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Logo for Valley Laboratories	Origination	3/23/2022	Owner: Lindsey Westerbeck: Director, Laboratory Services
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Quality Assurance of Patient Results

PURPOSE

This procedure provides guidelines for review and decisions and actions related to Quality Assurance (QA) failures by testing personnel. The goal is for all sections of the Clinical Laboratory to safely report patient results that exceed established Critical Values, Delta failures and/or Technical Limits. This procedure is used in conjunction with individual technical procedures.

POLICY

Timeliness of response	• Upon observation of a QA failure, respond immediately to investigate and resolve. Appropriate action steps should be completed without delay. • Communicate the situation if necessary to the patient's caregiver, coordinating action when applicable (e.g. recollect of sample).
Reporting of patient results that fail QA	• The numeric results are not to be reported until all QA failure follow-up is complete and the failure is resolved, with rare exceptions follows: ◦ Lactates run in duplicate that repeatedly exceed the technical limit. ◦ When approval is obtained from a Pathologist on a case-by-case basis. ▪ If specimen (or other) limitations

	prevent completing the QA failure follow-up, the Laboratory Medical Director (or designated Pathologist) must be immediately contacted for further instructions.
When a patient's caregiver requests results that failed QA	• Explain there is a QA failure and that the numeric result **cannot** be reported. • It is acceptable to state only that the test requires further analysis to get a result and will be delayed. ◦ **DO NOT** report numeric values, or describe the results as "high" or "low" until the QA failure follow-up is completed. • If the patient's caregiver insists on additional information being reported prior to the completion of the QA failure follow-up, an exception may be granted with approval from a Pathologist (see above).

Appended comments	• If comments need to be appended to the results to document actions taken, approved ETC(s) should be used whenever possible.
	  ◦ Free text comments are **only** to be used for QA failures if an ETC is not available to explain actions taken.
	• If additional notes are needed, they are to be recorded on shift report or worksheets.
	• Please be mindful with over documentation of appended comments in the LIS - all comments will become part of the permanent patient record.
	  ◦ Document only what is pertinent to the QA failure and actions taken, using the shift report or worksheets for additional notes.

Patient result QA failure trends	• Instruments or methods demonstrating unsual trends in QA failures, method performance issues, or significant events will be removed from service. • Respond immediately to investigate and resolve issues in order revalidate for patient testing.
Monitoring appropriateness and effectiveness of response	• A review of records related to QA failures of patient

	results will be conducted daily to determine appropriateness and effectiveness. • Appropriate follow-up will be provided to the involved personnel.

QUALITY ASSURANCE FAILURES

- Analyte, sex, age, time, and method-specific ranges or cut-off values that have been established through the method validation process.
- The Laboratory Information System (LIS) is defined to provide an alert at the time of result data entry of all QA failures that have occurred before reporting.
- Not all analytes have established delta check failures. When manually releasing or reporting results, it is important to display and review previous results (if available) for comparison.

Critical Values are laboratory test results that may indicate a life-threatening situation, which would usually require immediate adjustment of treatment or further testing. LIS flag "FAILED VERIFY" [Critical verify range for this patient/method] will display.

Delta Check Failures may have both change in patient result (delta) and time frame within which the change is significant. Delta failure in the LIS fires only based upon the change in patient result (not time frame) – so refer to method-specific guidelines for true delta failures. LIS flag "FAILED DELTA" and the patient's previous results/date and time of collection will display.

Delta failures are laboratory test results that are designed to detect the following:

1. Significant changes to the patient's clinical condition
2. Poor quality specimen (QNS, clotted, microclot, hemolysis)
3. Patient/specimen identification errors (bedside or in laboratory)
4. Method performance problems
5. Interfering substances (cross react/react with measurement to cause artificially high or low results)

Technical Limit failures are laboratory test results that exceed the analytic measuring range (AMR or Reportable range) of the method/instrument and may require further action before reporting (see method-specific references). LIS flag "TECHNICAL LIMIT" [Technical limit for this method] will display when the results at data entry exceed AMR.

Reference Range failures exceed the age/sex-specific defined normal low to high ranges for that test result. LIS flag "FAILED NORMAL" [specific Reference Range for this patient/method] will display when results at data entry are abnormal.

PROCEDURE A: CRITICAL VALUE

Follow the steps in the table below in the sequence listed to investigate Critical Values before reporting.

Step	Action

1	Consider repeat testing or repeat analysis using steps in technical procedure(s) if necessary to verify results.	
2	**If**	**Then**
	Result Verified	• Consider asking caregiver if results match patient's diagnosis and/or change in clinical condition. • Call critical value to the patient's caregiver, following appropriate procedure for notification of critical values. ◦ Report results in the LIS and document actions taken using the approved ETC comments. ◦ Document call notification in LIS. Refer to *Documenting Call Comments in LARS* procedure or other related SOP.
	Results Verified, but caregiver indicates the results do not match patient's clinical condition	• Notify other lab sections (if applicable). • Immediately coordinate a redraw of patient for all tests from same collection date/time that may have been affected. ◦ HOLD current results until redraw is compared to initial collection – do not cancel. • Proceed to Procedure B: Delta Check Failure - Step 5.
	Result Not Verified (i.e. repeat results do not match initial results)	• HOLD current results for further investigation. • Check sample acceptability. • Locate an alternate sample to run if possible. • Proceed to Procedure B: Delta Check Failure *(if applicable)*.

PROCEDURE B: DELTA CHECK FAILURE

Follow the steps in the table below in the sequence listed to investigate Delta Check failures before reporting.

Step	Action
1	When FAILED DELTA appears, take necessary actions to investigate results that may include: • Review time frame of change in results. • Review clinical correlation for potential change in condition. • Review sample to rule out improper sample handling/processing or inappropriate sample type. • Repeat analysis when necessary or if defined in method specific procedure. • Evaluate sample to rule out identification error or integrity issues (i.e. interfering substances, clots, hemolysis, or QNS). ◦ Cancel and redraw if sample is identified to not be acceptable for test requested. ◦ Review all other lab tests performed on same collection to ensure quality of all results reported. ◦ If suspected interfering substance, a redraw should be performed of patient for all tests from same collection date/time that may have been affected.
2	Investigate **specimen processing** issues: • Evaluate that appropriate sample handling/processing was performed for the test requested. ◦ Examples: ammonia sent at room temperature, centrifugation of PFA test, inadequate mixing of CBC run in manual mode, coagulation sample run with a bubbles. • Evaluate that appropriate sample received or poured off for the test requested. ◦ Examples: serum poured off instead of plasma for coagulation test, add-on test performed on inappropriate tube type, fluid run as urine. Investigate **interfering substances** – consider common sources first: • Determine if, for example, EDTA contamination due to incorrect order of draw, Coagulation specimen was drawn from a heparin lock, or a TDM specimen drawn above an IV that was running that drug, or a Chemistry specimen drawn above an IV that contains that analyte (sodium, potassium, glucose, calcium, magnesium, etc), or a patient is receiving TPN. • Question historic results. • Obtain a history of medications the patient is currently receiving. • Ask about other patient related issues going on.

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<tr><td></td><td>
Consult a Pathologist in rare cases before reporting results of unusual sources of interference.
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<tr><td>3</td><td>If unable to eliminate suspiciously abnormal findings, call the patient's caregiver to obtain Clinical Correlation. Use the information obtained to assess if the change in the result value is caused by changes in patient tests and/or treatments.
Inquire about the patient's transfusion history, discontinuation of medication, recent surgery, OB delivery, dialysis, new intravenous treatment, or other changes to tests/treatments since previous result.
If no changes, verify with caregiver if patient's clinical condition matches the result.</td></tr>
<tr><td>4</td><td>
<table>
<tr><th>If</th><th>Then</th></tr>
<tr><td>Current results match patient's clinical condition</td><td>Go to Step 7 to report the result.</td></tr>
<tr><td>Current results do NOT match patient's clinical condition
Such as: clinical correlation not obtained or potential specimen identification / integrity issue</td><td>
Notify other lab sections (if applicable).
Immediately coordinate a redraw of patient for all tests from same collection date/time that may have been affected.
HOLD current results until redraw is compared to initial collection – do not cancel.
Proceed to Step 5.</td></tr>
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<tr><td>5</td><td>Compare redraw results to initial and historical findings.
<table>
<tr><th>If</th><th>Then</th></tr>
<tr><td>Redraw matches initial collection</td><td>
Evaluate findings and report both results if verified to be acceptable.
Proceed to Step 7.</td></tr>
<tr><td>Redraw does not match initial results, but matches historical results</td><td>Report redraw results immediately.
Consider performing blood typing on all tubes used for testing if suspicion of patient misidentification.
Make copies of all tubes and documentation needed for superisor/ designee review and/or follow-up.</td></tr>
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		• Review all initial tests performed from same collection to account for any results needing to be corrected if already reported. ◦ If results already reported, amend results in the LIS and generate a corrected report. • Cancel initial pending test orders with cancel reasons that match findings of investigation. ◦ Refer to *Clarifying Laboratory Test Orders* procedure for listing of appropriate cancellation codes. Perform "credit - remove results" using the credit function in the LIS.
	Redraw result does not match historical or current results, and results appear unstable	Suspect methodology issues. Proceed to Step 6.
6	Investigate **method** issues: • Evaluate other patient results across analytes and within analytes for similar trends or critical/delta low or high results. • If trend identified, use back-up/alternate method to report results. • Communicate "method down" if troubleshooting does not resolve issues.	
7	Report results in the LIS and document actions taken using the approved ETC comments. • **NOTE**: If redraw matches initial collection and both sets of results are reported, perform "credit - retain results" for the redraw using the credit function in the LIS.	

PROCEDURE C: TECHNICAL LIMITS

Follow the steps in the table below in the sequence listed to investigate Technical Limits before reporting.

Step	Action	
1	Results that exceed the upper or lower limits must be compared to validated technical procedures and references for that specific method.	
2	**If**	**Then**

The result exceeds the high technical limit:	• Refer to technical procedure for specific instructions. • If reportable result (above technical limit) obtained by dilution, report verified result in the LIS with appended comment RVD (Results verified by dilution). Investigate **high** technical limit (may not be applicable for all methods): • Consider repeat without dilution (if sample volume allows). • Dilute according to technical procedure, using correct diluent and lowest dilution factor. ◦ Continue to make dilutions until a reportable result is obtained. ◦ Do not dilute beyond the maximum dilution allowed for analyte. ◦ Always report the result from the least dilution after ensuring it is consistent with undiluted results.
The result exceeds the low technical limit	• Refer to technical procedure for specific instructions. • If reportable result (below technical limit) is reported in LIS,document actions taken using the approved ETC comments when applicable. Investigate **low** technical limit (may not be applicable for all methods): • Check specimen for fibrin or clots or QNS. • Consider repeat testing using same or alternate method (if sample volume allows). ◦ If repeats do not match – go to Procedure B: Delta Failures.

PROCEDURE D: REFERENCE RANGES

Follow the steps in the table below in the sequence listed to investigate Reference Range (Normal Range) failures before reporting.

Step	Action
1	Results that exceed normal will have an "L" for low abnormal and an "H" for abnormal high results.

2	Review results and flags: **If** / **Then** No other QA flags are present — Accept the results, or alternately you may view previous historic results by selecting "Display Prior". Other QA failure flags are present — Do not accept results and refer to Procedures for Critical, Delta and Technical Limit failures above.

APPROVED ETCs FOR ACTIONS TAKEN

- Results verified by repeat analysis (RV)
- Results verified by redraw (RVR)
- Results verified by alternate method (RVA)
- Results verified by manual method (VMAN)
- Results verified by dilution (RVD)
- Reviewed by Clinical Lab Scientist (RVS)
- Reviewed by CLS/MLT (RVCLS)
- Reviewed by pathologist (REVIEW)

RELATED DOCUMENTS

- Appending Comments to a Result in LARS
- Clarifying Test Orders
- Documenting Call Comments in LARS

All Revision Dates

3/23/2022

Approval Signatures

Step Description	Approver	Date
Lab Directors/Managers	Mary Cabral: Mgr, Laboratory	3/23/2022
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Lab Directors/Managers	Michelle Roye: Mgr, Lab	3/21/2022
Lab Directors/Managers	Steven Stern: Mgr, Laboratory	3/21/2022

Lab Directors/Managers	Lise Bashe: Mgr, Ambulatory Lab	2/25/2022
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Lab Medical Directors	Ly Ma: Physician	2/23/2022
Lab Medical Directors	Andrea Ong: MD	2/16/2022
Lab Medical Directors	Zhen Yan: Physician	2/8/2022
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Lab Medical Directors	Amanda Mullins: MD	2/1/2022
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	Lindsey Westerbeck: Dir, Lab	1/25/2022