KFU

جامعة الملك فيصل

KING FAISAL UNIVERSITY

جامعة ووطن.. نماء.. واستدامة..

INSTRUMENT STANDARD OPERATING PROCEDURE MANUAL

College of Medicine

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

Prepared by

Document Number	Name	Signature	Date
CM 001 **CM/PHY-002**	**Mrs.Nourah AL Mulhim** **Mrs. Samar Alhamad**		**9/11/2020**
Revision Number	**Approved by**		
R0 **Write the revision number**	**Dean:** **Department:**		

Document History

Document Section	Details of Amendments	Date	Modified by (Initials)
SOP	First Draft on SOP for the operation of Blood Counter (CBC) Kx-21N		

1. OBJECTIVE

- ☐ The document describes the operation of Blood Counter (CBC) Kx-21N

2. SCOPE

The System KX-21 is an automatic multi-parameter blood cell counter for in vitro **.**diagnostic use in clinical laboratories

The KX-21 processes approximately 60 samples an hour and displays on the LCD screen the particle distribution curves of WBC, RBC, and platelets, along with data of 18 parameters, as the analysis results.

The KX-21 performs speedy and accurate analysis of 18 parameters in blood and detects the abnormal samples. To assure easy sorting of abnormal samples in the laboratory, the instrument displays abnormal analysis data with abnormal marks attached on the LCD screen. Thus, displayed analysis data allows detecting those samples, which are outside the tolerance and need further analysis and reconsideration.

The KX-21 employs three detector blocks and two kinds of reagents for blood analysis. The WBC count is measured by the WBC detector block using the DC detection method. The RBC count and platelets are taken by the RBC detector block, also using the DC detection method. The HGB detector block measures the hemoglobin concentration using the no cyanide hemoglobin method.

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.

4. REFERENCES

5. DEFINITIONS

KX-21N.
Data Printer.
Hand Held Barcode Reader.

6. SAFETY PRECAUTIONS

If this sign is ignored and the instrument is operated incorrectly, there is a potentially hazardous situation, which could result in death or serious injury of an operator, or grave property damage.

If this sign is ignored and the instrument is operated incorrectly, there is a potentially hazardous situation, which may result in injury of an operator, adverse effect on output results, or will cause property damage.

This product is a clinical instrument for screening of abnormalities. Clinical judgments by physicians should take into account results from clinical examinations and other test results besides hematology result.

7. PROCEDURE FOR OPERATING Blood Counter (CBC) Kx-21N

7.1. Turning on the instrument:

1-Check before turning ON the power.

2-Turn ON the power.

• Self-check

• Background check

7.2. Software Operation.

7.3. Steps of the Procedure

1-Select whole blood mode.
2-Select pre-diluted mode.
3-Set sample No.
4-Prepare analysis samples in pre-diluted mode (1:26 dilution).
5-Set sample No.
6-Set sample to the sample probe.
7-Press the start switch.
8-Execute analysis.
9-End analysis

7.4. Turning off the Instrument

1-Check after analysis.
2-Execute shutdown.
3-Turn off the power.

7.5. Warning

In the event the instrument emits abnormal odor or any smoke, turn off the power immediately and disconnect the power plug from the wall socket. If the instrument is used continuously in that state, there is a hazard that fire, electrical shock, or injury may result. Contact your Sysmex service representative for inspection.

• Take care not to spill blood or reagent, or drop wire staples or paper clips into the instrument. Those might cause short circuit or smoke emission. If such trouble should occur, turn off the power supply immediately and pull off the power plug from the wall socket. Then contact Sysmex service representative for inspection.

• Do not touch the electrical circuits inside the cover. Especially if your hands are wet, there is a hazard that electrical shock may result.

• Always wear rubber gloves when performing maintenance work or inspection. Use specified tools and parts. After work is over, wash your hands with disinfectant. There is a possibility that those areas of the hand which came in contact with blood could suffer infection, electrical shock, or burn.

• Be careful when handling samples. Always wear rubber gloves; otherwise, infection by bacteria could result. If bacteria happen to enter your eye or a cut, wash it off with plenty of water, and immediately see a doctor.

• When discarding waste liquid, or disassembling/assembling the related parts, do not touch the waste liquid. If it is contaminated with blood, infection of bacteria may result. If you should touch the waste liquid inadvertently, wash it off with disinfectant first, and then wash it off with soap.

• If a reagent happens to enter your eye, wash it off immediately using plenty of water, and take medical treatment at once.

• If you should swallow it inadvertently, call for a doctor immediately, drink plenty of water, and throw up.

• If it happens to adhere to the hand or the skin of other area, wash it off using plenty of water.

• When discarding waste liquid and instrument consumable, take proper disposing steps as medical, ineffective, and industrial wastes. If they are contaminated with blood, infection of bacteria may result.

• Never put the power plug in any socket other than the specified voltage. Otherwise, fire or electrical shock will result.

• When installing the instrument, be sure to ground it. Otherwise, fire or electrical shock will result.

• Take care not to damage the power cord, place a heavy device on it, or pull it forcibly. Otherwise, the wire may break causing fire or electrical shock.

• When connecting the instrument to a peripheral (host computer), be sure to switch off the power supply beforehand. Otherwise, electrical shock or instrument failure may result.

• After unpacking, be sure not to allow dust, dirt, or bacteria to come in touch with the reagent.

• Do not use reagents, which are out of the expiration date.

• Handle a reagent gently to prevent formation of bubbles.

• Take care not to spill a reagent. If it spills, wipe it off immediately using a wet cloth or the like.

• Follow other instructions described on the Package Insert on each reagent.

Use of Instrument

• When performing maintenance work or inspection, use specified tools and parts.

Do not use substitute parts, or modify the instrument. It is hazardous.

• Do not bring your body or clothes close to the instrument.

• Those who have no or only limited experience in using reagents are recommended to have guidance or assistance of those with sufficient experience.

• If the instrument has developed a trouble by any chance, a person in charge of it should take steps within the range specified in the OPERATOR'S MANUAL. As to troubles other than mentioned in it, contact Sysmex service representative for repair.

• Unpacking, installation, and confirmation of initial operation must be done by Sysmex service representative.

Environment for Use

• Install the instrument in a place, which is not subject to water splash.

• Install the instrument in a place, which is not subject to adverse effects of high temperature, high humidity, dust, direct sunlight, etc.

• Do not give the instrument a strong vibration or impact.

• Do not install the instrument near a chemical storage or a place where a gas is generated.