HEALTH HOLDING

HAFER ALBATIN HEALTH CLUSTER MATERNITY AND CHILDREN HOSPITAL

Department:	Laboratory and Blood Bank (Haematology)		
Document:	Internal Policy and Procedure		
Title:	Atellica HEMA580 Automated Hematology Analyzer		
Applies To:	All Haematology Staff		
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1. PURPOSE:

1.1 To establish system and set responsibilities
1.2 To elucidate the overall flow of operation procedure for Analyzing Samples on Atellica HEMA580 Automated Hematology Analyzer properly
1.3 To elucidate the Performing Calibrator Calibration on Atellica HEMA580 Automated Hematology
1.4 To improved measurement technologies for automated peripheral blood smear (PBS) preparation have led to a more efficient workflow. In this report, we evaluated the Atellica Hema 580 automated slide maker/ stainer

2. DEFINITONS:

N/A

3. POLICY:

3.1 More modern hematology analyzers are capable of analyzing all leukocytes using flow cytometry-based methods, some in combination with cytochemistry or fluorescence or conductivity, to count all the different types of WBCs, including neutrophils, lymphocytes, monocytes, basophils, and eosinophils (five-part differential)
3.2 Macroscopically, the automated PBS were of excellent quality, with a gradual transition in thickness, smooth edges, and sufficient length.
3.3 The morphology was comparable between manual and automated PBS. Correlations between the manual and automated PBS were 0.95 (95% confidence interval: 0.92 to 0.96) for neutrophils, 0.63 (95% CI: 0.50 to 0.74) for monocytes and 0.90 (95% CI: 0.85 to 0.93) for lymphocytes.

4. PROCEDURE:

4.1 **Checks prior to turning power ON**

4.1.1 **Instrument inspection**

4.1.1.1 Check if there are any bent tubes.
4.1.1.2 Check if there is any object on top of the instrument
4.1.1.3 Check for any misplaced racks.
4.1.1.4 Make sure that the network devices (hubs and network converters) are all powered
4.1.1.5 Discard any waste fluid in the waste container (if applicable).

4.1.2 **Reagent inspection**

4.1.2.1 Make sure there are extra supplies of reagents for the number of samples to be processed on the day of analysis. The amount of reagent needed varies with analysis mode. Therefore, check if enough reagents are available for the daily routine analyses. 6.2. 6.3.2 Turn power ON.

4.1.3 **Turn power ON**

4.1.3.1 Make sure that the main power of each device connected to the instrument is ON: Check the power for the following devices. The power for the connected devices is controlled by the IPU. Therefore, you can keep the main power switches in the "ON" position at al times I

4.1.3.2 When turning On the instrument's power, the following logon dialog box appears in the IPU*. Enter the required information, and then click [OK] to log on to the instrument. If you click [Abort], logon is not performed, and the IPU program exits.

4.1.3.3 Check the Status indicator LED on the analyzer. If the Status indicator LED is not lit green, wait until it does

4.1.3.4 If the tube holder has not ejected out, press the mode switch. The tube holder slides out forward.

4.1.3.5 Click the Change Analysis Mode button on the control menu. The dialog box on the right appears. In calibrator calibration (PLT-F), select (Whole Blood

4.1.3.6 Click (OK). The dialog box closes.

4.1.3.7 Click the Analyzer menu button in the Control menu. The

4.1.3.8 Click the Analyzer menu button in the Control menu. The menu on the right appears

4.1.3.9 Select [Calibration] - (Calibrator Calibration (PLT-

4.1.3.10 Select [Calibration] - (Calibrator Calibration (PLT-F)]. The dialog box on the right appears.

4.1.3.11 Mix the vial containing the calibrator as shown

4.1.3.12 Place the vial in the sample tube holder.

4.1.3.13 Press the start

4.1.3.14 Place the vial in the sample tube holder

4.1.3.15 Press the start switch on the analyzer.

4.1.3.16 Once the manual analysis starts, the analysis is performed 11 times consecutively, with the tube holder pulled into the analyzer

4.1.3.17 Once the analysis finishes, the tube holder slides out.

4.1.3.18 Wait until all analyses are complete

4.1.3.19 Redo the manual analysis

4.1.3.20 The results from the analysis in step 9 are displayed in the [Calibrator Calibration (PLT-F)] analysis

4.1.3.21 Dialog box. 6.10.2. If the following conditions are not met, (Calibration) in the [Calibrator Calibration (PLT-F)] analysis

4.1.3.22 Dialog box cannot be pressed. 6.10.2. a. All analysis results are normal

4.1.3.23 All calibration parameters are below the reproducibility standard(precision limit).

4.1.3.24 The analysis numbers of the analyses that need to be redone are displayed in the [Calibrator Calibration (PLTF)] analysis dialog box

4.2 **Atellica HEMA580 Control**

4.2.1 Performing Quality Control

4.2.1.1 For monitoring the accuracy and precision of Atellica HEMA QC

4.2.1.2 An analysis of the control must be carried out on a daily basis at the same time as the patient samples, including each time a calibration or a maintenance is carried out.

4.2.1.3 Follow government regulations or accreditation requirements for quality control frequency. Individual laboratory quality control programs and procedures may require more frequent quality control testing. Test quality control samples after a successful calibration.

4.2.2 Preparing the Quality Control

4.2.2.1 Bring Atellica HEMA Control to room temperature by rolling the tube between the palms of your hands until the red blood cell sediment is completely suspended. Do not shake.

4.2.2.2 Refer to the user manual to identify Atellica HEMA Control using the barcode reader or manually.

4.2.2.3 Run Atellica HEMA Control according to the procedure described in the user manual.

4.2.2.4 When ran in manual mode, gently invert the tube 8 to 10 times immediately before sampling.

4.2.2.5 Wipe threads and cap of the tube after use with lint free gauze.

4.2.2.6 Recap and refrigerate the tube promptly after use.

4.3 **Shutdown the analyzer**

4.3.1 Check the Status indicator LED on the analyzer

4.3.2 Click the Analyzer menu button on the control menu.

4.3.3 Click [Shutdown

4.3.4 Press the start switch on the analyzer.

4.3.5 Remove the sample tube: When the shutdown process is complete, the tube holder is automatically retracted to the analyzer

4.3.6 Shutdown the IPU

4.3.7 Click [Exit IPU] in the menu screen: A dialog box appears.

4.3.8 Click [Yes]: The IPU shuts down.

4.3.9 Shutdown Windows: Your computer shuts down.

4.3.10 Check the Status indicator LED on the analyzer

4.3.11 Click the Analyzer menu button on the control menu.

4.4. **Maintenance Schedule**

4.4.1 Daily

4.4.1.1 Execute shutdown (detector chamber and dilution line are cleaned automatically).

4.4.2 Monthly:

4.4.2.1 Lean the sampler right rack pool, lift rack pool, analysis line, and sample rack.

4.4.3 Every 15000 cycles

4.4.3.1 Clean the sample rotor valve (the massage clean the SRV is displayed)

4.4.4 As needed maintenance:

4.4.4.1 Supplies replacement, adjustment of pressure and vacuum).

5 MATERIALS AND EQUIPMENT:

5.1 N/A

6 RESPONSIBILITIES:

6.1 All hematology staff starting overall flow of operation of procedure for analyzing Samples on Atellica HEMA580

7 APPENDICES:

N/A

8 REFERENCES:

8.1 US Department of Health and Human Services. Biosafety in Microbiological and Biomedical Laboratories. 5th ed. Washington, DC: US Government Printing Office; December 2009.

8.2 World Health Organization. Laboratory Biosafety Manual. 3rd ed. Geneva: World Health Organization; 2004.

8.3 Clinical and Laboratory Standards Institute. Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline—Fourth Edition. Wayne, PA: Clinical and Laboratory Standards Institute; 2014. CLSI Document M29-A4.

8.4 Clinical and Laboratory Standards Institute. Reference and Selected Procedures for the Quantitative Determination of Hemoglobin in Blood; Approved Standard—Third Edition. Wayne, PA: Clinical and Laboratory Standards Institute; 2000. CLSI Document H15-A3. 5. Clinical and Laboratory Standards Institute. Procedure for Determining Packed Cell Volume by Microhematocrit Method; Approved Standard—Third Edition. Wayne, PA: Clinical and Laboratory Standards Institute; 2001. CLSI Document H7-A3.

9 APPROVAL

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