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Dearborn Laboratory Auto Technical ABBOTT A3600 Accelerator Automation Validation

Document Type: Procedure

I. PURPOSE AND OBJECTIVE:

A validation procedure is necessary to verify that the automation configurations and modules utilized for the Abbott a3600 Accelerator Automation line are performing as intended for normal daily operations. The validation encompasses all track modules, Architect instruments, and Data Management System (DMS)/Instrument Manager (IM) software configurations. This validation procedure defines the various scenarios to be tested on the automation line and expected outcomes in DMS and /or IM software as applicable.

II. PROCEDURE:

A. All validation samples must be ordered in the Laboratory Information System (LIS) Testing environment. All test orders must be received in the LIS prior to placing on the automation line to download to the DMS is based upon receipt in the LIS. Specimens with incomplete collection information will generate an UNKN message in DMS and the sample will route to a @Priority Output (PO) Exception lane.

B. Documentation required for each scenario will be the following (as applicable to scenario):

1. DMS Trace Log – this document will provide a detailed log of sample routing including centrifugation, decapping, instrument query, aliquoting, recapping, sorting, sealing, storage, and desealing. If sample is queried on instrument, results will also be available in DMS trace log to verify correct data transmission from DMS to IM.
2. IM Test Worksheet – this document is needed for all round-trip testing and

instrument exception testing. It will be checked against the DMS Trace Log and LIS report for accurate data transmission.

3. LIS Report – this document will provide validation of result posting to LIS for autofiling user Interface, 906351 Incoming Lab Results Di.
4. Entry into Abbott a3600 Automation Validation spreadsheet with documentation of Pass or Fail for each scenario tested.

C. Architect Routing and Round-Trip Validation

1. Round trip testing must be performed for each assay on all Architects
2. In cases of multiple test codes for a single assay, each test code requires 1 round trip test. Therefore, multiple codes for a single assay (i.e. Glucose) can be divided among instruments so that each instrument assay is tested in conjunction with each test code.
3. In order to ensure that samples are routed to the intended instrument for testing, place all instruments off-line in DMS except instrument to be tested.
4. Sample placement on track should be divided among the following scenarios:
    a. Priority Input (Input Output Module (IOM) IOM-1 and IOM-2) – Capped, Unspun
    b. Priority Input (IOM-1 and IOM-2) – Uncapped, Spun
    c. Routine Input (IOM-1 and IOM-2) – Capped, Unspun
    d. Routine Input (IOM-1 and IOM-2) – Uncapped, Spun
    e. Bulk Input Module (BIM) – Capped, Spun

D. Architect Scenarios

1. Instrument Exceptions
    a. Generate instrument exception at Architect, perform workflow for rejecting test code INSTRUMENT EXCEPTION in IM, verify sample routing to PO lanes at IOM-2 (based on error), select Reject/Rerun in IM, verify routing of sample back to instrument for completion.
2. Dilutions
    a. Perform at minimum 1 Chemistry and 1 Immunochemistry test that require auto-dilution and verify correct performance in DMS and IM.
3. WAIT Lane
    a. Order Beta human chorionic gonadotropin(Outpatient and Emergency Room), and Hepatitis / HIV test codes that qualify and verify samples go to WAIT lane and return to instrument for dilution / rerun or seal and store if negative.
4. INCOMPLETE Lane
    a. Order at least one test that will have assay not available on instrument and verify sample routes to Incomplete lane and returns to instrument once

assay is available.

E. Sorting Scenarios

1. CHEM sort
    a. Order test code OSMO, verify sort code download in DMS and correct tube sorting for:
        i. BIM: Decap and sort
        ii. Routine Input – Capped, Unspun: Spin, decap, sort
        iii. Routine Input – Uncapped, Spun: Sort
        iv. Routine Input – Capped, Spun: Decap, sort
        v. Architect test + OSMO, Priority Input – Capped, Unspun: Spin, decap, route to Architect, sort
    b. Send sample to SRM after sort via:
        i. Uncapped Seal and Store
2. SER sort
    a. Verify priority sorting of SER sort tests as follows:
        i. Order SER1 test and verify sampled sorted to SER1
    b. Send sample to SRM after sort via:
3. Uncapped Seal and Store
    a. Multiple Sorts for Chemistry
        i. Order test codes for CHEM, and SER on single order to verify priority and multiple sorts.
        ii. Send sample to SRM after all sorts are complete via:
            a. Uncapped Seal and Store
4. HEP sort
    a. Run known positive for HBSAG, HIV4G, HCV and verify correct sample routing and sorting for initial, duplicate runs, and neutralization runs.
5. HEMA sort
    a. Order each test code for HEMA sort and verify correct sample sorting (one test per sort scenario) for:
        i. BIM: Sort
        ii. Routine Input – Capped, Unspun: Sort
        iii. Priority Input – Capped, Unspun: Sort
    b. Order one test for HEMA sort and A1C test code and verify correct sorting for:
        i. HEMA priority sort, then A1C sort

c. Send sample to SRM after sort(s) are complete via Capped / Sealed to SRM.

6. A1C sort
    a. Order test code A1C and verify correct sample sorting for:
        i. BIM: Sort
        ii. Routine Input – Capped, Unspun: Sort
        iii. Priority Input – Capped, Unspun: Sort
    b. Send sample to SRM after sort is complete via Capped / Sealed to SRM.
7. COAG sort
    a. Order each test code for COAG sort and verify correct sample routing and sorting for:
        i. Routine Input – Capped, Unspun: Spin (CM-3 only), sort
        ii. Priority Input – Capped, Unspun: Spin (CM-3 only), sort

F. Aliquot Scenarios
1. Warde Send Out Tests
    a. Order one test for WDRF, WDFZ, and WDRT and verify correct sample routing and sorting for:
        i. BIM: Decap, aliquot and recap, sort aliquot tube, seal and store parent tube.
        ii. Routine Input – Capped, Unspun: Spin, decap, aliquot and recap, sort aliquot tube, seal and store parent tube.
        iii. Routine Input – Capped, Spun: Decap, aliquot and recap, sort aliquot tube, seal and store parent tube.
        iv. Routine Input – Uncapped, Spun: Aliquot and recap, sort aliquot tube, seal and store parent tube.
        v. Architect test + Warde test + SORT (any Chem sort), Priority Input – Capped, Unspun: Spin, decap, route to Architect, aliquot and recap, sort aliquot tube, sort parent to tube correct sort rack.
2. Beaumont Health (BH) Send Out Tests
    a. Order one test for BHRF, BHFZ, and BHRT and verify correct sample routing and sorting for:
        i. BIM: Decap, aliquot and recap, sort aliquot tube, seal and store parent tube.
        ii. Routine Input – Capped, Unspun: Spin, decap, aliquot and recap, sort aliquot tube, seal and store parent tube.
        iii. Routine Input – Capped, Spun: Decap, aliquot and recap, sort aliquot tube, seal and store parent tube.

iv. Routine Input – Uncapped, Spun: Aliquot and recap, sort aliquot tube, seal and store parent tube.

v. Architect test + BH test + SORT (any Chem sort), Priority Input – Capped, Unspun: Spin, decap, route to Architect, aliquot and recap, sort aliquot tube, sort parent to tube correct sort rack.

G. BIM

1. In scenarios above that indicate BIM loading, load all sample types together and verify that BIM correctly processes the multiple tube types, decaps only tubes that require decapping, routes to Architect, aliquots, sorts to lanes correctly, seals, and stores.

H. SRM

1. Verify samples sent to SRM are stored for 7 days and are then disposed by SRM.
2. Request delivery of samples stored in SRM and verify correct sorting to IOM-1.

I. Automation Exceptions

1. Generate automation exceptions (i.e. UNKN in DMS) and verify sample sorting to PO lanes at IOM-1.

J. Add-On Testing

1. Add on additional tests to a sample that has been sent to SRM for storage for the following scenarios and verify correct sample routing / sorting:
    a. Architect test – deseal, route to instrument, reseal, store
    b. Sort test - sort
    c. Aliquot test – deseal, aliquot, recap and sort aliquot tube, seal and store parent tube.

K. Non-Standard Tube Type Testing

1. Verify Architect sampling, sealing, and storage for all non-standard types in use on automation line (i.e. pour over tubes).

L. Load Testing

1. Perform at least 1 load test with minimum of 250 samples that have orders for all scenario categories for instrument testing, aliquoting, sorting, sealing, and storage on the automation line.
2. Samples will be loaded to simulate normal daily operations and tubes will be followed to verify correct routing and sorting.

III. NOTES:

A. For all sorting codes, LIS will download to DMS the sort code only, not the individual test code.

B. For all aliquot codes, LIS will download to DMS the individual test code. The aliquot tubes will then be sorted to the appropriate racks based on the DMS mapping for each aliquot test code.

Approval Signatures

Step Description	Approver	Date
Medical Director	Jeremy Powers: Chief, Pathology	6/21/2022
Policy and Forms Steering Committee Approval (if needed)	Michelle Alexander: Medical Technologist Lead	6/20/2022
Policy and Forms Steering Committee Approval (if needed)	Gail Juleff: Project Mgr Policy	6/19/2022
	Kimberly Geck: Dir, Lab Operations B	6/17/2022
	Michelle Alexander: Medical Technologist Lead	6/17/2022

Applicability

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