-screen guidance to load the EDTA whole blood sample into the OptiCell Hematology Blood Sampler capillary tubes. The OptiCell Hematology Blood Sampler must be fully snapped into the OptiCell Hematology Cartridge before initiating a test run. After the OptiCell Hematology Blood Sampler is snapped into a OptiCell Hematology Cartridge, immediately insert the test into the analyzer sample door.

2.7.3 Adding Blood into the OptiCell Hematology Blood Samplers Via Water–Repellent Sheet

- 1. Gently invert blood sample tube 15-20 times immediately before use
- 2. Open the EDTA anticoagulated tube cap and use a pipette to draw out blood from sample tube.
- 3. Gently transfer 1-2 drops of blood on clean sample sheet with a hydrophobic surface (such as a water-repellent sheet)
- 4. Fill both OptiCell Hematology Blood Sampler capillaries with blood directly from the hydrophobic surface and ensure capillaries are fully filled, with no air bubbles present.
- 5. If air bubbles are detected in the capillary tubes, discard, and use a new sampler.

*Note - It is not necessary to wipe off any excess blood on the capillary tubes.

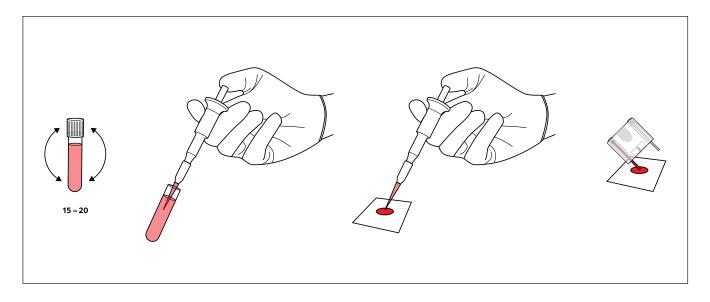


Figure 7: Adding Blood into the OptiCell Hematology Blood Samplers Via Water-Repellent Sheet

2.7.4 Add OptiCell Hematology Blood Sampler into OptiCell Hematology Cartridge

- 1. Confirm the correct patient and test has been selected according to the Vetscan Hub display.
- 2. Following the on-screen guidance of the Vetscan Hub display, snap the loaded Vetscan OptiCell Hematology Blood Sampler into the Vetscan OptiCell Hematology Cartridge by applying gentle and steady pressure until it fully snaps into place.*

*Note - Do not touch the microfluidic chip area, or apply pressure onto any of the reagent wells.

• Sampler must be fully snapped in place, with the flat end of the sampler aligned with a flush edge of the cartridge.*

*Note - Listen for a "click" sound to confirm it is fully snapped into place.

- By design, the sampler cannot be removed from the cartridge once it is secured in place. Do not attempt to remove the blood sampler from the cartridge.
- 3. Insert OptiCell Hematology Cartridge into the analyzer sample door once the LED light band begins to pulse green. The sample door remains closed and locked until the LED light band begins pulsing green.*

*Note – After initiating the hematology test run via Vetscan Hub, the user has a 10-minute timeout window to insert the cartridge into the analyzer sample door.

- OptiCell Hematology Cartridge can only be entered into the analyzer with the correct orientation.
- Ensure the hematology cartridge microfluidic chip area is not touched or smudged with debris, as this may result in a test error.

In < 6 minutes, the hematology test results will display on the Vetscan Hub screen for interpretation.

Reference: 1. TBD study on file.

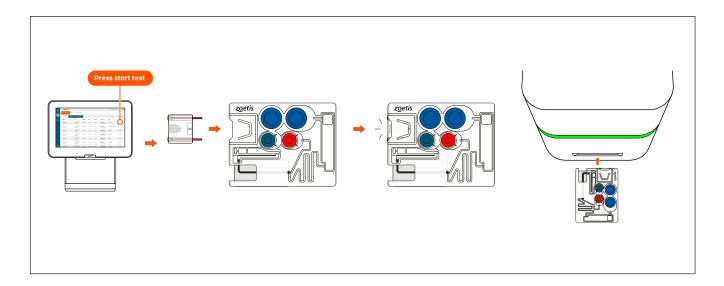


Figure 8: Add OptiCell Hematology Blood Sampler into OptiCell Hematology Cartridge

3. Technical Specifications

Parameter	Specification	
Assay	Complete Blood Count (CBC) + 5-part WBC Differential	
Technology	Flow Cytometry, Microfluidic Viscoelastic Focusing (VEF), and Digital Imaging with Artificial Intelligence.	
Cellular Focusing Technology	Viscoelastic Focusing (VEF)	
Sample Type	K2/K3 EDTA anticoagulated venous whole blood (canine or feline)	
Sample Preparation	Automated sample and reagent preparation within a single-use, self-contained Vetscan OptiCell Hematology Cartridge	
Sample Volume	40 μL total (2 capillary tubes x 20 μL each)	
Test duration	< 6 minutes	
Analyzer Environmental Conditions	Operating environment of ambient room temperature, range of 17 °C to 27 °C (63 °F to 81 °F).	
Consumable Test Storage and Environmental Conditions	Storage and operating environmental conditions: • Ambient temperature range of 17 °C to 27 °C (63 °F to 81 °F). Transportation Conditions: • Temperature range of 0°C to 60°C. • Relative humidity range of 10% to 90%, non-condensing humidity.	
Operating Voltage	19 V DC, 6.3 A	
Power Supply	100 – 240 VAC, 4 – 2 A, 50/60 Hz	
Power Consumption	120 W	
Dimensions (L x W x H)	Height 12.5" x Width 7.8" x Depth 9.8" (317.5 mm x 198 mm x 249 mm)	
Weight	17.6 lb (8 kg)	
Calibration Requirements	The OptiCell is factory-calibrated for optimal performance. There is no manual calibration requirement.	



3. Technical Specifications

Parameter	Specification
Maintenance Requirements	Minimal maintenance requirement is a periodic check of the fan filter (located on the analyzer back panel) for any fur or debris build up.
Service and Repair	Contact Zoetis Diagnostic Technical Support
OptiCell Hematology Cartridge and OptiCell Hematology Blood Sampler Composition	Propylene Glycol, Sodium Chloride, Dextran. For veterinary use only.
	Not a hazardous material. ¹

Reference: 1. Zoetis, Data on File.



Vetscan OptiCell requires minimal user maintenance. A fan filter cover is located on the analyzer back panel. Check for any debris or excessive fur buildup on the fan filter area every few months, depending on the laboratory environment. Replace the fan filter as needed, and do not attempt to wash/reuse an existing filter. Proper maintenance of the analyzer will assure reliable operation. A visual inspection of the analyzer for damage is recommended. Clean the exterior of Vetscan OptiCell as needed with a soft, damp cloth and 70% isopropyl alcohol. Follow universal precautions when removing spills on or near the Vetscan OptiCell analyzer.



Do not use Vetscan OptiCell if it appears to be damaged. Disconnect the power and contact Zoetis Diagnostic Technical Support.

Do not wash or reuse fan filters. Doing so may compromise the integrity of the fan filter material.

4.1 Monitoring System and Quality Control

Unlike traditional hematology devices, the Vetscan OptiCell analyzer includes a robust internal monitoring system that eliminates the need for routine external quality controls. If external quality control is needed, it is recommended to use the OptiCell Quality Control Cartridge (QCC) once per month (every 30 days) to confirm optimal analyzer performance. Under certain troubleshooting circumstances, Zoetis Diagnostic Technical Support may also recommend the use of the OptiCell QCC.

4.1.1 Internal Monitoring System

The OptiCell analyzer employs a comprehensive set of internal system evaluations during normal operation to ensure that all components are performing as expected. The monitoring system tests specific parameters which correspond to each step of the sample analysis. This includes preanalytical sample integrity checks, evaluation of Vetscan OptiCell Hematology Cartridge components (including lot and expiry date), and vigorous internal checks for system optical integrity and stability. The Vetscan OptiCell Hematology Cartridge and reagents are checked for the presence of contamination and/or air bubbles.¹

Reference: 1. Zoetis Data On File, 2024.



4.1.2 Quality Control Cartridge

A multi-use Quality Control Cartridge (QCC) is available to complement the comprehensive internal monitoring system built within the Vetscan OptiCell analyzer for performance verification. The specialized OptiCell QCC measurement area contains fixed cell-like targets for analysis, which eliminates the need for traditional liquid QC materials. No additional reagents or external liquid control material is needed to run the OptiCell QCC. The OptiCell QCC is stored at ambient room temperature.²

During the analysis of the Vetscan OptiCell QCC, designated image analysis is employed to capture images of the fixed cell-like targets at various focal positions on the Quality Control Cartridge. Internal software extracts detailed features during the QCC analysis to report characteristics of the optical system performance. This provides additional verification on the optical module, illumination system, and mechanical components in order to verify the overall analyzer performance.²

To perform an OptiCell QC Cartridge test, select a QC Test via the Vetscan Hub display. Under the "My Lab" section, select the Vetscan OptiCell and select "Create quality control test". The reusable QC cartridge can be inserted into the OptiCell following the on-screen guidance. After the first scan, the OptiCell QC cartridge can be reused multiple times within a 90-day expiry window. The OptiCell QC cartridge barcode information will be read by the analyzer and will alert the user once the 90-day expiry has been reached. When not in use, store the OptiCell QC cartridge in the original box packaging at ambient room temperature.

Reference: 2. Zoetis Data On File, 2024.



4.2 Changing the Fan Filter

Periodically check the fan filter on the back panel of the Vetscan OptiCell analyzer as needed to ensure proper ventilation and temperature control of the analyzer. Check and replace the filter as needed if the analyzer is in an environment with excessive dust or animal hair.*

*Note - Do not wash or reuse fan filters. Doing so may compromise the integrity of the fan filter material.

Directions:

- 1. Turn the analyzer off via the Vetscan Hub.
- 2. Remove the fan filter cover from the lower back panel.
- 3. Remove the fan filter and discard.
- 4. Place a new fan filter back into the cover.
- 5. Snap the filter cover back into place.
- 6. Power the analyzer back on via the power button on the lower back panel.
- 7. The analyzer will initialize and reconnect to Vetscan Hub.

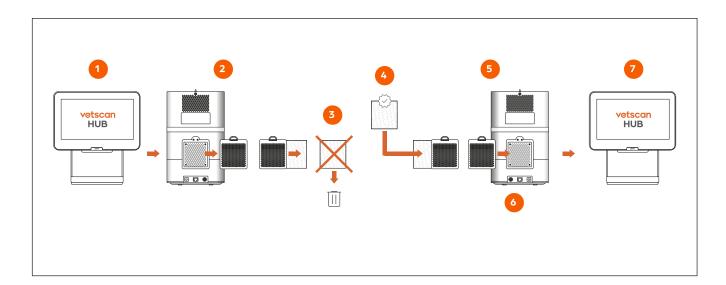


Figure 9: Changing the Fan Filter

4.3 Software Updates

Periodic software updates and enhancements for Vetscan OptiCell will become available via Vetscan Hub. The software update procedure is automated, occurs during overnight hours and does not require any user interaction. The LED light band will turn blue during the software update process.*

*Note - Do not power off the Vetscan OptiCell analyzer during the software update process.

4.4 Service

- Vetscan OptiCell internal monitoring system monitors the health of the analyzer and reports errors to the Vetscan Hub (see Troubleshooting Section). If the analyzer does not work properly and needs to be serviced, please contact your local Zoetis Diagnostic Technical Support.
- Contact information can be found at https://www.zoetis.com/customer-care.
- The warranty is void if the analyzer is opened by a non-authorized service provider.

4.5 Disposal of the Vetscan OptiCell

For disposal of the used Vetscan OptiCell hematology cartridges, follow your local regulations. Do not dispose of the Vetscan OptiCell analyzer as household waste. Contact Zoetis Diagnostic Technical Support for disposal.



5.1 Technical Support

Contact your local Zoetis Diagnostic Technical Support or distributor for technical assistance. Contact information can be found at https://www.zoetis.com/customer-care.

5.2 Errors and Warning Flags Displayed on Vetscan Hub

In certain cases, the OptiCell analyzer will send warning flags to be displayed on the Vetscan Hub. Table 2 outlines the different warning messages for issues that may be encountered. Contact Zoetis Diagnostic Technical Support in case the corrective action does not solve the issue.

Table 2: Vetscan Hub errors and warning flags

Flag	Symbol on Affected Parameter	Interpretation
The blood sample may contain morphologically abnormal cells. Blood smear review recommended.	Asterisk (*)	Abnormal cells/cell morphology detected. Blood smear review recommended.
The blood sample may contain PLT clumps. Blood smear review recommended.	Asterisk (*)	The blood sample may contain PLT clumps. Blood smear review recommended. Consider sample quality and use proper sample handling techniques
Abnormal distribution of PLT cell volumes suspected. Blood smear review recommended.	Asterisk (*)	Abnormal distribution of PLT cell volumes detected. Blood smear review recommended.

5.3 Preanalytical Guidelines

- 1. Use K2/K3 EDTA anticoagulated whole blood sample tube, filled appropriately to the manufacturer's fill line.
- 2. Collected blood sample is at ambient room temperature of 17 °C to 27 °C (63 °F to 81 °F).
- 3. Ensure minimum sample volume is met in the blood sample tube. Always fill to the manufacturer's fill line.
- 4. The EDTA sample tube is gently inverted 10-15 times immediately after sample collection, and again before starting the test.
- 5. The OptiCell Hematology Cartridge and the OptiCell Hematology Blood Sampler are valid (within the expiration date).
- 6. The OptiCell Hematology Blood Sampler capillary tubes are completely filled, without any air bubbles present.
- 7. The Vetscan OptiCell Hematology Blood Sampler is fully inserted into the Cartridge. Listen for a "click" sound when fully inserted into the Vetscan OptiCell Hematology Cartridge.
- 8. Insert the prepared Vetscan OptiCell Hematology Cartridge immediately into the Vetscan OptiCell analyzer.



5.4 Error Messages Displayed on Vetscan Hub

If a problem occurs during a test, Vetscan OptiCell analyzer will send error messages and warning flags to the Vetscan Hub. For a list of error numbers and corresponding corrective actions, refer to Table 3. If the problem persists after the corrective action listed for the relevant error, contact Zoetis Diagnostic Technical Support.

Error Categories:

1XXXXX - System Errors

2XXXXX - Errors that are related to the OptiCell Hematology Cartridge or analyzer during a measurement.

3XXXXX - Errors that are related to the patient blood sample.

4XXXXX - Errors that are related to operator error.

Table 3: Error Messages Displayed on Vetscan Hub

Error Number	Classification	Corrective Actions
110001 121001 123001 131117 122003 124001 131221	System Error	 System error occurred. Power off the analyzer via Vetscan Hub and wait 30 seconds before powering back on. Repeat the test using a new Vetscan OptiCell Hematology Cartridge and Vetscan OptiCell Hematology Blood Sampler. If errors persist, contact Zoetis Diagnostic Technical Support.
136201	System Error	 System overheated. Power analyzer off for 5 minutes via Vetscan Hub. Remove the fan filter and replace with a new filter. Then, restart the analyzer. If errors persist, contact Zoetis Diagnostic Technical Support.

Error Number	Classification	Corrective Actions
210011 231331 131331	Cartridge or System	 Repeat the test using a new Vetscan OptiCell Hematology Cartridge and Vetscan OptiCell Hematology Blood Sampler as follows: Verify both sampler capillaries are filled 100% to the end stopper. Verify that the sampler is inserted fully into the OptiCell Hematology Cartridge. Blood Sampler will "click" upon full connection. Verify that there is no trapped air bubble or blood smear/debris on the OptiCell Hematology Cartridge chip area. If errors persist, contact Zoetis Diagnostic Technical Support.
231225 131225	Cartridge or System	 Chip Position Error detected. Repeat the test using a new Vetscan OptiCell Hematology Cartridge and Vetscan OptiCell Hematology Blood Sampler. If the error persists, restart the analyzer and repeat the test with another OptiCell Hematology Cartridge, preferably from a different lot. If a different lot is not available, perform an OptiCell Quality Control cartridge run. If errors persist, contact Zoetis Diagnostic Technical Support.
231332 131332	Cartridge	 Chip debris or bubbles detected. Repeat the test with a new OptiCell Hematology Cartridge and verify there are no bubbles in the capillaries and no debris or smudges near the cartridge chip area. If the error persists, restart the analyzer. If possible, use a different lot and repeat the test using a new Vetscan OptiCell Hematology Cartridge and Vetscan OptiCell Hematology Blood Sampler. If a different lot is not available, perform an OptiCell Quality Control cartridge run. If errors persist, contact Zoetis Diagnostic Technical Support.



Error Number	Classification	Corrective Actions
232221	System	 Cartridge vacuum error. Repeat the test with a new OptiCell Hematology Cartridge. If errors persist, contact Zoetis Diagnostic Technical Support.
233222	Cartridge	 Invalid Scan Occurred Repeat the test using a new Vetscan OptiCell Hematology Cartridge and Vetscan OptiCell Hematology Blood Sampler. If errors persist, contact Zoetis Diagnostic Technical Support.
233223	Cartridge	Repeat the test using a new Vetscan OptiCell Hematology Cartridge and Vetscan OptiCell Hematology Blood Sampler. Verify there is no debris or smudges near the OptiCell Hematology Cartridge microfluidic chip area.
235658 235659 235655 135655 131445 231445	Cartridge or System	 Repeat the test using a new Vetscan OptiCell Hematology Cartridge and Vetscan OptiCell Hematology Blood Sampler. Verify there are no air bubbles in the capillaries and no debris or smudges near the OptiCell Hematology Cartridge microfluidic chip area. If the error persists, repeat the test with a new OptiCell Hematology Cartridge from another lot. If a different lot is not available, perform an OptiCell Quality Control cartridge run. If errors persist, contact Zoetis Diagnostic Support.
231443	Blood Sample	 Preanalytical error suspected. Repeat test using a new, fresh blood sample and confirm all preanalytical steps are correct. If errors persist, contact Zoetis Diagnostic Technical Support.
231522	Blood Sample	 Repeat test If the error persists, repeat the test with a new OptiCell Hematology Cartridge from another lot. If a different lot is not available, perform an OptiCell Quality Control cartridge run. If errors persist, contact Zoetis Diagnostic Technical Support.



Error Number	Classification	Corrective Actions
235651	Blood Sample	 Preanalytical or Sample Quality error. Verify that both capillaries are filled 100% to the end stopper. Verify that the OptiCell Hematology Blood Sampler is inserted fully into the OptiCell Hematology Cartridge. Blood Sampler will "click" upon full connection. Ensure proper sample mixing, and that no sample manipulation (i.e., dilution) was done to the blood sample. Repeat the test using a fresh blood sample.
331333	Blood Sample	 Preanalytical error suspected. Repeat the test using a new Vetscan OptiCell Hematology Cartridge and Vetscan OptiCell Hematology Blood Sampler. Verify there are no bubbles in the sampler capillaries. Verify that both capillaries are filled 100% to the end stopper. Verify that the sampler is inserted fully into the cartridge and "clicks" upon full connection.
335653	Blood Sample	 RBC per frame low. Potential low volume of sampled blood, or sample dilution occurred. Repeat with a fresh blood sample and ensure proper sample handling techniques.



Error Number	Classification	Corrective Actions
335654 135655 131445 231445	Blood Sample	 Bubbles Detected. Repeat the test using a new Vetscan OptiCell Hematology Cartridge and Vetscan OptiCell Hematology Blood Sampler. 1. Ensure proper sample handling techniques. 2. Verify that both capillaries are filled 100% to the end stopper and no bubbles are visible.
335656	Blood Sample	 Preanalytical error suspected. Repeat the test using a new Vetscan OptiCell Hematology Cartridge and Vetscan OptiCell Hematology Blood Sampler. Ensure proper sample handling techniques. Verify that both capillaries are filled 100% to the end stopper and no bubbles are visible.
335657	Blood Sample	 RBC ghost/hemolysis suspected. Repeat the test with a new OptiCell Hematology Cartridge and ensure proper sample handling techniques. Verify that both capillaries are filled 100% to the end stopper and no bubbles are visible.



Error Number	Classification	Corrective Actions
440001	Operation error	Warning message: Used OptiCell Hematology Cartridge detected. Repeat test using a new OptiCell Hematology Cartridge.
440002	Operation error	Warning message: Expired OptiCell Hematology Cartridge detected. Repeat test using a new, not expired OptiCell Hematology Cartridge.
440003	Operation error	Warning message: Expired Quality Control cartridge detected. Repeat test with a new, not expired OptiCell QC cartridge.
440004	Cartridge Half Inside	Warning message: Cartridge inserted halfway. Confirm if cartridge was left inside of sample door. If so, remove the cartridge and press ok to continue.
440005	Cartridge Insert Timeout	Warning message: Timeout occurred. A 10-minute timeout error will occur after the test is started on the Vetscan Hub without inserting a cartridge into the analyzer. Repeat the test and insert OptiCell Hematology Cartridge into the analyzer immediately after starting the test.
440006	QC cartridge in Test mode	Warning message: A Quality Control cartridge was detected in sample test mode. Use an OptiCell Hematology Cartridge for patient sample testing.
440007	Hematology cartridge in QC mode	Warning message: OptiCell Hematology Cartridge was detected in QC Cartridge mode. Use an OptiCell QC cartridge for QC testing.



6. Performance Specifications

6.1 Vetscan OptiCell Reportable Ranges (Linearity)

Data was generated using available linearity controls and whole blood patient sample pools for RETIC.¹

Parameter	95% Lower Limit	95% Upper Limit	R ²
RBC (x 106 cells/µL)	1.0	15.6	1.00
HGB (g/dL)	2.8	57.2	1.00
WBC (x 103 cells/µL)	0.3	180	0.999
PLT (x 103 cells/µL)	10	1900	0.999
RETIC (K/μL)	0	55	0.86

Reference: 1. TBD study on file.



7. Certifications

7.1 Countries of compliance

Countries of compliance available over Vetscan Hub.

7.2 USA Federal Communications Commission (FCC)

FCC CLASS B

- This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:
- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

7.3 Industry Canada (IC)

WARNING

This analyzer complies with Industry Canada license-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

7.4 Warranty

Contact your Zoetis representative for active warranty details, defect exclusions, and warranty coverage. If any defects in materials or workmanship occur in the analyzer during active warranty period, Zoetis will repair or replace the analyzer. The analyzer's protection will be impaired if used in a manner not specified by the manufacturer. Service warranty to be rendered by Zoetis Diagnostic Technical Support. Contact information can be found at https://www.zoetis.com/customer-care.



8. Contact information

8.1 Manufacturer



Zoetis, Inc. 333 Portage Street Kalamazoo, MI 49007, USA www.Zoetis.com

8.2 EU importer



Zoetis Belgium S.A. Rue Laid Burniat 1, 1348 Louvain-La-Neuve, Belgium

8.3 UK importer



Zoetis UK Ltd. First floor Birchwood Building, Springfield Dr, Leatherhead KT22 7LP, United Kingdom

8.4 Technical support

https://www.zoetis.com/customer-care

9. Symbols

Symbol

Definition/Use



Manufacturer of the device



Date of manufacturing at country of manufacturing



Importer

To indicate the identity and address of the Importer



Model number



Serial number



Catalogue number



Consult instructions for use or consult electronic instructions for use



Caution

Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences



Electronic instructions for use. Scan QR code for access.



Indoor use



Direct current



For veterinary use only



WEEE

Indicates that separate collection for waste of electric and electronic equipment (WEEE) is required



Biological Risk

Indicates that there are potential biological risks associated with the device





Manufacturer

Zoetis, Inc. 333 Portage Street Kalamazoo, MI 49007, USA www.zoetis.com

EU Importer

Zoetis Belgium S.A. Rue Laid Burniat 1, 1348 Louvain-La-Neuve, Belgium

UK Importer

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Learn more at **zoetisdiagnostics.com**

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Technical support

https://www.zoetis.com/customer-care

