18-Post-analytic Procedures

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ANNUAL REVIEW:

REVIEWED	Sanford N. Bandy, M.D	July-16-2025
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SUPERSEDES: Procedure titled _____

Purpose

This SOP serves to describe the Policy and Procedures for Post analytical services performed by the lab.

Scope

This SOP applies to all laboratory personnel

Health and Safety

Be sure to wear appropriate PPE when handling samples after analysis.

Abbreviations

CLIA- Clinical Laboratory Improvement Amendments
EMR – Electronic Medical Report
KPI- key performance indicator
LIS – Laboratory Information System
MMCCCL- Meharry Medical College Clinical Consolidated Laboratory
SOP- Standard Operating Procedure

Policy

This policy is on how to handle reporting results after passing through analytical phase, like reporting unacceptable specimens, critical results or corrected after first reporting, data interpretation, reference laboratory reports, turn-around-time and patient access to test results

Procedure

Result Reporting must have

• Name and second identifier of patient
• Name of laboratory where testing performed
• Name, address and CLIA ID number
• Specimen type or source where appropriate
• Date/time of specimen collection
• Date(s) of testing and reporting
• Test result and appropriate unit of measure
• Reference range of the test
• Other pertinent information for interpretation

Must be assured ordering clinician receives result
Readily accomplished with electronic reporting if non-interfaced laboratory results processes must be in place to assure securely delivery to appropriate clinician

Unacceptable Specimens
• For unacceptable specimen – should be reported indicate condition of specimen and action taken by the laboratory
• This Should be documented for all tests whether performed in house or at reference laboratory
• The lab to keep a log on unacceptable specimens for quality management review

Critical Results

All critical results as being identified as per laboratory policy should be shared with ordering physician or health care representative within 1 hour of results become available and this should be documented the following details:

Test identified as critical

Name of person call associated with time

Person received the results with read back associated with time

They should be establishing policy about escalating the case if unable to report critical results

All should be documented either on log sheet or electronically via LIS

This should be reviewed monthly as one of key performance indicator (KPI)

Table of Critical as per MMCCCL:

Test Name	≤	≥
Calcium (mg/dL)	6	13
T CO2 (mmol/L)	10	40
Bilirubin, Total (mg/dL)		15
Glucose (mg/dL)	55	450
Iron (µg/dL)		500
Potassium (mmol/L)	3.1	6.1
Sodium (mmol/L)	120	160
Magnesium (mg/dL)	1.0	9.0
Phosphorous (mg/dL)	1.0	9.0
Hematocrit (%)	21	65
Hemoglobin (g/dL)	7.0	21
Leukocytes (x 10^3/ µL)	2.0	40
Absolute Neutrophil Count (x 10^3/ µL)	0.5	
Platelets (x 10^3/ µL)	20.0	1000

Add on test:

Sample will be store for possibility to add on to avoid bleeding the patients. The samples will be stored not more than 1 week, once call received, the kit insert should be checked for the time frame of sample stability, do not accept to add tests if more than the manufacturer claim of sample stability

Correction of Laboratory Errors

• If error detected after report released either laboratory recognizes an erroneous result has been transmitted or the laboratory is notified that a reported result is incorrect
• The report must clearly indicate:

- ❖ Why the error occurs, time and date

- ❖ How and who correct the error
- ❖ Who to notify of error, time and date
- ❖ Prepared erroneous report as such and revised report as such
- ❖ Documentation of who was notified, by whom and date and time of notification
  Make sure the corrected report in hands of appropriate clinician
- ❖ The report must show the old and the corrected results

Post-Analytic Errors Occurring Most Commonly WITHIN Laboratory

• Improper data entry
• Erroneous validation of analytic data
• Failure in reporting (specimen never obtained, error in collection, incorrect entry of patient ID into reporting system, failure of report to reach clinician)
• Critical values not reported in timely manner

Post-Analytic Errors Occurring Most Commonly OUTSIDE Laboratory

▪ Available results not reviewed by receiving physician
▪ Sub-critical values overlooked
▪ Lack of interpretative information leading to incorrect interpretation of result

Reference Laboratory Results

• System in place to assure all referred tests are resulted and reported
• If no electronic interface between EMR and reference lab, The report should be attached as received from reference lab
• Any interface with reference laboratory should be periodically validated
• Preliminary vs Final Results issues to be reviewed

Reference Laboratory Error Correction

• The reference laboratory report cannot be altered by receiving laboratory
• If telephone notification by reference laboratory of an error, do not change original report
o Note may be appended to original report to indicate report is erroneous and
o Appropriate individuals notified immediately and documentation of this should be kept
• Obtain a copy of the corrected report from the reference laboratory and have it add to LIS and notify the ordering physician of the correction being made. Keep record

Patient Access to Results

• Upon request, patient or patient representative must have access to completed test results
• Procedures must be in place for receiving, processing and responding to test result requests
• Results must be provided within 30 days
• If not available at 30 days lab must notify patient in writing of reason for delay
• Results must be provided in format requested and if not available a readable hard copy may be issued

Exceptions to Direct Patient Access

• If lab does not perform any covered transactions electronically (e.g., billing, preauthorization) they are exempt
• This will be a rare facility

• If a licensed health care professional has determined that access is reasonably likely to endanger the life or physical safety of an individual or another person, request may be denied by laboratory

Authentication for Patient Result Access

• Procedure for direct patient access to results must include a defined authentication process to verify the identity of the patient or their personal representative and if personal representative, written documentation patient has given permission for them to receive results

References

CAP all common checklist 2023
COLA accreditation manual 2022