FAILED PATIENT RUN

☒ St. Joseph Medical Center, Tacoma, WA	☒ St. Anthony Hospital Gig Harbor, WA	☐ Harrison Medical Center, Bremerton, WA
☒ St. Francis Hospital, Federal Way, WA	☒ St. Elizabeth Hospital Enumclaw, WA	☐ Harrison Medical Center, Silverdale, WA
☒ St. Clare Hospital Lakewood, WA	☒ Highline Medical Center Burien, WA	☐ PSC

PURPOSE

To describe the process for troubleshooting a failed patient result or patient run due to out of range Quality Control values , failed calibration, instrument malfunction or other cause.

BACKGROUND

The FHS Laboratory has established policies and procedures for continuous monitoring and assessing problems identified during the analytical run and to insure corrective action is taken if problems are identified.

RELATED DOCUMENTS

R-F-AD-4368	Failed Patient Run Result Verification Form
R-PO-AD-0598	Error Correction Policy
Addendum	Failed Patient Run- Differential Cells Confidence Limits

POLICY

1. Assume that all patient test results are unacceptable in current run or since the last acceptable QC was performed. Do not report patient results for the affected test/instrument until the QC is acceptable.

2. Examine the QC results using the following criteria:
   - If the out of control QC is only out once and is between 2 and 3 SD and there is no shift in the mean of more than 1 SD, then patient samples do not need to be repeated (No lookback needed).
   - If the QC is outside of 3 SD or the mean is shifted by 1 SD or more, then you need to repeat some or all of the specimens run since last good QC.(Lookback is needed).
   - If QC is out twice by more than 2 SD, then you need to repeat some or all of the specimens run since last good QC.(Lookback is needed).
   - If 2 levels of QC for the same test are out by more than 2 SD, then you need to repeat some or all of the specimens run since last good QC (Lookback is needed).

3. Rule out the QC material itself as a possible cause. If the QC material is responsible for the out of range results, a patient look back is not necessary. This is true even if you ran the QC material several times. The reason is that bad QC material would not affect patient results for that test. Here are some things that could be checked:
   - Correct Lot being used
   - Correct QC material for that test
   - New lot QC material- but ranges are for the old lot
   - Control handling/storage/stability
   - Control mixing (especially after it has just been thawed)

4. If the QC material is not the cause of the out of range QC, begin evaluating patient results (begin the Lookback).

5. If patient results are delayed due to an assay problem, the Technician / Technologist must notify the appropriate individual / location based on the urgency of the patient tests requested; some tests warrant immediate notification.

6. If patient results were released and then a problem is identified, it's imperative that the lookback commence quickly and be done thoroughly so that any change in the originally released result can be communicated promptly to the person ordering or utilizing the tests (ordering physician, clinics, nursing, etc).

7. If a second instrument with good QC values is available, run the lookback repeats and new patient samples on the other instrument.

8. If there is no alternate instrument or method for reporting results, troubleshooting should commence immediately so the lookback can begin immediately. Troubleshooting may include but is not limited to:
    - Review of the LJ chart for the last 2 weeks. Look for evidence of a shift or drift in the mean or excessive random error.
    - Check that correct Calibrator lot disk is loaded, if applicable
    - Check that correct Calibrator was used for that test
    - Try New reagents
    - Try Instrument Calibration
    - Review Instrument problem log
    - Perform Instrument maintenance
    - Call Instrument hotline

9. Identify and repeat the 5 samples that were most recently run on the analyzer with the QC problem, for the test(s) in question. Repeat specimens on another instrument, when available. Or once the problem has been identified, fixed and QC is now in control on the original instrument, repeat the specimens run previously to check for accuracy of the results.

10. If no patient samples were run on the problem instrument in the affected time period:
    - Use the Failed Patient Run Result Verification Form to document the event
    - In the table at the bottom, indicate that no patients were run during the affected time period.
    - Document in your site's permanent QC record (this may be Unity or in the instrument or on a log) that a Lookback was performed and no patients were run during the affected time period.

11. Compare the repeat results to the results originally reported to determine if they are within the Clinically Acceptable Duplicate/repeat limits. See the table below for established Clinically Acceptable Duplicate/repeat Limits.

12. If the results exceed the duplicate/repeat limits, continue to repeat the previous specimens, 5 at a time, until you determine where the patient repeats fall within the duplicate/ repeat limits. You may need to look at all the patients run, clear back to the time of the previous good QC. You need to verify at what time the previous good QC was run. Don't assume previous QC was run and in control at the normally scheduled time. It could have been missed or run at a different time than expected.

13. Sample stability is a consideration. However, patient samples run during the affected time period for a test that is outside its stability must still be identified and reruns should be performed unless waived by Technical Manager, Manager or MTC. Correcting results for tests outside stability requires close scrutiny. Please consult Technical Manager, Manager or MTC before correcting results, especially results based on

reruns done outside the sample stability (e.g Ammonia stability <2 hours unable to repeat, but identify patients Accn# on form for MTC/Manager review).

14. The Manager or Designee will make or recommend the necessary results changes and notify the provider or ordering location or ask tech to do the notification. Before making result changes, the following will be considered:
    - medical decision levels
    - result interpretation (normal to abnormal)
    - previous patient history
    - previous and subsequent results for the test in question
    - patient diagnosis may considered
    - sample stability

15. Keep clear, concise and chronologic records of all remedial action steps taken to resolve the problem to include all instrument maintenance performed during troubleshooting.

16. Scrupulously document all communication in the appropriate location: communication log, maintenance log, etc.

17. Retain copies of the original and corrected reports, instrument printouts and worksheets. Complete the Failed Patient Run Result Verification form and route to the MTC/designee or Manager for review.

CLINICALLY ACCEPTABLE DUPLICATE/REPEAT LIMITS

ANALYTE	ACCEPTABLE REPEAT LIMITS	
CHEMISTRY		
Acetaminophen	< 50 ± 5 ug/mL	≥ 50 ± 10 %
Albumin	± 0.3 g/dL	
Alcohol	< 100 ± 10 mg/dL	≥ 100 ± 10 %
Alk Phos	< 100 ± 10 IU/L	≥ 100 ± 10 %
ALT	< 50 ± 6 IU/L	≥ 50 ± 12 %
Ammonia	< 65 ± 12 umol/L	≥ 65 ± 20 %
Amylase, Total & Pancreatic	< 150 ± 6 U/L	≥ 150 ± 10 %
AST	< 50 ± 6 IU/L	≥ 50 ± 12 %
BOHB	0.2 mmol/L	
Bilirubin, Direct	< 1.1 ± 0.1 mg/dL	≥ 1.1 ± 10 %
Bilirubin, Total	< 3.0 ± 0.3 mg/dL	≥ 3.0 ± 10 %
B-Type natriuretic peptides	<90 ± 9 pg/mL	≥90 ± 10%
BUN	< 30 ± 3 mg/dL	≥ 30 ± 10 %
Calcium	± 0.3 mg/dL	
Calcium, Ionized	2%	
Carbamazepine	< 4.0 ± 0.4 ug/mL	≥ 4.0 ± 10%
Chloride	± 5 mmol/L	
Cholesterol	< 200 ± 8 mg/dL	≥ 200 ± 4 %
CK	< 300 ± 20 IU/L	≥ 300 ± 10 %
CO2	± 3 mmo/L	

ANALYTE	ACCEPTABLE REPEAT LIMITS	
CKMB	<10 ± 1 ng/mL	≥ 10 ± 10%
Cortisol	< 5.0 ± 0.5 ug/dL	≥ 5.0 ± 10 %
Creatinine	< 2.0 ± 0.2 mg/dL	≥ 2.0 ± 10 %
CRP	< 3.0 ± 0.3 mg/dL	≥ 3.0 ± 10 %
Cyclosporin	<200 ± 20 ng/mL	≥200 ± 25%
CSF Protein	< 50 ± 5 mg/dL	≥ 50 ± 10 %
Digoxin	<1.0 ± 1 ng/mL	≥ 1.0 ± 10%
Estradiol	<50 ±5 pg/mL	≥ 50 ± 10%
FT4	<1.0 ± 0.1 ng/dL	≥1.0 ± 10%
Ferritin	<40 ± 6 ng/mL	≥40 ± 15%
Folate	<10 ± 1 ng/mL	≥ 10 ± 10%
Free, PSA	<0.2±0.02 ng/mL	≥ 0.2 ± 10 %
FSH	<10 ± 1 mIU/mL	≥ 10 ± 10%
Gentamicin	< 4.0 ± 0.4 ug/mL	≥ 4.0 ± 10%
GGT	< 50 ± 5 U/L	≥ 50 ± 10 %
Glucose	< 150 ± 6 mg/dL	≥ 150 ± 5 %
HDL,Cholesterol	< 40 ± 4 mg/dL	≥ 40 ± 10 %
HCG, Beta	<25±3 mIU/mL	≥ 25 ± 10%
Hemoglobin, A1C		± 6%
Iron	< 150 ± 15 ug/dL	≥ 150 ±10 %
Lactate	± 0.4 mmol/L	
LD	< 200 ± 20 IU/L	≥ 200 ± 10 %
LDL Cholesterol	±30%	
LH	<10 ± 1 mIU/mL	≥ 10 ± 10%
Lipase	±30%	
Lithium	± 0.3 mmol/L or ± 20% whichever is greater	
Magnesium	± 0.2 mg/dL or ±25% whichever is greater	
Micro Total Protein CSF	< 50 ± 5 mg/dL	≥ 50 ± 10 %
Osmolality, Serum	<419 ± 9 mOsm/Kg	≥419 ± 12 mOsm/Kg
pH	0.04 or 8% whichever is greater	
Phenobarbital	± 20% ug/mL	
Phenytoin	< 4.0 ± 0.4 ug/mL	≥ 4.0 ± 10%
Phosphorus	±0.4 mg/dL	
Potassium	± 0.3 mmol/L	
Prealbumin	± 5.0 mg/dL or 25% whichever is greater	
Procalcitonin	± 0.2 ng/mL or 12.5% which is greater	
Progesterone	<1.5 ±0.2 ng/mL	≥ 1.5 ± 15%
Prolactin	<20 ± 2.0 ng/mL	≥ 20 ± 10%
Prostate Specific Antigen, PSA	<0.2±0.02 ng/mL	≥ 0.2 ± 10%
PTH, Intact	< 50 ± 5 pg/mL	≥ 50 ± 10 %

ANALYTE	ACCEPTABLE REPEAT LIMITS	
PTH, IO	< 50 ± 5 pg/mL	≥ 50 ± 10 %
Rubella Ab, IgG	IU/mL	± 5 %
Salicylate	< 50 ± 5 mg/dL	≥ 50 ± 10 %
Sodium	± 4 mmol/L	
T3 Uptake %	± 8	
Testosterone	<200 ± 20 ng/dL	≥200 ± 10%
Theophylline	± 25% ug/mL	
Total Protein	± 0.4 g/dL or ± 10% whichever is greater	
Total T4	<5.0 ±5 ug/dL	≥ 5.0 ± 10%
Total Tricyclics	± 20 %	
Triglyceride	< 200 ± 20 mg/dL	≥ 200 ± 10 %
Transferrin	± 20 %	
Troponin I	<0.2±0.02 ng/mL	≥ 0.2 ± 10%
TSH	<2.000 ± 0.2 uIU/mL	≥2.000 ±10*%
Uric Acid	± 0.6 mg/dL	
Urine Amylase	± 15%	
Urine Urea NItrogen	± 21%	
Urine Calcium	± 31%	
Urine Chloride	26 %	
Urine Creatinine	±17%	
Urine Glucose	± 6 mg/dL or 20% whichever is greater	
Urine Micro Albumin	± 30%	
Urine, Osmolality	<610 ± 12 mOsm/Kg	≥ 610 ± 18 mOsm/Kg
Urine Phosphorus	± 23%	
Urine Potassium	± 29%	
Urine Micro Total Protein	< 50 ± 5 mg/dL	≥ 50 ± 10 %
Urine Sodium	± 26%	
Urine Uric Acid	± 24%	
Valproic Acid	± 25%	
Vancomycin	< 4.0 ± 0.4 ug/mL	≥ 4.0 ± 10%
Vitamin B 12	<200 ± 30 pg/mL	≥200 ±15%
Vitamin D, 25 OH	± 25%	
COAGULATION		
APTT	± 15%	
D-Dimer, Quant	<300 ± 10 %	≥300 ± 15% ng/mL
Fibrinogen	± 20%	
Heparin, Unfractionated	± 0.1 IU/mL	

ANALYTE	ACCEPTABLE REPEAT LIMITS	
Heparin, Low molecular weight	± 0.1 IU/mL	
Protime	± 15%	
Thrombin	<20 ± 4 sec	≥20 ± 20%
HEMATOLOGY		
WBC, Total	± 15%	
Red Cell Count	± 6%	
Hemoglobin, Total	± 7 %	
Hematocrit	± 6 %	
Platelet Count	± 25%	
Retic %	<5.6 ±0.32	≥5.6 ±0.7
Cell Identification	See Differential Counts Confidence Limits Addendum	

REFERENCE

CLIA-88, Subpart K Sec: 493.1291 Standard Test Report and Acceptable Test Performance Criteria.
College of American Pathologist, Proficiency Test Participant Summary, Evaluation Criteria and Target Value.
Standardization of the Manual Differential Leukocyte Count, Laboratory Medicine, Vol 11, No. 6, June 1980.

DOCUMENT APPROVAL	*Please Complete All Sections*
Purpose of Document: ***(to be completed for Forms, Flowcharts and other documents that will be uploaded as attachments to parent documents in PolicyStat)***	
To describe the process for troubleshooting a failed patient result or patient run due to Quality Control values, failed calibration, instrument malfunction or other cause.	
Was Document Title Changed? ☒ **No** ☐ **Yes – Previous Title:**	
Was New Document ID # Assigned? ☐ **No** ☒ **Yes – Previous ID #:** version 03	
Reason for Change:	
Added wording to clarify process, added hematology and coagulation to table, added tests to chemistry in table	
Attached Documents ***(list documents that should be linked/attached to this document in PolicyStat):***	
Failed Patient Run Result Verification Form Error Correction Policy Addendum – Failed Patient Run- Differential Cells Confidence Limits	
Committee Approval	☒ **Required (for multi-site / regional documents) Date Approved:** ☐ **Required for New Document Date Approved:** ☐ **N/A – revision of department-specific document which is used at only one facility**
Effective Date	☒ **As soon as approved by FLOAT and/or uploaded** ☐ **Specific Date:**
Medical Director Approval	☐ ***No significant change to process in above revision. Per CAP, this revision does not require further Medical Director approval.*** ☒ ***Medical Director approval needed – to be done in PolicyStat.***

Please Complete Review by date: 6/22/17

Reviewer	Approval Required?	Date Reviewed	OK?	Not?	Suggestions
Karen Anthony	Y				
Tracy Bradfield					
Eileen Cahill	Y	6/16/17	Y		This document says it's a Policy, but it describes the process/steps to take. Should this be a WI and a separate document be written just to define what the Policy is with reference to this WI for the procedure? In Policy STAT no difference in types of documents.
Teri Emerson					
Linda Guay					
Mike Harvey	Y	6/12/17	Y		

Inae Kim	Y	6/13/17	Y		
Sally Kramer	Author				
Karen Lea	Y	6/12/17			Edited the purpose in the approval grid to match the purpose in the document exactly.
Cheryl Orr					
Joanne Walsh	Y	6/16/17	Y		
Claudia Willis					