PATHOLOGY & LABORATORY MEDICINE SERVICE

Reporting of Incidents and Safety Concerns version 3

General Procedure # GEN00010

PRINCIPLE

Pathology and Laboratory Medicine Service (P&LMS) strives for good quality of care. Incident Report Monitoring is designed to help prevent errors, detect errors and to take appropriate action after an error has occurred to avoid adverse consequences. Additionally, it is use to capture customer feedback or suggestions for improvement. As part of the quality practices at Baltimore and Perry Point, all errors, accidents, incidents, complaints, compliments, safety concerns and other communication concerning established practices, policies, and procedures are continuously monitored.

Identification and reporting are key elements to maintaining good quality of care. Each error, accident, incident, complaint, concern and suggestion provides an opportunity for improvement. Incident reports and information captured through Risk Management and Patient Advocate Services is use to track processes, improve quality and minimize risk. Issues reported and discussed and decisions made are part of the peer review and quality improvement processes.

SCOPE

Pathology and Laboratory Medicine Service Personnel

DEFINITIONS

Incident is an error that contributed to delay of patient care or where patient care was at risk "near miss", (i.e. mislabeling specimen samples).

Internal Incident Report:
Use the Laboratory Incident Report (Attachment A) for any error, problem, deviation, mistake, concern or complaint concerning laboratory processes. These include, but are not limited to, poor customer service, corrected reports and patient care issues. This report is internally monitored for trends.

Sentinel Event is defined by The Joint Commission (TJC) as any unanticipated event in a healthcare setting resulting in death or serious physical or psychological injury to a patient or patients, not related to the natural course of the patient's illness.

Electronic Incident Report (External) Joint Patient Safety Reporting (JPSR): is used by all hospital staff to report incidents that require further review by Risk Management Services.

PROCEDURE

1. Laboratory Incident Report

    1. The tech or section supervisor identifying the problem documents the problem in the "Description of Incident" section of the Laboratory Incident Report form.
    2. Attach any supporting documentation.
    3. Investigation and corrective action should be completed in a timely manner as to prevent further errors.
    4. Supervisors and Quality Management Technologist review reports for trends or repeat problems. It may be necessary to address problems identified with other services to find the appropriate resolution. Risk Management should be notified when needed.
    5. To submit an electronic incident report using JPSR, use the intranet site and follow instructions under Electronic Incident Report option.

2. FDA Reportable Adverse Events

When information reasonably suggests that, any laboratory instrument, reagent, or other device, MDR (medical device reporting) has or may have caused or contributed to a patient death or serious injury, the FDA requires the laboratory to report the event.

1. If the event has caused a patient death, then it must be reported to both the instrument manufacturer and the FDA.
2. If the event is serious patient injury, a report may be sent to the manufacturer only unless the manufacturer is unknown, then a report must be made to the FDA.
3. All reports must be submitted on FDA form 3500A (Attachment B) within 10 working days of becoming aware of the event.
4. Device malfunctions or problems that relate to any aspect of a test including hardware, reagents or calibration or to user error noted spontaneously in the course of clinical care must be reported to the following chain of command:
    a. Immediate supervisor or designee
    b. Section Pathologist
    c. Laboratory Director
5. If the event caused a death or serious patient injury, the laboratory will notify Risk Management and inform them that a form 3500A FDA Safety Information and Adverse Event reporting form is being filled out and submitted to the FDA as required.

An adverse patient event that may have resulted from inherent limitations in an analytic system (e.g. limitations of sensitivity, specificity, accuracy, precision, etc.) is NOT reportable.

The FDA form 3500A can be found on the FDA Homepage go to forms then to medical devices. Submit form 3500A electronically, mail or fax to the address on the second page of the form.

3. CAP Notification

This laboratory is accredited by the College of American Pathologists (CAP). If you have concerns regarding quality patient testing or laboratory employee safety, which are not being addressed by the laboratory administration, you may contact the CAP at 866-236-7212. The call is strictly confidential.

4. The Joint Commission APR 17

1. Any employee who has concerns about safety or quality of care provided in the hospital may report these concerns to the Joint Commission.
2. The hospital is strictly forbidden from taking any form of disciplinary action against any employee reporting their concerns to the Joint Commission.

REFERENCES:

1. Code of Federal Regulations, 42 CFR, 493
2. CAP Checklist 2016
3. Joint Commission Element ARP 17
4. VAMHCS Policy Memorandum 512-00/PS-005, "Patient Safety Risk Management Program" May 2014.

ATTACHMENTS:

A. Laboratory Incident Report
B. FDA Form 3500A (2/13)

DATE ADOPTED	*Author of Procedure/Policy*	Chief of Service
11/30/2007	Paul D. Gruver, MT	Signature: Dong H. Lee M.D.

Policy/Procedure(s) Retired:		Date retired:

Review Date	Version Number	Signature of reviewer
11/13/15	2	Joanne Wade
10/16/17		Joanne Wade

REVISION HISTORY

Date revised	Revision #	Changes made	Signature
11/13/15	2	-Updated procedure on use of the Laboratory Incident Report. -Updated FDA form 3500A.	Wade
10/16/17	3	-Removed table 1. -Added instructions for submitting JPSR.	Wade

Laboratory Incident Report

GEN00010A

Division:				
Patient:		**Accession #:**		
Date of Incident:		**Patient Care Affected:**	**YES**	**NO**
Responsible Employee(s):		**Location:**		
Reported BY/ Date:				
Description of Incident **(to be reported by person identifying or reporting the incident)**				
Employee / Date:				
Investigation				
Employee / Date:				
Resolution / Action Taken **(To be completed by supervisor)**				
Supervisor / Date:				
ROOT CAUSE ANALYSIS / FOLLOW-UP				
Quality Management Tech / Date:				
NOTIFICATION				
Risk Management:	**YES**	**NO**	**Date Notified:**	
FDA Reportable:	**YES**	**NO**	**Date Notified:**	
Director / Date:				

U.S. Department of Health and Human Services
Food and Drug Administration

MEDWATCH

FORM FDA 3500A (2/13)

For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

Page 1 of ____

Form Approved: OMB No. 0910-0291, Expires: 6/30/20
See OMB statement on revers

Mfr Report #

UF/Importer Report #

FDA Use Onl

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event: or Date of Birth:	3. Sex	4. Weight
In confidence		☐ Female ☐ Male	____ lbs or ____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☐ Adverse Event and/or ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*
- ☐ Death: _____ *(mm/dd/yyyy)*
- ☐ Disability or Permanent Damage
- ☐ Life-threatening
- ☐ Congenital Anomaly/Birth Defect
- ☐ Hospitalization - initial or prolonged
- ☐ Other Serious (Important Medical Events)
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*

4. Date of This Report *(mm/dd/yyyy)*

5. Describe Event or Problem

(Continue on page 3)

6. Relevant Tests/Laboratory Data, Including Dates

(Continue on page 3)

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

(Continue on page 3)

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*
#1
#2

2. Dose, Frequency & Route Used	3. Therapy Dates *(If unknown, give duration)* from/to *(or best estimate)*
#1	#1
#2	#2

4. Diagnosis for Use *(Indication)*	5. Event Abated After Use Stopped or Dose Reduced?
#1	#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp. Date	8. Event Reappeared After Reintroduction?
#1	#1	#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2	#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

(Continue on page 3)

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name	2b. Procode

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
Serial #	Unique Identifier (UDI) #	

6. If Implanted, Give Date *(mm/dd/yyyy)*	7. If Explanted, Give Date *(mm/dd/yyyy)*

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

10. Device Available for Evaluation? *(Do not send to FDA)*
☐ Yes ☐ No ☐ Returned to Manufacturer on: _____ *(mm/dd/yyyy)*

11. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

(Continue on page 3)

E. INITIAL REPORTER

1. Name and Address

Phone #	Email Address

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☐ Yes ☐ No		☐ Yes ☐ No ☐ Unk.

MEDWATCH

FORM FDA 3500A (2/13) *(continued)*

FDA USE ONLY

F. FOR USE BY USER FACILITY/IMPORTER *(Devices Only)*

1. Check One ☐ User Facility ☐ Importer
2. UF/Importer Report Number
3. User Facility or Importer Name/Address
4. Contact Person
5. Phone Number
6. Date User Facility or Importer Became Aware of Event *(mm/dd/yyyy)*
7. Type of Report ☐ Initial ☐ Follow-up # ____
8. Date of This Report *(mm/dd/yyyy)*
9. Approximate Age of Device
10. Event Problem Codes *(Refer to coding manual)*
Patient Code ____ - ____ - ____
Device Code ____ - ____ - ____
11. Report Sent to FDA? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
12. Location Where Event Occurred ☐ Hospital ☐ Home ☐ Nursing Home ☐ Outpatient Treatment Facility ☐ Outpatient Diagnostic Facility ☐ Ambulatory Surgical Facility ☐ Other: ____ *(Specify)*
13. Report Sent to Manufacturer? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office (and Manufacturing Site for Devices)
Name
Address
Email Address
2. Phone Number
3. Report Source *(Check all that apply)* ☐ Foreign ☐ Study ☐ Literature ☐ Consumer ☐ Health Professional ☐ User Facility ☐ Company Representative ☐ Distributor ☐ Other: ____
4. Date Received by Manufacturer *(mm/dd/yyyy)*
5. (A)NDA # ____ IND # ____ BLA # ____ PMA/510(k) # ____ Combination Product ☐ Yes Pre-1938 ☐ Yes OTC Product ☐ Yes
6. If IND, Give Protocol #
7. Type of Report *(Check all that apply)* ☐ 5-day ☐ 30-day ☐ 7-day ☐ Periodic ☐ 10-day ☐ Initial ☐ 15-day ☐ Follow-up # ____
8. Adverse Event Term(s)
9. Manufacturer Report Number

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event ☐ Death ☐ Serious Injury ☐ Malfunction
2. If Follow-up, What Type? ☐ Correction ☐ Additional Information ☐ Response to FDA Request ☐ Device Evaluation
3. Device Evaluated by Manufacturer? ☐ Not Returned to Manufacturer ☐ Yes ☐ Evaluation Summary Attached ☐ No *(Attach page to explain why not)* or provide code: ____
4. Device Manufacture Date *(mm/yyyy)*
5. Labeled for Single Use? ☐ Yes ☐ No
6. Event Problem and Evaluation Codes *(Refer to coding manual)*
Patient Code ____ - ____ - ____
Device Code ____ - ____ - ____
Method ____ - ____ - ____ - ____
Results ____ - ____ - ____ - ____
Conclusions ____ - ____ - ____ - ____
7. If Remedial Action Initiated, Check Type ☐ Recall ☐ Repair ☐ Replace ☐ Relabeling ☐ Notification ☐ Inspection ☐ Patient Monitoring ☐ Modification/Adjustment ☐ Other: ____
8. Usage of Device ☐ Initial Use of Device ☐ Reuse ☐ Unknown
9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:
10. ☐ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

This section applies only to requirements of the Paperwork Reduction Act of 1995.

The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

OMB Statement: "An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Please DO NOT RETURN this form to the above PRA Staff email address.

MEDWATCH
FORM FDA 3500A (2/13) *(continued)*

B.5. Describe Event or Problem *(continued)*

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B.6. Relevant Tests/Laboratory Data, Including Dates *(continued)*

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B.7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)* *(continued)*

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Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)* *(For continuation of C.10 and/or D.11, please distinguish)*

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Other Remarks

Back to Item D.11