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Document Contact	Michelle Alexander: Medical Technologist Lead
Area	Laboratory-Chemistry
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Dearborn Laboratory Auto Technical Abbott Instrument Manager And Laboratory Information System (LIS) Validation Procedure

Document Type: Procedure

I. PURPOSE AND OBJECTIVE:

This procedure outlines testing to all operations that occur to produce a test result on the patient record. The validation procedure encompasses order download, result production from instrument(s), execution of all rules and calculations applied to a test result, comments added to the test record in the Instrument Manager (IM),transmittal of verified results from IM to Laboratory Information System (LIS), and appropriate autofiling of verified results in the LIS. This procedure is intended for the validation of the Abbott c16000, c8000 and i2000 chemistry and immunoassay analyzers interfaced with Data Innovations (DI) IM and LIS.

II. PROCEDURE:

A. For each parameter tested the following must be documented on the validation spreadsheet:
    1. Abbott upload and LIS download codes with LIS Sample Identification (SID)
    2. Order download to middleware (IM) occurred as expected (Y/N)
    3. Result(s) produced (wet or dry) as expected (Y/N)
    4. All rules fired as expected (Y/N)
    5. Calculations executed as expected (Y/N)
    6. Transmittal of verified results and test level comments from IM to LIS as expected

(Y/N)

7. Rounding of results to the proper decimal precision as expected (Y/N)
8. Autofiling in LIS of all results, test comments, and calculations as expected (Y/N)
9. All English Text Codes (ETC) for test comments autofiled in LIS as expected (Y/N)
10. All LIS results are transmitted to EPIC (Hospital Information System (HIS)) as expected (Y/N)

B. Screen shots from both IM and LIS are required as part of the documentation for the above items. LIS Reports will also be printed for documentation.

C. The following is the specific tests, rules, calculations, and comments to be tested in this validation procedure:

1. Order Download
    a. All test codes to be performed on the c16000 and i2000 must be ordered within the LIS test environment and verified that download occurs in IM.
        i. Includes serum, urine (random and 24 hour), cerebrospinal fluid (CSF), and body fluids
        ii. Includes all upload codes for the same test (i.e. Glucose)
    b. Tests should ordered both as a battery (i.e. BMET) and as individual components (i.e. BUN) as applicable.
    c. Tests orders should also include orders with multiple analytes (i.e. CMET, TSH, AHPT).
        i. Include orders that require runs on more than 1 instrument (i.e. Ammonia and AHPT)
        ii. Include orders that will be run at different times (i.e. AHPT AM shift only, Creatinine Clearance)

2. Rules
    a. Autoverifcation
        i. Every test which qualifies for autoverification must be tested on each analyzer that will generate these values.
        ii. This testing will encompass all normal range values for each analyte that has a normal range established (i.e. no normal ranges for random urines, 24 hr urines, body fluids). Normal ranges are set in LIS and will override any normal ranges within IM.
        iii. This testing also requires one low abnormal and one high abnormal (not critical) result per analyte to verify autoverification outside of normal range but within technical limits/Analytical Measurement Range (AMR)
    b. Criticals
        i. Every test with a critical value must be tested on each

instrument that will report these values.

ii. Both critical low and high values for each analyte must be tested and will include all age ranges that a critical value is reported.

c. AMR

i. All tests are required to have both the lower and upper end of the reportable range tested.

ii. If wet testing cannot be performed for any analyte, dry testing is acceptable.

iii. Perform 2 tests / analyte at both lower and upper end of AMR. Testing should follow this format: If AMR is set to <5, then test values of 5 and 4 to test lower limit. If AMR is set to > 1000, then test values of 1000 and 1001 to test upper limit. Use AMR limits established in IM for each analyte to perform this testing.

d. Delta Checks

i. All tests with Delta check rules must be tested for correct execution of rule.

a. If possible, test each delta rule on 2 different analyzers (i.e. 1st result ARCH#1 and 2nd result ARCH#2).

b. One delta check test / analyte is required.

e. Therapeutic drug monitoring (TDM)

i. All TDM assays must be tested for '<' values to ensure that result is held for tech review (i.e. examine sample) and re-run to confirm '<' value.

ii. Test will be manually validated upon review and re-run in IM.

iii. One test per analyte is required.

f. Alphanumeric Results

i. All tests that will translate a numeric instrument value into a qualitative result must be tested (i.e. Urine Drug Screen, Hepatitis, HIV)

ii. Both negative and positive test values must be tested for each analyte

g. Calculations

i. Every test that has an arithmetic calculation applied must be tested for correct execution of the rule.

a. The calculation will be manually performed to set the expected value and will be used to verify accuracy of IM calculation.

ii. Calculations must be checked as both individual tests and as

part of battery which includes Chemistry tests (i.e. FETRF).

iii. Calculations executed within IM must be verified that they autofile within LIS.

iv. Every test that has an ETC calculation in LIS must be tested to ensure that these calculations are executed and autofile as expected.

h. Manual and Automatic Dilutions

i. Every test that has an automatic dilution must be tested

ii. Every test that has a manual dilution option must be tested

3. Test Comments

a. Any test that has a test level comment appended in IM must be tested to ensure that comment autofiles within LIS as expected (i.e. ETC).

4. Quality Control (QC)

a. All QC results are to be managed through the Bio-Rad Unity Connect Real Time software application.

b. All tests must be verified to validate as expected with QC values within acceptable limits on all instruments.

c. All tests must be verified to HOLD results for all QC values outside of acceptable limits on all instruments.

5. Error Codes

a. To the extent possible, generate all instrument error codes that can be generated for each test.

6. Hemolysis, Icterus and Lipemia (HIL)

a. At least one sample per analyte that qualifies for HIL interpretation must be performed.

7. Order Priority

a. Order and run 1 sample for all eligible stat tests as STAT priority and verify order executed as expected.

8. Add-Ons

a. Add-on tests to previously resulted order and run add-on on a different analyzer and document that testing and result reporting occurred as expected.

b. Add-on tests to order that has been received but not run and document that testing and result reporting for all tests occurred as expected.

9. Time Delay

a. Test at least one order for collection and receive time from previous day with sample testing completed the next day and document that testing

and result reporting occurred as expected.

b. Test at least one calculation for time delay (i.e. Creatinine Clearance) in which one sample is run one day the other is run the next and document that all calculations and result reporting occurred as expected.

III. NOTES:

A. Any validation issue for either IM or LIS will be logged in the Chemistry Automation Line project file on SharePoint.

B. This plan does not specifically address receiving specimens in LIS. Any issues in this area will be sent to the LIS team for further troubleshooting and investigation.

Approval Signatures

Step Description	Approver	Date
Medical Director	Jeremy Powers: Chief, Pathology	7/14/2022
Policy and Forms Steering Committee Approval (if needed)	Gail Juleff: Project Mgr Policy	7/14/2022
Policy and Forms Steering Committee Approval (if needed)	Michelle Alexander: Medical Technologist Lead	7/14/2022
	Kimberly Geck: Dir, Lab Operations B	7/14/2022
	Anji Miri: Supv, Laboratory	7/14/2022
	Michelle Alexander: Medical Technologist Lead	7/12/2022

Applicability

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