

Nonconforming Event (NCE) Report Form☒
☐Existing nonconformity
Potential nonconformity**DATE/TIME OF NONCONFORMITY:** 13 August 2016 1700 **DATE/TIME OF REPORT:** 18 August 2016 1000**PERSONNEL REPORTING NONCONFORMITY:** Quality Manager**PATIENT'S NAME:** Alicia Ketema
(IF APPLICABLE)**PATIENT ID:** MR1299
(IF APPLICABLE)**PATIENT'S CLINICIAN:** Dr. Timela
(IF APPLICABLE)**LOCATION OF NONCONFORMITY:** Microbiology Section

BRIEF DESCRIPTION OF NONCONFORMITY: Several laboratory tests were ordered on a CSF specimen. All tests were completed except the gram stain and bacterial culture. The pediatric ward phoned the laboratory that evening on numerous occasions to be told the gram stain was still pending. No report was ever received for both microbiology tests.

HOW WAS THE NONCONFORMITY DISCOVERED? Dr. Timela spoke to the Laboratory Director noting that the laboratory's actions were a contributing factor in the child's death. Dr. Timela expressed that she is never sure what results, if any, she will receive from the laboratory.

REMEDIAL (IMMEDIATE) ACTION TAKEN: I spoke to Dr. Timela to obtain all the needed information to generate a NCE. Dr. Timela showed me the CSF results sent to her by the laboratory. I copied the laboratory results for our records. I assured Dr. Timela that a complete report will be forthcoming.

*Report provided to***Supervisor Name:** Microbiology Supervisor**Date/Time:** 18 August 2106 1015*Supervisor must obtain tracking number within 24 hours of receiving the occurrence; write number on top, right-hand corner.*

Nonconforming Event (NCE) Investigation and Management Form

Instructions

Tracking Number: NCE-2016-244

- *Begin investigation as soon as possible. Determine what, who, when, how, and then why (cause analysis) things went wrong in the process that led to the nonconforming event.*
- *Classify the event.*
- *Propose action to correct the problem or mitigate the risks*

Supervisor/Manager Investigation (attach pertinent information if required):

I spoke to Tech AA, who was working in microbiology and received the specimen. She explained that she never got an order for a culture, and she could not perform the gram stain because there were no reagents. She did make a fixed smear because the CSF was purulent and had a high white count. She explained she never got a phone call from pediatrics.

Name: Microbiology Supervisor

Date/Time: 18 August 2106 1100

Classification (check all that apply):

Non-laboratory Error	<input checked="" type="checkbox"/>	Laboratory Error	<input checked="" type="checkbox"/>	Laboratory Section: Microbiology			
Pre-examination	<input checked="" type="checkbox"/>	LIS problem		Receiving/Delivery		Complaint	<input checked="" type="checkbox"/>
Examination		Equipment		Waste Management		Safety/Injury	
Post-examination	<input checked="" type="checkbox"/>	Purchasing		Environmental Issue/Housekeeping		Reference Lab	

Proposed correction (attach action plan if approved): I spoke to the Pediatric Matron-in-Charge to remind her that laboratory must receive orders for testing to be performed. I held an emergency staff meeting to remind everyone to let me know when we cannot perform testing because there is a stock-out. Documentation of these meetings were noted in the section's communication log.

QA Officer Comments:

Due to the severity of this complaint and a review of other complaints similar in nature, this NCE will result in a CA investigation (CA-2016-244). A CA team will be assembled.

Risk Score: 3 Name: Quality Manager Date/Time: 18 August 2106/1130

NCE Management Database Entry:

NCE closed and entered into database Name: Quality Manager Date: 18 August 2106/1130