

STANDARD OPERATING PROCEDURE

Abbott m2000

RS232 ASTM Setup, Result Mapping and Routine Interface Operation

Document number	SOP-ABBOTT-M2000-001
Version	1.0
Effective date	_____
Application name	AbbotM2000
Applies to	Abbott m2000 serial ASTM result interface

1. Purpose

Define the controlled process for connecting, validating and operating the Abbott m2000 result interface so that HIV assay results are received from the analyzer through RS232, acknowledged using ASTM communication, mapped and stored correctly.

2. Scope

This SOP applies to the Analyzer Interface registration named AbbotM2000 and its serial ASTM result connection. It covers interface setup, communication verification, mapping, daily checks and troubleshooting. It does not replace Abbott instrument instructions for specimens, reagents, calibration, maintenance, quality control or clinical interpretation.

3. Responsibilities

- Laboratory operator: complete analyzer readiness and QC checks, process specimens, verify transmitted results and report discrepancies.
- Laboratory supervisor: approve mappings and validation evidence, authorize routine use and investigate result-integrity events.
- IT/interface support: configure the serial connection, maintain the interface service and troubleshoot communication failures.
- Biomedical engineer: configure and maintain the Abbott m2000 communication port according to the manufacturer documentation.

4. Required equipment and information

- Abbott m2000 system with an enabled ASTM serial host interface.
- Approved RS232 cable or validated USB-to-serial adapter.
- Available Windows COM port and approved baud rate, data bits, stop bits and parity.
- Analyzer model, serial number and authorized Analyzer Interface access.
- Approved LIS/system codes for HIV viral-load and early-infant-diagnosis results.

5. Serial communication configuration

Setting	Requirement
Connection type	Serial / RS232
Application analyzer name	AbbotM2000
Protocol	ASTM with ENQ, ACK, NAK, STX, ETB/ETX and EOT control characters

Setting	Requirement
COM port	Select the Windows port assigned to the physical serial connection
Baud/data/stop/parity	Must exactly match the Abbott host communication configuration; do not assume defaults

6. Register the analyzer

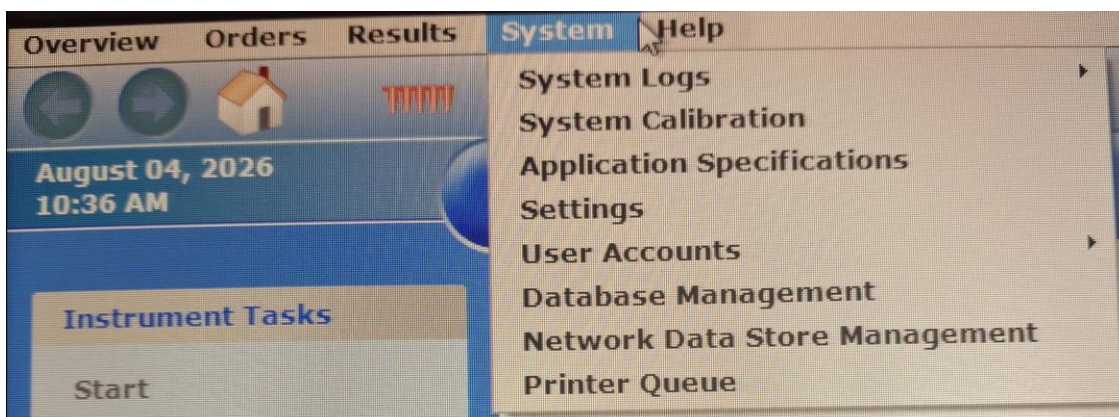
1. Connect the validated RS232 cable or USB-to-serial adapter and identify its COM port in Windows.
2. Open Analyzer Interface and choose New Analyzer.
3. Select AbbotM2000, enter the model and serial number, and select the correct COM port.
4. Enter baud rate, data bits, stop bits and parity exactly as configured on the Abbott host interface.

5. Create the analyzer and confirm the log reports that the handler started and the port connected successfully.
6. If the port fails to open, stop and correct the connection before testing patient-result transmission.

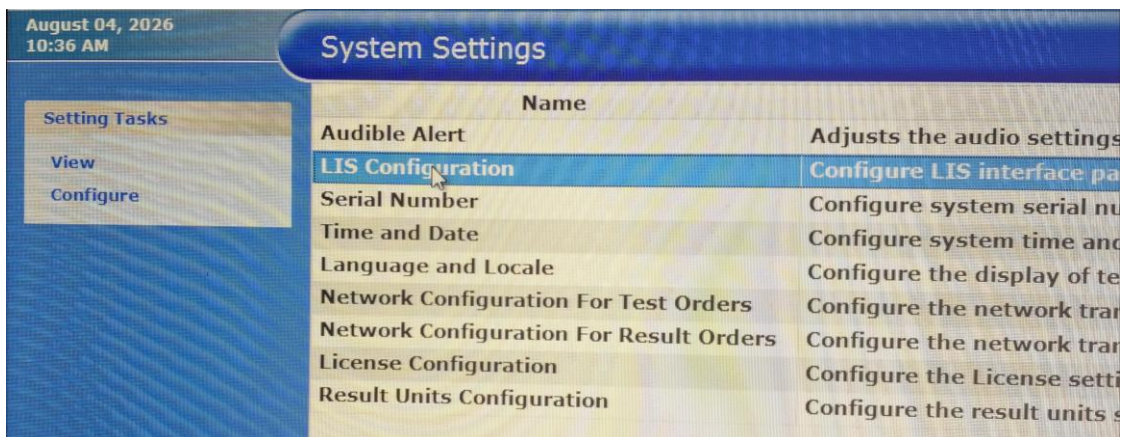
7. Abbot M2000 Configurations

- Login to the Abbot M200

- Select **System** -> **Settings**



- Under **System Settings**, tap or select **LIS Configuration**
- In the left select **Configure**.



- **LIS Configuration** will appear, switch **Communication: ON** | **Release Mode: Automatic**.
- Ensure the **Baud Rate, Parity, Data bits, & Stop bits** are the same as in Step 6.

The screenshot shows the 'LIS Configuration' window. It has a dark blue header with the title 'LIS Configuration'. Below the header, there are two main sections: 'Release Mode Configuration' and 'Serial Port Configuration'. In the 'Release Mode Configuration' section, there are radio buttons for 'Communication' (On is selected), 'Release mode' (Automatic is selected), and 'Number Format' (Invariant is selected). There are also checkboxes for 'Transmit to LIS' with options: 'Assay control result', 'Test exception', 'Genotype result' (checked), and 'Laboratory Defined Application result'. The 'Serial Port Configuration' section has dropdown menus for 'Port ID' (COM1), 'Baud rate' (19200), 'Parity' (Even), 'Data bits' (8), and 'Stop bits' (1).

- The interface recognizes HIV0.2ml and HIV-1 assay identifiers.
- The specimen ID is read from the ASTM order record. The result is read from the first result record.

8. Parameter mapping

Analyzer assay identifier	Interface parameter	Expected storage behavior
HIV0.2ml	HIV0.2ml	Viral-load result; numeric values retain the reported unit and threshold symbols such as < or >
HIV-1	HIV-1	Early-infant-diagnosis result; qualitative result text is preserved

7. Transmit a controlled verification result for each supported assay.
8. Open Mapping Settings and select AbbotM2000.
9. Map HIV0.2ml and HIV-1 to the laboratory-approved LIS/system codes.
10. Save the mappings, then transmit fresh results and compare analyzer, interface and LIS records.

9. Validation before go-live

Acceptance criterion	Pass requirement
Specimen identification	Exact match across analyzer, interface and LIS
Assay identification	HIV0.2ml or HIV-1 detected and mapped to the approved LIS test
Result integrity	Result text/value, threshold symbol and unit match the analyzer report

Acceptance criterion	Pass requirement
ASTM exchange	Frames receive ACK; rejected or malformed frames receive NAK and are investigated
Recovery	Communication resumes after a controlled disconnect without unresolved or missing samples

10. Daily operation

11. Start Analyzer Interface before enabling routine result transmission.
12. Confirm the serial handler reports a successful connection and that analyzer QC is acceptable.
13. Process specimens according to the approved Abbott testing SOP.
14. Verify specimen ID, assay, result text/value, unit and threshold symbol in Analyzer Interface.
15. Resolve unsupported assays, unmapped parameters and transmission warnings before LIS release.
16. At end of day, reconcile expected analyzer results against interface/LIS records and document downtime or manual entry.

11. Troubleshooting

Problem	Likely cause	Corrective action
COM port will not open	Wrong port, port already in use, disconnected adapter or driver fault	Confirm Device Manager assignment, cable and adapter; close competing software; restart the listener.
No ENQ or frames received	Analyzer host output disabled or mismatched serial settings	Confirm ASTM host mode and make every serial setting identical at both ends.
Unsupported assay warning	Assay identifier is not HIV0.2ml or HIV-1	Stop release; capture the raw ASTM record and obtain an approved interface update/mapping decision.
Result not mapped	Assay parameter has no LIS code	Map the detected parameter, save, and verify using a fresh result.
Wrong specimen ID	Order record or barcode mismatch	Compare the ASTM O record with the analyzer worklist and correct identification before release.
Release Button Disabled in Abbot M2000		Check out Step 7 and ensure Communication is ON

14. Approval

Role	Name	Signature	Date
Prepared by			

Role	Name	Signature	Date
Reviewed by			
Approved by			