QA.TEST.10.0 TEST RESULT REVIEW

PURPOSE
To define a system of detecting and correcting significant clerical and analytical errors and unusual laboratory results in a timely manner.

SCOPE
This policy applies to all MACL testing facilities.

POLICY OWNERS
QA and Safety Officer

RELATED DOCUMENTS
QA.REPORT.1.0 Critical Values—Reporting of Significant Results
QA.REPORT.1.1 Critical Values
COMP.PRIV.4.0 Correction of Manual and Computer Errors

DEFINITIONS

A. **Instrument system flag—** a predefined test parameter indicator used with automated and semi-automated testing. These system flags are specific to the instrument / analyte and correlate to specific directions for the user.

B. **Technical Limit—**a predefined value specific to each instrument/analyte which when exceeded, must be acknowledged or verified by the user. A low technical limit may require verification of sufficient specimen for analysis. A high technical limit may require dilution for verification.

C. **Delta Value—** an analytical value that is inconsistent with a patient's previous test results. See Delta Variations table below.

D. **Critical Value—**a value which represents a pathophysiological state at such variance to normal as to be potentially life threatening, or which requires immediate medical attention. See QA.REPORT.1.1 Critical Values.

TEXT
Laboratory results are entered into the LIS (laboratory information system) by either direct transmission through an interface or by manual entry. Both methods are subjected to a system of result review before results are released and again after results are released. Before results are released, results are evaluated using predefined instrument system flags, technical limits, delta value checks and critical value flags. Individual test procedures include discussions of common analytic errors and interferences. Specific instructions are listed for each and may require reanalyzing a specimen; using an alternate test method; or not reporting the result at all. Unusual or unexpected results are referred to a supervisor, pathologist, lead tech, or medical director. This may include unusual hematology or microbiology results, as well as other unexpected laboratory results that appear inconsistent with the patient's clinical picture.

TEST RESULT REVIEW

After results are released, results are reviewed by one or more of the following reports: the Corrected Result Report, various QA Failure Reports, Microbiology Culture Reports, and the Tech Result Log. When errors are identified, corrections are made immediately and the appropriate clinician or healthcare giver is notified as soon as possible. Rapid detection, correction, and notification of errors are necessary to ensure appropriate clinical decision making.

A. Review of Results Prior to Release

1. Instrument System Flags and Technical Limit Flags
   a. Evaluate results with instrument system and/or technical limit flags using criteria specific to the test procedure.
   b. Evaluate specimen for integrity, assessing whether sample contains hemolysis, clots, fibrin strands, etc.
   c. Determine if sample quantity is sufficient for analysis.
   d. Check for an instrument malfunction; repeat controls if necessary.
   e. Refer to list of test interferences and associated instructions.
   f. Perform appropriate next steps, per specific test procedure.
2. Delta Value Checks
   a. Evaluation
      i. Evaluate delta value checks using criteria specific to the test procedure. These checks are predefined in the LIS QA criteria and alert testing personnel to perform this evaluation.

DELTA VARIATIONS		
TEST	**TIME IN DAYS**	**VARIATION**
GLUCOSE	3	200%
BUN	3	50%
SODIUM (NA)	3	20 mEq/L
POTASSIUM (K)	3	1.0 mEq/L
CHLORIDE (CL)	3	20 mEq/L
CARBON DIOXIDE (CO2)	3	10 mEq/L
PHOSPHORUS (PHOS)	3	50%
CALCIUM (CA)	3	16%
HGB	7	3.0
WBC	7	50%
PLT	7	30%
MCV	7	4.0

      ii. Review patient's previous results.
         a) Use Sunquest Display Prior Function to view previous results.
         b) Compare previous results with current results.
      iii. Check specimen for correct labeling and patient identification.
      iv. Evaluate specimen for integrity, assessing whether sample contains hemolysis, clots, fibrin strands, etc.
      v. Determine if sample quantity is sufficient for analysis.
      vi. Check for an instrument malfunction; repeat controls if necessary.
      vii. Refer to list of test interferences and associated instructions.
      viii. Contact nursing unit for treatment patient is receiving or has received.
      ix. Identify problems and perform corrective action.
   b. Documentation

i. Release results flagged with a delta value check using the appropriate comments.
ii. If more than one parameter has a delta check, add the comment to each parameter.
iii. Possible comments include the following:
a) DR1 & DR2 – Difference noted from previous result noted. Specimen integrity and label verified.
b) PRB – Patient receiving blood
c) NVH – No visible hemolysis
d) POND – Patient on dialysis
e) CHEMO – Patient on chemotherapy
f) SURD – Patient in surgery
g) INT – Possible interfering substances
h) POSSU – Post surgery
i) POSDE – Post delivery

3. Critical Values
a. Evaluation
i. Evaluate critical values using criteria specific to the test procedure. These values are predefined in the LIS QA criteria and alert testing personnel to perform this evaluation.
ii. Review patient's previous results.
a) Use Sunquest Display Prior Function to view previous results.
b) Compare previous results with current results.
iii. Check specimen for correct labeling and patient identification.
iv. Evaluate specimen for integrity, assessing whether sample contains hemolysis, clots, fibrin strands, etc.
v. Determine if sample quantity is sufficient for analysis.
vi. Check for an instrument malfunction; repeat controls if necessary.
vii. Refer to list of test interferences and associated instructions.
viii. Contact nursing unit for treatment patient is receiving or has received.
ix. Identify problems and perform corrective action.
b. Documentation
i. Release Results with critical flags using the appropriate comments.
ii. Refer to Critical Values—Reporting of Significant Results, QA.REPORT.1.0. Minimum requirements include name of person called and time of call.
iii. If more than one parameter has a critical, add the comment to each parameter.
iv. Possible comments include the following:
a) CRIT – Critical result noted. Specimen appearance and label verified. Suggest repeat if questionable.
b) CRR – Critical result noted. Specimen appearance and label verified. Suggest repeat if questionable. Results called to:

4. Manual Entry of Results—Three Step Process
a. Entry

i. Hand enter results carefully into the LIS.
ii. Focus on computer entry and allow no distractions.

b. Review
i. Check data for accuracy before release by performing one of the following:
a) Review entry by second associate before results are released.
b) Check the entered result against the test record before result is released.
c) Print worksheet and verify result before result is released.
ii. Correct errors prior to proceeding to the release step.

c. Release
i. Document Check and Enter step on manual log sheet.

B. Review of Results After Release

1. Released results are reviewed by the supervisor or designee using a variety of department specific reports.
2. The Sunquest QA Failure Report is reviewed for appropriate response and documentation of technical limits, delta value checks, and critical values. See Printing the Quality Management Report below.
3. Other reports include the Corrected Result Report, Tech Logs, and the Microbiology Culture Report.
4. Errors identified after the release of the result are corrected immediately.
5. For results that change report category or do not fall within total allowable error, the appropriate clinician or healthcare giver is notified as soon as possible.
6. Document the name of the individual notified. The time and date stamp are captured when the correction is made.
7. Refer to COMP.PRIV.4.0 Correction of Manual and Computer Errors.

The rapid detection, correction, and notification of errors are necessary to ensure appropriate clinical decision making.

C. Printing the Quality Management Report

1. Report is requested from the Misys computer system as follows.
a. Enter Misys function “RP” (Laboratory Reports).
b. Select Printer: [site specific]
c. Select option 6, “Quality Assurance Reports”.
d. Enter the date desired (up to 7 days prior to current date).
e. Hospital ID prompt: Enter hospital location desired. Available location codes:
CHE—Community Hospital East
CHN—Community Hospital North
CHS—Community Hospital South
CHH—Indiana Heart Hospital
CHWD—Community Howard Regional Health
CWH—Community Westview Hospital
IOH—Indiana Orthopaedic Hospital

IOHS—Indiana Orthopaedic Hospital South
MACL—Mid America Clinical Labs (Regional)
SVAN—St Vincent Anderson
SVCL—St Vincent Clay
SVCR—St Vincent Carmel
SVDN—St Vincent Dunn
SVEV—St Mary's
SVFR—St Vincent Frankfort
SVHH—St Vincent Heart Center
SVIN—St Vincent Indianapolis
SVJN—St Vincent Jennings
SVJO—St Vincent Kokomo
SVNE—St Vincent Northeast
SVMR—St Vincent Mercy
SVRA—St Vincent Randolph
SVSA—St Vincent Salem
SVWP—St Vincent Williamsport
SVWH—St Vincent Women's

f. Select Options Prompt: Type "2, 3, and 4" and enter.
g. Select sort prompt: Enter #1, by tech code.
h. Tech prompt: Enter individual tech codes desired or use site specific group tech codes.
i. Location prompt: Hit enter/ return.