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Alere Medical Pvt. Ltd.
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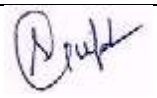
3PART HEMATOLOGY ANALYZERS IQ, OQ, PQ GUIDELINE AND DOCUMENTATION

Name/Address of Lab:	
Phone#:9310722824	**Contact Person: Sunil**
FAX: N/A	**Contact Email:** **staff.oscardiagnostics@gmail.com**
Instrument Model: Alere h380	**Instrument Serial #:** 730000729
Installation Date:10/12/2020	**Software Revision #: 4.0**
Install Engineer Name: Sanjeev Gupta	**Signature:** 

Instrument Installation Qualification:

The Installation Qualification (IQ) procedure verifies that the equipment and its sub-systems have been installed in accordance with the specifications. These requirements must all be satisfied before the IQ can be completed and the qualification process is allowed to progress to the Operational Qualification (OQ) procedure.

INSTALLATION QUALIFICATION CHECKLIST:

Shipping Cartons Received

☒ No external damage

Documentation

☒ Matched Serial # Packing List

☒ Matched Serial # Final Check Report

☐ Operator's Manual

☐ Barcode Calibration Manual (optional)

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Accessories

☒ Instrument Accessory Kit from Shipping Carton

☒ Diluent

☒ Lyse

☒ Cleaner

☒ Controls

☒ Calibrator

☐ Linearity Kit

☐ Barcode Reader (optional)

Instrument Location

☒ Within 1.8 m (6 feet) of an electrical outlet

☒ On stable countertop at a comfortable working height with proper working space (see User Manual)

☒ In a room between 15°C and 30°C (59°F and 86°F) and <85% humidity, without condensation

Power Requirements

☒ 100/240 Vac, 50/60 Hz, 2.0 A

☒ Female receptacle outlet with single-phase input power and ground

☒ Building outlet properly grounded and electrical panel protected against power fluctuations

☒ Confirmed third-wire earth ground capable of carrying full current of circuit

Connections and Setup

☒ Biohazard waste container tubing properly connected to container and to instrument

☒ Biohazard waste container located on floor or shelf lower than instrument

☒ Reagent tubing properly connected to all reagent containers and to instrument

☒ Reagent key removed from lyse reagent container

☒ Diluent container placed on floor or shelf lower than instrument

☒ Lyse reagent placed on countertop next to instrument or lower

☒ Cleaner reagent placed on countertop next to instrument or lower

☒ Reagent key inserted into hardware slot on the instrument (can be removed after upload)

☒ Instrument's power cord connected to instrument and plugged into electrical outlet

☐ Connect barcode reader (optional)

☒ Insert paper roll into onboard printer (where applicable)

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☐ Printer located next to instrument (optional)

☐ Printer cable connected to instrument and to printer (optional)

☒ Printer power cord plugged into electrical outlet (90 - 264 Vac range, 50/60 Hz, and 1.5 A) (optional)

Installation Qualification is now complete. You may begin the Operation Qualification Procedure.

OPERATION QUALIFICATION CHECKLIST:

Operational qualification is establishing confidence that the equipment and sub-systems are capable of operating within the stated limits and tolerances. In practice, the operational qualification is the executed test protocol documenting that a system meets the defined requirements or that the system does what it's supposed to do.

Instrument Startup:

☒ Instrument turned ON via switch in back of instrument
☒ Date and time set
☒ Run instrument self-test
☒ All self-test parameters indicate *PASS*
☒ Reporting units selected
☒ Normal range limits set
☒ Auto print set, if desired
☒ Report header customized with your laboratory information
☒ Verify instrument serial # in the software and on back of instrument (Self-test)
☐ Connect barcode reader (optional)
☐ Program barcode reader (if installed, see Barcode Programming Manual))
☒ Run background count
☒ Accept background count *See Operator's Manual for Acceptance Criteria*
☒ Run a 10 replicate precision study using a fresh patient sample. Review results against precision criteria.

CALIBRATION:

- Calibration must be performed initially at installation and then every 6 months thereafter.
- Interim recalibration must be performed when
  - The instrument is moved to a different location
  - After replacing any component related to the process of dilution or measurement
  - When QC results indicate recalibration may be needed
  - When instructed by technical support to recalibrate as part of troubleshooting

Refer to the *Operator's Manual* for detailed instructions in performing calibration.
The package insert which comes with the calibrator contains the target values to be used in calibrating. This insert must be saved per local regulations.

QUALITY CONTROL:

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1. Before using a new lot number of Quality Control (QC) materials, the target values and ranges must be entered into the instrument manually or via optional barcode reader. The values to be entered will be found on the package insert which comes with each set of controls provided by a manufacturer.

2. All three levels of Controls provided (low, normal, high) should be run every shift of patient testing.

3. Follow instructions found in the package insert for proper handling of Control samples.

4. Analyze each level and review results. All three levels must produce acceptable results in order to continue to the **Performance Qualification Procedure** or reporting of patient results.

5. A copy of all QC testing must be saved for at least 2 years. (If QC results are transmitted to a laboratory information system (LIS) saving the results electronically instead of on paper is acceptable.) The documentation must include the lot number and expiration date of the material as well as the expected target values and ranges.)

NOTES:

- QC material may not be used past the expiration date. Refer to the package insert for expiration date of the lot number as well as open expiration date of each vial once put into use.

- New lot numbers of QC materials must have assay values verified before using as QC. This is done by testing existing QC materials and the new lot of QC materials in parallel for 10 replicates. Save documentation of the parallel testing per local regulatory requirements.

Operational Qualification is now complete. You may now begin the Performance Qualification Procedure.

INSTRUMENT PERFORMANCE QUALIFICATION:

Performance qualification is establishing confidence through appropriate testing that the installed product meets all performance requirements for functionality and safety and that results are effective and reproducible. In practice, the performance qualification is the executed test protocol documenting that a system meets the defined requirements to function in the clinical laboratory environment.

NEW INSTRUMENT VALIDATION:

All new instruments must be tested to validate the manufacturer's claims for **Accuracy, Precision, Reportable Ranges (linearity), and Reference Ranges.**

New users will be assisted by the individual who installs and trains the operator in the use of the new analyzer. Instructions and guidance in the validation of **Accuracy**, **Precision**, and **Reportable Range** (AMR) will be included in the training process. These validations must be reviewed and approved by the Lab Director before the instrument can be used to test and report patient samples.

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REAGENTS AND SUPPLIES NEEDED:

Reagents used for validation:

- Diatro•Dil-DIFF diluent
- Diatro•Lyse-DIFF lysing agent
- Diatro•Cleaner cleaning agent

Additional reagents needed for occasional use:

- Hard cleaner (2% Sodium Hypochlorite Solution)
- Distilled water

Refer to the *Operator's Manual*, for detailed information regarding the reagents composition, storage requirements, usage, etc.

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CONTROLS AND CALIBRATOR:

- R&D Systems CBC-3D Hematology Control or any other commercially available hematology control product that has been assayed for the test instrument (refer to package inserts for detailed information about target values and ranges, storage, mixing instructions, etc.).

- R&D Systems CBC-CAL PLUS Hematology Calibrator or any other commercially available hematology calibrator product that has been assayed for the test instrument (Refer to package inserts for detailed information about target values and ranges, storage, mixing instructions, etc.)

LINEARITY:

- Use a commercially available linearity kit and follow the instructions on the package insert.
  or
- Perform manual linearity dilutions following CLSI EP06-A: "*Evaluation of the Linearity of Quantitative Measurement*".

The below attached Excel file contains the spreadsheets for data entry and calculation for Accuracy, Precision and Reportable Range. It also contains a data spreadsheet for Manual Reference Range validation.

3P Instrument
Validation Template.xl

The Laboratory Director must validate the Reference Ranges. There are several ways to do this:

- Empirically
- By comparing the ranges to those used in the area in which the lab is located since all are serving essentially the same patient population base
- By researching the ranges on the Internet and comparing the lab's ranges
- By comparing the ranges to an analyzer previously used
- By performing the "Rule of 20" test included in CLSI's C28-A3E: *"Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory; Approved Guideline".*

REPORTING RESULTS

Results will be reported according to established laboratory procedure.

INOPERABLE TEST SYSTEM:

Refer to established laboratory policies for what to do when the instrument is out of service.

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INSTRUMENT VALIDATION EVALUATION

Laboratory Name:	Pal Pathlabs Pvt Ltd
Address:	Block ED-18A Ground Floor Pitampura
	New Delhi -110034
Phone:	9310722824
Contact person:	Sunil
Contact email:	Staff.oscardiagnostics@gmail.com

Instrument Serial No.:	730000729	**Date installed:**	10/12/2020
Date(s) validated:	10/12/2020		

Istructions:

1. The Lab Director must review this data and determine if the results of the Accuracy and Precision testing are acceptable to validate the manufacturer's claims.
2. The Lab Director must review the Reportable Range study and accept or reject the reportable ranges established.
3. No Reportable Ranges may be established that exceed the manufacturer's linear testing range. The Reference Ranges must be validated by the Lab Director and the laboratory as being appropriate for the lab's patient population. There are numerous ways to do this:
    - empiric evaluation,
    - comparison to area hospitals' and practices' ranges,
    - Internet research,
    - research of literature,
    - or by methods outlined in the *CLSI Document C28-A3E "How to Define and Determine Reference Intervals in the Clinical Laboratory."*

I have evaluated the validation data for this analyzer and find the accuracy, precision, reportable range and reference ranges are within the limits stated by the manufacturer. ☒ **YES** ☐ **NO**

I approve this instrument for use in this clinical lab ☒ **YES** ☐ **NO**

Lab Director's Signature:.....

Date approved:.....

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HELPFUL INFORMATION

SPECIMEN REQUIREMENTS:

- No patient preparation is required; the patient need not be fasting.
- The required specimen is whole blood collected in EDTA. Ensure that the tube is filled to proper fill volume. Insufficient blood in the tube can result in over-dilution of the sample with the liquid EDTA. Follow the instructions in the *Operator's Manual* for manual and mechanical mixing instructions. (User Manual: *Sample processing/ How to load a sample into the analyzer*)
- The specimen is stable stored at room temperature for 7 hours.

SPECIMEN IDENTIFICATION:

- All accrediting agencies require a minimum of two forms of identification on the sample:
  - Patient first and last name is one form of identification
  - The second identifier should be unique and can be date of birth, medical record number or account number.
- The date and time of collection as well as the initials of the person collecting the specimen are also required on the sample.

SPECIMEN REJECTION CRITERIA:

- Unlabeled specimen
- Incompletely labeled specimen
- Mislabeled specimen
- Specimen collected in the wrong tube or in an incorrect medium
- Clotted specimen
- Specimen that has exceeded the time limit for accurate testing
- Specimen that has been stored inappropriately

DAILY PATIENT RUN PROCEDURE:

1. Remove the controls from the refrigerator and allow them to warm for the specified period of time.
2. Perform a background ("blank") count on the instrument; check to ensure results are within acceptable ranges for background counts. Repeat 2 – 3 times if needed to get acceptable background levels. Do not proceed if the background counts cannot be brought into the acceptable ranges.
3. Mix QC samples as instructed in the package insert. (Manual mixing of controls is required; ***do not mix on mechanical mixer***.)
4. Run QC samples according local requirements; review results to ensure the results produce acceptable results before testing patient samples.
5. Proceed to patient testing. Refer to *Operator's Manual* for detailed instructions in entering patient information and test orders. (UM.: *Sample processing/ How to load a sample into the analyzer*)
6. Samples should be mixed appropriately before testing. If manual mixing is to be done, refer to the *Operator's Manual* for instructions. (UM.: *Sample processing*)

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7. Refer to the *Operator's Manual* for detailed instructions in running patient samples. (UM.: *Sample processing*)
8. Results can be printed and/or transmitted electronically to an LIS, or exported into an external data drive (e.g.: USB drive) (UM.: *Managing the stored measurement data*)
9. Review results for critical values. If critical values are obtained, follow established laboratory procedures for critical value retesting and reporting.
10. Report results per established laboratory policies.
11. Save any printed reports for at least 2 years.

INTERPRETATION OF RESULTS:

- Results are reported with reference ranges ("normal ranges") to the right of the patient result.
- **Range flags** occur when the patient result exceeds the reference range established in the instrument. **H** indicates the result was higher than the range; **L** indicates the result was lower than the range. They are printed to the right of the result.
- **Measurement condition flags** indicate there is a question as to the accuracy of the result. These flags are printed in the bottom portion of the report.
  - **Upper case flags** refer to the WBC – HGB channel
  - **Lower case flags** refer to the RBC – PLT channel
- Results which fall within the reference ranges in the instrument will have no range flags; it is possible for them to have measurement condition flags so the report should be reviewed for both types of flags.
- Refer to the *Operator's Manual* for detailed information regarding measurement condition flags and their interpretation. (UM.: *Interpretation of Results/ The parameter flags and Warning flags*)

MAINTENANCE:

Daily maintenance – start of day:

1. Check reagent credits (UM.: *The Status bar on A1-1 model*)
2. Perform a background count (UM.: *Starting a new blank measurement*)
3. Run QC (UM.: *Performing a QC Measurement*)

Daily maintenance – end of day:

- Perform the hard cleaning (2% Sodium Hypochlorite solution) process found in the Maintenance menu (UM.: *Periodic Cleaning with HypoClean*) then shut down the instrument. (UM.: *Shutting down the 'Aquila' Analyzer/The standard Power OFF procedure*)

Weekly maintenance:

- Hard cleaning using 2% Sodium Hypochlorite solution (UM.: *Periodic Cleaning with HypoClean*)
- Manual cleaning of the wash head (UM.: *Manual Cleansing Of The Needle Washing Head*)

Semi-annual maintenance:

- Run self-test (UM.: *Analyzer Self Test*)