



# USER'S MANUAL

v1.2 Software

## zoetis

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Zoetis warrants the VETSCAN Sediment Analyzer System against defects in materials and workmanship for 1 year. Contact your Zoetis representative for the details of the warranty. If any defects occur in the analyzer during this warranty period, Zoetis will repair or replace the defective parts free of charge. The following defects, however, are specifically excluded:

- 1. Defects caused by improper operation.
- 2. Repair or modification done by anyone other than Zoetis or an authorized agent.
- 3. Use of fittings or other spare parts supplied by anyone other than Zoetis.
- 4. Damage caused by accident or misuse.
- 5. Damage caused by disaster.
- 6. Corrosion due to use of improper solvent or sample.

The device's protection will be impaired if used in a manner not specified by the manufacturer.

## **Declaration Of Conformity**

#### Manufacturer:

Zoetis Inc. 10 Sylvan Way Parsippany, NJ 07054

#### The Directives covered by this Declaration

EU Machinery Directive 2006/42/EC EU RoHS2 Directive 2011/65/EU

#### The Products Covered by this Declaration

VETSCAN SA sediment analyzer

#### The Basis on which Conformity is being declared

The manufacturer hereby declares under his sole responsibility that the products identified above comply with the essential health and safety requirements of the Machinery directive 2006/42/EC.

The manufacturer has applied the following standards:

EN ISO 13485:2016 Medical devices-Quality Management systems- Requirements for

regulatory purposes

EN 61326-1 Electrical Equipment for Measurement, Control and Laboratory Use -

EMC Requirements - Part 1: General Requirements

IEC/EN 61010-1 Safety Requirements for Electrical Equipment for Measurement, Control

and Laboratory Use Part 1: General Requirements

Particular Requirements for Automatic and Semi-Automatic Laboratory IEC/EN 61010-2-081

Equipment for Analysis and Other Purposes

The technical documentation required to demonstrate that the products meet the requirements of the Machinery directive 2006/42/EC can be made available to relevant authorities within a reasonable period of time.

EIC/EN 61326-2-6

EN 55011, EN 61000-3-2, EN 61000-3-3

EN 61000-4-2, EN 61000-4-3, EN 61000-4-4, EN 61000-4-5, EN 61000-4-6, EN 61000-4-8, EN 61000-4-11

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## Introduction

The VETSCAN SA enables practitioners to perform urine microscopy by evaluating the native urine sediment with consistent and efficient high quality images at the point of care. Combined with the VETSCAN UA for urine chemistry testing, it's the complete solution for your in-clinic urinalysis needs.

When paired with the VETSCAN Urine Analyzer (UA), the VETSCAN SA+UA system provides a comprehensive urinalysis solution.



#### **Intended Use**

The VETSCAN SA is intended for veterinary use only for testing of urine sediment in mammalian urine samples, particularly dogs and cats. Urine samples collected from other species may be run on the analyzer, but have not been validated. The VETSCAN SA will provide quantitative and semi-quantitative analysis of the following sediment particles in urine samples:

Blood Cells
1. Red Blood Cells
2. White Blood Cells
Epithelial Cells
3. Squamous Epithelial Cells
4. Non-Squamous Epithelial Cells
Casts
5. Hyaline Casts
6. Non Hyaline Casts
Bacteria
7. Bacteria Rods
8. Bacteria Cocci
Crystals
9. Struvite Crystals
10. Calcium Oxalate Crystals

Urine sediment evaluation on the VETSCAN SA is intended to help detect renal and urinary tract abnormalities. It is designed to be utilized in combination with urine chemistry testing, physical evaluation (including urine specific gravity), and other clinical diagnostics to obtain a complete evaluation of the disease process affecting the patient. It is best practice to review images provided with every sample run.

### **Result Classifications**

The VETSCAN SA reports both quantitative and semi-quantitative results.

#### **Quantitative Results**

Parameter	SA Display	≤ 5.0	Range	Above Range	Units
Red Blood Cells	RBC	NTR	5-500	>500	/µL
White Blood Cells	WBC	NTR	5-500	>500	/µL

Parameter	SA Display	≤ 1.0	Range	Above Range	Units
Squamous Epithelial Cells	Sq Epithelial	NTR	1-50	>50	/µL
Non-Squamous Epithelial Cells	Non Sq Epithelial	NTR	1-50	>50	/µL
Hyaline Casts	Hyaline	NTR	1-5	>5	/µL
Non Hyaline Casts	Non Hyaline	NTR	1-5	>5	/µL

#### **Semi-quantitative Results**

Parameter	SA Display	9	Semi-qua	ntitative	Results	
Bacteria Rods	Bacteria-Rods	NTR	+	++	+++	++++
Bacteria Cocci	Bacteria-Cocci	NTR	+	++	+++	++++
Struvite Crystals	Struvite	NTR	+	++	+++	++++
Calcium Oxalate Crystals	CaOx dihydrate	NTR	+	++	+++	++++

#### **NTR** = None To Rare

Result Bin	Definition
+	Few
++	Moderate
+++	Many
++++	Numerous

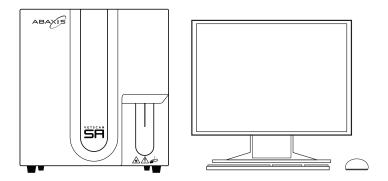
## Result Warnings

The VETSCAN SA also displays warnings above the test results in a section titled SA Test Results. It is best practice to review the images provided with every sample run.

The SA Test Results section will turn orange if "Review Images—Unclassified Elements Present," "Review Images—Bacteria Suspected," "Review Images—Multiple Elements Suspected," "TNTC— Dilute and retest" and "Possible short sample" are indicated.

SA Test Results display text:	Description	Action
Completed	Nothing abnormal or questionable	Review images
Review Images - Unclassified Elements Present	SA detected abnormal levels of undefined elements	Review images; review on manual slide and/or confirm with send-out laboratory
Review Images—Bacteria Suspected	SA detected presence of bacteria	Review images +/- urine culture sensitivity, and/or dry prep and interpreted in conjunction with patient history and clinical signs
Review Images - Multiple Elements Suspected	Any of the following 5 scenarios  1. RBC > 500/µL  2. RBC > 500/µL & abnormal levels of undefined sediment  3. RBC > 500/µL & detected presence of bacteria  4. RBC > 500/µL & abnormal levels of undefined sediment & detected presence of bacteria  5. abnormal levels of undefined sediment & detected presence of bacteria	Review on manual slide and/or confirm with send- out laboratory
TNTC - Dilute and retest	Too numerous to count; too many particles in image; sample dilution may be required.	Review images provided to determine if pathology can be determined without dilution. If this is not possible, the sample should be diluted to Lowest dilution ratio and rerun.
Possible short sample	SA may not have received enough sample to complete test	Retest and ensure sample probe touches tube bottom.
Not measured	UA only test selected	None

## **System Overview**



#### The VETSCAN SA Sediment Analyzer Final Assembly includes:

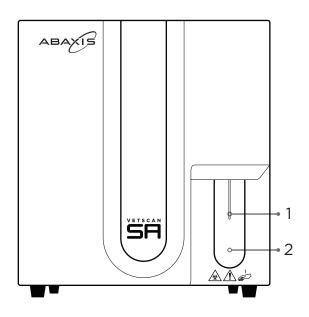
- VETSCAN SA Sediment Analyzer (PN 1550-1000)
- VETSCAN SA Tubing Kit (PN 1550-1001)
- VETSCAN SA Waste Bottle (PN 1550-1002)
- VETSCAN SA USA Power Cord (PN 1550-1005)

#### Accessories to be ordered separately (not included in the system):

- VETSCAN SA Keyboard (PN 1550-1003)
- VETSCAN SA Mouse (PN 1550-1004)
- VETSCAN SA Display Monitor (PN 1550-1007)
- VETSCAN SA International Power Cords (see Appendix G for listings)

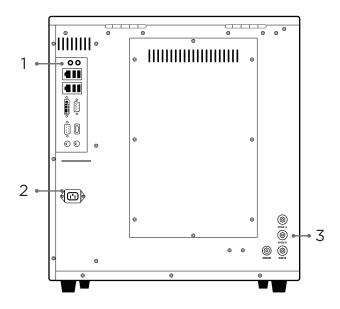
#### The VETSCAN SA analyzer works with the following reagent, cleaner and control:

- VETSCAN SA Reagent Kit (PN 1550-9000)
- VETSCAN SA Cleaner Kit (PN 1550-9001)
- VETSCAN SA Control Kit (PN 1550-9002)



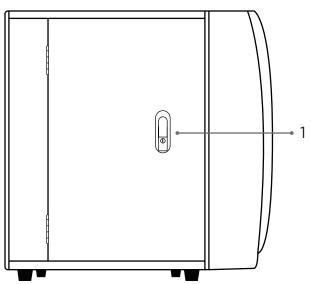
#### **Front Panel**

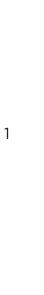
- 1. Sample probe
- 2. Blue start paddle



#### **Rear Panel**

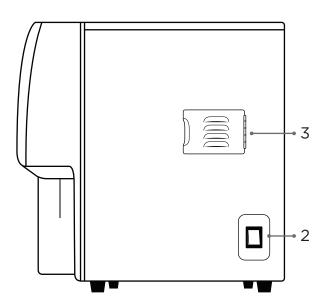
- 1. Input/output panel
- 2. Power connection
- 3. Reagent connection panel

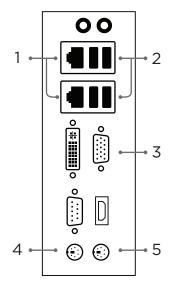


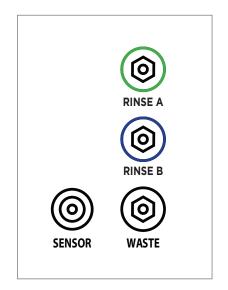


#### **Side Panels**

- 1. Door latch
- 2. Power switch
- 3. Fan filter door







Input/output panel

Reagent connection panel

#### **Ports**

- (1) Ethernet ports
- (2) USB ports
- (3) VGA monitor port

- (4) Mouse port
- (5) Keyboard port

Note: The HDMI and DVI ports are not supported and should not be used to connect a display monitor.

## Safety

The VETSCAN SA system is designed for maximum user safety and for indoor use only. The plastic enclosures are made of thick injection-molded acrylic to create a leak-free test environment. The safety metal cover surrounds the system to protect the user from exposure to electrical current.

Before use, inspect the VETSCAN SA system for cracks and chips, which may allow the test sample to leak from the tubes and cause a potential electrical hazard. Additionally, inspect all electrical cables and plugs for loose connections, cracks, breaks or corrosion. Do not use any part that is cracked, charred, or corroded. These parts may also cause a potential electrical hazard.

If leaking sample is detected, disconnect the power to the analyzer immediately.

Power to VETSCAN SA system is supplied by an external DC voltage power supply. All Zoetis's power supplies have met the safety requirements. Zoetis supplies the recommended power cords for this unit. Only use Zoetis supplied power supplies specified for the VETSCAN SA system. Refer to Appendix for listings of power cords for your region.

Important: The VETSCAN SA analyzer is certified to meet IEC 61010-1 safety standards. IECcertified products are safe to use when operated in accordance with the instruction manual. This analyzer should not be modified in any way. Alteration of this analyzer will:

- Void the manufacturer's warranty
- Void IEC 61010-1 safety certification
- Create a potential safety hazard

Contact your local Zoetis representative before using a part that may be considered hazardous or if leaking is detected.

When moving the SA analyzer, 2 people should handle any lifting.

Proper use of gloves is recommended when testing. OSHA requirements for personal protective Equipment (PPE) are set forth in the code of Federal Regulations (CFR) at 29 CFR 1910.132 (General Requirements); 29 CFR 1910.138 (Hand protection); 29 CFR 1926.95 (Criteria for standard personal protective equipment). Any gloves with impaired protective ability should be discarded and replaced. Consider the toxicity of the chemicals and factors such as duration of exposure, storage, and temperature when deciding to reuse chemically exposed gloves. Please also consider local Occupational Safety and Health regulations.

## **VETSCAN SA Menu**

When the VETSCAN SA powers on, the top menu has three selections:



**Measure** is for running samples.



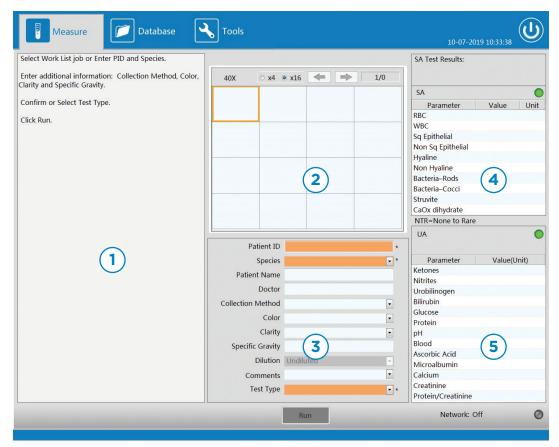
**Database** is for reviewing previous tests run.



**Tools** is for changing settings and maintenance of the analyzer.



The Measure menu screen is divided into five different panels.



Measure Menu Screen

- 1. Left Side Panel: guides the user through running a test using images and text.
- 2. SA Images Panel: images captured at end of sample analysis.
- 3. Sample Entry Panel: where a user enters in all the inputs related to the sample.
- 4. SA Results Panel: results classification of particles from the images captured.
- 5. UA Results Panel: results received from the UA analyzer.

## **Running a Sample**

#### Sample Collection

Urine samples may be collected by any of these methods for analysis on the SA.

- 1. Cystocentesis: Insert a small needle into the bladder through the skin and draw urine into the syringe. The technique is ideal for collecting urine samples for bacterial culture.
- 2. Catheter: Place a urinary catheter within the urethra and advance it into the bladder. Collect the sample using a sterile syringe. Sterile technique should be followed both for the patient's urinary tract health and integrity of bacterial culture, if needed.1
- 3. Free catch/voided (mid-stream): Using a sterile urine collection jar, collect a mid-stream urine sample. Free catch samples are most at risk for contamination by the genital tract, skin, and hair which can result in a false positive bacterial identification and culture.1 Urine collected from a litter box, floor or exam table will have additional sources of contamination. Bacteria, hyphal structures, and foreign material if identified, should be considered as such and another sample collected, especially if bacterial culture is needed.

It is recommended to acquire at least 1 mL of urine sample prior to running a test. The SA requires approximately 650 µL (0.65 mL) of sample to run a SA test and additional sample is required for application to UA strip, if also running a UA test.

#### Sample Handling

Do not centrifuge or stain urine samples before use on the VETSCAN SA and VETSCAN UA. Use fresh, well mixed urine.

Urine samples may be tested immediately after collection up to one-hour post collection, if stored at room temperature.

If urine samples are not tested within one hour of collection, samples may be refrigerated (36-46 °F, 2-8 °C) for up to 4 hours.

Cold samples must be warmed to room temperature prior to testing.

#### Dilution

For a dilution decision chart, see Appendix J. If a dilution is performed, it should be initiated at 1:2 (0.4 mL urine, 0.4 mL saline) and increased accordingly depending on the pathology that can be identified in the images provided by the VETSCAN SA.<sup>2</sup> When performing dilutions, use only sterile 0.9% NaCl to dilute urine samples. Invert the tube gently 10-15 times immediately prior to running the sample. The SA will automatically calculate results based on the dilution selected.

SPECIAL CASES: In SA Software v1.1 or higher, if a UA10 or UA14 strip is utilized and run with the SA for the same patient, pH is factored into the crystal classification to more accurately identify calcium oxalate crystals and struvites. If a patient with stones or severe crystalluria is currently on a prescription diet that alters the urine pH to decrease crystal formation or dissolve a urinary stone, update to the SA Software v1.1 crystal identification that factors in the urine pH should be disabled for more accurate results. The pH in this case may cause crystals to be misclassified due to the patient's clinical status. To disable the pH aspect of the classification, the SA must be run separately from the UA then combined later in the Database. See Database - Reviewing Previous Results section for detailed information on this process.

<sup>1.</sup> Sink CA and Weinstein NM. Practical Veterinary Urinalysis, Ames. IA; John Wiley & Sons Inc. 2012 2. Dennis and DiBartola, Stephen. Interpretation of Canine and Feline Urinalysis. Nestle Purina, Wilmington, De. 2004.

#### Running a Test

The VETSCAN SA and UA analyzers can be connected together to produce a full urinalysis report. The SA analyzer becomes the urinalysis workstation where all data entry will take place and sample runs are initiated.

Follow on-screen instructions. Patient ID, Species and Test Type are minimum required selections before the Run button is enabled. These required inputs are locked at the time the Run button is clicked and may not be changed during and after the measurement. All other inputs are optional and may be edited or entered after the test has been completed. Once a test begins, the measurement cannot be canceled.

There are three test workflows that can be initiated on the VETSCAN SA, two of which require a VETSCAN UA connected to the SA. Since there are two strip types (UA10 and UA14) on the VETSCAN UA, five unique Test Types can be selected.



See Appendix I for details on Gross Examination, Specific Gravity, and Dilution fields.

If a SA+UA test is selected, always start the SA test first. Each of the three test workflows are detailed below.

#### **SA+UA Test**

#### SA Test

1. Enter Patient Information:

Enter Patient ID and select Species (Cat, Dog, Other, Control). Enter Patient Name and Doctor Name if desired.

2. Enter physical characteristics of the sample (recommended):

Use the drop-down option lists to select gross examination fields for the sample (Collection Method, Color, and Clarity) for the medical record.

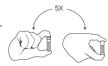
3. Enter specific gravity of the sample (recommended):

Input specific gravity value of the sample, if available, in format 1.xxx. It is recommended that specific gravity is measured using a refractometer.

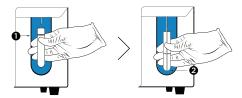
- 4. Enter any additional details in the comments section.
- 5. Select Test Type (2 options): SA+UA14, SA+UA10
- 6. Select Dilution if necessary:

Dilute the sample and select correct dilution. Undiluted is the default setting and appropriate for all initial analyses on the SA<sup>1</sup>. Diluted samples are to be used on the SA analyzer only. If diluting a sample, reserve undiluted sample for UA testing.

- 7. Click Run.
- 8. Mix urine sample by gently inverting. Ensure a thoroughly mixed sample.

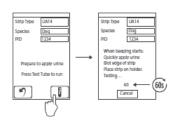


- 9. Immediately place tube below sample probe and press blue start paddle.
  - 1. Hold the sample below the sample probe leaving a gap to the probe tip to allow the sample probe to aspirate air prior to moving down for sampling.
  - 2. Ensure sample probe touches tube bottom. and maintains contact until the probe starts to move back up.



#### **UA** Test

- 10. Confirm Strip Type, Species, and PID (Patient ID) on UA analyzer. Prepare to apply urine to UA strip. If incorrect, the UA test can be canceled by pressing the UA Back button, and the overall test will be changed to SA only.
- 11. Press Test (Test Tube icon) button to start test. Countdown timer appears. Perform the next three steps before the timer reaches 35.

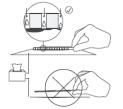


#### UA Test (continued)

- 12. Re-mix urine sample by gently inverting. Ensure a thoroughly mixed sample.
- 13. Immediately apply urine sample to strip. Use a dropper pipette to drop urine over entire strip, completely wetting each pad. Do not leave excess urine on strip for more than 2 seconds. Alternatively, strip may be dipped into urine sample, completely wetting every pad. Remove the strip after 2 seconds.



14. Blot either long edge of strip on absorbent paper to remove excess urine. DO NOT blot the top surface of the pads to avoid contamination. Work quickly to blot excess urine. Delays in blotting may affect results.



15. Place strip on the UA Strip Tray. The end of the strip should align with the end of the trough in the Strip Tray, approximately where the top cover of the UA analyzer is indented. This step MUST be completed before the countdown timer reaches 35 as the Strip Tray will begin to slide into the analyzer. The UA analyzer will time the reactions and scan when appropriate.



WARNING! Ensure the strip has been placed in the tray before the Strip Tray begins to move into the analyzer.

If a strip is not present in the Strip Tray at the conclusion of the measurement, an error will be reported on the UA and sent to the SA. The test will be changed to a SA only test.

While measuring, the SA screen is locked, and navigation to other screens is prohibited. Also, both the SA status indicator light (top right of the SA Results Panel) and the UA status indicator light (top right of the UA Results Panel) will display yellow during measurement process. Do not disconnect UA from SA during testing process. If the UA becomes disconnected during testing, the UA test will be canceled automatically on the SA, and complete as an SA only test. If the UA becomes disconnected from the SA during the measurement, wait until the SA completes its measurement to reconnect. If desired, manually send the UA results from the UA to the SA Database by pushing the "USB send" icon on the UA.

#### **SA Only Test**

1. Enter Patient Information:

Enter Patient ID and select Species (Cat, Dog, Other, Control). Enter Patient Name and Doctor Name if desired.

2. Enter physical characteristics of the sample (recommended):

Use the drop-down option lists to select gross examination fields for the sample (Collection Method, Color, and Clarity) for the medical record.

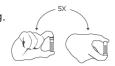
3. Enter specific gravity of the sample (recommended):

Input specific gravity value of the sample, if applicable, in format 1.xxx. It is recommended that specific gravity is measured using a refractometer.

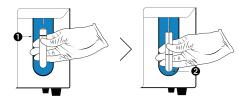
- 4. Enter any additional details in the comments section.
- 5. Select Test Type: SA
- 6. Select Dilution if necessary:

Dilute the sample and select correct dilution. Undiluted is the default setting and appropriate for all initial analyses on the SA1.

- 7. Click Run.
- 8. Mix urine sample by gently inverting. Ensure a thoroughly mixed sample.



- 9. Immediately place tube below sample probe and press blue start paddle.
  - 1. Hold the sample below the sample probe leaving a gap to the probe tip to allow the sample probe to aspirate air prior to moving down for sampling.
  - 2. Ensure sample probe touches tube bottom. and maintains contact until the probe starts to move back up.



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#### **UA Only Test**

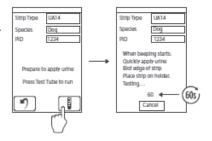
1. Enter Patient Information:

Enter Patient ID and select Species (Cat, Dog, Other, Control). Enter Patient Name and Doctor Name if desired.

2. Enter physical characteristics of the sample (recommended):

Use the drop-down option lists to select gross examination fields for the sample (Collection Method, Color, and Clarity) for the medical record.

- 3. Enter specific gravity of the sample (recommended): Input specific gravity value of the sample, if applicable, in format 1.xxx. Specific gravity is often measured using a refractometer.
- 4. Enter any additional details in the comments section.
- 5. Select Test Type (2 options): UA14, UA10
- 6. Click Run.
- 7. Confirm Strip Type, Species, and PID (Patient ID) on UA analyzer. Prepare to apply urine with dropper on UA strip. If incorrect, the UA test can be canceled by pressing the UA Back button.
- 8. Press Test (Test Tube icon) button to start test. Countdown timer appears. Perform the next three steps before the timer reaches 35.



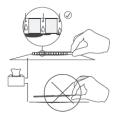
9. Mix urine sample by gently inverting. Ensure a thoroughly mixed sample.



10. Apply urine sample to strip. Use a dropper pipette to drop urine over entire strip, completely wetting each pad. Do not leave excess urine on strip for more than 2 seconds. Alternatively, strip may be dipped into urine sample, completely wetting every pad. Remove the strip after 2 seconds.



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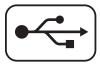
WARNING! Ensure the strip has been placed in the tray before the Strip Tray begins to move into the analyzer.

If a strip is not present in the Strip Tray at the conclusion of the measurement, an error will be reported on the UA and sent to the SA. The test will be changed to a SA only test.

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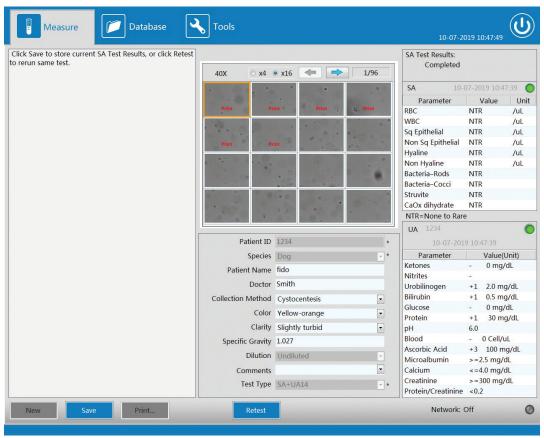
The UA analyzer can operate interdependently from the SA; however, if combined SA and UA reports are desired, the UA test must be initiated on the SA.

Operating the UA independently from the SA indicates that the test was not initiated from the SA or that the UA was disconnected from the SA. If UA test results need to be transferred to the SA, the UA will need to be connected to the SA. Next, navigate to the UA Database and select the desired test report to transmit and push the "USB send" icon to transmit the data to the SA.



## **Urinalysis Results**

Results will appear onscreen in approximately five minutes after the start of the test. Select images to print and input any comments into the comments section and select Save or Retest. Once the results are Saved, the SA analyzer will automatically print all results if Auto-Print is selected in the settings and the printer is connected and powered on. Results may be manually printed via the Print button or re-printed later from the Database screen. Once results are Saved, fields including Comments and the 6 selected images cannot be changed in Database.



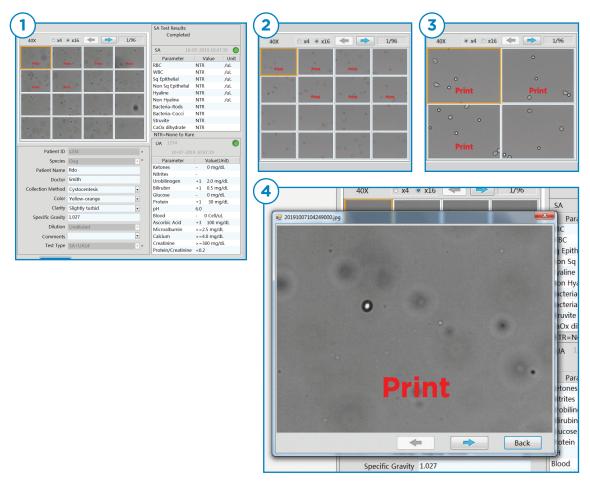
SA Results displayed on Measure screen after test completed.

- Click **Save** to store results. Once results are Saved, all fields which include Patient Name. Doctor, Collection Method, Color, Clarity, Specific Gravity and Comments and the 6 selected images cannot be changed in Database.
- · Click Retest the sample without any additional patient entry. Patient ID and Species are unchangeable. The retest function is only available for the SA test. If a UA test was also completed during the original test run, the UA results will be saved and displayed with the new SA test values.

## **SA Images Panel**

Up to 96 images from the urine sediment test will be displayed on the SA Images Panel. It is best practice to review images provided with every sample run.

- Select x4 for group of 4 images at a time, or x16 to see 16 images at a time
- Double-click any image to zoom in on the selected image
- Use arrows to page through images

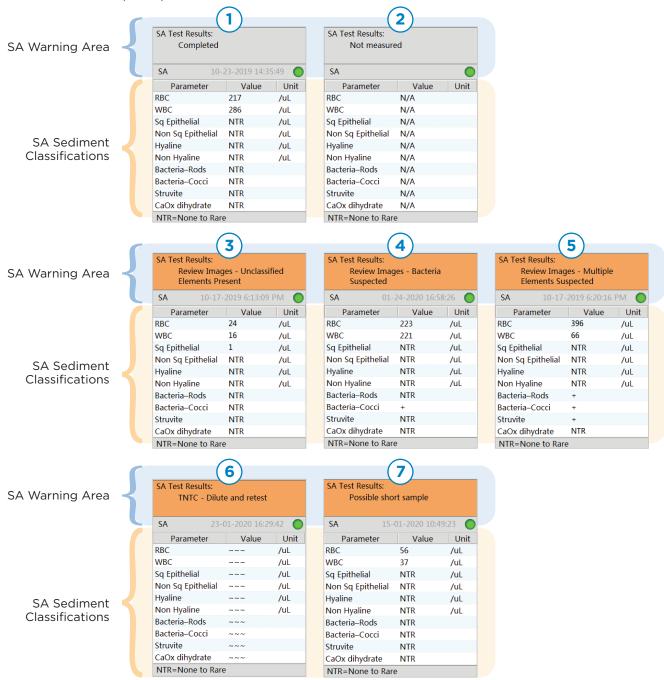


SA Image Views (1) Full results view (2) x16 image group (3) x4 image group (4) Zoomed-in image

Up to 6 images will display with red "Print" text on them. These 6 images will be printed on the printout. To modify and select different images, right click on any image and select "Cancel print image" or "Add print image". The newly selected image will replace the first auto-selected image for printing. The last selected 6 images will be included in the printout.

#### SA Results Panel

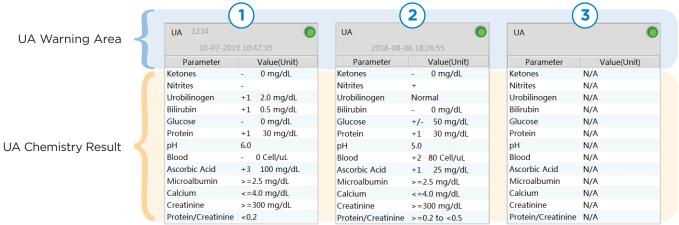
The SA result classifications from the urine sediment test are shown on the SA Results Panel by Parameter, Value, and Unit.



SA Results Panel Examples (1) Results with No Warnings, (2) No SA test measured where N/A represents Not Applicable, (3) Review images - Unclassified Elements Preset, (4) Review Images - Bacteria Suspected, (5) Review Images - Multiple Elements Suspected, (6) Results with "TNTC - Dilute and retest" Warning, (7) Results "Possible short sample'

#### **UA Results Panel**

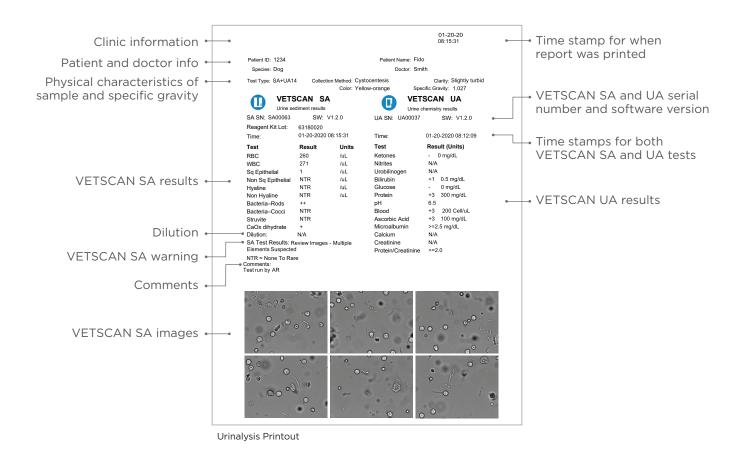
The UA results from the urine chemistry test are shown on the UA Results Panel by Parameter, Value, and Unit. The test results are classified into semi-quantitative bins. See Appendix J for all the bins grouped by test analyte.



UA Results Panel Examples (1) Results from UA10 strip test, (2) Results from UA14 strip test, (3) UA error during a SA+UA measurement. If parameters are toggled OFF on the UA, result will display as N/A.

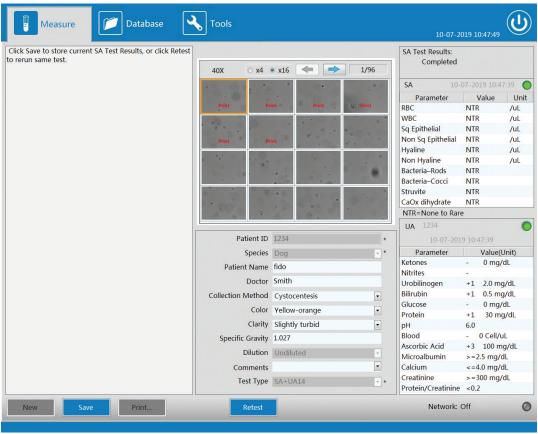
#### **Urinalysis Printout**

The SA analyzer will automatically print all results if Auto-Print is selected in the settings and the printer is connected and powered on. Results may be manually printed. Also a PDF may be saved to an external flash drive using Export button from Print preview screen accessed from Measure or Database menu.



#### **Retest SA**

The SA analyzer provides an immediate option to retest the sample without any additional patient entry. The retest function is only available for the SA test. If a UA test was also completed during the original test run, the UA results will be saved and displayed with the new SA test values.



SA Results displayed on Measure screen after test completed.

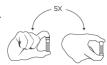
If a retest on the SA is not desired, just click "Save". If a retest is desired, the initial SA data will be saved to the Database, but not auto printed.

- 1. Click Retest button; all the inputs to the sample will automatically be populated. Patient ID and Species are unchangeable. All other inputs can be revised and comments can be added.
- 2. Select Dilution if necessary:

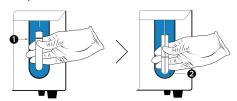
Dilute the sample and select correct dilution. Undiluted is the default setting and appropriate for all samples prior to initial analysis, as overdiluting the sample should be avoided. After reviewing the numerical sediment results and 96 images provided by the SA on the initial sediment analysis, a dilution may need to be performed if clinical insight cannot be gathered from the images<sup>1</sup>. The SA will automatically calculate results based on the dilution selected.

<sup>1.</sup> Zoetis Internal VETSCAN SA Dilution Study - TI-04858

- 3. Click Run.
- 4. Mix urine sample by gently inverting. Ensure a thoroughly mixed sample.



- 5. Immediately place tube below sample probe and press blue start paddle.
  - 1. Hold the sample below the sample probe leaving a gap to the probe tip to allow the sample probe to aspirate air prior to moving down for sampling.
  - 2. Ensure sample probe touches tube bottom. and maintains contact until the probe starts to move back up.

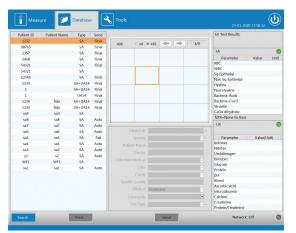


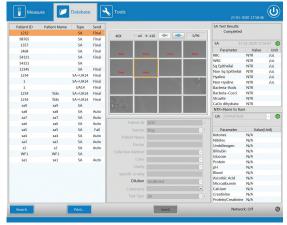
While measuring, the SA screen is locked and navigation to other screens is prohibited. Also, the SA status indicator light (top right of the SA Results Panel) will display yellow during measurement process. During a SA Retest of a SA+UA result, the completed UA results will continue to show on the UA Results Panel.

## **Database - Reviewing Previous Results**

The VETSCAN SA analyzer stores, at minimum, 500 test records. Results are stored chronologically by date and time with newest on top. Select Database on top menu to review past results. If free space on the analyzer is less than 2GB, an error will be displayed on the Tools screen. Contact Zoetis Technical Support to solve.

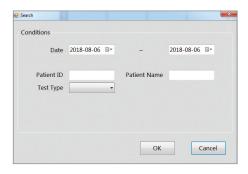
Select the desired patient result using the Database Table located on Left Side Panel. Use scroll bar if more than one page of results. Only results within the last 30 days are shown on the Database Table. Use Search button detailed below if results review of test ran more than 30 days prior is needed.



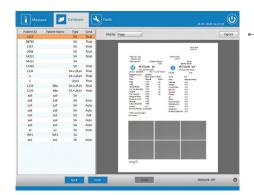


Database Menu (1) No selection (2) Test selected

• Search allows results stored in the database to be located by date range, Patient ID, Patient Name, or Test Type. The oldest and newest record dates are automatically entered into the search date range when the pop-up is opened. Select the desired date range to narrow search.



• Print... provides a print preview of the test performed so that results can be reviewed and printed if needed.



Display Page

The print preview screen can be viewed in Page, Real, or Width display options.

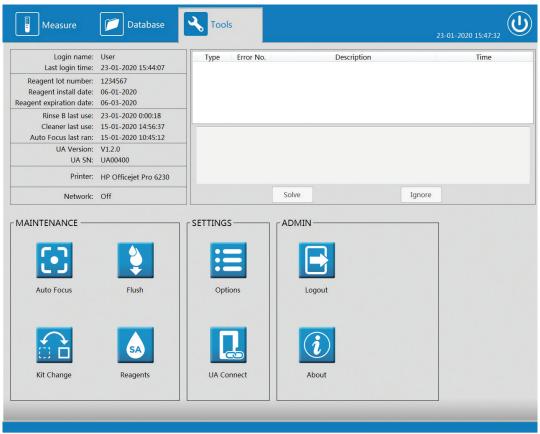
The PDF results can be exported. The file will save as PDF to external flash drive plugged into back of SA. The file name format is the PID + Date/Time of when the file is exported.

Export

#### **Maintenance**

Under the **Tools** selection from the top menu, all the maintenance buttons are provided. Important information is presented along the top left panel indicating login information, reagent lot and expiration, last use of Rinse B, last use of Cleaner, Auto Focus last use, and connection information.

On the right, a Warning and Error Handling Table is displayed with Solve and Ignore functions listed on the bottom. These functions are quick shortcuts to complete maintenance requirements or handle error conditions that are automatically alerted through the software to the user.



Tools Menu

#### Maintenance Schedule

Maintenance	Frequency	Software reminder
Cleaner Reagent Cycle	Once per week	Yes. Prompts user to complete Cleaner cycle before running a new test.
Kit Change	Depends on reagent usage	Yes. Reagent kit or individual rinse depleted warning. Additional time based reminder warning when the pack has been opened 53 days.
Empty Waste Container	Depends on reagent usage	Yes. Reagent waste full warning.
Clean Fan Filter	As needed	No. Check periodically.

It is recommended to complete daily cleaning around the analyzer including wiping off any sample spills. All VETSCAN SA external component parts should be kept clean. The outside and inside of the sample probe will be automatically cleaned with Rinse A after each use. Rinse B will be run automatically daily at midnight.

Do not use the following chemicals to clean VETSCAN SA parts. Exposure to these chemicals may cause plastic parts to crack, craze, etch, or warp.

- Alcohols
  - o Methanol
  - o Ethanol
  - o Isopropyl alcohol
- Chlorinated hydrocarbons
  - o Chloroform
  - o Carbon tetrachloride
- Aromatic hydrocarbons
  - o Benzene
  - O Phenol
  - O Acetone

Do not use abrasive or highly alkaline cleaners (example: undiluted bleach) on VETSCAN SA parts. Do not expose VETSCAN SA parts to temperature > 140 °F (60 °C). Do not sterilize VETSCAN SA parts by autoclaving or dry heat.

#### Cleaner Reagent Cycle

A Cleaner Reagent Cycle is required once per week. The SA software automatically alerts the user when this is required with an alert in the Warning and Error Handling Table:

Туре	Error No.	Description
Warning	W10	Cleaner use is due

#### To run a Cleaner:

- 1. Select the cleaner warning on the Warning and Error Handling Table and click "Solve" button
- 2. Select the Reagents button in the Maintenance section and select Cleaner.

Follow pop-up screens. Place Cleaner reagent bottle under the sample probe and press blue start paddle. Ensure sample probe touches bottom of bottle and maintains contact until the probe starts to move back up.



The Cleaner Reagent Cycle takes approximately 5 minutes to complete. Additional runs of Cleaner are recommended if debris are observed in repeated measurement images. Refer to Appendix H: Troubleshooting for more information.

**Caution**: Wear gloves while handling Cleaner Reagent.

#### Kit Change

Change the complete SA Reagent Kit if one or both Rinse A and Rinse B are empty in the Reagent Kit, or if the Reagent Kit has been installed for over 2 months. The SA software automatically alerts when Rinse A and/or Rinse B are empty or disconnected in the Warning and Error Handling Table:

Туре	Error No.	Description
Error	E5	No Rinse detected
Error	E6	Rinse A empty or disconnected
Error	E7	Rinse B empty or disconnected

Check reagent tubing first to verify the tubes have not been disconnected. Select the Kit Change button in the Maintenance section and follow instructions on the pop-up screen.





After the new Reagent Kit has been primed by the analyzer, the SA will indicate the reagents are ready to use. The SA automatically records the Reagent Kit install date, and then initiates the 2 month expiration countdown for the Reagent Kit on the left side of the Tools screen. If the Reagent Kit is used past its 2 month open expiration time, the SA software automatically alerts that the kit is expired and a new Reagent Kit needs to be installed with an alert in the Warning and Error Handling Table:

Туре	Error No.	Description
Error	E3	Reagent Kit issue - Lot not entered or expired.

Note: Reagents are lot specific, do not transfer Rinse bottles between Reagent Kits. To avoid reagent contamination, do not transfer reagents between bottles.

#### **Empty Waste Container**

The Waste Container must be emptied when full to continue testing. The SA software will automatically alert the user when this is required with a popup and an alert in the Warning and Error Handling Table:

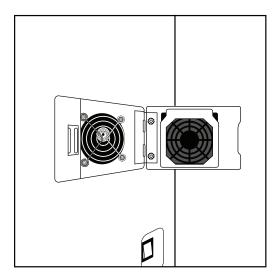
Туре	Error No.	Description
Error	E4	Waste container is full

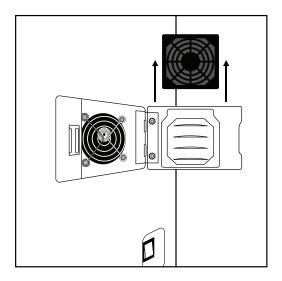
This error appears when the float on the cap of the waste container is lifted. Empty the waste container and click "Retry" on the software on the error warning popup. Before disposing of waste from the VETSCAN SA, consult your local waste disposal regulations and the VETSCAN SA Reagent Kit SDS/MSDS for recommendations.

#### Clean Fan Filter

Check the Fan Filter on the Side Panel Side Door periodically to ensure proper ventilation of the SA analyzer. Check the Fan Filter frequently if the analyzer is in an environment with excessive dust or animal hair.

- 1. Remove the Fan Filter (do not run sample measurement during this cleaning).
- 2. Rinse Fan Filter with warm water to remove debris. Do not remove the foam from the plastic frame.
- 3. Dry the Fan Filter to remove excess water and place it back into the analyzer.





For replacement Fan Filter contact your local Zoetis representative.

## **Software Updates**

The SA Analyzer supports software updates via USB flash drive. Zoetis or a local distributor will contact VETSCAN SA customers when a software update is required. The software update will be completed by Zoetis or a local distributor representative.

# **Settings**

Under the Tools selection from the top menu, two Settings buttons are provided.



1. Options: designed for setting up external printer, printer settings, date/time format, and inputting clinic information to be included on printout. Also the UA connection settings can be verified. See Appendices B and C for instructions.



2. About: details on VETSCAN SA software versions and serial number.



3. UA Connect: designed to reconnect the VETSCAN UA to the VETSCAN SA

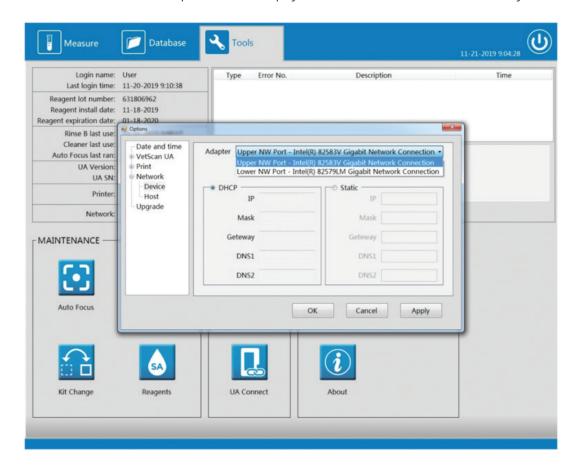


# **VETSCAN SA Network Configuration Settings**

# **SA Device Network Configurations**

Click the Options button under Tools menu and click Network and then Device

The VETSCAN SA has two completely functional network ports located on the back of the SA analyzer. Either port can be used to connect the VETSCAN SA to a network. In the SA Network Device configuration Adapter dropdown, the network ports are referred to as Upper NW Port and Lower NW Port to correspond with their physical location on the back of the analyzer.



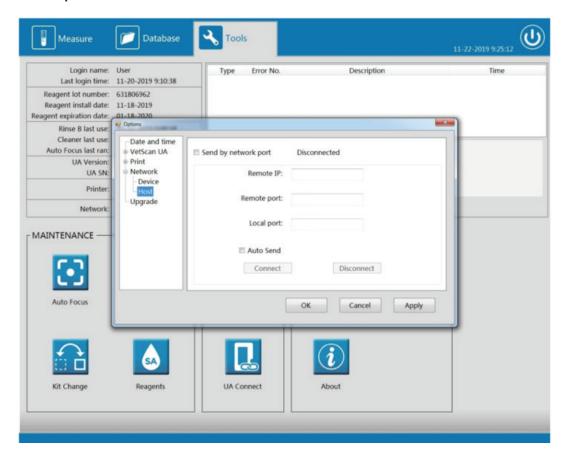
The VETSCAN SA offers both **DHCP** (dynamic) addressing and **Static** addressing capabilities. The SA will default to **DHCP** the first time it is connected to a network.

# **VETSCAN SA Host Configuration Settings**

The VETSCAN SA can connect to a SA compatible Host system, such as the VETSCAN FUSE, using a standard class C network. Once connected to the Host system, enabling bidirectional communication between the Host system and the SA allows the transmission of work orders to the SA from a software application such as a VETSCAN FUSE enabled PIMS.

### **SA Host Configurations**

Click the Options button under Tools menu and click Network and then Host

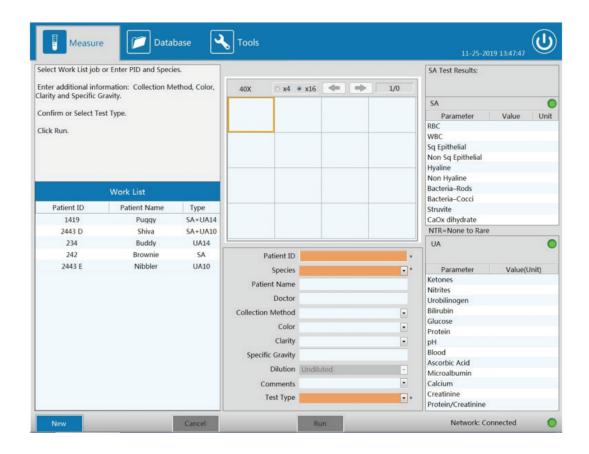


- 1. Enable Send by network port.
- 2. Input the IP address of the Host into the **Remote IP** field (If VETSCAN FUSE is being installed in conjunction with the VETSCAN SA input the VETSCAN FUSE IP address here).
- 3. Input the Local port of the Host (for the VETSCAN FUSE enter 65000).
- 4. Input the Remote port of the Host (for the VETSCAN FUSE enter 65100).
- 5. Enable Auto Send.
- 6. Press the Connect button.

Once the VETSCAN SA has connected to the Host the connection status will change to Connected and the Host configurations will be locked for editing until the VETSCAN SA is disconnected from the Host. Once the VETSCAN SA is disconnected from the Host, the VETSCAN SA's Host settings can be edited.

#### **VETSCAN SA Work List**

With bidirectional communication enabled, the VETSCAN SA will display a Work List on the Measure Screen for running tests ordered from the Host. The VETSCAN SA Work List will display the Patient ID, Patient Name, and the Test Type for each ordered test.



#### **Running Tests from the VETSCAN SA Work List**

- 1. Select the test from the Work List.
- 2. \*\*Use similar formatting and content as found on pg 17). Enter physical characteristics of the sample (recommended):
  - Use the drop-down option lists to select gross examination fields for the sample (Collection Method, Color, and Clarity) for the medical record.
- 3. Enter specific gravity of the sample (recommended): Input specific gravity value of the sample, if available, in format 1.0xx. Specific gravity is often measured using a refractometer.
- 4. Run analyzer workflow for running SA and/or UA tests.

## **Transmitting Results to the Host**

SA and UA results are transmitted to the Host in two ways:

- If the Auto Send option is enabled in the Host configurations, the VETSCAN SA will transmit the result to the Host when the result is saved to the SA's database at the end of a sample run. The result will not be transmitted to the Host until the result is saved to the SA Database. This rule applies to Retest workflows also.
- Results can be transmitted to the Host from the SA Database by selecting the result and clicking the **Send** button.

Once bidirectional communication with a Host is enabled, results in the Database will display the most resent transmission status of a result.

Send Status	Function
Auto	Result successfully, automatically sent to PIMS.
Fail	Result failed sending to PIMS. Network or EMR Error.
Sent	Result successfully sent to PIMS by user manually selecting result from the SA Database and clicking the Send button.
Print	Result has been sent to printer. Result has been manually printed or Auto Print is On with Auto Send Off.
Final	Result has been saved, but not sent to the PIMS and not printed. Auto Send Off and Auto Print is off.
(blank)	Result has been retested with Retest workflow. Result has not been printed and has not been sent to PIMS. If desired, select Print or Send.

PIMS - Practice Information Management System

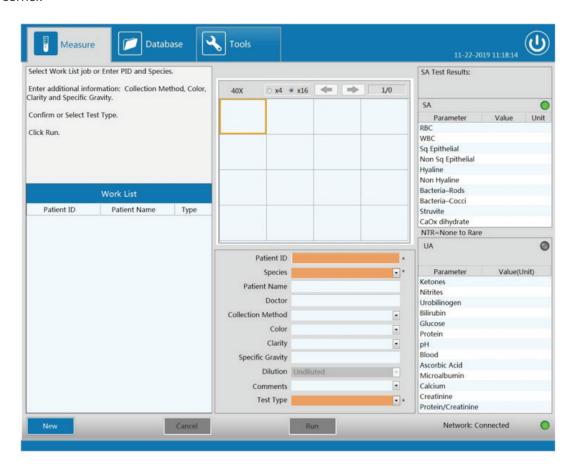
EMR - Electronic Medical Record

## **VETSCAN SA Network/Host Connectivity Statuses**

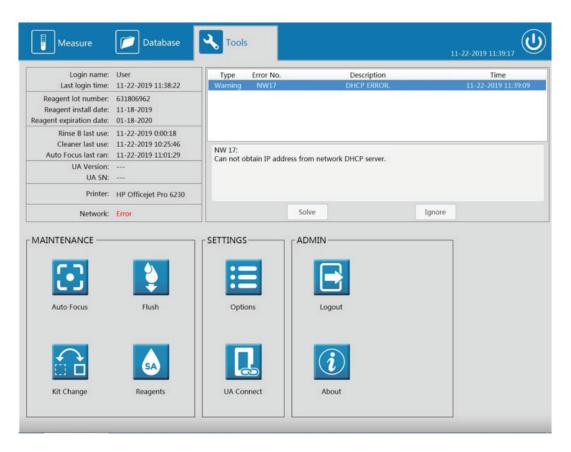
VETSCAN SA Network/Host Connectivity Statuses are only reported if Send by network port is enabled in the Host configurations of the SA.

Туре	Error No.	Description	Icon	Status Definition
N/A	N/A	Off		Send by network port is disabled.
N/A	N/A	Connected		Connectivity between the Host and SA is operational and ready for bidirectional communication.
Warning	NW14	Ethernet Cable Error		No connectivity with the Host because there is no network cable connected to the VETSCAN SA or the network cable connected to the VETSCAN SA is not connected to the network.
Warning	NW17	DHCP Error	0	No connectivity with the Host because VETSCAN SA was unable to get a valid IP address from the network's DHCP server.
Warning	NW18	EMR Error		Connectivity between the FUSE and SA is non-operational.

On the SA Measure and Database Screens, connectivity is displayed in the bottom right-hand corner.



On the SA Tools Screen Network connectivity status is displayed on the Left-Hand side under the Printer Status. Any Network/Connectivity Errors will be reported on the Tools Screen along with an explanation of the Error.



For information about connectivity capabilities, contact technical support. For assistance in the United States and Canada, call 1-800-822-2947 (toll-free phone), and select option 2. For Rest of World, dial +49 6155 780 210 or contact local Zoetis distributor.

# **Appendix A:** Installation Overview

Installation of the analyzer must be performed by an Zoetis authorized representative to ensure that all system components are functioning correctly and to verify system performance.

NOTE: Installation of the analyzer by an unauthorized or untrained personnel could result in damage to the analyzer which is exclusive of the warranty. Never attempt to install without an Zoetis authorized representative.

## **SA Analyzer Installation**

- Keep the analyzer away from direct sunlight.
- Avoid temperature extremes. Refer to Appendix E: VETSCAN SA Analyzer Specifications.
- Installation of the analyzer connected to an uninterruptible power supply (UPS) is recommended.
- · Keep away from sources of vibration or radiation (examples: centrifuge, X-ray equipment, and copier).
- When installing the unit, do not obstruct access to power switch or power cord.

## **SA Reagent Installation**

There are three tube-connectors on the rear panel: Rinse A, Rinse B, and Waste, each of which is covered with a cap to avoid contamination, along with a coaxial BNC Waste Sensor. Ensure containers are placed on the same level as the SA Analyzer and all caps are tight and secure.

Rinse A = Green; Rinse B = Blue; Waste = Black; BNC plug connects to "Sensor"

- Keep the tubes unkinked with slack, no distortion or folding.
- All the tubes should be installed manually by hand. Do NOT utilize any tool. Ensure the twist on connectors at the back of the analyzer are tight and the tube is fully seated on the fitting after every Reagent Kit change, and that there is no sign of reagent leakage.
- If any damage or leakage occurs in the reagent container, contact your local Zoetis representative.

Before disposing of waste from the VETSCAN SA, consult your local waste disposal regulations and the VETSCAN SA Reagent Kit SDS/MSDS for recommendations.

### Display, Keyboard and Mouse Installation

Display Monitor connects with VGA connection. Do not use HDMI or DVI video connectors. The Keyboard and Mouse connect with PS2 connections.

#### **Prepare to Ship**

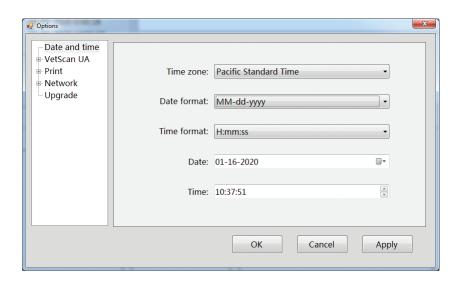
Contact Zoetis authorized representative for instructions.

# **Appendix B:** Date and time Settings

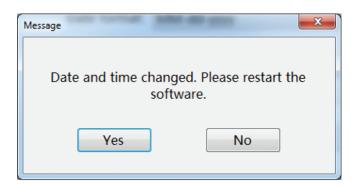
Date and time and date and time format may be updated on the VETSCAN SA.

Click the Options button under Tools menu. Ensure Date and time is selected.

- 1. **Time Zone:** Select time zone
- 2. Format: Select preferred date format. Options include yyyy-MM-dd, MM-dd-yyyy, dd-MM-yyyy.
- 3. Time format: Select preferred time format. Options include H:mm:ss and H:mm:ss tt
- 4. Date: Select date.
- 5. Time: Select time.
- 6. Select Apply.



The analyzer will prompt to restart the software. Click Yes.



# **Appendix C:** Printer Installation

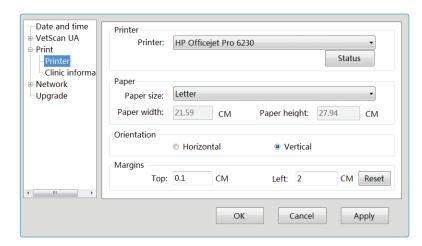
An external printer may be connected to the VETSCAN SA to print test results. Connect the printer and SA Analyzer using a USB cable only. The driver for the HP OfficeJet Pro 6230 is already installed. No other printer drivers are available at this time.

After the printer has been powered on and connected using USB cable to the SA, click the Options button under **Tools** menu and click Printer.

1. Printer: Select Printer Model HP OfficeJet Pro 6230

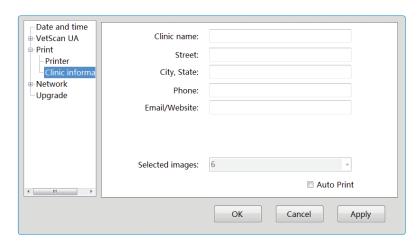
2. Paper size: Select A4 or Letter

3. Click Apply.



Next, go to Clinic information.

- 1. Input clinic information to be included on printout.
- 2. Select the Auto Print check box if desired.
- 3. Click Apply.



# **Appendix D:** UA Installation

A VETSCAN UA analyzer may be connected to the VETSCAN SA to produce a full urinalysis report. The SA analyzer becomes the urinalysis workstation where all data entry will take place and sample runs initiated.

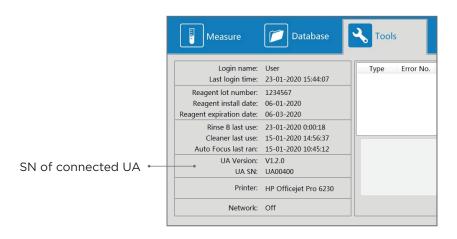
To connect the UA to the SA, use the UA Y Cable provided with the UA analyzer:

- 1. Power on the SA analyzer.
- 2. Plug the USB Standard A end of Y Cable into a USB port on the back of the SA. Do not connect the USB power charger to the third leg of the Y-cable. UA power is provided from the SA.
- 3. Plug the micro USB end of Y Cable into the UA.
- 4. Power on the UA analyzer.

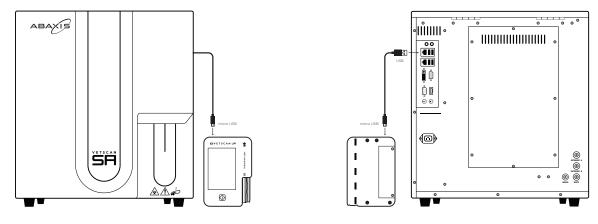
On the SA screen, the UA status indicator light (top right of the UA Results Panel) will turn green if connection is successful.



Also, by clicking on the Tools section from the top menu, you can verify software and Serial Number (SN) of connected UA.



While the UA is connected to the SA, it will no longer be able to print results on the portable UA printer.



# **Appendix E:** VETSCAN SA Analyzer Specifications

## **Dimensions**

• Width: 15.1 in. (383 mm) • Depth: 19.1 in. (485 mm) • Height: 16.8 in. (427 mm) • Weight: 67 lbs. (30 kg)

# **Power Supply**

• AC 100 V - 240 V

• Frequency: 50/60 Hz • Rated Power: 150 VA

## **Operational Requirements**

• Temperature 15-30 °C (59-86 °F)

• Relative Humidity ≤ 85%

• Barometric Pressure 75.0 kPa~106.0 kPa

# **Transport and Storage Requirements**

• Temperature -10-55 °C (14-130 °F)

• Relative Humidity ≤ 95%

• Barometric Pressure 75.0 kPa~106.0 kPa

Display Monitor: VGA connection, 17-inch LCD, resolution 1280 x 1024

Analyzer Software Language: English

# **Appendix F:** Symbols

Symbol	Definition/Use
[i	Consult User's Manual for detailed use instructions.
	Keep away from sunlight.
	Keep away from radiation, heat and direct sunlight.
<b></b>	Protect from moisture. Do not allow to be wet.
<u>11</u>	Keep package right side up.
<b>U</b>	Fragile, handle with care.
1	Storage and transit temperatures; does not indicate operating temperatures.
Z	Recycle only as electronic waste.
<u></u>	Caution: Indicates a hazardous situation, which if not avoided, could result in minor or moderate injury or damage to the equipment.
	Corrosive: Concentrated solution of strong acids or alkalis. Wear gloves and eye protection when using corrosive.
	Potential Biohazard Risk: Treat as biohazard. Use standard safety procedures.
	Manufacturer of record.
	Date of manufacture.
EC REP	Authorized Representative in the European Community.
CE	Denotes conformity to specific European directives.
C VS	Indicates compliance with the requirements of one or more appropriate product safety test standards in the USA and Canada"
	Indicates compliance with Australian safety test standards
RoHS	Compliance with RoHS environmental standards.
3	Do not stack more than 3 units vertically on top of another unit.

Symbol	Definition/Use
5	Do not stack more than 5 units vertically on top of another unit.
<b>∳</b>	Team lift. Required 2 people to lift package of estimated 60-80 lbs (27-36 kg).
FOR VETERINARY USE ONLY	For Veterinary Diagnostic Use only. Not for use for humans.
SN	Serial number.
REF	Catalogue number, list number, or reference.
LOT	Lot number of reagent or control.
$\square$	Expiration date of product.
214	Expiration date of product once opened, 2 months.
HIBC	Health Industry Bar Code standards.

# **Appendix G:** Safety and Regulatory Compliance

### **Safety Warning Labels**

Warning labels posted on the analyzer and in this manual warn you about potential sources of injury or harm. Refer to the Symbols Table to review the meaning of each safety warning label.

Use only the provided power supply and cable when connecting the SA analyzer.

The SA analyzer has been tested and found to be in compliance with all applicable requirements of the following safety and electromagnetic standards:

### **Safety Compliance**

- IEC 61010-1:2010 Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory Use, Part 1: General Requirements
- IEC 61010-2-081:2015 Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory use, Part 2-081: Particular Requirements for automatic and semiautomatic laboratory equipment for analysis and other purposes
- CAN/CSA-C22.2 No. 61010-1-12 Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory Use - Part 1: General Requirements
- UL 61010-1:2012 Safety Requirements for Electrical Equipment For Measurement, Control, And Laboratory Use - Part 1: General Requirement

#### **Electromagnetic Compatibility (EMC)**

- IEC 61326-1:2012 Electrical Equipment for Measurement Control and Laboratory Use EMC Requirements - Part 1: General Requirements, Class A
- EN61326-1:2013 Electrical Equipment for Measurement Control and Laboratory Use EMC Requirements - Part 1: General Requirements, Class A
- EN 61326-2-6:2013 Electrical Equipment for Measurement, Control And Laboratory Use -EMC Requirement- Part 2-6: Particular Requirements - In Vitro Diagnostic (IVD) Medical Equipment
- FCC Part 15 Subpart B:2016

#### **FCC Warnings and Notes**

- Warning: Changes or modifications to this unit, not expressly approved by Zoetis, could void the user's authority to operate the equipment.
- Note: This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable production against harmful interference when the equipment is operated in a commercial environment. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference, at his
- Note regarding FCC compliance. Although this analyzer has been tested and found to comply with Part 15, Subpart B of the FCC Rules for a Class A digital device, please note that this compliance is voluntary, in regard to the cited FCC regulations in effect at the time of manufacture.
- Note regarding Canadian EMC compliance: This digital apparatus does not emit radio noise exceeding the limits for class A digital apparatus prescribed in the Radio Interference Regulations made by the Department of Communications of Canada.

### Waste Disposal

- · A re-usable waste bottle is provided with your new VETSCAN SA. Before disposing of waste from the VETSCAN SA, consult your local waste disposal regulations and the VETSCAN SA Reagent Kit SDS/MSDS for recommendations.
- For equipment disposal, please consult your local waste disposal regulations.

# **Appendix H:** Part Numbers

Zoetis Part Number	Zoetis Part Name
1550-1001	VETSCAN SA Tubing Kit
1550-1002	VETSCAN SA Waste Bottle
1550-1003	VETSCAN SA Keyboard
1550-1004	VETSCAN SA Mouse
1550-1005	VETSCAN SA USA Power Cord
1550-1007	VETSCAN SA Display Monitor
1550-9000	VETSCAN SA Reagent Kit
1550-9001	VETSCAN SA Cleaner Kit
1550-9002	VETSCAN SA Control Kit
750-1500	VETSCAN External Printer
1980-0026	USB Printer Cable
1550-1006	USB Extension Cable
1100-UK	Power Cable UK
1100-JP	Power Cable Japan
1100-EU	Power Cable Europe
1100-AU	Power Cable Australia
1100-DN	Power Cable Denmark
1100-CH	Power Cable Switzerland
1100-IT	Power Cable Italy
1100-IL	Power Cable Israel
1500-8020	VETSCAN UA Y Cable
1500-0014-25	VETSCAN UA14 Strips
1550-0013-50	VETSCAN UA10 Strips
1500-0025	VETSCAN UA Check Strips
1500-0023	VETSCAN UA Control Kit

# **Appendix I:** Troubleshooting

Three troubleshooting techniques can be completed either to remedy a reagent error or as directed by an Zoetis representative:

- 1. Prime: Used to remedy errors occurring with Rinse A or Rinse B, such as a bubble in the line, or loose tubing connections, or as directed by Zoetis representative. Click the Reagents button on the Tools Menu and then select the Rinse desired to Prime. This reagent priming of both Rinse A and Rinse B occurs automatically when changing to a new Reagent Kit.
- 2. Flush: If debris and/or bubbles are observed in the images over repeated measurements, run a Flush to clear the measurement chamber or as directed by Zoetis representative. Click the Flush button in the Tools Menu.
- 3. Drain: used in preparation for shipping or moving a VETSCAN SA.

The VETSCAN SA analyzer hardware is not intended to be serviced by operators. Contact a Zoetis authorized representative if you suspect a problem inside the analyzer. Familiar problems and corrective actions are listed below.

Error/Failure	Potential Causes	Possible Solutions
SA analyzer power and Green Light on SA Power Switch is OFF	<ul><li>1-SA analyzer not powered on.</li><li>2-SA analyzer not plugged in.</li><li>3-No power from power outlet.</li><li>4-SA plug or cord damaged.</li></ul>	1-Turn on SA power switch. 2-Check SA analyzer power cord is firmly connected to back panel of SA and ensure SA analyzer is connected into appropriately grounded power outlet. 3-Confirm power outlet by plugging in another device. Try another power outlet.
		4-Try another SA power cord.
SA analyzer power and Green Light on SA Power Switch is ON	1-SA software not running. 2-Power Supply failure.	1- Check if fan of SA analyzer is running on right side panel vent. If fan is off, the SA software was shut down but the power switch was not turned off. Power the SA analyzer off for 30 seconds and then switch back on.  2-Contact Zoetis representative.

Error/Failure	Potential Causes	Possible Solutions
No Display and Display LED light is OFF	1-Display not powered on. 2-Display not plugged in. 3-No power from power outlet. 4-Display plug damaged.	1-Turn on Display power button. 2-Check Display power cord is firmly connected to Display plug-in and ensure Display is connected into appropriately grounded power outlet. Try another power outlet. 3-Confirm power outlet by plugging in another device. Try another power outlet. 4-Try another Display power cord.
No Display and Display LED light is ON	<ul><li>1-SA analyzer power is off.</li><li>2-SA analyzer is on but SA software is not running.</li><li>3-Display VGA cable loose.</li><li>4-Display has failed.</li></ul>	1-Confirm if SA power switch is set to on and lit with green light. 2-Check if fan of SA analyzer is running on right side panel vent. If fan is off, the SA software was shut down but the power switch was not turned off. Power the SA analyzer off for 30 seconds and then switch back on. 3-Check and reconnect Display VGA cable to SA analyzer and to Display. 4-Connect another Display.
Mouse Error	<ul><li>1-Mouse does not have good optical surface.</li><li>2-Mouse is damaged.</li><li>3-Mouse cable loose.</li></ul>	1-If the mouse is inverted and the red LED is illuminated, it is a surface issue. Use a suitable mouse pad or surface for the type of mouse being used. 2-Replace mouse. 3-Reconnect the mouse cable.
Keyboard Error	1-Keyboard cable loose. 2-Keyboard cable broken.	1-Reconnect the keyboard cable. 2-Replace keyboard.

Error/Failure	Potential Causes	Possible Solutions
Printer Error	1-Printer power LED not on.	1-Power Printer on.
	2-Printer not selected on Tools screen. 3-Printer not shown as option to	2-Select Printer in Settings > Options.
	select in Settings > Option > Print.  4-Printer power cord not plugged in.  5-No power at power outlet.  6-Power cord damaged.  7-USB Printer cable not plugged in correctly.  8-USB Printer cable damaged.  9-Printer error on SA Display.  10-Printer Error only at Printer - Flashing Printer LED's.	<ul> <li>3-Contact Zoetis representative.</li> <li>4-Check Printer power cord connection on Printer and at power outlet.</li> <li>5-Confirm power outlet by plugging in another device.</li> <li>6-Replace power cord.</li> <li>7-Check USB Printer cable connections at SA and Printer</li> <li>8-Replace USB Printer cable.</li> <li>9-Correct Printer popup: paper out, ink out, etc.</li> <li>10-See Printer user manual for details.</li> </ul>
Fuzzy or Blurry Images	<ul><li>1-Thermal conditions have changed - need to refocus.</li><li>2-Bubbles in reagents (black lines in Images).</li><li>3-Chamber needs cleaning.</li></ul>	<ul><li>1-Run Auto Focus; Contact Zoetis representative.</li><li>2-Run Flush; Contact Zoetis representative.</li><li>3-Run Cleaner; Contact Zoetis representative.</li></ul>
Bacteria showing up in all samples	1-Analyzer needs anti-microbial cleaning.	1-Run Cleaner cycle; Run Rinse B cycle.
Sample is not picked up by sample probe	1-Sample probe did not contact sample liquid. 2-Sample probe is clogged.	1-Re-run sample. 2-Run Cleaner; Contact Zoetis representative.
UA analyzer power	1-UA analyzer not powered on. 2-SA analyzer not powered on. 3-UA not plugged into back of SA. 4-UA Y Cable cord damaged. 5-SA USB port damaged.	<ul> <li>1-Turn on UA.</li> <li>2-Turn on SA power switch.</li> <li>3-Plug UA-connected Y Cable into USB port on back of SA analyzer.</li> <li>4-Try another Y Cable.</li> <li>5-Try plugging Y Cable into another SA USB port.</li> </ul>

Error/Failure	Potential Causes	Possible Solutions
UA analyzer not connecting to SA	<ul> <li>1-UA analyzer not powered on.</li> <li>2-UA not plugged into back of SA.</li> <li>3-UA Y Cable damaged.</li> <li>4-SA USB port damaged.</li> <li>5-UA settings not correct on SA analyzer.</li> <li>6-UA settings not correct on UA analyzer.</li> </ul>	<ul> <li>1-Turn on UA.</li> <li>2-Plug UA-connected Y Cable into USB port on back of SA analyzer.</li> <li>3-Try another Y Cable.</li> <li>4-Try plugging Y Cable into another SA USB port.</li> <li>5-Verify settings by selecting VETSCAN UA after clicking Options button under Tools menu and contact Zoetis representative.</li> <li>6-Verify UA Settings by selecting Settings on UA screen. USB Send is ON.</li> </ul>
UA results not transferring over to SA	<ul><li>1-UA analyzer operated independently from the SA.</li><li>2-UA disconnected from SA.</li></ul>	1-Locate UA test report on the UA database and transmit the data by pushing "USB Send" icon. Start next test process on SA.  2-Reconnect UA to SA using Y Cable.

The VETSCAN SA also displays some specific error and warning codes.

Туре	Error No.	Description	Remedy
Error	EO	Comms timeout	Check external connections and restart. Contact Zoetis representative.
Error	E1	Failed to open camera connection	Contact Zoetis representative.
Error	E3	Reagent Kit issue - Lot not entered or expired.	Install a new Reagent Kit.
Error	E4	Waste container is full	Empty the waste container to continue testing.
Error	E5	No Rinse detected	Check tubing, Prime, or do Reagent Kit change if empty.
Error	E6	Rinse A empty or disconnected	Check tubing, Prime Rinse A, or do Reagent Kit change if empty.
Error	E7	Rinse B empty or disconnected	Check tubing, Prime Rinse B, or do Reagent Kit change if empty.
Error	E8	Insufficient space on the disk	Contact Zoetis representative.
Warning	W10	Cleaner use is due	Run Cleaner cycle now.
Warning	W11	Auto Focus is due	Run Auto Focus
Warning	W12	Insufficient space on system disc	Contact Zoetis representative.
Warning	N/A	Warning or Error: Please go to Tools to correct; There is one or more Warnings or Errors shown on the Tools Screen that needs to be corrected before a run can occur (After clicking Run or pressing blue start paddle).  NOTE: The SA Status Light color on the Measure screen will be changed to solid red during these Warning or Error states.	Go to Tools section, Select the Error(s) and/or Warning(s), press the "Solve" button, and follow the Instructions. Solve Errors first.
Camera Error	N/A	Problem with camera connection and this test may be invalid	Check the results for incomplete thumbnails. Contact Zoetis representative.
Camera Error	N/A	Cannot connect to camera	Contact Zoetis representative.
Logged Error	N/A	Serious SA software error condition occurred.	Follow on screen instructions to quit the SA software, and then power cycle the SA analyzer to recover. Contact Zoetis representative.
Warning	NW14	Ethernet Cable Error	Check Ethernet cable is connected at back of analyzer and to network.
Warning	NW16	Static IP Conflict	Contact Zoetis representative.
Warning	NW17	DHCP ERROR	Contact Zoetis representative.
Warning	NW18	EMR Error	Contact Zoetis representative.

## **Zoetis Resources**

Zoetis provides many resources for animal health laboratories and hospitals. The Zoetis website (www.Zoetis.com) contains useful information for running the VETSCAN SA Sediment Analyzer and the VETSCAN SA Reagent Kits. It also contains links to technical notes, manuals, product information, and technical support information as well as technical resources on a variety of applications related to the VETSCAN SA analyzer.

Resource	How to Contact
Local Authorized Zoetis Distributors	Find local Zoetis authorized Distributors on the Zoetis website (www.Zoetis.com).
Technical Information	Find technical information, package inserts and manuals on the Reference Center on the Zoetis website (www.Zoetis.com).
Technical Support	For technical support assistance in the United States and Canada, call 1-800-822-2947 (toll-free phone), and select option 2. For Rest of World, dial +49 6155 780 210 or contact local Zoetis distributor.

# **Appendix J:** Gross Examination, Specific Gravity, and Dilution Fields

On the VETSCAN SA, users can use drop-down option lists to select the Collection Method, Color, and Clarity of each sample for the medical record. Pre-set options included in these lists are:

<b>Collection Method</b>
Cystocentesis
Catheter
Voided
Free catch
Unknown

Color
Colorless
Pale yellow
Dark yellow
Yellow
Yellow-orange
Yellow-brown
Green-blue
Brown-black
Red
Milky
Other

Clarity
Clear
Slightly turbid
Moderately turbid
Extremely turbid

Users can also input a Specific Gravity of each sample for the medical record.

Specific Gravity
1.xxx
1.000 minimum
1.199 maximum

Also, the SA allows the user to dilute the sample with normal saline and will automatically calculate results based on the dilution selected. The SA defaults to "Undiluted" but gives users 3 additional selection options. All sample should initially be analyzed as native or undiluted prior to performing dilutions<sup>1</sup> (Please see Appendix J)

Dilution
Undiluted
1:2
1:4
1:8

- For a 1:2 dilution, add 1 part sample to 1 parts saline. (ex: 0.4 mL, 0.4 mL)
- For a 1:4 dilution, add 1 part sample to 3 parts saline. (ex: 0.2 mL, 0.6 mL)
- For a 1:8 dilution, add 1 part sample to 7 parts saline. (ex: 0.1 mL, 0.7 mL)

<sup>1.</sup> Zoetis Internal VETSCAN SA Dilution Study - TI-04858

# **Appendix K:** Understanding Urine Dilutions on the VETSCAN SA

# Why dilutions are sometimes needed

The VETSCAN SA is able to evaluate cellular and non-cellular elements of the urine by identifying individual elements that are not grouped together or stacked. If large amounts of debris or cellularity are present, dilution may be necessary to enable the identification of individual elements.

#### **Pre-analytical evaluation**

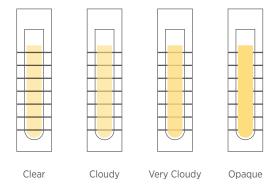
The physical properties of the urine include color and urine clarity, urine odor and urine specific gravity.1 When evaluating the urine color and clarity, urine samples should be evaluated through a clear specimen container.2

Abnormal urine color can result from metabolic conditions, pathological conditions, physical exertion, or drug administration. Urine turbidity could be caused by crystals, cells, mucus, fat, bacteria, casts, and potentially spermatozoa in the urine. A full urinalysis must be performed to differentiate between the potential causes for urine color and urine turbidity.

#### **Analysis**

Urine turbidity can be changed or increased for several reasons, including the presence of crystals, mucus, lipids, bacteria, or casts in the urine. To avoid over dilution and underdiagnosis of pathology in urine sediment, urine samples should not be diluted prior to initial analysis on the VETSCAN SA.3

#### Different levels of urine clarity are shown below:



#### **VETSCAN SA Workflow**

- 1. Evaluate urine sample. Note collection method, color, clarity and specific gravity on the VETSCAN SA Measure screen.
- 2. Mix urine by gently inverting and run sample on the VETSCAN SA.
- 3. Review the VETSCAN SA results and 96 images provided on the initial sediment analysis.
- 4. If enough clinical insight cannot be gathered from the images, a dilution may need to be performed.

1. Sink CA and Weinstein NM. Routine Urinalysis: Physical Properties In: Practical Veterinary Urinalysis. Ames, IA: John Wiley & Sons Inc. 2012. pgs. 19-28. 2. Sink CA and Weinstein NM. Specimen Procurement In: Practical Veterinary Urinalysis. Ames, IA: John Wiley & Sons Inc. 2012. pgs. 9-18. **3.** Zoetis Data on File. Study No. TI-04858

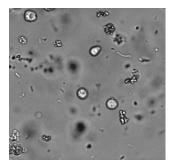
#### Post-analytical evaluation

Dilutions are sometimes necessary on the VETSCAN SA when there are excess amounts of sediment elements that may be overlapping, such as red blood cells.

When this situation is encountered, the VETSCAN SA will not provide quantitative or semiquantitative results and a 'TNTC - Dilute and Retest' message will be provided to the user.

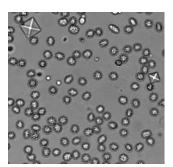
# When 'TNTC - Dilute and Retest' message appears, review the 96 images provided to determine next appropriate steps

Image provides clinical insight



Bacteriuria and pyuria

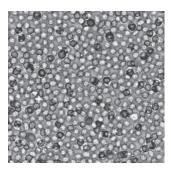
present in sample No dilution required



Calcium oxalate dihydrate crystals present in sample

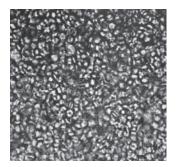
No dilution required

Image provides minimal to no clinical insight



Moderately dense sample due to hematuria; formed elements may be hidden

#### Dilution required



Extremely dense sample due to hematuria; unable to identify additional formed elements due to overlapping cells

#### **Dilution required**

It is not recommended to perform a dilution prior to initial evaluation with the VETSCAN SA, as this could result in missing pathology that is present.<sup>1</sup>

<sup>1.</sup> Zoetis Data on File. Study No. TI-04858

#### How to perform a dilution

If the provided images do not deliver clinically actionable information, a 1:2 dilution should be performed initially3. Increasing dilutions (1:4, 1:8) should be performed until images and/or quantitative or semi-quantitative values provide clinical direction.

<b>Dilution Ratio</b>	Urine Volume	Sterile 0.9% NaCl (saline) Volume
1:2	0.4 mL	0.4 mL
1:4	0.2 mL	0.6 mL
1:8	0.1 mL	0.7 mL

### When performing dilution:

- Use only sterile 0.9% NaCl to dilute urine samples
- Invert tube gently 10-15 times immediately prior to running the sample

NOTE: Diluting a urine sample may alter the sample pH and osmolality, which could lead to changes in cellular appearance or the presence of non-pathogenic crystal formation. Analysis should be performed immediately following dilution.

# **Appendix L:** VETSCAN SA Suggested Normal Ranges

Suggested Ranges - cats and dogs1

Cell Type	Types	Cell/ µL			
	Voided/Free Catch	NTR-50			
Red Blood Cells	Catheterized	NTR-25			
	Cystocentesis <sup>2</sup>	NTR-15			
	Voided/Free Catch	NTR-50			
White Blood Cells	Catheterized	NTR-25			
	Cystocentesis	NTR-15			
	Hyaline	NTR-2			
Casts	Non-Hyaline	NTR-1			
Full alial Calla	Squamous	NTR-10			
Epithelial Cells <sup>3</sup>	Non-Squamous⁴	NTR			
Do atovio 5	Rods	NTR			
Bacteria⁵	Cocci	NTR			
Constala6	Struvite (Triple Phosphate)	NTR to '+'			
Crystals <sup>6</sup>	Calcium Oxalate Dihydrate	NTR to '+'			

#### NTR=none to rare

A single "+" refers to a low level of crystalluria.

For accuracy, normal SA ranges must be interpreted in conjunction with patient clinical signs, sample collection method, urine chemistry analysis, urine specific gravity, and blood chemistry.

<sup>&</sup>lt;sup>1a</sup> Adapted from Chew, Dennis and DiBartola, Stephen, Interpretation of Canine and Feline Urinalysis. Nestle Purina, Wilmington, De, 1998, p 65.

 $<sup>^{1</sup>b}$  SA directly measures cells in cells/ $\mu$ L of urine. Due to no prior published veterinary ranges in urinary cells/ $\mu$ L, suggested ranges are converted from reference la using conversion formula with VETSCAN SA specific variables on file at Zoetis. Formula cited in Conrad dos Santos, Juliana et al. "Evaluation of Urinalysis Parameters to Predict Urinary Tract Infection," Brazilian Journal of Infectious Disease, 2007;11 (5); 479-481.

<sup>&</sup>lt;sup>2</sup> An increased number of erythrocytes may be present due to trauma from needle puncture.

<sup>&</sup>lt;sup>3</sup> Few transitional squamous epithelial cells can be normal in dog and cat urine depending on collection method used. The size can be variable, but cell clumping is considered abnormal.

<sup>&</sup>lt;sup>4</sup> Non-squamous epithelial cells are rare with cystocentesis, but their limited presence on catheter samples and free catch is to be expected.

<sup>&</sup>lt;sup>5</sup> Bacteria are not normally present in the urine of dogs or cats, however, small numbers may contaminate samples collected by voiding or catheterization.

<sup>6</sup> Crystals are evaluated qualitatively. Struvite and calcium oxalate crystals may be found in normal dogs and cats, and do not guarantee ooliths are present. Urate crystals can be normally found in Dalmatian urine.

# **Appendix M:** VETSCAN UA Results Bins

On the VETSCAN UA, the test results are classified into semi-quantitative bins.

Analyte	Result Type Species Semi-Quantitative Symbol and Concentration											
	Semi-Quantitative	*	-		/-	+1		2	+3			
LEU	Cell/µL (CON)	*	0	15	5	70	1	25	500			
	Cell/µL (SI)	*	0	15	5	70	1	25	500			
KET	Semi-Quantitative	*	-		/-	+1	+	-2	+3			
	mg/dL (CON)	*	0			15		10	≥80			
	mmol/L (SI)	*	0	0	.5	1.5			≥8.0			
	Semi-Quantitative (CON)	*										
NIT	Semi-Quantitative (SI)	*										
URO	Semi-Quantitative	*		+	1	+2	+	·3				
	mg/dL (CON)	*	Normal	2	2.0 4.0		2	≥8.0				
	μmol/L (SI)	*		3	33 66		2	±131				
	Semi-Quantitative	*	-		1	+2	+	·3				
BIL	mg/dL (CON)	*	0	0	.5	2	6	j				
	μmol/L (SI)	*	0	8	.6	33	1	00				
	Semi-Quantitative	*	-	+	/-	+1	+	2	+3	+4		
GLU	mg/dL (CON)	*	0	5	0	100	2	50	500	≥10	≥1000	
	mmol/L (SI)	*	0	2	.8	5.5	1	4	28	≥55	≥55	
PRO	Semi-Quantitative	*	-	+	/-	+1	+	2	+3			
	mg/dL (CON)	*	<15	15	5	30	1	00	300			
	g/L (SI)	*	<0.15	0	.15	0.3	1		3			
SG	(no units)	*	1.000 1.01		1.015	1.020	1.020 1.030		1.045	1.050	1.060	
рН	(no units)	*	5.0	5.5	6.0	6.5	7.0	7.5	8.0	8.5	9.0	
•	Semi-Quantitative	*	-	+	/-	+1 +2		2	+3		1	
BLD	Cell/µL (CON)	*	0	10	0	25	8	80	200			
	Cell/µL (SI)	*	0	10	0	25	8	80	200			
	Semi-Quantitative	*	-	4	+/-	+1	+	-2	+3			
ASC	mg/dL (CON)	*	0	10	0	25	5	0	100			
	mmol/L (SI)	*	0	0	.6	1.4	2	.8	5.6			
	/ !!	*	<2.5		2.5							
	mg/dL (CON)											
MA	4. (0)	*	<25	:25 ≥2								
	mg/L (SI)											
C-	mg/dL (CON)	*	≤4.0	10	0	20	3	0	≥40			
Ca	mmol/L (SI)	*	≤1.0	2	.5	5	7	.5	≥10			
CR	mg/dL (CON)	*	<b>≤</b>	5	0	100	2	00	≥300			
	mmol/L (SI)	*	≤0.9		.4	8.8	1	7.6	≥26.4			
		Dog &	.0.2		≥0.2 to ≥0.5 to			»2 N				
PRO/	(no units)	Other	<0.2		0.5	<2.0	2	2.0				
CR	CON & SI same	Cat			:0.2 to 0.4	≥0.4 to <2.0	2	2.0				
C-1	( , , , , , , , , , )	*	T		· II			\l	-	2		
Color	(no units)		Transparent		Yellow Orange		1	Red	Green	Oth	el	

In general, urine dipsticks including those for the VETSCAN UA contain a number of different parameters, some of which are not reliable or have not been well linked to disease processes in veterinary medicine. Parameters which should be ignored include nitrites, leukocytes, ascorbic acid, calcium and urobilinogen.<sup>1</sup> For improved precision, urine specific gravity is best assessed with a refractometer and color is best assessed visually. The primary use of CRE on the UA14 strip is for calculating the urine protein: creatinine ratio, and CRE should not be evaluated on its own.

<sup>1.</sup> Sink CA and Weinstein NM. Routine Urinalysis: Chemical Analysis In: Practical Veterinary Urinalysis. Ames, IA: John Wiley & Sons Inc. 2012. pgs. 29-53.



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