Beaumont Laboratory
Royal Oak

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Supersedes:
Related Documents:

RU-20 REAGENT UNIT OPERATION

RC.HM.PR.081.r00

Purpose

The purpose of this procedure is to provide guidelines for the laboratory technologists regarding the operation of the RU-20 reagent unit.

Principle

The RU-20 Reagent Unit dilutes concentrated CELLPACK® DST with RO (Reverse Osmosis) water to the required density and feeds the prepared reagent to the connected XN analyzers. The prepared reagent is then aspirated from this unit automatically by the analyzers.

Reagents

1. Cellpack DST (DST)
    a. Concentrated diluent of reagent for use in hematology analyzers connected to RU-20.
    b. Cellpack DST Storage-Store at 2º-35ºC away from direct sunlight.
    c. If frozen, thaw and mix thoroughly before using.
    d. Cellpack DST is clear and colorless. If it is showing signs of contamination or instability such as cloudiness or discoloration, replace.
    e. Cellpack DST Stability:
        i. It is stable until expiration date printed on the container.
        ii. Opened, it is stable for 60 Days.

CELLPACK DST Hazard Risk-The OSHA Hazard Communication Standard of 29CFR part 1910.1200 requires MSDS documentation of ingredients which have been determined to be health hazards, comprise 1% or greater of the composition, are physical hazards, are capable of release to exceed permissible exposure limit/threshold limit values or have been identified as carcinogens. CELLPACK DST does not have ingredients with those characteristics.

CAUTION: Do not ingest. Avoid skin and eye contact. Flush with plenty of water immediately. Consult with a physician in case of ingestion and/or eye contact.

2. RO (Reverse Osmosis) Water
    a. Dilute CELLPACK DST concentrated reagent for use on XN-Series analyzers.
    b. Water must meet the following specifications:
        i. Electric conductance: 1.0 µS/cm or less
        ii. Supply pressure: 0.2 MPa to 0.4 MPa
        iii. Supply volume: 10 L/hr to 50 L/hr
        iv. Water temperature: 100C to 300C
        v. TOC (Total Organic Compounds 500 ppb or less
    c. Water meeting these specifications is commonly referred to as Special Reagent Water (SRW) or Type I per CLSI guidelines.

Quality Control

1. Reagent is prepared and checked internally by a conductivity sensor, which allows the software to determine if the mixed reagent is within specifications. This ensures that diluted Cell-Pak from the DST cube is within proper specifications and will not allow contaminated diluent to be used when sampling specimens on the XN.
2. Within the software menu, the Quality Log records the reagent preparation history with:
    a. Date
    b. Time
    c. Conductivity
    d. Reference Voltage
    e. Result
    f. Electrode
    g. Temperature
    h. Thermistor voltage results
3. Up to 1000 events can be recorded in this log and are removed from the list by first-in-first out process.

Procedure

1. **Start-up [Not Routinely Performed]**
    a. Power ON the Reagent Unit using the switch located on the left front of the Main Unit.
    b. Once start-up is complete, the Status screen displays.
    c. Power ON the connected XN-Series analyzers.

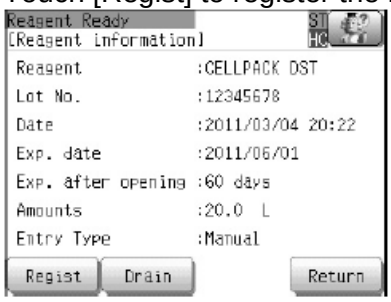
NOTE: The Reagent Unit must be powered on and "Ready" prior to turning on the power to the connected analyzers. Reagent errors may occur on the connected analyzers if start-up is not performed in the appropriate sequence.

2. **Shutdown [Not Routinely Performed]**
    a. Power OFF the Main Units of the XN-Series analyzers connected to the Reagent Unit.
    b. Touch [Shutdown]-Screen below appears.

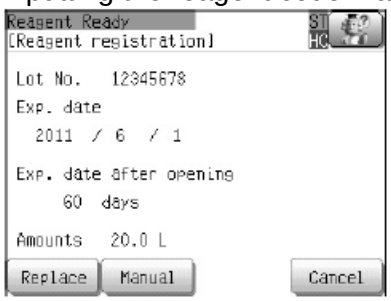
    c. Touch [OK]
    d. Turn off the power switch on the RU-20 Main Unit.
    e. Warning: Do not turn the RU-20 power off unless instructed by an authorized Sysmex representative. Re-starting the RU-20 without first performing the shutdown sequence will take approximately 40 minutes.

NOTE: The system cannot be shutdown when the instrument is in the [Not ready] state. If the reagent adjustment operation is not finished, shutdown will take place without starting the next adjustment operation when the adjustment operation currently being executed is completed. If an error occurs during shutdown, the [Error] dialog will appear. Touch [OK] to close the dialog, clear the error, and then re-execute shutdown.

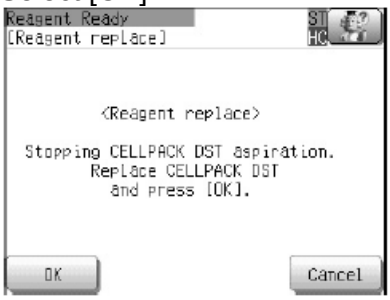
3. **Reagent Replacement via IPU –Normal routine process for DST replacement**
    a. Click on DST icon in lower right corner.
    b. Double click and follow prompts at IPU
4. **Reagent Replacement-on RU-20 Screen- [Not Routinely Performed]**
    a. Display the [Reagent information] screen by touching [Reagent] in the [Status] screen, the screen below appears
    b. Touch [Regist] to register the new lot



    c. Input new reagent information by scanning the reagent code on the new box or inputting the reagent code manually. Either way this screen appears.



    d. Select [OK]



    e. Remove the cap from new container.
    f. Pull dispensing set out by lifting straight up from the old reagent and immediately place into new reagent. Close cap.
    g. Touch [OK]
5. Reagent Replenish – ONLY to be performed when the reagent has run dry or expired.
    a. In the event that the concentrated reagent in the instrument has expired or otherwise become unusable, the concentrated reagent in the instrument and the prepared reagent in the supply tank must be drained and replenished with new reagent.
        i. Press [Select] on the Status screen.

ii. Select [Maint], then [Replenish]. The screen below displays.

iii. **WARNING: Reagent Replenish takes 4-6 hours**

iv. Press [OK] to refresh the supply of CELLPACK DST in the RU-20

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6. **Needed Maintenance**
    a. Adjust pressure according to specifications in the RU-20 *Instructions for Use* manual.
    b. The following procedures are performed by a Sysmex Service Representative. A message displays 10 days prior to the required service date:
        i. Replace filter every 72,000 L or 2 yrs.
        ii. Replace diaphragm pumps every 3 million cycles or 2 years.
        iii. Calibrate Conductivity Meter once per year.
    c. Check and maintain RO water quality on a routine basis determined by laboratory policy.

7. **Error Recovery**
    a. Press [Help] button in the upper right corner of LCD screen.
    b. Press [Detail] on the LCD screen.
    c. The error recovery process will be performed.

    Note: Please refer to RU-20 *Instructions for Use* manual, Chapter 7 for additional information on specific errors and troubleshooting.

8. **Switching from Cellpack DST to Cellpack DCL-**
    a. Perform this process when the RU- 20 becomes inoperable. Allows the use of Cellpack DCL connected directly to the analyzer in place of reagent from the RU-20.
        i. Refer to RU-20 Reagent Preparation Unit Quick guide, pages 8-9, Emergency Use Only section.

9. **Errors on XN-Series related to Cellpack**.
    a. Determine if analyzer is connected to RU-20 reservoir (normal set-up) or to Cellpack DCL cubitainer (emergency set up).

b. If connected to Cellpack DCL cubitainer, follow instructions from the Help screen on XN-Series analyzer.
c. If connected to reagent from the RU-20 reservoir:
    i. Inspect for kinked tubing or air bubbles in the lines from the RU.
    ii. Ensure that the float switch sensor is connected properly
    iii. Contact the appropriate Helpdesk for assistance if unable to resolve

References
CLSI RU 20 Procedure

Authorized Reviewers
Chair, Pathology and Laboratory Medicine
Medical Director, Hematology

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Document Control

Location of Master: Hematology Procedure Manual
Master electronic file stored on the Beaumont Laboratory server:
S:\HEMACOAG\Document Control\Hematology\Procedure\Master Documents\
Number of Controlled Copies posted for educational purposes: 1
Number of circulating Controlled Copies: 0
Location of circulating Controlled Copies: Stat Lab

Document History

Signature	Date	Revision #		Related Documents Reviewed/ Updated
Prepared by: Rebecca Bacarella, MLS(ASCP)	03/18/2019			
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Ann Marie Blenc, MD	03/25/2019	**00**	New procedure	
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