OPERATION, SMEAR PREPARATION AND STAINING

SYSMEX SP-1000*i* – HST

PRINCIPLE The Sysmex SP-1000*i* is a fully automated hematology slide preparation and staining system. Whole blood specimens are mixed and aspirated and a wedge type blood smear is prepared using hematocrit information from the Sysmex XE-2100 to determine optimum smearing criteria. The smear is labeled with the patient’s first and last name, accession number and the date slide was prepared. The dried smear is automatically loaded into an individual slide cassette and is then advanced to the staining area. In the staining area, stain and buffer are dispensed into the cassette at operator-defined intervals.

Slides prepared by the Sysmex SP-1000*i* are used for differentiation and morphologic evaluation of cellular elements of whole blood.

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| WORKPLACE SAFETY | Laboratory employees are expected to maintain a safe working environment and an injury-free workplace. Laboratory employees are responsible for their own safety, the Safety of others and adhering to all departmental and medical center safety policies and procedures. Refer to Policy and Procedures Safety Manual Infection Control 11-030-01**.** |

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| REAGENTS/ SUPPLIES | This table contains the consumable supplies and reagents that are  needed to operate the instrument. Reagents specific to each  assay are found on the individual assay procedures   * The status of all supplies maybe monitored with the on-board supply screen. * All supplies are barcoded for scanning. |

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| Supplies |  |
| Phosphate Buffer  pH 6.6-7.2 | Ready to use.   * Store at room temp. * Good until expiration. |
| Cell Pack | Ready to use.   * Store at room temp. * Good until expiration. * Good for 60 days when opened. |
| Harleco-Wright’s Stain | Ready to use.   * Store at room temp. * Good until expiration. |
| Methanol-Anhydrous | Ready to use.   * Store at room temp.   Good until expiration |
| De-ionized water  pH~7.0 | * Store at room temp. |
| Clorox Ultra bleach 5% | * Store at room temp. |
| Microscope slides | * Size 76x26mm;thickness =0.9-1.2mm * Clipped corners and straight/90º edge |
| Alcohol prep pad |  |

SPECIMEN

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| The specimen of choice is whole blood anticoagulated with a potassium of EDTA |
| The SP-1000i aspirates 200µl of blood. |
| A minimum of 1 mL whole blood is required for running the specimen in the automode. Collection tube, 12x75 or 15x75, should be filled to a minimum of one-half full for optimum results. |
| Optimal time to analyze the specimen is within 4 hours of collection |

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| MAINTENANCE | This table explains the required maintenance for system operation.   * Refer to Operator’s Manual, Section 9 for detailed instructions on performing each task. * Document on the appropriate record. |

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| Frequency | Tasks |
| Daily | * Verify that there are sufficient supplies and reagents. * Inspect the trap chamber * Clean Spreader glass * Clean single cassettes * Perform daily shutdown1 |
| Weekly | * Perform daily shutdown1 |
| As needed | * Clean sampler area * Perform **[RINSE] [WHOLE LINE]** |

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| QUALITY CONTROL | 1. Daily, examine a stained smear from the routine workload for smear and stain quality. Document results on the appropriate log. 2. Review the blood smears microscopically for acceptability 3. Document results on the appropriate log   If smear quality is unsatisfactory, clean it or if necessary, replace the spreader glass. If still unable to obtain an acceptable smear, notify supervisor. |

Use the following chart to resolve issues with unsatisfactory stain:

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| PROBLEM | RESOLUTION |
| 1. WBCs too light in color, 2. RBCs and/or PLTs too light, 3. RBCs are too red in color or too blue | 1) Verify that stain times have not changed. (Refer to “Current Laboratory Settings” in this document for current settings.)   1. Replace external stain container. Perform “Replace Stain”. (Refer to Maintenance in this document.) 2. Perform Shutdown 2 procedure (Refer to Maintenance in this document.) 3. Check pH of buffer; if necessary, make fresh buffer and replace. 4. Check pH of deionized water. Replace if necessary. 5. Make and stain a test smear. |
| 1. Stain precipitate on slide | 1. Replace external stain container. Perform “Replace Stain”. (Refer to Maintenance in this document.) 2. Ensure that clean, dry single cassettes are in use. 3. Perform Shutdown 2 procedure (Refer to Maintenance in this document.) 4. Make and stain a test smear. |
| 1. Water artifact on slides | 1. Verify that the stain cycle limit is correct. (Refer to “Current Laboratory Settings” in this document for current settings.) 2. Ensure that clean, dry single cassettes are in use. 3. Perform Shutdown 2 procedure (Refer to Maintenance in this document.) 4. Make and stain a test smear.   If water is still observed then:   1. Replace external stain container. Perform “Replace Stain”. (Refer to Maintenance in this document.) 2. Make and stain a test smear. |

If the above troubleshooting steps do not resolve the problem, notify your Supervisor and/or Key Operator when available, or call the Sysmex Technical Assistance Center (TAC) at 1-888-879-7639. Document all Problems/Corrective Action(s) in the instrument's Action Log.

Sample Processing

System (auto) mode:

1. Place bar coded samples in a Sysmex rack.
2. Place the rack in the Start Yard (STY).
3. Racks will be transported to an XE-analyzer and then to the SP-1000i where a smear will be prepared when appropriate criteria are met.

Manual Mode: Smear and Stain (May be used to process one tube at a time in a rack)

1. Press [MANUAL] on the main screen.
2. Press [Op Mode] and select [Smr+Sta].
3. Press [Sample ID] and enter the sample ID number by using the barcode wand or the alpha-numeric keypad. Press [Enter] after the manual entry.
4. Press [Sample Tube] and select [Closed].
5. Press [Level] and select [HCT] level.
6. Press [Slide] to select tower to dispense a slide. Then select [None (either), Pos 1, Pos 2].
7. Press [No of slide] to indicate whether 1 or 2 slides will be made.
8. Place MIXED sample tube in position 10 of sample a sample rack.
9. Place the rack so that it is lined up with the rack position label on the CVR. It is marked on the instrument.
10. Press [Start].

Stain Only Operation (for pre-made blood smears)

1. Press [MANUAL] on the main screen after all slides from the smear table have been fed to the stain area.
2. Press [Op Mode] and select [Stain].
3. Insert labeled slides, smear side facing the operator, into cassettes at the front of the cassette supply table.
4. Press [START].

REFERENCES

1. SP-1000i (Automated Slide Preparation Unit), Instructions for Use, Sysmex Corporation, Kobe, Japan, revised December 2004.
2. Operators Manual, LASC-HST (System Software), Sysmex Corporation, Kobe, Japan, September 2004.
3. Operator’s Manual, HS Transportation System (HST-N), Sysmex Corporation,
4. Kobe, Japan, revised September 2004.

Document History Page

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| Change type: New, Major, Minor etc. | Changes Made to SOP – describe | Name of responsible person/date | Med. Dir. Reviewed/ Date | Lab Manager reviewed/ date | Date change Imp. |
| Major | Reviewed. | Charles Park  11/13/12 |  |  |  |
| Major | Added Manual Mode: Smear & Staining on page 4. | Julius Salomon 5/29/14 |  |  |  |
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