REF 034C

General Regenerating Solution

034C-19161

INTENDED USE

EC Regenerating Solution is intended to be used to perform a regular cleaning of measuring electrodes, during and/or after EC Milk analyses performed with the EC CL-10 Plus, EC CL-10 Micro and EC Microlab EFA instruments. This kit is not to be used in any human clinical or veterinary diagnostic application.

Part No: 034C

KIT COMPOSENTS

R1 : Regenerationg solution – Ready to use – 1 × 200 ml

MATERIALS

For the procedure performed with the EC CL-10 Plus and EC CL-10 Micro

- 2 mL vial
- 250 mL bottle
- Pasteur pipette
- Distilled water
- EC Polif (Part No: 034A)

For the procedure performed with the EC Microlab EFA

- 1 mL vial
- Electrode protection solution (i.e. skimmed milk)
- Disposable Pasteur pipette
- EC Combi Clean (Part No: 034D)
- EC Polif (Part No: 034A)

USE OF THE REAGENT

The regenerating cleaning procedure must be performed once a week as routine maintenance and when storing the instrument.

CLEANING PROCEDURE

The procedure is described on page 2-3 of this directions for use.

Figure 1 defines the different steps of the procedure performed with the EC CL-10 *Plus* and EC CL-10 *Micro* instrument.

Figure 2 defines the different steps of the procedure performed with the EC *Microlab EFA* instrument.

For trouble-shooting and further maintenance use, please consult the respective instrument operating manual.

Figure 1 – ***Flowchart for EC CL-10 Plus, EC CL-10 Micro***

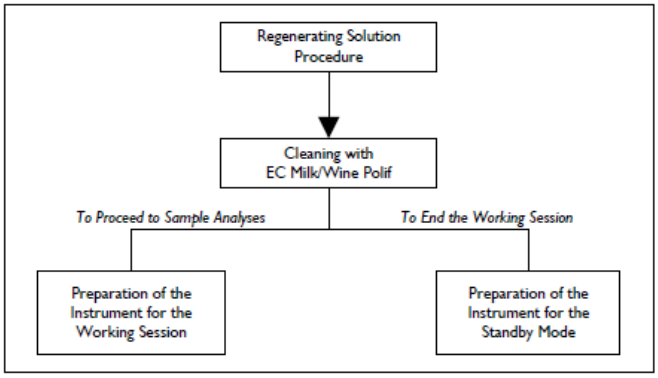
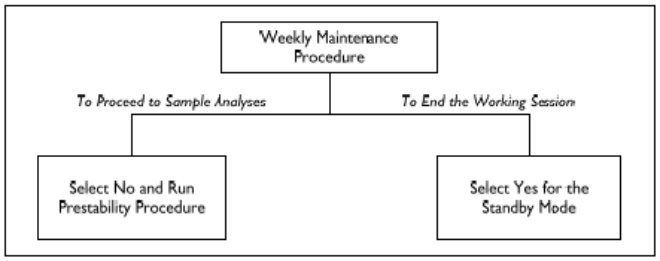


Figure 2 – ***Flowchart for EC Microlab EFA***



A. Cleaning Procedure Performed with EC CL-10 Plus and CL-10 Micro

a) For instrument regular weekly maintenance

1. Start the EC CL-10 Plus or EC CL-10 Micro software.
   In the *File* menu choose *Select method* and click on intended method *(*.MD)* to use.
2. Place the Regenerating Solution in the buffer position.
   Place the inlet tube going from buffer pump 4 into the bottle.
3. Insert the starter needle going into enzyme pump 6 into a vial containing at least 2 mL of distilled water.
4. Run *Prime enzyme* once using the prime enzyme icon or the F2 function key.

5. Run *Clean* twice using the clean icon or the F3 function key.
6. Wait for five minutes.
7. Run *Clean* again using the clean icon or the F3 function key

8. Replace the Regenerating Solution with a bottle containing reconstituted wash solution from EC *Polif* kit.

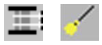
9. Run *Clean* five times using the clean icon or the F3 function key.
10. If you intend to proceed to the sample analyses: follow the procedure in the package insert of the respective EC Milk product from the session, “Preparation of the instrument.”
11. Instead, if you intend to leave the instrument in standby mode:
    a. Check that enough diluted wash solution is left for the estimated stand-by period (the wash cycle automatically runs every 90 minutes and consumes about 5.0 mL of reconstituted wash buffer for each cycle).
    b. In the Service menu, choose Enter REST mode.
    c. Leave the instrument with the power on. Turn the monitor off.

    Note: If the instrument will not be used for a longer period of time make sure that a sufficient amount of wash buffer is available or consult the operator manual for instructions on shutting down the instrument.

b) Instrument preparation for long periods of inactivity

12. Start the EC CL-10 Plus or EC CL-10 Micro software. In the *File* menu choose *Select method* and click on intended method *(*.MD)* to use.

13. Place the Regenerating Solution in the buffer position. Place the inlet tube going from buffer pump 4 into the bottle.
14. Insert the starter needle going into enzyme pump 6 into a vial containing at least 2 mL of distilled water
15. Run *Prime enzyme* once using the prime enzyme icon or the F2 function key.
16. Run *Clean* twice using the clean icon or the F3 function key.



17. Wait for five minutes.
18. Run *Clean* again using the clean icon or the F3 function key
19. Replace the Regenerating Solution with a bottle containing distilled water.

20. Run *Clean* three times using the clean icon or the F3 function key.
21. Replace the distilled water bottle with an empty bottle.

22. Run *Clean* three times using the clean icon or the F3 function key. The system will intake air.
23. Empty the waste bottle.
24. Unplug the pump tubings from their housings (see Appendix A).
25. Switch the instrument off.
26. Switch the PC off.
27. Unplug.

B. Cleaning Procedure Performed with EC Microlab EFA

c) For instrument regular weekly maintenance

Note: Recommended procedure to be carried out on weekly basis as routine maintenance (it grants electrodes decontamination after intense use).

28. Select the *Maintenance* button from the main EFA Instrument window.
29. A *Method Message* window will appear. Click the *Continue* button.
30. Select the *Weekly Maintenance (option 1)* and press *OK*. A message will appear to confirm the choice: press *OK*.
31. Select the *option 1 (Complete Maintenance*) and press *OK*.
    Pipettor (Option 2) may be used when you wish to clean only the needle.
32. A Method Message window will appear. Follow the instructions:
    d. Place a vial containing *Combi Clean Solution* (from EC *Combi Clean* kit, GEN674) in position 12 of the buffer rack.
    e. Place the Regenerating Solution in position 11 of the buffer rack.
    f. Connect a vial containing wash solution (from EC Polif, GEN718) to peripump no. 3 of the measuring unit.
    g. Place a vial containing 1 mL of Electrode Protection Solution (i.e. skimmed milk) in position 1 of the sample rack.
    h. Press any key.
33. The pipettor will decontaminate the needle and the measuring unit with the Combi Clean Solution.
    A timer will appear indicating the remaining time necessary for the contamination. Wait for the completion of process.
34. After this step the pipettor will decontaminate the measuring unit with the Regenerating Solution.
    A timer will appear indicating the remaining time necessary for the contamination. Wait for the completion of process.
35. At the end of the process, the Maintenance window appears again. Abort the program.
36. A Method Message window will appear:
    a. If you intend to leave the instrument in standby mode, select *Yes*. Turn off the PC and the pipettor arm.
    b. If you intend to proceed to the working session, select *No.* From the Service menu select *Prestability (option 1)* and follow the instructions *(for the details please consult the instrument's Operator Manual)*.

d) Instrument preparation for long periods of inactivity

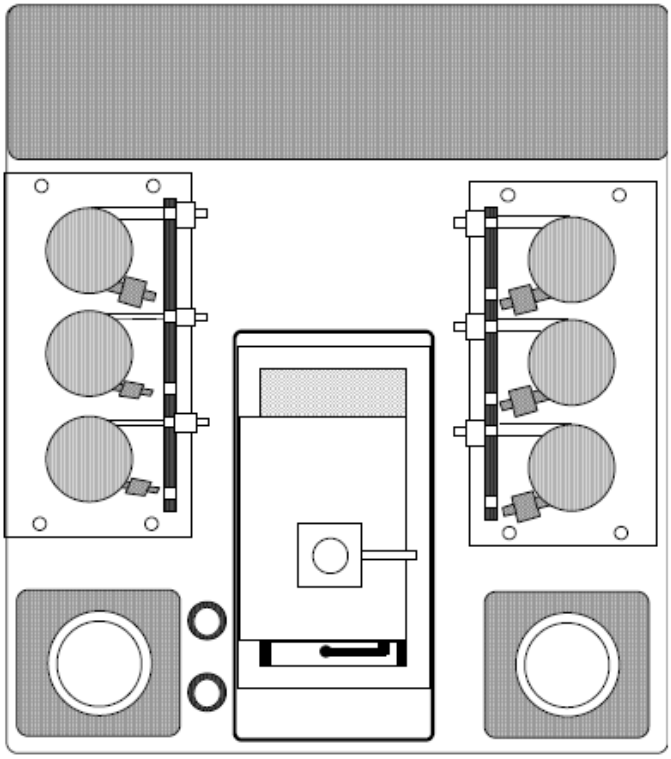
Before switching off the measuring unit, remove all liquid in the mixing chamber, electrodes and tubes.

37. Run and complete the Weekly Maintenance program (see above instructions steps 1-9).
38. Replace the vial containing the wash solution (from EC *Polif*, GEN718) with a vial containing distilled water.
39. Press the *PrimeTools* button. Select *Measuring Unit Prime (option 2)* and press *Yes*. Repeat the wash cycles at least three times.
40. Replace the bottle containing distilled water with an empty bottle.
41. Press the *PrimeTools* button. Select *Measuring Unit Prime (option 2)* and press *Yes.* Repeat the wash cycles at least four times until the circuit is empty.
42. Unplug all the pump tubings.
43. Put the black cap on top of mixing chamber.
44. Empty the water reservoir.
45. Press the *PrimeTools* button. Select *Needle Prime (option 1)* and press *Yes*. Repeat the wash cycles at least two times until all the system is dry.
46. Switch off the measuring unit and the pipettor.
47. Remove syringe and plunger from the syringe.

Note: For instrument start up, please consult the Operator manual following the installation procedure.

APPENDIX A – UNPLUG THE PUMP TUBINGS

Figure 3 – ***Overview of the EC CL-10 Plus and EC CL-10 Micro instruments.***



STORAGE CONDITIONS

The reagent is stable at room temperature.

SAFETY

Good laboratory practice should be employed when using this kit. Safety clothing should be worn and skin contact with reagents avoided. Do not ingest.

Material safety data sheets are available on request.

EXP *use before* *Date d'expiration*	REF *catalogue number* *N° dans le catalogue*	⚠ *Attention*	*Biosentec* *65 Allée Campferran* *31320 Auzeville-Tolosane*
LOT *Lot* *N° de lot*	*Store at room temperature* *Conserver à temperature ambiante*	*Notice utilisation* *Operation note*	