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INSTRUMENT STANDARD OPERATING PROCEDURE MANUAL

College of Medicine

SAFETY AND LABORATORY COOMMITTEE, C.O.M, K.F.U.

Prepared by

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Document History

Document Section	Details of Amendments	Date	Modified by (Initials)
SOP	**First Draft on SOP for the operation of Automated hematology analyzer XT-2000i**		

1. OBJECTIVE

- **The document describes the operation of Automated hematology analyzer XT-2000i**

2. PRINCIPLE

The System XT-2000i is a quantitative automated hematology analyzer for in-vitro diagnostic use for determining 21 hematological parameters. Examination of the numeric and/or morphologic findings of the complete blood count are useful in diagnosis of such disease states as anemias, leukemia's, allergic reactions, viral, bacterial, and parasitic infections. The Sysmex XT-2000i analyzer directly measures the WBC, RBC, HGB, HCT, PLT, LYMPH#, NEUT#, MONO#, EO# and BASO#. The remaining parameters are calculated or derived: MCV, MCH, MCHC, RDW-CV, RDW-SD, MPV, and differential percentages.

The Sysmex XT-2000i counts and sizes red blood cells (RBC) and platelet (PLT) using electronic resistance detection enhanced by hydrodynamic focusing. Hematocrit (HCT) is measured as the ratio of the total RBC volume to whole blood using cumulative pulse height detection. Hemoglobin (HGB) is converted to SLS-hemoglobin and read photometrically.

WBC count and differential are evaluated using flow cytometry with a semiconductor laser utilizing scattered light and fluorescence to determine the differences in cell size, complexity and RNA/DNA content. The WBC differential channel classifies neutrophils (NEUT), lymphocytes (LYMPH), monocytes (MONO), eosinophils (EO), and basophils (BASO) by cellular complexity and nucleic acid content. The differential cell placement is then enhanced utilizing Adaptive Cluster Analysis.

3. RESPONSIBILITIES

- It is the responsibility of designated personnel in the lab to train staff and students on this procedure and to ensure adherence to this procedure under supervision.
- It is the responsibility of designated personnel (staff or Student) to follow the instructions of this procedure under supervision.
- The head of the physiology department must resolve any problem with the process and difficulties in using this SOP.

4. SPECIMEN:

About 2-3 ml of venous blood collected into EDTA tubes. Specimens should be transported at room temperature 25ºC and can be store in the refrigerator of 2 - 8ºC up to 6 hours.. If stored in a refrigerator, samples should be returned to room temperature, for approximately 30 minutes, before analysis.

5. Reagents:

Reagent	Storage
CELLPACK	5-30 ºC
STROMATOLYSER-FB	5-30 ºC
SULFOLYSER	1-30 ºC
STROMATOLYSER-4DL	2-35 ºC
RET-SEARCH	2-35 ºC

6. REFERENCES

- Sysmex **XT-2000i** Operator's Manual, Sysmex Corporation, Kobe, Japan. Jan, 2005

7. DEFINITIONS

CBC: Complete blood count

WBC: White Blood Cell

NEUT%: Neutrophil percent

LYMPH%: Lymphocyte percent

MONO%: Monocyte percent

EO%: Eosinophil percent

BASO%: Basophil percent

NEUT#: Neutrophil Count

LYMPH#: Lymphocyte Count

MONO#: Monocyte Count

EO#: Eosinophil Count

BASO#: Basophil Count

RBC: Red Blood Cells

HGB: Hemoglobin

HCT: Hematocrit

MCV: Mean Corpuscular Volume

MCH: Mean Corpuscular Hemoglobin

MCHC: Mean Corpuscular Hemoglobin Concentration

RDW: Red cell distribution width

PLT: Platelet

MPV: Mean Platelet Volume

PDW: Platelet distribution width

P-LCR: Platelet larger cell ratio

EDTA: Ethylene diamine tetra acetic acid

8. SAFETY PRECAUTIONS

- ☐ Wear gloves, a lab coat and safety glasses for protection.

9. PROCEDURE FOR OPERATING Automated hematology analyzer XT-2000i

9.1. Turning on the instrument:

A. Start-Up Procedure
1. Press startup on computer screen.
2. Check reagent boxes for sufficient run volume.
3. Check printer paper supply.
4. The instrument automatically performs self-check on the:
a. Microprocessor
b. Mechanical parts
c. Temperatures
d. Background count
5. Analyzer Quality Control.
B. Patient Sample Processing
1. Manual Mode – (20 uL aspirated sample volume) minimum of 500 uL in tube or 90 uL in a micro-sample container.
a. On the IPU, click (Manual) or press (F2).
b. Enter the specimen number (alpha or numeric characters) using the keyboard or using the handheld bar code reader.
c. Click on CBC or CBC + Diff if this information is not being provided by the Host Computer.
d. Click (OK).
e. Attach appropriate sample tube adapter.

f. Mix the patient sample 10 times by end-to-end inversion.
g. Place sample in sample tube adapter. It is not necessary to remove the cap except when using non-pierceable micro-sample containers.
h. Press Start switch.
i. When Ready LED is lit green, repeat steps a – I for each additional sample.
2. Sampler Mode with Bar Codes – XT-2000i with Sampler (20 uL aspirated sample volume). A minimum of 1.0 cc of blood is required in the tube for the sampler mode.
a. Place a Sysmex rack in a rack position of the Sampler with the notch on the rack to the right.
b. Place up to 2 racks at one time (up to 20 samples).
c. Place bar coded specimens in the rack. Ensure that labels are smooth with no loose edges.
d. Attach the appropriate sample tube adapter.
e. Close the Sampler cover.
f. On the IPU, click (Sampler) or press (F3). The Sample number dialog box displays.
g. Click on the starting position for the rack and tube position in which the tubes have been placed. Press (OK).
h. Press sampler Start switch on the left side of the Main Unit.
i. The Sysmex XT-2000i automatically mixes the sample 10 times, aspirates, and analyzes the sample according to the bar code discrete order if bidirectional interface is used. Results print as completed if auto-output is selected.
j. A dialog box displays when analysis is complete.
3. SHUT DOWN – Perform every 24 hours.
a. Cleans the detector and dilution lines.
i. Click (Menu) or press (F4).
ii. Double click on the "Shut down" icon.
iii. After 2 minutes, a dialog box on the IPU displays "Please power off the analyzer".
iv. Power off the Sysmex XTMain Unit.
v. To power off the IPU, click (File) from the menu bar, then click (Exit).
vi. Dialog box displays "Do you really want to Log off?" Click (OK).
vii. Click on Start button at the bottom of Windows desktop.
viii. Click (Shut Down). NOTE: The Restart key displays on this dialog box. If desired, click (RESTART) to begin IPU start up process.
ix. The system displays: "Please wait while the system writes unsaved data to the disk".
x. Record on Maintenance Log
b. Daily shutdown procedure at the end of shift
i. Power Up Sequence

a. Press power switch on Information Processing Unit (IPU). IPU log on must be done before powering up the Main Unit.

b. Sysmex XT-2000i program log-on displays. Log on the IPU with your User Name (___) and press (ENTER). No password is required. Substitute your user name and password if they have been assigned.

ii. Press the power switch on printer.

iii. Press the power switch on right side of the Main Unit.

9.2. Warning

All patients specimens should be considered potentially infectious and must be handled with precautions used for human blood