STANDARD OPERATING PROCEDURE

Biobase FBC Auto Hematology Analyzer

Setup, Connectivity, Result Mapping and Routine Interface Operation

Document number	SOP-BIOBASE-FBC-001
Version	1.0
Effective date	_____
Department	Laboratory / Analyzer Interface Support
Applies to	Biobase Auto Hematology Analyzer connected by TCP/IP using HL7 over MLLP
Prepared for	Laboratory users, supervisors, biomedical engineers and IT support

Document scope: This SOP governs the connection between the Biobase FBC analyzer and Analyzer Interface. Follow the current Biobase manufacturer IFU and local laboratory procedures for specimens, reagents, calibration, maintenance and quality control.

1. Purpose

To define a consistent method for registering, connecting, validating and operating a Biobase FBC analyzer with Analyzer Interface so that patient identifiers and complete blood count results are received, mapped and stored correctly.

2. Scope

This procedure applies to Biobase Auto Hematology Analyzers configured to send HL7 result messages over TCP/IP using MLLP framing. It covers interface setup and result handling; it does not replace the analyzer operating manual or laboratory testing SOPs.

3. Responsibilities

Role	Responsibility
Laboratory operator	Confirm analyzer readiness and QC acceptability; run specimens; verify transmitted results and report discrepancies.
Laboratory supervisor	Approve mappings, review validation evidence, authorize routine use and investigate result integrity incidents.
IT/interface support	Configure the network and listener, maintain firewall access, monitor logs and resolve connectivity faults.
Biomedical engineer	Configure analyzer communication settings and maintain the instrument according to the manufacturer IFU.

4. Safety and quality requirements

- Treat all patient material as potentially infectious and follow local biosafety and waste-disposal procedures.
- Do not release patient results solely because transmission succeeded. Apply the laboratory's technical validation, delta-check and critical-result rules.
- Use only an approved static IP configuration and an authorized firewall port.
- Do not alter parameter mappings during active patient processing without supervisor authorization and documented verification.
- Complete analyzer QC and maintenance requirements before routine patient testing.

5. Prerequisites

- Biobase analyzer model and serial number
- Analyzer Interface PC IP address
- Approved TCP listener port
- Biobase analyzer IP address and subnet details
- Administrative access to Analyzer Interface
- Firewall rule permitting analyzer-to-interface traffic
- Approved LIS/system codes for every reportable FBC parameter

6. Connection architecture

The Analyzer Interface PC acts as the TCP server. The Biobase analyzer acts as the client and sends HL7 messages framed with MLLP control characters. The interface listens on the configured port, records received data, extracts results, stores parameters and returns an HL7 AA acknowledgement only when processing permits it.

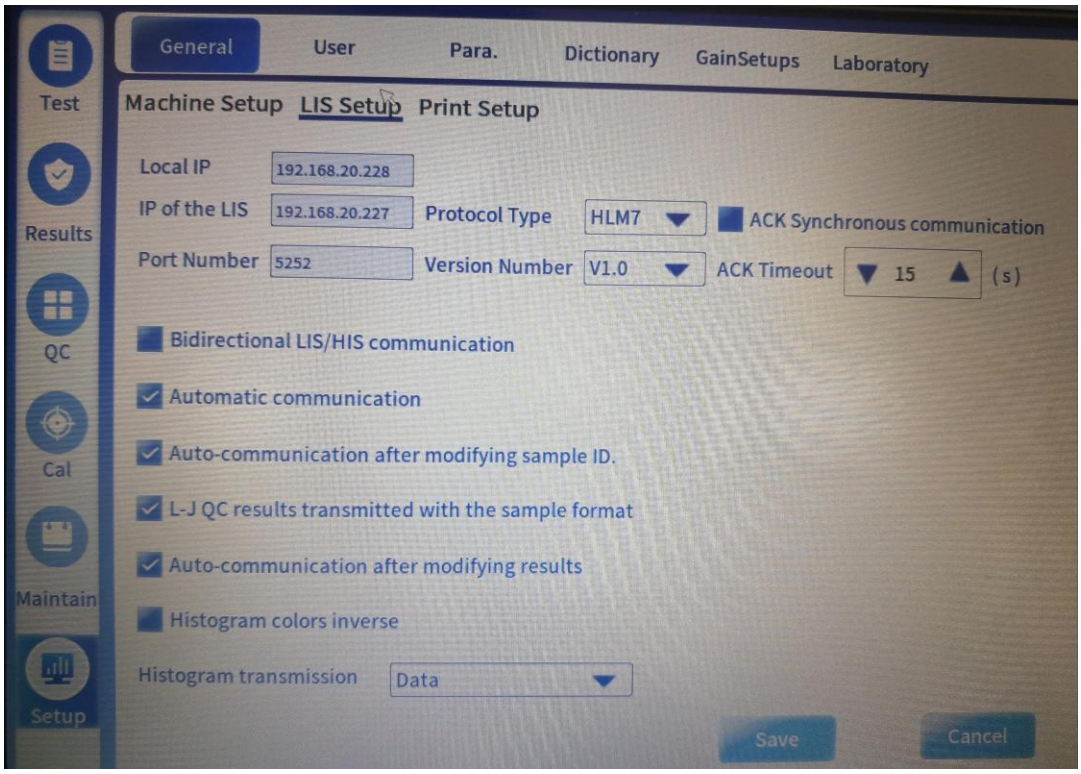
Component	Required setting
Protocol	HL7 over TCP/IP with MLLP framing
Analyzer role	TCP client
Analyzer Interface role	TCP server/listener
Character encoding	UTF-8 unless the analyzer communication specification requires otherwise
Endpoint format	One entry per line as ip:port or port for a listener on all interfaces

7. Initial configuration

7.1 Configure the analyzer and network

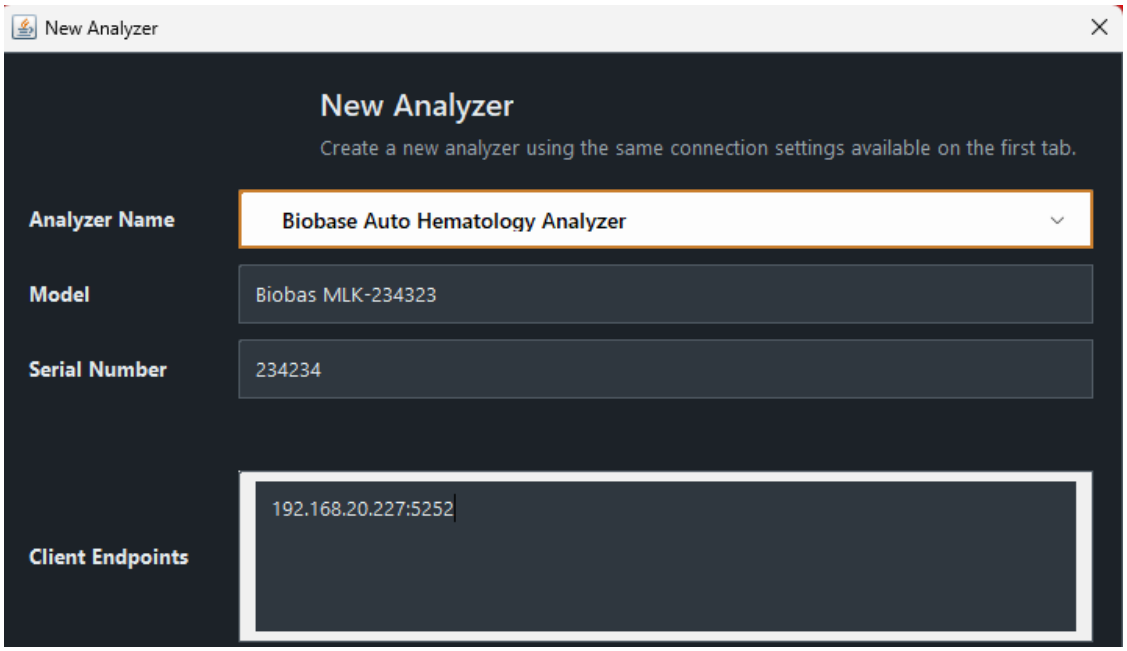
1. Login to the analyzer with Username: **admin** / Password: **admin**
2. On the analyzer, Select **SETUP**
3. Select **GENERAL -> LIS Setup**
4. Assign a **Local IP** to the biobase -> **IP of LIS** AND **Port Number** as in Analyzer Interface.

5. Select Protocol Type: **HLM7** and version: **v1.0** host communication and TCP/IP client mode.
6. Select **Automatic communication**.
7. Enable automatic result transmission or the laboratory-approved send mode.
8. Save the analyzer communication settings and restart the communication service if required by the manufacturer.
9. From the network team, confirm that the analyzer can reach the interface PC and that the listener port is allowed through the firewall.



7.2 Register the analyzer in Analyzer Interface

1. Open Analyzer Interface and choose New Analyzer.
2. Select Biobase Auto Hematology Analyzer.
3. Enter the analyzer model and serial number.
4. In Client Endpoints, enter the listener endpoint. Use one endpoint per line in ip:port or port format.



5. Select Create Analyzer and confirm the registration.
6. Verify that the application reports that the Biobase analyzer is listening on the configured port.
7. Confirm the analyzer connects and that the interface displays the remote analyzer endpoint.

8. Parameter mapping

8. Transmit a complete verification sample from the analyzer.
9. Open Mapping Settings and select the registered Biobase analyzer.
10. Review every detected analyzer parameter, including units and flags.
11. Map each parameter to the approved LIS/system code.
12. Save the mappings and transmit a new sample; mappings are confirmed using a fresh result, not only the original message.
13. Compare the analyzer printout, interface record and LIS record parameter by parameter.

Typical parameter	Verification expectation
WBC, RBC, HGB, HCT	Correct value, decimal precision, units and abnormal flag
MCV, MCH, MCHC, RDW	Correct index mapping; no transposition between codes
PLT and platelet indices	Correct platelet code, units and flags
Differential counts/percentages	Absolute and percentage results mapped to distinct LIS codes
Analyzer flags	Retained for review; never interpreted as a numeric result

9. Validation before go-live

The supervisor must approve documented validation before routine patient reporting. Test at least the following scenarios:

- Normal FBC result with all expected parameters
- Abnormal/high and abnormal/low results with flags
- A sample ID containing the longest format routinely used
- Decimal values and parameters with units
- Analyzer disconnect and successful reconnection
- Message resend or duplicate-result handling
- End-to-end comparison of analyzer, Analyzer Interface and LIS values

Acceptance criterion	Pass requirement
Patient/sample identification	Exact match in analyzer, interface and LIS
Result completeness	Every reportable parameter received
Result accuracy	Values, units, precision and flags match the analyzer output
Mapping	Every parameter routes to the approved LIS/system code
Acknowledgement	Analyzer records successful transmission without an unresolved retry
Recovery	Connection resumes without loss after a controlled interruption

10. Daily operating procedure

10.1 Start-of-day checks

- Start Analyzer Interface before routine analyzer transmission.
- **Note:**
  Before running any sample enter the Machine ID from ALIS as Medical Number
- Confirm the Biobase listener is active and the analyzer is connected.
- Send or review a known result when required by local policy to confirm end-to-end connectivity.

10.2 Processing patient results

1. Identify and process the sample on the Biobase analyzer according to the approved testing SOP.
2. Confirm the analyzer completes the run and transmits the final result.
3. In Analyzer Interface, verify the patient ID (**Medical Number** from biobasae), parameters, values, units, status and flags. 10.3 End-of-day checks

11. Troubleshooting

Problem	Likely cause	Corrective action
Analyzer will not connect	Wrong IP/port, listener stopped or firewall blocked	1. Confirm endpoint settings, listener status, network reachability and firewall rule. 2. Ensure the IP address of the PC where the Analyzer Interface is installed is static and not in DHCP. 3. Turn off firewall or create rule to allow Interface to communicate.
Connected but no results	Auto-send disabled, incomplete message or wrong protocol	Confirm HL7/MLLP mode and send a completed sample; review received-data logs.
No acknowledgement	Message processing or result storage failed	Review application error messages and logs; correct the failure before resending.
Sample ID missing/wrong	Barcode entry or HL7 field mismatch	Compare the analyzer message with the displayed result and correct analyzer identification settings.
Parameter unmapped	New or changed analyzer code	Map the parameter to an approved LIS code and verify with a fresh sample.
Incorrect units/precision	Mapping or analyzer configuration mismatch	Stop result release; compare analyzer, interface and LIS configuration, then revalidate.
Repeated results	Analyzer retry after withheld/late ACK	Determine why processing failed before deleting or suppressing any duplicate.

12. Approval

Role	Name	Signature	Date

Role	Name	Signature	Date
Prepared by			
Reviewed by			
Approved by			