

## Nonconforming Event (NCE) Report Form

☒  
☐

Existing nonconformity  
Potential nonconformity

**DATE/TIME OF NONCONFORMITY:** 3 May 2016/ morning specimens **DATE/TIME OF REPORT:** 3 May 2016/  
1300

**PERSONNEL REPORTING NONCONFORMITY:** Biochemistry Tech DD

**PATIENT'S NAME:** 5 Pediatric Patients  
(IF APPLICABLE)

**PATIENT ID:**  
(IF APPLICABLE)

**PATIENT'S CLINICIAN:** Dr. Timela  
(IF APPLICABLE)

**LOCATION OF NONCONFORMITY:** Biochemistry section at XYZ analyzer workstation

**BRIEF DESCRIPTION OF NONCONFORMITY:** The Pediatric ward delivered 5 samples for biochemistry testing this morning. Results for only 1 patient was received from the laboratory for Dr. Timela to review during morning rounds. All requested results were reported except the electrolytes. The 4 patient reports not returned to the ward only had electrolytes ordered.

**HOW WAS THE NONCONFORMITY DISCOVERED?** Dr. Timela requested the pediatric ward clerk to walk the list of missing results for her patients to the laboratory.

**REMEDIAL (IMMEDIATE) ACTION TAKEN:** I informed the pediatric ward clerk that the analyzer did not have reagent to perform the electrolyte testing (no reference solution available). I explained that I did not know how long there will be no reagents. She still wanted reports on the missing 4 patients to give to Dr. Timela. I wrote *no reagent* on the reports. I reminded the Technical Supervisor to notify the wards according to a *Delay Notification Procedure*. He said the memo will be sent out later this afternoon.

*Report provided to*

**Supervisor Name:** Biochemistry Section Supervisor

**Date/Time:** 3 May 2016/1315

*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-2016-194

- 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 the purchasing department to see how long it will be before we received the reagent. Purchasing thought it might be 1-2 weeks.

I spoke with the Technical Supervisor as to why there was a delay in the memo being sent. He explained that he did not know until I asked him to send this memo. I checked to ensure the Delay Notification Procedure requires the memo to be sent by the Technical Supervisor.

I spoke to Dr Timela to ensure she received the memo. She noted that she did, well after the fact. She explained that she knows there are purchasing issues; the pediatric ward is missing supplies as well. The issue she is frustrated with is that she never knows what is going on with her laboratory requests.

Name: Biochemistry Section Supervisor

Date/Time: 3 May 2016/1400

### Classification (check all that apply):

Non-laboratory Error		Laboratory Error	X	Laboratory Section: Biochemistry	
Pre-examination		LIS problem		Receiving/Delivery	
Examination		Equipment		Waste Management	
Post-examination	X	Purchasing		Environmental Issue/Housekeeping	
				Complaint	
				Safety/Injury	
				Reference Lab	

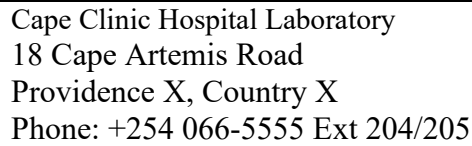
Proposed correction (attach action plan if approved): Send the memo broadcasting no reagents immediately so our customers do not get angry.

QA Officer Comments:

Risk Score: 2 Name: Quality Manager Date/Time: 3 May 2016/1430

NCE Management Database Entry:

NCE closed and entered into database Name: Quality Manager Date: 3 May 2016/1430



Patient Name:	Habtamu	Age:	2 years	Sex:	Male
Ward:	Pediatric	Lab No.:	38	Specimen:	capillary blood
Ordering Physician:	Dr. Timela				
Collector:	JD	Collection Date:	3 May 2016	Collection Time:	0630
Clinical history of the patient:					

[illegible]

<input checked="" type="checkbox"/> <u>Glucose</u>	<u>3.8 mmol/L</u>	<input type="checkbox"/> <u>AST</u>
<input checked="" type="checkbox"/> <u>Urea</u>	<u>3.2 mmol/L</u>	<input type="checkbox"/> <u>ALT</u>
<input checked="" type="checkbox"/> <u>Sodium</u>		<input type="checkbox"/> <u>Alkaline Phosphatase</u>
<input checked="" type="checkbox"/> <u>Potassium</u>		<input type="checkbox"/> <u>LDH</u>
<input checked="" type="checkbox"/> <u>Chloride</u>		<input type="checkbox"/> <u>GGT</u>
<input checked="" type="checkbox"/> <u>CO2</u>		<input type="checkbox"/> <u>CK</u>
<input type="checkbox"/> <u>Creatinine</u>		<input type="checkbox"/> <u>Amylase</u>
<input type="checkbox"/> <u>Uric Acid</u>		<input type="checkbox"/> <u>Calcium</u>
<input type="checkbox"/> <u>Total Protein</u>		<input type="checkbox"/> <u>Phosphorus</u>
<input type="checkbox"/> <u>Albumin</u>		<input type="checkbox"/> <u>Cholesterol</u>
<input type="checkbox"/> <u>Total Bilirubin</u>		<input type="checkbox"/> <u>Triglycerides</u>
<input type="checkbox"/> <u>Direct Bilirubin</u>		<input type="checkbox"/> <u>HDL-C</u>
<input type="checkbox"/> <u>Lactic Acid</u>		<input type="checkbox"/> <u>LDL-C calculated</u>
		<input type="checkbox"/> <u>Other</u>

### Additional Comments and Interpretation

I/C Laboratory Reviewer    Biochemistry CLS    Date/Time..... 3 May 2016/ 0815