SediVue Dx* Urine Sediment Analyser User Guide

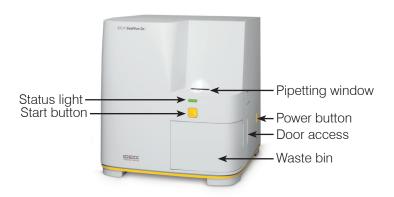




Analyser components

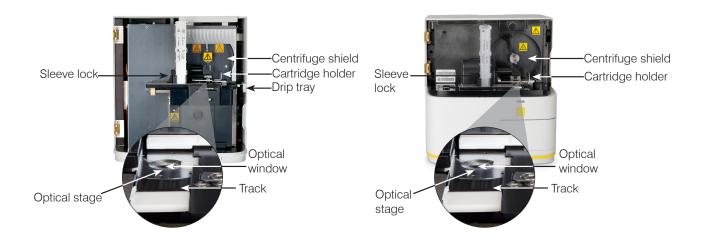
Note: Your analyser may look slightly different from the photos shown below.

Front of the analyser



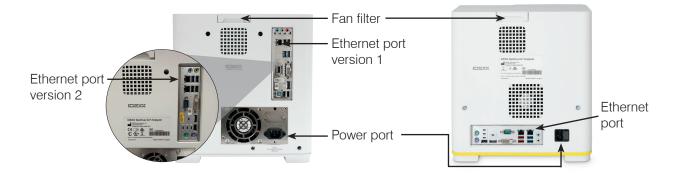
Inside of the analyser

Match the inside of your analyser to the applicable image below.



Back of the analyser

Match the back of your analyser to the applicable image below.



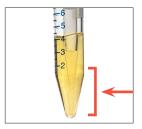
Sample preparation

Urine samples can be obtained via cystocentesis, catheterisation or free catch method, and should be analysed within 30 minutes of collection (or stored in the refrigerator and returned to room temperature prior to analysis).

If the sample is in a container:

- 1. Cap the container and invert it 10 times to mix a wellmixed sample is essential to obtaining accurate results.
- 2. Immediately after inversion, use the SediVue* Pipette to aspirate 165 μ L of sample from the bottom half of the container, ensuring there are no bubbles in the sample.

When using the pipette, follow these important guidelines:



- Crystals settle immediately after inversion. Aspirate from the bottom half of the container.
- Remove excess urine on the tip with a lint-free wipe.



- Hold vertically.
- ONLY depress plunger to the first stop.
- Use only IDEXXsupplied pipette tips.

If the sample is in a syringe:

- 1. In a 1 cc–5 cc syringe containing at least 0.5 cc of urine, draw 0.5 cc of air into the syringe.
- 2. Replace the needle with a SediVue* Syringe Tip.
- Gently invert the syringe 10 times to mix the sample.
- Immediately after inversion, purge all of the air from the syringe and inject 165 μL of urine into the cartridge fill port.



Analysing a sample

- 1. Initiate the sample run on the IDEXX VetLab* Station.
- 2. Confirm the patient information, select the **SediVue Dx** icon and then tap **Run**.
- 3. Follow the sample preparation guidelines on the previous page.

IMPORTANT – When injecting sample into the cartridge:

- Ensure the sample fills the cartridge window but not the overflow channel.
- Make sure the pipette tip is firmly seated into the fill port on the cartridge.
- Using light downward pressure, depress the plunger slowly to avoid air bubbles.
- Only depress plunger to the first stop.
- Lift the pipette from the fill port before you release the plunger.
- 4. Press the **Start** button on the front of the analyser.

Replacing the cartridge sleeve

You'll receive a message on the IDEXX VetLab Station when the cartridge sleeve is almost empty. You can choose to be reminded again after the next run or when the cartridge sleeve is empty.

1. Tap the **SediVue Dx** icon on the IDEXX VetLab Station Home screen and then tap **Replace Cartridges**.

OR

Tap Replace Cartridges in the alert message.

2. Follow the on-screen instructions.

IMPORTANT: Do not remove the tape from the sleeve until it is locked into place.

- 3. Close the analyser door.
- 4. Tap **OK** to confirm that the loading process is complete.



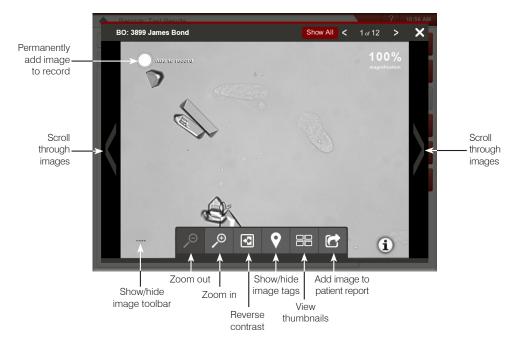


Reviewing and selecting images

By default, the first three images display alongside the results on the Records: Test Results screen. You can use the View Images feature to add up to three additional images, change the magnification of an image and show image tags next to identified sediment.

Note: The View Images feature will display 12 of the 70 images captured during analysis. If additional images are required to confirm results, tap **Show All** (at the top of the screen) to view the remaining 58 images.

- 1. On the SediVue Dx tab of the Records: Test Results screen, tap View Images.
- 2. Tap the image that you want to view. Then you can:



Performing a dilution

1. Initiate the sample run on the IDEXX VetLab Station. OR

If the patient has already been run once, select the patient from the Recent Test Results list, tap **Add Test** and then tap the SediVue Dx icon.

- 2. Tap Run Dilution.
- 3. Use the up/down arrows to specify the desired dilution factor (total parts).
- 4. Tap Run or Append Results.
- 5. In a test tube, mix the urine with the selected parts of 0.9% normal saline.
- 6. Mix the sample 10 times and then immediately inject $165 \,\mu\text{L}$ of the diluted sample into the cartridge fill port.
- 7. Press the **Start** button on the analyser. The results will be adjusted by the dilution factor and noted that the sample was diluted.
 - If the dilution does not yield semiquantitative results, repeat the process using a higher dilution factor.

Note: Diluting a urine sample may affect the pH and osmolality of the sample and lead to changes in cellular appearance and the presence of crystals.



Enter the dilution information in the centre of the Select Instruments screen.

Running quality control on your analyser

The purpose of quality control is to verify the integrity of your results and to verify that your analyser is functioning optimally. IDEXX recommends that you perform quality control once per month.

Note: Keep SediVue* QC in the refrigerator – DO NOT freeze. SediVue QC has a 12-month dating.

- 1. Tap the SediVue Dx icon on the IDEXX VetLab* Station Home screen.
- 2. Tap Quality Control, select the QC lot you are using and then tap Run QC.
- 4. Gently invert the vial 10 times to ensure the cells at the bottom of the vial are completely suspended.
- 5. Using the SediVue* Pipette with a new pipette tip, aspirate $165 \,\mu$ L of L1 QC fluid and inject it into a cartridge.
- 6. Press the **Start** button on the analyser.
- 7. Repeat the above steps for the L2 QC vial.
- 8. Verify the results are in the target ranges and that the images are sharp and in focus.

Cleaning the analyser

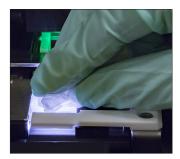
To ensure the optimal performance of your SediVue Dx* Urine Sediment Analyser, it's recommended that you clean the internal components of the analyser on a routine (monthly) or as-needed basis.

Note: You'll need alcohol prep pads and optical tissues when performing routine and preventive maintenance. Need to order more? Get them free at order.idexx.com.

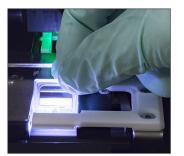
To clean after a cartridge was overfilled or filled incorrectly

For best results, after you notice that the cartridge has been inappropriately filled, **do not press the Start button as this will drag urine into the internal components of the analyser**. Instead, follow the instructions below.

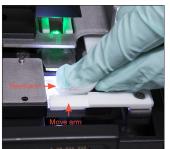
Note: Already pressed the Start button? Follow the instructions for routine monthly maintenance.



 Open the analyser door. Then with gloved hands, use an optical tissue to absorb urine on top of the cartridge.



2. Remove and dispose of the cartridge.



3. Using a new alcohol prep pad, clean the feed arm (dispense area), including the front of the move arm. Then dry the components with an optical tissue.



 Close the analyser door. Once the SediVue Dx icon has a green, "ready" status, tap the patient icon on the IDEXX VetLab* Station Home screen and tap Start Run. A new cartridge is placed in the pipetting window.

To clean the internal components

There are two very similar models of the SediVue Dx analyser, and the process for cleaning their internal components (see next pages) can vary slightly. The biggest visual difference between the two models is their analyser door – one model's door is the full size of the front of the analyser and the other is about half the size of the front of the analyser. Be sure to follow the appropriate steps for your model.









IMPORTANT: Be sure to use these specific tools as mentioned in the following steps.

Tools needed:

- 1 pair powder-free latex or nitrile gloves
- 9 dry optical tissues
- 1 damp optical tissue (dampened with warm water)
- 3 rinsed alcohol prep pads (rinsed in warm water and squeezed dry)
- 3 alcohol prep pads (not rinsed)
- Paper towels



 On the SediVue Dx Settings screen, tap Clean and then tap Turn Off SediVue.



Is your analyser door the full size of the front of the analyser?

your analyser (monthly or more frequently, if needed)

If so, use the instructions on this page to clean the internal components of

If your analyser door is about half the size of the front of the analyser, use the instructions to the

 Open the analyser door and clean the top and bottom of the pipetting window with a damp optical tissue. Then dry with a new dry optical tissue.



 Remove the cartridge holder, clean it with a new alcohol prep pad, dry it with a new dry optical tissue and then set it aside.



4. Using a new rinsed alcohol prep pad, clean the left side of the pusher arm five times (ensuring the right edge of the track is cleaned thoroughly) and then dry it with a new dry optical tissue.



5. Press the pusher lever to the left and repeat step 4 on the right side of the pusher arm using a new rinsed alcohol prep pad.



6a. Using a new rinsed alcohol prep pad, clean the optical stage and track repeatedly to remove all debris. Then dry with a new dry optical tissue.

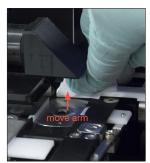


6b. Using a new alcohol prep pad (not rinsed), clean the optical window using a circular motion (3–4 times) and then dry it in a circular motion with a new dry optical tissue.

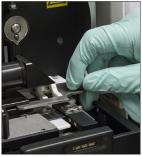
IMPORTANT: Do not exert excess pressure on the optical window.



 Remove the centrifuge shield, waste bin and drip tray. Then clean them with warm water and dry them with paper towels.



 Using a new alcohol prep pad (not rinsed), clean the move arm and then dry it with a new dry optical tissue.



9. Return the waste bin, drip tray, centrifuge shield and cartridge holder to their locations in the analyser.



10. Remove the fan filter, rinse it thoroughly with warm water, pat it dry with a paper towel and return it to its location in the analyser. Then on the SediVue Dx Cleaning Guide screen, tap **Done** to power on the SediVue Dx.



IMPORTANT: Be sure to use these specific tools as mentioned in the following steps.

Tools needed:

- 1 pair powder-free latex or nitrile gloves
- 6 dry optical tissues
- 1 damp optical tissue (dampened with warm water)
- 4 alcohol prep pads
- Paper towels



 On the SediVue Dx Instruments screen, tap Turn Off SediVue and then tap Shut Down.



Is your analyser door about half the size of the front of the analyser? If so, use the instructions on this page to clean the internal components of

If your analyser door is the full size of the front of the analyser, use the instructions to the left.

your analyser (monthly or more frequently, if needed)

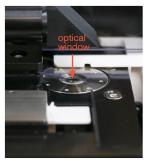
2. Open the analyser door and clean the top and bottom of the pipetting window with a damp optical tissue. Then dry with a new dry optical tissue.



 Remove the cartridge holder, clean it with a new alcohol prep pad, dry it with a new dry optical tissue and then set it aside.



4. Using a new alcohol prep pad, clean the cartridge track and the white feed arm thoroughly. Then dry them with a new dry optical tissue.



- Using a new alcohol prep pad, clean the optical window using a circular motion (3–4 times) and then dry it in a circular motion with a new dry optical tissue.
 - **IMPORTANT:** Do not exert excess pressure on the optical window.



 Remove the centrifuge shield and waste bin. Then clean them with warm water and dry them with paper towels.



 Gently move the centrifuge arm to the left and inspect the area below it for debris. If it's dirty, use a new alcohol prep pad to clean it and then dry it with a new optical tissue.



 Using a new alcohol prep pad, clean the move arm and then dry it with a new dry optical tissue.



 Return the waste bin, centrifuge shield and cartridge holder to their locations in the analyser.



10. Remove the fan filter on the back of the analyser, rinse it thoroughly with warm water, pat it dry with a paper towel and return it to its location in the analyser.



11. On the SediVue Dx Instruments screen, tap **Turn On SediVue Dx** to power on the SediVue Dx.

Understanding your results

In addition to determining results, the SediVue Dx* convolutional neural network verifies image and result quality with each run. If the image quality cannot be verified or if confirmatory methods should be considered, a message will appear at the bottom of your results indicating possible next steps.

Dilutions

Samples containing large quantities of overlapping cells, crystals or debris may require manual review of the images to determine results or a dilution to spread the sediment apart so the convolutional neural network can detect and classify the formed elements.

Preanalysis dilutions

There are times during the physical evaluation of the **clarity** and **colour** of urine samples when it's obvious that samples will be crowded with cells, bacteria, debris or crystals (e.g., gross haematuria). This evaluation will aid in determining if a dilution should be considered preanalysis.

Image: state s	Does the colour of the sample suggest evidence of haematuria?
	Red Dark red Brown

Consider a 1:5 dilution with 0.9% normal saline, remix the diluted sample and rerun.

Postanalysis dilutions

When a *crowded* sample is run on the SediVue Dx analyser, a message will appear, the semiquantitative results are not reported and you will be prompted to review the images and consider a dilution. If the images do not provide clinical insight, diluting the urine sample will help to spread the elements apart for more accurate analysis. The dilution ratio will vary depending on the severity of the crowding in the sample.

If the images are crowded and:

- Provide clinical insight, no dilution is needed just add comments to the patient record.
- There is a moderate amount of cells or crystalline material, perform a 1:5 dilution with 0.9% normal saline and rerun.
- There are marked amounts of cells or crystalline material, perform a 1:10 dilution with 0.9% normal saline and rerun.

Note: If the majority of sediment is able to be visually identified in the original images, the SediVue* Bacteria Confirmation Kit may be more helpful than a dilution in determining the presence of bacteria.

Out of focus

When the *Review images to confirm results* message appears, the convolutional neural network cannot verify the quality of focus in the images. This may occur when the sample does not have enough sediment to confirm the quality of focus or if the images are out of focus. If this message appears in several consecutive samples with sediment present, the optical window may require cleaning.

Bacteria (suspect presence)

When the Confirm bacteria with one of the following: image review, SediVue Bacteria Confirmation Kit, air-dried, stained cytological preparation ("dry prep") or urine culture message appears, bacteria may be present in the sample. The images should be reviewed to determine if there is sufficient evidence of bacteriuria by identifying uniformly sized structures or if the small structures are in the form of chains or doublets. If bacteria cannot be visually confirmed in the images, consider additional confirmatory steps as recommended. For more information on how to run the SediVue Bacteria Confirmation Kit or how to perform a dry prep, visit **idexx.com/library**.



Bacteria (present)

When the *Consider urine culture and sensitivity* message appears, bacteria are present in the sample. When this occurs, consider a culture to confirm the bacteria are viable and to provide additional evidence of bacteriuria.

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