



**Quality Division Use Only**

Quality Tracking #:	<input type="text" value="2018-015"/>	Classification:	<input type="text" value="Corrective Action"/>
Non-Conformance Level:	<input type="text" value="Class I"/>	Section:	<input type="text" value="Biology/DNA"/>
Date of Discovery:	<input type="text" value="02/12/18"/>	Date of Incident:	<input type="text" value="02/05/18"/>

Forensic Case Number(s), if applicable:	Agency Case Number(s), if applicable:
Group 1 (processed on February 5, 2018): 2017-23103, 2017-16125, 2018-01279, 2018-00761, 2018-00627, 2017-22736, 2017-23559, 2018-01277, 2018-01276, 2018-01604, 2018-00998, 2017-23712, 2018-01167, 2018-01166, 2018-01215, 2018-00545, 2018-00768, 2018-00262, 2018-01002, 2018-01004, 2018-00624, 2017-12645, 2016-12515, 2016-17758, 2016-15234, 055010409, 2018-01278, 2018-00770, 2018-01280, 2018-00628, 2018-00948, 2018-01003, 2018-00626, 2018-00651, 2018-01008, 2018-01027, 2016-03658, 2016-01055, 2017-10596, 2017-16665, 2018-00955, 2018-01419, 2018-01422, 2018-01421, 2018-01439 Group 2 (processed on February 12, 2018): 2018-01931, 2017-23468, 2018-00001, 2018-00779, 2018-00945, 2018-00546, 2017-23560, 2017-23518, 2018-01328, 2016-17238, 2018-01444, 2018-00502, 2018-01006, 2018-00655, 2018-00661, 2018-01606, 2018-01440, 2018-01420, 2017-20113, 2017-23103, 2015-08214, 2017-21803, 2018-00542, 2018-01712, 2018-01514, 2018-01743, 2018-01738, 2018-00303, 2018-01932, 2018-01237	Group 1 (processed on February 5, 2018): 156441017, 107765717, 005172618, 003600718, 001542318, 153679017, 126937917, 005815018, 008682318, 011681618, 007788318, 140661417, 008252418, 008589618, 009025518, 002871018, 003764118, 000895718, 005874018, 005231618, 161674617, 034085617, 051803416, 117581216, 097940916, 055010409, 005024118, 004954718, 009005418, 003278118, 007149318, 006241818, 003267518, 003658118, 008500118, 007091718, 029113516, 007762916, 063138017, 108416317, 007451518, 010428918, 009987818, 010557818, 009768718 Group 2 (processed on February 12, 2018): 014391918, 159537117, 163309917, 151143617, 160087917, 002204818, 159901017, 161627917, 142928416, 114327916, 011030418, 002804918, 008189618, 025794417, 004288818, 011846218, 008055518, 010102718, 134747217, 156441017, 071171715, 146010917, 001810918, 012307318, 012096118, 012976718, 007627918, 000928118, 014717618, 009364118

**Description of Non-conformance:**  
 A Forensic Biology staff member failed to follow laboratory standard operating procedures and subsequently incubated a reagent at an unvalidated temperature during the extraction procedure. A total of 75 cases were affected: group 1 had 45 cases that were processed on February 5, 2018. Group 2 included 30 cases that were processed on February 12, 2018. The samples in group 1 were also processed with a critical reagent that had not been quality checked prior to use in casework (see 2018-009/ID# 21429).

**Actions Taken:**



The Technical Leader consulted with a representative from the reagent vendor and it was determined the effect of a higher incubation temperature on the reagent is unknown. Therefore, because of the unknown effect of this temperature and the fact that the SOP was violated, the results obtained during this procedure were not reported by the laboratory. Reports were issued with the following statement for the affected samples, "A sample preparation error occurred with this item; therefore, no results will be reported for this item." The statement "Retesting will require the consumption of these items, which may not be conducted until permission to consume is received." was added where applicable.

**Summary of Root Cause Analysis:**

Note: Incidents are documented for tracking purposes and trend analysis. Root Cause Analysis is not required for incidents.

When the analyst was interviewed about this nonconformance, she indicated she incorporated the incubation step into her practice without consulting the laboratory SOP or the instrument's on-screen prompts. Therefore, she was not cognizant of the temperature setting. The other technicians who are authorized to perform this procedure were interviewed and confirmed they follow both the laboratory SOP and the instrument's on-screen prompts. This information supports the conclusion that the root cause was personnel-related. This nonconformance (along with 2018-009/ID# 21429) was referred to the Human Resources Division in accordance with HFSC policy. This staff member is no longer employed in the Forensic Biology section.

**Additional Information/Follow-Up:**

The overall effect of this higher incubation temperature will be investigated by comparing the quantification results from the affected samples to the quantification results of the samples that were reportioned. If a determination is made concerning the effect of the temperature, that information will be uploaded to the workflow as a supplemental document and provided to the vendor for informational purposes.

Section Manager: Courtney Head

Date: 11/19/18

Division Director: Amy Castillo

Date: 11/19/18

Incidents or Corrective Actions that involve the Biology/DNA section are reviewed by the Technical Leader and CODIS Administrator.



**Houston Forensic Science Center**  
**Incident/Corrective Action Report**  
Quality Division

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**Technical Leader:** Robin Guidry

**Date:** 11/19/2018

**CODIS Administrator:** Jennifer Clay

**Date:** 11/19/2018

**Quality Director:** Lori Wilson

**Date Closed:** 11/21/18