TITLE: CRITICAL RESULTS OF TESTS

IDENTIFIER: S-LAB-PC-15600

APPROVED: MEDICAL DIRECTOR
ORIGINAL FORMULATION: 7/1/99

REVISED: 02/2024
REVIEWED: see respective review log

EFFECTIVE DATE RECORDED IN MEDIALAB:

☒ Acute Care:	ENC: ✓	GH: ✓		
	LJ: ✓	MER: ✓		
☐ Home Health:				
☐ SHAS:				
☒ SMF:	SC:	SCMC:		
	CSC:	SML: ✓		

KEYWORDS: critical values, notification, read-back, documentation

I. PURPOSE

A. This policy establishes requirements for identification of critical results, expected time frames and staff and provider or clinician responsibilities for notification of results.

II. POLICY

A. This policy applies to all laboratory personnel in Scripps Health.

B. Critical results are the results of specific tests or examinations that fall significantly outside the normal range and may represent life-threatening values, significant morbidity, or serious adverse consequences. They require immediate evaluation in order to make decisions regarding the need, if any, to adjust the care for the patient.

C. Results of tests that are information sensitive but may not require immediate action are defined in the technical procedure manuals with reporting requirements for notification.

D. Critical results for testing performed at Scripps laboratories are defined in consultation with the laboratory Medical Director(s) and the hospital medical staff or clinicians served. New or revised critical results are approved by each hospital Medical Executive Committee. Specific documentation is recorded in the Committee minutes.

E. The acceptable length of time between the availability of critical results and receipt by a responsible caregiver is defined by the laboratory medical director in consultation with clinicians served. Measurement is the time interval from the identification of the critical result to the receipt by a responsible licensed caregiver or physician.

F. The critical results reported by a reference laboratory are determined by the reference laboratory and are available in the reference laboratory's catalogue. Critical results of tests reported from a reference laboratory are reported and documented in the same manner as testing performed by Scripps laboratories. The referral laboratory must have a written agreement with the referring laboratory that indicates to whom the referral laboratory reports critical results.

G. The testing personnel are responsible for recognizing, reporting, and documenting critical results

H. Initiate notification of critical test results within 5 minutes of availability.

I. Report critical results verbally or on a hard copy in person with two (2) patient identifiers (name and medical record number or date of birth), the date and time of collection, analyte name, result, and analyte units of measure.

J. For hospital-admitted patients, a critical result is reported to **a licensed caregiver or physician responsible for patient care.** A licensed caregiver is a registered nurse (RN), licensed vocational nurse (LVN), nurse practitioner (NP), physician assistant (PA), or allied health professional licensed to practice under the supervision of a physician.

K. For outpatients, a critical result is reported to one of the following:
   1. ordering physician
   2. ordering physician's office patient-care staff (Example: NP, PA, RN, LVN, MA, or PSR)
   3. Scripps Coumadin Clinic pharmacist, or patient service representative (PSR), or pharmacy technician
   4. physician on-call for the ordering physician. **See policy note III.A.1.h.**

L. In the point-of-care setting, the identity of the testing individual and person notified need not be recorded when the individual performing the test is the same person who treats the patient. In this circumstance, however, there must be a record of the critical result, date, and time in the test report or elsewhere in the medical record.

M. The following transfusion related critical results are reported directly to the physician:
   1. Acute hemolytic transfusion reaction
   2. Incompatibility of emergency-released un-cross matched blood
   3. Positive culture on products from a transfusion reaction

N. The following transfusion related critical values are reported directly to the patient's caregiver:
   1. Prenatal titer of clinically significant alloantibody ≥ 16
   2. Positive fetal cell stain
   3. Identification of anti-Kell in prenatal patients

   Note: The caregiver may be notified if there will be a delay in the delivery of blood products relative to the expected turn-around-time as determined by the order:
      a. STAT priority - 1 hour
      b. ROUTINE priority - 4 hours
      c. NEXT DAY - not ready at the specified time of transfusion

O. In the event a licensed caregiver or physician responsible for the patient is unable to be reached within 30 minutes of critical result availability for a hospital inpatient, one of the following personnel is contacted in this order: unit charge nurse, hospital operation coordinator or supervisor, hospitalist (if applicable), pathologist on call.

P. In the event one of the persons listed in K. above cannot be reached within 2 hours of critical result availability for an outpatient, the specimen originating-site pathologist on-call is contacted for further guidance.
   1. The following information is provided to the on-call pathologist
      a. Patient name and medical record number
      b. Complete critical value(s) and normal range
      c. Ordering provider name and contact information
      d. Date and time specimen collected
      e. Date and time of test completion
      f. Patient contact phone number
      g. Description of attempts to contact physician or physician's patient-care staff which includes phone numbers, names, and date/times of attempts.

2. The Customer Services department at Sorrento Mesa is provided by email with all the above information immediately after contacting the pathologist. Customer Services continues attempts to contact the physician during regular business hours.
3. The specimen originating-site laboratory Medical Director is provided with all the above information the next working day.

Q. When the patient's care-giver or physician cannot be reached, laboratory personnel record in the Electronic Medical Record (EMR) all the attempts to reach the appropriate person including the time(s) and person(s) called. This may include using the Comm Log in Epic Beaker or Adding a Follow Up Task for the provider.

R. Testing personnel confirm a critical result when the patient's test results are inconsistent, incompatible, unusual, or unexpected. The specimen is recollected when QNS or contamination affecting test results is suspected.

S. Critical Result Read-Back and Documentation

1. Request the person receiving a verbal critical result to read back the result with 2 patient identifiers (name and medical record number or date of birth) to ensure accuracy.
2. Laboratory personnel document direct critical result notification of the appropriate clinical individual defined in Policy II.J above (inpatient) or II.K (outpatient) and read-back to the same individual by encoding in the EMR using the Comm Log in Epic Beaker. For Transfusion Services, document using an external free text comment in Wellsky Blood Bank module. See policy notes for specific instructions. Documentation records must include:
   a. Responsible laboratory individual who made the notification.
   b. Person notified using identifiers traceable to that person. A first name alone is inadequate documentation. <u>Either of the following is acceptable:</u>
      i. Corporate identification number
         Example: 123456
      OR
      ii. Last name, first initial and title
         Example: Smith S., RN
   c. Critical test result/s – analyte name, result, and analyte units of measure.
   d. Date/Time the result was reported
3. If critical results are transmitted electronically (eg, secure email or fax), the laboratory must confirm receipt by the responsible individual; however, no read-back is necessary
4. Laboratory personnel must read back all critical results reported verbally by reference laboratory personnel.
   a. Results received at the Sorrento Mesa Core lab will be communicated to either the hospital laboratory (for inpatients) or to the clinician or appropriate designee (outpatient).
   b. On occasion, results may be received at the Torrey Pines lab or another laboratory after normal business hours at the Sorrento Mesa Core lab. The person who receives the results must communicate the critical result to the originating laboratory or to the SML Client Services at (858) 554-9552 for appropriate follow-up. Document in the Comm Log following procedure S.2 above.

5. Critical results are flagged in laboratory-generated patient reports using icons (two red exclamation marks or two down arrows or two up arrows), or indicators like CH (Critical High) or CL (Critical Low).
6. Critical results are identified in downtime forms. Documentation is on the hard copy. Results and communication of the critical value will be transcribed in the EMR when the system is back up. See 11200 Information Systems Downtime Procedures and 11201 Extended Downtime Procedures and Recovery Plan

T. Exceptions to calling critical results:

Critical results must be called at the first instance and documented per this policy. The following are exceptions to calling subsequent critical values. Append a comment "Previous Critical" to the result field, or to the Comm Log as configured in Epic. The caregiver need not be called again.

1. Chemistry:
   a. Results of CO2 within the last 24 hours
   b. Results of lactic acid (arterial and venous) within the current hospital admission
   c. Troponin I results during the same hospital admission. However, if Troponin I within the same admission increases after a series of results that were trending down, the elevated Troponin value will be called to the primary caregiver.
   d. Procalcitonin (PCT) within the current hospital admission
2. Hematology
   a. WBC, platelet count, or preliminary absolute neutrophil count (PANEU) for the duration of the inpatient's current hospital admission.
3. Microbiology:
   a. Notify ordering providers of initial positive blood cultures but subsequent identical positive blood cultures (i.e. containing exactly the same organism) that flag positive within 5 days (120 hours) of the initial positive critical call notification need not be called to ordering provider. Enter "Previous critical" to the Comm Log in Epic for these cultures.
4. There are no exceptions for outpatient testing results. All critical results must be called on all outpatients.

U. Anatomic Pathology and Cytopathology – Refer to the following procedures:
1. S-LAB-PC-80050 Communication of Urgent and Significant or Unexpected Pathology Findings (Scripps Clinic Medical Group)
2. S-LAB-PC-80070 Communication of Urgent and Significant or Unexpected Pathology Findings (San Diego Pathology Medical Group)
3. S-LAB-PC-87012 Cytopathology Reporting (SCMG)
4. S-LAB-MA-81750 Cytopathology Quality Assurance Policy (SDPMG)

V. Discharged Hospital Patients – for critical lab results that are resulted after a patient has been discharged from the hospital, follow the guidance below:
   1. Lab testing personnel are still responsible for notifying a patient care giver.
   2. On a patient discharged to another facility, contact the laboratory in the current facility of admission. Request assistance in reaching the provider, or give the result

to a licensed person, who will communicate it to the appropriate floor or unit, with documentation of the call entered in Epic Beaker.

3. On a discharged ED patient, the lab will contact the ED pharmacist, ED charge RN, or the ED physician on duty and communicate the critical result, with documentation of the call entered in Epic Beaker.
4. On a patient discharged from the unit or floor, contact the ordering provider, discharging doctor, primary care provider or the hospitalist, with documentation of the call entered in Epic Beaker.
5. If lab personnel are unable to reach the physician, or result is not taken for any reason, the lab personnel will contact the on-call pathologist for further guidance and follow up.
6. When a patient's caregiver cannot be reached or result is not taken, lab personnel will record in Epic Electronic Medical Record (EMR) all the attempts to reach the appropriate person, including the time(s) and person(s) called. If referred to the on-call pathologist, this will also be recorded in the Comm Log in Epic Beaker

W. **Quality Assurance**

1. Monitors and threshold values for the acceptable timeliness of reporting critical results are included in Quality Assurance and Performance Improvement Program. This data is assessed and reported according to the plan to determine whether a need for improvement exists. See S-LAB-PI-14000 Quality Management Program.
2. Critical result notification and documentation is reviewed on a daily basis by a laboratory supervisor or designee and kept on file in the laboratory for three years according to S-LAB-PI-17000 Retention and Storage of Laboratory Records and Testing Materials. Documentation encoded in the EMR is retained indefinitely.
3. Any problem encountered in accomplishing this task must be investigated to prevent recurrence. File a Quality Assurance Variance Report (QAV). Refer to policy S-LAB-PI-16200 Occurrences, Complaints, and Quality Assurance Variance Management.

III. POLICY NOTES:

A. To document a critical call in Epic, any of these two methods may be used in Result Entry:

1. If the recipient of the call is in the Epic database:
   a. Go to Result Entry
   b. Click on Comm Log
   c. The Contact field will auto-populate with the name and contact number of the Authorizing Provider. To change this information to the actual recipient of the call, click "Other."
   d. Enter the name of the recipient and click **Search**.
   e. Click on the name of the recipient. The Contact field will be populated with the information of the chosen recipient.
   f. If the critical result was successfully communicated to the caregiver, click **Accept**.
   g. If a caregiver cannot be immediately reached, each call attempt must be documented. Click the No Answer/Busy tab, or the Left Message tab, and then click Accept. The call attempt will be time-stamped.

h. For outpatient laboratories: The on-call pathologist is not to be contacted unless all other options are exhausted. When an on-call pathologist assists in this matter, the name of the pathologist should not be recorded as the physician taking the results. Instead, inquire from the pathologist the name and corporate ID of the provider who ultimately accepted the results.

i. On occasion, Torrey Pines Urgent Care (TPUCC) which is open 24/7 may be called outside of business hours for outpatient results when the provider cannot be reached. Examples are:

i. Sorrento Mesa Core Laboratory calling positive blood culture results for outpatients

ii. To assist with calling providers for results for patients seen in Rancho Bernardo or Jefferson Urgent Care.

2. This alternate method may be used, especially if the recipient's name is not in the Epic database:
   a. Go to Result Entry
   b. Click on Comm Log
   c. Enter **.RA**
   d. Press F2
   e. Overwrite *** with provider name and title
   f. Accept

B. To add a Follow up Task:
1. From Result entry, select test
2. Actions
3. Add Follow-up Task
4. Select Follow up type
5. Insert name
6. Type message
7. Start Date/Time
8. Due date/time
9. Assign to user/self
10. Accept

C. To add a Critical Call Comment in the Blood Bank Wellsky Module
1. Click on the Testing icon
2. Go to Search All Tests
3. Enter the MRN of patient
4. Click Search
5. Highlight the test you want to comment on
6. Click on the Comment icon
7. Click Add
8. Choose FT (*free text)* from the dropdown box
9. Enter the following information:
   Called to and read back by: Name and credentials (**see section II.S. above)**
   Date, Time and Reason
10. To make the comment appear in Epic, click on the drop-down box with the I/E and change it an E so it is an external comment.
11. Click Save

D. If a patient has expired, enter in the Comm Log “Not indicated, patient expired.”
Epic Smartphrase is *CALLNIEXP

IV. RELATED POLICIES/PROCEDURES

A.	S-FW-PC-0022	Critical Result Reporting
B.	S-LAB-IM-11200	Information Systems Downtime Procedures
C.	S-LAB-IM-11201	Extended Downtime Procedures and Recovery Plan
D.	S-LAB-PI-16200	Occurrences, Complaints, and Quality Assurance Variance Management
E.	S-LAB-PC-54000	Blood Bank Policies and General Information
F.	S-LAB-MA-81750	Cytopathology Quality Assurance Policy (SDPMG)
G.	S-LAB-PC-80050	Communication of Urgent and Significant or Unexpected Pathology Findings (Scripps Clinic Medical Group)
H.	S-LAB-PC-80070	Communication of Urgent and Significant or Unexpected Pathology Findings (San Diego Pathology Medical Group)
I.	S-LAB-PC-87012	Cytopathology Reporting (SCMG)
J.	S-LAB-PI-14000	Quality Management Program
K.	S-LAB-PI-17000	Retention and Storage of Laboratory Records and Testing Materials

V. REFERENCES:

A. College of American Pathologists, CAP All Common Checklist COM.30000 and COM.30100, 08/24/2023
B. College of American Pathologists, Anatomic Pathology Checklist, ANP.12175, 08/24/2023
C. College of American Pathologists, Cytopathology Checklist, CYP.06450, 08/24/2023
D. The Joint Commission, Comprehensive Accreditation Manual for Laboratory and Point-of-Care Testing, Standard DC.02.01.01, NPSG.02.03.01, January 2023

VI. REVIEW/UPDATE

Policy/Procedure Development		
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Approvals/Reviews		
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Laboratory Compliance Committee	Recorded in minutes	11/10/2023
Medical Executive Committee La Jolla	Recorded in minutes	11/21/2023
Medical Executive Committee Green Hospital	Recorded in minutes	01/26/2024
Medical Executive Committee Mercy Hospital (SD & CV)	Recorded in minutes	01/17/2024
Medical Executive Committee Encinitas	Recorded in minutes	12/15/2023

The charts below list the critical results of tests for testing performed by Scripps laboratories.

Analyte or Examination	Criteria		Units of Measure
CHEMISTRY			
Acetaminophen		> 45	mcg/mL
Acetaminophen – newborn ≤ 28 days		> 30	mcg/mL
Alcohol		> 300 (0.3%)	mg/dL
Alcohol – newborn ≤ 28 days		> 13	mg/dL
Amikacin, trough (adult)		>10	mcg/mL
Amikacin, peak (adult)		>80	mcg/mL
Ammonia - newborn ≤ 28 days		> 100	mcmol/L
B-Hydroxybutyrate		> 30	mg/dL
Bilirubin, total - newborn ≤ 28 days		>15	mg/dL
Bilirubin, neonatal or direct, newborn ≤ 28 days		≥1.5	mg/dL
Calcium	≤ 7.0	≥ 12.0	mg/dL
Carbamazepine		> 12	mcg/mL
Carboxyhemoglobin		>8	%
CO_2 total	< 10	> 40	mmol/L
Creatinine <24 months		>1.5 or 50% increase from previous	mg/dL
Digoxin		> 2.5	ng/mL
Gentamicin Trough		> 3	mcg /mL
Gentamicin Trough – newborn ≤ 28 days		> 2.5	mcg /mL
Gentamicin Peak		> 30	mcg/mL
Gentamicin Peak – newborn ≤ 28 days		> 15	mcg/mL
Glucose, Serum or plasma	< 50	> 500	mg/dL
Glucose – newborn ≤ 28 days	< 40	> 250	mg/dL
Glucose CSF newborn ≤28 days	25		mg/dL
HCO3 (bicarbonate)	< 10	> 40	mmol/L
Ionized Calcium	< 0.78	> 1.58	mmol/L
Ionized Calcium newborn ≤28 days	< 0.9	> 1.59	mmol/L
Lactic Acid (Arterial & Venous)		≥ 4.0	mmol/L
Lactic acid newborn ≤28 days		>5.0	mmol/L
Lithium		> 1.4	mmol/L
Magnesium	≤ 1.0	≥ 4. 0	mg/dL
Magnesium – newborn ≤ 28 days	< 1.0	> 3.0	mg/dL
Methemoglobin		> 4	%
Phenobarbital		> 60	mcg/mL
Phenobarbital - newborn ≤ 28 days		> 50	mcg/mL
Phenytoin		> 30	mcg/mL
Phenytoin - newborn ≤ 28 days		> 25	mcg/mL
Phosphorus	< 1.1		mg/dL

Analyte or Examination	Criteria		Units of Measure
Potassium	≤ 2.7	≥ 6.0	mmol/L
Potassium newborn ≤28 days	<3.0	>6.0	Mmol/L
pCO_2	< 30	> 60	MmHg
pCO_2 Arterial - newborn ≤ 28 days	< 15	> 70	MmHg
pCO_2 Venous- newborn ≤ 28 days	< 20	> 70	MmHg
pCO_2 Capillary- newborn ≤ 28 days	< 15	> 70	MmHg
pO_2 Arterial	< 60		MmHg
pO_2 Arterial - newborn ≤ 28 days	< 40		MmHg
pH	< 7.30	> 7.60	units
pH Arterial - newborn ≤ 28 days	< 7.25	> 7.60	units
pH Venous - newborn ≤ 28 days	< 7.15	>7.55	units
pH Capillary - newborn ≤ 28 days	< 7.20	> 7.60	units
Procalcitonin (PCT)		>2.0	ng/mL
Salicylate		> 30	mg/dL
Sodium	< 120	> 160	mmol/L
Sodium - newborn ≤ 28 days	< 125	> 150	mmol/L
Theophylline		> 25	mcg/mL
Thyroid Stimulating Hormone newborn ≤ 28 days	< 0.1	> 10.0	mcIU/mL
Thyroxine (Total T4) - newborn ≤ 28 days	< 5.0	> 20.0	mcg/dL
Tobramycin Trough		> 3	mcg/mL
Tobramycin Trough - newborn ≤ 28 days		> 2.5	mcg/mL
Tobramycin Peak		> 30	mcg/mL
Tobramycin Peak - newborn ≤ 28 days		> 15	mcg/mL
Troponin I		≥ 0.120	ng/mL
Valproic Acid		> 150	mcg/mL
Vancomycin Trough		>25	mcg/mL
Vancomycin Trough - newborn ≤ 28 days		> 15	mcg/mL
Vancomycin Peak		> 50	mcg/mL
Vancomycin Peak - newborn ≤ 28 days		> 45	mcg/mL

HEMATOLOGY/COAGULATION			
Analyte or Examination	**Criteria**		**Units of Measure**
CSF Nucleated Cells, adult		≥ 10	mcL
CSF Nucleated Cells – newborn ≤ 28 days		≥ 30	mcL
Hematocrit - newborn ≤ 28 days	≤ 30	> 65	%
Hematocrit - adult	≤ 20		%
Hemoglobin - adult	≤ 7.0	≥ 20.0	gm/dL
Hemoglobin – newborn ≤ 28 days	< 10.0	> 22.0	gm/dL
Heparin induced thrombocytopenia antibody (HIT)		Positive	
Platelets	≤ 50	> 1,000	K/mcL
Platelets - newborn ≤ 28 days	≤ 100	> 1,000	K/mcL
WBC	≤ 1.0	≥ 50.0	K/mcL
WBC – newborn ≤28 days	<4.0	>30.0	K/mcL
WBC >28 days-18 yr	<2.0	>30.0	K/mcL
Absolute Neutrophil Count, preliminary (PANEU)	≤ 0.50		K/mcL
Fibrinogen	< 100		mg/dL
Prothrombin Time 0-6 months		>19.0	seconds
Prothrombin Time 6 mos to < 18 yrs old		>17.0	seconds
INR <18 years old		> 4.0	ratio
INR >18 years old		≥ 4.0	ratio
PTT 0-6 months		> 49	seconds
PTT 6 mos to < 18 yrs old		> 45	seconds
PTT >18 years old		≥ 90	seconds
Malaria Smear		Positive	

TRANSFUSION SERVICES	
TEST	**CRITICAL VALUE**
Antibody identification	Identification of anti-Kell (anti-K) in prenatal patients
Clinically significant antibody	Titer > = 16 in prenatal patients
Transfusion reaction workup	Results indicating acute hemolytic reaction, and/or positive culture from the product transfused
Compatibility testing (cross-match)	Incompatibility of emergency-released un-crossmatched blood
Fetal Cell Stain	Positive

MICROBIOLOGY & MOLECULAR MICROBIOLOGY	
TEST	**CRITICAL VALUE**
Smear, culture, or molecular assay of blood, brain abscess, cornea, mitral valve, CSF, pericardial fluid, placenta, synovial fluid, or stem cell (cells or freezing media)	Any positive detection of pathogenic bacteria, fungus, or parasite
Smear, culture, or molecular assay of CSF or brain material	Any positive detection of pathogenic infectious agent
Any culture	Isolation of a dimorphic or Zygomycete fungus from any site