|  |  |  |  |
| --- | --- | --- | --- |
| **Laboratory:** | **Document Type:** | **Original Date Adopted:** | **Previous Document:** |
| Lab Admin | Policy  | 11/20/2000 | ADMIN-24 Revision 20 |

|  |  |  |
| --- | --- | --- |
| **Document Author:** | **Document Owner:** | **Acknowledgement / Required Copy Holders\*:** |
| Sandra VanVranken | Sandra VanVranken | All laboratory testing personnel, and other deemed applicable staff members and faculty |

|  |
| --- |
| **Approval\*:** |
| Laboratory Administration Division DirectorLaboratory Medical DirectorsOSUWMC Clinical Laboratory Medical Director, OSUWMC East Hospital Laboratory Medical Director, Morehouse Laboratory Medical Director, Spielman Laboratory Medical Director, Outpatient Care East Laboratory Medical Director, Outpatient Care Lewis Center Laboratory Medical Director, Outpatient Care Gahanna Laboratory Medical Director, James Molecular Laboratory Medical Director, Ackerman Laboratory Medical DirectorHistology LLC Medical Directors at Doan, East, Morehouse and Chambers Road |

|  |
| --- |
| **\*Approval and Acknowledgements\*** |
| Refer to QPulse system and Document Details report for laboratory directors(s)’ electronic signature approval, employee acknowledgment and effective date. |

1. **POLICY**
	1. Critical tests, critical results, and courtesy calls on inpatients, outpatients, and outreach patients will be communicated to a clinical professional responsible for the patient’s care in a consistent and timely manner.
		1. **Critical Tests**:
			1. Critical tests are those tests which will always require rapid communication of the results, even if normal.
			2. Critical tests will be communicated to a clinical professional responsible for the patient’s care, regardless of the test result, within specified time interval from order/collection to. Such notification shall be documented.
			3. Critical test specimens should be delivered to the Clinical Laboratories within 10 minutes of order/collection.
			4. True collection times should be documented on the specimen/lab label.
			5. Critical Tests: Critical Care Batteries (CRITB), rapid intact parathyroid hormone (RPTH) and single block frozen sections
		2. **Critical Results / Critical Values**
			1. Critical results, also known as “critical values,” are test results that fall significantly outside the normal range and may represent life-threatening values, even if from routine tests.
			2. Critical results will be communicated to a clinical professional responsible for the patient’s care within 20 minutes of completion of the test, and such notification documented as a component of the test results report.
		3. **Critical Results in Point of Care Testing (Glucose)**
			1. The PCA, (unlicensed assistant personnel) must notify the RN and document first and last name in the medical record.
			2. Per CAP if the RN performing the test is the RN taking care of the patient, then we do not need a name; Select comment MD  notified on the meter and document in IHIS the names of the LIP Or select comment RNOnly\_OrderPresent on the meter.
		4. **Courtesy telephone notification**
			1. Courtesy telephone notification for other specified tests/results will be communicated to a clinical professional responsible for the patient’s care and such notification documented as a component of the test results report.
		5. Personal Health Information (PHI) including name and medical record cannot be included when paging a critical value. Use appropriate language such as: *Please call the OSUWMC Lab at 293.xxxx for a critical result.*
	2. Manual and automated results are verified before final acceptance and reported by the computer.
		1. Laboratories should have a system in place for verification of manual entries – can be performed by same tech or another technologist.
		2. Staff members should review all results that are not auto-verified in the computer – evaluating flags, reference ranges, and improbable results, as applicable.
2. **PURPOSE OF DOCUMENT**
	1. This policy is to provide a mechanism for pathology and laboratory staff to communicate and document rapid communication of laboratory test results.
3. **SCOPE OF DOCUMENT**
	1. This document applies to all areas within the Clinical Laboratories, as well as medical center collection sites.
4. **RESPONSIBILITY**
	1. The Medical Directors of the Clinical Laboratories are responsible for establishing the *Rapid Communication of Laboratory Results* policy. Laboratory Compliance is responsible for maintaining the policy and ensuring at least biennial review.
	2. Laboratory Compliance is responsible to providing the policy to clinical staff, available on the laboratory website.
5. **Critical tests – process**
	1. Critical tests are those tests which will always require rapid communication of the results, even if normal.
	2. Critical test specimens should be delivered to the Clinical Laboratories within 10 minutes of order/collection.
	3. Critical tests will be communicated to a clinical professional responsible for the patient’s care, regardless of the test result, within specified time interval from order/collection to reporting (see below). Such notification will be documented.

**Critical tests**

|  |  |  |
| --- | --- | --- |
| **Tests** | **collection** | **TAT (collection to notification)** |
| **RPTH** | **Collected in OR; Call 293-3443 to notify lab staff and deliver directly to Special Functions Laboratory.** | **40 minutes (30 minutes receive to notification)** |
| **CRITB** | **\*\* Write true collection time on lab label for accurate documentation****Deliver directly to Critical Care Laboratory** | **30 minutes (20 minutes receive to notification)** |
| **Frozen sections** | **Specimen is delivered to surgical pathology gross room.  The results are communicated via telephone by the pathologist signing out the frozen section to an attending or resident physician in the operating room.** | **40 minutes (30 minutes receive to notification)** |

1. **Critical Results - PROCESS**
	1. When rapid communication of laboratory results is required, testing and client services personnel of the Clinical Laboratories notify a clinical professional (e.g. RN, LPN, physician, nurse practitioner, respiratory therapist, pharmD, physician assistants, etc) responsible for the patient's care. Other titles can be approved by the Laboratory Medical Director.
		1. Determine the location from which the patient specimen was sent.
		2. Call the area that submitted the specimen and tell them you have a laboratory result to report. Ask for a clinical professional taking care of the patient.
			1. For inpatients:
				1. If the nurse involved with direct patient care cannot be reached or cannot take the result, request to speak to the floor charge nurse.
				2. If the charge nurse is not available or cannot take the results, page the ordering physician.
				3. If the ordering physician does not call back within 10 minutes, proceed with section 6.5 if necessary.
			2. If the communication for an inpatient or ED patient is not to a physician and the clinical professional indicates that the patient has been discharged, page the division director or the Laboratories medical director.
		3. Report **ALL** of the following elements:
			1. your first and last name and laboratory from which you are calling
			2. patient's name
			3. patient’s MRN
			4. **patient phone number:** **for all non-inpatients or non-ED patients’ notifications**
			5. name of attending physician
			6. collect date and time of specimen
			7. test name(s)
			8. test results
			9. units of measure, for NICU patients only
		4. Request read-back verification of the test result(s). This must include patient name, MRN, test name(s), test result(s) and units of measure for NICU patients.
		5. Document telephone communications / notifications in the results report in the applicable LIS.
			1. Include all of the following elements:
				1. First and last name and title (e.g. Dr. or RN) of person notified / who verified/read-back the results
				2. Date of notification
				3. Time of notification
		6. Process:
			1. Click on **Comm Log** located in the upper left corner of the screen. The Comm Log opens as a side bar.
			2. Click Other.
			3. Enter name in the **Search by Name** field and press **Enter**.
			4. Click on appropriate name. Notice how it populates in the Contact field.
			5. Click **Accept**.
			6. Click the **Verify** to review your result.
	2. Outpatient / Outreach Patients **- MANDATORY**: For any notification for non-ED outpatients or outreach patients, obtain the patient's phone number and **provide to the clinical professional along with the results.** Look in IHIS by patient name for phone number.
		* 1. Outreach – *OSU Lab Test* DTC (U18115 through U18122):
* Notify the Medical Director of the Clinical Laboratories, pager 6370.
* Provide the Accession Number, ID number, collect date and time, test name(s), and test result(s).
* The Medical Director of the Clinical Laboratories will work with the appropriate personnel at URL to determine the identity of the DTC consumer and contact the consumer directly so that such results are communicated to them in a timely manner.
	1. Exceptions to Rapid Notification Requirements: If the patient is located in a location/on a service for which the medical director or designee authorized an exception for immediate notification of a laboratory result -
		1. Critical Results, Previously Called
			1. Review the previous result for the analyte and determine if it was a critical result and the collect date for that specimen.
			2. If there was no previous result for the analyte, call the result within 10 minutes of test completion and document as indicated above.
			3. If the previous result for the analyte was not a critical result, call the result within 10 minutes of test completion document as indicated above
			4. If the previous result was not from the current admission, call the result within 10 minutes of test completion document as indicated above.
			5. If the previous result was called or “CVPC” (critical value, previously called) code was appended to that result, and the specimen was collected during the current admission, append code “CVPC” to the current result.
				1. This code can be utilized on WBC (C14, C16, C15, C20, C21), ALT, AST, and Troponin.
		2. Pre-Transplant Clinic
			1. For after hours’ notification for the **Pre-Transplant Clinic** (PRET, PRETX): WebXchange page the Pre-transplant On-call Coordinator at pager 614.346.4051.
			2. From OneSource/ WebXchange/Quick Page
				1. Enter Pager ID: 4051
				2. Enter the Alpha Msg: “Please call the OSUMC Lab at 293.xxxx for a critical result”
* NOTE: Be sure to use a phone number which can be accessed from the outside.

* + - 1. There will be times that the coordinator staff will be on the phone dealing with organ procurement/processing, so there might be some delays with call backs.
			2. Enter the time the coordinator was paged and the time that they returned the call as part of the documentation of the call.
	1. After Hours Notifications: If the notification must be made after the care area closes, contact the on-call physician, or other person as designated by the client, directly UNLESS the patient care area has submitted a written request for notification to be made only during business hours.
* Obtain phone and/or beeper number from the hospital operator, directory on OneSource, or URL account / client database listing.

If an area has requested in writing that results be called only during business hours, free-text the the following in the “yellow comment” field in the IHIS communication log: “Critical test (or result) to be called in am”. This result will remain on the outstanding list until communication is made during business hours.

* + 1. If an “after business hours” communication is not successful and the pathologist determined an immediate notification was not required, leave a note for the following day shift to contact the appropriate person.
		2. The ordering physician is ultimately responsible for acting on the critical value.
			1. When appropriate and as a second hand effort call the current on-call person for the service from which the patient was discharged by looking in IHIS. This is just another tool to find the most appropriate physician to follow up on the critical value:
			2. In IHIS - Look in the right hand side in the admission box under “discharge summaries” written in brown it has the service in
			3. There is always a current on call schedule, by service, in webex and if for some reason the tech can’t tell from webex they can always call the operator and ask for (in this case) the current resident covering neurosurgery
			4. The result remains on the outstanding list until communication is made. You have the ability to document multiple attempts until it is communication. You do not have to modify the results, you are just adding communications via the Comm log.
		3. Document communication trail, through problem log, or other means of handoff communication.
		4. Client services personnel:
			1. Review daily problem log for patients with “Critical test (or result) to be called in am”; obtain report of appropriate patient’s result, call client and notify them of the results, and document notification
	1. Attending, Ordering, “On Call” Physician, Or Other Person As Designated By The Client Cannot Be Reached following 2 attempts, 20 minutes apart:
		1. During routine business hours (Monday through Friday 7:00am to 5:00pm): page the division director. They will assist with identifying an alternate physician for notification.
			1. Review the patient identification, test result information, and attending/ordering physician information with the director.
			2. If the division director is unable to identify a physician to accept the value they should contact the Laboratories medical director or the Critical Event/Results Officer.
			3. If the division director cannot be reached, page the Laboratories medical director.
		2. After 5:00pm and on weekends/holidays:
			1. Contact the CP pathology resident on-call
			2. Review the patient identification and test result information with the resident. Make sure you have the patient contact information including phone number available to provide to the resident.
			3. The resident, in conjunction with the CP faculty pathologist on call, will determine if notification can wait until the next day, whether the Critical Event / Results Officer needs to be paged to assist in the management of the patient, or the patient needs to be contacted directly and advised to seek medical attention
				1. ONLY the resident / CP faculty pathologist on call will page the Critical Event/Results Officer if needed.
				2. If the patient is to be contacted directly, the resident or the CP faculty pathologist will contact the patient.

 6.5.2.3.3 Resident or faculty pathologist will provide the name of the person notified and the date and time of notification to the laboratory. Document the notification in the computer.

* 1. Specimens Referred From Another Laboratory: When rapid communication of laboratory results is required for specimens referred from an outside, non-OSUWMC laboratory, a laboratory professional from that laboratory is notified and the communication documented per described above.
	2. Anonymous Specimens: critical results, critical tests, or courtesy call notifications for anonymous specimens will be made only during business hours.
		1. For specimens identified as research subjects: contact information for critical results notification is pre-printed on the customized, study-specific requisition form. The information is also available in the Laboratory Research Accounts database on the L Drive at L:\Common\Laboratory Research Accounts. Search the database by the LIS number (include the letter) or the Billing number.
			1. Copy and paste the Primary Office address and phone information in the corresponding fields
	3. Research Specimens
		1. For critical values, following the directions in the URL database or on the research set up paperwork. All research studies should list directions for critical values when establishing research accounts with Research Billing and LIS.
1. **RELATED DOCUMENTS**
	1. Refer to QPulse System or Document Detail Report for related Laboratory Policies, Procedures, and Master Forms

|  |
| --- |
| **Table A: Critical Values** |
| **Outpatients only (ED is outpatient) Neonate/Pediatric only James Patients only** |
| **CHEMISTRY** | **HEMATOLOGY** |
| Analyte | Critical Results | Analyte | Critical Results |
|  |  |  | WBC | < 1.5 | > 35.0 K/uL |
| ALT initial **only** |  | ≥ 1000 U/L | C14, C16, C15, C20, C21 | < 0.5 | > 35.0 K/uL |
| AST initial **only** |  | ≥ 1000 U/L | **initial** only |  |  |
| Amylase |  | ≥ 500 (≥ 400 under 19 yr) U/L |  |  |  |
| Beta Hydroxybutyrate |  | ≥ 1.2 mmol/L | Other Oncology | < 0.5 | > 35.0 K/uL |
| Bilirubin, total |  | ≥ 14.0 mg/dL (neonates only) | Hemoglobin | < 7.0  | > 22.0 g/dL  |
| BUN |  | ≥ 101 mg/dL | Pediatric | 0-7d: < 11.0 8d – 12y: <8.0>12y: <7.0 | > 22.0 g/dL> 22.0 g/dL> 22.0 g/dL |
|  |  |  |  |  |  |
| Calcium | < 6 | > 12 mg/dL |  |  |  |
| Chloride | < 75 | > 130 mmol/L | Platelet | < 30  | > 1,000 K/uL |
| CO2 | < 10 | > 40 mmol/L | C-James locations | < 10 | > 1,000 K/uL |
| Creatine Kinase |  | ≥ 500 U/L (outpatients only ) | Bands + Segs Ratio | > 0.25 (Neonates only) |
| GCRC Mendell: do not call | CSF WBC |  | ≥ 41 cells / uL |
| Mendell ICD10 = G71.0 outpatients: do not call (approved 12/2015) | Bacteria | Any intracellular on peripheral blood smear, |
| Creatinine  |  | > 10.00 mg/dL |  | Any on direct smear of any sterile body fluid OR |
|  |  |  |  | count if direct smear is not already positive |
|  |  |  |  |  |
| Free T4 (ED only) |  | ≥ 4.5 ng/dL | **COAGULATION** |
| Glucose | < 50 | > 400 mg/dL | Analyte | Critical Results |
| Neonates | < 40 | > 200 mg/dL | INR | > 4.9  |
| CSF Glucose | < 30 | > 300 mg/dL | PTT | > 150.0 sec (inpat) > 60.0 (outpat) |
| Lactate |  | ≥ 5.0 mmol/L | Fibrinogen | < 75 mg/dL |
| Lithium |  | ≥ 2.0 mmol/L | Factor Activity | < 5% |  |
| Phosphorus | < 1.0 | > 10.0 mg/dL |  |  |
| Ionized Calcium | <3.40 | > 6.20 mg/dL |  |  |
| Magnesium | < 1.0 | > 4.4 mg/dL | URINALYSIS |
| Osmolality | < 250 | > 325 mOsm/kg | Analyte | Critical Results |
| Potassium | < 3.0 | > 6.0 mmol/L | Urine Microscopic | Any RBC casts |
| Neonates | < 3.0 | > 7.0 mmol/L |  | Any WBC casts |
| Sodium | < 125 | > 160 mmol/L |  |  |
| pH | Arterial < 7.20 Venous:<7.17 | > 7.55> 7.52 |  |
| pCO2 | Arterial < 20Venous < 24 | > 65 mmHg> 64 |  |  |
| pO2 | ≤44  | mmHg | **TRANFUSION SERVICES** |
| Troponin I | > 5.00 FIRST critical result, additional calls ONLY if no previous >5.00 within past 24 hours. | Newborn Positive Direct Coombs Test (DAT) |
| Transfusion Reaction |
| Significant Technical error(s) |
| TSH  |  | ≥150.000 uIU/mL (ED only) | Positive Kleihauer-Betke stain |
|  |  |  | Titer > 32 in pregnancy Titer >8 for Anti-K |
|  |  |  | Suspected passenger lymphocyte syndrome |

|  |
| --- |
| **Table A: Critical Values continued** |
| **THERAPEUTIC DRUGS / TOXICOLOGY** |
| Analyte | **Critical Results** | Analyte | **Critical Results** |
| Acetaminophen | > 150 ug/mL | Pentobarbital | ≥ 45 ug/mL |
| Amikacin | Peak ≥60.0 ug/mL; Trough ≥6.0 ug/mL | Phenobarbital | ≥ 45.0 ug/mL |
| Carbamazepine | ≥ 15.1 ug/mL | Phenytoin | ≥ 22.0 ug/mL |
| Digoxin | ≥2.1 ng/mL | Salicylate | ≥ 30.0 mg/dL |
| Free Phenytoin | ≥ 3.0 ug/mL | Theophylline | ≥ 20.0 ug/mL |
| Gentamicin | Peak ≥20.0 ug/mL; Trough ≥ 1.1 ug/mL | Tobramycin | Peak ≥ 20.0 ug/mL; Trough ≥ 1.0 ug/mL |
| Lidocaine | ≥ 6.0 ug/mL | Valproic Acid | ≥ 150 ug/mL |
| Lithium | ≥2.00 mmol/L | Vancomycin | ≥ 25.1 ug/mL Trough |
| Acetone | ≥ 10 mg/dL | Ethylene Glycol | ≥ 10 mg/dL |
| Methanol | ≥ 10 mg/dL | Ethanol (blood) | ≥ 300 mg/dL |
| Isopropanol | ≥ 10 mg/dL |  |  |

|  |
| --- |
| **MICROBIOLOGY** |
| Positive Blood Culture (blood, blood products, transfusion reaction) or new positive blood culture smear with Nanosphere BC GN or BC GP PCR result when indicated  |
| Positive direct smear and culture of any sterile body fluid/device (if smear is positive and culture is positive, an additional call needs to be made to physician to update him with the organism species e.g. Staphylococcus-like, Pseudomonas-like) Ascites/Peritoneal fluid Pleural fluid Blood vessels Bone marrowHeart valve Pacemaker/Pacemaker pocket Pericardial fluid Joint/Synovial fluid Amniotic fluid VitreousAqueous Cornea Organ CAPD fluid Dialysis/perfusate Grafts/Vascular Lymph nodes Prosthetic devices Cellulitis specimens with purulence or amorphous Orthopedic devices debris and organisms Pancreas transport solution |
| Positive direct smear and/or culture from any central nervoussystem specimen (brain and related sources, CSF, shunt) |
| Positive LOOP cultures- contact LOOP coordinator 291-LOOP (5667) |
| Positive Cytomegalovirus (CMV) by PCR- CSF |
| Positive Herpes simplex (HSV) by PCR- CSF and sterile body fluids |
| Positive AFB smear / Tissue section |
| Positive TB by PCR  |
| Mycobacterium tuberculosis complex identified in culture from any source |
| Positive Fungal smear |
| Cultures positive for any Class A reportable diseases |
| *Neisseria meningitidis* in blood or CSF (invasive disease) |
| Diseases of the newborn: Group B beta Streptococci, CMV, HSV, *H. influenza*, *Listeria spp*., *Neisseria gonorrhoeae*, *Chlamydia trachomatis* identified from any newborn culture |
| Positive Epstein-Barr Virus by PCR if greater than 10,000 copies/ml – blood or CSF*Exception: BMT unit: Any viral loads >10,000 within a month of the initial result does not need to be called again (approved by Dr. Devine 02/2017)* |
| RSV by PCR (inpatient is a critical value, outpatient is a courtesy call) |
| Positive *Influenza A/B* tests: (inpatient is a critical value, outpatient is a courtesy call) **Exception: Calls DO NOT need to be made to the emergency room at UH or OSUE.****NOTE:** if an *Influenza A* has been called initially and is positive by another methodology, the code CVPC (critical value previously called) can be added to the report instead of making several calls   |
| Dimorphic molds : *Coccidiodes immitis/posadasii ,Histoplasma capsulatum, Blastomyces dermatidis, Paracoccidoiides brasiliensis* from any source |
| Any Biofire CSF ME detected results, if CSF culture grows what was detected by Biofire, an additional phone call does not need to be made |

|  |
| --- |
| **table B: Critical Tests**  |
| ***Expected Notification: Order/Collect to Result*** |
| Critical Care Whole Blood Gas Labs | 30 minutes |
| Single Block Frozen Sections | 40 minutes |
| Intra-Operative PTH | 40 minutes |

|  |
| --- |
| **TABLE C: courtesy calls**  |
| Abnormal AFP Pre-natal Screens | Non tuberculosis Mycobacteria species in cultures from any source |
| Acid fast bacilli in culture from any source | Parasites |
| BAL Studies for Cell Count / Morphologic review – OSU inpatients or outpatients only | PF4 IgG Elisa Assay – positive and inconclusive results |
| Blood Gas Labs from OR’s or PACU | Pneumocystis carinii / jiroveci – surgical pathology or BAL specimen |
| Chlamydia trachomatis (L & D only) NAAT | Positive *C. difficile* tests on outpatients |
| *Clostridium tetani* | Positive *Influenza A/B*  PCR tests: (inpatient is a critical value, outpatient is a courtesy call) Calls do not need to be made to ED |
|  Dimorphic molds : *Sporothrix schenckii, Penicillium marneffei,* from any source | Positive Pregnancy Tests for OR, ASU |
| STAT Drug Screens (upon client request) | Rapid HIV – Blood/Body Fluid Exposure Protocols – Reactive results |
| Fetal Fibronectin Tests – L&D, ED ONLY | Reportable diseases other than Class A |
| Filamentous fungus sterile site | RSV by PCR (inpatient is a critical value, outpatient is acourtesy call) |
| Gas gangrene | Staphylococcal pneumonia |
| Herpes simplex (HSV) by PCR from BAL’s | Staphylococcal pneumonia(Gram stain represents Gram positive cocci in groups only on respiratory Gram stains) |
| Isolates of *Clostridium perfringens* *C*. *septicum* or *C. sordelli* | Stat Microbiology Direct Exams |
| Lamellar Body Count | *Streptococcus pneumoniae* (sterile site, invasive disease) |
| *Legionella pneumophila* from any source | *Streptococcus pyogenes* (wound or tissue culture, cellulitis) |
| Legionella Urinary Antigen – positives | Troponin (>0.49) from the ED display “Call this result to ED” and require a Courtesy Call to ED nursing unit – includes ICC locationTroponin: A courtesy call will be given to the ED for any extended delay of troponin results (including dilutions) |
| *Listeria spp*., any site | Virus, Direct Detection, Herpes / Varicella (Tzanck Preparation) |
| *Neisseria gonorrhoeae* (L & D only) culture or NAAT | VISA or VRSA (vancomycin I or R S. *aureus*) |
| *Nocardia spp.* from any source |  |