GP 1/16/19

Wake Forest Baptist Medical Center	Policy for Laboratory and Point of Care Testing (POCT) Product Recall and Alert Notifications (ECRI Alerts) Lab Admin 20	Type:	
		Effective Date:	01/2017
		Revised Date:	
		Contact:	Laboratory Compliance, QA, Safety and Point-of-Care Testing
CLIA Laboratory Medical Director Signature:		Date Approved:	2/2/17
Name and Title: Gregory Pomper, MD, Medical Director, Clinical Laboratories			

1) **General Policy Statement:**

It is the policy of Wake Forest Baptist Medical Center to address manufacturer and FDA laboratory product recall and alert notifications according to established protocols. The ECRI Institute Alerts Tracker is used to monitor such recall and alert notifications. Each laboratory section has one or more responders who are responsible for addressing these alerts each week. Each specific responder has been trained and instructed on how to address these alerts by ECRI specialists and Laboratory Compliance staff members.

Only staff members from each laboratory area who have been trained and instructed on responding to ECRI alerts will address them.

The purpose of this policy is to provide guidelines for these responders and ensure they are competent to address ECRI alerts.

a) **Scope:** All staff members who are trained and qualified to address ECRI alerts are responsible for following this policy.
b) **Responsible Department/Party/Parties:**
   i. Policy Owner: Laboratory Compliance, QA, Safety and Point-of-Care Testing Manager
   ii. Procedure: All staff members who are trained and qualified to address ECRI alerts shall adhere to processes outlined in this document.
   iii. Supervision: The Medical Director and/or laboratory director, as indicated on covering CLIA certificate for Point-of-Care Testing, shall supervise the person(s) performing activities outlined in this document.
   iv. Implementation: Each laboratory or site manager is responsible for ensuring compliance with processes stated in this document.

2) **Definitions:** For purposes of this policy, the following terms and definitions apply:

a) **ECRI:** An organization that identifies and informs subscribers about health technology hazards and risks that could impact patient safety and quality of care.
b) **FDA:** Food and Drug Administration, Public Health Service in the Department of Health and Human Services, oversees safety and quality issues related to drugs, biological products, medical devices and nutritional products.
c) **Point-of-Care Testing (POCT):** Tests designed to be used at or near the site where the patient is located, do not require permanent dedicated space, and are performed outside the physical facilities of the clinical laboratory.
d) **Quality Assurance (QA):** A system for ensuring a desired level of quality.

e) **Quality Improvement (QI):** Activities implemented to improve the quality of process.
f) **UMDNS:** Universal Medical Device Nomenclature System which is used by ECRI to reference device terms.

3) Policy Guidelines:

a) ECRI alert emails arrive weekly – Lab section responders only need to open those that apply or possibly may apply to their area of expertise (lab specialty).

b) All alert emails should be saved to an Outlook folder for future reference.

c) ECRI Alerts are categorized according to priority.
- **Auto-Match, Class I and Critical priority** – act on within 1 business day of notification
- **Class II and High Priority** – act on within 2 business days of notification
- **Class III and Normal Priority** – act on within 5 business days of notification

d) Near the top of the alert page, under the Accession Number and UMDNS Device Term(s), there is information indicating the area/specialty that the alert involves.

e) **If an alert does NOT pertain to a responder's area of expertise or lab section, NO ACTION is needed.**

f) If an alert **DOES** pertain to a responder's area of expertise or lab section, i.e. a product that is related to and could feasibly be used in your lab section, the alert should be opened and reviewed. Depending on the situation, one of the following steps should be taken:

1. **If the product is NOT USED in your laboratory:**
   a. Scroll down to "Alert Tracking" and for Status enter "Not Applicable".
   b. In Action Taken, enter "None".
   c. In Action Notes enter **your full name and date**, click Save.
2. **If the product is USED in your laboratory, and you need to investigate further:**
   a. Scroll down to "Alert Tracking" and for Status enter "Applicable – Open".
   b. In Action Taken, enter appropriate response from drop down list ("Other" if not listed).
   c. In Action Notes, enter notes as to your course of action, **your full name and date**, click Save.
   d. **LATER** - When the alert has been resolved and action completed, open the alert and for Status enter "Applicable – Closed".
   e. In Action Taken, enter appropriate response from drop down list ("Other" if not listed).
   f. In Action Notes, enter all actions taken to resolve the alert, **your full name and date**, click Save.
   g. Documentation should be clear as to all actions that were taken.
3. **If the product is used in your laboratory, and you have already taken appropriate action:**
   a. Scroll down to "Alert Tracking" and for Status enter "Applicable –Closed".

b. In Action Taken, enter appropriate response from drop down list ("Other" if not listed).
c. In Action Notes, enter details of actions you have taken, **your full name and date**, click Save.
d. Documentation should be clear as to all actions that were taken.

****NOTES:**

i. **Auto-Matched alert:**
- Indicates that our facility has purchased this product/reagent/device at some time
- Auto-match e-mail alerts will come any day of the week and will also be resent with the regular weekly alerts.
- The alert will indicate "Automatch!" above the title when you open the alert.
- These alerts should be addressed within 1 business day of notification or as soon as possible
- Requires response by laboratory expert and any lab section that received the product.

ii. **All ECRI alerts should be addressed within 1 week of notification.**

iii. **Resource contacts:**
- Christy Sowell, ECRI specialist – (610) 825-6000, ext 5139
- Jonathan Kepley – 336-716-5085
- Laboratory Compliance team –LabPOC_Testing_DL@wakehealth.edu

4) Review/Revision/Implementation:

a) Review Cycle: Each 2 years
i. All new policies/procedures/guidelines and those that have major revisions must be reviewed/signed by the CLIA Laboratory Medical Director.
ii. Review/sign-off can be completed by the designated section Medical Director or section manager in the following circumstances:
- Biennial review
- Minor document revisions

b) Office of Record: Laboratory Compliance, QA, Safety and Point-of-Care Testing

5) Related Policies: None

6) Governing Law or Regulations:

1. Food and Drug Administration. Department of Health and Human Services. Available online: www.fda.gov/safety/medwatch
2. College of American Pathologists Standard, Laboratory General Checklist, Gen.20340, 08/2016.
3. ECRI Institute

7) Attachments:

Attachment A: ECRI Alert Categories

8) Revision Dates:

Implemented: 1/17

Attachment A: ECRI Alert Categories

Specialty Area	Definition	Inclusion Criteria	Exclusion Criteria	Overlaps & Related Terms
Clinical Laboratory/Pathology	Healthcare facility activity concerned with the analysis of patient specimens. A clinical laboratory contains several functional units including chemistry, hematology, coagulation, urinalysis, microbiology, histology, cytology and immunohematology. Pathology, the study of disease, uses information produced by the laboratory to diagnose disease.	Devices, materials, and supplies used in central clinical laboratories; including analyzers, general chemistry equipment, lab ware, and laboratory furniture. Reagents for use on any analytical system that produces a result used for patient treatment should be included. Devices also include autopsy and morgue devices.		Phlebotomy and Point-of-Care Testing/ Coordination are frequently considered part of the Clinical Laboratory but can be overseen by Nursing. Immunohematology/Blood Bank can be part of the laboratory or a stand-alone entity.
Immunohematology/Blood Bank (category)	Area of clinical laboratory science (CLS) that is involved with immune, or antibody-antigen reactions involving the blood. This CLS area is involved in transplant medicine, for example, tissue typing and bone marrow compatibility. This field is sometimes referred to as Transfusion Medicine.	Devices and disposables such as pheresis equipment, blood grouping analyzers, reagents used in hepatitis testing, crossmatching, and blood collection bags.	Excludes blood products.	Since this area can be stand alone or included in the Clinical Laboratory, information about hepatitis B and C testing, syphilis, HIV, HTLV and West Nile Virus testing should be sent to both places.
Phlebotomy	The letting of blood for transfusion, pheresis, diagnostic testing or experimental procedures.	Usually the devices related to phlebotomy are disposables like phlebotomy needles, tube holders, blood gas syringes, lancets and blood collection tubes.	Usually items such as pheresis equipment are included in Immunohematology/Blood Bank instead of Phlebotomy.	Could overlap with Nursing and Immunohematology/Blood Bank.

Specialty Area	Definition	Inclusion Criteria	Exclusion Criteria	Overlaps & Related Terms
Point-of-Care Coordination	Laboratory testing performed outside of the clinical laboratory. It can be performed at the patient's bedside or in a centralized area within a unit, such as an intensive care unit.	Devices and necessary disposables, like test strips, cartridges, reagents, syringes and lancets. May include alerts that include user training issues for equipment such as blood glucose meters.		When the alert involves user training, it may Overlap with Staff Education.
Tissue Bank	Area responsible for the procuring, receiving, processing, and/or storage of donated cells or tissues for transplantation into patients.	Devices include refrigerators, freezers, centrifuges, analyzers capable of testing for infectious diseases (e.g., HIV 1/2, HBV, HBC, CMV), flow cytometers, and molecular methods for these tests. Also include disposables, such as specialty fluids (tissue storage/reprocessing). Regulatory notices referring to good manufacturing practices, sterility recalls, laboratory reagent notices, etc.		May overlap with Infection Control, OR/Surge Clinical Laboratory/Pathology, and Materials Management.