TITLE: CRITICAL RESULTS OF TESTS

IDENTIFIER: S-LAB-PC-15600

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

REVISED: 04/2021
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

I. PURPOSE

A. This policy establishes requirements for identification of critical results, expected time frames and staff 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 determined to require immediate evaluation in order to make decisions regarding the need, if any, to adjust the care for the patient. Critical results may be the value/finding of a test that was ordered with a routine priority.

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 identified 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 chart below lists the critical results of tests for testing performed by Scripps laboratories.

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 should 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. Critical results are reported 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.

I. The person receiving a verbal critical result is required to read back the result with 2 patient identifiers (name and medical record number or date of birth) to ensure accuracy.

J. For hospital admitted patients, a critical result is reported to **a licensed caregiver or physician responsible for the patient.** 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

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. Positive culture on products from a transfusion reaction
   3. Incompatibility of emergency-released un-cross matched blood
   4. Delay in transfusion with BOTH of the following criteria met
      a. Hemoglobin is $\leq$ 7 gm/dL
      b. The delay in service is relative to the expected turn-around-time as determined by the order: STAT priority = 1 hour, ROUTINE priority = 4 hours, or NEXT DAY = not ready at the specified time of transfusion

N. The following transfusion related critical values are reported directly to the patient's caregiver:
   1. Delay in transfusion with hemoglobin $\leq$ 7 gm/dL
   2. Prenatal titer of clinically significant alloantibody ≥ 16
   3. Positive fetal cell stain

O. Notification of critical test results is initiated within 5 minutes of availability.

P. 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.

Q. 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.

R. 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.

S. 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.

T. 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:
   1. Responsible laboratory individual who made the notification
   2. Name and title of person notified. Either of the following is acceptable:
      a. Corporate identification number and title
         Example: 123456 RN
         OR
      b. Last name, first initial and title
         Example: S. Smith RN (first initial, last name and title)
   3. Critical test result/s – analyte name, result, and analyte units of measure.
   4. Date/Time the result was reported

U. Laboratory personnel must read back all critical results reported verbally by reference laboratory personnel. 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).

V. Critical results are indicated on laboratory generated patient result reports, except Microbiology critical results.

W. Exceptions to calling critical results:
   1. Chemistry:
      a. Results of CO2 that were previously critical results with reporting documented within the last 24 hours may append a comment, "Previous Critical". The caregiver need not be called again.
      b. Results of lactic acid (arterial and venous) that were previously critical results with reporting documented within the current hospital admission may append a comment, "Previous Critical". The caregiver need not be called again.
      c. During a hospital admission, the first elevated Troponin I value that is above the critical value is called, and the reporting is documented in the laboratory information system. For repeat Troponin I results that are above the critical value reported during the same hospital admission, the result may be appended with a

comment “Previous Critical.” The caregiver need not be called again. 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 care giver with reporting documented in the current hospital admission.

d. A Procalcitonin (PCT) result of > 2.0 ng/mL is considered a critical value. All first time critical PCT per admission should be called and read back by the licensed caregiver and documented on the report in accordance with Scripps’ Critical Values reporting procedure. Results of PCT that were previously critical results with reporting documented within the current hospital admission may append a comment, “Previous Critical”. The caregiver need not be called again.

2. Hematology
   a. Results of WBC, platelet count, or preliminary absolute neutrophil count (PANEU) that were previously critical results with reporting documented may append the comment “Previous Critical” for the duration of the inpatients current hospital admission.
   b. Results of a preliminary absolute neutrophil count (PANEU) with a critical WBC $\leq$ 0.5 that has been called may append the comment “Critical WBC $\leq$ 0.5 has been called” to the PANEU. The caregiver need not be called with the results of the PANEU.
3. All critical results are always called on all outpatients.

W. 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 medical staff at each hospital. Measurement is the time interval from the identification of the critical result to the receipt by a responsible licensed caregiver or physician.

X. Anatomic Pathology and Cytopathology – Refer to the following procedures:
   1. S-LAB-PC-80050 or S-LAB-PC-80070 Communication of Urgent and Significant or Unexpected Pathology Findings
   2. S-LAB-PC-87012 Cytopathology Reporting
   3. S-LAB-MA-81750 Cytopathology Quality Assurance Policy

Y. 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. Testing personnel will call the hospitalist on duty to notify them of the critical lab result.
   2. 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.
   3. 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
   4. 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.

5. 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.
6. If necessary, consult the physician dyad leader or chief of staff to determine the proper person to receive the critical call.

Z. 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.

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.

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 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-PI-14000	Quality Management Program
C.	S-LAB-PI-17000	Retention and Storage of Laboratory Records and Testing Materials
D.	S-LAB-PC-80050	Communication of Urgent and Significant or Unexpected Pathology Findings (Scripps Clinic Medical Group)
E.	S-LAB-PC-80070	Communication of Urgent and Significant or Unexpected Pathology Findings (San Diego Pathology Medical Group)
F.	S-LAB-PC-87012	Cytopathology Reporting (SCMG)
G.	S-LAB-MA-81750	Cytopathology Quality Assurance Policy (SDPMG)

V. REFERENCES:

A. College of American Pathologists, CAP All Common Checklist COM.30000 and COM.30100, 06/04/2020
B. College of American Pathologists, Anatomic Pathology Checklist, ANP.12175, 06/04/2020
C. College of American Pathologists, Cytopathology Checklist, CYP.06450, 06/04/2020

VI. REVIEW/UPDATE

Policy/Procedure Development		
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Approvals/Reviews		
Committee/Department:	Chair Name /Title:	Date:
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Laboratory Compliance Committee	Recorded in minutes	12/21/2020
Medical Executive Committee La Jolla	Recorded in minutes	01/19/2021
Medical Executive Committee Green Hospital	Recorded in minutes	1/22/2021
Medical Executive Committee Mercy Hospital (SD & CV)	Recorded in minutes	1/20/2021
Medical Executive Committee Encinitas	Recorded in minutes	3/26/2021

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)		>35	mcg/mL
Ammonia - newborn ≤ 28 days		> 100	mcmol/L
B-Hydroxybutyrate		> 30	mg/dL
Bilirubin - newborn ≤ 28 days		>15	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		> 12	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
Potassium	≤ 2.7	≥ 6.0	mmol/L
Potassium newborn ≤28 days	<3.0	>6.0	Mmol/L

Analyte or Examination	Criteria		Units of Measure
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		> 12	mcg/mL
Tobramycin Peak - newborn ≤ 28 days		> 15	mcg/mL
Troponin I		≥ 0.120	ng/mL
Troponin I (SM and RB)		≥ 0.1	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	
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 Any delay in blood product availability relative to the expected TAT
Prenatal titer of clinically significant alloantibody	≥ 16
Fetal cell stain	Positive
MICROBIOLOGY & MOLECULAR MICROBIOLOGY	
Smear, culture, or molecular assay of blood, brain abscess, cornea, mitral valve, CSF, pericardial 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 body site