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| **Policy Statement** | It is the policy of St. Agnes Hospital Laboratory that all significant or unusual events be reported on the Occurrence Report Form (ORF). |
| **Purpose** | To provide instructions for generating an ORF. |
| **Scope** | This policy applies to all associates and physician affiliates in all sections of the Laboratory. |
| **Responsibility** | It is the responsibility of the Laboratory associate encountering the event to report the event using the ORF. It is the responsibility of the Quality Coordinator or designee to review and disperse the ORF to the appropriate supervisory individual, as needed. It is the responsibility of the supervisory individual to address the issue, take appropriate action, complete LADM Ff ORF Follow Up Form, and if necessary, develop a process to improve and monitor the situation. |
| **Event Examples** | Significant, unexpected or unusual events are to be documented using the occurrence reporting system.<br><br>These events include, but are **not** be limited to:<br>➢ Patient, visitor or associate safety issues or injuries<br>➢ Failure to provide appropriate customer service<br>➢ Unsafe working conditions<br>➢ Equipment failures and maintenance issues<br>➢ Unplanned computer downtime<br>➢ Significant quality control problems or inappropriate remedial actions or documentation<br>➢ Inventory shortages and wastage<br>➢ Unusual events or requests<br>➢ Deviations from policy or procedure<br>➢ Service issues such as delay of test results<br>➢ Communication issues<br>➢ Vendor recalls/urgent product notifications/medical device related events<br>➢ Incomplete requisitions or request forms<br>➢ Order entry errors<br>➢ Rejected or returned specimens<br>➢ General complaints |
| **Procedure** | **Completing the ORF**<br>1. The ORF is available as an icon on the desktop of most Laboratory PCs in various formats:<br>a) Occurrence Report Form<br>b) BB Occurrence Report Form |

A. **Creating an Occurrence Report Form(ORF)** (Each section should include the following):

1. **Initiated By or Employee Name:** Individual completing ORF
2. **Occurrence Date:** Date Incident Occurred
3. **Time:** Time Incident Occurred
4. **Patient's Name:** Name of Patient involved in incident
5. **Account#:** Patient Account Number (SA, LO, etc.)
6. **Accession#:** Specimen Number(s) affected
7. **Location#:** (This section must be completed): Location of Patient at the time of Incident or Location of Equipment (if applicable) i.e. 7100N, EHS Please do not document room number in this section. Room number can be documented in the body of the ORF
8. **Brief Description of Occurrence:** (This section must be completed)**:** Describe the problem in detail
    a) What happened
    b) Who was involved
        1. Include other laboratory sections
        2. Include the name(s) of internal and external associates
    c) Where incident occurred
    d) If specimen issue, include date/time specimen was received, who received the specimen, individual that collected specimen
    e) Some ORF forms require a check box be selected. Select the most appropriate box with additional comments (if applicable)
9. **Immediate Action Taken:** (This section must be completed)**:** Describe what was done to resolve the problem including individuals contacted and/or name of supervisor notified. Equipment Failures should include notification to Help Desk, Technical Service desk, and/or Biomed with documentation of work order/ticket number(s) on the ORF. An Out of Order sign should be placed on all defective equipment.
10. **Time Spent on Occurrence Resolution:** Document how long it took to resolve incident or complete immediate action.
11. **Pathologist Notified( if applicable):** Check Yes or No
12. **Pathologist Name (if applicable):** Document Pathologist Name
13. **Was a Hospital Incident Report Completed?( if applicable):** Check Yes or No
14. **Save and Email ORF(Pay attention to where ORF is being saved):** Save as: Brief Description of ORF-Date-Initials (#) (i.e. Mislabel-020911-ZZ, Mislabel-020911-ZZ2, Equipment Malfunction-011211-XY) Specified format is optional

B. **Emailing An ORF**

1. **Outlook Web Access Users**
   a) Select New 
   b) Select To: Type “labquality” in the search section of the dialog box or find labquality email MDBAL-MB-Labquality in the address book.
   c) Select Find
   d) Select MDBAL-MB-Labquality or Double Click MDBAL-MB-Labquality
   e) Add Supervisor and/or Lead using steps b-d
   f) Include Supervisor or Lead of any other Laboratory Section involved
   g) Click Okay
   h) Click Attachment  to include ORF document
   i) Select Browse and find saved ORF document
   j) Click Open
   k) Then click attach
   l) Document file name of ORF in the subject line
   m) Document “See Attached” in the body of the email

2. **Outlook Desktop Users**
   a) Select New in Email
   b) Select To: Search labquality or MDBAL-MB-Labquality and supervisor/lead from the address book
   c) Include Supervisor or Lead of any other Laboratory Section involved in incident
   d) Document file name of ORF in the subject line
   e) Document “See Attached” in the body of the email
   f) Select insert from the Menu and choose File to include attachment or use attachment icon
   g) Find saved ORF document and click Insert
   h) Document file name of ORF in the subject line
   i) Document “See Attached” in the body of the email

3. **Follow-Up (Managers, Supervisors, Leads, Coordinators)**
   a) Immediate follow-up should occur when an ORF is received
      1. Complete LADM 8000 Ff ORF Follow-Up Form
      2. Follow-Up should be sent to the Labquality email and manager of your area
   b) Follow-up should at a minimum include:

1. Investigational findings
2. Associate counseling and/or re-education with date
3. Any documented process change with date of implementation
4. Documented procedural change with date
5. Completed equipment repair with date
6. Discussions with staff regarding complaints
7. Referral to meeting minutes if discussed at a meeting with associates

c) If applicable, attach the procedure/policy reviewed with associate, revised procedure/policy, email communication, re-training form(s), requisition(s), meeting minutes, etc. to the follow up email

c) Outreach Occurrence Report Form
d) Core Laboratory Occurrence Report Form
e) Transfusion Service Rejected Specimens Form
f) Referral Testing

2. Select the appropriate occurrence report form as determined by section or type of occurrence.
3. Complete the Occurrence Report Form as follows:
   a) Complete Initiated By with the name of the author of the report.
   b) Complete Occurrence Date and Time with the date/time of the occurrence.
   c) Provide patient name and 12 digit account # if applicable. This can be left blank for issues not involving a specific patient.
   d) Provide the patient location, when applicable.
   e) Provide a brief description of the occurrence. Include source of issue when possible, i.e. collection station, associates involved, date/time specimen received, who received specimen – do not leave blank. The associate names will be removed and coded for filing. Details expedite investigation.
   f) Complete the immediate action taken – do not leave blank. Details expedite investigation.
   g) Complete name of contact person and time spent working toward a resolution.
   h) Specify if a pathologist is notified. If notified, include the pathologist's name.
   i) Specify if a hospital incident report was completed.
   j) Do not complete anything beyond this point. The Quality Coordinator will complete this.

   Note: Section specific forms are similar and require completion of designated blocks as indicated.

4. Save the file to the current computer station in which you are working. The name of the ORF should briefly describe the incident and include the date of occurrence: i.e. Equipment Malfunction 010110, QC Failure 010110, Missed Test Request 010210. .
5. E-mail Process defined below.

**Emailing the ORF**

| | |
|---|---|
| | a) Log into email system.<br>b) Create a new email.<br>c) Address the email to Labquality and lead or supervisor.<br>d) In the subject line enter the file name of the ORF.If emailing multiple ORFs, select a file name.<br>e) In the message section say "See Attached ORF".<br>f) Attach the ORF.<br>g) Send. |
| **ORF Follow Up** | All internal ORFs will be followed up utilizing LADM Ff ORF Follow Up form. The ORF Follow Up form will reside on the Supervisor desktop for immediate documentation upon receipt of an ORF by the Quality Coordinator, other Section Supervisor, or associate.<br>1. Complete all required and other appropriate fields of the LADM Ff ORF Follow Up form. (Select "Highlight Required Fields" in the upper right hand corner of the form to view required fields).<br>2. Save the file to a designated file on your workstation. The file name should be documented as the same name of the ORF in which the follow up is associated with followed by "follow up." (i.e. Equipment Malfunction 010110 RR Follow Up)<br>3. Send Follow Up form to the labquality mailbox**.** |
| **ORF Review** | **Quality Coordinator Review of the ORF**<br>1. The Quality Coordinator receives the Occurrence Report Form electronically through the labquality email.<br>2. The ORF is then directed to the appropriate supervisor/manager and/or externally for review and action.<br>3. The Quality Coordinator assigns the ORF number and files it in the database with electronic copies of additional documentation (i.e. requisition, etc) attached and filed electronically. |
| **Reports** | **Report Generation from the ORF System**<br>Reports are generated for quality improvement purposes. |
| **Related Documents** | CLSI<br>LADM 0000 QP Lab Quality Management<br>LADM 8000 Q Laboratory Occurrence Reporting System |

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| | LADM 8000 Ja Laboratory Occurrence Reporting System<br>LADM 8000 Fa Laboratory Occurrence Reporting System-General ORF Form<br>LADM 8000 Fb Laboratory Occurrence Reporting System-Outreach ORF Form<br>LADM 8000 Fc Laboratory Occurrence Reporting System-Transfusion Services ORF Form<br>LADM 8000 Fd Laboratory Occurrence Reporting System-Corelab ORF Form<br>LADM 8000 Fe Laboratory Occurrence Reporting System-Support Services ORF Form<br>LADM 8000 Ff ORF Follow Up Form<br>LADM 8000 Fg Laboratory Occurrence Reporting System-Referral Testing ORF Form<br>LADM 8000 Fh Transfusion Service Rejected Specimens |
| **References** | Application of a Quality Management System Model for Laboratory Services-Approved Guideline- 3rd Edition, GP26-A3, Clinical Laboratory Standards Institute.<br><br>Management of Nonconforming Laboratory Events – GP32 –A Clinical Laboratory Standards Institute<br><br>Laboratory General Checklist, College of American Pathologists, current version. |

SAINT AGNES HOSPITAL

**Saint Agnes Laboratory Services**
900 South Caton Avenue
Baltimore, MD 21229

# Core Laboratory Occurrence Report Form

**ORF #** _____

**Employee Name** _____ **Location Code** _____

**Date of Occurrence** _____ **Time of Occurrence** _____ ☐ AM ☐ PM

**Patient's Name** _____ **Accession #** _____

**Medical Record #** _____ **Account #** _____

## Description of Occurrence:

- ☐ QC not performed or failures not properly documented
- ☐ Maintenance not performed and/or not properly documented
- ☐ Deltas on Plt not investigated and documented with appropriate coded comment
- ☐ Patient Plt result < 100 released with no record of previous results
- ☐ Inpatient MCV >5% change not given to charge tech for investigation
- ☐ No attempt to correct MCHC >37.4
- ☐ PTT < 19 not checked for clot
- ☐ K < 2.5 with accompanying CA < 6.5 not referred to the charge tech for investigation
- ☐ Mixing of reagent on board and/or reagent not dated & initialed
- ☐ Alert value with no Smartweb Called, or Faxed comment entered
- ☐ Free text comment not approved by Charge Tech
- ☐ Inappropriate comment entered
- ☐ No reason entered when editing result

**Additional Comments**

**Correct Action**



Print ORF | Clear ORF | Save ORF | E-mail ORF

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Baltimore, MD 21229

# Laboratory Support Services Occurrence Report Form

**ORF #** _____

| | | | |
|---|---|---|---|
| **Employee Name** | | **Location Code** | |
| **Date of Occurrence** | | **Time of Occurrence** | |
| **Patient's Name** | | **Account #** | |
| **Medical Record #** | | **Accession #** | |

## Brief Description of Occurrence:

- ☐ **CI** Improperly Collected
  - ☐ Not protected from light
  - ☐ Not on heat pack
- ☐ **CMS** Specimen(s) mislabeled
- ☐ **CWT** Specimen(s) collected in the wrong container
- ☐ **CWTO** Wrong Test Ordered
- ☐ **ICE** Specimen(s) not sent to lab on ice
- ☐ **OTHER** Please specify below.
- ☐ **LEAKED** Specimen(s) leaked in transit
- ☐ **NS** Ordered specimen(s) not received in laboratory
- ☐ **WP** Wrong patient drawn
- ☐ **ORD** Order Entry Error
  - ☐ CBN, ordered as lab draw
  - ☐ Ordered on wrong patient
  - ☐ Ordered under wrong account #
- ☐ **Sharps** Container Full
- ☐ **CBN** Wrong Test Ordered
  - ☐ Dialysis Draw
  - ☐ IV Therapy Draw
- ☐ **Identification Issues**
  - ☐ No Bracelet
  - ☐ Incorrect Information
- ☐ **Isolation**
  - ☐ No Sign
  - ☐ No PPE
- ☐ **No Procedure** No Bracelet

**Additional Comments**

## Immediate Action Taken:

☐ Notified _____ on _____ at _____

☐ Requested a specimen recollection. All tests affected by this error were cancelled in Meditech and appropriate documentation was made.

☐ Other (please specify below).

**Additional Comments**

**Time Spent on Resolution** _____

Print ORF | Clear ORF | Save ORF

# ORF Follow Up Form

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ORF ID

Was this an isolated incident? Was this is a system/process issue?

If system/process issue identified, please document:

What environmental factors influenced this incident?

What human factors influenced this incident?

Which other associates were involved in the incident?

Were there adequate policies/procedures in place at time of incident? Was the policy/procedure followed as written?

Was the policy reviewed with the associate(s)? Which policy/procedure? Date Completed

Require a policy/procedure revision? Which policy/procedure? Date Completed

Is staff re-training required? When will re-training begin? Date Completed

Was there a change in patient treatment? Were any patient samples affected by error? Were any patient samples repeated?

**Issues Related to Equipment:**

Were there any quipment issues identified? Was tech support notified? Did Service come to fix the problem?

Date Repaired Was a re-validation/re-verification required? Was testing delayed?

If testing delayed, was patient care area notified? Additional information- Equipment issue

**Immediate Actions:**

Will immediate action be effective in resolution? Will immediate action be effective in preventing recurrence?

Will an RCA/Process Improvement Project be conducted?

Additional Follow-Up performed:

**Notification/Discussions**

Was a Pathologist Notified? Date Completed Which pathologist?

Was an email notification sent to staff? Date Completed

Was this discussed at a staff meeting? Date Completed

Was this discussed at a huddle? Date Completed Which huddle(s)?

Was an associate counseled? Date Completed

Was this discussed at any other meeting? Date Completed Which meeting?

Was this reported to Risk Mgt? Date Completed

Individual(s) completing form

Additional Comments Related to the Occurrence

Clear Form | Print Form

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900 South Caton Avenue
Baltimore, MD 21229

# Referral Testing Occurrence Report Form

**ORF #** _____

**Employee Name** _____ **Patient Location** _____

**Date of Occurrence** _____ **Time of Occurrence** _____

**Patient's Name** _____ **Accession #** _____

**Medical Record #** _____ **Tube Initialed by** _____

## Description of Occurrence: (check all that apply)

- ☐ Inappropriate specimen saved
- ☐ All specimen types were not saved
- ☐ Hemolyzed Specimen
- ☐ Specimen not saved in appropriate container
- ☐ Specimen not saved with correct additives (acid, base, etc.)
- ☐ Quantity Not Sufficient
- ☐ Specimen saved at wrong temperature
- ☐ Specimen source not indicated
- ☐ No specimen saved
- ☐ Incorrect test ordered

Additional Comments _____

## Corrective Action: (check all that apply)

- ☐ Retrieved original sample from archive
- ☐ Specimen canceled. Notified patient care area
- ☐ Retrieved a different sample which was appropriate for testing
- ☐ Sample to be run at reference lab with a disclaimer
- ☐ Specimen able to be saved under appropriate conditions once retreived. Still within stability

Other: _____

LADM 8000 Fg
Created: 3/2013

Print ORF | Clear ORF | Save ORF | E-mail ORF

SAINT AGNES HOSPITAL

ORF ID #: _____

# Rejected Specimens ORF Form

| | | | |
|---|---|---|---|
| Collect Date | | Patient Account | |
| Collect Time | | Patient Name | |
| Collect Location | | Test Requested | |
| Collector Name | | Technologist Name | |

Reason(s) for Rejection:

- ☐ Quantity Not Sufficient
- ☐ Unsigned
- ☐ Double-labeled
- ☐ Hemolyzed
- ☐ Initials Only
- ☐ Foot Labels Used
- ☐ Adulterated
- ☐ Illegible Signature
- ☐ Missing Patient Identifiers
- ☐ Unlabeled
- ☐ Mislabeled

Comments

Saint Agnes Hospital, 900 S Caton Avenue, Baltimore, MD 21229
LADM 8000 Fh Transfusion Services Rejected Specimens ORF Form
3-2013

Clear the Form