

ESR Analyzer

Alifax[®] 20PN[™]

Quick Guide



Roller 20PN Start-up

Start-up and Login

NOTE: Sample collection tubes, wash tubes, and tubes used for bleach should be the 13 x 75 mm tubes, or 13 mm in diameter, and from 75 to 83 mm high (including the cap). Use the Hemogard type of cap.

1. Prepare:
 - Check the Waste Tank level. Replace if needed, per instructions on Page 13.
 - Check the Internal Wash Bottle level; refill as needed.

NOTE: There is no liquid level control for this Wash Bottle, and manual observation is required. See page 13 for further instruction.

2. Press the Main Switch on upper backside. Internal checks begin automatically, and the Main Menu displays.
 - At the first switch on, wait 3 minutes before starting analysis cycle to allow thermal stabilization.

3. Touch [Setup], then touch [Log In-Out].

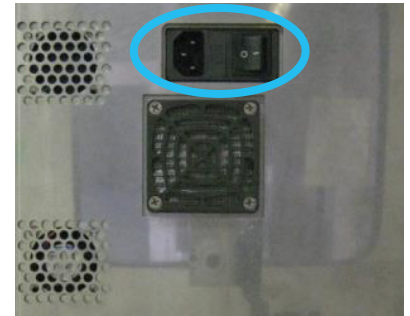
4. Touch [LOGIN]; a keypad displays.

NOTE: To Log-out, touch [LOGOUT].

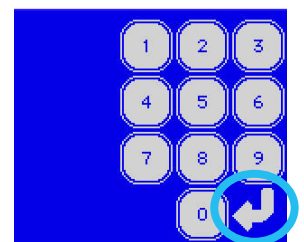
5. Type the password "1010" (user-level access).

6. Touch the "left arrow," to confirm.

7. Touch [Back] to return to the Main Menu.



Main Switch



Daily maintenance and quality control

Daily Maintenance and Quality Control

NOTE: At the beginning of each Latex Control session, perform one of the two washes below, depending on which mode will be used:

- Use the Internal Wash if samples will be analyzed internally
- Use the External Wash if samples will be analyzed externally (using the sample probe)

Internal Wash and Quality Control (perform prior to internal analysis)

NOTE: Always follow any bleaching procedure with washes of distilled water.

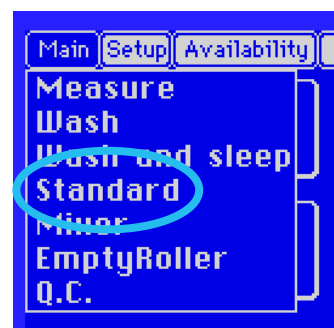
Materials required:

- 3 vials of distilled water, filled to 3/4 full (please use standard 13 mm diameter x 75 size vials)
- 1 vial of 5% sodium hypochlorite, filled 3/4 full
- 3 vials of Latex Control (1 Triplet; vials, 2, 3, and 4)



Latex Control Triplet

1. From the Main Menu, touch [Wash], then touch [Internal].
2. When prompted, load 2 vials of distilled water into roller positions 1 and 2.
3. When prompted, close the front door. When the wash completes, extract the vials as prompted. "WAIT" displays.
4. From the Main Menu, touch [Wash], then touch [Internal].
5. Insert the vial of 5% sodium hypochlorite into roller position 1.
6. Insert a vial of distilled water into roller position 2.
7. When prompted, close the front door.
8. When the wash completes, extract the vials as prompted. "WAIT" displays.
9. From the Main Menu, touch [Main], touch [Standard], then touch [Internal]. "WAIT" displays.
10. When prompted, insert a capped vial of distilled water into roller position 1.
11. When prompted, enter the ID for Latex Control vial 2, either manually or with the handheld Barcode Reader.
12. Insert the tube into roller position 2.
13. Follow the steps above to enter the IDs for Latex Control vials 3 and 4, and insert the vials into roller positions 3 and 4.
14. Insert 2 capped vials of distilled water into roller positions 5 and 6, as prompted.
15. Close the door. "WAIT" displays, and analysis begins.
16. When analysis is complete, the Latex Reference Values display on the screen. The Latex Absolute Levels for Sens1 and Sens2 are displayed and printed. Select [EXIT].
17. Follow the prompts to remove the tubes and close the door. The Main Menu returns.
18. Compare the Latex Reference Values which display with the values on the Latex Control outer packaging.



Follow laboratory protocol for documenting and troubleshooting Quality Control results exceeding the upper or lower limit of acceptability.

(Steps for the External Wash and Quality Control procedure are listed on the next page)

Roller 20PN Daily maintenance

External Wash and Quality Control with Internal Mixing (perform prior to external analysis, which uses the sample probe)

NOTE: Always follow any bleaching procedure with washes of distilled water.

Materials required:

- 3 vials of distilled water, filled to 3/4 full (please use standard 13 mm diameter x 75 size vials)
- 1 vial of 5% sodium hypochlorite, filled to 3/4 full
- 3 vials of Latex Control (1 triplet; vials 2, 3 and 4)



1. From the Main Menu, touch [Wash], then touch [External].
2. When prompted, insert an uncapped vial of distilled water into the sample probe.
3. Select [START] to begin aspirating. "WAIT" displays. "PHOTOMETER OK" displays and prints when Wash is complete.

NOTE: After the complete contents of the distilled water are aspirated, the analyzer continues to sound as if it's aspirating; this is not of concern, as one vial of water 3/4 full is adequate.

4. From the Main Menu, touch [Main], touch [Standard], then touch [External].
5. "INSERT WASH TUBE" displays. Insert a vial of distilled water into roller position 1.
6. When prompted, enter the ID of Latex Control vial 2, either manually or by using the handheld Barcode Reader.
7. Insert Latex Control vial 2 into roller position 2.
8. Follow the prompts to enter the IDs for Latex Control vials 3 and 4, and insert the vials into roller positions 3 and 4.
9. Insert 2 capped vials of distilled water into roller positions 5 and 6. When prompted, close the door.
10. "WAIT" displays, and mixing begins. When "WASH" and "START" display, remove the vial of distilled water from roller position 1, uncap it, and insert the vial into the sample probe.
11. Select [START].
12. After aspiration, the analyzer prompts to "wipe the probe." Follow the prompts that display on the screen.
13. Extract Latex Control vial 2, uncap it, and insert the vial into the sample probe to begin the priming process.
14. Select [START] and follow the prompts.
15. After priming, gently mix Latex Control vial 2, and insert the vial into the sample probe. Select [START] to begin analysis.
16. Repeat the steps to extract Latex Control vials 3 and 4 from the roller, aspirate each vial using the sample probe, and aspirate washing vials 5 and 6 using the sample probe; wipe the probe after each aspiration.
17. After processing is complete, the Latex Absolute Levels for Sens1 and Sens2 display and print. Select [EXIT].
18. Compare the final displayed Reference Values with the values on the Latex Control outer packaging.
19. The analyzer returns to the Main Menu.

Interpreting Analyzer QC Print-out

Latex Control Printout:

```
LATEX 2: 1534 257889
LATEX 3: 0980 257889
LATEX 4: 0637 257889
```

Part 1:

Barcodes of latex inserted:
 Latex 2: first barcode of latex read
 Latex 3: second barcode of latex read
 Latex 4: third barcode of latex read

```
LOT N: 1237 R11 887
=====
JAC 1   736  -> 734
JAC 2   753  -> 748
JAC STOP 716  -> 713
```

Part 2:

Latex lot number and progressive number of the lot.
 Values of the DAC before and after washing

```
:external Wash
sens 1   3803
sens 2   3801
sens STOP 3805
PHOTOMETER OK
```

```
:external Wash
sens 1   3794
sens 2   3791
sens STOP 3794
PHOTOMETER OK
```

Part 3:

Washing sequence, here instrument print out the water values of the three tubes (1st before latex and then last 2 after latex)
 Also report if Photometer is OK or NOT OK

```
:external Wash
sens 1   3796
sens 2   3791
sens STOP 3794
PHOTOMETER OK
```

```
Reading latex
```

```
ROLLER 20 Plus Needle
SN: 1
Y10_UI-03.00B
Y10MOT-03.00B
Y10ANA-03.10B
14/03/2012
14:03:06
```

Part 4:

Operative parameters set to the Reading Unit:
 Type of reference (EDTA)
 BoosterY (EDTA, in base to the reference chosen)
 MFact 1
 MFact2
 Temperature

```
PREAUTOSET
REFERENCE: EDTA
BY EDTA: 1.3448
MF1: 1.3900
MF2: 1.3910
Offset1: -60.74
Offset2: -74.85
:thermo: 37.0 (Set: 37)
```

Part 5:

This part of the instrument printout provides the Control Values

```
Reference values
LEVEL2 = 9 ( 6 : 11)
LEVEL3 = 19 (15 : 22)
LEVEL4 = 65 (56 : 74)
      sens1 sens2
LEVEL2 =   9   9
LEVEL3 =  20  20
LEVEL4 =  69  68
```

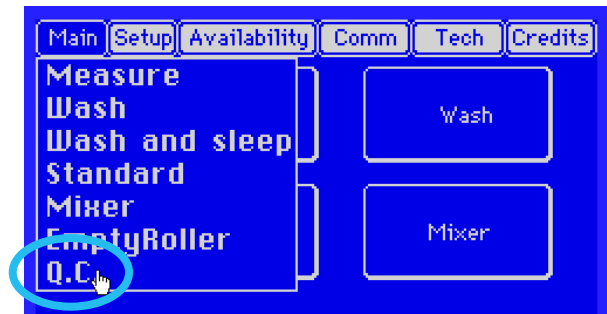
Reference values (range)

Measured values (QC Results)

Quality control checks

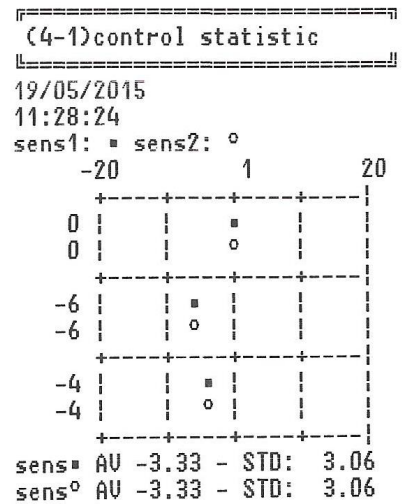
Quality Control Checks

- A photometrical check is performed each washing cycle.
- Data from Latex Control and Washing results may be viewed by touching [QC] from the Main Menu.
- Choose Internal or External



Latex Control Kit Verification

Touch [Print (4-1)] to print. The printout covers the last 30 days of analysis, and shows how the read Latex values differ from the reference values on the box. If the values obtained by the analyzer fit the expected range in Table 2 of the Latex Control Kit package, the analyzer is calibrated; if the values are out of range, contact the Technical Assistance Center. Most recent values are displayed at the top.

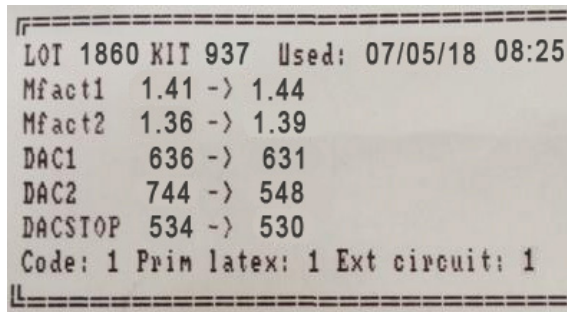


Datalogger

Touch [Datalogger] to print a report of results from the latex calibration procedure, including:

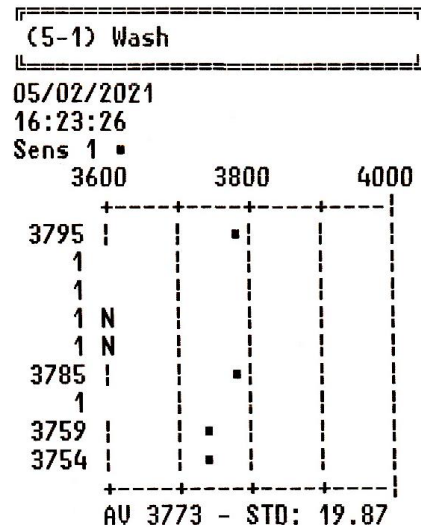


- LOT number
- KIT number
- Date of withdrawal
- Mfact1 old and new
- DAC1 and DAC2 old and new
- DACSTOP old and new
- Ext circuit
- Prime latex
- Code for how the barcode was entered



Washing Quality Control Printout

Touch [Print (5-1)] to print. This displays the trend in Washing values detected by the analyzer's sensors, which correlate to the photometric signal. The analyzer is automatically regulated to a value of 3800 during Washing with distilled water; the value decreases as residue builds.



Roller 20PN Sample processing

Sample Processing

Sample volume requirements	
Minimum sample volume (dead space)	800 uL
Internal Aspiration volume	
- First 2 samples (also contains priming volume)	232 uL
- Each additional analysis	175 uL
External Aspiration volume	
- Single analysis	100 uL
- Additional needed for priming	100 uL
Result range	2 - 120 mm/h

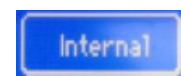
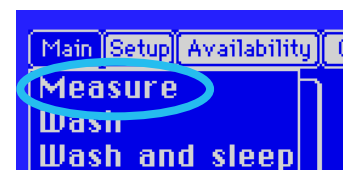
NOTES:

- If samples are run after a wash is performed, the analyzer will execute Priming during the sample analysis procedure.
- If the waste tank is full, replace the waste tank; otherwise, the analyzer remains in standby.

Internal Analysis with Internal Mixing

NOTE: Up to 20 samples may be processed in the roller at one time.

1. From the Main Menu, touch [Measure].
2. The available credits display, if <1000. Touch [OK]. Select [Internal].
3. Enter the Sample ID, using one of the following ways:
 - Using an external handheld Barcode Reader.
 - Manually; touch [Manual ID], type the ID, touch the [left arrow]
 - Auto-generate a progressive ID; touch [Auto].
4. Open the front door.
5. Insert the sample vial into roller position 1, as prompted.
6. Add additional tubes or touch [Measure].
7. Close the door. Mixing and Priming begin.
8. Analysis results display and print. Touch [OK].
9. When prompted, open the door and remove the sample vial. The display returns to the Main Menu.



Sample processing

External Analysis with Internal Mixing

1. Touch [Main] in the Main Menu. Touch [Measure]. The available credits display, if < 1000. Touch [OK].
2. Select [External]. "WASH" displays, then "WAIT" displays.
Refer to the External Wash and Quality Control with Internal Mixing procedure on Page 4.
3. Enter the Sample ID, using one of the following ways:
 - Using an external handheld Barcode Reader.
 - Manually; touch [Manual ID], type the ID, touch the [left arrow].
 - Auto-generate a progressive ID; touch [Auto].
4. Touch [OK]. Open the front door.
5. Insert the sample vial into roller position 1.
6. Add additional tubes or touch [Measure].
7. When prompted, close the door.
8. If this analysis is performed after a wash, the analyzer will now request Priming; when prompted, remove the sample vial from roller position 1 and close the door. Priming may be executed using a previously analyzed sample or using the same sample that is to be analyzed, given that it is at least 1.5 mL. If Priming is not triggered, proceed to Step 12.
9. Insert the sample probe into the uncapped Priming sample vial; if using a previously analyzed sample, mix it first, according to laboratory protocol.
10. Touch [START]. When prompted, remove the Priming vial, cap it, and wipe the probe.
11. The screen displays "Insert." Open the door and insert a capped sample into roller position 1.
12. Close the front door. Mixing begins.
13. Mixing completes. When "Extract Vial" displays, remove the sample vial from roller position 1.
14. Uncap the sample vial and insert the sample probe. Touch [START].
15. The analyzer begins the measurement process. After the vial is aspirated, wipe the probe.
16. Repeat these steps to extract the remaining sample vials from the roller and aspirate them using the sample probe. As prompted, wipe the probe after each vial is aspirated.



External Analysis without Internal Mixing

NOTES:

- It is recommended to mix patient samples for at least 3 minutes prior to external analysis.
 - If this analysis is performed after a wash, the analyzer will now request Priming. Priming may be executed using a previously analyzed sample or using the same sample that is to be analyzed. If Priming is not triggered, proceed to Step 3.
1. From the Main Menu, touch [Main] then touch [Measure]. The credit availability displays, if < 1000. Touch [OK].
 2. Touch [External without mixing]. Enter the Sample ID. Touch [OK].
 3. Mix the sample as directed by the note above, then uncap the vial.
 4. Insert the sample probe into the sample vial. Touch [START].
 5. When aspiration completes, the analyzer beeps. Remove the vial and re-cap. When prompted, wipe the probe.
 6. Touch [OK]. Follow these steps to process additional samples, or touch [Back]. The Main Menu returns.



Roller 20PN Sample processing

Analysis Results

The analyzer displays the results of each analysis. Based on printer setup, the analyzer may also print the results of each analysis as follows:

Havailability
 ESR = 137
 10/03/2012
 10:38:30
 R10_UI-03.00B
 SN: 101
 10/03/2012
 10:39:05
 SESS. 01

Date and time of analysis
 Session number (01 = first session of the day)

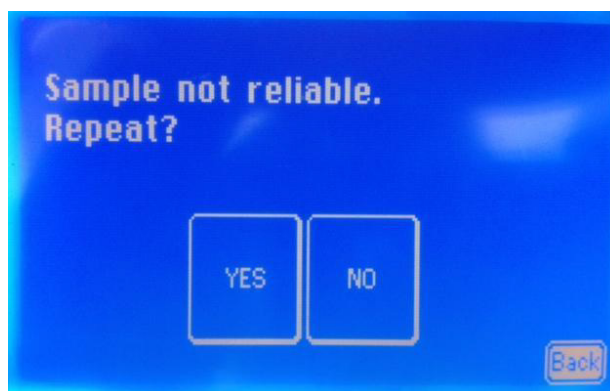
In order of analysis,	patient ID and	ESR results	(mm/h)
1	4049208802	ESR	7
2	4048984703	ESR	46
3	4049141205	ESR	2
4	4049169002	ESR	15



Analysis Results - Repeat

If a value is undetected during the first sample analysis, the analyzer displays the screen to the right:

- Select [YES], then [START] to process the sample again.
- OR Select [NO] or [Back] not to run the sample again; the analyzer displays and prints one of the following:
 - "NF" = No blood flow was detected; the vial was removed prematurely, there was not enough blood, or a clot obstructed the tip.
 - OR "NR" = Sample not reliable; repeat the sample or examine the profile for possible pathologies.



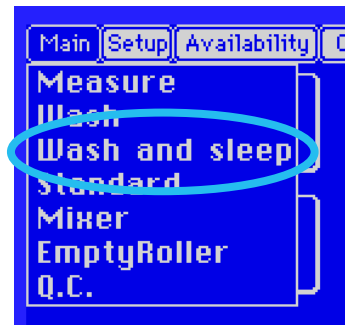
NOTE: The following may appear in the printout of the analysis results:

- * = the Hematocrit may affect the Westergren result, if comparing to this method; Alifax result is valid.
- NF = the analysis wasn't completed properly; 3 consecutive "NF"s will trigger analysis to stop and prompt a wash cycle.
- NR = result is not reliable

Daily maintenance

Daily Wash and Shutdown (End of day washing procedure - Wash and Sleep)

1. From the Main Menu, touch [Main], then touch [Wash and Sleep].
2. Touch [Internal] or [External] depending on modes used.
3. Choose [Internal]. Open the door when prompted.
 - a. Load two capped vials of DI water filled $\frac{3}{4}$ full, into the rotor. When prompted, close the door.
 - b. The analyzer prints a report on the photometer. When prompted, remove the vials and close the door.
 - c. When prompted, insert a third capped vial filled $\frac{3}{4}$ full of DI water into position 1.
 - d. When prompted, close the door. The "POWER OFF please" screen appears.
 - e. Press the Main Switch to Power off the analyzer.
4. For [External], insert the probe into a vial $\frac{3}{4}$ full of DI water.
 - a. Touch [Start].
 - b. Remove vial when aspiration is complete. Wipe probe.
 - c. Analyzer information prints. Touch [Back].
 - d. Power off when prompted.



Main Switch

Wash for Maintenance

Perform this wash based on number of ESR samples analyzed a day or for troubleshooting needle or capillary obstructions.

- 1-20 samples per day: perform every 2 weeks
 - 21-40 samples per day: perform weekly
 - >41 or more samples per day: perform twice a week
1. Execute a first washing procedure by touching [Main] then [Wash], then [Internal].
 2. Load 2 capped vials filled $\frac{3}{4}$ full of DI water into the first and second positions of the rotor. Close the door.
 3. Execute a second washing procedure by touching [Main] then [Wash], then [Internal].
 4. Load one capped tube filled $\frac{3}{4}$ with 5% Sodium Hypochlorite and place in the first position of the rotor followed by a vial filled $\frac{3}{4}$ with DI water in the second position. Close the door.
 5. Execute a third washing procedure by touching [Main] then [Wash], then [Internal].
 6. Load 2 capped vials filled $\frac{3}{4}$ full of DI water into the first and second positions of the rotor. Close the door.

Roller 20PN As-needed maintenance

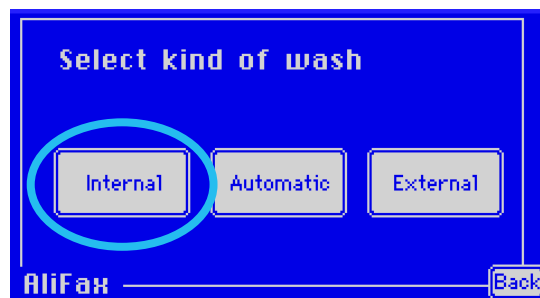
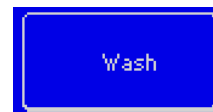
NOTE: If a Wash procedure runs incorrectly and the screen displays "PHOTOMETER NOT OK," perform the wash again.

Internal Wash

NOTE: Perform this wash if analyzing samples using internal withdrawal.

Materials required:

- 2 vials of distilled water, filled to 3/4 full
1. In the Main Menu, touch [Wash].
 2. Select [Internal].
 3. When prompted, load 2 vials of distilled water into the roller.
 4. When prompted, close the front door.
 5. The analyzer prints a report on the photometer. Touch [OK].
 6. When the wash completes, remove the vials.



External Wash

NOTE: Perform this wash if analyzing samples using external withdrawal.

Materials required:

- 1 vial of distilled water, filled to 3/4 full
1. In the Main Menu, touch [Wash]. Select [External].
 2. Insert the sample probe into a vial of distilled water. Touch [START]. After all of the water aspirates, remove the vial.
 3. The analyzer prints a report on the photometer. Touch [Back].



Automatic Wash

NOTES:

- Perform this wash throughout the day when a wash is needed, such as after a period of sitting idle.
 - When the wash time limit has exceeded, an Automatic (Internal) wash will be performed.
1. In the Main Menu, touch [Wash]. Select [Automatic].
 2. The analyzer uses the water available in the internal washing tank to execute the wash; no vials are required.
 3. The analyzer prints a report on the photometer. Touch [OK].



Analyzer-Prompted Wash Procedure

NOTE: Automatic wash can also be performed for the internal mode.

Materials required:

- 2 vials of distilled water, filled to 3/4 full
1. From the Main Menu, touch [Wash]. Select the type of wash: Internal OR External
 2. Load 2 vials of distilled water, into positions 1 and 2 of the roller. Touch [OK].
 3. When the Wash completes, the analyzer prints a report on the photometer parameters and displays the message "PHOTOMETER OK." Press [OK].
 4. If requested to by an on-screen message, repeat the procedure. Press [OK]; the Main Menu displays.

As-needed maintenance

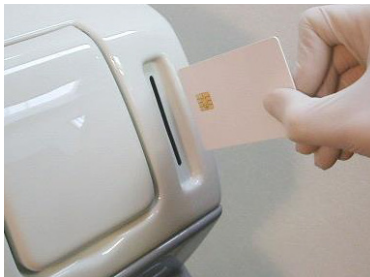
Alifax Smart Test Card - Increase Tests

NOTE: Blood analysis with the Roller 20PN requires the use of a Smart Card. At the beginning of each analysis session, a warning message alerts the user that they must increase the test availability. If there is no test availability, the analyzer will display "no credits available," and the analyzer will be idle.

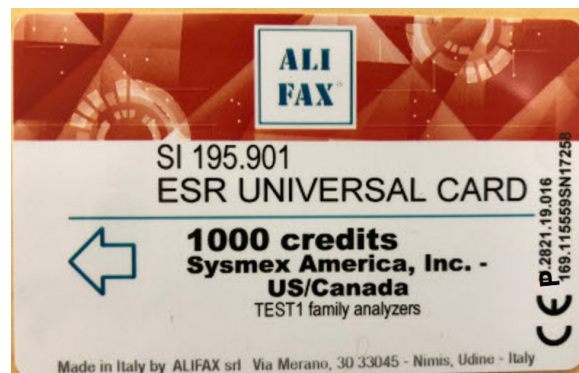
1. While the Main Menu displays, insert the Smart Card into the slot.
The credit availability displays and prints.
2. Press [OK], then remove the card when prompted by the analyzer.
The Main Menu returns, and displays the increased credits.



Correct



Incorrect



Roller 20PN As-needed maintenance

Refill/Replace Internal Wash Bottle

NOTE: Check the water level in the Internal Wash Bottle at least once per day, to ensure proper maintenance.

1. Open the main, gray door of the unit, using the "push" button on the bottom.
2. Open the Internal Wash Bottle, and refill/replace with distilled water.

Internal
Wash
Bottle



Waste
Tank

Replace Waste Tank

- An internal sensor checks the level of the waste tank every time the analyzer is powered on, and at the beginning of every Wash procedure and at the end of every cycle.
- It's important to NEVER REMOVE OR CUT the waste tank discharge tube, which must be AT LEAST 45 mm long.
- To dispose of the waste tank contents, follow your laboratory's procedure.



Replace Printer Paper Roll

NOTE: When replacement is required, a message displays "PAPER ENDED."

1. Pull the plastic lever of the printer. Lift up the plastic cover and remove the old roll's plastic core.



2. Insert the new paper roll, with the paper feeding underneath and through the slot at the bottom.



3. Close the plastic cover. Press the [>>] button, then touch [OK]. Wait for the analyzer to complete internal checks.



Due to regulatory requirements, the products listed herein are available for sale in any relevant Country territory provided that they have been registered according to the applicable domestic law. Program availability varies by location. Programs and specification subject to change without notice. Sysmex has exclusive distribution rights with Alifax to provide ESR analyzers in Mexico, US and Canada.

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