		Dept:	Pathology
Wake Forest BAPTIST MEDICAL CENTER	**Critical Values and Result Correction**	Origin Date:	08/06/2016
		Contact:	Core Laboratory-Chemistry Department
CLIA Lab Director: Gregory Pomper, MD		**Signature on file**	

1) **General Procedure Statement:**

    a. **Scope:** To provide laboratory testing personnel with instructions for performing laboratory procedures of calling critical values and result correction as deemed appropriate by industry practices and regulatory agencies to assist in quality patient care.

    b. **Responsible Department/Party/Parties:**
        i.   Procedure owner: Clinical Core Laboratory Management-Chemistry
        ii.   Procedure: Clinical Core Laboratory Personnel
        iii.   Procedure prepared by: Emily Dockery
        iv.   Supervision: Clinical Core Laboratory Management-Chemistry
                              Clinical Core Laboratory Specialist and Designees
                              Medical Director Clinical Chemistry
        v.   Implementation: Clinical Core Laboratory Management-Chemistry
                                Clinical Core Laboratory Specialist and Designees
                              Medical Director Clinical Chemistry

2) **Definitions:**

    a) Critical Value: a value that may require rapid clinical attention to avert significant patient morbidity or mortality.

    b) Corrected Result: any change in a previously reported value.

3) **Procedure:**

CRITICAL VALUES

If the patient results exceed the limits below, the nurse or physician has to be notified on the phone of the results. Check to make sure the proper sample handling was done to eliminate reasons for the critical value, example: drawing from arm with IV. These values should be called to a nurse or responsible physician. Identify the patient by name and medical record number. Append a comment to the critical value with the name to whom the result was called, the date and time of the call, "read back" of the result given, tech initials if resulting in Remisol, and any other appropriate comments into the LIS system to ensure that the proper procedure was followed. If reporting a critical value in Beaker, verify that the date, time, and the name of the person taking the value are

attached when using the ".CTRB" smart phrase. See the department of Pathology Critical Value Policy for more information.

Calling Critical Values for INPATIENTS and WFBH OUTPATIENT CLINICS:

1) If after-hours in-network clinic, call the after-hours Critical Value Line at 6-7344.
2) Call the floor if it is an inpatient.
3) You are required to make 3 call attempts to alert providers of a critical value.
4) Intervals for these calls should be 5-10 minutes if inpatient and around 30 minutes for outpatients
5) If no one will answer the phone or you cannot find someone to take the value after 3 attempts, page the Pathologist on call.
6) Give the Pathologist on call the patient name, date of birth, medical record number, and critical value to them and they will attempt to contact an appropriate provider.
   a. At this point, you can document the critical value as outlined above using the Pathologist on call as the person contacted and release to the chart
7) If you are unable to contact any of the above, page the CP Attending on-call.

*Note: If calling a critical troponin to the ED and the patient has been transferred to the Cath Lab, the ".CATH" smart phrase should be used in Beaker. It will append the following statement to the result:

Critical value called to the ED. Patient disposition to Cath Lab. Critical Value discontinued per SOP (DD/MM/YYYY TIME).

Date and time must be entered. Once completed, the result can be final verified.

Calling Critical Values for OUTREACH CLINIC PATIENTS:

1) Call the number provided on the Outreach phone numbers spreadsheet or number provided on the patient requisition in CP or Customer Service
2) Make 3 attempts to contact the person on call for the clinic in 30-45 minute intervals.
3) If you have received no call back after 3+ hours and you have made 3 attempts do the following:
   a. In place of the "Called to readback by" comment type
      i. Called XXX-XXX-XXXX X3 at HHMM, HHMM, and HHMM. No Response.
   b. Release the value and email lab_specimenissue_dl with the following information:
      i. Subject: (CLINIC ACRONYM) – CRITICAL VALUE
         1. Example: XACML – CRITICAL VALUE
   c. In the email include patient information, critical value, phone number called, time of attempts, and any other important information
      i. Example:
         The Chemistry Lab received a sample on JANE DOE this afternoon that was collected at the XACML clinic. The sample has a critical K value of 6.4 –

No Visible Hemolysis. I have called the number provided on the Outreach Spreadsheet of 336-760-0000 at 1830, 1905, and 1950 with no response. The value has been released. Could someone please verify with the clinic they are aware of the critical value?

It is imperative for critical values to be called as soon as the results are available and should be reported no more than 30 minutes after availability. When critical results are communicated, a "read-back" of the results is requested and documented via the Laboratory Information System. The first and last name of the nurse or physician the tech spoke with, time, and date will need to be documented with the critical value. First name alone is not acceptable.

If a critical value is called and the patient has since expired, results will be appended with the comment "Critical Value Called, Patient Expired". The first and last name of the nurse or physician the tech spoke with, time, and date will need to be documented.

Information Needed When Calling a Critical Value:

When calling an inpatient critical value, the basic information the nurse or physician will need are the patient's first and last name, medical record number, and critical value. If they request any other information, the tech should be able to look in Remisol or Beaker to obtain what is requested. When calling the After Hours Critical Value Hotline more patient information is required. The tech should be prepared to provide the following patient information:

- The tech's first and last name along with your department and location (i.e. Chemistry Lab at Wake Forest Baptist Medical Center)
- Patient's first and last name and how to spell them
- Medical record number
- Clinic location patient was seen by physician
- Physician's name
- Critical value
- Hi. This is [Tech's name] calling from the [Chemistry Lab at Wake Forest Baptist Medical Center]. I have a critical lab value to report. Patient's last name is [pronounce last name and spell it]. First name is [pronounce first name and spell it]. Medical record number is [MRN]. The patient was seen at the [clinic location] by [physician's name]. The critical lab value is…

Example:

Hi. This is Bob calling from the Chemistry Lab at Wake Forest Baptist Medical Center. I have a critical lab value to report. Patient's last name is Doe spelled D-O-E. First name is Jane spelled J-A-N-E. Her medical record number is 12345556. She was seen at Internal Medicine Country Club today by Dr. Meghan Alexander. She has a critical Potassium of 6.1 with No Visible Hemolysis.

A QA report will be generated the following day of all critical values. The Manager or designee checks if there are critical results that were missed/not called or documented incorrectly. Any missed calls or documentation will be brought to the attention of the tech by management. They also get reported on the department's monthly QA report and put in the employee's file.

Chemistry List of Critical Values:

Assay	Lower Limit	Upper Limit	Ages / Comments
Sodium	< 120 mmol/L	>160 mmol/L	All Ages
Potassium	< 3.0 mmol/L	> 6.2 mmol/L	0-7 days
	< 3.0 mmol/L	> 7.0 mmol/L	7 days old - 1 month
	< 3.0 mmol/L	> 7.5 mmol/L	1 month - 3 months
	< 3.0 mmol/L	> 6.5 mmol/L	3 months - 1 year
	< 3.0 mmol/L	> 6.0 mmol/L	1 year and up
CO2	<10 mmol/L	>40 mmol/L	All Ages
Glucose	< 45 mg/dL	> 300 mg/dL	0-7 days
	< 50 mg/dL	> 300 mg/dL	7 days - 18 years
	< 50 mg/dL	> 600 mg/dL	18 years and up
Calcium	< 6.0 mg/dL	> 13.0 mg/dL	All Ages
Phosphorus	< 1.0 mg/dL	>12.0 mg/dL	All Ages
Bilirubin, Total	N/A	>18.0 mg/dL	Newborns only (0 days – 1 month)
Magnesium	< 1.0 mg/dL	>6.0 mg/dL	All Ages
Acetaminophen	N/A	> 20.0 ug/mL	All Ages
Carbamazepine	N/A	> 20 ug/mL	All Ages
Digoxin	N/A	>2.0 ng/mL	All Ages
Phenobarbital	N/A	> 40.0 ug/mL	All Ages
Phenytoin	N/A	>20.0 ug/mL	0 days - 18 years
	N/A	>30.0 ug/mL	18 years and up
Salicylate	N/A	> 29.9 mg/dL	All Ages
Theophylline	N/A	> 30.0 ug/mL	All Ages
Valproic Acid	N/A	> 120.0 ug/mL	0 days - 18 years
	N/A	> 150.0 ug/mL	18 years and up
Amikacin	Trough >10.0 mcg/mL	Peak > 30.0 mcg/mL	Outpatient only-All Ages
Gentamicin	Trough >2.5 mcg/mL	Peak >10.0 mcg/mL	Outpatient only-All Ages
Tobramycin	Trough >2.5 mcg/mL	Peak >10.0 mcg/mL	Outpatient only-All Ages
Vancomycin	Trough >25.0 mcg/mL	N/A	All Ages/Locations
Lactic Acid	N/A	>4.0 mmol/L	All Ages
Lithium	N/A	>2 mmol/L	All Ages
Ammonia	N/A	>150 µmol/L	0 days - 18 years
Troponin	N/A	>= 18 pg/mL	First elevated value for ED patient only

Correction of Laboratory Values:

In the event that a result reported by the Clinical Chemistry Laboratory must be corrected, the following protocol will be followed.

1. The corrected result will be entered into the EPIC/BEAKER LIS. At this time the LIS appends a correction statement onto the result. The physician or charge nurse will be notified by telephone of the correction. The result will then be modified so that a free text comment is added stating that the physician or nursing station was notified along with the date and time of the telephone call. Document the date and time the correction was called and the name of the person who was notified and read-back the values.

   All corrections must be reported as soon as the corrected results are available.

2. Any lab correction or credit request will require the tech to fill out the corrected result or the incident/credit form found in the binder beside the Remisol computer. Place the completed form on the manager's door for them to follow up.

3. The EPIC/BEAKER LIS generates a "Daily Corrected Component Lab Results" report daily, showing all amended and appended results from the previous day. This report is checked daily by management. If needed, management will make sure that a RL6 and/or CAPA was generated for the correction.

Possible reasons for correction:

- Corrected after retesting
- Corrected due to QC investigation
- Corrected result due to user error
- Instrument malfunction
- Results entered on wrong patient
- Test done on wrong patient
- Test done on wrong specimen
- Results removed at request of physician for cancellation

4) Review/Revision/Implementation:

All procedures must be reviewed at least every 2 years.

- All new procedures and procedures that have major revisions must be signed by the CLIA Laboratory Medical Director.

- All reviewed procedures and procedures with minor revisions can be signed by the designated section medical director.

5) Related Procedures: N/A

6) References, National Professional Organizations, etc.: N/A

7) Attachments: N/A

8) Revision Dates:

Review/Revision Date	Review/Revision Description	Signature
01/29/2020	Initials requirement added to critical value comment, ammonia critical value added, troponin critical value added, ".CATH" smart phrase added for patients with critical troponins transferred from ED to Cath Lab	
05/14/2020	Add more detail for calling critical values to pg. 2	